HEALTH, SPORTS & REHABILITATION MEDICINE

Published since 2000 as *Palestrica of the Third Millennium - Civilization and Sport*

A quarterly of multidisciplinary study and research

© Published by The "Iuliu Haţieganu" University of Medicine and Pharmacy of Cluj-Napoca
and
The Romanian Medical Society of Physical Education and Sports
in collaboration with
The Cluj County School Inspectorate

A journal rated B+ by CNCS (Romanian National Research Council) since 2007,
certified by CMR (Romanian College of Physicians) since 2003,
CFR (Romanian College of Pharmacists) since 2015 and CMDR since 2018

A journal with a multidisciplinary approach in the fields of biomedical science, health, medical rehabilitation, physical exercise, social sciences

2

Vol. 21, No. 2, April-June 2020

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020

Editorial Board

Editorial Office of the Journal
“Health, Sports & Rehabilitation Medicine”
Street: Clinicilor no. 1
400006, Cluj-Napoca
Telephone: 0264-598575
E-mail: *hesrehab@gmail.com*

pISSN 2668-2303
eISSN 2668-5132
ISSN-L 2668-2303
www.jhsrm.org

Contents

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 74–81

ORIGINAL STUDIES

Single oral dose of chlorogenic acid attenuates the experimental carrageenan-induced oxidative stress

Daniela-Rodica Mitrea, Malkey Ronny, Nadina-Liana Pop, Adriana Filip, Simona Clichici, Remus Moldovan, Cristina Bidian, Alina-Mihaela Toader, Teodora-Larisa Florian
"Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, Department of Physiology

Abstract

Background. Carrageenan-induced inflammation implies the release of inflammatory cytokines and also, oxidative stress, with high amounts of reactive oxygen species (ROS) production.

Aims. The present study aimed to investigate the effects of a unique dose of chlorogenic acid, orally administered at one hour after a paw inflammation was produced.

Methods. The paw edema and oxidative stress parameters in rats that were injected with 0.2 ml carrageenan solution 1% for paw inflammation production were investigated, and after 1 hour they received a single dose of either chlorogenic acid (100 mg/kg or 150 mg/kg) or indomethacin (1 mg/kg), by oral gavage. The paw edema was investigated using the plethysmometer test (at 2, 6 and 24 hours after carrageenan injection) and oxidative stress by spectrophotometry. Malondialdehyde (MDA), glutathione (GSH) and oxidized glutathione (GSSG) levels were investigated from blood samples, paw inflamed skin and kidneys.

Results. The present study showed that chlorogenic acid (both doses) and indomethacin produced significant decreases of inflamed paw volume, compared to the control group (rats without treatment). Lipid peroxidation was reduced significantly and the antioxidant protection investigated through the GSH/GSSG ratio was increased significantly in all rats that received medication, in all the tested samples: inflamed skin, serum, kidneys.

Conclusions. Chlorogenic acid may reduce efficiently oxidative stress and edema if it is administered during the first phase of carrageenan-induced inflammation.

Keywords: chlorogenic acid, oxidative stress, inflammation, antioxidants, carrageenan, green coffee

Abbreviations: CGA – chlorogenic acid, CGN – carrageenan, GSH – reduced glutathione, GSSG – oxidized glutathione, MDA – malondialdehyde, ROS – reactive oxygen species.

Introduction

Carrageenan is an irritant polysaccharide that may produce inflammation, largely used in experiments to initiate paw edema to test the anti-inflammatory effects of different substances, and to study the mechanisms involved. The cascade of chemical events is initiated by the release in the lesion area of histamine, serotonin, bradykinin, prostaglandins, and in addition, different complement fractions, coagulation products, and numerous lymphokines released by the sensitized T lymphocytes. Under their action, macrophages become activated, initiate phagocytosis of the tissue debris and release mediators that recruit the circulatory inflammatory cells, maintaining the local reaction. The decrease of paw edema in mice is constantly accompanied by the inhibition of monocyte migration into the inflammatory zone (Iqbal et al., 2016).

During inflammation, monocytes and neutrophils produce high levels of reactive oxygen and nitrogen species, leading to local oxidative stress (Mittal et al., 2014). The reactive species induce the oxidation of proteins, lipids, carbohydrates and nucleic acids, intervene in cellular membrane and organelle destruction, initiating cancerous cell development and proliferation, and also enzyme alterations.

Antioxidants, endogenous and exogenous substances with important roles in the protection of biological systems against the noxious action of excessive oxidation products may block the enzymatic reactions, inflammatory agent synthesis and the cleansing of oxidative products. Inflammation and oxidative stress can be reduced by

Received: 2020, April 6; *Accepted for publication:* 2020, April 20
Address for correspondence: Department of Physiology, "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, 1-3 Clinicilor Street, 400006 Cluj-Napoca, Romania
E-mail: cristina_bidian@yahoo.com
Corresponding author: Cristina Bidian; cristina_bidian@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.74

numerous natural substances such as curcumin (Bidian et al., 2020), quercetin (Bidian et al., 2019) or resveratrol (Mitrea et al., 2017).

Chlorogenic acid (CGA) is a biologically active polyphenol identified in tea or green coffee beans (Naveed el al., 2018). It has numerous favorable effects: antioxidant, anti-inflammatory, antibacterial, anti-diabetic, anti-obesity, it may protect the heart, liver, kidneys, etc. (Kim & Park, 2019).

In the present research, indomethacin was used as a positive control. It is known that oral administration of high doses of this non-steroidal anti-inflammatory drug can activate oxidative stress in the stomach (Mureșan et al., 2008), but in our experiments we used a low dose that was proved to be safe for the gastric mucosa (Uçar et al., 1998) and able to block the synthesis of prostaglandins, eicosanoids involved in edema development in the carrageenan injection area (Necas & Bartosikova, 2013).

In our study, we investigated the antioxidant and anti-inflammatory effects of chlorogenic acid, in comparison with indomethacin, a well-known anti-inflammatory drug, in a rat model of carrageenan-induced paw edema.

Hypothesis

This experimental study was designed to assess the hypothesis that chlorogenic acid may decrease paw edema after carrageenan injection and can protect against the oxidative stress generated by inflammation.

Material and methods

Research protocol

a) Place of the research

The research was performed in the Experimental Research Laboratory of the Physiology

Department, at "Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca.

Adult male albino Wistar rats were used for the experiments, being provided by the University Animal Facility. The animals were hosted in plastic lab cages in standard conditions: environmental temperature 22 ± 2ºC, relative humidity 45-50% and day-night cycle of 12 hours, with a 1-week environmental accommodation period before the experiments.

All procedures were performed with the approval of the Ethics Committee of "Iuliu Haţieganu" UMPh Cluj-Napoca (No 15/14.11.2016), in accordance with Directive 86/609/EEC.

b) Experimental design

Adult male albino Wistar rats with weights between 180 and 200 g were used, which were randomly allocated to 4 groups, with six rats per group (n=6). All groups of rats received for 7 days, between 8 a.m. - 9 a.m., physiological saline, 0.5 ml/day by oral gavage. On the eighth day of the experiment, the rats were intraplantarly injected, in the posterior right paw, with 0.2 ml fresh prepared carrageenan solution 1%. One hour after carrageenan (CGN) injection, the rats received, by oral gavage, 0.5 ml physiological saline or medication solution.

According to the treatment administered by oral gavage after the CGN injection, the groups of rats were: *C* (*Control)*, which received physiological saline; *I (Indomethacin)*, which received indomethacin 1 mg/kg; *II (CGA 100)*, receiving chlorogenic acid 100 mg/kg, and *III (CGA 150*), receiving chlorogenic acid 150 mg/kg.

Carrageenan, indomethacin and chlorogenic acid were purchased from Sigma-Aldrich Co. LLC, Germany. At the time of the treatment administration, they were dissolved in physiological saline.

c) Tests applied

The plethysmometer test was performed using a plethysmometer UGO BASILE North America 7140. The measurements for all rats were done before carrageenan injection and at 2, 6 and 24 hours after CGN administration.

The differences in the rat paw volume (dv) were calculated using the formula:

dv (mL) = inflamed paw volume (mL) – basal volume of the same paw (mL)

The basal paw volume represented the paw volume before carrageenan injection.

To establish the efficiency of chlorogenic acid administration, antiedematous activity (AE) was calculated at every measurement using the formula:

$$\%AE = \frac{control\ group\ average\ dv - test\ group\ average\ dv}{control\ group\ average\ dv} \times 100$$

If the difference between the *control group average dv* and the *test group average dv* gave a negative result, the antiedematous activity was considered zero (Stepanovic-Petrovic et al., 2012).

d) Biochemical determination

After the last measurement of paw edema, the rats were humanely euthanized under general anesthesia. To investigate oxidative stress, blood, paw skin and kidney samples were collected to determine malondialdehyde (MDA), glutathione (GSH) and oxidized glutathione (GSSG). Malondialdehyde (MDA) was determined using Conti's method (Conti et al., 1991), reduced glutathione (GSH) using the method developed by Hu (Hu, 1994), and oxidized glutathione (GSSG) by the method described by Vats (Vats et al., 2008). The GSH/GSSG ratio was calculated as a valuable indicator for oxidative stress.

e) Statistical processing

The oxidative stress parameters were statistically analyzed using GraphPad Prism version 5.03 for Windows, GraphPad Software (San Diego California USA), one-way ANOVA followed by the Tukey post-test. The paw volume variations over 24 hours after carrageenan injection were observed and were statistically analyzed by two-way ANOVA followed by Bonferroni post-tests. The threshold significance level was set at $p<0.05$ (*$p<0.05$; **$p<0.01$; ***$p<0.001$).

Results

a) Antiedematous activity

The volume of the inflamed paws was measured at 2, 6 and 24 hours after carrageenan injection. At 2 hours after CGN injection (1 hour after treatment administration), all groups that received medication presented significant decreases of the paw volume compared to the control group ($p<0.001$). At 6 hours after CGN injection, compared to group C, the volume of inflamed paws was significantly decreased in the rats receiving indomethacin (group I; $p<0.001$) and in those

receiving chlorogenic acid, 100 mg/kg (group II, $p<0.05$). At 24 hours after rat posterior paw inflammation, all rats that received medication presented significant decreases of the paw volume compared to the control group (group I, $p<0.001$; groups II and III, $p<0.01$) (Fig. 1a).

Chlorogenic acid administered in a 100 mg/kg dose had similar antiedematous effects to those of indomethacin, but only at 2 hours after carrageenan injection. The administration of 150 mg/kg of CGA presented a reduced antiedematous activity along the entire experiment (Fig. 1b).

b) Oxidative stress evaluation

- In *inflamed skin*, compared to the control group (C group), malondialdehyde (MDA) level was significantly decreased in all treated groups (group I, $p<0.001$; groups II and III, $p<0.05$) Chlorogenic acid inhibited lipid peroxidation but had a lower efficiency than that of indomethacin: MDA levels were significantly higher ($p<0.05$) compared to group I (Fig. 2a). Compared to the carrageenan group (group C), all the rats that received medication had significantly increased levels of reduced glutathione (group II, $p<0.001$; groups I and III, $p<0.01$) (Fig. 2b) and significantly decreased concentrations of glutathione disulphide (groups I and III, $p<0.001$; group II $p<0.01$) (Fig. 2c). Indomethacin and chlorogenic acid significantly increased the antioxidant protection investigated based on the GSH/GSSG ratio ($p<0.001$), compared to the control group (Fig. 2d).

- In *serum*, compared to the carrageenan group (group C), the administration of 100 mg/kg chlorogenic acid significantly reduced MDA concentration, an effect that was similar to the indomethacin effect ($p<0.001$).

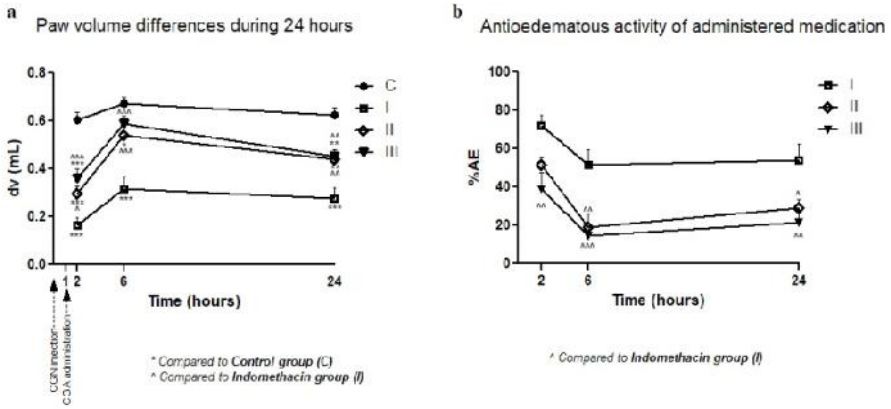


Fig. 1 – (a) Temporal course of changes in the paw volume of rats with or without medication. The graph represents the paw volume differences (dv) between inflamed and basal paw volume (volume of the same paw before carrageenan injection, indicated by arrow. (b) Temporal course of the local antiedematous effect of indomethacin and chlorogenic acid (100 mg/kg; 150 mg/kg).

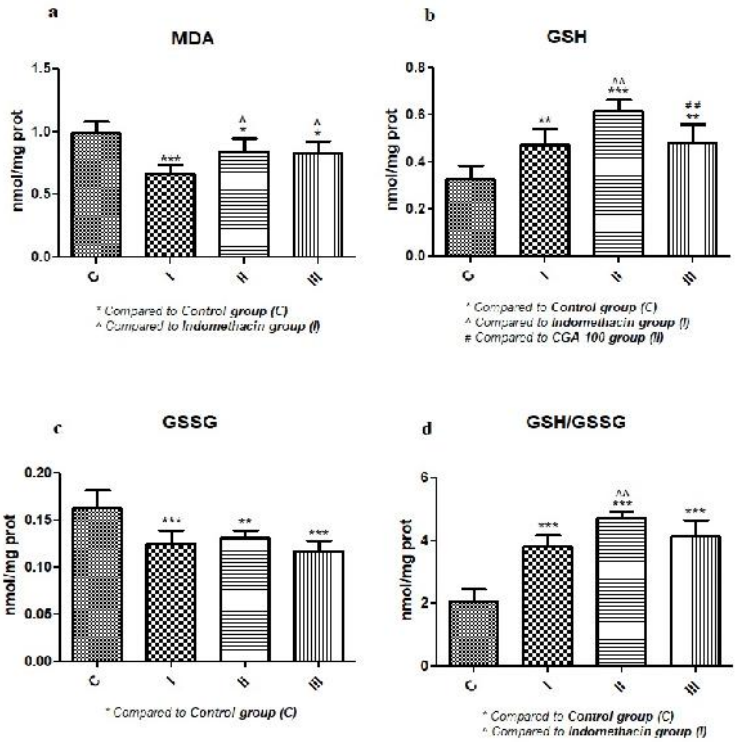


Fig. 2 – Oxidative stress parameters in inflamed rat paw. Modifications of malondialdehyde (a), reduced glutathione (b), oxidized glutathione (c) and GSH/GSSG ratio (d) in inflamed paws. Data are expressed as mean ± SEM (n=6).

Chlorogenic acid administered in a dose of 150 mg/kg had a lower effect on malondialdehyde decrease ($p<0.01$) (Fig. 3a). Compared to the control group, all the treated rats presented significant increases of GSH, (groups I and III, $p<0.001$; group II, $p<0.01$) (Fig. 3b), but did not exhibit any significant modifications of GSSG concentration (Fig. 3c). The best antioxidant protection in the serum was provided by indomethacinadministration($p<0.001$),whileCGAoralgavage showed a dose-dependent effect (group II, $p<0.05$; group III, $p<0.01$) compared to the carrageenan group (Fig. 3d).

- In *kidneys*, lipid peroxidation was significantly decreased in all treated rats ($p<0.001$) compared to the control group (Fig. 4a). The reduced glutathione levels were significantly increased by chlorogenic acid (group II, $p<0.01$; group III, $p<0.001$) compared to group C (Fig. 4b). The glutathione disulphide levels did not present significant variations compared to the control group (Fig. 4c). The best antioxidant protection was provided by the administration of 100 mg/kg chlorogenic acid (group II, $p<0.001$), but significant increases of the GSH/GSSG ratio were also recorded in the other treated groups of rats (group I, $p<0.05$; group III, $p<0.01$), compared to the control group (Fig. 4d).

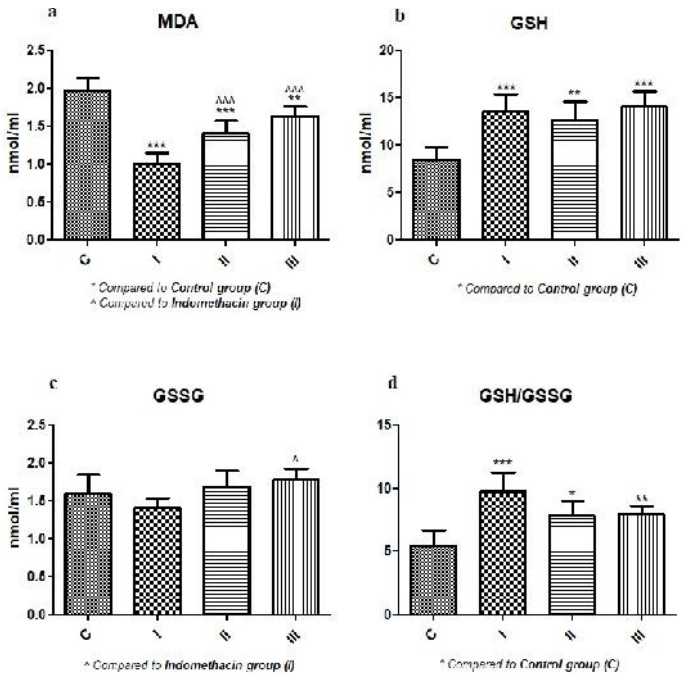


Fig. 3 – Oxidative stress parameters in the serum of rats with carrageenan-induced paw inflammation: modifications of malondialdehyde (a), reduced glutathione (b), oxidized glutathione (c) and GSH/GSSG ratio (d). Data are expressed as mean ± SEM (n=6).

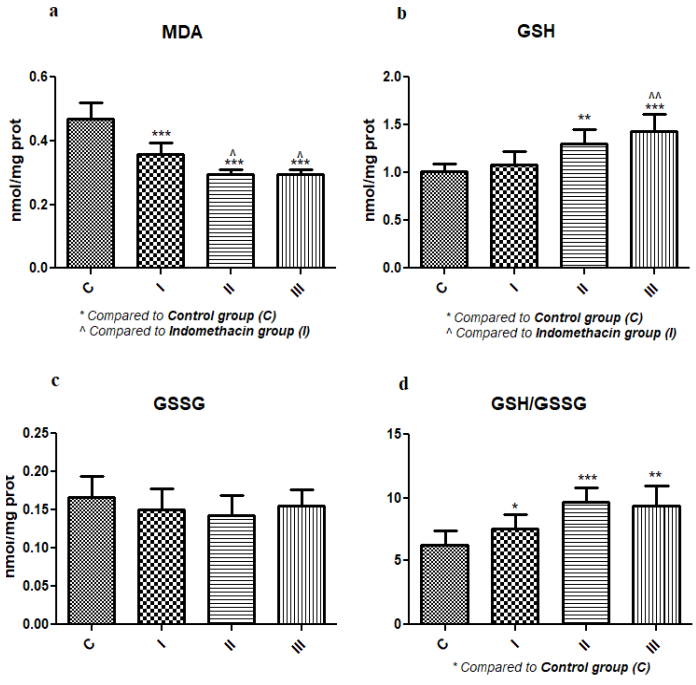


Fig. 4 – Oxidative stress parameters in the kidneys of rats with carrageenan-induced paw inflammation: modifications of malondialdehyde (a), reduced glutathione (b), oxidized glutathione (c) and GSH/GSSG ratio (d). Data are expressed as mean ± SEM (n=6).

Discussion

In the present study, the administration of a single dose of chlorogenic acid (CGA) showed antiedematous and antioxidant effects on the carrageenan-induced paw edema model of inflammation.

Carrageenan is a natural compound that may initiate reactive oxygen species production when injected in skin tissue, leading to edema development (Di Rosa, 1972; Posadas et al, 2004).

In the present study, indomethacin was used as a positive control, in 1 mg/kg administration, a dose that was demonstrated to reduce edema without causing gastrointestinal lesions, even in long-term administration (Uçar et al., 1998).

Chlorogenic acid, a phenolic compound from herbs, fruits and vegetables, showed important antioxidant (Bonita et al., 2007) and anti-inflammatory (Dos-Santos et al., 2006) effects in previous studies.

The present experiments investigated the CGA effects in oral administration to rats with inflamed paw and the results were concordant with those of other researchers that investigated this polyphenol in carrageenan-induced inflammation. The *plethysmometer test* performed at two hours after carrageenan injection presented significant decreases of the edema in all the rats that received medication, with the best effects in the indomethacin group (I). The oral administration of CGA, in a single dose, one hour after CGN injection, reduced significantly the paw edema, an effect that was also observed at 24 hours after inflammation. Our results were in accordance with those presented by Azza et al. in their study with CGA administered by intraperitoneal injection at two hours post-carrageenan injection (Azza et al., 2011), showing the efficiency of the same doses (100 and 150 mg/kg) of chlorogenic acid in both types of administration: oral and intraperitoneal. Chagas-Paula et al. showed in their study that chlorogenic acid (100 and 150 mg/kg) administered orally 30 minutes before carrageenan injections presented antiedematogenic effects and inhibited oxidative stress (Chagas-Paula et al., 2011). The same effects were shown by our study with chlorogenic acid that was administered 1 hour after carrageenan injection.

Chlorogenic acid is absorbed and metabolized through complex and dynamic processes and has an apparent bioavailability of 33 ± 23%, with plasma peaks at 0.5–8 hours after oral ingestion (Farah et al., 2008). These mechanisms can explain our results: the effects of CGA administration were much more favorable during the first hour. Carrageenan inflammation evolves in three phases: the first phase with histamine and serotonin release (0-1.5 hours), the second phase that involves kinins (1.5-2.5 hours), and the third phase with prostaglandin synthesis (2.5-6 hours) (Di Rosa et al., 1971). The results of the present research are in agreement with those of previous studies that showed the lower significant effects of oral CGA at 6 hours after CGN injection, even in prolonged administration of chlorogenic acid (Mitrea et al., 2020).

Indomethacin, a non-steroid inflammatory drug used as positive control, maintained its anti-inflammatory effects throughout the experiment and significantly decreased the rat paw edema, results that are concordant with those found in the literature (Ferreira & Vane, 1974).

Carrageenan injection induces acute inflammation by the release of bradykinin, serotonin, histamine, reactive oxygen and nitrogen species. Neutrophil recruitment may also produce reactive species that exacerbate the inflammation (Morris, 2003). Our study investigated *oxidative stress* in oral CGA administration to rats with carrageenan-induced paw edema.

In *inflamed skin*, oxidative stress was significantly reduced by both doses of chlorogenic acid. *Lipid peroxidation* was significantly decreased by CGA, but indomethacin had the best effects. The results of our study are in agreement with those presented in the literature (Bonita et al., 2007; Azza et al., 2011). Bagdas et al. reported in their study a decrease of MDA concentration in the lesion area in CGA administration, and an acceleration of wound healing (Bagdas et al., 2015), an effect that was also visible in our groups of rats. Tsai et al. demonstrated that chlorogenic acid inhibited ROS synthesis and decreased the oxidation of low density proteins in their study performed on endothelial cells that were pretreated with CGA (Tsai et al., 2018). The same effects on lipid peroxidation were shown by our study. Chlorogenic acid, in our study, significantly increased the concentration of *reduced glutathione (GSH)* in inflamed skin, the administration of 100 mg/kg providing better protection against the carrageenan-induced oxidative stress. These results are concordant with those presented by Azza et al. with the same dose (100 mg/kg) of chlorogenic acid, but in intraperitoneal administration (Azza et al., 2011). In our study, *glutathione disulphide (GSSG)*, the oxidized form of GSH, was significantly reduced in the rats that received medication, compared to the control group. The oxidation of GSH was reduced significantly in all treated rats, the best results being shown in the groups that received indomethacin or 150 mg/kg of CGA. Antioxidant protection (investigated through the *GSH/GSSG* ratio) was significantly increased in the inflamed skin in all rats that received medication, but administration of 100 mg/kg of CGA presented the best effect. These results are in agreement with those presented by Park et al. in hepatic tissue in their study on a colorectal cancer model where the administration of CGA significantly increased the GSH/SSG ratio (Park et al., 2010).

In our study, the *serum* determinations of oxidative stress parameters showed that a single dose of chlorogenic acid, orally administered, had significant antioxidant effects. *Lipid peroxidation* was reduced significantly in all treated groups, with the best effects in the rats that received indomethacin. Compared to the control group, *reduced glutathione (GSH)* levels were increased significantly in the serum of rats that received 150 mg/kg chlorogenic acid or indomethacin, while *GSSG* did not present significant variations. These results are in accordance with the results presented by Budryn et al. in their study performed in rats that received a modified diet with bread supplemented with CGA (Budryn et al., 2017). In the literature, chlorogenic acid is presented as a potent scavenger of superoxide anion ($O_2^{\cdot -}$) (Cha et al., 2014) and of hydroxyl radical ($HO^{\cdot}$) (Zhang et al., 2003), and in our study, these effects were

indirectly observed by the significantly increased GSH concentration in the serum. The potentiality of CGA to reduce the concentration of these reactive oxygen species left the glutathione unused (Fiser et al., 2013), a mechanism that may explain the insignificant GSSG modifications. The best antioxidant protection in serum was provided by indomethacin even if it was administered in a low dose (1 mg/kg), our results being in accordance with the literature data. Chao et al. demonstrated in their study that similar low doses of indomethacin can reduce the release of IL-1β (Chao et al., 2012). During carrageenan inflammation processes, this non-steroidal anti-inflammatory drug may block the production of prostaglandin E_2 (Hwang et al., 2008), diminishing in this way the activation of macrophages that can produce IL-1β. The study performed by Hammad et al. on humans showed increases of this mediator in serum during inflammatory processes (Hammad et al., 2015). In our experiments, 1 mg/kg indomethacin decreased rat paw inflammation, possibly by reducing the level of serum pro-inflammatory cytokines, and had an antioxidant effect.

In the scientific literature, chlorogenic acid is described as a renoprotective natural polyphenol (Domitrović et al., 2014) and our study presented the antioxidant effects of oral CGA administration on *kidney* tissue. The end-product of lipid peroxidation, *malondialdehyde*, was reduced significantly in the rat kidneys by both types of medication (chlorogenic acid and indomethacin), compared to the carrageenan group. Different animal-based models were presented by Liang and Kitts in a review that showed the CGA antioxidant protective effects in the brain or gastrointestinal tract, with significant decreases of MDA concentration (Liang & Kitts, 2015). Basivireddy et al. showed that high doses of indomethacin (20 mg/kg/day) cause renal damage (Basivireddy et al., 2004), effects that appear to be related to the administered dose because, in our research, 1 mg/kg of this anti-inflammatory drug decreased lipid peroxidation. In kidney tissue, the level of *reduced glutathione* was increased significantly by chlorogenic acid, with the highest concentration in the group of rats that received 150 mg/kg CGA. The antioxidant protection investigated through the *GSH/GSSG* ratio increased significantly in all the treated rats, with the best results in the group that received 100 mg/kg CGA, results that are in accordance with the literature data (Domitrović et al., 2014; Feng et al., 2016).

The present study demonstrated the antioxidant and antiedematous effects of a single dose of chlorogenic acid, orally administered, in the treatment of carrageenan-induced paw inflammation. The study had expected outcomes, but also unexpected results regarding the effectiveness of a single oral dose of chlorogenic acid. Many studies present the weak antioxidant effects of oral CGA administration in relation to the low detectable levels of CGA in the blood (Rodriguez-Mateos et al., 2014). After its ingestion, chlorogenic acid is poorly absorbed in the small intestine, most of the chlorogenic acid reaches the colon, is metabolized and its metabolites are absorbed, conjugated in the liver and transported to the tissues (Stalmach et al., 2009). After the filtration of CGA conjugates, they can be identified in urine (Fumeaux et al., 2010).

The present study showed that chlorogenic acid can exert antioxidant effects through its conjugates in the inflamed skin, in kidneys as well as in the serum, and this polyphenol can be considered as an agent with therapeutic effects.

Conclusions

1. The oral administration of a single dose of chlorogenic acid at one hour after carrageenan injection showed antiedematous and antioxidant effects in inflamed skin. The protection against oxidative stress in the serum and kidneys presents this polyphenol as a potent antioxidant substance.

2. Oral indomethacin administration had antioxidant and antiedematous effects, even in a low single dose.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgements

The authors are thankful to Nicoleta Decea, at the Laboratory of Oxidative Stress Research, Department of Physiology, "Iuliu Haţieganu" UMPh Cluj-Napoca, for oxidative stress measurement.

This work was carried out using the researchers' own funds.

References

Azza EM, Yieldez B, Mahmoud K, Abdullatif M. Chlorogenic acid as potential anti-inflammatory analgesic agent: an investigation of the possible role of nitrogen-based radicals in rats. Int J of Pharmacology & Toxicology Science, 2011;1:24-33.

Bagdas D, Etoz BC,Gul Z, Ziyanok S, Inan S, Turacozen O, Gul NY, Topal A, Cinkilic N, Tas S, Ozyigit MO, Gurun MS. In vivo systemic chlorogenic acid therapy under diabetic conditions: Wound healing effects and cytotoxicity/genotoxicity profile. Food Chem Toxicol, 2015;81:54-61. doi:10.1016/j.fct.2015.04.001.

Basivireddy J, Jacob M, Pulimood AB, Balasubramanian KA. Indomethacin-induced renal damage: role of oxygen free radicals. Biochem Pharmacol. 2004;67(3):587-599. doi: 10.1016/j.bcp.2003.09.023.

Bidian C, Filip A, Albu A, Catoi AF, Mandrila G, Moldovan R, Decea N, Mitrea DR. The effects of reveratrol and quercetin administration in experimental pleural inflammation. Health Sports Rehab Med. 2019; 20(4):159-164. doi:10.26659/pm3.2019.20.4.159.

Bidian C, Mitrea DR, Vasile OG, Filip A, Cătoi AF, Moldovan R, Decea N, Albu A. Quercetin and curcumin effects in experimental pleural inflammation. Med Pharm Rep, 2020;93(3). In press. doi:10.15386/mpr-1484.

Bonita J, Mandarano M, Shuta D, Vinson J. Coffee and cardiovascular disease: In vitro, cellular, animal, and human studies. Pharmacol Res. 2007;55(3):187-198. doi:10.1016/j.phrs.2007.01.006.

Budryn G, Zaczyńska D, Żyżelewicz D, Grzelczyk J, Zduńczyk Z, Juśkiewicz J. Influence of the Form of Administration of Chlorogenic Acids on Oxidative Stress Induced by High fat Diet in Rats. Plant Foods Hum Nutr. 2017;72(2):184-191. doi:10.1007/s11130-017-0608-3.

Cha JW, Piao MJ, Kim KC, Yao CW, Zheng J, Kim SM, Hyun

CL, Ahn YS, Hyun JW. The Polyphenol Chlorogenic Acid Attenuates UVB-mediated Oxidative Stress in Human HaCaT Keratinocytes. Biomol Ther (Seoul). 2014;22(2):136-142. doi: 10.4062/biomolther.2014.006.

Chagas-Paula DA, De Oliveira BR, Da Silva VC, Gobbo-Neto L, Gasparoto TH, Campanelli AP, Faccioli LH, Da Costa FB. Chlorogenic acids from Tithonia Diversiflora demonstrate better anti-inflammatory effect than indomethacin and its sesquiterpene lactones. J Ethnopharmacol. 2011; 136(2):355-362. doi: 10.1016/j.jep.2011.04.067.

Chao PK, Lu KT, Jhu JY, Wo YYP, Huang TC, Ro LS, Yang YL. Indomethacin protects rats from neuronal damage induced by traumatic brain injury and suppresses hippocampal IL-1β release through the inhibition of Nogo-A expression. J Neuroinflammation. 2012;9:121. doi:10.1186/1742-2094-9-121.

Conti M, Morand PC, Levillain P, Lemonnier A. Improved fluorometric determination of malonaldehyde. Clin. Chem. 1991;37(7):1273-1275.

Di Rosa M, Giroud JP, Willoughby DA. Studies of the mediators of the acute inflammatory response induced in rats in different sites by carrageenan and turpentine. J Pathol, 1971;104(1):15-29. doi:10.1002/path.1711040103.

Di Rosa M. Biological properties of carrageenan. J Pharm Pharmacol. 1972;24(2):89-102. doi:10.1111/j.2042-7158.1972.tb08940.x.

Domitrović R, Cvijanović O, Šušnić V, Katalinić N. Renoprotective Mechanisms of Chlorogenic Acid in Cisplatin-Induced Kidney Injury. Toxicology. 2014;324:98-107. doi:10.1016/j.tox.2014.07.004.

Dos-Santos MD, Almeida MC, Lopes NP, Petto de Souza GE. Evaluation of the anti-inflammatory, analgesic and antipyretic activities of the natural polyphenol Chlorogenic acid. Biol Pharm Bull. 2006;29(11):2236-2240. doi:10.1248/bpb.29.2236.

Farah A, Monteiro M, Donangelo CM, Lafay S. Chlorogenic Acids from Green Coffee Extract are Highly Bioavailable in Humans. J Nutr. 2008;138(12):2309-2315. doi:10.3945/jn.108.095554.

Feng Y, Yu Y, Wang S, Ren J, Camer D, Hua Y, Zhang Q, Huang J, Xue D, Zhang X, Huang X, Liu Y. Chlorogenic acid protects d-galactose-induced liver and kidney injury via antioxidation and anti-inflammation effects in mice. Pharm Biol. 2016;54(6):1027-1034. doi:10.3109/13880209.2015.1093510.

Ferreira SH, Vane JR. New aspects of the mode of action of non-steroid anti-inflammatory drugs. Ann Rev Pharmacol. 1974;14:57-73. doi:10.1146/annurev.pa.14.040174.000421.

Fiser B, Jójárt B, Csizmadia IG, Viskolcz B. Glutathione – Hydroxyl Radical Interaction: A Theoretical Study on Radical Recognition Process. PLoS One. 2013;8(9):e73652. doi:10.1371/journal.pone.0073652.

Fumeaux R, Menozzi-Smarrito C, Stalmach A, Munari C, Kraehenbuehl K, Steiling H, Crozier A, Williamson G, Barron D. First synthesis, characterization, and evidence for the presence of hydroxycinnamic acid sulfate and glucuronide conjugates in human biological fluids as a result of coffee consumption. Org Biomol Chem. 2010;8(22):5199-5211. doi:10.1039/c0ob00137f.

Hammad DR, Elgazzar AG, Essawy TS, Abd El Sameie SA. Evaluation of serum interleukin-1 beta as an inflammatory marker in COPD patients. Egypt J Chest Dis Tubercul. 2015;64:347-352. doi:10.1016/j.ejcdt.2015.01.005

Hu ML. Measurement of protein thiol groups and glutathione in plasma. In Methods in Enzymol. vol. 233, Academic Press, Inc. 1994, 380-384.

Hwang HJ, Lee HJ, Kim CJ, Shim I, Hahm DH. Inhibitory Effect of Amygdalin on Lipopolysaccharide-Inducible TNF-α and IL-1β mRNA Expression and Carrageenan-Induced Rat Arthritis. J Microbiol Biotechnol. 2008;18(10):1641-1647.

Iqbal AJ, Fisher EA, Greaves DR. Inflammation - a critical appreciation of the role of myeloid cells. Microbiol Spectr. 2016;4(5): doi:10.1128/microbiolspec.MCHD-0027-2016.

Kim JK, Park SU. Chlorogenic acid and its role in biological functions: an up to date. EXCLI J. 2019; 18:310-316. doi:10.17179/excli2019-1404.

Liang N, Kitts DD. Role of Chlorogenic Acids in Controlling Oxidative and Inflammatory Stress Conditions. Nutrients. 2015;8(1):16. doi:10.3390/nu8010016.

Mitrea DR, Clichici S, Filip A, Olteanu D, Baldea I, Moldovan R, Decea N, Hoteiuc OA. Resveratrol and loratadine effects on oxidative stress induced by experimental inflammation. Studia UBB Chemia, 2017;LXII (1):89-100. doi:10.24193/subbchem.2017.1.07.

Mitrea DR, Malkey R, Florian TL, Filip A, Clichici S, Bidian C, Moldovan R, Hoteiuc A, Toader AM, Baldea I. Daily oral administration of chlorogenic acid prevents the experimental carrageenan-induced oxidative stress. J Physiol Pharmacol. 2020;71(1). doi:10.26402/jpp.2020.1.04.

Mittal M, Siddiqui MR, Tran K, Reddy SP, Malik AB. Reactive Oxygen Species in Inflammation and Tissue Injury. Antioxid Redox Signal. 2014;20(7):1126-1167. doi:10.1089/ars.2012.5149.

Morris CJ. Carrageenan-Induced Paw Edema in the Rat and Mouse. Methods Mol Biol. 2003;225:115-121. doi:10.1385/1-59259-374-7:115.

Mureşan A, Suciu Ş, Mitrea DR, Alb C, Login C, Crişan D, Daicoviciu D. Oxidative stress implications in experimental gastric ulcer induced by indomethacin. Bull UASVM, Veterinary Med. 2008; 65(1):444-449.

Naveed M, Hejazi V, Abbas M, Kamboh AA, Khan GJ, Shumzaid M, Ahmad F, Babazadeh D, FangFang X, Modarresi-Ghazani F, WenHua L, XiaoHui Z. Chlorogenic acid (CGA): A pharmacological review and call for further research. Biomed Pharmacother. 2018; 97:67-74. doi: 10.1016/j.biopha.2017.10.064.

Necas J, Bartosikova L. Carrageenan: a review. Veterinarni Medicina, 2013; 58(4), 187-205. doi:https://doi.org/10.17221/6758-VETMED.

Park HJ, Davis SR, Liang HY, Rosenberg DW, Bruno RS. Chlorogenic Acid Differentially Alters Hepatic and Small Intestinal Thiol Redox Status Without Protecting Against Azoxymethane-Induced Colon Carcinogenesis in Mice. Nutr Cancer. 2010;62(3):362-370. doi:10.1080/01635580903407239.

Posadas I, Bucci M, Roviezzo F, Rossi A, Parente L, Sautebin L, Cirino G. Carrageenan-induced mouse paw oedema is biphasic, age-weight dependent and displays differential nitric oxide cyclooxygenase-2 expression. Br J Pharmacol. 2004;142(2):331-338. doi:10.1038/sj.bjp.0705650.

Rodriguez-Mateos A, Vauzour D, Krueger CG, Shanmuganayagam D, Reed J, Calani L, Mena P, del Rio D, Crozier A. Bioavailability, bioactivity and impact on health of dietary flavonoids and related compounds: An update. Arch Toxicol. 2014;88(10):1803-1853. doi:10.1007/s00204-014-1330-7.

Stalmach A, Mullen W, Barron D, Uchida K, Yokota T, Cavin C, Steiling H, Williamson G, Crozier A. Metabolite profiling of hydroxycinnamate derivatives in plasma and urine after the ingestion of coffee by humans: Identification of biomarkers of coffee consumption. Drug Metab Dispos. 2009;37(8):1749-1758. doi: 10.1124/dmd.109.028019.

Stepanovic-Petrovic RM, Micov AM, Tomic MA, Ugresic ND. The local peripheral antihyperalgesic effect of levetiracetam

and its mechanism of action in an inflammatory pain model. Anesth Analg. 2012;115(6):1457-1466. doi: 10.1213/ANE.0b013e31826c7fc2.

Tsai KL, Hung CH, Chan SH, Hsieh PL, Ou HC, Cheng YH, Chu PM. Chlorogenic Acid Protects Against oxLDL-Induced Oxidative Damage and Mitochondrial Dysfunction by Modulating SIRT1 in Endothelial Cells. Mol Nutr Food Res. 2018;62(11):e1700928. doi:10.1002/mnfr.201700928.

Uçar A, Sak SD, Melli M. Effects of chronic treatment with indomethacin at clinically relevant doses on intestinal tissue 6-keto prostaglandin F1 alpha and leukotriene B4 level in relation to gastroenteropathy. Inflammation. 1998;22(3):243-252. doi:10.1023/a:1022354614385.

Vats P, Singh VK, Singh VK, Singh SN, Singh SB. Glutathione metabolism under high altitude stress and effect of antioxidant supplementation. Aviat Spac Environ Med. 2008;79(12):1106-1111. doi:10.3357/asem.2305.2008.

Zhang LY, Cosma G, Gardner H, Vallyathan V, Castranova V. Effect of chlorogenic acid on hydroxyl radical. Mol Cell Biochem. 2003;247(1-2):205-210. doi:10.1023/a:1024103428348.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 82–87

The use of occlusal splints in the management of temporomandibular disorder

Andreea Kui[1], Smaranda Buduru[1,3] , Simona Iacob[1], Manuela Manziuc[1], Loredana Mitariu[2], Marius Negucioiu[1]
[1]Department of Prosthodontics, "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca
[2]Department of Dental Morphology, "Lucian Blaga" University, Sibiu
[3]Stomestet Dental Clinic, Cluj-Napoca, Romania

Abstract

Background. Treatment options in cases of temporomandibular disorders (TMD) include occlusal adjustment, drug therapy, occlusal splint therapy, physiotherapy, reassurance, or even surgical in-terventions or combined treatments. Occlusal splints represent a removable artificial device applied on the occlusal surface, used either for diagnosis or for treatment, in order to alter the relationship of the mandible to the upper jaw. It is widely accepted that occlusal splints provide occlusal disen-gagement, masticatory muscle relaxation, unloading and repositioning of the temporomandibular joints (TMJ), and modification of the vertical dimension of occlusion (VDO). As TMD exhibits muscular symptoms, a correct redistribution of occlusal forces through the occlusal appliances will produce muscle relaxation, in different areas; splint therapy produces a complete disengagement of the arches, eliminating interferences and premature contacts, and this will improve motor activity and overall muscle tone, improving sports performance.

Aims. The purpose of this study was that, indicated according to the diagnosis, each type of occlusal splint can be effective in reducing the symptoms of TMD.

Methods. This retrospective observational study included 41 patients, examined, diagnosed and treated between 2018 and 2019. The data was collected from the medical charts. All the sub-jects were diagnosed with either intraarticular TMD or extraarticular TMD and distributed in one out of three groups – for each group of subjects a different occlusal splint was indicated – Michigan splint, a hydrostatic appliance and Jeanmonod anterior bite plane.

Results. The results confirmed the hypothesis, as all three occlusal appliances were effec-tive, but with no significant difference among the three groups of subjects. In other words, each splint used in the therapy accomplished its purpose, but the statistical analysis revealed no signifi-cant difference between each splint's capabilities of treatment as long they are indicated according to the type of TMD.

Conclusions. Taking into consideration the limitations of this study we can conclude that, if indicated correctly, splint therapy is an effective method to reduce the specific symptoms encoun-tered in patients with TMD.

Keywords: temporomandibular disorders, occlusal splints, hydrostatic appliance

Introduction

Patients complaining of temporomandibular joint (TMJ) pain are often misdiagnosed, and the proper type of temporomandibular disorder (TMD) should be considered. Common clinical symptoms which can lead to a correct assessment for those types of disorders are represented by joint sounds (clicking, grating), limitations or asymmetrical jaw movement, all having a negative effect on the patient's quality of life (Alqutaibi & Aboalrejal, 2015).

TMD are classified into articular disorders (intraarticular) and masticatory muscle disorders (extraarticular). Among intraarticular disorders, the most common are either inflammatory joint disorders (capsulitis, synovitis, arthritis) or disc displacement disorders with or without reduction. Among extraarticular disorders, myofascial pain disorder, myospasm or myofibrotic contracture are often encountered in clinical practice (De Leeuw & Klasser, 2013; Schiffman et al., 2014).

Patients with temporomandibular dysfunction exhibit muscular symptoms as well. In these cases, the symptoms will be localized in the masticatory muscles, but may have distant repercussions in cervical, neck, paravertebral,

Received: 2020, March 24; *Accepted for publication:* 2020, March 31
Address for correspondence: Department of Prosthodontics and Dental Materials, "Iuliu Haţieganu" University of Medicine and Pharmacy Cluj-Napoca, Romania, 32 Clinicilor street, Cluj-Napoca, PC 400006
E-mail: smarandabudurudana@gmail.com
Corresponding author: Smaranda Buduru; smarandabudurudana@gmail.com
https://doi.org/10.26659/pm3.2020.21.2.82

upper and lower limb muscles, influencing posture. This will particularly influence sports performance (Dias et al., 2019; Maurer et al., 2018).

Treatment options in cases of TMD include occlusal adjustment, drug therapy, occlusal splint therapy, physiotherapy (ultrasound, acupuncture, laser therapy, TENS, etc.), reassurance (self-care and behavioral therapy, including patient's education), or even surgical interventions or combined treatments (Alqutaibi & Aboalrejal, 2015).

Occlusal splints represent a removable artificial device applied on the occlusal surface, used either for diagnosis or for treatment, in order to alter the relationship of the mandible to the upper jaw. Occlusal appliances can be used for occlusal stabilization, to prevent dental wear or as a treatment in case of a temporomandibular disorder (Deshpande & Mhatre, 2010).

TMD can be caused by dental malocclusions; splint therapy produces a complete disengagement of the arches, eliminating interferences and premature contacts. As a result, the correct redistribution of occlusal forces through the occlusal appliances will produce muscle relaxation, on multiple levels, and thus will improve motor activity and overall muscle tone (Leroux et al., 2018; Militi et al., 2020).

The use of occlusal splints in sports is frequent, as those appliances are known to influence motor performance, by increasing upper body isometric exercises (Dias et al., 2018). Also, it seems that splints may improve the neuromuscular dynamics in the case of athletes (D'Ermes et al., 2012).

Although the mechanism of action for occlusal splints is not completely understood, it is accepted that they provide occlusal disengagement, masticatory muscle relaxation, unloading and repositioning of TMJs, and modification of the vertical dimension of occlusion (VDO) (Okeson, 2012).

The literature reported several types and designs of occlusal splints with different mechanisms of action.

Michigan splint (flat plane stabilization appliance) is one of the most commonly used occlusal appliances. It is usually fabricated for the maxillary arch, and according to the American Academy of Orofacial Pain guidelines, this splint "provides joint stabilization, protects the teeth, redistributes occlusal forces, relaxes the elevator muscles, and decreases bruxism" (De Leeuw & Klasser, 2013; Al-Ani, 2005; Nishigawa, 2012; Naikmasur et al., 2008).

Hydrostatic appliance (Aqualizer®), which was originally designed by Lerman, is a bilateral water-filled plastic chamber attached to an acrylic palatal appliance, which allows the posterior teeth to occlude with water-filled chambers. Those water-filled chambers are positioned on the lateral teeth. This splint allows the mandible to find its ideal position, without being guided by the appliance itself (self- adjusting splint) (Sung-Wen, 2010; Klasser & Greene, 2009). This hydrostatic appliance is also indicated in case of orthodontic triggered muscle pain, pre-surgical differential diagnosis, post-surgical pain and in case of inflammation (Srivastava et al., 2012).

Anterior deprogrammer (Lucia jig, Jeanmonod anterior bite plane, NTI, etc.) is another type of occlusal splint. For example, Jeanmonod anterior bite plane is used to reduce the hyperactivity of masticatory muscles. It is designed as a palatal-coverage horseshoe shape with an occlusal table covering the 6 maxillary anterior teeth, and it has the ability to prevent clenching, as the posterior teeth will no longer be engaged in functional or parafunctional activities. The result is muscle relaxation (Jeanmonod, 1998; Klasser & Greene, 2009).

Hypothesis

As TMD symptoms often have the same pattern for different patients, some practitioners tend to apply the same approach regardless of the type of disorder; when, in fact, identical symptoms may need different treatment plans, according to etiology and individual circumstances. The hypothesis of this study was that, indicated according to diagnosis, each type of splint can be effective.

The *aim* of this study was to evaluate the effectiveness of three different types of occlusal splints and to assess any differences in their therapeutic effect.

Material and methods

Research protocol

The study was approved by the Ethics Committee of the "Iuliu Hatieganu" University of Medicine and Pharmacy in Cluj-Napoca. Participants were fully informed about the examination and treatment procedures, care, and follow-up. Before starting the splint therapy, each patient signed an informed consent form, in accordance with the Declaration of Helsinki.

a) Period and place of the research

This retrospective observational study was conducted in collaboration with a private clinic in Cluj-Napoca, Romania, between January 2018 and May 2019. The data was collected from the medical charts. All the patients were diagnosed with either intraarticular TMD (inflammatory disorder) or extraarticular TMD (masticatory muscle disorder). Intraarticular TMD is associated with TMJ inflammation and pain, or with disc displacement with or without reduction.

b) Subjects and groups

This study included 41 patients. All subjects met the following criteria: (1) the symptoms met the diagnosis of TMD as defined in "The Research Diagnostic Criteria for Temporomandibular Disorders"; (2) all the patients had an axiography (performed with Cadiax Compact 2 as a paraclinical examination; (3) no arthritis changes in the condylar head/genial tubercle visible on panoramic X-ray; (4) no more than two posterior teeth missing (without taking into consideration the third molar); (5) compliant patient during the implementation and the follow-up of the treatment plan; (6) before the splint therapy, no other therapy, specific treatment or medication for TMD was applied.

In order to establish a complete diagnosis, each patient underwent a clinical examination (history taking, chief complaint, extraoral and intraoral evaluation, examination of masticatory muscles and TMJ, occlusal examination) and paraclinical examinations (panoramic X-ray and axiography using Cadiax Compact). Each examination was performed by the same physician with over 20 years

of experience in the field. In order to assess the severity of pain in the masticatory muscles and temporomandibular joint, a visual analogue scale was used (VAS) (0-100), which is considered to be a reliable method (Chang et al., 2010).

c) Tests applied

For the patients included in this study, three types of occlusal splints were used. *Michigan splint* was used for patients diagnosed with intraarticular disorders associated with disc displacement with or without reduction (DDwR and DDwoR). *Jeanmonod anterior bite plane* was applied to patients diagnosed with TMD associated with muscle disorder, and a *hydrostatic appliance (Aqualizer®)* was applied to patients diagnosed with inflammatory intraarticular disorders.

After examination and establishment of diagnosis, a full-mouth impression was performed, associated with a centric relation record and face bow registration, in order to mount each patient's casts into a semi-adjustable articulator. The technician manufactured the splint for each patient (Michigan Splint and Jeanmonod anterior bite plane) (Figs.1 and 2).

Fig. 1 – Michigan splint applied on the mandibular arch.

Fig. 2 – Jeanmonod anterior bite plane.

Fig. 3 – Hydrostatic appliance (Aqualizer)®.

The intraoral adjustments for the Michigan splint implied multiple contact points in centric relation and anterior guidance which allowed disocclusion in posterior areas during both protrusive and lateral movements. For the Jeanmonod anterior bite plane the adjustment implied contacts in centric relation only with the lower anterior teeth and no posterior interferences during eccentric mandibular movements.

The occlusal appliances underwent finishing and polishing, and the patients were asked to wear the splint according to the indications.

For Aqualizer® the model selected was Ultra and the size (low, medium, high) was chosen according to patient's Angle class and VDO (Fig. 3).

Each patient was reexamined after 7 days of wearing the respective splints, in order to evaluate the symptoms and occlusal contacts. Adjustments were performed weekly during 3 months.

The criteria for assessing the success of each splint were the improvement or disappearing of the symptoms. If the symptoms were not reduced or they even aggravated, while the splint was correctly adjusted, then either the diagnosis was incorrect or the TMD was secondary to another disease. Our study assessed symptoms 3 months after splint application.

d) Statistical processing

All the information received was gathered into an Excel document and the data was statistically analyzed using IBM SPSS software. Descriptive analysis was performed, and for the evaluation of the efficiency of each occlusal splint compared with another, Fisher's exact test was applied.

Results

Before treatment

The most frequent symptoms found during examination were muscle pain, TMJ pain, and TMJ noises when opening and closing the mouth, as described in Table I. Masseter and temporal muscle pain was the most frequent symptom (in 26.8% of cases, 29.2% respectively). Muscular hypertonicity and hypotonicity were also observed, but in a lower percentage (9.6%).

Table I

Distribution of patients based on symptoms.

Symptom	Number of subjects	Total
Pain in the masseter muscle	11 (26.8%)	41
Pain in the temporal muscle	12 (29.2%)	
Pain in the lateral pterygoid muscle	10 (24.3%)	
Pain in the medial pterygoid muscle	12 (29.2%)	
Pain on TMJ palpation	11 (26.8%)	
TMJ pain during mouth opening/closing	12 (29.2%)	
TMJ pain during anterior guidance	5 (12.1%)	
TMJ pain during lateral guidance	8 (19.5%)	
Limited opening of the mouth	14(34.14%)	
Joint clicking	25 (60.9%)	
Lateral deviation of the chin during mouth opening	17 (41.2%)	

Related to TMJ symptoms, pain was the most frequent symptom, during palpation of the joint, but also during

closing/opening of the mouth (29.2%), or during eccentric movements of the mandible (31.6%) (anterior and lateral guidance). Also, one of the most frequent signs observed during patients' examination was lateral deviation of the chin during opening of the mouth (41.2%).

Out of the 41 subjects included in the study, 23 subjects were diagnosed with intraarticular disorder associated with disc displacements, 12 subjects were diagnosed with masticatory muscle disorder, while other 6 were diagnosed with inflammatory disorder (Table II).

Table II

Distribution of patients based on diagnosis and treatment.

Diagnosis	No. of subjects	Type of splint
Intraarticular disorder (DDwR/DDwoR)	23 (56.09%)	Michigan splint
Intraarticular disorder (inflammation)	6 (14.6%)	Hydrostatic splint
Extraarticular disorder (muscle disorder)	12 (29.2%)	Jeanmonod splint
Total 41 (100%)		

For temporomandibular disorders associated with disc displacements with reduction (DDwR) and without reduction (DDwoR), the most common signs were the presence of joint clicking associated or not with pain or limited mouth opening (34.14%). Out of 60.9% of the patients who exhibited joint noises, 17.1% had a clicking index of 1 and 2 (meaning that the click was heard either after the first 15 mm of opening or between 15-30 mm of mouth opening), and another 17.1% had a clicking index of 3 (clicking was heard after more than 30 mm of mouth opening).

After treatment

Twenty-three subjects diagnosed with disc displacements with reduction (DDwR) or disc displacement without reduction (DDwoR) were treated with a *Michigan splint*. After 3 months of therapy with the splint, 21 patients (88%) reported the absence of pain, while 2 patients still reported pain (Fig. 4). Out of the 14 subjects with limited opening of the mouth, 9 (62.4%), had an improvement of this symptom after 3 months of splint therapy. Regarding the clicking sound of the temporomandibular joint, for 8 (19.5%) subjects the intensity of clicking was reduced after the 3 months of therapy.

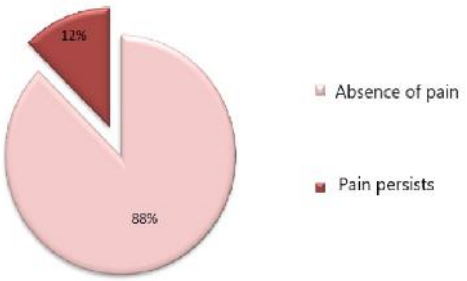


Fig. 4 – Results for the groups of subjects treated with Michigan splint.

Twelve subjects diagnosed with TMD associated with muscle disorders were treated with *Jeanmonod anterior bite plane.* Ten (85%) out of 12 subjects reported the absence of symptoms after 3 months of splint therapy, while 2 did not notice any improvement (Fig. 5).

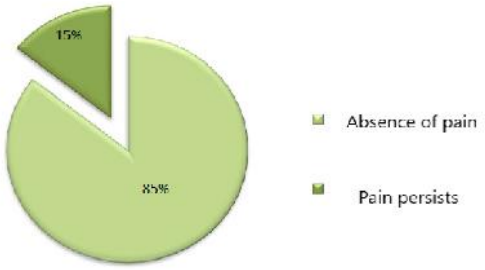


Fig. 5 – Results for the groups of subjects treated with Jeanmonod anterior bite plane.

For the subjects diagnosed with TMD associated with joint inflammation, a hydrostatic splint (Aqualizer®) was used as a treatment. Those subjects had pain in the temporomandibular joint, during palpation, as well as during mandibular movements (closing/opening, protrusion, laterality).

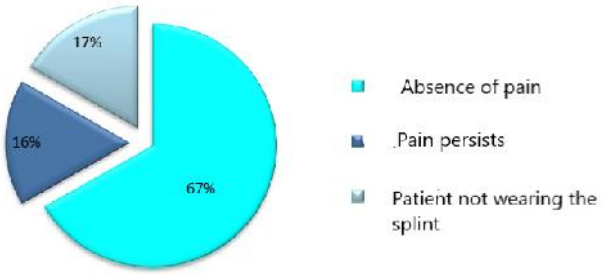


Fig. 6 – Results for the group treated with Aqualizer® splint

After 3 months of Aqualizer® splint treatment, 4 (67%) out of 6 subjects observed a remission of pain, while 1 patient reported not being able to adapt to the splint (Fig. 6).

Regarding the correlation of the efficiency of one splint over another, *Fisher's exact test* was applied. The statistical analysis revealed values of $p>0.05$ ($p=0.166$, $p=0.175$, $p=0.175$ respectively).

Discussions

The aim of this retrospective study was to evaluate the efficiency of three different types of occlusal splints in the case of patients diagnosed with TMD. In this context, the most common symptoms were evaluated before and after treatment, for each group of patients. Pain localized in the masticatory muscles and temporomandibular joint is frequent in patients suffering from TMD. Therefore, a correct TMD diagnosis and treatment is often difficult, because of the multifactorial etiology of TMD (Gauer & Semidey, 2015). In this observational study, each subject underwent complete clinical and paraclinical examination, in order to establish a correct diagnosis.

Splint therapy is commonly used for patients diagnosed with TMD, and the large variety of occlusal appliances

allows practitioners to apply treatment according to the type of disorder (Alqutaibi & Aboalrejal, 2015).

Several studies proved the efficiency of Michigan splint for patients suffering from disc displacements with reduction (DDwR) or disc displacements without reduction (DDwoR) (Ekberg et al., 1998; Nilner et al., 2008; Doepel et al., 2012). Our retrospective study also highlighted the efficiency in reducing pain and a lower efficiency in reducing joint clicking (87% of the subjects included reported the absence of pain after 3 months and only 19.5% exhibited a decrease in the intensity of clicks). Flat stabilization splints, such as Michigan splint, are known to reduce abnormal muscular activity, to increase the vertical dimension of occlusion (VDO) and stabilize the TMJ. Therefore, they are especially used for intraarticular disorders, particularly associated with disc displacements (Al-Ani et al., 2005).

Also, 66% of the subjects treated with the hydrostatic splint (Aqualizer®) reported a remission of pain, while 83% of the patients treated with the Jeanmonod splint observed the disappearance of painful symptoms in the masticatory muscles.

Aqualizer® is a hydrostatic appliance with several indications in clinical practice, including TMJ pain, headache, post-surgical pain and inflammation. The water-filled chamber optimizes, immediately after placement, the biomechanics and allows the muscles to automatically reposition the jaw. Therefore, it is also indicated for TMD associated with inflammation, as the relief obtained by using this appliance is considered essential (Srivastava et al., 2013).

Jeanmonod is a type of anterior deprogrammer, which modifies the maxillomandibular relationship, so that the mandible will move to a more anterior position. It is indicated as a therapeutic measure in muscular disorders as it prevents clenching or other parafunctional activities; as a result, the muscle pain is reduced (Srivastava et al., 2013).

The hypothesis of this retrospective study was that, indicated according to diagnosis, each type of splint can be effective. The results confirmed the hypothesis, as all three occlusal appliances were effective, but with no significant difference among the three groups of subjects. In other words, each splint used in therapy accomplished its purpose, but statistical analysis revealed no significant difference between each splint's capabilities of treatment as long they were indicated according to the type of TMD.

The amount of time a splint should be worn depends on three factors, according to Dawson: (1) until the pain disappears; (2) when the joint becomes stable; (3) when the occlusal relationships are also stable. At the same time, stability of the occlusal relationships and temporomandibular joint is influenced by other three factors: eliminating the painful symptoms, examining centric relation and identifying any interference and establishing stable occlusal contacts between the splint and the antagonist teeth (which can be obtained after a few days/ or even weeks of wearing the splint) (Dawson, 2007).

Fisher's exact test was used as the group sizes were small and unpaired. Statistical analysis revealed no significant difference regarding the type of splint. Each type of splint used for the subjects included in this study was efficient, as long as it was indicated according to the type of TMD. The findings of our study are in accordance with those of other studies published in the literature (Gözler et al., 2012; Yadav et al., 2011; Asbjorn et al., 2005).

However, splint therapy alone will not eliminate the occlusal interferences. This is why occlusal appliances will not treat the main cause of the temporomandibular disorder. In this context, a further step after the splint therapy would be occlusal equilibration (Dawson, 2007).

An important aspect regarding the splint therapy is that the patient should follow the practitioner's instructions (Klineberg & Jagger, 2004; Re et al., 2009): (1) the splint should be worn during the night; (2) although the splint will initially determine hypersalivation, this effect will disappear in a few hours; (3) the patient might feel that the splint is too tight on certain teeth, but the discomfort will be reduced after a while; (4) the patient must pay special attention to oral hygiene as the splint favors bacterial plaque accumulation which will lead to carious lesions and gingival inflammation; (5) in the case of dental restorations performed after the splint was applied, the appliance should be adjusted to the new dental morphology.

Conclusions

1. Taking into consideration the limitations of this study, we can conclude that, if indicated correctly, splint therapy is an effective method to reduce the specific symptoms encountered in patients with TMD.

2. Although efficient, this therapy should not replace other treatment options, such as occlusal equilibration, medication, patient education, or physical therapy.

3. Therefore, we consider that correct diagnosis and indicating the type of splint according to the subtype of TMD are very important aspects which will influence the overall treatment prognosis.

4. As occlusal splints are also used in sports, they may influence motor performance and improve the neuromuscular dynamics, especially in the case of athletes. Further clinical studies should be conducted in this matter.

Conflicts of interests

No conflicts of interests

References

Al-Ani Z, GrayRJ, Davies SJ, Sloan P, Glenny AM. Stabilization splint therapy for the treatment of temporomandibular myofascial pain: a systematic review. J Dent Educ 2005;69(11):1242-1250.

Alqutaibi AY, Aboalrejal AN Types of Occlusal Splint in Management of Temporomandibular Disorders (TMD). J Arthritis. 2015;4(4):176. doi:10.4172/2167-7921.1000176.

Chang SW, Chuang CY, Li JR, Lin CY, Chiu CT. Treatment Effects of Maxillary Flat Occlusal Splints for Painful Clicking of the Temporomandibular Joint. Kaohsiung J Med Sci, June 2010; 26(6):299-306. doi: 10.1016/S1607-551X(10)70043-7.

D'Ermes V, Basile M, Rampello A, Paolo C Di. Influence of occlusal splint on competitive. Ann Stomatol (Roma). 2012;3(3-4):113-118.

Dawson PE. Functional Occlusion: From TMJ to Smile Design, Mosby Elsevier, 2007.

De Leeuw R, Klasser GD.Orofacial Pain: Guidelines for assessment, diagnosis, and management. (5th ed). Quintessence Publishing Co, Inc, Chicago, 2013.

Deshpande RG, Mhatre S. TMJ disorders and occlusal splint therapy A Review. Int J Dent Clinics 2010; 2(2): 22-29.

Dias A, Redinha L, Mendonça GV, Pezarat-correia P. A systematic review on the effects of occlusal splint therapy on muscle strength. CRANIO® J Craniomandib Sleep Pract [Internet]. 2018;1-9. Available from: https://doi.org/10.1080/08869634.2018.1505085.

Dias A, Redinha L, Vaz R, Cordeiro N, Silva N, Pezarat–Correia P. Effects of occlusal splints on shoulder strength and activation, Annals of Medicine, 2019;51:sup1, 15-21, DOI: 10.1080/07853890.2019.1566766

Doepel M, Nilner M, Ekberg E, Le Bell Y. Long-term effectiveness of a prefabricated oral appliance for myofascial pain. J Oral Rehab. 2012;39(4):252-260. doi:10.1111/j.1365-2842.2011.02261.x.

Ekberg E, Vallon D, Nilner M. Occlusal appliance therapy in patients with temporomandibular disorders. A double-blind controlled study in a short-term perspective. Acta Odontol Scand. 1998;56(2):122-128. doi: 10.1080/00016359850136102.

Gauer RI, Semidey MJ. Diagnosis and Treatment of Temporomandibular Disorders. American Family Physician. 2015;91(6):378-388.

Gözler S, Vanlioglu B, Evren B, Gözneli R, Yildiz C, Özkan Yk., The Effect of Temporary Hydrostatic Splint on Occlusion With Computerized Occlusal Analysis System. Indian J Dent Res. 2012;23(5):617-622. doi: 10.4103/0970-9290.107353.

Jeanmonod A. Occlusodontologie: Applications Cliniques. Edition CDP, 1998

Jokstad A, Mo Ar, Krogstad BS. Clinical comparison between two different splint designs for temporomandibular disorder therapy. Acta Odont Scandin. 2005;63(4):218-226. doi: 10.1080/00016350510019982.

Klasser GD, Greene CS. Oral appliances in the management of temporomandibular disorders. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2009;107(2): 212-223. doi: 10.1016/j.tripleo.2008.10.007.

Klineberg I, Jagger RG. Occlusion and Clinical Practice: An Evidence-Based Approach. 1st edition, Wright, 2004.

Leroux, Eric, Leroux S, Maton F, Xavier R. Influence of dental occlusion on the athletic performance of young elite rowers: a pilot study. Clinics (Sao Paulo, Brazil) vol. 73 e453. 29 Nov. 2018, doi:10.6061/clinics/2017/e453.

Maurer C, Heller S, Sure J, Fuchs D, Mickel C, Wanke EM, Groneberg DA, Ohlendorf D. Strength improvements through occlusal splints ? The effects of different lower jaw positions on maximal isometric force production and performance in different jumping types. PLoS One. 2018;1-17.

Militi A, Cicciù M, Sambataro S, Bocchieri S, Cervino G, De Stefano R, Fiorillo L. Dental occlusion and sport performance [published online ahead of print, 2020 Mar 16]. Minerva Stomatol. 2020;10.23736/S0026-4970.20.04350-2. doi:10.23736/S0026-4970.20.04350-2.

Naikmasur V, Bhargava P, Guttal K, Burde K. Soft Occlusal Splint Therapy In The Management Of Myofascial Pain Dysfunction Syndrome: A Follow-Up Study. Indian J Dent Res. 2008;19(3):196-203. doi: 10.4103/0970-9290.42950.

Nilner M, Ekberg EC, Doepel M, Andersson J, Selovuo K, LeBell Y. Short-term effectiveness of a pre fabricated occlusal appliance in patients with myofascial pain. Orofac Pain. 2008;22(3):209-218.

Nishigawa K, Suzuki Y, Ishikawa T, Bando E. Effect of occlusal contact stability on the jaw closing point during tapping movements. J Prosthodont Res. 2012;56(2):130-135. doi: 10.1016/j.jpor.2011.04.005.

Okeson JP. Management of temporomandibular disorders and occlusion: Elsevier Health Sciences, 2012.

Re JF, Chossegros C, Zoghby A El, Carlier JF, Perez C, Ortholieb JD. Review on occlusal splints: why, how, when? Rev Odont Stomat. 2009;38:159-176. Available athttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760352/.

Schiffman E, Ohrbach R, Truelove E, Look J, Anderson G, Goulet JP, List T, Svensson P, Gonzalez Y, Lobbezoo F, Michelotti A, Brooks SL, Ceusters W, Drangsholt M, Ettlin D, Gaul C, Goldberg LJ, Haythornthwaite JA, Hollender L, Jensen R, John MT, De Laat A, de Leeuw R, Maixner W, van der Meulen M, Murray GM, Nixdorf DR, Palla S, Petersson A, Pionchon P, Smith B, Visscher CM, Zakrzewska J, Dworkin SF; International RDC/TMD Consortium Network, International association for Dental Research; Orofacial Pain Special Interest Group, International Association for the Study of Pain. Diagnostic criteria for temporomandibular disorders (DC/TMD) for clinical and research applications: recommendations of the International RDC/TMD Consortium Network and Orofacial Pain Special Interest Group. J Oral Facial Pain Headache. 2014 ;28 (1):6-27. doi: 10.11607/jop.1151.

Srivastava R, Jyoti B, Devi P. Oral splint for temporomandibular joint disorders with revolutionary fluid system. Dent Res J (Isfahan). 2013;10(3):307-313. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760352/

Sung-wen C, Ching-ya C, Jau-rong L, Che-yi L, C C. Treatment Effects of Maxillary Flat Occlusal Splints for Painful Clicking of the Temporomandibular Joint. Kaohsiung J Med Sci June. 2010;26(6):299-307.

Yadav S, Karani JT. The essentials of occlusal splint therapy. Int J Prosthetic Dent 2011;2:12-21.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 88–92

Monitoring healing of orthopedic ailments with an original instrumented crutch

Cristina Reynders-Frederix[1], Peter Reynders-Frederix[2], Innocenti Bernardo[3], Tamas Illes[4,5], Mihai Berteanu[6]

[1]University Hospitals Brussels, campus Saint-Pierre, Université Libre de Bruxelles
[2]University Hospitals Brussels, campus Brugmann, Université Libre de Bruxelles
[3]BEAMS (Bio Electro and Mechanical Systems), Université Libre de Bruxelles
[4]University Hospitals Brussels, campus Brugmann, Department of Orthopedic Surgery, Université Libre de Bruxelles
[5]University of South Denmark, Department of Orthopedics & Traumatology, Odense
[6]Department of Revalidation & Physiotherapy, Carol Davila University of Medicine and Pharmacy, Bucharest, Romania

Abstract

Background. Walking aids are often prescribed in the aftermath of an orthopedic condition of the lower limbs to ensure balance and reduce loading of the injured limb. Correct use of these crutches is difficult because efficient instruments are lacking to monitor the forces acting on the lower limb and crutches.

Aims. The aim of this project was to produce an atraumatic, cheap, and portable tool to assist patients and therapists in rehabilitation, and in conducting gait analysis. With the development of these instrumented crutches, the authors hope to increase their possibilities to monitor the functional evolution of a person during recovery after musculoskeletal ailments.

Methods. We describe the development of a wireless instrumented forearm crutch to monitor the gait of eighteen orthopedic patients during their convalescence. Seven volunteers served as a control group. By using four strain gauges installed as a full Wheatstone bridge, pure compression in the crutch bar is measured. A tri-axial accelerometer is used for determining the movement speed of the crutch in the sagittal plane. The pitch and roll angles in the frontal plane were measured using a tri-axial accelerometer and gyroscope.

Results. Unfortunately, no difference was found between a control group of healthy volunteers and the group of orthopedic patients. Also, the authors did not find a relation between the different gait parameters.

Conclusions. Using the three parameters obtained from the wireless connected forearm crutch, we could not create an algorithm to characterize gait in a group of patients with different orthopedic conditions of the lower leg. The results were not different from the parameters obtained from a group of healthy volunteers.

Keywords: rehabilitation, partial weight bearing, strain gauges, instrumented crutches, real time monitoring, end user program, compression, full Wheatstone bridge.

Introduction

Around six million people in the US are crutch users, and more than 575,000 patients in the USA are prescribed crutches each year (Kaye et al., 2000).

Walking aids are often used as an essential rehabilitation tool to help patients in their functional recovery. Often, the crutch is the last stage in the rehabilitation program after lower limb orthopedic surgery. In addition, much of the time, these patients are somehow reluctant to leave the comfort of a wheelchair. This is not ideal because the use of crutches places the patient in a more physiological upright position (Rasouli & Reed, 2020). Crutches are often difficult to use. Problems such as fatigue and soreness of hands, axillae, and chest wall are often mentioned. Also, the underestimated difficulties patients have when trying to use these crutches without them falling to the ground makes the crutches cumbersome (Merrett et al., 2009; Merrett et al., 2010; Tonutti, 2015).

Received: 2020, March 12; *Accepted for publication:* 2020, March 21
Address for correspondence: Department of Rehabilitation Medicine, Elias University Hospital, Mărăşti Av, No. 17, 1st District, PC 011416, Bucharest, Romania
E-mail: Cristina_reynders-frederix@stpierre-bru.be
Corresponding author: Cristina Reynders-Frederix, Cristina_reynders-frederix@stpierre-bru.be
https://doi.org/10.26659/pm3.2020.21.2.88

Although crutches are often prescribed by a physiotherapist to facilitate postoperative walking, the exact knowledge of the forces acting on the affected limb in a certain clinical situation is difficult to obtain (Rasouli & Reed, 2020; Tonutti, 2015); however, this information is important as instruments used to monitor the progression of functionality and proprioception during rehabilitation are missing. Radiographs provide a lot of information on the healing process. For example, patients often perform poorly on a functional level, even with an excellent radiological outcome. A typical example is total knee arthroplasty, which does not give satisfaction in 20% of the patients. In these cases, radiographs look good, but the patient is lacking functional recovery and has persistent pain and muscle wasting (Kahlenberg et al., 2018).

The aim of this project was to develop an instrumented wireless crutch that records *force, pitch and roll* movement in a plane perpendicular to the line of movement and angle speed of the crutch in a sagittal plane, in line with the patient's progression. Hence, we wanted to increase our armamentarium to monitor gait in an objective way. In part, this work is inspired by previous studies that developed a similar tool (Merrett et al., 2009; Sardini et al., 2014).

Our null hypothesis was to see a clear difference between the control group and the patient group by using force, angle speed of the crutch in the sagittal plane and crutch position as the parameters.

Methods and patients

Between 2015 and 2018 the departments of Biomedical Engineering, Physiotherapy and Orthopedic Surgery of the Free University of Brussels developed a wireless instrumented elbow crutch (Merrett et al., 2009; Sardini et al., 2014; Lofstrand 1948, 1955). In contrast to these previous studies, we were more interested in monitoring the actual loading of the injured limb than the percentage of weight bearing (% PWB). The % PWB indicates the percentage of body weight divided by the crutch and affected limb. Although partial weight bearing is commonly used as a guide in postoperative rehabilitation, % PWB is rather ambiguous. The current subjective method asks the patient to rest on the weight scale to evaluate what the target PWB feels like. Patients are unable to follow prescribed instructions on how much to load the affected limb. In our setting, with real load recording, no audible biofeedback was needed. In total, we gathered 18 patients and seven volunteers for the current pilot study.

Design of the instrumented crutch. The crutch in the current study is a standard elbow crutch with an aluminum frame. The advantage of using these crutches has been previously described (Papadosifos, 2014; Rasouli & Reed, 2020). Therefore, an aluminum crutch was the optimal choice, because of its lightness (2,700 kg/m^3), tensile strength (70-700 MPa) and Young's modulus (69 GPa) (***, 2015).

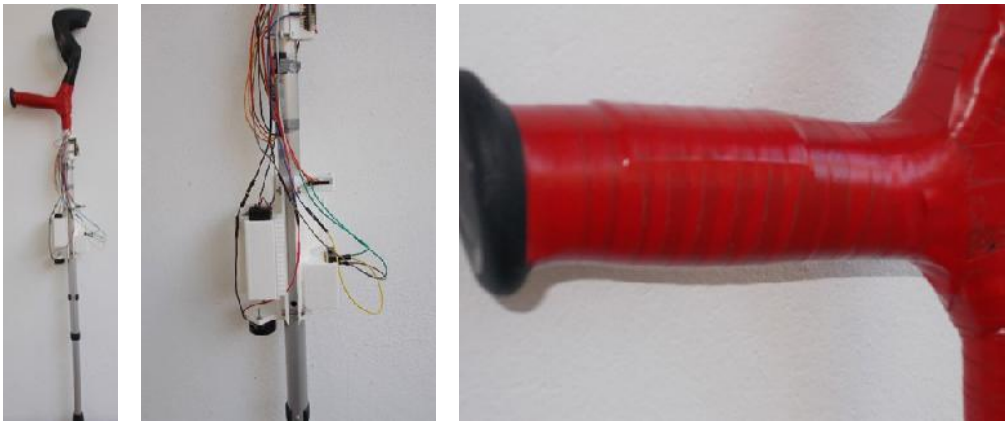
The prototype includes four strain gauges installed as a full Wheatstone bridge. Pure compression in the crutch bar is measured. In addition, a gyroscope and a tri-axial accelerometer (GY-521) are used to compute the roll and pitch angle. Lastly, the data is sent by Bluetooth to a developed end user program made in Python by means of a microcontroller (ESP32) (Fig. 1).

Data can then be visualized simultaneously on a computer, or retrieved at a later time. These data could give the examiner an idea of the cadence (smoothness) of walking expressed as periods in time.

The gyroscope was used to calculate the position of the crutch in relation to the center of the body in the frontal plane. In theory, leaning away from the neutral axis of the body could bring a higher load on the crutch and a lower load on the contralateral leg (Fig. 2a, b).

We made an assumption that, with the Lofstrand crutch, the torque, because of the eccentric loading of the crutch, would be minimal due to the resting position of the forearm, seated well in the forearm cuff of the crutch (Brinckmann et al., 2016).

A summary of component choices for the instrumented crutch is presented in Table I.



a) b) c)

Fig. 1 – Instrumented crutch.

Fig. 2a – Crutch position: negative

Fig. 2b – Crutch position: positive

Table I

A summary of component choices for the instrumented crutch.

Purpose	Component
Microcontroller & Interface	Arduino Uno
Pitch sensing	MPU-6050 Gyroscope/ Accelerometer IMU
Wireless transmission	ESP32 LoRa
Off/On Switch	Rocker Switch
Graphic Software	PyCharm version 2019.1.3 (Jet Brains Czech)

Patients used for the study

All patients gave their informed consent to participate in the study.

A feasibility study was conducted with 18 patients who displayed different orthopedic ailments. Also, seven normal volunteers (three females and four males) were included in the current pilot study as controls. Patients with neurological problems and elderly with dementia who were not able to understand the purpose of the study were excluded from participation. We chose a two-point contact contralateral crutch gait because this type of support is mostly prescribed at the end of the revalidation period of an orthopedic ailment.

The main objective of the current study was the feasibility or handling of the instrumented crutches. In addition, we wanted to characterize the quality of walking, which was taken into account using the three parameters obtained from the crutch: angular speed of the crutch in the sagittal plane, expressed as cycles per second (Hz), force (Newton) and crutch position (index).

The position of the crutch was represented by a curve with positive and negative parts. The positive and negative areas under the curve were calculated and presented as an index; the positive area divided by the negative area.

An index above 1 means the crutch was leaning away from the body center, and that patients were putting more pressure on the crutch. An index of less than 1 means the crutch was kept closer to the midline of the body, with more pressure on the contralateral limb.

The crutch position index is the ratio between the positive area and the negative area of the recorded curve (Fig. 3).

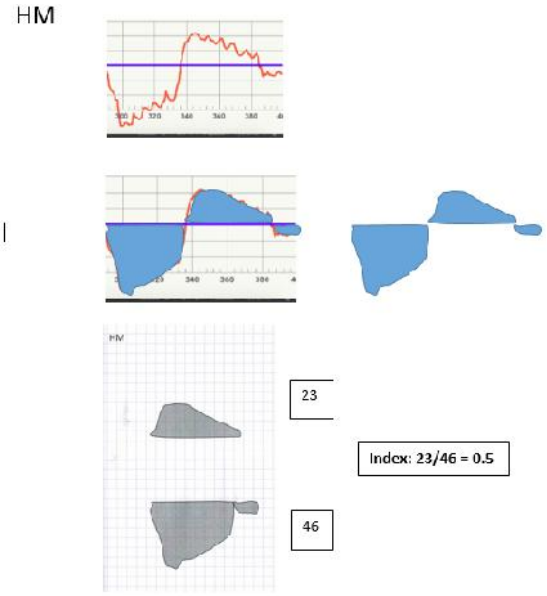


Fig. 3 – Measuring the area under the curve for positioning of the crutch in the frontal plane.

Data of the patients were compared with data from the volunteers (Table I).

The load on the affected leg was calibrated with a mechanical scale, and this was repeated before every recording (Fig. 4).

Fig. 4 – Callibration of the crutch before each test was done with a bathroom scale. The crutch was positioned on wooden blocks to be level with the mechanical scale.

The patients and volunteers were asked to practice with regular crutches for 15 minutes. After that, they were asked to walk in bare feet across an indoor trajectory three times over a distance of 5 meters with the instrumented crutches; this was done on a non-slip conductive rubber walkway. The test was repeated five times for every crutch position.

The data, force, frequency and crutch positions were recorded by a portable computer with Bluetooth capabilities (Fig. 5).

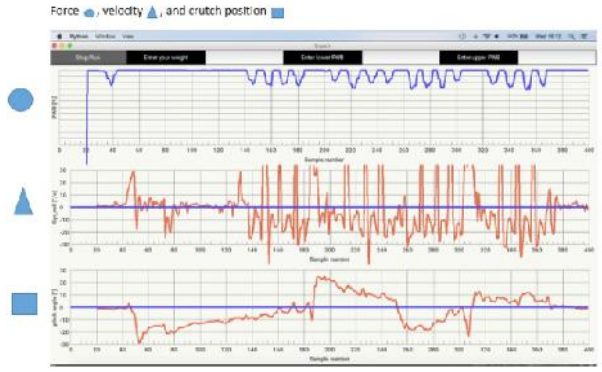


Fig. 5 – Example of data acquired from the instrumented crutch.

Statistics

GraphPad Instat 3 was used. The statistical analyses assessed the Gaussian distribution by using the Kolmogorov–Smirnov test. An unpaired non-parametric Mann-Whitney test was used to compare the means. Regression and correlation were tested with multiple X variables (multiple regression). The level of significance was set at 5%.

Results

In two cases, we could not record the data for technical reasons. For these reasons, one volunteer and one patient were excluded.

a) A multiple regression analysis between the *force as a constant* variable with frequency and position of the crutch (pitch) within the *group of volunteers* is as follows:

- Force = 32.529 +6.187xV- 0.4981xPitch
- R^2= 2.24% percent of the variance in force explained by the model.
- P value is 0.8533 and is considered not significant.
- Looking for the significant contribution of one variable, we could not find a variable that contributed to the results significantly.

b) The multiple regression analysis between *force as a constant* variable with frequency and position of the crutch (pitch) within the *group of patients* is as follows:

- Force= 87.677- 0.8762xV-0.3186xPitch
- R^2=2.84% percent of the variance in force explained by the model.
- *P value is 0.7609*, which is considered not significant.
- Looking for the significant contribution of one variable, we found force as a variable that contributes significantly to the equation.

c) A non-parametric Mann-Whitney test was performed to compare the variable *force* between volunteers and patients. The two-tailed *P value is 0.1197*, which is considered not significant.

d) A non-parametric Mann-Whitney test was performed to compare the variable *frequency* between volunteers and patients. The two-tailed *P value is 0.7233*, which is considered not significant.

e) A non-parametric Mann-Whitney test was performed to compare the variable *pitch* between volunteers and patients. The two-tailed *P value is 0.4509*, which is considered not significant.

Discussion

This is the first study where an instrumented crutch was used to monitor the walking gait of patients, using healthy subjects as the control group. Other studies have merely used healthy subjects (Merrett et al., 2009; Sardini et al., 2014). Very few articles exist on the subject of instrumented crutches. Sometimes, these are also called "intelligent crutches" (Merrett et al., 2009; Sardini et al., 2014; Tonutti 2015).

Interestingly, previous scholars recorded the loading as a percent of the total load bearing capacity of a limb (Stallard et al., 1980). The % PWB is often used to indicate how much weight a patient can bear. In reality, this has little value. In contrast to some authors who stated that overdue weight bearing on the injured leg was possible (Aro & Chao, 1993), it was never proven that normal patients, without severe proprioceptive deficits, were able to overload and damage healing limbs. Also, the notion of % PWB is exceedingly difficult to use as a communication tool with physiotherapists. Overall, patients do not understand what it means to load the injured limb to a certain percentage.

Therefore, we adopted another strategy in our pilot study: the real loading of the injured limb was measured.

In combining this new strategy with angular frequency of the crutch movement in the sagittal plane and positioning of the crutch in the frontal plane, we hoped to create an algorithm that could characterize the quality of walking. With this algorithm we could express, in percentage, the progress in recovery from an orthopedic ailment of the lower limb.

Unfortunately, we could not find any significant difference between patients and volunteers for all three studied parameters: *force, angle speed of the crutch in the sagittal plane* and *crutch position*. Also, a multiple regression analysis could not give a clear explanation of the variance between the other variables.

Our results do not corroborate with the findings of Smidt and Mommens who showed in their study that normal gait is faster than walking with crutches (Smidt & Mommens, 1980). Also energy consumption, which is the area under the force versus velocity curve, did not show any differences between patients and the control group. In other studies, the indoor track also included stair climbing indicating a variation in difficulties (Merrett et al., 2009; Merrett et al., 2010; Tonutti, 2015; Sardini et al., 2014; Stallard et al., 1980).

In our study, the walking pad was smooth, without any obstacles, making walking easy, too easy?

Although the results are rather disappointing, it is worth noting that:

a) For a healthy volunteer who has no knowledge of crutch handling, it seems rather difficult to learn this. In most other studies, only healthy subjects were used. This makes their results difficult to compare with the results of the current study, where patients were predominantly investigated.

b) As we can see from the position of the crutch, this varied from patient to patient. In the recorded curve of a same patient, the position of the crutch could be both positive (upper part of the crutch away from the axis of the patient) and negative (upper part of the crutch near to the axis of the patient). The index values varied from 0.01 to 79.

c) The knowledge of loads and inclinations of the crutch can provide valuable information for walking correctly. The recorded data can be used for a variety of applications. The previous instrumented crutches were merely developed with an audible biofeedback system that warned the patient when he or she was overloading his or her limbs. The cut-off point for overloading the injured limb is an intuitive process made by the physiotherapist and is merely based on his opinion as an expert (level V of evidence). As previously mentioned, the patients seemed unable to follow the prescribed instructions on how much load to place on the affected limb.

We would like to acknowledge some shortcomings of the study as well.

A major drawback was the fixed length of the crutch. Because of the applied equipment of the inbuilt sensors, adapting the length of the crutch to the patient length was difficult. As a general guideline, the length of the crutch should be approximately 75% of patient's height (Kendall et al., 2005).

Because of the insufficient packaging of the hardware around the crutch, the wired crutch became fragile and difficult to use outside the laboratory.

The reason for not finding a cluster of data that could be used to characterize gait progress in patients is not straightforward and represents a rather counter-intuitive observation. Obviously, characterizing walking with only three parameters looks futile. Probably, more variables play an important role in walking with a crutch. For example, the damping of loading by proprioception and muscle action could not be incorporated in our model.

Conclusions

1. We constructed an instrumented crutch that could record the actual loading of the limbs together with the angle velocity of the crutch in the sagittal plane and position of the crutch in the frontal plane.

2. Unfortunately, with the data recorded, we failed to obtain a significant algorithm that could be used to evaluate the progress of the patient while recovering from an orthopedic ailment. Regarding the above mentioned analyses and results, we have to reject our null hypothesis.

Conflicts of interests

The authors declare to have no conflict of interest in the above mentioned article.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

Aro H, Chao E. Bone-Healing Patterns Affected by Loading, Fracture Fragment Stability, Fracture Type, and Fracture Site Compression. Clin Orthop Relat Res. 1993;(293):8-17. https://pubmed.ncbi.nlm.nih.gov/8339513/ .

Brinckmann P, Frobin W, Leivseth G. Orthopedic Biomechanics. Thieme G Pub Stuttgart, 2016. DOI: 10.1055/b-0036-140415.

Kahlenberg CA, Nwachukwu BU, McLawhorn AS., Cross MB, Cornell CN, Padgett DE. Patient satisfaction after total knee replacement: A systematic review. HSS Journal 2018;14(7):192-201. doi: 10.1007/s11420-018-9614-8.

Kaye HS, Kang T, LaPlante MP. Mobility device use in the United States. Nat Inst Disab Rehab Res. 2000;14:1-60. Available at: https://www.researchgate.net/publication/238271865.

Kendall FP, McCreary EK, Provance PG, Rodgers M, Romani W, eds. Muscles Testing and Function, 5th edition. Philadelphia, PA: Lippincott Williams and Wilkins; 2005.

Lofstrand ARJ. Crutch. US Patent No. 2.453.632, 1948; Lofstrand ARJ. Crutch. US Patent No. 2.711.183, 1955.

Merrett GV, Ettabib MA, Peters C, Hallett White NM. Augmenting forearm crutches with wireless sensors for lower limb rehabilitation. Measurement Sci Tech, 2010;21(12):5-8. DOI: 10.1088/0957-0233/21/12/124008.

Merrett GV, Peters C, Hallet G, White NM. An instrumented crutch for monitoring patients' weight distribution during orthopaedic rehabilitation. Proc Chem 2009;1(1):714-717. Doi:10.1016/j.proche.2009.07.178.

Papadosifos N. The Complications of Crutches - A Summary of a Systematic Review of the Literature. ARGnote. 2014;1(4):1-2.

Rasouli F, Reed KB. Walking assistances using crutches: A state of the art review. J Biomechanics 2020;98:109489. doi: 10.1016/j.jbiomech.2019.109489.

Sardini E, Serpelloni M, Lancini M, Pasinetti S. Wireless Instrumented Crutches for Force and Tilt Monitoring in Lower Limb Rehabilitation. Proc Engin 2014;87:348-351. doi:10.1016/j.proeng.2014.11.745.

Smidt GL, Mommens MA. System of reporting and comparing influence of ambulatory aids on gait. Phys.Ther. 1980;60(5):551-558. https: //doi.org/10.1093/ptj/60.5.551.

Stallard J, Dounis E, Major RE, Rose GK. One leg swing through gait using two crutches. An analysis of the ground reaction forces and gait phases. Acta Orthop Scand. 1980;51(1):71-77. doi: 10.3109/17453678008990771.

Tonutti M. The Companion Crutch: Design and Development of a Wireless Instrumented Crutch. CID:00689643, 2015. DOI: 10.13140/RG.2.2.20813.33763.

Vanderlinden G. Design and implementation of an instrumented crutch for rehabilitation. Master's Degree in Master of Science in Electromechanical Engineering . ULB, 2020

***. Aluminium Properties, 2015. Available at: http:// www.aluminiumdesign.net/why-aluminium/properties-ofaluminium. Retrieved 2015, June 15.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 93–96

REVIEWS

The importance of the clavicle biomechanics in the shoulder movement

László Irsay[1,2], Adela Raluca Nistor[2], Alina Ciubean[1], Ileana Monica Borda[1,2], Rodica Ungur[1,2], Ioan Onac[1,2],Viorela Ciortea[1,2]
[1] *"Iuliu Hatieganu" University of Medicine and Pharmacy Cluj-Napoca, Romania*
[2] *Clinical Rehabilitation Hospital Cluj-Napoca, Romania*

Abstract

The sternoclavicular joint (SC) provides the attachment belt for the upper limb. It is the only direct joint that attaches the upper limb to the trunk. Practically, the clavicle moves while the sternum remains fixed. The SC joint is an important fulcrum for the movement of the shoulder girdle. The disc and ligaments of the SC joint offer such an effective support that the dislocation of the sternoclavicular joint is rare. The acromioclavicular joint (AC) connects the acromial process of the scapula and the clavicle. The movements of the AC joint are minimal, but crucial for the normal shoulder motion.

In clinical practice, the movement of the clavicle is often neglected. This movement occurs in 3 planes; the integrity of these movement planes is essential in the complex motion of the arm. Any disturbance in the normal movement of the clavicle will automatically limit the range of motion of the arm, especially the abduction.

The researchers consider that, from the practical point of view, the knowledge regarding the biomechanics of the clavicle is critical, since any limitation of the mobility of the shoulder can shroud a pathology that can block the mobility of the clavicle.

Keywords: sternoclavicular joint, acromioclavicular joint, shoulder.

Introduction

The clavicle is a long, paired bone that connects the shoulder girdle to the trunk. The importance of the clavicle is often underestimated when assessing the shoulder.

From an embryological point of view, the clavicle ossifies in membranes and it is the first bone in the skeleton for which ossification begins in the fifth week of pregnancy (Palastanga et al., 2002).

Biomechanics of the clavicle

The sternoclavicular (SC) joint provides an attachment belt for the upper limb. It is the only direct joint through which the upper limb attaches to the trunk. The sternoclavicular joint is a synovial membrane joint that is flat in shape and has a sliding motion in two planes. The movements appear in three planes and accompany the motions of the shoulder girdle. Although these movements are more subtle than those of most joints, they are still important.

Practically, the clavicle moves while the sternum remains fixed.

The SC joint has a synovial membrane, and consequently, it has an articular capsule. It also has three major ligaments and one disc. The articular capsule surrounds the joint and is strengthened by the anterior and posterior sternoclavicular ligaments.

The main function of the articular disc is to cushion, especially by using the forces that appear when an individual falls on the outstretched hand. The disc and ligaments provide such an effective support that the dislocation of the sternoclavicular joint is rare. The fastening of the disc contributes to the possibilities of movement at this level - it has a double fastening, similar to a swing door, and allows movement in both directions. During the lifting and lowering of the shoulder girdle, the movement occurs between the clavicle and the disc. During pre- and post-projection, the movement occurs between the disc and the sternum.

The disc plays an important biomechanical role; according to some MRI imaging studies, the disc is the structure that is most frequently damaged in about 80% of the situations (Benitez et al., 2004). The sternoclavicular

Received: 2020, February 3; *Accepted for publication:* 2020, February 20
Address for correspondence: Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, the Department of Medical Rehabilitation within the Rehabilitation Hospital in Cluj-Napoca, 46-50 Viilor Street, Cluj-Napoca, PC 400437
E-mail: adela_raluca_nistor@yahoo.com
Corresponding author: Adela Raluca Nistor, adela_raluca_nistor@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.93

joint is supported by 3 ligaments: sternoclavicular (anterior and posterior), costoclavicular and interclavicular. The costoclavicular ligament extends from the lower edge of the clavicle to its upper edge and plays a major role in blocking clavicle lifting, but especially in stabilizing the clavicle lifting movement. The interclavicular ligament is located above the handlebar, connecting the superior sternal ends of the clavicles. Its purpose is to limit the lowering of the clavicle. Injuries and pain related to trauma of the anterior, posterior, interclavicular and costoclavicular ligaments were seen in 73%, 39%, 29% and 14% of patients, respectively (Benitez et al., 2004).

The anterior sternoclavicular ligament is the most involved structure during antepulsion and depression movements. During antepulsion, lesions of the posterior sternoclavicular ligament are most frequent during elevation, and the costoclavicular ligament is the most frequently injured ligament. The resistance of the sternoclavicular joint is significantly greater during the antepulsion movement when compared to retropulsion (Negri et al., 2014).

The sternal end of the clavicle and handlebar are incongruous, they are tangent through a small contact surface. The medial upper portion of the clavicle has no contact with the handlebar, but it serves as an attachment site for the sternoclavicular disc and interclavicular ligament. At rest, the sternoclavicular joint has an upper V-shaped opening (Rudzki et al., 2003).

Cadaver studies focusing on sternoclavicular stability have shown that cutting the costoclavicular and interclavicular ligaments had little effect on sternoclavicular joint translation. Cutting the anterior capsule only produced significant increases in anterior translation, but to a lesser degree (25%) than sectioning of the posterior capsule. The conclusion was that the posterior capsule is the most important constraint for posterior and anterior translation of the distal clavicle. The fact that the posterior capsule of the SC joint is stronger than the anterior one also explains the higher frequency of the anterior dislocation (Renfree et al., 2003; Spencer et al., 2002).

Dislocation of the SC joint is rarer, around 1% of all dislocations and about 3% of those affecting the upper limb, well below what appears at the level of the glenohumeral or acromioclavicular joint. It usually occurs in young men after activities with a high-energy mechanism of injury. Most of them, however, are the equivalent of a sprain, and have no long-term functional consequences (Robinson et al., 2008).

Another source of shoulder girdle dysfunction is sternoclavicular instability. Anterior dislocation is often unstable and conservative treatment is recommended if shoulder functionality is maintained. However, surgical intervention is indicated if the pain or disability of the shoulder girdle has an impact on activities of daily living. In case of surgery, the figure-of-eight semitendinosus technique has superior initial biomechanical properties and may produce improved clinical outcomes in SC joint instability (Spencer & Kuhn, 2004; Van Tongel & De Wilde, 2012; Sewell et al., 2013; Thut et al., 2011; Little et al., 2012).

Posterior dislocation is rarer, but with possibly worse consequences due to the anatomical structures that may be damaged. Surgical treatment is often recommended in this case to stabilize the SC joint (Macdonald & Lapointe, 2008; Martetschläger et al., 2014). In surgical stabilization, the figure-of-eight reconstruction using the free tendon graft method is preferred; it has been shown to recreate the native anatomy with the most robust biomechanical profile (Warth et al., 2014a).

The acromioclavicular joint (AC) connects the acromial process of the scapula to the lateral part of the clavicle. It is a flat synovial joint, but it has three planes of motion. The range of motion is minimal, but very important for the normal function of the shoulder. The weaker joint capsule is strengthened by two ligaments, superior and inferior. These ligaments provide support to the joint by maintaining the acromion to the clavicle and thus preventing clavicle dislocation. The coracoclavicular and coracoacromial ligaments are two accessory ligaments of the AC joint. Together, they prevent the scapula from slipping backwards and, individually, each limits the scapula's rotation movements (Lippert, 2006). Cadaver-based studies have shown that sectioning of the AC ligament increased clavicular retraction during sagittal plane elevation and horizontal plane adduction. Sectioning of the trapezoid ligament decreased scapular external rotation during sagittal plane elevation and horizontal plane adduction. Sectioning of the conoid ligament decreased scapular posterior tilting during sagittal plane elevation and horizontal plane adduction. Acromioclavicular and coracoclavicular ligament sectioning also delayed clavicular posterior rotation and increased clavicular upward rotation during coronal plane elevation (Oki et al., 2014).

When elevating and lowering the clavicle, the medial extremity of the clavicle runs and slides on the disc which is relatively fixed. The upper point of the disc serves as a pivot point. When lifting the shoulder, the lateral extremity of the clavicle rotates upward, and when lowering the shoulder the movement is in the opposite direction.

Lifting movements are usually limited to 48 degrees and passive descent to 15 degrees. These movements in daily activities are not usually used to the fullest extent. Biomechanical studies have shown a variation of 15-31 degrees in the SC joint through the rotation of the clavicle during the movements of the arm in the frontal plane (abduction) and less in the sagittal plane (flexion). It was appreciated that the movement of the clavicle is 4 degrees for every 10 degrees of arm lifting, in the movement sector up to 90 degrees. Above this value, the movement of the clavicle appears to be smaller or even negligible. If the clavicle is blocked, the abduction of the arm will not exceed 110 degrees. It has been shown that the rotation movement of the clavicle in the SC joint (approximately 30 degrees) is significantly higher than in the AC joint. This fact has also been demonstrated clinically in different situations: the fixation of the clavicle by the coracoid process with a screw does not significantly limit the abduction of the arm; or, significant ectopic calcifications around the AC joint still allow functional abduction of the arm. On the other hand, ankylosis, trauma, fibrosis of the SC joint cause greater disability in terms of shoulder range of motion (Itoi et al., 2009; Warth et al., 2014b).

Clavicle fractures that strengthen viciously and lead to shortening of the clavicle severely affect the biomechanics of the shoulder girdle. A computational study that simulated a clavicle shortening of 0%, 5%, 10%, 15% and 20% from

its original size demonstrated a decrease in the shoulder elevation movements of the upper extremity muscles during abduction. Internal rotation movements are also decreased with shortening. Flexion movements were affected less through physiologic range of motion. The observed effects are due to a combination of changes in arm movements of the individual muscles, as well as a decrease in the force generating capacity of the muscles. Additionally, shortening of the clavicle increases coronal angulation of the clavicle in the SC joint (Patel et al., 2012).

The movement of the SC joint is reciprocal with the movement of the AC joint for all types of motion, excepting rotation, which of course takes place simultaneously. For example, the lowering of the medial extremity of the clavicle is simultaneous with the elevation of the lateral extremity of the clavicle, and when the lateral clavicle passes to the posterior plane, the medial one passes to the anterior plane (Ludewig et al., 2004).

In the antepulsion/retropulsion of the clavicle, the SC disc and the lower handlebar face of the clavicle serve as a pivot point. In these complex movements of the clavicle, the axis of the movements is not at the level of the SC joint, but rather at the level of the costoclavicular ligament that is located laterally. During antepulsion, the lateral extremity of the clavicle rotates anteriorly, and with retropulsion the rotation is posterior (Fig. 1). It is estimated that antepulsion occurs on an area between 15-20 degrees, and retropulsion between 20-30 degrees. The clavicular rotation along the anterior-posterior axis is the most important movement for the normal functionality of the arm. Particularly, compared to most joints in which rotation can be performed in both directions, the clavicle, from a neutral position, performs only a posterior rotation. Thus, the lower surface is oriented anteriorly. The anterior rotation is basically the return rotation to the neutral position. The posterior rotation is rated up to 50 degrees, and the anterior rotation is rated up to less than 10 degrees. The axis of this movement intersects the SC and AC joint (Ludewig & Borstead, 2005).

Symptomatic individuals consistently demonstrated less sternoclavicular posterior rotation, regardless of the angle, phase, or plane of shoulder motion. Even if the magnitude of these differences is small, from the perspective of functionality it can be important. Symptomatic individuals also demonstrated less scapulothoracic upward rotation at 30° and 60° of humerothoracic elevation during shoulder abduction and scapular plane abduction (Lawrence et al., 2014).

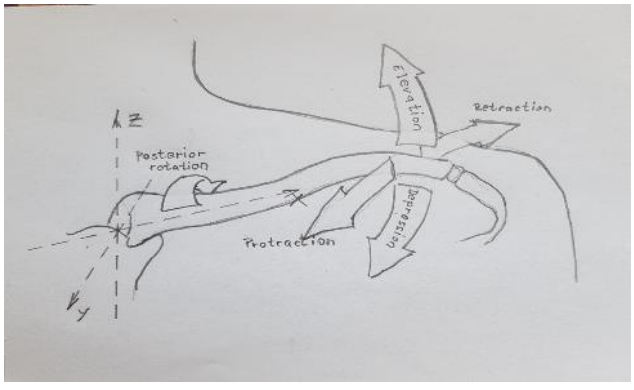


Fig. 1 – Clavicle movement in 3 planes.

Biomechanical studies of the forces in the clavicle during movements have shown that active abduction caused the greatest increase in middle clavicle forces and torque. Abduction resulted in the most significant axial compressive force, while active external rotation caused the greatest tensile force across the intact middle clavicle. This is important not only for the surgical techniques, but also for the rehabilitation protocols that must be considered postoperatively or after a fracture treated conservatively (Iannolo et al., 2010).

Conclusions

From a clinical point of view, it is essential that in any situation in which scapulohumeral redness occurs, the integrity of the clavicle movement should be evaluated. Even if the rotations of the clavicle are difficult to highlight clinically, at this stage a pathology targeting this sterno-claviculo-acromial complex should be excluded. As it has been shown, limiting movement in the SC joint has greater functional consequences than limiting movement in the AC joint.

Conflicts of interest

There were no conflicts of interest during the research period.

References

Benitez CL, Mintz DN, Potter HG. MR imaging of the sternoclavicular joint following trauma. Clin Imaging. 2004;28(1):59-63. doi: 10.1016/S0899-7071(03)00096-2.

Iannolo M, Werner FW, Sutton LG, Serell SM, VanValkenburg SM. Forces across the middle of the intact clavicle during shoulder motion. J Shoulder Elbow Surg. 2010;19(7):1013-1017. doi: 10.1016/j.jse.2010.03.016.

Itoi E, Morrey B, An K-N. Biomechanics of the Shoulder in Charles A Rockwood, Jr. The Shoulder. Philadelphia, PA, 2009, 213-267.

Lawrence RL, Braman JP, Laprade RF, Ludewig PM. Comparison of 3-dimensional shoulder complex kinematics in individuals with and without shoulder pain, part 1: sternoclavicular, acromioclavicular, and scapulothoracic joints. J Orthop Sports Phys Ther. 2014;44(9):636-645. doi: 10.2519/jospt.2014.5339.

Lippert LS. Clinical Kinesiology and Anatomy. Ed F. A. Davis Company. PA. 2006, 95-96.

Little KJ, Riches PE, Fazzi UG.Biomechanical analysis of locked and non-locked plate fixation of the clavicle. Injury. 2012;43(6):921-925.

Ludewig PM, Behrens SA, Meyer SM, Spoden SM, Wilson LA. Three-dimensional clavicular motion during arm elevation: reliability and descriptive data. J Orthop Sports Phys Ther. 2004;34(3):140-149. doi: 10.2519/jospt.2004.34.3.140.

Ludewig PM, Borstead JD. The Shoulder Complex. In Levangie PK, Norkin CC. Joint Structure and Function: A Comprehensive Analysis. Ed FA Davis Company, Philadelphia, Fourth Edition, 2005,234-240.

Macdonald PB, Lapointe P. Acromioclavicular and sternoclavicular joint injuries. Orthop Clin North Am. 2008;39(4):535-545. doi: 10.1016/j.ocl.2008.05.003.

Martetschläger F, Warth RJ, Millett PJ. Instability and degenerative arthritis of the sternoclavicular joint: a current concepts review. Am J Sports Med. 2014;42(4):999-1007. doi: 10.1177/0363546513498990.

Negri JH, Malavolta EA, Assunção JH, Gracitelli ME, Pereira CA, Bolliger Neto R, Croci AT, Ferreira Neto AA. Assessment of the function and resistance of sternoclavicular ligaments: A biomechanical study in cadavers. Orthop Traumatol Surg Res. 2014;100(7):727-731. doi: 10.1016/j.otsr.2014.07.011.

Oki S, Matsumura N, Iwamoto W, Ikegami H, Kiriyama Y, Nakamura T, Toyama Y, Nagura T. The function of the acromioclavicular and coracoclavicular ligaments in shoulder motion: a whole-cadaver study. Am J Sports Med. 2012;40(11):2617-2626. doi: 10.1177/0363546512458571.

Palastanga N, Field D, Soames R. Anatomy and Human Movement Structure and Function. Butterworth-Heinemann, Edinburgh, UK, 2002, 50.

Patel B, Gustafson PA, Jastifer J. The effect of clavicle malunion on shoulder biomechanics; a computational study. Clin Biomech. 2012;27(5):436-442. doi: 10.1016/j.clinbiomech.2011.12.006.

Renfree KJ, Wright TW. Anatomy and biomechanics of the acromioclavicular and sternoclavicular joints. Clin Sports Med. 2003;22(2):219-237. doi: 10.1016/s0278-5919(02)00104-7.

Robinson CM, Jenkins PJ, Markham PE, Beggs I. Disorders of the sternoclavicular joint. J Bone Joint Surg Br. 2008;90(6):685-696. doi: 10.1302/0301-620X.90B6.20391.

Rudzki JR, Matava MJ, Paletta GA Jr. Complications of treatment of acromioclavicular and sternoclavicular joint injuries. Clin Sports Med. 2003;22(2):387-405. doi: 10.1016/s0278-5919(03)00013-9.

Sewell MD, Al-Hadithy N, Le Leu A, Lambert SM. Instability of the sternoclavicular joint: current concepts in classification, treatment and outcomes. Bone Joint J. 2013;95-B(6):721-731. doi: 10.1302/0301-620X.95B6.31064.

Spencer EE Jr, Kuhn JE. Biomechanical analysis of reconstructions for sternoclavicular joint instability. J Bone Joint Surg Am. 2004;86(1):98-105. doi: 10.2106/00004623-200401000-00015.

Spencer EE, Kuhn JE, Huston LJ, Carpenter JE, Hughes RE. Ligamentous restraints to anterior and posterior translation of the sternoclavicular joint. J Shoulder Elbow Surg. 2002;11(1):43-47. doi: 10.1067/mse.2002.119394.

Thut D, Hergan D, Dukas A, Day M, Sherman OH. Sternoclavicular joint reconstruction--a systematic review. Bull NYU Hosp Jt Dis. 2011;69(2):128-135.

Van Tongel A, De Wilde L. Sternoclavicular joint injuries: a literature review. Muscles Ligaments Tendons J. 2012;1(3):100-105.

Warth JR, Lee TJ, Millett JP. Figure-of-Eight Tendon Graft Reconstruction for Sternoclavicular Joint Instability: Biomechanical Rationale, Surgical Technique, and a Review of Clinical Outcomes. Oper Tech Sports Med. 2014a;22(3):260-268.

Warth JR, Lee TJ, Millett JP. Anatomy and Biomechanics of the Sternoclavicular Joint. Oper Tech Sports Med. 2014b;22(3):248-252.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 97–103

Exercise for the prevention of non-specific chronic low back pain: systematic review

Miriam Covalschi[1], Simona Giurgiuveanu[1], László Irsay[1,2]
[1]Department of Rehabilitation, Rehabilitation Clinical Hospital, Cluj-Napoca, Romania
[2]"Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

Abstract

Low back pain is the most common musculoskeletal condition in the general population, affecting almost 80% of individuals during their lifetime. It is also a major public health burden, associated with numerous consequences such as disability, low quality of life, care seeking, work loss, compensation, generating substantial healthcare costs.

The purpose of this article was to determine if exercise therapy (recreational exercises, aerobics, stretching, core strength and stabilization exercises) may prevent the recurrence of non-specific low back pain (NSLBP). A specific program focusing on one area of fitness may not be appropriate, but a multimodal prevention training program integrating major physical activity contents (muscular endurance, strength, stretching and aerobic fitness) seems promising and can be beneficial for NSCLBP. Until now, based on what we know from the literature, prevention of NSCLBP using ET is complex, difficult and remains unclear because there is limited evidence for many aspects of prevention in LBP.

Keywords: non-specific chronic low back pain, recurrent low back pain, physical activity, exercise therapy, prevention, rehabilitation.

Introduction

Low back pain (LBP) is the most common musculoskeletal condition in the general population, affecting almost 85% of individuals during their lifetime. As the population ages, the global number of individuals with low back pain is likely to increase substantially over the coming decades (Hoy et al., 2012). It is also one of the most burdensome health problems, generating enormous costs for treatment and a lot of time lost from work (Steffens et al., 2016; Macedo et al., 2013). Its management comprises a range of different intervention strategies including surgery, drug therapy and non-medical intervention such as rehabilitation (Paolucci et al., 2019).

The secondary prevention of LBP is classically described as a prevention of the development of chronic low back pain (CLBP) arising from an acute episode of LBP. Considering the latter, 60-70% of patients with acute LBP are symptom-free after treatment, but a considerable amount of patients will experience one or more relapses within a year of the first occurrence of LBP (Niederer et al., 2018; Machado et al., 2017).

Overall, the non-specific chronic low back pain (NSCLBP) is important not so much for its existence as for its consequences, such as recurrence (including severity and disability), care seeking, work loss, health-related quality of life, compensation. Therefore, the consequences of common LBP are a primary concern for prevention (Burton et al., 2005).

Whereas the vast majority of LBP episodes are associated with return to work in a convenient time, recurrent and CLBP is widely acknowledged to account for a substantial proportion of total work absenteeism. This is reflected in the social costs of LBP, where some 80% of the health care and social costs are for the treatment of this pathology, and 10% are spent with chronic pain and disability. These issues present interpretative difficulties in the matter of prevention, where low back pain and its consequences tend to occur in an episodic manner (Burton et al., 2005). However, there is great interest in preventing recurrent episodes using physical activity (PA) or exercise therapy (ET) because they are a common treatment method. Recurrences can be more expensive to treat than the original episode, and can be as debilitating as the initial episode. Therefore, the prevention of such episodes may be an important component in the management of patients with LBP (Macedo et al., 2013).

ET is one of the most commonly recommended treatment methods for patients with CLBP, with clear evidence for effectiveness, but it is unknown whether exercise therapy is effective for the prevention of LBP

Received: 2020, February 15; *Accepted for publication:* 2020, February 25
Address for correspondence: Rehabilitation Hospital, 46-50 Viilor Street, Cluj-Napoca, PC 400437
E-mail: irsaylaszlo@gmail.com
Corresponding author: Irsay Laszlo, irsaylaszlo@gmail.com
https://doi.org/10.26659/pm3.2020.21.2.97

recurrences (Macedo et al., 2013; Koes et al., 2010; Henchoz & Kai-Lik, 2008). A plethora of established and validated exercises are available for the therapy of LBP, but for secondary and tertiary prevention the number is lower. The preventive approaches used for relapse prevention are twofold: ET during treatment and ET following primary / initial treatment. Conflicting evidence supporting the relevance of exercise during initial treatment exists, but moderate evidence supports the relevance of exercise programs subsequent to primary care (Niederer et al., 2018; Macedo et al., 2013).

Post-treatment exercises can reduce both the rate and the number of recurrences of back pain, but healthcare providers and patients need to understand their options in relation to what works and what is cost-efficient to make a confident and well-educated decision regarding their choice of a rehabilitation program (Choi et al., 2010; Privett et al., 2012).

Hypothesis

This study aimed to investigate the effectiveness of physical activity and exercise in the prevention of non-specific chronic low back pain. Our primary hypothesis was that PA and ET can be beneficial in NSCLBP. Our secondary hypothesis was that the risk of relapse would be lower after ET than after primary care management.

Leisure time physical activity

Leisure time physical activity (LTPA) is any bodily movement produced by the contraction of skeletal muscles that requires energy expenditure, such as walking or climbing stairs (Booth et al., 2012). Exercise is a specific form of LTPA, which is a purposeful, planned and repetitive activity often with the purpose of improving or maintaining physical fitness, or even for losing weight. Obesity is a lifestyle risk factor associated with CLBP, a condition that can be treated with PA or ET combined with health education and diet (Shiri et al., 2017). Muscle imbalance and vicious posture are also modifiable risk factors that can be reduced with interventions such as postural control or muscle endurance exercises (Steiger et al., 2012).

Although it is well known that PA can reduce all-cause mortality and risk factors of a wide variety of chronic diseases such as cardiovascular and respiratory diseases, diabetes, obesity and musculoskeletal diseases, unfortunately, there is a lack of evidence linking the effects of exercise to changes in the musculoskeletal system for CLBP patients (Steiger et al., 2012; Alzahrani et al., 2019).

However, there is an intense association between physical activity and LBP. A recent meta-analysis reported that medium to high level of leisure-time physical activity (LTPA) reduces the risk of developing chronic LBP by 11–16% (Alzahrani et al., 2019). Also, another study showed that high-intensity physical activity is a feasible, well tolerated, and effective therapy choice in CNSLBP. Moreover, it has shown a greater improvement of disability and exercise capacity than a similar ET performed at moderate intensity (Verbrugghe et al., 2019).

Measuring physical activity (PA) levels in CLBP is known to have important clinical implications, but is constrained by time or resources. Regarding clinical presentation, patients with chronic symptoms and high disability are more likely to have a low PA level (Carvalho et al., 2017). Clinicians can assume that patients with CLBP have low levels of physical activity and can design treatment accordingly, but direct monitoring of physical activity using an instrument of movement registration, such as a pedometer or accelerometer, can be used to provide patient feedback or set quotas for activity progression, and may be a useful treatment adjunct (Lin et al., 2011).

Also, it is equally important to search for the "yellow flags", which are risk factors for the chronification of acute LBP and are often found in psychosocial limitations such as fear, depression, excessive demands on oneself, self-esteem deficits, fear-avoidance-beliefs, dissatisfying employment and mobbing. Targeting the yellow flags and risk factors in CLBP patients should allow a prescription of the most appropriate treatment, maximizing the likelihood of a favorable clinical outcome (Macedo et al., 2013; Niederer et al., 2018; Underwood et al., 2000).

The multifactorial genesis of LBP indicates that PA alone may not be enough for the prevention of CLBP, although a relation between the amount and characteristics of PA/ET and LBP exists. Individualization of the treatment seems to be crucial. More specifically, the fastest possible early onset of PA after the non-specificity diagnosis of pain may be helpful; in fact, this was demonstrated in some studies where early ET showed improvements in comparison with the usual care (Niederer et al., 2018). Resumption of normal activities shortens the duration of acute and subacute episodes of LBP, leading to the assumption that chronic disability will also be reduced. As regular PA is thought to reduce the proportion of LBP patients that progress to disability, it is plausible that regular PA before the onset of pain would have a similar effect. If combined with educational aspects, as described above, PA may be efficient in preventing recurrent NSLBP, but evidence at this moment is yet inconclusive (Niederer et al., 2018; Underwood et al., 2000).

Understanding the links between physical activity and LBP will allow future multi-component interventions aimed at LBP prevention. Examining each domain of physical activity separately will enable easier translation of the knowledge generated in observational studies into real-life prevention (Alzahrani et al., 2019).

Although the evidence for PA preventing LBP is weak, patients should be encouraged to stay as active as possible and progressively increase their physical activity levels (Koes et al., 2010). The other potential benefits of exercising mean that it is reasonable to encourage regular physical activity as part of a strategy to reduce the overall impact of back pain disability, on both the individuals and society (Underwood et al., 2000).

Aerobic exercises

Aerobic exercises are a form of low intensity physical activity (PA) that maintains a 60% maximal heart rate for at least 30 minutes. They are more commonly known for improving cardiovascular endurance, but benefits to muscular endurance and flexibility are seen as well (Privett et al., 2012). Aerobic exercises increase the blood flow and nutrients to the soft tissues in the back, improving

the healing process, but also increase the production of endorphins known as "natural pain killers", which is a natural alternative for pain relief for the body, and can reduce CLBP (Gomes-Neto et al., 2017). Additional benefits are provided, such as improving the functional status of patients and reducing the fear of movement, which is a predictor for functional limitation associated with disability (Gordon et al., 2016; Gasibat et al., 2017).

Most of the studies evaluating ET for NSLBP patients, measuring pain, function, recurrence, global improvement outcomes, demonstrated that regular aerobic exercises may be helpful in alleviating pain, disability and psychological strain and appear to improve the mood states and the work status (Chatzitheodorou et al., 2007; Murtezani et al., 2011).

Studies on pain, physical and psychosocial disability of CLPB showed that psychologists play essential roles, but unfortunately most of individuals with chronic pain never receive behavioral therapy. Behavioral therapy is effective in reducing pain, distress, pain interference with activities, disability, and also lacks the risks associated with chronic pain medications, surgeries or other interventional procedures (Ehde et al., 2014). This suggests that behavioral therapy can be applicable to CLBP patients as an alternative treatment method, and combined with aerobic exercises offers promising outcomes.

Regarding the intensity of aerobic exercise programs, studies indicate that similar outcomes can be achieved despite differences of intensity. However, the most prescribed aerobic exercises for CLBP are moderate intensity programs, used to reduce risks, enhance compliance and have an optimal impact (Murtezani et al., 2011; Gordon et al., 2016).

Many researchers in the field who compared the effectiveness of aerobic programs with different types of exercises or even with active physiotherapy in CLBP patients found a similar effectiveness between the different therapeutic methods applied (Shnayderman et al., 2013; Mannion et al., 2001; Kell & Asmundson, 2009). In a randomized clinical trial on subjects treated for CLBP, three different types of therapy were compared (active physiotherapy, muscle reconditioning on training devices and low impact aerobics), and the authors reported that the therapies were equally efficacious and significantly reduced pain intensity and frequency for up to 1 year after therapy. For the physiotherapy group, disability increased again during the first six months of follow-up, whilst the other two groups showed a further decline. Also, in all groups the values then remained stable up to the 12-month of follow-up, which shows that aerobic exercise programs for patients with CLBP may reduce the enormous costs associated with its treatment (Mannion et al., 2001). Prophylactic rehabilitation involving moderate intensity aerobic exercise should be prescribed more often for NSCLBP, but the key to success in having the best outcomes is to individualize ET for each patient depending on functional status or other medical conditions. A multidisciplinary program which includes aerobic fitness and behavioral therapy may be more efficient in reducing CLBP recurrence, but further research is needed.

Stretching exercises

LBP is a common cause of decrease in physical activity (PA), creating a vicious cycle that is difficult to change. Restoring muscle balance and improving the mobility of the spine are the most important tasks of kinetotherapy in lumbar pain syndrome.

Stretching is a therapeutic method included in medical rehabilitation, used to increase muscle length and also to strengthen the collagen fibers. Details on stretching exercises are rarely supplied. The isometric technique seems to be the most widely used method, but static stretches, proprioceptive or ballistic neuromuscular facilitation could also be performed. Stretching exercises focus not only on the back, but also on other muscle groups in the legs, thighs, hips, or trunk (Niederer et al., 2018).

The difficulty of determining the effectiveness of stretching comes from the fact that the rehabilitation events are supplemented by other means of impact on the muscles. The most effective types of exercises for CLBP are still controversial, but ET is one of the most widely used conservative treatments around the world (Lizier et al., 2012). Modern studies show that the good condition of the lumbar spine depends on many factors, one being muscle elasticity. Static stretching of muscles can lead to greater improvements in flexibility in people's spine (Feland & Marin, 2004).

Patients with chronic musculoskeletal pain who follow a stretching program for three weeks have an increased tolerance to stretching the muscles. Muscle relaxation and stretching exercises are useful, allowing patients to participate in an active exercise program (Fleckenstein et al., 2010). The stretching programs for CLBP patients that have been reported in the literature show that they are effective in reducing pain, improving functional condition and quality of life (emotional, limitations in physical functioning, vitality and mental health), accelerating the return to normal daily activity or even to work (Lawand et al., 2015; Gawda et al., 2015). A systemic stretching program focused on the back, trunk, thighs, hips and legs is effective in CLBP patients, and can be performed before and after other exercises, as part of prevention (Johnson, 2012; Niederer et al., 2018).

Prevention of recurrent NSLBP is an important part of rehabilitation, and stretching exercises are an affordable, easily workable method with a good therapeutic effect on the pain of the musculoskeletal system. Muscle spasm and muscle imbalance are positively influenced by the administration of stretching exercises, which may prevent recurrent CLBP. The studied publications advocate that stretching exercises should be recommended in the management of LBP, but the modalities of implementation and the results remain controversial due to some discrepancies in terms of duration and frequency of stretching therapy. More evidence should be gathered to allow conclusions to be drawn about the prevention of NSCLBP involving stretching exercises (Angelova et al., 2019).

Core strength and stability exercises

Core strength and stability exercises have become a major focus in the prophylactic care of LBP. The difference between them is that core stability refers to the ability of

stabilizing the spine as a result of muscle activity, whereas core strength refers to the ability of the musculature to produce force through contractile forces and intra-abdominal pressure (Gomes-Neto et al., 2017; Hibbs et al., 2008).

When the core muscles function normally, they can maintain segmental stability, protect the spine, and reduce stress impacting the lumbar vertebrae and intervertebral discs. In order to function normally every day, our body needs to have enough strength and stability, but after a low back pain episode, muscles do not regain their full strength and endurance (Shiju Majeed et al., 2019; Hibbs et al., 2008).

A core program which incorporates both core stability and core muscular strength, emphasizing spinal mobility, back muscle strength, muscular endurance, coordination and proprioception, is more effective for NSCLBP patients than muscular strength exercises alone. These training programs should be directed against adjusting deficits and imbalances, which can be predictors of increased low back pain recurrences (Gordon et al., 2016; George et al., 2007).

A poor sitting posture determines a lower activation of the core muscles; consequently, they become weaker, having a negative impact upon the ability to maintain an upright posture. The increase in the number of sick leave days also increases the risk for chronic LBP, and ET alone might be unable to help patients with many days of sick leave. A core program combined with education on the correct techniques for maintaining an upright sitting posture and for lifting can be more effective in reducing LBP, and these techniques should be prescribed together more often (Gordon et al., 2016).

Some studies compared the efficiency of core exercises to that of conventional spine exercises, and core stabilization exercises were found to be more effective in reducing pain, improving functional status by decreasing disability of NSCLBP patients (Inani et al., 2013), but also more effective than muscular strength exercises (Alhakami et al., 2019). The conclusion of a systematic review was that lumbar low load specific stabilization exercises would be more efficient than muscle strengthening in the improvement of CLBP, but strengthening exercises are considered more valuable in effectively 'pre-habilitating' and in reducing the injury risk (Hadala & Gryckiewicz, 2014).

Many studies highlighted the importance of these programs for CLBP disability. In comparison with standard medical care treatment, core stabilization programs emphasizing activation of the transversus abdominis and multifidi cause fewer recurrences of LBP 3 years after treatment (George et al., 2007). This motor control exercises can be effective for some patients, but most of them are unable to voluntarily contract their muscles and may be inhibited from doing so due to arthrogenic muscle inhibition. In combination with restorative neurostimulation, a new approach for NSCLBP patients can be promised (Russo et al., 2018). Motor control of the trunk comprises modulation of intrinsic stiffness through tonic muscle activity, anticipatory control, and feedback control. Moreover, individuals with LBP may show more noticeable changes when they perceive the task that they perform as threatening in terms of pain provocation or re-injury (Van Dieen et al., 2019). There is also evidence suggesting that exercises designed to condition the lumbar extensors may also result in significant activation of this musculature during their performance (Steele et al., 2015).

However, other studies showed that some stabilization exercises were not more effective than others, suggesting that there is no evidence to support the superiority of one form of exercises over another. A more general program as opposed to focus on one particular area of fitness may be more effective to reduce NSCLBP (Gomes-Neto et al., 2017; Gordon et al., 2016; Van Middelkoop et al., 2010). Nevertheless, multiple studies have shown that not all subjects with LBP benefit equally from stabilization exercise (Hicks et al., 2005).

Core exercises can be encouraged for recurrent NSCLBP, but it is difficult to make a definitive and pragmatic recommendation, because of the variation in the duration of exercise programs, progression criteria, muscle activation, and type of feedback used during the interventions (Gomes-Neto et al., 2017). A clearer understanding of the roles that specific muscles have during core stability and core strength exercises would enable more functional training programs to be implemented in rehabilitation.

However, many articles in the literature promote core strength and stabilization programs in the rehabilitation sector, but additional research to determine the optimal approaches for recurrence prevention should be conducted, testing different type of exercises to determine their essential attributes, such as mode, intensity, frequency, duration, and timing, and also to match the prescription to the clinical characteristics of patients (Gomes-Neto et al., 2017).

Discussions

Until now, based on what we know from the literature, prevention of NSCLBP using ET is complex, difficult and remains unclear (Gomes-Neto et al., 2017). Overall, there is limited evidence for many aspects of prevention in LBP, yet there is evidence that prevention of various consequences of LBP is feasible (Foster et al., 2018). However, there are many clinical guidelines with similar recommendations for the prevention of NSCLBP, but the most promising approaches seem to involve PA, ET and appropriate education (Hasenbring et al., 2012; Burton et al., 2005). One of the reasons for the similarity of the guidelines might be that guideline committees are usually aware of the content of other guidelines and are motivated to produce similar recommendations that are deemed sensible and relevant (Koes et al., 2010).

The findings from this review indicate that ET was significantly better for relieving pain, functional outcomes, recurrence, disability, or psychological strain, and may have a positive effect in CLBP management (Gordon et al., 2016). Given that there is no strong evidence that one particular type of exercise is clearly more effective than others (general versus specific exercises, individualized versus group programs, supervised versus home exercises), it remains unclear which patients can benefit most from a specific exercise program (Henchoz et al., 2008). A

specific program focusing on one area of fitness may not be appropriate, but a multimodal prevention training program integrating major PA contents (muscular endurance, strength, stretching and aerobic fitness) seems promising and can be beneficial for NSCLBP (Gordon et al., 2016; Macedo et al., 2013).

Within rehabilitation approaches to CLBP, it is known that the behavioral or bio-psycho-social approach offers the foundation for a better insight into persistent pain, and that combined with ET it may reduce the risk of occurrence (Niederer et al., 2018; Paolucci et al., 2019). However, ET is not optimal in all patients because the physiological, psychological and social effects of exercise vary across patients (Gordon et al., 2016). Anecdotally, individuals might report that various strategies work for them, but in the absence of scientific evidence they cannot be generally recommended for prevention. It is not known whether some of these strategies have disadvantageous long-term effects (Burton et al., 2005). Also, it has been generally observed that patients may have an exacerbation of symptoms after starting the exercise and that they drop out of the exercise therapy. Hence, it is important to train patients in the correct way of performing the exercise. The exercises should be easy to train and perform with minimum resources (Shiju Majeed et al., 2019).

However, most clinicians prescribe a combination of these exercises, because they seem to be more effective than other alternatives, but the effects need to be balanced with their costs in terms of money, resources and time. A multidisciplinary prevention program is intensive, expensive, and may be appropriate for NSCLBP patients with a high rate of recurrence (Kamper et al., 2014; Shiju Majeed et al., 2019).

We think that the best prescription of ET in NSCLBP needs to be determined by innovative studies with increased reliability and validity to identify the modalities of implementation and the patient subsets that are likely to benefit from specific exercises (Burton et al., 2005; Privett et al., 2015; George et al., 2007; Paolucci et al., 2019).

Conclusions

1. Prevention of recurrent NSLBP with exercise therapy is an important part of rehabilitation programs to avoid complications, worsening and lesions of the structures of the spine.

2. Physical activity is significantly better: for relieving pain and for functional outcomes, for reducing recurrence and disability, for improving the quality of life and for accelerating the return to normal daily activities and work, in patients with chronic low back pain.

3. Other potential benefits of exercise mean that it is reasonable to encourage regular physical activity as part of a strategy to reduce the overall impact of back pain disability, on both the individuals and society.

4. Exercise therapy is not optimal in all patients because the physiological, psychological and social effect of exercise varies amongst patients, but combined with behavioral therapy it can be more effective in reducing the risk of recurrence.

5. Healthcare providers and patients need to understand their options in relation to what works and what is cost-efficient to make a confident and well-educated decision regarding their choice of a rehabilitation program.

6. A multimodal prevention training program aimed at adjusting the deficits or imbalance by integrating major physical activity contents (muscular endurance, strength, stretching and aerobic fitness) can be beneficial in the prevention of NSCLBP.

7. The best prescription of ET needs to be determined by additional research on the optimal approaches for recurrence prevention, by testing different types of exercises to establish their essential attributes (mode, intensity, frequency, duration and timing) and to match the prescription to the clinical characteristics of patients.

Conflicts of interest

Nothing to declare.

References

Alhakami AM, Davis S, Qasheesh M, Shaphe A, Chahal A. Effects of McKenzie and stabilization exercises in reducing pain intensity and functional disability in individuals with nonspecific chronic low back pain: a systematic review. J Phys Ther Sci, 2019;31(7):590-597. doi: 10.1589/jpts.31.590.

Alzahrani H, Mackey M, Stamatakis E, Zadro JR, Shirley D. The association between physical activity and low back pain: a systematic review and meta-analysis of observational studies. Sci Rep. 2019;9(1):8244. doi: 10.1038/s41598-019-44664-8.

Angelova P. Stretching as a part of a strategy for the prevention and management of chronic low back pain. Trakia J Sci. 2019;17(Supp.1):905-908. doi:10.15547/tjs.2019.s.01.149.

Booth FW, Roberts CK, Laye MJ. Lack of exercise is a major cause of chronic diseases. Compr Physiol 2012;2(2):1143-1211. DOI: 10.1002/cphy.c110025.

Burton AK, Balague F, Cardon G, Eriksen HR, Henrotin Y, Lahad A, Leclerc A, Müller G, van der Beek AJ, et al. How to prevent low back pain. Best Pract Res Clin Rheumatol. 2005;19(4):541-555. doi: 10.1016/j.berh.2005.03.001.

Carvalho FA, Morelhao PK, Franco MR, Maher CG, Smeets RJEM, Oliviera CB, Freitas Junior IF, Pinto RZ. Reliability and validity of two multidimensional self-reported physical activity questionnaires in people with chronic low back pain. Musculoskelet Sci Pract. 2017;27:65-70. doi: 10.1016/j.msksp.2016.12.014.

Chatzitheodorou D. Kabitsis C, Malliou P, Mougios V. A pilot study of the effects of high-intensity aerobic exercise versus passive interventions on pain, disability, psychological strain, and serum cortisol concentrations in people with chronic low back pain. Phys Ther. 2007;87(3):304-312. doi: 10.2522/ptj.20060080.

Choi BKL, Verbeek JH, Tam WWS, Jiang JY. Exercises for Prevention of Recurrences of Low-Back Pain. Occup Environ Med. 2010;67(11):795-796. doi: 10.1136/oem.2010.059873.

Ehde DM, Dillworth TM, Turner JA. Cognitive-behavioral therapy for individuals with chronic pain: efficacy, innovations, and directions for research. Am Psychol, 2014;69(2):153-166. doi: 10.1037/a0035747.

Feland JB, Marin HN. Effect of submaximal contraction intensity in contract-relax proprioceptive neuromuscular facilitation stretching. Br J Sports Med. 2004;38(4):E18. doi: 10.1136/bjsm.2003.010967.

Fleckenstein J, Zaps D, Ruger LJ, Lehmeyer L, Freiberg F, Lang PM, Irnich D. Discrepancy between prevalence and perceived effectiveness of treatment methods in myofascial

pain syndrome: results of a cross-sectional, nationwide survey. BMC Musculoskelet Disord. 2010;11:32. doi: 10.1186/1471-2474-11-32.

Foster NE, Anema JR, Cherkin D, Chou R. Steven P Cohen , Douglas P Gross , Paulo H Ferreira , Julie M Fritz , Bart W Koes , Wilco Peul , Judith A Turner , Chris G Maher: Low Back Pain Series Working Group Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018;391(10137):2368-2383. doi: 10.1016/S0140-6736(18)30489-6.

Gasibat Q, Suwehli W, Bawa RA, Adham N, Al Turkawi Kheer RM, Baaiou JM. The Effect of an Enhanced Rehabilitation Exercise Treatment of Non-Specific Low Back Pain - A suggestion for Rehabilitation Specialists. Am J Med Stud. 2017;5(1):25-35. DOI: 10.12691/ajms-5-1-3.

Gawda P, Dmoszyńska-Graniczka M, Pawlak H, Cybulski M, Kiełbus M, Majcher P, Buczaj A, Buczaj M. Evaluation of influence of stretching therapy and ergonomic factors on postural control in patients with chronic non-specific low back pain. Ann Agric Environ Med. 2015;22(1): 142-146. doi: 10.5604/12321966.1141384.

George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009). BMC musculoskelet Disord, 2007;8:92. doi: 10.1186/1471-2474-8-92.

Gomes-Neto M, Lopes JM, Conceição CS, Araujo A, Brasileiro A, Sousa C, Carvalho VO, Arcanjo FL. Stabilization Exercise Compared to General Exercises or Manual Therapy for the Management of Low Back Pain: A Systematic Review and Meta-Analysis. Phys Ther Sport. 2017;23:136-142. doi:10.1016/j.ptsp.2016.08.004.

Gordon R, Bloxham S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. Healthcare (Basel). 2016;4(2):22. doi: 10.3390/healthcare4020022.

Hadala M, Gryckiewicz S. The effectiveness of lumbar extensor training: local stabilization or dynamic strengthening exercises. A review of literature. Ortop Traumatol Rehabil, Nov-Dec 2014;16(6):561-572. doi: 10.5604/15093492.1135044.

Hasenbring MI, Rusu AC, Turk DC. From acute to chronic back pain: Risk factors, mechanisms and clinical implications. Oxford Univ Press. 2012, 209.

Henchoz Y, Kai-Lik SA. Exercise and nonspecific low back pain: a literature review. Joint Bone Spine. 2008;75(5):533-539. doi: 10.1016/j.jbspin.2008.03.003.

Hibbs AE, Thompson KG, French D, Wrigley A, Spears I. Optimizing Performance by Improving Core Stability and Core Strength. Sport Med 2008;38(12):995-1008. doi: 10.2165/00007256-200838120-00004.

Hicks GE, Fritz JM, Delitto A, McGill SM. Preliminary development of a clinical prediction rule for determining which patients with low back pain will respond to a stabilization exercise program. Arch Phys Med Rehabil, 2005;86(9):1753-1762. doi: 10.1016/j.apmr.2005.03.033.

Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, Woolf A, Vos T, Buchbinder R. A systematic review of the global prevalence of low back pain. Arthritis Rheum, 2012;64(6):2028-2037. https://doi.org/10.1002/art.34347.

Inani SB, Selkar SP. Effect of core stabilization exercises versus conventional exercises on pain and functional status in patients with non-specific low back pain: A randomized clinical trial. J Back Musculoskelet Rehabil. 2013;26(1):37-43. doi: 10.3233/BMR-2012-0348.

Johnson J. Therapeutic stretching. Hands-on Guides for Therapists. Human Kinetics Publishers, Champaign, United States, 2012, 43.

Kamper SJ, Apeldoorn AT, Chiarotto A, Smeets RJ, Ostelo RW, Guzman J, van Tulder MW. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. Cochrane Database Syst Rev. 2014;(9): CD000963.

Kell RT, Asmundson GJG. A comparison of two forms of periodized exercise rehabilitation programs in the management of chronic nonspecific low-back pain. J Strength Cond Res., 2009;23(2):513-523. doi: 10.1519/JSC.0b013e3181918a6e.

Koes BW, van Tulder M, Lin Cw, Macedo LG, McAuley J, Maher C. An updated overview of clinical guidelines for management of non-specific low back pain in primary care. Eur Spine J., 2010;19 (12):2075-2094. doi: 10.1007/s00586-010-1502-y.

Lawand P, Lombardi I Jr, Jones A, Sardim C, Ribeiro L, Natour J. Effect of a muscle stretching program using the global postural reeducation method for patients with chronic low back pain: A randomized controlled trial. Joint Bone Spine, 2015;82(4):272-277. doi: 10.1016/j.jbspin.2015.01.015.

Lin C-WC, McAuley JH, Macedo L, Barnett DC, Smeets RJ, Verbunt JA. Relationship between physical activity and disability in low back pain: A systematic review and meta-analysis. Pain. 2011;152(3):607-613. doi: 10.1016/j.pain.2010.11.034.

Lizier D, Perez M, Sakata R. Exercises for Treatment of Nonspecific Low Back Pain. Rev Bras Anestesiol, 2012;62(6):838-846. doi: 10.1016/S0034-7094(12)70183-6.

Macedo LG, Bostick GP, Maher CG. Exercise for prevention of recurrences of nonspecific low back pain. Phys Ther. 2013; 93(12): 1587-1591. doi: 10.2522/ptj.20120464.

Machado GC, Maher CG, Ferreira PH, Latimer J, Koes Bw, Steffens D, Ferreira ML. Can Recurrence After an Acute Episode of Low Back Pain Be Predicted? Phys Ther., 2017; 97 (9):889-895. doi: 10.1093/ptj/pzx067.

Mannion AF, Muntener M, Taimela S, Dvorak J. Comparison of three active therapies for chronic low back pain: results of a randomized clinical trial with one-year follow-up. Rheumatology. 2001;40(7):772-778. doi: 10.1093/rheumatology/40.7.772.

Murtezani A, Hundozi H, Orovcanec N, Sllamniku S, Osmani T. A comparison of high intensity aerobic exercise and passive modalities for the treatment of workers with chronic low back pain: a randomized, controlled trial. Eur J Phys Rehab Med. 2011;47(3):359-366. http://europepmc.org/abstract/MED/21602759.

Niederer D, Vogt L, Banzer. Physical Activity, Training and Exercise in the Prevention of Low Back Pain: a Focus Review with Special Emphasis on Motor Control. Dtsch Z Sportmed, 2018;69:282-266. DOI: 10.5960/dzsm.2018.321.

Paolucci T, Attanasi C, Cecchini W, Marazzi A, Capobianco SV, Santilli V. Chronic low back pain and postural rehabilitation exercise: a literature review. J Pain Res. 2019;12:95-107. doi: 10.2147/JPR.S171729.

Privett T. Aerobic exercise as a means of reducing low back pain a systematic review. Thesis Dissertation. HIM 1990-2015/1293, 2012. https://stars.library.ucf.edu/honorstheses1990-2015.

Russo M, Deckers K, Eldabe S, Kiesel K, Gilligan C, Vieceli J, Crosby P. Muscle control and non-specific chronic low back pain. Neuromodulation, 2018;21(1):1-9. doi: 10.1111/ner.12738.

Shiju Majeed A, Anish TS, Asha Sugunan, Arun MS. The effectiveness of a simplified core stabilization program (TRICCS—Trivandrum Community-based Core Stabilisation) for community-based intervention in chronic non-specific low back pain. J Orthop Surg Res. 2019;14(1):86. doi: 10.1186/s13018-019-1131-z.

Shiri R, Falah-Hassani K. Does leisure time physical activity protect against low back pain? Systematic review and meta-analysis of 36 prospective cohort studies. Br J Sports Med.

2017;51(19):1410-1418. doi: 10.1136/bjsports-2016-097352.

Shnayderman I, Katz-Leurer M. An aerobic walking programme versus muscle strengthening programme for chronic low back pain: a randomized controlled trial. Clin. Rehabil. 2013;27(3):207-214. doi: 10.1177/0269215512453353.

Steele J, Bruce-Low S, Smith D. A Review of the Specificity of Exercises Designed for Conditioning the Lumbar Extensors. Br J Sports Med, 2015;49(5):291-297. http://dx.doi.org/10.1136/bjsports-2013-092197.

Steffens D, Maher CG, Pereira LSM, Stevens ML, Oliveira VC, Chapple M, Teixeira-Salmela LF, Hancock MJ. Prevention of low back pain: A systematic review and meta-analysis. JAMA Intern Med., 2016;176(2):199-208. doi:10.1001/jamainternmed.2015.7431.

Steiger F, Wirth B, de Bruin ED. Is a positive clinical outcome after exercise therapy for chronic non-specific low back pain contingent upon a corresponding improvement in the targeted aspect(s) of performance? A systematic review. Eur Spine J. 2012;21(4):575-598. doi: 10.1007/s00586-011-2045-6.

Underwood MR. Exercise and the prevention of back pain disability. Br J Sports Med. 2000;34(1):5. doi: 10.1136/bjsm.34.1.5.

Van Dieën JH, Reeves NP, Kawchuk G, Van Dillen RL, Hodges PW. Analysis of Motor Control in Patients With Low Back Pain: A Key to Personalized Care? J Orthop Sports Phys Ther, 2019;49(6):380-388. https://doi.org/10.2519/jospt.2019.7916.

Van Middelkoop M, Rubinstein SM, Verhagen AP, Ostelo RW. Exercise therapy for chronic nonspecific low-back pain. Best Pract Res Clin Rheumatol. 2010;24(2):193-204. doi: 10.1016/j.berh.2010.01.002.

Verbrugghe J, Agten A, Stevens S, Hansen D, Demoulin C, Eijnde BO, Vandenabeele F, Timmermans A. Exercise intensity matters in chronic non-specific low back pain rehabilitation. Med Sci Sports Exerc, 2019;51(12):2434-2442. doi: 10.1249/MSS.0000000000002078.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 104–109

Recommendations on rehabilitation after shoulder arthroplasty

Theodor Popa[1], Dănuţ Georgel Perja[1], László Irsay[1,2]
[1]Department of Rehabilitation, Rehabilitation Clinical Hospital, Cluj-Napoca, Romania
[2]"Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania

Abstract
Shoulder arhtroplasty is the third most common joint replacement surgery after the knee and hip. There are three different types of surgery, total shoulder arthroplasty, reverse total shoulder arthroplasty and hemiarthroplasty, each being better suited for an array of affections. Following a rehabilitation program after surgery helps the patient regain confidence and return to his daily life activities. The program is structured in phases with goals that allow a better management of the recovery process. Exercise therapy begins with passive exercises that gradually progress with an improved range of motion towards active training that gradually returns the patient to his former activities. Studies suggest that most patients used to practicing sports before surgery are able to gradually return to practicing them after surgery with some guidance from the specialist. This article aims to provide recommendations for shoulder rehabilitation after arthroplasty by reviewing and joining strategies and protocols used in recovery programs.
Keywords: shoulder arthroplasty, replacement surgery, rehabilitation, exercise therapy.

Introduction

A functional shoulder is completely necessary for a certain grade of independence. Otherwise, simple activities of daily living, such as washing or cooking can become strenuous and can hinder the patient's self care. In a lot of working environments, employees are required to use physical strength in daily tasks, where a shoulder mobility and muscular strength deficit can leave the worker unable to perform his duties.

Shoulder arthroplasty is one of the most common joint replacement surgeries worldwide. It is used as a solution for glenohumeral osteoarthritis in patients with severe pain and loss of function where conservative treatment is not sufficient (Kraus et al., 2014).

Following a rehabilitation program after surgery is mandatory in order to achieve a fully functional joint. Through the rehabilitation program, the patient ideally gains a full range of motion with better strength and stability of the joint. The pain and swelling are also diminished after exercise. Following physiotherapy and exercise recommended by a professional, the patient can gain confidence that helps him gradually return to his/her daily life activities.

The first shoulder replacement implant was manufactured in France from platinum and rubber and it was used in the first glenohumeral arthroplasty performed by the surgeon Jean Penn in 1894. Shoulder replacement surgery is indicated in patients with afflictions such as primary osteoarthritis, posttraumatic arthritis, osteonecrosis and severe fractures of the proximal humerus. There are three types of surgeries for shoulder replacement: hemiarthroplasty, total shoulder replacement (TSA) and reverse shoulder arthroplasty (rTSA) (Wilcox et al., 2005).

Shoulder arthroplasty types

a) Hemiarthroplasty

Through hemiarthroplasty the proximal side of the humerus is replaced with a round cup held in place by a stem. The procedure is indicated when only the humerus is affected or when the glenoid part of the scapula is not suited for a prosthesis. Hemiarthroplasty is indicated in osteonecrosis of the humeral head where the glenoid is not affected, fractures of the proximal humeral bone without the implication of the glenoid, reumathoid arthropathy and cuff tear arthropathy.

Another option would be the use of resurfacing implants. These are components that are not fixed through stems, they are cemented or coated with hydroxyapatite and are used to reproduce the round side of the humeral head in order to grant the joint a physiological function.

Received: 2020, February 3; *Accepted for publication:* 2020, February 25
Address for correspondence: Rehabilitation Hospital, 46-50 Viilor Street, Cluj-Napoca, PC 400437
E-mail: irsaylaszlo@gmail.com
Corresponding author: Irsay Laszlo, irsaylaszlo@gmail.com
https://doi.org/10.26659/pm3.2020.21.2.104

The resurfacing implants can be used in patients with proximal humeral deformities that would normally need an osteotomy. In this case the revision surgery would be easier and the bone somehow spared; however, good stability is difficult to achieve (Sanchez-Sotelo, 2011).

b) Total shoulder arthroplasty

Total shoulder replacement is a type of surgery where both the humeral head and the glenoid are replaced by a metal and polyethylene prosthesis, it is a ball and socket replacement. The indication for this type of surgery is primary osteoarthritis, after severe bone trauma, osteonecrosis with the affecting of the glenoid cavity and inflammatory joint disorders (Sanchez-Sotelo, 2011). The humeral prosthesis consists of a head-like component attached to a metaphyseal stem that can be cemented with polymethylmethacrylate or press fit. Bone density and various factors are taken into consideration when choosing between the two aforementioned. The glenoid prosthesis used in total shoulder replacements are polyethylene implants with a keel used for the insertion in the glenoid side of the scapula and fixed with polymethylmethacrylate (Gregory et al., 2007). According to the current literature, total shoulder arthroplasty is better suited for osteoarthritis and rheumatoid arthritis in terms of functional improvements and pain management (Sanchez-Sotelo, 2011).

c) Reverse total shoulder arthroplasty

Reverse shoulder arthroplasty is a type of surgery where a prosthesis replaces the glenohumeral joint while reversing the components of the joint, a polyethylene socket is placed on the humerus replacing the head, and a round metal glenosphere is inserted in order to replace the glenoid cavity (Gregory et al., 2007). The main indication for rTSA is a deficiency in the rotator cuff such as cuff tear arthropathy. Reverse shoulder arthroplasty surgery is also used in inflammatory arthritis with cuff tear, proximal fractures of the humerus, reconstruction after resection of a tumor or failed TSA (Sanchez-Sotelo, 2011).

d) Complications

Some of the complications that follow shoulder arthroplasty are infections, instabilities and periprosthetic fractures. Although the infection rates are relatively low, they can still be found after surgery in patients showing no abnormalities in symptomatology or blood tests. Microorganisms such as Propionibacterium acnes (a gram-positive commensal bacterium that thrives in anaerobic conditions) may be at fault according to Sanchez-Sotelo (2011). The treatment of choice is two-stage implantation for deeper infections. Most of the instability cases are secondary to a combination of factors such as soft tissue imbalance and an undesirable positioning of the prosthesis components (Ratajczak et al., 2019). When the instability at fault is anterior, there is usually a deficient subscapularis muscle and an allograft with pectoralis major may be required because of a high rate of failure associated with regular tendon repair. Retroversion of the humeral component or glenoid component could be the cause for posterior instability and it usually requires a revision with tensioning of the rotator cuff and the posterior capsule (Sanchez-Sotelo, 2011).

Superior instability seems to be associated with a tear or a failed repair of the rotator cuff. The cause may also be an imbalance between a strong deltoid muscle and a deficit of the rotator muscles, which indicates the need of exercise therapy to strengthen the rotator cuff after surgery. Inferior instability appears in patients with proximal humeral fractures and TSA revision. Restoring the humeral length and a well balanced deltoid tension could stabilize the joint. Neural injuries such as brachial plexopathies consisting of neuropraxia can occur; the treatment is usually conservative with good results (Wirth & Rockwood, 1996).

Periprosthetic fractures may appear during or after surgery. The fractures situated in the humerus distal to the tip of the implant could be treated orthopedically, otherwise surgical methods are needed to ensure stability of the fracture with osteosynthesis materials and a revision of the prosthesis. The glenoid component seems to be more prone to instability and pain, with a higher rate of radiographic glenoid loosening. Glenoid components may be changed if there is enough healthy bone left (Sanchez-Sotelo, 2011).

Rehabilitation program phases

The specialist who develops the rehabilitation program must take into consideration the comorbidities of the patient and the type of surgery that was performed. For regular total shoulder arthroplasty (TSA), subscapularis integrity is necessary for a full rehabilitation, while for reverse total shoulder arthroplasty (rTSA), subscapularis integrity is not that critical. In rTSA, soft tissues need less protection, so the rehabilitation process used will be more aggressive in order to show a faster recovery. However, complications such as stress fractures and dislocation seem to be higher for rTSA, indicating the need for a more calculated approach (Bullock et al., 2019). The joint replaced using the rTSA technique seems to dislocate during a complex movement such as abduction with extension and internal rotation (hand behind back). The greatest vulnerability after rTSA is inferior and anterior instability, which must be taken into consideration while elaborating the program. There is a discussion if the rehabilitation program should start immediately after surgery or if the arm with the prosthesis should be held in a sling for a couple of weeks. Most specialists indicate the use of a sling in order to protect the joint with the prosthesis from dislocation or loosening (Boudreau et al., 2007). However, recent studies showed that there is no significant difference between starting the rehabilitation program right away after surgery or holding the arm in a sling for 6 weeks without passive or active movements followed by a rehabilitation program (Edwards et al., 2018). Studies suggest that strength and functional scores can be correlated with the size and fatty infiltration of the deltoid muscle; also, reducing atrophy in the deltoid muscle leads to improved function after surgery (Buchmann et al., 2019).

Most rehabilitation protocols are set in stages or phases. Phase zero is defined as a short period before surgery and it is used to instruct the patient in the after surgery care and exercises. The next phase represents the immediate after care following the surgery, where passive movements are used in order to reduce edema and restore some degree

of function of the joint. Through phase 2, the patient is expected to perform active assisted exercises in order to reeducate muscles. In phases 3 and 4, the main focus is on active strengthening exercises and regaining a full range of motion, thus granting the joint more stability and function.

Although the aftercare is the main focus of the rehabilitation program, the patient should be instructed before surgery. In phase 0, the physician explains the procedures in order to prepare the patient for the procedure. During this stage the patient is instructed in the exercises and the aftercare that is needed for full recovery, also gentle stretching of the soft tissues that were restricted by the affected joint (Seitz & Michaud, 2012).

Phase 1

Phase 1 lasts 6 weeks according to most shoulder rehabilitation programs. The rehabilitation process starts 1 day after surgery. In this phase, the hygiene of the surgical site is very important in order to prevent infection and the patient starts passive exercises in order to acquire a gradual range of motion (ROM). Patients that had rTSA surgery after a revision or a failed TSA will require a longer immobilization in a sling in order to acquire greater bone density; Boudreau also recommends a delay in starting the passive movements, for 3 to 6 weeks in this case. For patients with rTSA surgery and deltopectoral surgical approach, their indication is to start exercise therapy after the interscalene block has been resolved with PROM at very low intensity (Boudreau et al., 2007).

Most surgeons indicate the use of a sling for protection during this phase; however, C. Payne indicates using a brace to allow the anterior capsule and subscapularis time to heal. The brace can be removed for non-aggressive exercise and bathing. After rTSA or revision surgery there is a lack in rotator cuff that demands careful positioning; while the patient is lying on his back, pillows must be placed under the arm in order to avoid excessive extension. On day 1 after surgery, the recommendations are active movements in joints such as fingers, wrist, elbow and neck. The therapist must find a safe range of motion zone where the patient can gradually perform exercises in order to avoid complications (Payne et al., 2015). Internal rotation is not indicated in the first 6 weeks due to a high risk of dislocation. Hyperextension must also be avoided for the same reason. External rotation should gradually progress to 20-30º in the scapular plane, but if the subscapular muscle has been repaired, external rotation must be restricted (Boudreau et al., 2007; Payne et al., 2015). Flexion can be performed passively in the scapular plane in order to gradually reach 90º, but the level of discomfort for the patient must be taken into consideration at all times. In rTSA, the rotator cuff is deficient and the stability of the joint is conferred by the deltoid and periscapular muscles. Through isometric exercises the stability of the joint is greater. Isometric exercises performed at a submaximal and pain-free level can start 4 days after surgery for the deltoid and periscapular muscles with the humerus fixed in the scapular plane. After 3 weeks the flexion can be gradually increased to 120º and after 6 weeks flexion can reach 140º according to Boudreau. Passive external rotation can be progressed to 30-45º while taking into consideration the limitations of the possible subscapularis repair during arthroplasty. Passive internal rotations should start after 6 weeks, but an abduction of 60º in the scapular plane must be added in order to avoid adduction and a high risk of dislocation.

Cryotherapy is recommended in this phase in order to reduce pain, spasm of the muscles and inflammation (Boudreau et al., 2007). Pain is reduced when the soft tissues reach 16 to 18º. In a study conducted by KP Speer on the effects of cryotherapy on postoperative shoulder pain, pain was less severe during the night after surgery for the cryotherapy group, with less medication used, and by day 10 the patients in the cryotherapy group reported less swelling and pain through shoulder movement exercises (Speer et al., 1996).

Training can commence the first day after surgery, with pendulum exercises supervised by the therapist that allow a gradual wider circular movement through the joint without active movement. The patient is required to flex the abdomen on the thighs at ~90º and allow the arm to dangle relaxed with the fingers pointing towards the ground and use his body by swaying to the front, back and sides in order to passively move the arm. The second day following surgery, another exercise can be added where a pulley is used with the healthy arm in order to elevate the affected arm as high as possible in accordance with pain. During the third day, the patient can start external passive rotation exercises using a rod and exercises that use gradual supination of the forearm with rotation and elevation of the injured arm by using the healthy arm for assistance (Seitz & Michaud., 2012).

The patient can progress to phase 2 after 6 weeks if he can tolerate passive range of motion exercises (PROM) and has achieved at least 90º passive flexion in the scapular plane, 45º passive external rotation and 60º passive internal rotation measured at 30º abduction in the scapular plane (Wilcox et al., 2005).

Phase 2

The second phase of the rehabilitation program for shoulder arthroplasty starts after 6 weeks and lasts for another 6 weeks. Payne suggests taking an X-ray before starting the second phase if bone quality was lacking prior to surgery; this indication is more common after revision surgery in order to ensure good bone integration of the implant. Using the arm for activities in front of the body is indicated, but the patient should avoid movements that require excessive extension. In order to avoid instability the indication starts with active assisted exercises and gradually progresses to active exercises. External rotation should be encouraged even in rTSA because it helps develop the posterior side of the deltoid and teres minor which helps with returning forward flexion to neutral position. According to Payne, through clinical experience, the patients who are unable to elevate (flex) the arm to a 90º angle respond poorly to eccentric deltoid programs. Contractures in the glenohumeral and periscapular area can lead to pain and an inability of the deltoid to contract accordingly.

During the rehabilitation process, the specialist might encounter a compensatory response that the patient

developed in order to perform certain tasks using the injured shoulder. This can result in a difficulty to recruit the muscles required for a complex movement. Payne recommends using functional electric stimulation (FES) in order to stimulate recruitment of the muscles by altering the sensory input. Functional electric stimulation is usually used in nervous affections such as plegia, but it may help before and after surgery in patients with weak deltoid muscle.

After surgery the patient can experience pain of different causes that range from inflammatory response after the traumatic event to infection that may hinder the results of rehabilitation; an X-ray and blood tests may indicate the cause. A type of pain that concerns a rehabilitation specialist is diffuse pain caused by ischemia in the deltoid or the rotator cuff muscles, usually caused by tension in the soft tissues or a slight mismatch of the implant. The pain must be differentiated from the one that irradiates from the cervical spine due to bad posture or insufficient tonus in the scapular elevator muscles. The solution for these problems can be kinesio-taping or shoulder support (Payne et al., 2015).

The goals for phase 2 are restoring dynamic shoulder stability by using rotator cuff and periscapular muscles. Elevation of the arm while standing is the end goal of the second phase (Seitz & Michaud, 2012); the patient should gradually progress from active assisted exercises to active exercises in order to allow the joint to accommodate to the new program and avoid complications. Active assisted and active exercises should be performed with the scapula stabilized and the arm in supine position. Active assisted and active exercises that require internal and external rotation should start after 8 weeks at a submaximal level to allow the teres minor and subscapularis muscle time to heal. Starting internal and external active assisted and active rotation exercises sooner than 8 weeks could tear the muscles in the rotator cuff that were repaired during the intervention. Rotation exercises should be performed in the plane of the scapula (Boudreau et al., 2007).

Seitz recommends training in water for a more fluent transition between active and passive exercises. Exercises in water make for a more synchronized use of the muscles surrounding the joint and an easier way to adapt the movements necessary for elevation, rotation, arm positioning that will be later used in a normal environment. As the patient progresses, paddles can be added in phase 3 for more resistance during the training (Seitz & Michaud, 2012). In the beginning, the exercises could use a type of support such as a chair, a table or an inflated exercise ball where the hand is sliding on the table/chair or rotating the ball forward while keeping contact with its surface. In order to use and isolate internal or external rotator muscles, the patient's shoulder girdle and arm should be supported; for sitting in bed in supine position he must support his scapula, arm and elbow on the bed's surface and maintain a 90º elbow flexion while performing internal and external rotation at a submaximal level/ for sitting on a chair position he needs a table at elbow height where he should rest his elbow and perform the rotation exercises (Payne et al., 2015). A type of exercise used in the beginning of the phase consists of passive elevation using a pulley, followed by an active contraction for lowering the arm. Another type of exercise is lifting the arm in supine position with the elbow flexed, making it easier for the patient to elevate the arm because the center of gravity is closer to the fulcrum of the glenohumeral joint and thus, less force is required. Passive exercises are recommended in order to stretch the soft tissues. Exercises could include doorway stretching and stretching while the patient is holding on to a chin-up bar and is slowly squatting (Seitz & Michaud, 2012).

During this phase, isotonic exercises for deltoid and periscapular muscles should be added to the isometric ones. While performing posterior deltoid training, the patients must avoid extension higher than neutral due to the risk of placing strain on anterior tissues. When starting the isotonic strengthening exercises, a program with low weight and high repetition is recommended. Isotonic training for the glenohumeral joint should commence only if the mechanics and active range of motion exercises in the entire shoulder girdle are adequate (Boudreau et al., 2007).

The patient can progress to the 3rd phase of the rehabilitation program if he can tolerate active assisted exercises and has achieved a passive flexion of 140º in the scapular plane, passive external rotation of 60º, passive internal rotation of at least 70º (the measurement must be done in the plane of the scapula with abduction of 30º) and is able to elevate the shoulder to 100º through active movement (Wilcox et al., 2005).

Phase 3

Phase 3 begins at ~12 weeks after surgery, but only if the patient can perform passive exercises, active assisted exercises and active exercises at an adequate level. The patient must also be able to contract isotonically each portion of the deltoid and periscapular muscles while maintaining appropriate shoulder mechanics. The goals of this phase are increasing patient's independence and strength in the arm while retaining good shoulder mechanics and painless movement in the joint (Boudreau et al., 2007).

The recommended exercises are those that include a higher number of repetitions with lighter weight; elastic bands with increasing weight load or paddles for the water exercises can be used. The advantage of elastic training is that the patient can decide what level of strength he can use and can relax if it becomes too intense. Weight exercises should start only after the patient is accustomed to elastic bands or paddle exercises in water. The goals for phase 3 are restoration of functional independence in daily life activities (Seitz & Michaud, 2012). Training of the deltoid with weight between 0.5-1.5 kg in supine elevation can commence at variable elevation degrees. Weight exercises with <1.5 kg is considered to provide good functional and strength outcome for patients following rTSA surgery, according to Boudreau et al. (2007). Training of the deltoid with weight between 0.5-1.5 kg in supine elevation can commence at variable elevation degrees (Wilcox et al., 2005).

The patient can start active exercises with a light weight load in vertical or semi-reclined supine position (back of the chair at a ~120º angle). During this stage, daily activity tasks such as taking light housework or preparing food

can be introduced in the rehabilitation program in order to raise the patient's confidence; however, repetitive use above shoulder level or heavy loads should be avoided for at least 6 months after surgery (Payne et al., 2015). The patient must be informed that lifting weights heavier than 3 kg, sudden lifting and sudden jerking movements should be avoided because they could lead to injury.

Progressing to phase 4, the patient must tolerate active and strengthening exercises and has achieved active elevation in the scapular plane of at least 140º, active external rotation of at least 60º, active internal rotation of at least 70º and can elevate the shoulder to at least 120º (Wilcox et al., 2005).

Phase 4

In phase 4, the patient is expected to perform active range of motion exercises pain-free and must have an advanced degree of independence (Boudreau et al., 2007).

Exercises for strengthening, coordination and shoulder stability must be continued at home at least 3-4 times a week (Wilcox et al., 2005).

The goal in this phase is to gradually return the patient to his old hobbies. Exercises during stage 4 should incorporate overhead resistance, muscle balance and coordination in order to prepare the patient's return to the tennis field, golf course, swimming pool (Seitz & Michaud, 2012).

Studies suggest that a high number of patients that undergo shoulder replacement surgery return to practicing sports after the rehabilitation program has been completed. There are different rates in returning to sports that can be correlated to the type of surgery performed. Following TSA the return rates are between 75-100%, for rTSA the rate is lower, 75-85%, while hemiarthroplasty (HA) surgery has the lowest rate of returning to practicing sports, 67-76% (Johnson et al., 2016).

The study also showed that most of the patients that practiced a sport are likely to be able to return to practicing it after shoulder replacement. Data shows that low-impact sports such as cycling, golf, swimming and jogging can be safely practiced by most of the patients (Johnson et al., 2016). A study conducted by McCarthy reveals that on average patients doubled their time practicing sports after surgery and the sports most often performed were tennis, golf and swimming (McCarthy et al., 2008).

Even though HA seems to have a lesser impact on the structures and is less prone to implant failure, studies show that patients are less likely to return to sports in comparison to rTSA and TSA and that about 25% of patients are satisfied after 17 years of follow-up. TSA surgery seems to show pain relief superior to HA, a better range of motion and function; however, many surgeons permit returning to sports with fewer restrictions after HA surgery than TSA. Comparing rTSA with HA, the first one seems to provide a better range of motion and functionality, but HA is perceived to be safer than rTSA in terms of returning to sports. Most surgeons recommend higher restrictions after rTSA than HA.

Sports that require lower loads can be safely practiced after all types of shoulder replacement surgery, but for sports that involve a higher risk of falling or a higher load, the opinions and approaches differ (Johnson et al., 2016).

Conclusions

1. There are 3 types of arthroplasty, each being better suited for an array of disorders. Each shoulder replacement type has certain contraindications that the specialist must take into consideration when recommending exercise therapy.
2. Rehabilitation programs are set in phases or stages that have goals. Patients must reach certain goals in order to begin the next phase.
3. Phase zero represents a short period of time before surgery that is used to instruct the patient on surgery and the aftercare.
4. Phase one starts next day after surgery. Emphasis is placed on adequate healing of the soft tissues surrounding the joint and gaining a suitable range of motion through passive exercises. Cryotherapy can be used to reduce inflammation, muscle spasm and pain.
5. During phase two, active assisted exercises and active exercises are introduced in the training program. Exercises that strengthen the deltoid and periscapular muscles should be performed.
6. Phase three is focused on strengthening the shoulder muscles while maintaining good mechanics and pain free motion.
7. In phase four, the patient continues strengthening and coordination exercises in order to gradually return to his previous activities and hobbies.

References

Boudreau S, Boudreau ED, Higgins LD, Wilcox RB. Rehabilitation following reverse total shoulder arthroplasty. J Orthop Sports Phys Ther. 2007;37(12):734-743. doi: 10.2519/jospt.2007.2562.

Buchmann S, Schoch C, Grim C, Jung C, Beitzel K, Klose M, Mauch B, Pfalzer F, Tepohl L, Tholen R, Gottfried T, Ortmann H, Scheibel M, Mauch F. Rehabilitation following reverse shoulder arthroplasty. Obere Extremität. 2019; 14: 269-283. https://doi.org/10.1007/s11678-019-0513-5.

Bullock GS, Garrigues GE, Ledbetter L, Kennedy J. A Systematic Review of Proposed Rehabilitation Guidelines Following Anatomic and Reverse Shoulder Arthroplasty. J Orthop Sports Phys Ther. 2019;49(5):337-346. doi: 10.2519/jospt.2019.8616.

Edwards PK, Ebert JR, Littlewood C, Ackland T,Wang A. Effectiveness of formal physical therapy following total shoulder arthroplasty: A systematic review. Shoulder & Elbow. 2018;12(2):136-143. https://doi.org/10.1177/1758573218812038 2018.

Gregory T,Hansen U, Emery R, Augereau B, Amis A. Developments in shoulder arthroplasty. Proc Inst Mech Eng H. 2007;221(1):87-96. doi: 10.1243/09544119JEIM167.

Johnson CC, Johnson DJ, Liu JN, Dines JS, Dines DM, Gulotta LV, Garcia GH. Return to sports after shoulder arthroplasty. World J Orthop. 2016;7(9):519-526. doi: 10.5312/wjo.v7.i9.519.

Kraus M, Krischak G,Tepohl L. Postoperative Rehabilitation of Patients with Shoulder Arthroplasty - A Review on the Standard of Care. Int J Phys Med Rehabil 2014; S5:001. doi:10.4172/2329-9096.S5-001.

McCarty EC, Marx RG, Maerz D, Altchek D, Warren RF. Sports Participation after Shoulder Replacement Surgery. Am J Sports Med. 2008;36(8):1577-1581. doi: 10.1177/0363546508317126.

Payne C, Jaggi A, Le Leu A, Garofalo R, Conti M. Rehabilitation for shoulder arthroplasty. Orthopaedics and Trauma. 2015;29(5):313-323. doi: 10.1016/j.mporth.2015.09.003.

Ratajczak K, Szczęsny G, Małdyk P. Comminuted fractures of the proximal humerus - principles of the diagnosis, treatment and rehabilitation. Ortop Traumatol Rehabil. 2019;21(2):77-93. doi:10.5604/01.3001.0013.1544.

Sanchez-Sotelo J. Total shoulder arthroplasty. Open Orthop J. 2011;5:106-114. doi: 10.2174/1874325001105010106.

Seitz WHJr, Michaud EJ. Rehabilitation after Shoulder Replacement: Be All You Can Be! Seminars in Arthroplasty, 2012;23(2):106-113. DOI: 10.1053/j.sart.2012.03.009.

Speer KP, Russell MD, Warren F, Horowitz L. The efficacy of cryotherapy in the postoperative shoulder. J Shoulder Elbow Surg. 1996;5(1):62-68. doi: 10.1016/s1058-2746(96)80032-2.

Wilcox RB, Arslanian LE, Millett P. Rehabilitation following total shoulder arthroplasty. J Orthop Sports Phys Ther. 2005;35(12):821-836. doi:10.2519/jospt.2005.35.12.821.

Wirth M, Rockwood C. Complications of total shoulder-replacement arthroplasty, J Bone Joint Surg Am. 1996;78(4):603-616. doi: 10.2106/00004623-199604000-00018.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 110–112

Medication and cognitive-behavioral therapy treatment effects on the brain in depression

Cristiana Cojocaru[1], Cosmin Popa[2], Alina Schenk[3], Nicoleta Suciu[2], Simona Szasz[2]
[1] *Braun Dialysis Centre, Sighişoara, Mureş County, Romania*
[2] *George Emil Palade University of Medicine, Pharmacy, Sciences and Technology of Tîrgu-Mureș, Romania*
[3] *Save the Children, Romania*

Abstract
Major depression is an affective disorder with a huge impact both on the quality of life at a personal level and on social or economic functioning. At a neurobiological level, depression may disturb brain activity, which emphasizes even more the need for implementing a highly efficient treatment in the case of major depressive disorder. The purpose of the present article is to present medication and cognitive-behavioral therapy (CBT) effects on the brain and to mention their implications in clinical practice. Research indicates that pharmacological treatment is associated mostly with a rapid remission of some symptoms, and psychotherapy may produce cognitive changes with long-term benefits.
Keywords: depression, brain, cognitive-behavioral therapy, medication, antidepressants.

Introduction

Major depression is one of the most frequent affective disorders and may strongly affect a person's functioning in the personal, professional or social area. Depression prevalence was estimated at 8% in the case of adults in Europe and the United States in 2018 (Brody et al., 2018).

The diagnosis of major depressive disorder involves the presence of significant modifications for at least two weeks, which are necessary to include a sad/ depressed mood or anhedonia. In addition, many symptoms may appear, such as significant and unintentional weight loss or gain, sleep problems, fatigue, inutility or guilt, psychomotor agitation or retardation, reduced thinking or concentration ability, and recurrent thoughts of death or suicide attempts (***, 2013).

Depression correlates negatively with multiple social functioning dimensions, such as interpersonal communication, group affiliation or expressing empathy (Kupferberg et al., 2016). In terms of its relation to physical health, research demonstrates that depression is commonly coupled with two or more somatic conditions (Stubbs et al., 2017).

Besides affecting the quality of life at an individual level, depression may have a significant economic impact through work performance impairments. It was shown that depression is associated with annual financial costs of more than $5500 per person in some countries (Evans-Lacko & Knapp, 2016).

Given the massive and global costs of depression, the collaboration between mental health professionals is important for the establishment of the most appropriate and efficient therapeutic scheme in its treatment.

Depression impact on the brain

At a cerebral level, depression is associated with particular changes related to the brain structure or functioning. For example, in the case of people who face depression, brain activity is reduced in the left part of the prefrontal cortex, a region which is correlated with reward seeking and positive emotions (Davidson, 2000). Thus, these people are less likely to look for pleasurable experiences. Generally, depression is correlated with a diminished activity in the prefrontal cortex, especially with medial prefrontal cortex deficits that are linked to high stress levels (Debener et al., 2000; Belleau et al., 2019). Moreover, it was shown that the hippocampus, an important area for both memory and emotion regulation, has a smaller volume in people who are diagnosed with

Received: 2020, February 9; *Accepted for publication:* 2020, February 21
Address for correspondence: George Emil Palade University of Medicine, Pharmacy, Science and Technology of Tîrgu Mureș, Faculty of Medicine in English, Department of Ethics and Socio-Human Sciences, 38 Gheorghe Marinescu Street, Tîrgu Mureș, 540142, Romania
E-mail: cosmin_popa24@yahoo.com
Corresponding author: Cosmin Popa; cosmin_popa24@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.110

depression (Sheline et al., 2019). Probably due to prolonged negative states, the amygdala is also more activated in those who display a cognitive vulnerability to depression (Drevets, 2001; Zhong et al., 2011).

The anterior cingulate cortex is a brain region that is more active in novel situations, especially in those requiring a fast decision and the adjustment of previously established action plans, activities that involve attention and executive functions (MacDonald et al., 2000). In the case of depression, the anterior cingulate cortex is less active, and these patients' reactions are slower (Pandya et al., 2012).

Nevertheless, depression effects on brain morphology and functioning may vary across individuals, which points to the necessity for adjusting different types of treatment to specific structures and traits (Müller et al., 2017).

Moreover, early negative experiences, which are common among patients who suffer from depression, may alter brain connectivity in many areas that are essential to emotion-regulation and cognitive functions (Yu et al., 2019).

The impact of pharmacologic and non-pharmacologic treatment on the brain in depression

In the case of major depression, research using neuroimaging techniques demonstrated that its treatment is associated with modifications related to the brain functioning or structure, but the effects of interventions are different (Linden, 2006). Medication is often accompanied by modifications at the level of subcortical regions such as the hippocampus or amygdala, which suggests a bottom-up effect, while CBT may influence brain activity especially at the level of the prefrontal cortex, exerting a top-down effect (Goldapple, 2004). A number of studies support this hypothesis. For example, a meta-analysis concluded that medication and CBT have different roles that complement each other in the treatment of depression (Boccacia et al., 2016). Specifically, medication treatment produces changes which are related mostly to subcortical areas of the brain, such as the amygdala or insula, which may provide a quick relief of some symptoms, particularly physical sensations and reward processing (Kalani et al., 2009). On the other hand, CBT mainly influences the prefrontal cortex, the temporal lobe and the middle cingulate cortex areas (Boccacia et al., 2016). These regions are responsible for cognitive processes involved in memory, retention and retrieval (de Zubicaray et al., 2001), but also for self-relevant information processing (Kelley et al., 2002). Hence, pharmacologic treatment generates an instant relief of some symptoms, especially physiological ones, while psychotherapy may profoundly influence the evolution of cognitive and emotional problems, bringing about stable and sustainable benefits for patients with depression (Boccacia et al., 2016). Li et al. (2018) also reported a different pattern of depressive symptom improvement after medication and psychotherapy, with medication preferentially reducing somatic manifestations such as diurnal variation in the first two weeks of treatment, and attribution retraining group therapy (a form of CBT) relieving anxiety, cognition disturbance, retardation and hopelessness in the sixth week of intervention (Li et al., 2018).

However, other investigations do not support the existence of a segregation of effects. The findings of another meta-analysis indicate decreases in the cingulate gyrus, inferior frontal gyrus and insula activation after patients with anxiety and depression received psychotherapy, suggesting that differentiation between treatment options may be more complex (Marwood et al., 2018).

Conclusions

1. Medication and cognitive-behavioral therapy interact in the treatment of major depressive disorder, accomplishing different functions that ensure the efficiency in reducing emotional difficulties on the long run. Research indicates that these treatment modalities have separated and interactive effects on brain functioning, thus targeting several clusters of symptoms.

2. The instant symptom remission due to medication, particularly related to somatic complaints, may represent the foundation for psychotherapeutic intervention, which is characterized by broader state improvements that persist after pharmacologic treatment has ended. Given their complementary effect, the implementation of a treatment scheme that combines the two intervention modalities is recommended, notably in the case of patients with severe depression.

Conflicts of interests

The authors declare that there is no conflict of interests.

References

Belleau EL, Treadway MT, Pizzagalli DA. The Impact of Stress and Major Depressive Disorder on Hippocampal and Medial Prefrontal Cortex Morphology. Biol Psychiatry. 2019;85(6):443-453. doi: 10.1016/j.biopsych.2018.09.031.

Boccacia, M, Piccardi L, Guariglia P. How treatment affects the brain: meta-analysis evidence of neural substrates underpinning drug therapy and psychotherapy in major depression. Brain Imaging Behav. 2015;10(2):619-627. doi: 10.1007/s11682-015-9429-x.

Brody DJ, Pratt LA, Hughes JP. Prevalence of Depression Among Adults Aged 20 and Over: United States, 2013-2016. U.S. NCHS Data Brief. 2018;(303):1-8.

Davidson RJ. Affective style, psychopathology, and resilience: Brain mechanisms and plasticity. Am Psychol. 2000;55(11):1196-2214. doi: 10.1037//0003-066x.55.11.1196.

de Zubiacaray GI, McMahon K, Wilson SJ, Muthiah S. Brain activity during the encoding, retention, and retrieval of stimulus representations. Learn Mem. 2001;8(5): 243-251. doi: 10.1101/lm.40301.

Debener S, Beauducel A, Nessler D, Brocke B, Heilemann H, Kayser J. Is resting anterior EEG alpha asymmetry a trait marker for depression? Findings for Healthy Adults and Clinically Depressed Patients. Neuropsychobiology. 2000;41(1):31-37. doi: 10.1159/000026630.

Drevets WC. Neuroimaging and neuropathological studies of depression: Implications for the cognitive-emotional features of mood disorders. Curr Opin Neurobiol. 2001;11(2):240-249. doi: 10.1016/s0959-4388(00)00203-8.

Evans-Lacko S, Knapp M. Global patterns of workplace productivity for people with depression: absenteeism and presenteeism costs across eight diverse countries. Soc Psychiatry Psychiatr Epidemiol. 2016;51(11):1525-1537. doi: 10.1007/s00127-016-1278-4.

Goldapple K, Segal Z, Garson C, Lau, Bieling P, Kennedy S, Mayberg H. Modulation of the cortical-limbic pathways in major depression: treatment-specific effects of cognitive behavior therapy. ArchGen Psychiatry. 2004;61(1):34-41. doi: 10.1001/archpsyc.61.1.34.

Kalani MY, Kalani MA, Gwinn R, Keogh B, Tse VC. Embryological development of the human insula and its implications for the spread and resection of insular gliomas. Neurosurg Focus. 2009;27(2): E2. doi: 10.3171/2009.5.FOCUS0997.

Kelley, W.M., Macrae, C.N., Wyland, C.L., Caglar, S., Inati, S., & Heatherton, T.F. "Finding the self? An event-related fMRI study." J Cogn Neurosci. 2002;14(5):785-794. doi: 10.1162/08989290260138672.

Kupferberg A, Bicks L, Hasler G. Social functioning in major depressive disorder. Neurosci Biobehav Rev. 2016;69:313-332. doi: 10.1016/j.neubiorev.2016.07.002.

Li J, Zhang J, Yang H, Zhang N, Zhang Y, Heffner KL, Wang C. Differential Change in Depressive Symptoms during Psychotherapy and Medication in Clinical Care. NeuroQuantology. 2018;16(12):1-9. DOI: 10.14704/nq.2018.16.12.1860.

Linden DE. How psychotherapy changes the brain - the contribution of functional neuroimaging. Mol Psychiatry. 2006;11(6):528-538. doi: 10.1038/sj.mp.4001816.

MacDonald AW, Cohen JD, Stenger VA, Carter CS. Dissociating the role of the dorsolateral prefrontal and anterior cingulate cortex in cognitive control. Science. 2000;288(5472):1835-1838. doi: 10.1126/science.288.5472.1835.

Marwood L, Wise T, Perkins AM, Cleare AJ. Meta-analysis of the neural mechanisms and predictors of response to psychotherapy in depression and anxiety. Neurosci Biobehav Rev. 2018;95:61-72. doi: 10.1016/j.neubiorev.2018.09.022.

Müller VI, Cieslik EC, Serbanescu I, Laird AR, Fox PT, Eickhoff SB. Altered Brain Activity in Unipolar Depression Revisited. Meta-analysis of Neuroimaging Studies. JAMA Psychiatry, 2017;74(1): 47-55. doi:10.1001/jamapsychiatry.2016.2783.

Pandya M, Altinay M, Malone Jr. DA, Anand A. Where in the Brain is Depression? Curr Psychiatry Rep. 2012;14(6):634-642. doi: 10.1007/s11920-012-0322-7.

Sheline YI, Liston C, McEwen BS. Parsing the Hippocampus in Depression: Chronic Stress, Hippocampal Volume, and Major Depressive Disorder. Biol Psychiatry. 2019;85(6):436-438. doi: 10.1016/j.biopsych.2019.01.011.

Stubbs B, Vancampfort D, Veronese N, Kahl KG, Mitchell AJ, Lin P-Y, Tseng P-T, Mugisha J, Solmi M, Carvalho AF, Koyanagi A. Depression and physical health multimorbidity: Primary data and country-wide meta-analysis of population data from 190 593 people across 43 low- and middle-income countries. Psychol Med. 2017;47(12):2107-2117. doi: 10.1017/S0033291717000551.

Yu M, Linn KA, Shinohara RT, Oathes DJ, Cook PA, Duprat R, Moore TM, Oquendo MA, Phillips ML, McInnis M, Fava M, Trivedi MH, McGrath P, Parsey R, Weissman MM, Sheline YI. Childhood trauma history is linked to abnormal brain connectivity in major depression. Proc Natl Acad Sci U S A 2019;116(17):8582-8590. doi: 10.1073/pnas.1900801116.

Zhong M, Wang X, Xiao J, Yi J, Zhu X, Liao J, Wang W, Yao S. Amygdala hyperactivation and prefrontal hypoactivation in subjects with cognitive vulnerability to depression. Biol Psychol. 2011;88(2-3):233-242. doi: 10.1016/j.biopsycho.2011.08.007.

***. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Washington, DC 20024-28-12, 2013. https://doi.org/10.1176/appi.books.9780890425596.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 113–116

Doctor-patient communication from the perspective of the Rogerian model

Alina Schenk[1], Cristiana Cojocaru[2], Nicoleta Suciu[3], Cosmin Popa[3], Simona Szasz[3]
[1]*Save the Children, Romania*
[2]*Braun Dialysis Centre, Sighișoara, Mureș County, Romania*
[3]*George Emil Palade University of Medicine, Pharmacy, Sciences and Technology of Tîrgu-Mureș, Romania*

Abstract

Communication is a fundamental process that ensures the exchange of information necessary to maintain an interpersonal relationship and achieve specific goals within it. The field of medicine is characterized by human interaction, and communication has an important role, having significant effects on treatment outcomes and patient well-being. The purpose of this article is to review the most important findings related to the application of communication theories in the medical context. An overview of the architecture of the human cognitive system will be approached to understand the processing of information and its assimilation by patients.

In this context, the Rogerian Communication Model and its implications for clinical practice will be explained. Relevant research on two components of Rogers' approach - congruence and empathy - will be reviewed. Congruence refers to the authenticity of the act of communication, the match between the inner world and the manifest behavior of an individual. Empathy is the adoption of the patient's perspective and the way he views the interaction with the doctor and the medical act. Finally, the importance of these elements in the doctor-patient relationship will be analyzed, highlighting the elements that can have a significant impact on the success of treatment.

Keywords: communication, doctor-patient relationship, clinical practice, Rogerian communication model, congruence, empathy.

Introduction

Communication is the process through which information exchange takes place within a society or even between two different societies on the basis of words, symbols and meanings by which an individual manages to understand what another person conveys and to relate to other people. Therefore, this process represents an intentional and benevolent act that may appear either in a manifest or latent form, serving as the main process underlying social interaction (Neculau, 2004).

Communication skills are extremely important in the medical field. Communication courses for medical students develop their communication competencies, producing changes later in real clinical practice, at the level of the physician-patient relationship, when they become doctors. This happens because the advantage of this kind of communication reflects into a good collaborative relationship, with the patient directly displaying increased treatment compliance and indirectly having a stronger trust regarding the physician and the medical act (Brown, 2008).

Many studies showed that communication skills may be enhanced through efficient instruction and that efficient communication increases medical results, safety, patient's adherence to treatment, and both patient's and provider's satisfaction (Boissy et al., 2016).

A good collaboration with the patient is important for the appropriate assessment of his or her needs, the establishment of a correct diagnosis and the development of a treatment plan. In medical practice, appropriate information transmission is not enough for patient's collaboration, suggesting the need for an active contribution of the patient to the medical act. To meet this kind of implication from the patient, it requires the physician to develop a relationship based on trust, empathy, active listening, unconditional acceptance and congruence.

Exploring the history of the patient from a bio-psycho-social point of view (for example, relevant information, his or her understanding level, verbalizing emotional

Received: 2020, March 2; *Accepted for publication:* 2020, March 19
Address for correspondence: George Emil Palade University of Medicine, Pharmacy, Science and Technology of Tîrgu Mureș, Faculty of Medicine in English, Department of Ethics and Socio-Human Sciences, 38 Gheorghe Marinescu Street, Tîrgu Mureș, 540142, Romania
E-mail: cosmin_popa24@yahoo.com
Corresponding author: Cosmin Popa; cosmin_popa24@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.113

content, etc), gathering as much information from the patient and adjusting it in terms of quantity and quality, and synthesizing the required contents to elaborate an efficient therapeutic plan are important objectives in the context of the physician-patient relationship, which were accepted by 121 experts in medical communication.

Brain architecture and communication

Regarding the communication techniques, one of the most important findings from recent years resulted from LeDoux's research on human emotions, which is about brain architecture. Brain architecture offers a privileged location of the amygdalian nucleus, which becomes a kind of emotional guard that is able to block the brain. His study showed that sensory signals from the eyes and ears first arrive in the brain at the thalamus and then - through a single synapse - at the amygdalian nucleus; a second signal from the thalamus is directed to the neocortex - that part of the brain which involves reasoning. Thus, there are two pathways inside the brain, the superior path and the inferior path of emotions, and when people face unpleasant/ anxiogenic/ conflicting situations, the first path to get into action is that of emotions (LeDoux, 2018). After about 20 minutes, the superior path, which corresponds to reasoning, takes over. In other words, efficient communication techniques offer the patient time to accommodate to an unpleasant situation, speeding up the action of the superior path at the same time (Goleman, 2008). A calm approach based on understanding and empathy from the physician to the patient reduces amygdalian activation and reactivates the neocortex areas, improving the efficacy of the medical act.

Rogerian approach in medical communication

Carl Rogers is one of the most important psychologists and psychotherapists of the 20th century and is one of the founders of the humanistic perspective in person centered psychology and psychotherapy. Rogers' theory relies on the idea that a human being is positively reinforced, with a natural impulse to grow and adapt. Rogers makes an analogy between person centered psychotherapy and learning to ride a bike. One cannot learn to ride a bike just by explaining it, the person needs to try on his or her own and one cannot support himself or herself all the time - at some point, the person needs to keep the balance, and if he or she will fall, that is part of the learning process. In any form of therapy or treatment, the patient needs to gain autonomy, freedom to choose and to be responsible. According to Rogers, a therapeutic relationship is based on three essential aspects: congruence, empathy and positive regard towards the patient.

Congruence

Through congruence, Rogers refers not only to being aware of oneself, of one's inner experience, but also to share one's feelings with another person. Thus, congruence has two components, an internal one that implies the awareness of one's own inner experience and an external one that refers to an honest explicit communication.

Our social contacts are mediated by our attitudes and emotions. When that contact is authentic, communication is facilitated. In that sense, a congruent position of the physician in the relationship with a patient is synonymous to authenticity (Frankel et al., 2016).

Imagine that you are a doctor and you've been on duty in an emergency service (or that you are simply tired), and one of your patients with whom you have a good collaboration, comes to an outpatient service for a consultation. The moment you begin the consultation, your patient tells you the fact that you seem a little tired. If then you deny it (besides the events) and say: "No, by no means, probably it looks like I am", this defensive reaction places you exactly in the incongruent position described above. Through logical deduction, your patient may have the following thoughts: "If my doctor hides from me such a simple thing, is it possible that he doesn't like me?" or "My doctor is not sincere to me and doesn't admit that he is tired, is it possible that he did the same regarding the diagnosis? Did he tell me everything?" Thereby, incongruence within the physician-patient relationship may lead to the therapeutic relationship "rupture". A congruent response to the patient's question if you are tired may be the following: "Yes, indeed I had a pretty difficult duty and I'm a little tired. Instead, I assure you that this doesn't affect my ability to consult you. If I had felt that my strain affected me, I would have surely asked another co-worker to substitute me. However, I appreciate your observation."

Goleman (2019) shows the fact that when a leader/ a person with authority from a group is dissimulating his or her behavior, trying to use manipulation and lying to reach some objectives/purposes inside an organization, the other members of the group immediately perceive that and punish the dissimulated behavior, and this way the leader loses this position. Actually, subordinates simply use their emotional intuition to identify the lie/ pretence of the leader. In contrast to this type of behavior, in the case of a leader who acts according to group values, who clearly presents his or her principles and sometimes without holds barred, who "emotionally adjusts" to the affective states of the subordinates with whom he or she interacts, that person is readily accepted and supported by the whole group in achieving the pursued objectives.

In conclusion, Goleman states that authenticity is at the core of the development and maintenance of a harmonious human relation, in other words a certain type of behavior needs to be similar to the real feelings/emotions that a specific person feels (Goleman, 2019).

Empathy

Rogers (1957) considers empathy as a necessary and sufficient condition of the therapeutic process. Empathy means to sense the client's private world as if it were your own, but without ever losing the "as if" quality—this is empathy, and this seems essential to therapy (Rogers, 1957).

Starting from Rogers' definition of empathy, more recently, Clark (2010) stated that empathy is related to the "knowledge modalities" and it can manifest through subjective, objective and interpersonal means. Subjectively, a therapist may experience empathy starting from his personal experience using his intuition and imagination to

understand the client's reality. Objectively, a therapist may use external information, such as hypothesis, diagnosis or other methods to understand the client's reality. Interpersonal empathy, the type which relates the most to Rogers's concept, is the therapist's process that perceives the inner reality of a client and communicates this to him (Neukrug et al., 2013).

We need to make a clear distinction between the capacity to reason as if one were in one's patient's shoes, which is to be empathic, and how it is to be in one's patient's shoes, which means the identification with the patient's problems. Identification is a dysfunctional defensive mechanism because it leads to the occurrence of dysfunctional negative feelings (Rogers, 2015).

Gerdes and Segal (2011) state that empathy can be trained and developed. They say that giving attention to the patient creates new neuronal pathways that enhance the capacity to be empathic, allowing the therapist to be aware of those behaviors that limit empathy at the same time.

In treating patients with chronic disease, the alliance between physician and patient is very important. The patient needs his ambivalence, pain and worries to be understood. In an empathic manner, the physician needs to inoculate hope, support and to admit the patient's ability, and he also has a role in the patient's guidance throughout the treatment (Hudon et al., 2012).

Most nowadays theories embrace empathy, which is important because empathy as a general construct may help in identifying the patient's problems and has been demonstrated to be strongly linked to the positive results of the patients (Elliot et al., 2011; Norcross, 2010; Wampold, 2010a; Wampold, 2010b).

Empathy should also be accompanied by other qualities, such as the unconditional acceptance of a person, tolerance, respect.

To check the level of empathic implication between the physician and the patient, we need to analyze the existence of six fundamental conditions (Rogers, 1957), which are sufficient for the patient's evolution:

a) The existence of a constant attitude, at a psychological level, between physician and patient.

b) A person should play the role of a patient, presenting a vulnerability state, such as: an emotional disturbance that may be caused by a disease, including the so-called incongruent state.

c) The existence of a good therapeutic relationship, so that the physician is congruent.

d) The physician manifests unconditional acceptance towards the patient.

e) The physician shows empathy for the patient's problems.

f) Communication with the patient relies upon unconditional positive regard.

Especially during an initial consultation, the physician needs to adopt an empathic, congruent, respectful, neutral, non-evaluative attitude and a reserved affective expression (for example, he does not seem surprised by the patient's speech). The physician's creativity plays a primary role and as creativity is more present in the medical act, communication is more stimulated. It is important to understand that the relationship with a patient with chronic disease takes time. In the acute phases of pain/ major discomfort, there may be time intervals in which the patient is discontented/ upset with the medical services/ treatment, and this fact may negatively influence the doctor-patient communication. In those conditions, the physician needs a lot of patience and understanding towards the patient, and from the point of view of increasing compliance with treatment, the implementation of motivational interviewing elements may be required.

Within the therapeutic relationship, it is necessary to be conscious of what represents the balance between too little and too much. In other words, a didactic approach, persuasion, taking a critical stance towards a reserved attitude of the patient, and the physician's body language may activate the psychological resistance of the patient. Resistance behaviors are psychological reactions that are integrated within the classic defensive mechanisms, besides rationalizing and feedback. For example, when the patient has a negative thought that is determined by the particular content of a specific disease, he attempts to replace it with a positive thought, and if that does not work, the patient feels nervous and anxious (David, 2012).

Conclusions

1. The active involvement of patients in the recovery process is influenced by the physician's attitude and communication skills manifested at the time of the consultation.

2. A collaborative relationship between the physician and the patient provides a good prognosis of the evolution of the patient's disease / disorder.

3. Understanding the neurological processes that occur in patients reinforces the importance of the use of effective communication techniques by the physician in order to develop a collaborative relationship.

4. The Rogerian approach, through the use of empathy, congruence, and unconditional acceptance, overwhelmingly influences the therapeutic relationship between physician and patient. Based on this, the patient's involvement, collaboration, adherence to treatment will increase, ensuring a successful treatment.

Conflicts of interests

The authors declare that there is no conflict of interests.

References

Boissy A, Windover AK, Bokar D, Karafa M, Neuendorf K, Frankel RM, Merlino J, Rothberg MB. Communication Skills Training for Physicians Improves Patient Satisfaction, Gen Intern Med. 2016;31(7):755-761. doi: 10.1007/s11606-016-3597-2.

Brown J. How clinical communication has become a core part of medical education in the UK. Medical Education, 2008;42(3):271-278. doi: 10.1111/j.1365-2923.2007.02955.x.

Clark AJ. Empathy: An integral model in the counseling process. J Counseling Develop. 2010; 88(3):348-356. https://doi.org/10.1002/j.1556-6678.2010.tb00032.x.

David D. Tratat de psihoterapii cognitive și comportamentale. Ed. Polirom, 2012

Elliott R, Bohart AG, Watson JG, Greenberg LS. Empathy.

Psychotherapy, 2011;48(1):43-49. doi: 10.1037/a0022187.
Frankel M, Johnson MM, Polak R. Congruence: the social contract between a client and therapist. J Person-Centered Exper Psychother. 2016;15(2):1-19. DOI: 10.1080/14779757.2016.1182061.
Gerdes KE, Segal E. Importance of empathy for social work practice: Integrating new science. Social Work, 2011;56(2):141-148. doi: https://doi.org/10.1093/sw/56.2.141.
Goleman D. Inteligenţa emoţională (ed. a 4-a). Ed. Curtea Veche. București, 2018.
Goleman D, Boyatzis R, McKee A. Inteligenţa emoţională în leadership (ed. a 4-a). Ed Curtea Veche București, 2019.
Hudon C, Fortin M, Haggerty J, Loignonc C, Lambert M, Poitras ME . Patient-centered care in chronic disease management: A thematic analysis of the literature in family medicine. Patient Educ Couns. 2012;88(2):170-176. doi: 10.1016/j.pec.2012.01.009.
LeDoux J. Anxios. Cum ne ajuta creierul să înțelegem și să tratăm frica și anxietatea. Ed. ASCR Cluj- Napoca, 2018.
Neculau A. Psihologie socială. Ed. Polirom Iași, 2004.
Neukrug E, Bayne H, Dean-Nganga L, Pusateri C. Creative and Novel Approaches to Empathy: A Neo-Rogerian Perspective. J Mental Health Counselling 2013;35(1):29-42. doi: https://doi.org/10.17744/mehc.35.1.5q375220327000t2.
Norcross JC. The therapeutic relationship. In Duncan BL, Miller SD, Wampold BE, Hubble MA(Eds.).The heart and soul of change (2nd ed.). Washington, DC: Am Psychol Assoc. 2010; 113-142.
Rogers CR. The necessary and sufficient conditions of therapeutic personality change. J Consulting Psychol.1957;21:95-103.
Rogers CR. Terapia centrata pe client Practica ei actuală, implicații și teorie. Ed. Trei București, 2015
Wampold BE. The great psychotherapy debate: Models, methods, and findings. Mahwah NJ: Lawrence Erlbaum Associates, 2010a.
Wampold BE. The research evidence for common factors models: A historically situated perspective In Duncan BL, Miller SD, Wampold BE, Hubble MA. The heart and soul of change (2nd ed.). Washington, DC: American Psychological Association, 2010b; 49-82.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 117–121

What about rehabilitation medicine after COVID-19

Rodica Ungur[1,2], Calina Ciubotariu[2], Mihai Emil Russu[2], Ileana Monica Borda[1,2], László Irsay[1,2], Viorela Ciortea[1,2], Ioan Onac[1,2]
[1] *"Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania*
[2] *Clinical Rehabilitation Hospital Cluj-Napoca, Romania*

Abstract

The SARS-CoV-2 virus has taken the medical world by surprise in 2020 by determining the COVID-19 pandemic. This disease affects the respiratory tract in most cases, although cardiac and digestive tract involvement are not uncommon, thus making COVID-19 a disease of the whole body.

Facing this threat, the doctors' attention shifted towards prevention and the reorganization of the whole medical system to combat this threat and also towards finding the most appropriate medical treatment. To date, the disease has reached its peak in some countries and medical rehabilitation can show its valuable role in reintegrating those affected or those that are healing back into society.

Among those that can benefit from rehabilitation programs are those that were quarantined or in self-isolation and also healthcare professionals that deal with COVID-19 and are predisposed to the burnout syndrome.

The types of rehabilitation that capture our attention are those that deal with respiratory, mental health and neuromotor recovery. Also, balneotherapy programs can have a healthful effect in the current context. Nevertheless, maintaining close relations with loved ones through technology, special positioning exercises and physical therapy for those admitted in wards are also rehabilitation techniques that are being studied in the present context.

To sum up, medical rehabilitation is the key for regaining a normal life after being diagnosed with COVID-19 and thereafter.

Keywords: COVID-19 disease, post-pandemic, cardiopulmonary rehabilitation, mental health rehabilitation.

Introduction

At the end of 2019, the city of Wuhan in the Chinese province of Hubei had witnessed the emergence of a new type of pneumonia of unknown etiology (Hongzhou Lu et al., 2020). The culprit pathogen was a new type of coronavirus which was later renamed SARS-CoV-2 by the World Health Organization and subsequent infection with it causes COVID-19 disease (1). The province of Hubei is a densely populated area having a total population of 58 million residents as of 2010, with Wuhan being its largest city, and also its capital (2). Initially, the first 27 cases were linked to Huanan market, a place where a large variety of animals including fish, bats, poultry and others are being sold (Guo et al., 2020).

This combination between a densely populated area and a place that sells bats which are a natural reservoir of the new SARS-CoV-2 has led to the rapid spread of this new pathogen at first locally and then globally. It is considered that the first interhuman transmission took place in the middle of December 2019 (Guo et al., 2020; Li et al., 2020).

To date, we know that these viruses can cause a number of infections in various animals and more notably respiratory tract infections in humans, such as severe acute respiratory syndrome (SARS) in 2003 and Middle East respiratory syndrome (MERS) (Yin et al., 2018; Drosten et al., 2003; Zaki et al., 2012).

Overview of SARS-CoV-2 infection

While most patients that became infected developed symptoms such as fever, cough, shortness of breath, some progressed to more severe diseases such as acute respiratory distress syndrome or ARDS which led to multiple organ failure or even death in some patients. The vast majority of these new cases had an epidemiological link to Huanan market, many victims declaring that they worked or shopped there. The incubation period varies between 0 and 24 days, averaging 6.4 days, while the mean duration until the onset of symptoms is 5.2 days (Chen et al., 2020; Li et al., 2 020).

Received: 2020, May 30; *Accepted for publication:* 2020, June 19
Address for correspondence: "Iuliu Haţieganu" University of Medicine and Pharmacy, Cluj-Napoca, the Department of Medical Rehabilitation within the Rehabilitation Hospital in Cluj-Napoca, 46-50 Viilor Street, Cluj-Napoca, PC 400437
E-mail: calina.ciubotariu@gmail.com
Corresponding author: Calina Ciubotariu; calina.ciubotariu@gmail.com
https://doi.org/10.26659/pm3.2020.21.2.117

One of the largest epidemiologic studies on the SARS-CoV-2 virus stated that among 44,642 confirmed cases, 80.9% had mild pneumonia, similar to community acquired pneumonia, 13.8% were severe cases, while 4.7% were critically ill (***, 2020).

Currently, the death rates differ between the various countries that are struck by the illness, with high numbers occurring even in some highly developed nations such as the UK (14.14%). While some Chinese data reveal a mortality rate of 2-3% among those affected, as of 26.05.2020 the calculated global death rate has been 6.29% of the total number of confirmed COVID-19 cases (***, 2020; Roser et al., 2020).

Taking into account the situation determined by the new virus, until a vaccine is discovered, all attention is directed towards finding the best and most effective medical treatment.

Typical features of the 2019 coronavirus disease

The first autopsies conducted in China revealed pulmonary modifications similar to those previously encountered in the SARS epidemic of the Middle East, such as diffuse alveolar pneumonia and the presence of fibro-myxoid cellular exudates. Although the main encountered diagnosis was interstitial pneumonia, pulmonary microthrombosis and peripheral pulmonary hemorrhages were also detected (Xu et al., 2020; Buja et al., 2020).

Furthermore, autopsies conducted on COVID-19 patients in the US have outlined that the major pathologies leading to death were those linked to respiratory and cardiac failure and also the hypercoagulable state (Buja et al., 2020). Affected patients are at risk of developing venous thromboembolic disease and pulmonary embolism, and a new hypothesis of inflammatory microthrombosis has been lately advanced. One such study has shown a 31% incidence of thrombotic events in patients diagnosed with COVID-19 admitted to intensive care units (Ciceri et al., 2020; Klok et al., 2020; Danzi et al., 2020). The curious aspect is that patients with no known or prior major risk factors for thrombosis are being diagnosed with pulmonary embolism whilst also positive for the virus; therefore, we can understand the need for prophylactic anticoagulants in COVID-19 patients (Danzi et al., 2020; Bikdeli et al., 2020; Tang et al., 2020).

Even if cardiac involvement is often found in a lot of registries dealing with COVID-19 patients, we have to take into consideration the fact that many patients had prior cardiac issues (Clerkin et al., 2020). More often we see that viral myocarditis is found and many case studies have been presented lately (Zeng et al., 2020; Kim et al., 2020; Inciardi et al., 2020). Heart biopsy studies in these patients revealed diffuse myocardial inflammation and viral particles were found in interstitial cells of the myocardium (Inciardi et al., 2020; Tavazzi et al., 2020). For instance, one study in China on 416 patients showed that cardiac involvement was present in 19.7% of cases, being confirmed by the increase in cardiac specific biomarkers such as CK-MB, myoglobin, and highly sensitive troponin I (Shi et al., 2020).

Medical treatment in COVID-19

Having to deal with this new situation created by the virus, until a vaccine is discovered, all attention has shifted towards discovering the optimal and most effective medical treatment. At the beginning of the pandemic, in China, the disease was treated empirically using drugs such as hydroxychloroquine, remdesivir, favipiravir, umifenovir, alpha-interferon, after which clinical trials were started to test their efficacy. Previously, remdesivir was used for treating HIV, alpha-interferon for hepatitis, hydroxychloroquine is an antimalarial agent, and drugs like umifenovir and favipiravir were used for treating flu (Dong et al., 2020).

The clinical trials that were conducted did not match in vitro studies and thus, multiple changes in drug guidelines were seen. We should not neglect the adverse effects that some of these drugs have, such as anemia, hypoglycemia, QT-interval lengthening, retinopathy requiring individual adaptation of the drug scheme in every patient with COVID-19 (Sanders et al., 2020; Touret & de Lamballerie, 2020).

Currently, a couple of months away from the first case of SARS-CoV-2, the treatment guidelines include antithrombotic therapy and immunotherapy in combination with other drugs used at the beginning such as hydroxychloroquine and remdesivir (3). Until now, there is no known treatment that can cure COVID-19, only drugs that are capable of reducing the harmful effects of the virus while helping the immune system fight the disease (4).

The role of rehabilitation in the context of the COVID-19 pandemic

Since WHO declared COVID-19 a pandemic, most efforts have been guided towards limiting the spread of the disease and preventing hospitals from being crowded, some countries being overwhelmed by the high number of people diagnosed with the virus (5). For instance, Italy used its intensive care units at maximum capacity in an effort to treat patients with severe forms of the disease (Remuzzi et al., 2020).

Regarding medical rehabilitation, the prevention of COVID-19 can consist of moving medical services from large centers towards a home-based medical rehabilitation service, disinfecting all physiotherapy equipment, or even using sterile, antimicrobial gels while performing muscle and tissue ultrasound (Koh & Hoenig, 2020).

Although prevention is an important aspect of care, we should not overlook the situation of patients that are in the process of healing or even quarantined because of the virus. Stepping up their rehabilitation process psychically but most importantly from a respiratory and musculoskeletal standpoint could also positively impact society as a whole.

In northern Italy, while trying to improve their strategy against COVID-19, doctors and physiotherapists have reorganized. As such, the cardiopulmonary rehabilitation wards have been converted into care units for patients that are past the acute phase of the disease but still have in most of the cases remnants of interstitial pneumonia. After restructuring, the rehabilitation ward takes care of the following: oxygen monitoring and therapy, non-invasive

ventilation such as CPAP, positional maneuvers for enhancing ventilation, reconditioning physical therapy of light and moderate intensity together with initial and final testing of respiratory and motor functions. Such a program could help create new and targeted protocols for the rehabilitation of COVID-19 positive patients (Simonelli et al., 2020).

After reaching the so-called peak of the pandemic, society starts to also become aware of the economic impact of this disease. Each month during the COVID-19 pandemic can lead to a decrease in national GDP of up to 2.5-3%. Some state that the forthcoming economic crisis is the second big critical point after the health crisis generated by the disease (Fernandez, 2020).

Means of rehabilitating patients with COVID-19. Mental health rehabilitation

Fundamentally, medical rehabilitation is a key aspect as it can positively influence society by accelerating the reintegration process of those that are healed or in the process of healing and even for those that are being quarantined or in self-isolation. This aspect was also observed in the past during the SARS epidemic in 2003, where it was demonstrated that supervised physical therapy exercises improved the cardiorespiratory and musculoskeletal functions of those affected (Lau et al., 2005).

Concurrently, psychic rehabilitation could improve outcomes given the fact that mental health issues are rising among patients and healthcare workers dealing with COVID-19 (Khan et al., 2020; Mazza et al., 2020). Undoubtedly, patients with multiple comorbidities are at high risk for developing depression and anxiety, but we should not forget the healthcare staff facing the same issues. One study conducted among medical personnel in China dealing with COVID-19 patients showed that out of 1257 subjects, 634 (50.4%) manifested depressive symptoms, 540 (44.6%) had symptoms of anxiety, while most were affected by stress-related issues (899 or 71.5%) (Lai et al., 2020). That being said, the most important aspect of psychic rehabilitation is the regaining of social interaction and interpersonal relation skills.

One simple and safe way to socially interact in these new circumstances is by using the telephone or internet and social networks. However, a very long time spent on the telephone could have negative consequences by increasing our dependence on such devices. Another method of loosening up the atmosphere when in self-isolation or when admitted to the hospital is by using humor such as jokes, magazines and comedy shows that are encouraged to boost the morale of patients. Likewise, telephone counseling between patient and therapist can also be facilitated (Chaturvedi et al., 2020).

Respiratory rehabilitation

The rehabilitation of the respiratory system can be utilized especially for patients presenting with severe forms of COVID-19 associated pneumonia usually requiring admission to intensive care units (Kiekens et al., 2020). Out of all patients positively diagnosed with COVID-19, 15% usually have life threatening forms of the disease and 42% require oxygen supplementation. In the case of serious complications, patients are usually mechanically ventilated and in most cases they are bedridden. Physical therapy exercises that stimulate mucociliary clearance such as gravity assisted drainage positions and using active respirations as well as percussion or vibration techniques are recommended for patients that have a productive cough. Despite the fact that productive cough is not a common symptom of COVID-19, it is present in patients who have other comorbidities such as neuromuscular disease, cystic fibrosis or COPD. The majority of patients with mild forms of COVID-19 related disease have dry cough. In this case, rehabilitation maneuvers that stimulate coughing are strictly prohibited. Also, a series of precautions should be taken into consideration for increasing the safety of the staff and other patients in COVID-19 designated care units. Among these, the following can be mentioned: keeping a safe distance from the patient, wearing protective equipment, using individual rooms for patients, instructing patients with productive cough to minimize the aerosols generated when they cough by using face masks or single use tissues (Thomas et al., 2020).

One study that included 72 old patients diagnosed with COVID-19 has shown a considerable improvement of respiratory function after only 6 weeks of rehabilitation programs (Liu et al., 2020).

Neuromotor rehabilitation

Another branch of physical and rehabilitation medicine that could be used in COVID-19 patients is that of neuromuscular function recovery. Due to prolonged immobilization, sedation or after the use of muscle relaxants in order to facilitate ventilation, patients can develop muscle weakness or even atrophy during hospitalization, as shown in studies performed on critically ill patients (Koukourikos et al., 2014).

Exercises that facilitate mobilization in bedridden patients, active workouts done with the help of a physiotherapist, and even balance increasing movements can be helpful to those kinds of disabled patients. Among patients benefiting from a respiratory rehabilitation program, an improvement in numerous parameters can be seen: FEV1(L), FVC(L), FEV1/FVC%, DLCO% and also the six minute walk test (Liu et al., 2020).

Balneotherapy in COVID-19 patients

For those cured of COVID-19 and having suffered from the effects of deconditioning, as well as for those enduring a high degree of stress while in self-isolation or while respecting the social distancing measures, balneary treatments can have a positive effect and should be taken into consideration. The staff in dedicated COVID-19 units that are predisposed to burnout can also benefit from balneotherapy to regain their well-being. One such study shows a considerable improvement in health for those suffering from burnout after 3 weeks of balneotherapy (Xu et al., 2013; Matsumoto, 2018; Dubois et al., 2010; Rapoliene et al., 2016; Blasche et al., 2010; Segers, 2020).

In balneotherapy dedicated facilities, patients can benefit from walking sessions or other forms of open-air physical activity and they can also be aided by the favorable mountain climate and the healthful effects of thalassotherapy.

Conclusions

1. Prevention is key for combating the spread of a virus during a pandemic.

2. A solid rehabilitation program could be the essence in regaining a normal life after being diagnosed with COVID-19.

3. Psychic, motor, and respiratory rehabilitation techniques can be beneficial in wards that deal with COVID-19 both for treating patients and for maintaining the mental health of the staff.

References

Bikdeli B, Madhavan MV, Jimenez D, Chuich T, Dreyfus I, Driggin E, Der Nigoghossian C, Ageno W, Madjid M, Guo Y, Tang LV, Hu Y, Giri J, Cushman M, Quéré I, Dimakakos EP, Gibson CM, Lippi G, Favaloro EJ, Fareed J, Caprini JA, Tafur AJ, Burton JR, Francese DP, Wang EY, Falanga A, McLintock C, Hunt BJ, Spyropoulos AC, Barnes GD, Eikelboom JW, Weinberg I, Schulman S, Carrier M, Piazza G, Beckman JA, Steg PG, Stone GW, Rosenkranz S, Goldhaber SZ, Parikh SA, Monreal M, Krumholz HM, Konstantinides SV, Weitz JI, Lip GYH. COVID-19 and Thrombotic or Thromboembolic Disease: Implications for Prevention, Antithrombotic Therapy, and Follow-Up: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(23):2950-2973. doi: 10.1016/j.jacc.2020.04.031.

Blasche G, Leibetseder V, Marktl W. Association of spa therapy with improvement of psychological symptoms of occupational burnout: a pilot study. Complementary Medicine Research. 2010; 17(3):132-136. doi: 10.1159/000315301.

Buja LM, Wolf D, Zhao B, Akkanti B, McDonald M, Lelenwa L, Reilly N, Ottaviani G, Elghetany MT , Trujillo DO, Aisenberg GM , Madjid M , Kar B. The Emerging Spectrum of Cardiopulmonary Pathology of the Coronavirus Disease 2019 (COVID-19): Report of 3 Autopsies From Houston, Texas, and Review of Autopsy Findings From Other United States Cities. Cardiovasc Pathol. 2020;48:107233. doi: 10.1016/j.carpath.2020.107233.

Chaturvedi SK. Covid-19, Coronavirus and Mental Health Rehabilitation at Times of Crisis. J Psychosoc Rehabil Ment Health. 2020(7);1-2. doi: 10.1007/s40737-020-00162-z. Online ahead of print.

Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y, Qiu Y Wang J Liu Y Wei Y Xia J Yu T Zhang X Zhang L. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. Lancet, 2020;395(10223):507-513. doi: 10.1016/S0140-6736(20)30211-7.

Ciceri F, Beretta L, Scandroglio AM, Colombo S, Landoni G, Ruggeri A, Peccatori J, D'Angelo A, De Cobelli F, Rovere-Querini P, Tresoldi M, Dagna L, Zangrillo A. Microvascular COVID-19 lung vessels obstructive thromboinflammatory syndrome (MicroCLOTS): an atypical acute respiratory distress syndrome working hypothesis. Crit Care Resusc. 2020, Online ahead of print.

Clerkin KJ, Fried JA, Raikhelkar J, Sayer G, Griffin JM, Masoumi A, Jain SS , Burkhoff D, Kumaraiah D, Rabbani LR, Schwartz A, Uriel N. COVID-19 and cardiovascular disease. Circulation. 2020;141(20), 1648-1655. doi: 10.1161/CIRCULATIONAHA.120.046941.

Danzi GB, Loffi M, Galeazzi G, Gherbesi E. Acute pulmonary embolism and COVID-19 pneumonia: a random association? Eur Heart J. 2020;41(19):1858. doi: 10.1093/eurheartj/ehaa254.

Dong, L, Hu S, Gao J. Discovering drugs to treat coronavirus disease 2019 (COVID-19). Drug Discov Ther. 2020;14(1):58-60. doi: 10.5582/ddt.2020.01012.

Drosten C, Günther S, Preiser W, van der Werf S, Brodt HR, Becker S, Rabenau H, Panning M, Kolesnikova L, Fouchier RA, Berger A, Burguière AM, Cinatl J, Eickmann M, Escriou N, Grywna K, Kramme S, Manuguerra JC, Müller S, Rickerts V, Stürmer M, Vieth S, Klenk H-D, Osterhaus ADME, Schmitz H, Doerr HW. Identification of a novel coronavirus in patients with severe acute respiratory syndrome. N Engl J Med. 2003;348(20):1967-1976. doi: 10.1056/NEJMoa030747.

Dubois O, Salamon R, Germain C, Poirier MF, Vaugeois C, Banwarth B, Mouaffak F, Galinowski A, Olié JP. Balneotherapy versus paroxetine in the treatment of generalized anxiety disorder. Complementary therapies in medicine. 2010;18(1):1-7. doi: 10.1016/j.ctim.2009.11.003.

Fernandes N. 2020 Economic effects of coronavirus outbreak (COVID-19) on the world economy. Available at SSRN 3557504. http://dx.doi.org/10.2139/ssrn.3557504.

Guo Y, Cao Q, Hong ZS. Tan YY, Chen SD, Jin HJ, Tan KS, Wang DY, Yan Y. The origin, transmission and clinical therapies on coronavirus disease 2019 (COVID-19) outbreak - an update on the status. Military Med Res 2020;7(1):11. doi: 10.1186/s40779-020-00240-0.

Inciardi RM, Lupi L, Zaccone G, Italia L, Raffo M, Tomasoni D, Cani DS, Cerini M, Farina D, Gavazzi E, Maroldi R, Adamo M, Ammirati E, Sinagra G, Lombardi CM, Metra M. Cardiac involvement in a patient with coronavirus disease 2019 (COVID-19). JAMA Cardiol. 2020; doi: 10.1001/jamacardio.2020.1096. Online ahead of print.

Khan S, Siddique R, Li H, Ali A, Shereen MA, Bashir N, Xue M. Impact of coronavirus outbreak on psychological health. J Glob Health. 2020;10(1) :010331. doi: 10.7189/jogh.10.010331.

Kiekens C, Boldrini P, Andreoli A, Avesani R, Gamna F, Grandi M, Lombardi F, Lusuardi M, Molteni F, Perboni A, Negrini S. 2020 Rehabilitation and respiratory management in the acute and early post-acute phase. "Instant paper from the field" on rehabilitation answers to the Covid-19 emergency. Eur J Phys Rehabil Med. doi: 10.23736/S1973-9087.20.06305-4. Online ahead of print.

Kim IC, Kim JY, Kim HA, Han S. COVID-19-related myocarditis in a 21-year-old female patient. Eur Heart J. 2020;41(19):1859-1859. doi: 10.1093/eurheartj/ehaa288.

Klok FA, Kruip MJHA, Van der Meer NJM, Arbous MS, Gommers DAMPJ, Kant KM, Kaptein FHJ , van Paassen J , Stals MAM , Huisman MV, Endeman H. 2020 Incidence of thrombotic complications in critically ill ICU patients with COVID-19. Thromb Res. 191:145-147. doi: 10.1016/j.thromres.2020.04.013.

Koh GCH, Hoenig H. How should the rehabilitation community prepare for 2019-nCoV?. Arch Phys Med Rehab. 2020;101(6):1068-1071. doi: 10.1016/j.apmr.2020.03.003.

Koukourikos K, Tsaloglidou A, Kourkouta L. Muscle atrophy in intensive care unit patients. Acta Info Med. 2014;22(6):406. 22(6):406-10. doi: 10.5455/aim.2014.22.406-410.

Lai J, Ma S, Wang Y, Cai Z, Hu J, Wei N, Wu Jiang, Du Hui, Chen Tingting, Li Ruiting, Tan Huawei, Kang Lijun, Yao Lihua, Huang Manli, Wang Huafen, Wang Gaohua, Liu Zhongchun, Hu Shaohua. Factors associated with mental health outcomes among health care workers exposed to coronavirus disease 2019. JAMA Netw Open. 2020;3(3):e203976. doi: 10.1001/jamanetworkopen.2020.3976.

Lau HMC, Ng GYF, Jones AYM, Lee EWC, Siu EHK, Hui DSC. A randomised controlled trial of the effectiveness of an exercise training program in patients recovering from severe acute respiratory syndrome. Aus J Physiother. 2005;51(4):213-219.

doi: 10.1016/s0004-9514(05)70002-7.

Li Q, Guan X, Wu P, Wang X, Zhou L, Tong Y, Ren R, Leung KS, Lau EH, Wong JY, Xing X, Xiang N, Wu Y, Li, Chen Q, Li D, Liu T, Zhao J, Liu M, Tu W, Chen C, Jin L, Yang R, Wang Q, Zhou S, Wang R, Liu H, Luo Y, Liu Y, Shao G, Li H, Tao Z, Yang Y, Deng Z, Liu B, Ma Z, Zhang Y, Shi G, Lam TTY, Wu JT, Gao GF, Cowling BJ, Yang B, Leung GM, Feng Z. Early transmission dynamics in Wuhan, China, of novel coronavirus–infected pneumonia. New England Journal of Medicine. N Engl J Med. 2020 Mar 26; 382(13):1199-1207. doi: 10.1056/NEJMoa2001316.

Liu K, Zhang W, Yang Y, Zhang J, Li Y, Chen Y. Respiratory rehabilitation in elderly patients with COVID-19: A randomized controlled study. Complement Ther Clin Pract, 2020; 39:101166. doi: 10.1016/j.ctcp.2020.101166.

Lu H, Stratton CW, Tang YW. Outbreak of pneumonia of unknown etiology in Wuhan, China: The mystery and the miracle. J Med Virol. 2020;92(4):401-402. doi: 10.1002/jmv.25678.

Matsumoto S. Evaluation of the role of balneotherapy in rehabilitation medicine. J Nippon Med Sch. 2018;85(4):196-203. doi: 10.1272/jnms.JNMS.2018_85-30.

Mazza M, Marano G, Antonazzo, Cavarretta E, Di Nicola M, Janiri L, Sani G, Frati G, Romagnoli E. What about heart and mind in the covid-19 era? Minerva cardioangiologica. 2020, May 12. doi: 10.23736/S0026-4725.20.05309-8. Online ahead of print.

Rapolienė L, Razbadauskas A, Sąlyga J, Martinkėnas A. Stress and fatigue management using balneotherapy in a short-time randomized controlled trial. Evid Based Complement Alternat Med. 2016;2016:9631684. doi: 10.1155/2016/9631684.

Remuzzi A, Remuzzi G. COVID-19 and Italy: what next? Lancet. 2020;335(10231):1225-1228.

Roser M, Ritchie H, Ortiz-Ospina E, Hasell J. Coronavirus Pandemic (COVID-19). Our World in Data. 2020/3.

Sanders JM, Monogue ML, Jodlowski TZ, Cutrell JB. Pharmacologic treatments for coronavirus disease 2019 (COVID-19): a review. JAMA, 2020;323(18):1824-1836. doi: 10.1001/jama.2020.6019.

Segers C. Psychological Resilience, Burnout Syndrome, and Stress-related Psychiatric Disorders among Healthcare Professionals during the COVID-19 Crisis. Psychosociol Iss Hum Res Manag. 2020;8(1):7-12. doi:10.22381/PIHRM8120201.

Shi S, Qin M, Shen B, Cai Y, Liu T, Yang F, Gong W, Liu X, Liang J, Zhao Q, Huang H, Yang B Huang C. Association of cardiac injury with mortality in hospitalized patients with COVID-19 in Wuhan, China. JAMA Cardiol. 2020; e200950. doi: 10.1001/jamacardio.2020.0950. Online ahead of print.

Simonelli C, Paneroni M, Fokom AG, Saleri M, Speltoni I, Favero I, Garofali F, Scalvini S, Vitacca, M. How the COVID-19 infection tsunami revolutionized the work of respiratory physiotherapists: an experience from Northern Italy. Monaldi Arch Chest Dis. Int. J Cardiopul Med Rehab. 2020;90(2). https://doi.org/10.4081/monaldi.2020.1085.

Tang N, Bai H, Chen X, Gong J, Li D, Sun Z. Anticoagulant treatment is associated with decreased mortality in severe coronavirus disease 2019 patients with coagulopathy. J Thromb Haemost. 2020;18(5):1094-1099. doi: 10.1111/jth.14817. Epub 2020 Apr 27.

Tavazzi G, Pellegrini C, Maurelli M, Belliato M, Sciutti F, Bottazzi A, Sepe PA, Resasco T, Camporotondo R, Bruno R, Baldanti F, Paolucci S, Pelenghi S, Iotti GA, Mojoli F, Arbustini E. Myocardial localization of coronavirus in COVID-19 cardiogenic shock. Eur J Heart Fail. 2020;22(5):911-915. doi: 10.1002/ejhf.1828.

Thomas P, Baldwin C, Bissett B, Boden I, Gosselink R, Granger CL, Hodgson C, Jones AY, Kho ME, Moses R, Ntoumenopoulos G, Parry SM, Patman S, van der Lee L. Physiotherapy management for COVID-19 in the acute hospital setting: clinical practice recommendations. J Physiother. 2020; 66(2):73-82.doi: 10.1016/j.jphys.2020.03.011.

Touret F, de Lamballerie X. Of chloroquine and COVID-19. Antiviral Res. 2020;177:104762.doi: 10.1016/j.antiviral.2020.104762.

Xu L, Shi R, Wang B, Geng J, Zhou L, Zhang Y, Guo G, Chen J, Cao X, Zhang S. 21-day balneotherapy improves cardiopulmonary function and physical capacity of pilots. J Phys Ther Sci. 2013;25(1):109-112. DOI: https://doi.org/10.1589/jpts.25.109.

Xu Z, Shi L, Wang Y, Zhang J, Huang L, Zhang C, Liu S, Zhao P, Liu H, Zhu L, Tai Y, Bai C, Gao T, Song J, Xia P, Dong J, Wang ZF-S. Pathological findings of COVID-19 associated with acute respiratory distress syndrome. Lancet Respir Med. 2020;8(4):420-422. doi: 10.1016/S2213-2600(20)30076-X.

Yin Y, Wunderink RG. MERS, SARS and other coronaviruses as causes of pneumonia. Respirology. 2018;23(2):130-137. doi: 10.1111/resp.13196.

Zaki AM, Van Boheemen S, Bestebroer TM, Osterhaus AD, Fouchier RA. Isolation of a novel coronavirus from a man with pneumonia in Saudi Arabia. New England Journal of Medicine, 2012;367(19):1814-1820. doi: 10.1056/NEJMoa1211721.

Zeng JH, Liu YX, Yuan J, Wang FX, Wu WB, Li JX, Wang LF, Gao H, Wang Y, Dong CF, Li YJ, Xie XJ, Feng C, Liu L. First case of COVID-19 infection with fulminant myocarditis complication: case report and insights. Infection. 2020; 1-5. doi: 10.1007/s15010-020-01424-5.

***. Epidemiology Working Group for NCIP Epidemic Response, Chinese Center for Disease Control and Prevention. [The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) in China]. Zhonghua liu xing bing xue za zhi. 2020;41(2):145-151. doi: 10.3760/cma.j.issn.0254-6450.2020.02.003.

Websites

(1) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. Accessed on 25.05 2020.

(2) „Communiqué of the National Bureau of Statistics of People's Republic of China on Major Figures of the 2010 Population Census [1] (No. 2)". National Bureau of Statistics of China. 29 April 2011. Accessed on 25.05.2020.

(3) COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed on 29.05.2020.

(4) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses#:~:text=protect. Accessed on 29.05. 2020.

(5) https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic. Accessed on 15.05. 2020.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 122–126

The impact the establishment of the state of emergency had on the medical system in the context of the pandemic generated by the SARS CoV-2 virus (Note I)

George Coca[1], Mihai Berteanu[2], Florina-Andreea Pașcu[3]
[1] *"Spiru Haret" University – Faculty of Juridical and Administrative Sciences Bucharest, Permanent lawyer Bar of Bucharest*
[2] *"Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania*
[3] *"Babeș-Bolyai" University of Cluj-Napoca, Permanent lawyer Bar of Bucharest*

Abstract
The premises for adopting Decree no. 195 of March 16, 2020 regarding the establishment of the state of emergency on Romanian territory were the evolution of the epidemiological situation in Romania and the assessment of public health risks for the next period. This indicated a massive increase in the number of people infected with the SARS-CoV coronavirus 2, and considering the fact that failure to take urgent, exceptional social and economic measures to limit the infection with SARS-CoV-2 coronavirus among the population would have had a particularly serious impact, mainly on the right to live, and, alternatively, on the individuals' right to health.
Keywords: epidemiological situation, public health, presidential decree, execution of sentences.

Introduction

Decree no. 195 of March 16, 2020 regarding the establishment of the state of emergency on Romanian territory was adopted considering the evolution of the international epidemiological situation determined by the spread of SARS-CoV-2 coronavirus at a level of more than 150 countries, in which approximately 160,000 people were infected and more than 5,800 died, and also considering the experience of the countries which were severely affected by the virus evolution and the measures which had a positive impact on limiting the spread (3).

The measures established by the Decree targeted actions in the field of public health, together with limiting or discontinuing non-essential socio-economic activities, but especially restricting the exercise of certain fundamental rights and liberties by establishing certain exceptional states with the aim of preventing the spread of the infection within the community, without which the other actions performed could not have had the intended impact, in the context of measures adopted at the European level.

Taking note of the evolution of the epidemiological situation on Romanian territory and assessing the public health risk for the next period, which indicates a massive increase in the number of people infected with the SARS-CoV-2 virus, it became obvious that failure to take urgent, exceptional social and economic measures to limit the infection with the SARS-CoV-2 coronavirus among the population would have a particularly serious impact, mainly on the right to live, and, alternatively, on the individuals' right to health (2).

The establishing of the state of emergency was necessary in order to reduce the negative effects on the economy caused by the measures adopted both at a national and at an international level in order to fight the spread of the SARS-CoV-2 coronavirus, considering the fact that the aforementioned elements define an exceptional context which could not have been foreseen, and which concern the general public interest (2); (3).

Restricting the exercise of certain rights must not affect their substance, but has a legitimate purpose, being necessary in a democratic society and being proportional to the aim, as it was based on the Resolution of the Supreme Council of National Defense no. 30/2020 regarding the necessity to establish the state of emergency, also considering the proposition to institute the state of emergency issued by the Governement (1); (3); (4).

Received: 2020, May 18; *Accepted for publication:* 2020, June 10
Address for correspondence: "Spiru Haret" University of Bucharest, Faculty of Juridical and Administrative Sciences Bucharest, Romania
E-mail: georgecoca59@yahoo.com
Corresponding author: George Coca, georgecoca59@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.122

Medical services for the treatment of COVID-19 for all persons on Romanian territory

The enforceability of the legislative acts regarding the provision of medical services and medicine within the health insurance system, national health programs – preventive and curative, valid until March 31, 2020, was extended by the decree for the duration of the state of emergency. The presidential decree specifies that medical services for the treatment of COVID-19 cases and their complications are to be provided to all persons on Romanian territory and shall be borne by the budget of the Unique National Fund of Health Insurances (FNUASS).

The prescription of "off-label" treatments is authorized for patients infected with the SARS-CoV-2 virus, after such treatments are approved by the commission of drug policy within each sanitary unit. These measures also refer to the prescription of drugs by family physicians, including restricted drugs from the List of drugs approved by Government Resolution no. 720/2008, for chronic patients (3); (5).

It is also set out that medical services and medicine may be granted and validated without using the national health insurance card and without the obligation to report within 3 working days from the date of provision of services.

According to the Decree, the settlement of medical leaves granted to individuals quarantined for COVID-19 shall be done with priority by ensuring additional sums to the FNUASS budget at the necessary level.

Thus, Article 17 of the Decree provides for the extension of the enforceability of legislative acts valid until March 31, 2020, regarding the provision of medical services and medicine within the health insurance system, national health programs - preventive and curative, for the duration of the state of emergency, with the modification of provisions, if necessary, as follows: a) medical services for the treatment of COVID-19 cases and their complications are provided for all persons on Romanian territory and borne by the FNUASS budget; b) medical services and drugs can be granted and validated without using the national health insurance card and without the obligation to report within 3 working days from the date of provision of services; c) settlement of sums contracted and settled from the FNUASS budget or the Ministry of Health budget for sanitary units with contractual relation to health insurance authorities, regardless of the number of cases realized or, if applicable, at the level of actual activity performed if it exceeds the contracted amount; d) settlement of medical services in sanitary units of primary medical assistance and clinical ambulatory care at the level of actual activity performed, with a maximum of 8 consultations/hour; e) prescription of drugs by family physicians, including of restricted drugs from the List of drugs approved by Government Resolution no. 720/2008, for chronic patients (3); (5).

During the state of emergency, the structural modifications within sanitary units will be notified by local public health directorates depending on necessity, and new health programs and medical services for the prevention and fight against COVID-19 can be introduced through an Ordinance of the Minister of Health.

Furthermore, the Decree provides the possibility to limit the activity of public hospitals to hospitalization and treatment of urgent cases. In this regard, there can be emergencies of the first order which include patients hospitalized through emergency admission units/ compartments who could lose their life in 24 hours, emergencies of the second order which include patients who must be treated within the same hospital stay (once diagnosed cannot be released) and, thirdly, patients infected with the SARS-CoV-2 virus, namely diagnosed with COVID-19. The state secretary, chief of the Department for Emergency Situations, or their substitute shall issue orders with regard to these measures.

Employment without an admission contest for doctors, nurses and pharmacists

Heads of sanitary units, public health directorates, health insurance authorities, ambulance services, as well as of local and central public authorities and institutions with duties in the assistance and social protection fields can be suspended from power for failing to perform their work duties during the state of emergency, regardless of their status. It is not necessary that the persons assigned to perform these duties temporarily be public officials (3).

It is also specified that contractual medical personnel, auxiliary personnel, pharmacists, laboratory personnel and other categories of necessary contractual personnel can be employed without an admission contest in the structures of the Ministry of Internal Affairs, in sanitary units and in social assistance services if necessary, for a limited period of 6 months. The FNUASS budget bears the financial influences determined by the salary increase for medical and non-medical personnel in public sanitary units and those who have as sole associate territorial administrative units.

According to Article 20 of the Decree, during the state of emergency, transfers between the Ministry of Health budget and the Unique National Fund of Health Insurances are allowed (in both ways), as well as between the different budgetary lines of the Ministry of Health or the Unique National Fund of Health Insurances, depending on the requirements (3).

Criteria for first emergency measures with gradual enforceability

The presidential decree sets out that all these measures shall be adopted as a result of the assessment performed by the National Committee for Emergency Situations, with the approval of the prime minister. This Committee shall take account of the intensity with which COVID-19 is transmitted within the community, the frequency with which outbreaks appear in a geographical area, and the number of critical patients compared to the capacity of the sanitary system.

The assessments mentioned will take into account the capacity and continuity to ensure social and utility services for the population, the public authorities' capacity to maintain and ensure public safety and order measures, and the capacity to ensure measures for placement in quarantine. Certainly, the Committee will also monitor

the measures adopted by other states which impact on the Romanian population or economic situation and the occurrence of new emergency situations.

Public procurement

According to Article 27 of the Decree, the prescription of "off-label" treatments is authorized for patients infected with the SARS-CoV-2 virus, after these treatments are approved by the commission of drug policy within each sanitary unit (3).

The amounts in the Ministry of Health budget required in order for public health directorates to purchase necessary materials during the pandemic are ensured by transfers from the Ministry of Health, and the purchase will be performed by the public health diretorates by means of direct procurement.

Ministries with their own health system can make direct purchases for their own sanitary units from the budgets of competent ministries, as well as from the budgets of the sanitary units.

Support measures for individuals in home isolation as a result of measures to limit the spread of COVID-19 are established through a Ministry of Health Ordinance. Support measures are applied by local public administration authorities. The necessary expenses are ensured through transfer between the state budget, the Ministry of Health budget and local budgets.

In case drugs are purchased by sanitary units for the treatment of COVID-19 patients, the prices of drugs can exceed the maximum prices approved by the Ministry of Health.

Article 23 of Decree 195/2020 states that for medical services, medicine, paraclinical investigations performed during the state of emergency, the amounts committed will not be limited to the ones approved for the first trimester of the year 2020 (3).

Statement of the National Health Insurance Authority (CNAS) regarding the provision and settlement of medical and pharmaceutical services

A series of modifications of legal provisions will be applied during the state of emergency regarding the manner of providing and settling medical and pharmaceutical services, as follows:

1. Medical services for the treatment of COVID-19 cases and their complications are granted to all persons on Romanian territory and are borne from the FNUASS budget;

2. Medical services and medicine may be granted and validated without using the national health insurance card and without the obligation to report within 3 working days from the date of provision of services;

3. Settlement of sums contracted and settled from the FNUASS budget or the Ministry of Health budget for sanitary units with contractual relation to health insurance authorities, regardless of the number of cases realized or, if applicable, at the level of actual activity performed if it exceeds the contracted amount;

4. Settlement of medical services in sanitary units of primary medical assistance and clinical ambulatory care at the level of actual activity performed, with a maximum of 8 consultations/hour;

5. Prescription of drugs by family physicians, including restricted drugs from the List of drugs approved by Government Resolution no. 720/2008, for chronic patients (5).

Also, the National Health Insurance Authority considers the fact that measures will be needed in order to facilitate the access of ill persons to treatments in the next period. Thus, family physicians can issue medical prescriptions for patients with chronic illnesses and stabilized treatment without a new evaluation from specialized doctors during this period.

During this period, the family phsyician shall be allowed to issue prescriptions for patients with chronic illnesses who are undergoing treatment with drugs regularly prescribed by specialized doctors, including drugs subjected to cost-volume and cost-volume-result agreements which are sold in open-circuit pharmacies, based on medical documents (discharge papers, medical referral letter) and/or registration confirmation of the specific prescription form.

The measures adopted in health units ensure special circuits with limited interaction with other people - medical personnel or patients - for patients who require moving to health units in order to continue treatment within the aforementioned curative national health programs.

Particularly patients with oncologic diseases, spinal muscular atrophy or other rare diseases who started the specific treatment benefit from facilities to continue their treatment, as discontinuation of therapy cancels the therapeutic effects obtained, with implications on the health status of the patient.

First emergency measures with gradual enforceability

1. Isolation and quarantine of persons coming from risk areas, as well as those who came in contact with such individuals; quarantine measures for certain buildings, cities, or geographical areas;

2. Gradual closing of border crossing points;

3. Limiting or forbidding the circulation of vehicles or people in/to certain areas at certain hours, as well as exit from such areas;

4. Gradual interdiction of road, railway, maritime, fluvial or aerial traffic on different routes and of the subway;

5. Temporary closure of certain restaurants, hotels, coffee places, clubs, casinos, association headquarters and of other public establishments;

6. Ensuring institutional guarding and protection of water, energy, and gas supply stations, of economic operators who have capacities of national strategic importance;

7. Identification and requisition of stocks, production and distribution capacities, protection equipment, disinfectants and drugs used/useable in the treatment of COVID-19;

8. Limiting the activity of public hospitals to hospitalization and treatment of urgent cases: (i) emergencies of the first order - patients hospitalized

through emergency admission units/compartments who could lose their life in 24 hours; (ii) emergencies of the second order - patients who must be treated within the same hospital stay (once diagnosed cannot be released); (iii) patients infected with the SARS-CoV-2 virus, namely diagnosed with COVID-19.

Military ordinances adopted during the state of emergency with direct impact on the medical system

By *Military ordinance no. 1 of March 17, 2020 regarding some first emergency measures concerning gatherings of individuals and cross-border circulation of certain goods* certain medical measures were adopted, which we convey verbatim. We want to mention that by military ordinance, the measures prescribed in Addendum 2 of the Decree to establish a state of emergency no. 195/2020, which is an integral part of the decree, are adopted. (3); (9):

1. Starting on March 8, 2020 interns in the specializations emergency medicine, anesthesia and intensive care, infectious diseases, will suspend their practice stages in all other sections they are assigned to and come to the guidance centers for inclusion in the shifts and watches of the sections in their specialization.

2. Interns in the specializations internal medicine and family medicine will also suspend their training stages and come to the Public Health Directorates for distribution to County Ambulatory Services, emergency admission units, emergency rooms or hospital sections, depending on necessities.

3. Interns from medical specializations other than the ones listed will be taken into account for distribution according to necessities.

4. Interns in centers other than the guidance centers will come to the internship representatives for recording and distribution according to necessities.

5. In cities with more hospitals, the interns will be distributed according to the requirements of each hospital unit, in collaboration with Public Health Directorates.

6. The training program for obtaining the certificate in pre-hospital emergency medicine shall be suspended and the trainees will return urgently to the units they belong to.

7. Students starting from the fourth study year in the faculties of medicine will be recruited at the level of each university center on a volunteering basis, in order to provide support to emergency room activities. The students recruited perform support activities only in case the medical units' current capacity is exceeded.

Similar recruitments will be carried out in each county where there are post-secondary sanitary schools, starting with students in the second year. Similarly, the students recruited will perform support activities only in case the medical units' current capacity is exceeded. County and local emergency committees will ensure the accommodation and food of the recruited students.

The order of the action commander also established that the National Public Health Institute is the authority responsible for monitoring the testing and integrated reporting of the situations generated by the new type of coronavirus.

In addition, by order of the action commander, the National Intervention Coordination and Leadership Center was made operational.

Furthermore, 162 special tents were installed for medical triage and for a smooth traffic flow at border crossings.

At the same time, the Ministry of National Defense will build and operationalize a new building on the premises of the *Ana Aslan* Hospital, which will serve as a ROL II military hospital.

The activity in dental practices is termporarily suspended by *Military ordinance no. 2 of March 21, 2020 regarding measures to prevent the spread of COVID-19*, taking into account the provisions of article 24 of the Government Emergency Ordinance no. 1/1999 regarding the state of siege and the state of emergency, considering the assessment performed by the National Committee for Special Emergency Situations, approved by Resolution no. 13 of March 21, 2020, article 1 (10). Emergency dental interventions are excepted, the measure coming into force on March 22, 2020, 10 PM EET.

A series of measures concerning the medical system were prescribed by *Military ordinance no. 2 of March 21, 2020 regarding measures to prevent the spread of COVID-19*, taking into account the provisions of article 24 of the Government Emergency Ordinance no. 1/1999 regarding the state of siege and the state of emergency, considering the assessment performed by the National Committee for Special Emergency Situations (11):

Article 1 - (1) The movement of persons who have reached the age of 65 outside their home/household is also allowed outside the timeframe 11 AM – 1 PM if it is done *for taking care of medical issues, such as planned oncological treatments, dialysis,* etc. using their own means of transport or those of their family/caretakers or, if applicable, specialized medical means of transport. In order to check the reason for travelling in the situations prescribed in paragraph (1), a statutory statement filled out in advance must be presented, containing the first and last name, date of birth, home address, reason and place of travel, date and signature (11).

Article 7 - (1) Ministries with their own sanitary network and local public authorities who have in their subordination or who coordinate sanitary units *will supply upon demand hotel spaces destined for the personnel in the public sanitary system to rest between shifts*, in order to prevent the spread of the COVID-19 virus among health professionals or their families. (2) The measure comes into force on March 31, 2020 (11).

Article 10 - (1) The Center for Medical-Military Scientific Research, the Center of Scientific Research for CBRN Defense and Ecology, the Agency for Military Technique and Technology Research and the "Cantacuzino" National Medical-Military Research and Development Institute are authorized for the endorsement/ approval of materials, components, equipment and medical devices necessary for the prevention and combat of the spread, as well as for the treatment of the infection with the SARS-CoV-2 virus, namely biocides, during the state of emergency (11).

The National Committee for Emergency Situations declares the State of alert at a national level for a period of 30 days, starting from May 15, 2020 through *Resolution no.24 of May 14, 2020* (6).

The resolution is adopted considering the analysis and propositions formulated by the Technical-Scientific Support Group for managing highly contagious diseases on Romanian territory, regarding measures which must be maintained/established for the prevention and control of the spread of infection and taking into account the persistence of an increased number of infected persons on national territory, as well as the daily appearance of new cases of infected individuals, which maintain a constant pressure on the managing ability of administrative-territorial units and the sanitary system.

The state secretary, chief of the Department for Emergency Situations within the Ministry of Internal Affairs, can dispose of any measures necessary for the situations in which there is an imminent risk for public health, in connection with the need to create the socio-economic conditions required for a gradual relaunch of the national economy, while maintaining an adequate degree of alertness at the component level of the National System for the Management of Emergency Situations.

References

(1) Codul Civil din 2009 (Legea nr. 287/2009) - Republicat.
(2) Constituția României, actualizată și republicată în Monitorul oficial nr. 767 din 31 octombrie 2003.
(3) Decretul nr. 195 din 16.03.2020 privind instituirea stării de urgenţă pe teritoriul României, 2020
(4) Hotărârea Consiliului Suprem de Apărare a Țării nr. 30 din 2020.
(5) Hotărârea de Guvern nr. 720 din 2008 pentru aprobarea Listei cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, precum şi denumirile comune internaţionale corespunzătoare medicamentelor care se acordă în cadrul programelor naţionale de sănătate – Republicată.
(6) Hotărârea nr. 24 din 14.05.2020 a Comitetului Național pentru Situații de Urgență.
(7) Legea 95 din 2006 privind reforma în domeniul sănătății – Republicată
(8) Ordonanța de urgență nr. 1 din 1999 privind regimul stării de asediu și regimul stării de urgență.
(9) Ordonanța militară nr. 1 din 17.03.2020 privind unele măsuri de primă urgență care privesc aglomerările de persoane și circulația transfrontalieră a unor bunuri.
(10) Ordonanța militară nr. 2 din 21.03.2020 privind măsuri de prevenire a răspândirii COVID -19
(11) Ordonanța militară nr. 4 din 29.03.2020 privind măsuri de prevenire a răspândirii COVID-19.
(12) Ordonanța militară nr. 5 din 2020 privind măsuri de prevenire a răspândirii COVID-19.
(13) Ordonanța militară nr. 7 din 2020 privind măsuri de prevenire a răspândirii COVID-19.
(14) Ordonanța militară nr. 8 din 2020 privind măsuri de prevenire a răspândirii COVID-19.
(15) Ordonanța militară nr. 9 din 2020 privind măsuri de prevenire a răspândirii COVID-19.
(16) Ordonanța militară nr. 12 din 2020 privind măsuri de prevenire a răspândirii COVID-19.

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 127–130

The contribution of the European Union in terms of medical assistance for combating COVID-19 (Note II)

George Coca[1], Mihai Berteanu[2], Florina-Andreea Pașcu[3]
[1] *"Spiru Haret" University – Faculty of Juridical and Administrative Sciences Bucharest, Permanent lawyer Bar of Bucharest*
[2] *"Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania*
[3] *"Babeș-Bolyai" University of Cluj-Napoca, Permanent lawyer Bar of Bucharest*

Abstract
In the context of the onset of the COVID-19 pandemic, the European Commission adopted a series of measures meant to ensure a good cooperation between member states, which target both cross-border medical assistance and the financing and procurement of monetary resources necessary for the efficiency and cover of medical services required for the treatment of patients affected by this virus. In order to support this endeavor, conventions were adopted for the medical assistance of cross-border patients and for the acknowledgement of the medical professionals' qualifications, as well as for the formation of emergency medical teams with the aim of coordinating and financing cross-border medical assistance and emergency transport of patients infected with COVID-19.
Keywords: cross-border medical assistance, acknowledgement of medical qualifications, financing and emergency transport for patients with Covid-19.

Introduction

The crisis caused by the COVID-19 pandemic represents a global challenge which requires urgent solutions with immediate impact on an international level. The European Union supports the efforts of member states in combating the virus, offering financial support in the amount of almost 36 billion EURO in order to respond to the immediate health crisis and the humanitarian needs generated by it.

In accordance with the European Union treaties, the member states are responsible for adopting measures to respond to the COVID-19 pandemic at a national level, especially regarding the national health systems, the repatriation of citizens and the restrictions imposed on the citizens' public and private lives (1); (3); (5).

The European Union (EU) adopted a series of measures for combatting this virus. For this purpose, measures were adopted for the coordination of cross-border medical assistance, the coordination and financing of emergency transport for patients infected with COVID-19, the reimbursement of patients' medical expenses in the member state in which they receive treatment, the free movement of patients outside internal borders, the free movement of medical professionals, the formation of emergency medical teams, the adoption of medical assistance conventions for cross-border patients, as well as the acknowledgement of the medical professionals' qualifications.

Also, the European Union approved new rules which allow member states to request financial aid from the EU Solidarity Fund in order to cover health emergencies. By the recent extension of the fund's area of application, an amount of up to 800 million EURO will be at the disposal of member states this year for combating the pandemic caused by the coronavirus (12); (14).

All this led to the activity's efficiency to limit the spread of COVID-19 and the successful treatment of those infected.

Emergency assistance granted by the EU within cross-border cooperation in terms of medical assistance granted in the context of the COVID-19 pandemic

As shown in the Official Journal of the European Union series CI 111/1 of April 3, 2020, the COVID-19 pandemic already exerted great pressure on the health systems in several EU member states, many of which signaled that

Received: 2020, May 18; *Accepted for publication:* 2020, June 20
Address for correspondence: "Spiru Haret" University of Bucharest, Faculty of Juridical and Administrative Sciences Bucharest, Romania
E-mail: georgecoca59@yahoo.com
Corresponding author: George Coca, georgecoca59@yahoo.com
https://doi.org/10.26659/pm3.2020.21.2.127

their places in the intensive care units could be insufficient. Several countries already requested emergency assistance from the EU and other EU member states, and the request was answered by some member states. A series of recent regional initiatives were registered in this regard in the area of hospital cooperation targeting the treatment of patients affected by COVID-19, which contributed to the relief of the capacities of the health systems which were in difficulty, offering places in intensive care sections. Thus Germany, Poland and Romania sent teams of doctors to help treat patients in the hospitals of north and south Italy; Austria, Belgium, Germany and Luxembourg put their intensive care units at the disposal of Dutch, French, and Italian patients in critical state; Luxembourg and Germany sent aerial ambulances, pilots and specialized personnel to help Italy, France and the Netherlands in the fight against the virus (14); (15).

In this international context generated by the COVID-19 pandemic, the European Commission appeals to the national, regional and local authorities in the health field to use the existing structures and mechanisms to collaborate in offering assistance to patients who are in need of intensive care, offering the possibility of hospitalization. The Commission directs to the creation of possibilities for medical professionals to exchange expertise and knowledge, working together with other members of medical personnel at a cross-border level, so that overloaded sanitary units of member states in need of help can be relieved and the functioning of their own health systems is not endangered (14); (15).

The European Commission is committed to supporting sanitary authorities through the concordance of requests with offers of places in intensive care sections for patients and of qualified medical personnel, with the help of the Health Security Committee and of the Early alert and quick response system (EARS). The coordination and co-financing of emergency medical transport for patients and qualified medical personnel teams are also ensured at a cross-border level, when member states request assistance through the EU Civil protection mechanism.

For a good international cooperation, ensuring clarity regarding patient mobilization methods, at a cross-border level, is wanted through: transfer of patient medical files, ensuring the continuity of medical assistance and mutual acknowledgement of medical networks in accordance with the Directive regarding cross-border medical assistance; encouraging health authorities at local, regional, and national level to use, if they exist, bilateral and regional agreements and contact points for relieving intensive care units in neighboring areas where patients with COVID-19 are treated, and encouraging member states or non-governmental specialized organizations to send qualified medical personnel teams to other member states (9); (10); (14).

Coordination of cross-border medical assistance

- The EU Health Security Committee, consisting of representatives from member states and presided by the Commission, will coordinate the cross-border medical assistance. The Committee supports the exchange of information and the coordination of training and reactions to severe cross-border health threats.

- The Commission will facilitate, with the help of the EU Health Security Committee and of the Early alert and quick response system, the coordination of the requests for cross-border medical assistance. The requests for assistance could refer to places in the intensive care units, to the treatment and transfer of patients, as well as to qualified medical personnel teams.

- The competent authority of the member state in need of assistance shall address the member states and the European Commission through EARS for this matter. The criteria to determine the appropriate moment to request help from the EU is at the competence of the national authorities.

- Member states who can offer assistance can respond to the request through EARS. Once an offer has been accepted, the cooperating member states coordinate the direct support among themselves and the hospitals regarding the details of the assistance.

- The Commission will update a summary table containing the requests and the available assistance, and the Health Security Committee will be continuously informed (9); (10); (15).

Reimbursement of patient's medical costs in the member state in which they receive treatment

- Covering medical assistance costs shall be regulated based on the Regulations regarding the coordination of social security systems.

- Patients who must be transported to a hospital in a neighboring state or member state which is offering medical assistance must, usually, carry a prior authorization from the competent social security institution. The Commission appeals for member states to adopt a pragmatic approach for patients who require emergency medical aid and, considering the emergency in the public health field, take into account a general prior authorization in order to ensure coverage of all costs borne by the medical assistance supplier.

- It is recommended that the competent member state consider it sufficient if a patient presents a document which proves that they have health insurance upon entering the hospital or that they are subject to another practical convention which can be established between the member states involved. These guidelines are applied to emergency medical assistance only in the context of the COVID-19 pandemic (4); (13); (15).

Medical assistance conventions for cross-border patients

- Patients must receive a copy of their medical files in order to facilitate treatment in another member state, as well as subsequent treatment received at home.

- It is possible that health authorities will be obliged to adopt additional measures in order to ensure the continuity of medical assistance, considering the possible differences of treatment protocols in different states.

- The general principle of mutual acknowledgement of medical networks is applied in accordance with the Directive regarding cross-border medical assistance.

- National contact points regarding cross-border medical assistance can offer general information for cross-border patients (10); (14); (15).

Free movement of patients outside internal borders

- The rules set out in the Directive regarding free movement are still applicable for EU citizens. Patients who need emergency medical assistance in a medical unit in another member state cannot be refused entrance if temporary controls are set up at internal border crossings. Patients who travel in order to receive non-emergency treatment in another member state must check if border crossing controls will allow them passage (7); (8).

Medical personnel cooperation at cross-border level

- The European Commission advises member states to facilitate the smooth passage of medical professionals across borders and to allow their unrestricted work in a medical unit in another member state.

- Member states or specialized NGOs can send qualified medical personnel teams to other member states in response to requests for assistance.

- Eight European emergency medical teams are already certified or in the process of being certified by WHO in order to offer assistance, with the aim of managing emergency situations on an international level and can be deployed through the Union's Civil protection mechanism, based on a request. The current capacity is limited at present, as it is possible that the personnel is already fully busy in their country of origin, for the most cases. Nevertheless, European medical teams could be extended by activating additional financial support from the EU (10); (14); (15).

Acknowledgement of the medical professionals' qualifications

- Many professions in the medical field, such as doctors with basic medical training, a series of medical specializations, such as respiratory medicine, immunology or communicable diseases, and general nurses are based on minimal harmonization pursuant to the Directive regarding the acknowledgement of professional qualifications.

In case of temporary or occasional supply of services, the European Commission considers that a simple statement is sufficient for these professionals, without the need to wait for a decision from the authorities in the host member state. A mutual acknowledgement procedure can take place for other medical professions, in case competent authorities consider it necessary to compare the basis of the professional training.

- The Directive regarding the acknowledgement of professional qualifications sets out the maximum requirements which medical professionals need to fulfill if they wish to be transferred within the EU. The Directive does not oblige member states to establish restrictions concerning acknowledgement procedures and, therefore, does not hinder member states from adopting a more liberal approach regarding medical professionals who wish to work in a certain member state, regardless if it involves provision of services or establishing residence in the respective member state.

In order to facilitate international medical cooperation also based on the situation targeted, the requirement of a prior statement and prior qualification check can be removed, or shorter time frames for the processing of requests can be applied, as well as requesting less documents than normally, not requiring authorized translations or not insisting on a compensatory measure in case the host member state considers that there is no major risk for the safety of patients (11); (14); (15).

Financial assistance for cross-border cooperation in the medical assistance field

- The EU offers financial assistance through the Solidarity fund to member states affected by a public health emergency.

- Health expenses are also eligible within the Structural funds for countries and regions, and a greater flexibility is ensured regarding the allocation of funds as part of the coordinated economic response to the COVID-19 pandemic.

- It is possible that soon additional financial means will be provided from the EU budget through the Emergency Support Instrument (ESI), subject to the approval of the budgetary authorities. It is predicted that the funds directed through ESI will cover the cross-border cooperation in order to diminish the pressure placed on health systems in the most affected areas of the European Union (12); (13); (15).

References

(1) Ordonanța de urgență 1 din 1999 privind regimul stării de asediu și regimul stării de urgență.
(2) Legea 95 din 2006 privind reforma în domeniul sănătății - Republicată
(3) Hotărârea Consiliului Suprem de Apărare a Țării nr. 30 din 2020
(4) Hotarârea de Guvern nr. 720 din 2008 pentru aprobarea Listei cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, precum şi denumirile comune internaţionale corespunzătoare medicamentelor care se acordă în cadrul programelor naţionale de sănătate - Republicată
(5) Decretul nr. 195 din 16.03.2020 privind instituirea stării de urgenţă pe teritoriul României
(6) Ordonanța militară nr. 1 din 17.03.2020 privind unele măsuri de primă urgență care privesc aglomerările de persoane și circulația transfrontalieră a unor bunuri
(7) Directive 2004/38/CE of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States
(8) Regulation (EU) No 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union
(9) Decision No 1082/2013/UE of the European Parliament and of the Council of 22 October 2013 on serious cross-borders threats to health
(10) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients'

rights in cross-border healthcare
(11) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications
(12) Regulation (EU) 2020/461 of the European Parliament and of the Council of 30 March 2020 amending Council Regulation (EC) No 2012/2002 in order to provide financial assistance to Member States and to countries negotiating their accession to the Union that are seriously affected by a major public health emergency
(13) https://ec.europa.eu
(14) https://eur-lex.europa.eu
(15) Official Journal of the European Union CI 111/1 of 3 April 2020

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 131–132

RECENT PUBLICATIONS

Book reviews

Penalty kicks in football – from lottery to science
Author: Gheorghe Dumitru
Publisher: ExPonto, Constanta, Romania, 2020
462 pages; price: 45 RON (paperback)

I was very happy to be informed about the very existence of this important book. Penalty kicks in soccer are very interesting – from both the scientific and applied perspectives. Research on penalties has been conducted by sport scientists from different disciplines who aspire to help shooters and goalkeepers improve their respective performances. However, as Nobel Laureate Daniel Kahneman observed, penalties in soccer are highly rewarding tasks, performed under conditions of extreme stress and anxiety. As such, no wonder that an increasing number of psychologists and economists (as well as scientists from other disciplines) conceive the penalty kick situation as a wonderful field in which different general phenomena (e.g., action bias) can be investigated.

It took over 8 years for the author – Dr. Gheorghe DUMITRU – to finish this unprecedented project, namely to collect, translate into Romanian and systematize *de novo* the information (i.e., 364 bibliographic sources) published to date on penalty kicks in football/soccer. It was a long-lasting and exhausting intellectual endeavor which finally seems to have been accomplished, if we take into consideration that it resulted in a book of 462 pages – with 6 parts, 22 chapters and 35 tables, which approaches the penalty kicks not only from a technical and tactical perspective, but also from a psychological one.

This is one of the occasions where the advantage of being literate in a foreign language becomes evident: I really regret not speaking, reading or writing the Romanian language. I wish I could, only for the sake of being able to read this exciting book. Therefore, I recruited a friend who speaks this language, who informed me about the content of the book. Based on this information and the Table of Contents sent to me in English, I will try to share with the JHSRM readers my opinion on this book.

The first part provides general information, with the history and ways to approach the topic scientifically (Ch. 1); ball flight parameters (duration and speed) of the penalty kicks and their outcome within the official matches (Ch. 2).

The second part – the largest one, as reflected by the number of pages – is dedicated to the penalty takers, and contains four chapters. The first chapter presents actual information about how the kickers are nominated and practice for the respective task, while the second (Ch. 4) provides the readers with current knowledge on the kicker's actions after the ball is placed on the spot, and on gaze behavior. What strategies are at the disposal of the kickers, their advantages and disadvantages, and why the keeper-independent strategy is preferable over the keeper-dependent strategy are thoroughly explained in the next chapter (Ch. 5). The part ends with factors that can influence the outcome of the penalties awarded during play time (Ch. 6).

Part III is dedicated solely to the goalkeepers – more specifically, to the difficulties and dilemmas they have to solve (Ch. 7), to anticipation as a condition for success (Ch. 8), to their outcomes in official penalties (Ch. 9) and to the strategies, methods and means to prepare them for dueling with the kickers (Ch. 10). Part IV investigates their interrelation with the kickers. Therefore, after some consideration about the penalty kick as a particular form of social interaction (Ch.11), the next chapter teaches us how to rely solely on the non-verbal behaviors of the penalty taker – the keeper perceives the opponent and forms a given impression about him/her, and also in what manner the respective impression influences his/her own outcome expectations (Ch. 12). The final chapter of this part offers the scarce current knowledge about the penalty taker's perception of the keeper.

Part V addresses the very special and extremely exciting topic of shootouts. It starts with extensive considerations on the role, rules and rationale of the shootouts (Ch. 13), goes on to the attributes and characteristics of the players taking

https://doi.org/10.26659/pm3.2020.21.2.131

penalty kicks within shootouts (Ch. 14), and continues with factors that influence the individual performance of the respective kickers (Ch. 15).The last chapter is dedicated to the factors that can influence the final outcome of penalty shootouts (Ch. 16).

Part VI of the book is entitled *"Stress, anxiety and penalty kicks"*. It begins with a chapter (Ch. 17) named *"Stress in general and in sport"*. Information about the factors of stress operating in ordinary penalties and in penalty shootouts is provided next (Ch. 18). The following chapter (Ch. 19) deals with emotions experienced in shootouts, especially with the problems and action mechanisms of anxiety, which is the main and most frequent emotion reported by the players involved. Then, the next chapter addresses coping (Ch. 20), while the following one develops the very special subject of choking in both ordinary penalties and in penalty shootouts (Ch. 21). Lastly, the final section (Ch. 22) provides some tips and recommendations for football professionals. In other words, it presents in detail the so-called preparatory and practical components of a specific training program, undertaken to improve the likelihood of winning the penalty shootouts.

So, taking into account the table of contents – succinctly presented above, the exhaustive information on which it is based, and the merits of approaching the problems from both theoretical and practical perspectives, it may be concluded that with this book's release we are witnessing a real publishing event in the specific field of football, as well as in the general area of sports sciences.

Michael Bar-Eli
Professor, Ben-Gurion University of the Negev
and the Wingate Academic College, Israel
mbareli@som.bgu.ac.il

Health, Sports & Rehabilitation Medicine
Vol. 21, no. 2, April-June 2020, 133–135

FOR THE ATTENTION OF CONTRIBUTORS

The subject of the journal

The journal has a multidisciplinary nature oriented toward biomedical, health, exercise, social sciences fields, applicable in activities of physical training and sport, so that the dealt subjects and the authors belong to several disciplines in these fields. The main sections are: "Original studies" and "Reviews".

Regarding "Reviews", the main subjects that are presented are: oxidative stress in physical effort; mental training; psychoneuroendocrinology of sport effort; physical culture in the practice of family doctors; extreme sports and risks; emotional determinants of performance; recovery of patients with spinal column disorders; stress syndromes and psychosomatics; Olympic education, legal aspects of sport; physical effort in the elderly; psychomotricity disorders; high altitude sports training; fitness; biomechanics of movements; EUROFIT tests and other evaluation methods of physical effort; adverse reactions of physical effort; sport endocrinology; depression in sportsmen/women; classical and genetic drug usage; Olympic Games, etc.

Among articles devoted to original studies and research, we are particularly interested in the following: methodology in physical education and sport; influence of some ions on effort capacity; psychological profiles of students regarding physical education; methodology in sport gymnastics; selection of performance sportsmen.

Other articles approach particular subjects regarding different sports: swimming, rhythmic and artistic gymnastics, handball, volleyball, basketball, athletics, ski, football, field and table tennis, wrestling, sumo.

The authors of the two sections are doctors, professors and educators from university and pre-university education, trainers, scientific researchers etc.

Other sections of the journal are: the editorial, editorial news, reviews of the latest books in the field and others that are rarely presented (inventions and innovations, university and pre-university programs, forum, memories, competition calendar, portraits, scientific events).

We highlight the section "The memory of the photographic eye", where photos, some of which extremely rare, of sportsmen in the past and present are presented.

Articles signed by authors from the Republic of Moldova regarding the organization of sport education, the variability of cardiac rhythm, the stages of effort adaptability, and articles by some authors from France, Portugal, Canada must also be mentioned.

The main objective of the journal is highlighting the results of research activities, as well as the permanent and actual dissemination of information for specialists in the field. The journal assumes an important role in the achievement of necessary scores by the teaching staff in university and pre-university education, as well as by doctors in the medical network (through recognition of the journal by the Romanian College of Physicians), regarding didactic and professional promotion.

Another merit of the journal is the obligatory publication of the table of contents and a summary in English for all articles. Frequently, articles are published in extenso in a language of international circulation (English, French).

The journal is published quarterly and papers are accepted for publication in Romanian and English. The journal is sent by e-mail or on a floppy disk (or CD-ROM) and printed, by mail to the address of the editorial staff. The works of contributors that are resident abroad and of Romanian authors must be mailed to the editorial staff to the following address:

Health, Sports & Rehabilitation Medicine
Chief Editor: Prof. Dr. Traian Bocu
E-mail address: hesrehab@gmail.com; traian_bocu@yahoo.com
Postal address: Clinicilor street no. 1, postal code 400006, Cluj-Napoca, Romania
Phone: +400264-598575
Website: www.jhsrm.org

Objectives

Our intention is that the journal continues to be a route to highlight the research results of its contributors, especially by stimulating their participation in project competitions. Articles that are published in this journal are considered as part of the process of promotion in one's university career (accreditation that is obtained after consultation with the National Council for Attestation of University Titles and Diplomas).

We also intend to encourage the publication of studies and research that include relevant original elements, especially by young people. All articles must bring a minimum of personal contribution (theoretical or practical), that will be highlighted in the article.

In the future, we propose to fulfill criteria that would allow the promotion of the journal to superior levels according international recognition.

THE STRUCTURE AND SUBMISSION OF ARTICLES

The manuscript must be prepared according to the stipulations of the International Committee of Medical Journal Editors (http://www.icmjee.org).

The number of words for the electronic format:

– 4000 words for original articles;

– 2000 words for case studies;

– 5000-6000 words for review articles.

Format of the page: edited in WORD format, A4. Printed pages of the article will be numbered successively from 1 to the final page.

Font: Times New Roman, size 11 pt.; it should be edited on a full page, with diacritical marks, double spaced, with equal margins of 2 cm.

Illustrations:

The images (graphics, photos, etc.) should be numbered consecutively in the text, with Arabic numerals. They should be edited with EXCEL or SPSS programs, and sent as distinct files: "figure 1.tif", "figure 2. jpg", to the editors. Every graphic should have a legend, written under the image.

The tables should be numbered consecutively in the text, with Roman numerals, and sent as distinct files, accompanied by a legend that will be placed above the table.

PREPARATION OF THE ARTICLES

1. Title page: Includes the title of the article (maximum 45 characters), the first name of the authors followed by their surname, workplace, postal address of the institute and postal address and e-mail of the first author. It will follow the name of the article in English.

2. Abstract: Original articles require a summary structured in: (Background, Aims, Methods, Results, Conclusions), of maximum 250 words, followed by 3-8 key words (if possible from the list of established terms). All articles will have a summary in English. Within the summary (abstract), abbreviations, footnotes or bibliographic references should not be used.

Background. Description of the importance of the study and explanation of premises and research objectives.

Methods. Include the following aspects of the study:

Description of the basic category of the study: of orientation and applicative.

Localization and the period of study. Description and size of groups, sex (gender), age and other socio-demographic variables should be given.

Methods and instruments of investigation that are used.

Results. Descriptive and inferential statistical data (with specification of the statistical tests used): the differences between the initial and the final measurement for the investigated parameters, the significance of correlation coefficients are necessary. The level of significance (the value ***p*** or the dimension of effect ***d***) and the type of the statistical test used, etc. should be mentioned.

Conclusions. Conclusions that have a direct link with the presented study should be provided.

Orientation articles and case studies should have an unstructured summary (without respecting the structure of experimental articles) up to a limit of 150 words.

3. Text

Original articles should include the following chapters which will not be identical with the summary titles: Introduction (General considerations), Hypothesis, Materials and methods (including ethical and statistical information), Results, Discussing results, Conclusions and suggestions. Other types of articles, such as orientation articles, case studies, editorials, do not have an obligatory format. Excessive abbreviations are not recommended. The first time an abbreviation is used in the text, it should follow the term *in extenso*, being placed in parentheses, and thereafter the short form should be used.

Authors must take responsibility for the correctness of the published materials.

4. References

The bibliography should include the following data:

For articles from journals or other periodical publications, the international Vancouver Reference Style should be used: the first name of all authors as initials and their surname, the year of publication, the title of the article in its original language, the title of the journal in its international abbreviated form (italic characters), number of volume, pages.

Articles: Carlos S, de Irala J, Hanley M, Martínez-González MÁ. The use of expensive technologies instead of simple, sound and effective lifestyle interventions: a perpetual delusion.See comment in PubMed Commons below 2014;68(9):897-904. doi:10.1136/jech-2014-203884.

Books: Fox SI. Human Physiology. Twelfth Ed. Publ MCGraw Hill. New York, 2011,403-470.

Chapters from books: Sternfeld B, Lee IM. Physical activity and cancer: the evidence, the issues and the challenges. In: Lee IM, Eds. Physical Activity and Health Epidemiologic Methods and Studies. New York: Oxford University Press, 2009.

Starting with issue 4/2010, every article should include a minimum of 15 and a maximum of 100 bibliographic references, mostly journal articles published in the last 10 years. Only a limited number of references (1-3) older than 10 years will be allowed. At least 20% of the cited resources should be from the recent international literature (not older than 10 years).

Conflict of interest

The authors must mention all possible conflicts of interest including financial and other types. If you are sure that there is no conflict of interest, we ask you to mention this. The financing sources should also be mentioned in your work.

Acknowledgements

The specifications must concern only people outside the study who have had a substantial contribution, such as statistical processing or review of the text in English. The authors have the responsibility to obtain the written permission from

the persons mentioned within the respective chapter, in case readers refer to the interpretation of results and conclusions of these persons. Also it should be mentioned if the article uses partial results from certain projects or if these are based on master or doctoral theses defended by the author.

Peer-review process

In the final stage, all materials will be closely reviewed by at least two competent referees in the field (professors and docent doctors) so as to correspond in content and form to the requirements of an international journal. After this stage, the materials will be sent to the journal's referees, according to their profiles. After receiving the observations from the referees, the editorial staff shall inform the authors of the necessary corrections and publishing requirements of the journal. This process (from receiving the article to transmitting the observations) should last about 4 weeks. The author will be informed if the article has been accepted for publication or not. If it is accepted, a period of correction by the author will follow, in order to meet the publishing requirements.

Ethical criteria

The Editors will notify the authors in due time whether their article is accepted or not or if there is a need for modifying the text. Also, the Editors reserve the right to edit articles accordingly. Papers that have been printed or sent for publication to other journals will not be accepted. All authors should send a separate letter containing a written statement proposing the article for submission, pledging to observe the ethics of citation of the sources used (bibliographic references, figures, tables, questionnaires).

For original papers, according to the requirements of the Helsinki Declaration, the Amsterdam Protocol, Directive 86/609/EEC, and the regulations of the Bioethical Committees from the locations where the studies were performed, the authors must provide the following:

- the informed consent of the family, for studies in children and juniors;
- the informed consent of adult subjects, patients and athletes, for their participation;
- malpractice insurance certificate for doctors, for studies in human subjects;
- certificate from the Bioethical Committees, for human study protocols;
- certificate from the Bioethical Committees, for animal study protocols.

This information will be mentioned in the paper, in the section Materials and Methods. The documents will be obtained before the beginning of the study. The registration number of the certificate from the Bioethical Committees will also be mentioned.

Editorial submissions will not be returned to the authors, whether published or not.

FOR THE ATTENTION OF SPONSORS

Requests for advertising space should be sent to the Editors of the *Health, Sports & Rehabilitation Medicine* journal, 1, Clinicilor St., 400006, Cluj-Napoca, Romania. The price of an A4 full color page of advertising, will be EUR 250 and EUR 800 for an advert in all 4 issues. The costs of publication of a logo on the cover will be determined according to its size. Payment should be made to the Romanian Medical Society of Physical Education and Sports, CIF 26198743. Banca Transilvania, Cluj branch, IBAN: RO32 BTRL 0130 1205 S623 12XX (RON).

SUBSCRIPTION COSTS

The *Health, Sports & Rehabilitation Medicine* journal is printed quarterly. The subscription price is 100 EUR for institutions abroad and 50 EUR for individual subscribers outside Romania. For Romanian institutions, the subscription price is 150 RON, and for individual subscribers the price is 120 RON. Note that distribution fees are included in postal costs.

Payment of subscriptions should be made by bank transfer to the Romanian Medical Society of Physical Education and Sports, CIF 26198743. Banca Transilvania, Cluj branch, IBAN: RO32 BTRL 0130 1205 S623 12XX (RON), RO07 BTRL 01,304,205 S623 12XX (EUR), RO56 BTRL 01,302,205 S623 12XX (USD). SWIFT: BTRLRO 22

INDEXING

Title of the journal: *Health, Sports & Rehabilitation Medicine*
pISSN 2668-2303, ISSN-L 2668-2303
Profile: a Journal of Study and interdisciplinary research
Editor: "Iuliu Haţieganu" University of Medicine and Pharmacy of Cluj-Napoca and The Romanian Medical Society of Physical Education and Sports in collaboration with the Cluj County School Inspectorate
The level and attestation of the journal: a journal rated B+ by CNCS (Romanian National Research Council) since 2007, certified by CMR (Romanian College of Physicians) since 2003, CFR (Romanian College of Pharmacists) since 2015 and CMDR since 2018
Journal indexed in International Databases (IDB): EBSCO, Academic Search Complete, USA and Index Copernicus, Journals Master List, Poland; DOAJ (Directory of Open Access Journals), Sweden, CiteFactor, Canada/USA, CrossRef, Lynnfield, MA (US)/Oxford (UK)
Year of first publication: 2000
Issue: quarterly
The table of contents, the summaries and the instructions for authors can be found on the internet page: http://www.jhsrm.org. Access to the table of contents and full text articles (in pdf format) is free.