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ORIGINAL PAPER

Pediatric neurosurgery malpractice claims in Germany

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Abstract

Purpose There is limited data regarding malpractice claims in pediatric neurosurgery. Aim of this study was to analyze the rate, subject, and outcome of malpractice claims faced by pediatric neurosurgeons.

Methods We analyzed malpractice claims in pediatric neurosurgical patients assigned to the review board of North Rhine Medical Council from 2012 to 2016. Claims were categorized as "medical error" or "adverse event, no medical error." Severity was graded from negligible (grade 1) to death (grade 6).

Results Of 391 pediatric malpractice claims, seven (1.8%) concerned pediatric neurosurgery. Claims were related to cranial surgery ($N = 5$), spinal surgery ($N = 1$), and a neuro-interventional procedure ($N = 1$). Of operative cases, three were shunt operations, two were cranioplasty procedures, and one was a spinal fusion. Complications of medical care (adverse events) had occurred in all cases. A medical error was detected in only one case. Severity of damage was grade 2 (transient minor) in three, grade 3 (transient major) in one, and grade 5 (permanent major) in three cases, respectively.

Conclusions Pediatric neurosurgery accounted for 1.8% of all pediatric malpractice claims. In 14% of these claims, a medical error was confirmed. Malpractice claim rate thus appears to be lower than expected for a high-risk specialty. , adverse events were confirmed in all cases, a negligent medical error was rare. Adverse event rate appears to be a predictor for malpractice claim burden, highlighting the importance of surgical checklists, standard operating procedures and morbidity and mortality surveillance.

Keywords Medical error · Adverse event · Litigation · Children

Introduction

Medical errors and malpractice claims have significant implications for all parties involved: Affected patients and their families not only face the physical and psychological burden of additional morbidity or even mortality, but also the financial impact such complications may have. Society and health care systems carry direct or indirect costs arising from indemnity payments, administrative expenses, so-called defensive medicine, and lost physician working time and productivity. Surgeons face increasing premiums for medical liability insurance in response to rising claim rates and a frequent lack of caps on non-economic damages [1]. While this provides financial and legal protection, physicians remain largely unprotected against the reputational, psychological, and emotional implications of such claims [2]. The likelihood of malpractice claims varies across medical specialties, with neurosurgery being described as a high-risk specialty [3].

The key domains of medical errors are (1) failure to execute an action as planned, (2) using a wrong plan to address a clinical problem, (3) omitting an indicated procedure, and (4) failure to meet the standard of care, i.e., negligence. In contrast, an unintended result per se is not a feature exclusively found in connection to medical errors. Unintended results can also develop after adverse events, many of which are neither preventable nor ameliorable [4].

In surgical units, adverse events are typically subject to morbidity and mortality surveillance. Such surveillance systems have been devised for pediatric neurosurgery [5]. The published overall significant adverse event rates for this subspecialty range from 15 to 20%, and high-risk procedures,

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such as cerebrospinal fluid diversions and tumor resections, have been defined [5–7].

In contrast, the literature on actual medical errors and malpractice claims in pediatric neurosurgery is scarce, and to the best of our knowledge, no systematic analysis has been published before. Interestingly, it has been suggested, among other factors, that the perceived risk of malpractice claims among physicians may be increased by a lack of access to accurate information about the actual risk of litigation [8]. Therefore, the aim of the present study was to analyze the rate, subject, and outcome of malpractice claims encountered by pediatric neurosurgeons in Germany.

Methods

Malpractice claims in neurosurgical patients aged 18 years and younger were extracted from the database of the review board of the North Rhine Medical Council (NRMC), covering the years 2012 to 2016. Raw data was extracted from a prospectively maintained database and anonymized by the NRMC before being distributed to the authors. The NRMC covers approximately 60,000 physicians and 10 million inhabitants. The arbitration and review boards of German Medical Councils can be commissioned by patients to investigate a suspected malpractice case. The board will then collect necessary information (e.g., medical notes, radiological imaging) and consult an external medical expert reviewer. On the basis of the review, the independent medical and legal members of the board will finally determine whether a medical error has been committed and whether this error caused harm to the patient. For this purpose, a medical error is defined as medical care deviating from the common standard at the time as judged by expert peers. In more than 90% of cases investigated by such boards, out-of-court agreements can be reached. In 2004, the German review boards completed 7744 malpractice claims [9]. In the same year, German courts dealt with 7659 medical malpractice lawsuits. A substantial proportion of malpractice claims in Germany is thus processed by German Medical Councils and their database can be considered representative, as demonstrated in previous publications [10, 11].

For this study, malpractice claims were grouped into cranial surgery, spinal surgery, and neuro-interventional procedures. The review decisions were summarized as either "medical error" as defined above, or as "adverse event, no medical error," which refers to unintended injury or complication resulting from medical care rather than the patient's underlying disease [4]. The severity of damage sustained by the patient was graded on a 6-item scale as either negligible (grade 1), transient minor (grade 2), transient major (grade 3), permanent minor (grade 4), permanent major (grade 5), or death (grade 6) [11].

Results

Baseline data of patients and procedures

In the study period, a total of 8381 malpractice claims were submitted to the NRMC review board, including 391 pediatric cases. Of these, seven (1.8%) were malpractice claims in pediatric neurosurgery (Fig. 1). Four patients were female and three were male, with a median age of 12 years (range 1–17 years). The majority of claims ($N = 5$) were related to cranial operations, comprising three ventriculoperitoneal shunt (VPS) operations and two cranioplasty procedures. The remaining malpractice claims referred to a case of spinal reposition and fusion after trauma and a neuro-interventional embolization of an intracerebral arteriovenous malformation (AVM).

Cranial procedures

Three malpractice claims in this category were related to VPS operations. As summarized in Table 1, only one claim referred to an adverse event directly related to the surgical procedure, namely a postoperative CSF infection with *Staphylococcus aureus* leading to removal of the VPS, while the other two claims referred to difficult vascular access in a premature baby prior to a shunt operation and to a deep vein thrombosis after a shunt revision in a 12-year-old girl. The severity was grade 3 for the postoperative infection and grade 2 for the latter claims, respectively. In all three claims, the review board detected adverse events causing transient, treatment-associated,

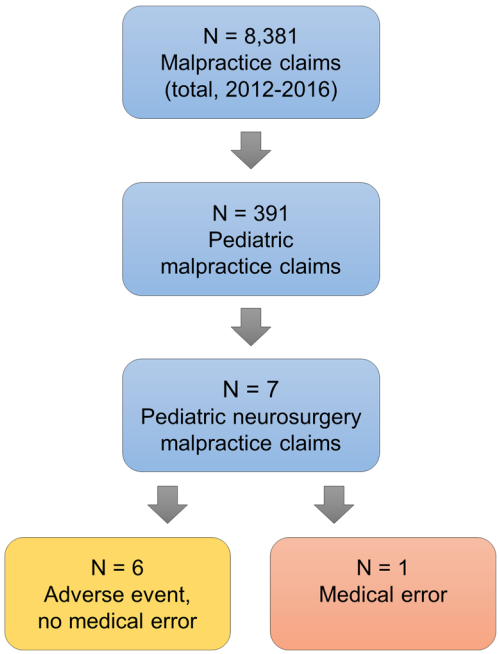

Fig. 1 Flowchart of the data analysis for the current study

Table 1 Overview of malpractice claims in pediatric neurosurgery in the current study

No.	Age [years]	Sex	Category	Diagnosis	Procedure	Adverse event	Severity grade	Malpractice claim	Decision after expert review
1	1	M	Cranial	Raised ICP in syndromic cranio-synostosis (Apert syndrome)	Calvarial remodeling and fronto-orbital advance-ment	Intraoperative hemorrhage, cardiopulmonary resuscitation	5	Inappropriate surgical technique leading to hemorrhage, incomplete consent	Adverse event, no medical error
2	1	M	Cranial	Premature baby, arachnoid cyst, hydrocephalus	VPS insertion	Difficult vascular access, accidental puncture of femoral artery with transient ischemia of leg secondary to vasospasm	2	Inappropriate attempt to cannulate the femoral vein with accidental arterial puncture	Adverse event, no medical error
3	3	M	Cranial	Chiari malformation, hydrocephalus	VPS insertion	Postoperative CSF infection with Staphylo-coccus aureus requiring VPS removal	3	Inappropriate surgical decision making, initial procedure not indicated	Adverse event, no medical error
4	12	F	Cranial	Spina bifida, hydrocephalus, VPS malfunction	VPS revision	Postoperative deep vein thrombosis (DVT)	2	Negligent omission of postoperative DVT prophylaxis	Adverse event, no medical error
5	13	F	Cranial	Bone flap osteolysis after previous trauma	Cranioplasty (artificial implant)	Postoperative surgical site infection (SSI)	5	Inappropriate treatment of SSI with omission of timely implant removal	Medical error
6	13	F	Inter-ventional	Cerebral AVM	Percutaneous transluminal embolization	Accidental internal carotid artery occlusion with histoacryl glue, subsequent cerebral infarction	5	Inappropriate neuro-interventional technique leading to iatrogenic arterial occlusion	Adverse event, no medical error
7	17	F	Spinal	Traumatic fracture of the eighth thoracic vertebra	Reposition and posterior spinal instrumentation	Postoperative pain due to misplaced pedicle screw	2	Inappropriate surgical technique leading to pedicle screw misplacement	Adverse event, no medical error

additional morbidity. However, a medical error was detected in none of these malpractice claims.

Two malpractice claims in this category were made concerning cranioplasty procedures. As summarized in Table 1, both claims addressed adverse events directly related to the surgical procedure: In a 1-year-old boy with Apert syndrome, a severe intraoperative hemorrhage during calvarial remodeling and fronto-orbital advancement required cardiopulmonary resuscitation. The child suffered permanent neurological damage, including visual and auditory impairment, corresponding to a severity grade 5. The expert review detected no medical error.

The second case was a 13-year-old girl who had sustained a severe traumatic brain injury at the age of 5 years and required a craniotomy at that time. The malpractice claim referred to a cranioplasty procedure performed to replace an osteolytic bone flap with an artificial implant. Following this procedure, the patient suffered epileptic seizures due to an intracranial hemorrhage and subsequently required multiple revision surgeries for cerebrospinal fluid leaks and surgical site infections. The severity was considered grade 5. After expert review, the board concluded that a medical error had been committed by leaving the artificial implant in situ despite conclusive evidence of infection. This malpractice claim was thus affirmed as a medical error in the form of negligent omission.

Spinal procedures

The only malpractice claim in this category was made after a spinal fusion. A 17-year-old male patient with a history of epilepsy suffered a generalized seizure, leading to a spinal trauma with a fracture of the eighth thoracic vertebra. A closed reposition and posterior spinal instrumentation from T7 to T9 were performed. Postoperatively, the patient complained of severe back pain. A computed tomography scan revealed misplacement of a pedicle screw, which was immediately revised. The back pain disappeared, corresponding to grade 2 severity. No medical error was detected in this case after expert review.

Neuro-interventional procedures

This malpractice claim was made after endovascular embolization of an intracerebral AVM. A 13-year-old girl was diagnosed with a right frontal AVM after a first-time epileptic seizure. During neuro-interventional embolization of the AVM, an accidental dislocation of histoacryl glue lead to occlusion of the right internal carotid artery. The patient subsequently suffered a cerebral infarction and required decompressive craniectomy. Due to permanent hemiparesis, the severity corresponds to grade 5. No medical error was detected after expert review.

Discussion

The malpractice claim rate in pediatric neurosurgery was low, accounting for only 1.8% of all pediatric claims in the current study. A medical error leading to treatment-associated damage sustained by the patient was detected by the review board in only one in seven claims. The other six cases were considered to be adverse events, but without medical error.

Published reports on malpractice in medicine vary due to different definitions, data sources, and ways of analyzing and presenting the data. For example, Pukk-Härenstam et al. reported an overall claims rate of 0.20% and a claims rate for surgical specialties of 0.36% [12]. In their series, 49.5% of all claims were considered valid by physician reviewers and thus eligible for compensation payment. In contrast, in the present series, only 14% of claims were judged eligible. In Germany, the Medical Councils decided on 7215 malpractice claims across all medical specialties in the year 2015; in 28.8% of these cases, a medical error was detected and the claims thus judged valid [13]. Similar results were published for the USA, with 78% of claims not leading to payments to plaintiffs in a recent analysis by Jena et al. [3]. The authors conclude that the lifetime risk of facing a malpractice claim is high, but the risk of a claim being affirmed and thus resulting in indemnity payments is low. Another observation from their study is a substantial variation of risk across medical specialties, with neurosurgery being among the high-risk specialties.

We hypothesize that the variation observed in the percentage of malpractice claims can be partially attributed to differences in the overall morbidity and mortality rates between medical specialities. In all cases analyzed in the present study, an adverse event occurred during the medical treatment. Adverse event rates for general pediatric neurosurgery range between 12 and 20% for morbidity, but can be significantly higher when selecting high-risk subgroups, such as children undergoing intracranial tumor resection or shunt surgery [5, 6]. For this selected population, adverse event rates of up to 69% have been described [7]. The morbidity rates for general adult neurosurgical cohorts range from 7 to 13% [14, 15]. The reasons for higher adverse events rates in pediatric neurosurgery have been recently discussed by Campbell et al. in detail, and a major contributor is probably the case-mix in this subspecialty: A larger proportion of high-risk procedures, e.g., CSF-related operations, in high-risk patients, e.g., premature babies, causes an increase in complication rates [6].

The purposes of adverse event surveillance or analysis of malpractice claims are quality improvement and quality assurance, which reduce the additional burden for the patient and family, the risk of getting sued for the physician, and the additional costs for health care systems. Our detailed analysis of malpractice claims in pediatric neurosurgery in Germany demonstrates that claims arise in cases where adverse events are encountered. Our interpretation is that adherence to

common principles of neurosurgical care (e.g., timely revision of a misplaced pedicle screw or immediate removal of infected implants) protects physicians against malpractice litigation. While this might appear to be "common sense," this conclusion emphasizes the importance of assuring and improving quality in pediatric neurosurgery through prospective surveillance, but also through research and development of new devices and refined techniques. Surgical safety checklists are an example of widely implemented tools leading to profound reduction of complication rates and ultimately also to a prevention of several malpractice claims [16–18]. Devising and following in-house guidelines regarding commonly encountered situations (such as VPS infections or other infected implants) could further increase the surgeon's protection from liability. Such standard operating procedures (SOPs) aim to reduce variation, uncertainty, and confusion and to increase consistency, quality and safety [19]. Low adherence to SOPs is associated with a higher rate of adverse events [20]. From a theoretical point of view, these measures reduce the weaknesses and gaps in the defensive layers and thereby make it more difficult for a hazard to manifest itself into harm for the patient [21].

The physician's perceived risk of a malpractice claim depends on the actual risk of a claim, the chance of a claim being affirmed and the average amount of the indemnity payments [3]. Considering our results and the reviewed literature, the two latter aspects are probably not sufficient to explain the perceived pressure expressed by neurosurgeons to protect themselves by practicing defensive medicine or even eliminating high-risk operations from their practice [22]. However, in virtually all studies on this topic, the overall number of claims is significantly higher than the number of claims finally leading to a payment. While a physician can prepare for such payments through malpractice insurance, the reputational, psychological, and emotional implications will remain, independent of the outcome of a claim [23]. There is evidence that this perceived pressure leads to defensive medicine in a significant proportion of physicians [22, 24]. While higher healthcare costs due to additional diagnostic tests or imaging studies are certainly an important aspect, we would like to emphasize an even more relevant aspect in pediatric neurosurgery: Defensive medicine in pediatric neurosurgical patients may cause (potential) harm to the child when it comes to additional general anesthetics for MRI scans or radiation exposure for additional CT scans ordered to reduce a perceived legal risk rather than based on unequivocal medical indications.

Limitations of the present study are mainly due to the retrospective study design and the usual limitations of big data approaches. Databases of different German Medical Councils vary in terms of included data elements, which hamper the pooling of data and led us to limit our analysis to one coverage area. Additionally, malpractice cases can be directly taken to court without prior consultation of a review board, resulting in selection bias in this study.

Conclusions

Pediatric neurosurgery accounted for 1.8% of all pediatric malpractice claims. In 14% of these claims, a medical error was confirmed. The malpractice claim rate thus appears to be lower than expected for a high-risk specialty. In all cases entailing malpractice claims, complications of medical care had occurred. While such adverse events were confirmed in all cases by expert review, a medical error was detected in only one case, and this malpractice claim was thus affirmed. Adverse event rate appears to be a predictor for malpractice claim burden, highlighting the importance of surgical checklists, standard operating procedures, and morbidity and mortality surveillance. The most common scenario in this study leading to a malpractice claim was a CSF diversion procedure with a complicated course, likely reflecting the high volume of hydrocephalus cases encountered in pediatric neurosurgery.

Compliance with ethical standards

Conflict of interest The authors report no conflicts of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. Kessler DP (2011) Evaluating the medical malpractice system and options for reform. J Econ Perspect 25:93–110
2. Mello MM, Chandra A, Gawande AA, Studdert DM (2010) National costs of the medical liability system. Health Aff (Millwood) 29:1569–1577. https://doi.org/10.1377/hlthaff.2009.0807
3. Jena AB, Seabury S, Lakdawalla D, Chandra A (2011) Malpractice risk according to physician specialty. N Engl J Med 365:629–636. https://doi.org/10.1056/NEJMsa1012370
4. Grober ED, Bohnen JMA (2005) Defining medical error. Can J Surg 48:39–44
5. Drake JM, Riva-Cambrin J, Jea A, Auguste K, Tamber M, Lamberti-Pasculli M (2010) Prospective surveillance of complications in a pediatric neurosurgery unit. J Neurosurg Pediatr 5:0–544. doi: https://doi.org/10.3171/2010.1.PEDS09305,
6. Campbell E, Beez T, Todd L (2017) Prospective review of 30-day morbidity and mortality in a paediatric neurosurgical unit. Childs Nerv Syst 33:483–489. https://doi.org/10.1007/s00381-017-3358-5
7. Neervoort FW, Van Ouwerkerk WJR, Folkersma H et al (2010) Surgical morbidity and mortality of pediatric brain tumors: a single center audit. Childs Nerv Syst 26:1583–1592. https://doi.org/10.1007/s00381-010-1086-1
8. Carrier ER, Reschovsky JD, Mello MM, Mayrell RC, Katz D (2010) Physicians' fears of malpractice lawsuits are not assuaged by tort reforms. Health Aff (Millwood) 29:1585–1592. https://doi.org/10.1377/hlthaff.2010.0135

9. Schaffartzik W, Neu J (2007) Injuries in anaesthesia. Results of the Hannover arbitration procedure 2001-2005. Anaesthesist 56:444–448. https://doi.org/10.1007/s00101-007-1170-4
10. Scheppokat KD, Neu J (2007) Medical data and quality management. Dtsch Arztebl Int 104:A-3172
11. Vinz H, Neu J (2009) Out of court settlement of malpractice claims relating to the treatment of fractures in children. Dtsch Arztebl Int 106:491–498. https://doi.org/10.3238/arztebl.2009.0491
12. Pukk-Härenstam K, Ask J, Brommels M et al (2008) Analysis of 23 364 patient-generated, physician-reviewed malpractice claims from a non-tort, blame-free, national patient insurance system: lessons learned from Sweden. Qual Saf Health Care 17:259–263. https://doi.org/10.1136/qshc.2007.022897
13. Bundesärztekammer (2015) Statistische Erhebung der Gutachterkommissionen und Schlichtungsstellen für das Statistikjahr 2015
14. Steiger H-J, Stummer W, Hänggi D (2010) Can systematic analysis of morbidity and mortality reduce complication rates in neurosurgery. Acta Neurochir 152:2013–2019. https://doi.org/10.1007/s00701-010-0822-3
15. Landriel Ibañez FA, Hem S, Ajler P et al A new classification of complications in neurosurgery. World Neurosurg 75:709–15–11. https://doi.org/10.1016/j.wneu.2010.11.010
16. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA, Safe Surgery Saves Lives Study Group (2009) A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 360:491–499. https://doi.org/10.1056/NEJMsa0810119
17. de Vries EN, Prins HA, Rogier M et al (2010) Effect of a comprehensive surgical safety system on patient outcomes. Nejm 363:1928–1937. https://doi.org/10.1016/j.juro.2011.01.004
18. de Vries EN, Eikens-Jansen MP, Hamersma AM, Smorenburg SM, Gouma DJ, Boermeester MA (2011) Prevention of surgical malpractice claims by use of a surgical safety checklist. Ann Surg 253:624–628. https://doi.org/10.1097/SLA.0b013e3182068880
19. Amare G (2012) Reviewing the values of a standard operating procedure. Ethiop J Health Sci 22:205–208
20. Nachtigall I, Tafelski S, Günzel K, Uhrig A, Powollik R, Tamarkin A, Wernecke KD, Spies C (2014) Standard operating procedures for antibiotic therapy and the occurrence of acute kidney injury: a prospective, clinical, non-interventional, observational study. Crit Care 18:R120. https://doi.org/10.1186/cc13918
21. Reason J (1997) Managing the risks of organizational accidents, First Edit. Ashgate Publishing Limited
22. Nahed BV, Babu MA, Smith TR, Heary RF (2012) Malpractice liability and defensive medicine: a national survey of neurosurgeons. PLoS One 7:e39237. https://doi.org/10.1371/journal.pone.0039237
23. Shanafelt TD, Balch CM, Bechamps G, Russell T, Dyrbye L, Satele D, Collicott P, Novotny PJ, Sloan J, Freischlag J (2010) Burnout and medical errors among American surgeons. Ann Surg 251:995–1000. https://doi.org/10.1097/SLA.0b013e3181bfdab3
24. Studdert DM (2005) Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 293:2609–2617. https://doi.org/10.1001/jama.293.21.2609