

Siedlecki Zygmunt, Gutkowska Agnieszka, Nowak Karol, Śniegocki Maciej. Cranioplasty as neurosurgical procedure with potential risk of legal claims. *Journal of Education, Health and Sport*. 2021;11(01):170-176. eISSN 2391-8306. DOI <http://dx.doi.org/10.12775/JEHS.2021.11.01.017> <https://apcz.umk.pl/czasopisma/index.php/JEHS/article/view/JEHS.2021.11.01.017> <https://zenodo.org/record/4485714>

The journal has had 5 points in Ministry of Science and Higher Education parametric evaluation. § 8. 2) and § 12. 1. 2) 22.02.2019.

© The Authors 2021;

This article is published with open access at License Open Journal Systems of Nicolaus Copernicus University in Torun, Poland

Open Access. This article is distributed under the terms of the Creative Commons Attribution Noncommercial License which permits any noncommercial use, distribution, and reproduction in any medium, provided the original author (s) and source are credited. This is an open access article licensed under the terms of the Creative Commons Attribution Non commercial license Share alike. (<http://creativecommons.org/licenses/by-nc-sa/4.0/>) which permits unrestricted, non commercial use, distribution and reproduction in any medium, provided the work is properly cited.

The authors declare that there is no conflict of interests regarding the publication of this paper.

Received: 20.01.2021. Revised: 30.01.2021. Accepted: 31.01.2021.

Cranioplasty as neurosurgical procedure with potential risk of legal claims

Zygmunt Siedlecki¹, Agnieszka Gutkowska², Karol Nowak¹, Maciej Śniegocki¹

1 Department of Neurosurgery, Neurotraumatology and Pediatric Neurosurgery, The Ludwik Rydygier Collegium Medicum in Bydgoszcz, The Nicolaus Copernicus University in Toruń

2 Department of Criminology, Faculty of Law and Administration, University of Warsaw

Corresponding address:

Dr. med. Zygmunt Siedlecki Department of Neurosurgery, Neurotraumatology and Pediatric Neurosurgery,

the Ludwik Rydygier Collegium Medicum in Bydgoszcz,

ul. Skłodowskiej-Curie 9

85-094 Bydgoszcz

tel.: + 48 606 302680

e-mail: siedlecki@cm.umk.pl

Abstract

We present the current state of affairs regarding the legal claims of patients after cranioplasty operations who are dissatisfied with the treatment effect and have claims that the perioperative course is unfavorable. In the period of 11 years (2010-2020), 2 legal claims were submitted in our neurosurgical center after cranioplasty. Both are civil claims. One of them about purulent infection of the bone prosthesis was found by the judgment to be unfounded. The second one concerning the alleged general condition deterioration as a consequence of cranioplasty has been declared obsolete. A cranioplasty is a surgical procedure used to correct a defect in a bone of the skull. It is not urgent surgery and is performed in patients who had been previously in serious condition. The same medical staff who previously saved the lives of patients by performing brain decompression may be subject of legal claims in the case of cranioplasty. Thus, according to authors, claims of patients regarding the alleged negative effects of cranioplasty is an interesting psychological phenomenon. Authors emphasized that cranioplasty should be considered as a procedure of increased risk of potential legal claims for medical staff.

Key words: cranioplasty, legal claims, judgment

Introduction

A cranioplasty is a surgical procedure used to correct a defect in a bone of the skull. The defect is common the result of brain injury or previous surgery in case of severe brain edema [1]. In clinical practice, brain decompression consisting in the removal of the bone flap is performed most common in patients with severe brain injuries (e.g. traffic accidents), in the case of severe hemorrhages or strokes [2]. Such procedures are performed urgently, often in unconscious patients, and from the legal point of view they are performed on the basis of

implied consent, because informed written is impossible. In our department, each time the decision on surgical treatment was signed by two doctors with a view to saving the patient's life. Patients with bone defects, who survived and their neurological condition improved after some time, require surgery to replace the skull bones. A cranioplasty will not only improve the head appearance, but also may provide several medical benefits [2].

Honeybul et al. (2013) reported that the functional state of patients improved after cranioplasty. Therefore, one always strives to perform this procedure for the sake of the patient [1]. The restoration of the defect is usually performed 4 - 9 months after decompressive procedure [1]. From a legal point of view, it is a planned procedure, so the patient always signs a written consent for it. Each time the patient is informed about the course of the surgery and possible complications [3]. Bleeding complications may occur during the operation or in the postoperative period. These may require a blood transfusion. During the operation or in the postoperative course, cerebral edema may also occur, requiring complex pharmacological treatment [3]. Complications may result in the need for emergency surgery to remove intracranial hematomas or reduce brain edema. Due to the necessity of dura incision, complications may occur in the form of cerebrospinal fluid (CFC) leak through the wound. CFS leak may disturb wound healing and the need for reoperation of the damaged dura [3,4].

It should be emphasized that some of the complications of the surgery may be life-threatening [4,5]. The course of the surgery may cause changes in planned activities, which may result in narrowing or extending the scope of the operation. One of the possible complications of surgery, despite the application of appropriate perioperative prophylaxis, may be infection of the operated site and the central nervous system [5]. Postoperative treatment in cases of such infectious complications is often long-term. You should take into account even a three-month period of taking antibiotics. Sometimes infectious complications lead to subsequent operations, even multiple ones [4,5].

Cases descriptions

In the years 2010-2020, the our neurosurgical department 94 cranioplasty procedures were performed. They consisted in supplementing the skull bone defect with Cobudix® material, which is a bone prosthesis used in our department. Of the operated patients, 85.11% were people after severe brain injury (most often car accidents, then falls from heights), 9.57% were people after surgery for a ruptured brain aneurysm, while 5.32% were people

after decompression craniectomy in severe ischemic stroke. Each of the operated patients was conscious and able to make decisions about himself. He had full legal capacity and was not incapacitated.

It this period - 2010-2020 - there were 2 legal claims from a civil action for alleged deterioration of the neurological condition and purulent infection of the skull bone prosthesis.

The first claim was made of purulent prosthesis infection 9, what had happened days after cranioplasty surgery. The neurological condition of the patient worsened, computed tomography (CT) revealed a pathological volume under the bone prosthesis, compressing the brain. The patient was operated as soon as possible (ASAP). Empyema under the prosthesis, which was evacuated. The Codubix® prosthesis has been removed. The patient's neurological condition improved. The patient went home in good neurological condition. Two months after the incident, a lawsuit was filed with the Civil Judgment concerning the alleged health impairment of the patient. After a judgment trial that lasted about 2 years, based on expert opinions, the Judgment dismissed the claim in its entirety. Expert in the field of neurosurgery stated that the medical activities carried out from the beginning of the patient's treatment at the time of severe trauma saved the patient's life. The patient has severe brain damage, and for such severe injuries, his functional state was satisfactory, besides, the patient also suffered other injuries, his immunity was significant weakened and this led to purulent infection. There were no medical neither organizational shortcomings in this case.

The second claim related to the alleged deterioration of the patient's neurological condition, which was allegedly (in patient's relatives' opinion) due to the cranioplasty procedure performed. The skull defect was a consequence of a life-saving craniectomy for acute epidural hematoma with cerebral edema performed 8 months earlier. In addition, the patient developed hydrocephalus treated with a ventricular – peritoneal shunt. After the cranioplasty, which was performed smoothly and without complications, the patient was discharged home without any disturbing symptoms. He was also treated later in our hospital for hydrocephalus and valve dysfunction. After 9 years, a complaint was filed in which the patient's family claimed that after cranioplasty, his neurological condition had allegedly worsened. Interestingly, there was no information in the medical documentation that such deterioration took place. From medical point of view, patient's health problems resulted from hydrocephalus, not from cranioplasty. It is interesting that despite the fact that the patient had a history of severe brain trauma, hydrocephalus - which together meant that his functional

state was moderate (disability), in patient's relatives' opinion cranioplasty was the reason of these complications. According to all medical papers, cranioplasty was the shortest treatment that went most smoothly and did not require any follow-up. The case was statute - barred and, to the knowledge of the authors of this manuscript, it was not brought before a civil judgment.

Discussion and legal point of view

Proceedings before a civil judgment in the case of liability for alleged damage after cranioplasty operations, as in any other medical procedure, was initiated as a result of a lawsuit brought by the aggrieved party to a common, district or regional judgment in the territory of the Republic of Poland, i.e. in the country where cranioplasty, as described in our manuscript. In such civil proceedings, the hospital was the defendant while the patient and his family acted as plaintiffs [6]. In Polish law, civil proceedings are adversarial - which means that the initiative to take evidence in the scope of the pending proceedings belongs to the parties, and the claims and evidence are presented to the court as an impartial arbitrator in the pending dispute [6].

In the lawyer's opinion, in accordance with the principle of mutual independence in conducting proceedings in the field of professional liability of doctors and criminal and civil liability, irrespective of civil proceedings, the aggrieved party or - in the case of acts which are prosecuted *ex officio* - the prosecutor may demand that a doctor be called committed a medical error, to criminal liability, which will be adjudicated by a common judgment [7]. In addition, a doctor may be professionally liable before a regional medical judgment [7]. However, in the discussed cases of claims for cranioplasty surgery, such situations did not take place, and the opinion of neurosurgery experts was clearly favorable to doctors from the neurosurgery department.

The lawyer emphasizes that in civil proceedings, it is the plaintiff - i.e. the patient and his family - that is obliged to prove all the circumstances from which it derives legal effects, however, the defendant's passive procedural attitude may, in some situations, cause negative procedural consequences for him [7]. In the case of the claims we are discussing, all medical records were beneficial to doctors [7]. Moreover, in the case of the second patient, the deterioration of his neurological condition was a subjective assessment of the patient's relatives and there was no indication that cranioplasty could have any connection with it.

The hospital and physicians who have performed cranioplasty, as a party to an adversarial process in which the court is limited to the role of an impartial arbitrator, should take the initiative by raising statements and evidence to support its position [8]. The evidence may include, in particular, documents, expert opinions and testimonies of witnesses, which was exactly in the described cases.

Conclusions

Cranioplasty procedures are potentially burdened with the risk of claims of patients and their relatives, who are dissatisfied with the effect of the treatment and have an extremely demanding attitude towards a possible adverse postoperative course.

These procedures should be especially taken into account, the more so that in many neurosurgical centers they are performed by young residents.

Each case of a patient qualified for cranioplasty must be analyzed individually, and be supervised by neurosurgeon with clinical and legal experience.

Abbreviations

ASAP - as soon as possible

CFC - cerebrospinal fluid

CT - computed tomography

Declarations

- Availability of data and materials: All relevant data are within the paper.
- Competing Interests: The authors declare that they have no conflict of interest.

References

1. Honeybul, S., Janzen, C., Kruger, K., & Ho, K. M. (2013). The impact of cranioplasty on neurological function. *British journal of neurosurgery*, 27(5), 636-641.
2. Miller, K., Siedlecki, Z., Kiec, M., Bereźnicka, W., & Śniegocki, M. (2014). Wyniki procedur kranioplastyki czaszki u chorych operowanych z powodu ubytków kości czaszki= Results of cranioplasty procedures of patients operated because of skull bone defect. *Journal of Health Sciences*, 4(10), 18-24.

3. Zanaty, M., Chalouhi, N., Starke, R. M., Clark, S. W., Bovenzi, C. D., Saigh, M., ... & Tjoumakaris, S. I. (2015). Complications following cranioplasty: incidence and predictors in 348 cases. *Journal of neurosurgery*, 123(1), 182-188.
4. Brommeland, T., Rydning, P. N., Pripp, A. H., & Helseth, E. (2015). Cranioplasty complications and risk factors associated with bone flap resorption. *Scandinavian journal of trauma, resuscitation and emergency medicine*, 23(1), 1-7.
5. Li, A., Azad, T. D., Veeravagu, A., Bhatti, I., Long, C., Ratliff, J. K., & Li, G. (2017). Cranioplasty complications and costs: a national population-level analysis using the marketscan longitudinal database. *World neurosurgery*, 102, 209-220.
6. Tymiński, R. (2018). Znaczenie dowodu z dokumentacji medycznej w sprawach cywilnych o błąd medyczny—refleksje na tle praktyki i orzecznictwa sądowego. *Medyczna Wokanda*, 11(11), 123-138.
7. Białkowski, M. (2013). Poglądy doktryny prawa cywilnego i orzecznictwa na pojęcie błędu medycznego. *Przeгляд Prawniczy Uniwersytetu im. Adama Mickiewicza*, (2), 57-70.
8. Sadowska, J. (2016). Odpowiedzialność za szkodę medyczną wynikającą ze zdarzenia medycznego—pojęcie zdarzenia medycznego.