Adverse event (AE)

- Interventions to Improve Nontechnical Skills in Surgery: A Systematic Review And Meta-Analysis
- Cranial Remolding Orthosis Therapy for Positional Deformational Head Shape Abnormalities: The Parental Perspective
- Optimized stereoelectroencephalography-guided thermocoagulation versus anterior temporal lobectomy in mesial temporal epilepsy: A pilot randomized controlled study
- Responsive Neurostimulation of Thalamic and Nonthalamic Targets in Pediatric and Young Adult Patients With Intractable Epilepsy
- Prospective insights into pediatric neurosurgery: transforming care through adverse event analysis
- Effects of blood pressure lowering in relation to time in acute intracerebral haemorrhage: a pooled analysis of the four INTERACT trials
- Comparison of survival benefit and safety profile between lenvatinib and donafenib as conversion therapy in patients with hepatocellular carcinoma
- First-In-Human Application of Human Umbilical Cord-Derived Extracellular Vesicles in Tethered Spinal Cord Release Surgery

see also Outcome.

Definition

Any untoward event occurring to a patient while on the neurosurgical service. These morbidity & mortality classifications that are so broadly inclusive result in higher complication rates than the narrower M&M criteria for defining complications.

The literature is rife with the terms ‘adverse event’ and ‘complication’, yet no standardized definitions exist for these labels, and there is no consensus as to a grading system or classification schema. Although data from Morbidity and mortality conferences can yield valuable information regarding trends in morbidity, and can potentially uncover areas in need of improvement, this data is typically not systematically collected or stored [1] probably in large part due to concerns about medicolegal ramifications if ever published or analyzed outside of the M&M setting. Subsequently, comparison of complication rates between different hospitals, or even between different time periods within the same institution, is usually not possible [2] [3] [4]

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Classification

Adverse event classification.

Adverse event prevention

Adverse event prevention.

MAUDE

see MAUDE.

Common Terminology Criteria for Adverse Events

Common Terminology Criteria for Adverse Events

Predictability and Avoidability

Houkin et al. classified neurosurgery specific adverse events into 5 types, basing them on relation to the procedure, predictability of the event, and possibility of avoidance [5]. In this schema, type I events are unrelated to the index procedure, i.e., it is a completely incidental event that occurs during the perioperative period. A type II event is related to a procedure but unpredictable, even upon deliberate focus retrospective review. Events that are classified as types III to V are predictable procedural-related events. A type III event is predictable yet unavoidable. A type IV event is avoidable, but not due to carelessness. A type V event is due to obvious human error or carelessness. These events were further classified into one of three categories: neurological events (neurological deficits), local events without neurological deficit (ex: wound infection, leakage of CSF), and systemic events (systemic infection and adverse effects of surgery related drugs). Type III events occurred with the greatest frequency in this report (65.4%), suggesting that most adverse events within neurosurgery are predictable yet unavoidable, although often minor and transient. As mentioned earlier, there is no consensus in the literature whether an unavoidable event should be considered a complication. Identifying such events, which would be considered “expected failures” by Bohnen can however differentiate them from “unexpected failures”, which would be more relevant for discussion in neurosurgical M&Ms.

Epidemiology

Adverse events reportedly occur in 5% to 10% of Healthcare episodes.

A follow-up study examining 8 years of reported surgical adverse events and root causes from US Veterans Health Administration (VHA) medical centers, compared with the previous studies of 2001 to 2006 and 2006 to 2009, and to recommend actions for future prevention of such events.

This quality improvement study described patient safety adverse events and close calls reported from 86 VHA medical centers from the approximately 130 VHA facilities with a surgical program. The surgical procedures and programs vary in size and complexity from small rural centers to large, complex urban facilities. Procedures occurring between January 1, 2010, and December 31, 2017,

were included. Data analysis took place in 2018.

The categories of incorrect procedure types were wrong patient, side, site (including wrong-level spine), procedure, or implant. Events included those in or out of the operating room, adverse events or close calls, surgical specialty, and harm. These results were compared with the previous studies of VHA-reported wrong-site surgery (2001-2006 and 2006-2009).

The review produced 483 reports (277 adverse events and 206 close calls). The rate of in-operating room (in-OR) reported adverse events with harm has continued to trend downward from 1.74 to 0.47 reported adverse events with harm per 100 000 procedures between 2000 and 2017 based on 6 591 986 in-OR procedures. When in-OR events were examined by discipline as a rate, dentistry had 1.54, neurosurgery had 1.53, and ophthalmology had 1.06 reported in-OR adverse events per 10 000 cases. The overall VHA in-OR rate for adverse events during 2010 to 2017 was 0.53 per 10 000 procedures based on 3 234 514 in-OR procedures. The most common root cause for adverse events was related to issues in performing a comprehensive time-out (28.4%). In these cases, the time-out either was conducted incorrectly or was incomplete in some way.

Over the period studied, the VHA identified a decrease in the rate of reported adverse events in the OR associated with harm and continued reporting of adverse event close calls. Organizational efforts continue to examine root cause analysis reports, promulgate lessons learned, and enhance policy to promote a culture and behavior that minimizes events and is transparent in reporting occurrences [6].

Etiology

Not all adverse events are the result of error; they may arise from systemic faults in the delivery of Healthcare. Catastrophic events are not only physically devastating to patients, but they also attract medical liability and increase Healthcare costs. Root cause analysis (RCA) has become a key tool for Healthcare services to understand those adverse events.

It is well recognized that the occurrence rate of adverse events related to surgical procedures is considerably high in neurosurgery compared with other specialties.

Adverse events during diagnostic and therapeutic procedures and medical errors associated with them are an important source of patient morbidity. In an attempt to reduce these, the WHO has proposed a series of measures applicable to medical and surgical patients. Within these last ones is the surgical safety checklist (SSC), a brief questionnaire that does not increase healthcare costs, is accessible to all surgical centres and can be adapted to each specific environment.

Related to surgery and endovascular intervention in neurosurgery

One hundred eighty-two events (28.3%) among 643 neurosurgical interventions over 2 years were recognized as adverse events. Among these 182 adverse events, 165 (90.7%) were closely related to procedures and 125 events (68.7%) were predictable before or during the procedures. However, even when retrospectively reviewed, only 6 (3.3%) of events were deemed avoidable. Of these 6 avoidable events, there were only 2 (1.1%) that were considered to have been caused by error.

Adverse events are not invariably rare in neurosurgery. Most of them are predictable; however, their

avoidance is not necessarily easy. Avoidable adverse events caused by medical errors were observed in only 1.1% of cases [7].

Undesired harmful effect resulting from a medication or other intervention such as surgery.

An adverse effect may be termed a “side effect”, when judged to be secondary to a main or therapeutic effect. If it results from an unsuitable or incorrect dosage or procedure, this is called a medical error and not a complication. Adverse effects are sometimes referred to as “iatrogenic” because they are generated by a physician/treatment. Some adverse effects occur only when starting, increasing or discontinuing a treatment.

Using a drug or other medical intervention which is contraindicated may increase the risk of adverse effects. Adverse effects may cause complications of a disease or procedure and negatively affect its prognosis. They may also lead to non-compliance with a treatment regimen.

The harmful outcome is usually indicated by some result such as morbidity, mortality, alteration in body weight, levels of enzymes, loss of function, or as a pathological change detected at the microscopic, macroscopic or physiological level. It may also be indicated by symptoms reported by a patient. Adverse effects may cause a reversible or irreversible change, including an increase or decrease in the susceptibility of the individual to other chemicals, foods, or procedures, such as drug interactions.

see Side error.

Spine adverse events

see Spine adverse events.

Cardiac complications

Cardiac complications

Complications were defined as any deviation from the normal postoperative course occurring within 30 days of surgery [8].

Kosic reported that between 46% and 65% of complications in hospitals occur during surgery, resulting in significant loss of revenue [9]. According to scientists at the World Health Organization [10], globally, inpatient surgical complications account for 25% of medical errors annually. In the United States, annual costs due to medical errors account for $17 billion USD, with preventable surgical errors costing healthcare organizations nearly $1.5 billion USD annually [11].

Surgical complications

Surgical complications

Preoperative identification of neurosurgery patients with a high risk of in-hospital complications

Extremes of age were associated with readmission; pre-operative steroid use, long operative time, and post-operative length of stay greater than 3 days were associated with reoperation. Surgeons should consider these factors when assessing risk of post-operative complications for benign cranial nerve tumors (BCNTs) [12)].

Advanced age (≥ 60-65 years), elevated C reactive protein level (> 3 mg/L), and high Helsinki ASA score (Class 4) were associated with in-hospital systemic and infectious complications, and a combination of these could identify one-fourth of the patients with postoperative complications. Moreover, this combination of preoperative assessment parameters was significantly associated with increased resource use.

In a first prospective and unselected cohort study of outcome after elective craniotomy, simple preoperative assessments identified patients with a high risk of in-hospital systemic or infectious complications as well as extended resource use. Presented risk assessment methods may be widely applicable, also in low-volume centers, as they are based on composite predictors and outcome events [13)].

Example listing of patients used in the monthly staff discussion of complications in Zurich

(November 2015).

Age

Subtotal

Intervention

Number of surgeries on this patient

Surgery due to complications

Length of stay in hospital after surgery

New neurological deficit

First time epileptic seizure

Recurrent bleeding

Death within 30 days after surgery

Other complication

Urinary tract infection

Number of complications noted at discharge

Place of residence after discharge

Surgeon of first intervention

Skull treatment

External ventricular drain

Shunt obstruction

Shunt obstruction.

Neuropsychiatric adverse events

Neuropsychiatric adverse events have been previously reported following deep brain stimulation for Parkinson's disease. Most cases described have involved DBS of the subthalamic nucleus (STN). Hanna et al. reported a unique case of acute-onset and reversible psychosis, suicidality, and depressive symptoms following DBS of the globus pallidus internus (GPi) and review the relevant literature [14].

Bleeding Complications

Bleeding Complications

Ischemia

Ischemia.

Case series

2016

In 2013, Sarnthein et al., have installed a patient registry focused on cranial neurosurgery. Surgeries are characterized by indication, treatment, location and other specific neurosurgical parameters. Preoperative state and postoperative outcome are recorded prospectively using neurological and sociological scales. Complications are graded by their severity in a therapy-oriented complication score system (Clavien Dindo Grading system, CDG). Results are presented at the monthly clinical staff meeting.

Data acquisition compatible with the clinic workflow permitted to include all eligible patients into the registry. Until December 2015, they have registered 2880 patients that were treated in 3959 surgeries and 8528 consultations. Since the registry is fully operational (August 2014), they have

registered 325 complications on 1341 patient discharge forms (24%). In 64% of these complications, no or only pharmacological treatment was required. At discharge, there was a clear correlation of the severity of the complication and the Karnofsky Performance Status (KPS, ρ = -0.3, slope -6 KPS percentage points per increment of CDG) and the length of stay (ρ = 0.4, slope 1.5 days per increment of CDG).

While the therapy-oriented complication scores correlate reasonably well with outcome and length of stay, they do not account for new deficits that cannot be treated. Outcome grading and complication severity grading thus serve a complimentary purpose. Overall, the registry serves to streamline and to complete information flow in the clinic, to identify complication rates and trends early for the internal quality monitoring and communication with patients. Conversely, the registry influences clinical practice in that it demands rigorous documentation and standard operating procedures [15].

2015

The aim of this article is to investigate the frequency of neurosurgical complications according to Landriel-Ibañez Classification and their impact on patients' health status.

Patients undergoing neurosurgical procedures were enrolled in an observational longitudinal study at Neurological Institute Carlo Besta from January 2012 to September 2013. We evaluated patients' health status before surgery, at discharge, and follow-up with the Karnofsky Performance Status Scale (KPS), whereas the Landriel-Ibañez Classification was used to record complications. Descriptive statistics were performed to illustrate the distribution of sociodemographic and clinical data. We used nonparametric tests to compare KPS scores of patients with different grades of complication and to evaluate the differences between preoperative KPS scores, KPS scores at discharge and follow-up. The effect sizes were also calculated.

They enrolled 1008 patients. They registered 228 complications (139 grade 1 complications, 63 grade 2 complications, 20 grade 3 complications, and 6 grade 4 complications). All patients with a complication showed KPS scores at discharge that were lower than preoperative scores and KPS scores at follow-up greater than scores at discharge. After patients with grade 4 complications, who had the worst outcomes, those with grade 3 complications were the most compromised after surgery whereas patients with grade 2 complications seemed to have a better health status than patients with grade 1 complication.

The study highlights the impact of neurosurgical complications on patients' life and contributes to the debate on how define and classify adverse events because a classification only based on treatment seems to be not adequate [16].

2011

Each grade was classified as surgical complications or medical complication. An observational test of this system was conducted between January 2008 and December 2009 in a cohort of 1190 patients at the Hospital Italiano de Buenos Aires.

Of 167 complications, 129 (10.84%) were classified as surgical, and 38 (3.19%) were classified as medical complications. Grade I (mild) complications accounted for 31.73%, grade II (moderate) complications accounted for 25.74%, and grade III (severe) complications accounted for 34.13%. The overall mortality rate was 1.17%; 0.84% of deaths were directly related to surgical procedures.

Landriel Ibañez et al., present a simple, practical, and easy to reproduce way to report negative outcomes based on the therapy administered to treat a complication. The main advantages of this classification are the ability to compare surgical results among different centers and times, the ability to compare medical and surgical complications, and the ability to perform future meta-analyses [17].

Articles

Postoperative neurosurgery complication in 2017: A new window to take into account surgical ischaemic events [18].

1)
Seely AJE, Ivanovic J, Threader J, et al. Systematic Classification of Morbidity and Mortality After Thoracic Surgery. ATS. 2010;90(3):936-942. doi:10.1016/j.athoracsur.2010.05.014
2)
Landriel Ibañez FA, Hem S, Ajler P, et al. A New Classification of Complications in Neurosurgery. World Neurosurg. 2011;75(5-6):709-715. doi:10.1016/j.wneu.2010.11.010.
3)
Antonacci AC, Lam S, Lavarias V, Homel P, Ph D, Eavey RD. A Morbidity and Mortality Conference-Based Classification System for Adverse Events : Surgical Outcome Analysis : Part I. 2008;177:172-177. doi:10.1016/j.jss.2008.02.054.
4)
Bortz CA, Passias PG, Segreto FA, et al. Grading of Complications After Cervical Deformity-corrective Surgery Are Existing Classification Systems Applicable ? 2018;0(0):1-6.
5)
Houkin K, Baba T, Minamida Y, Nonaka T, Koyanagi I, ISatoshi I. Quantitative analysis of adverse events in neurosurgery. Neurosurgery. 2009;65(3):587-594.
6)
Neily J, Soncrant C, Mills PD, Paull DE, Mazzia L, Young-Xu Y, Nylander W, Lynn MM, Gunnar W. Assessment of Incorrect Surgical Procedures Within and Outside the Operating Room: A Follow-up Study From US Veterans Health Administration Medical Centers. JAMA Netw Open. 2018 Nov 2;1(7):e185147. doi: 10.1001/jamanetworkopen.2018.5147. PubMed PMID: 30646381.
7)
Houkin K, Baba T, Minamida Y, Nonaka T, Koyanagi I, Iiboshi S. Quantitative analysis of adverse events in neurosurgery. Neurosurgery. 2009 Sep;65(3):587-94; discussion 594. doi: 10.1227/01.NEU.0000350860.59902.68. PubMed PMID: 19687705.
8)
Landriel Ibañez FA, Hem S, Ajler P, Vecchi E, Ciraolo C, Baccanelli M, Tramontano R, Knezevich F, Carrizo A. A new classification of complications in neurosurgery. World Neurosurg. 2011 May-Jun;75(5-6):709-15; discussion 604-11. doi: 10.1016/j.wneu.2010.11.010. PubMed PMID: 21704941.
9)
Kosic K 2015 Raise patient care and lower hospital costs by reducing surgical errors Available from https://adora-med.com/blog/raise-patient-care-and-lower-hospital-costs-byreducing-surgical-errors/[Accessed May 2018]
10)
Semel ME, Resch S, Haynes AB et al 2009 Adopting a surgical safety checklist could save money and improve the quality of care in US hospitals Available from: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2009.0709 [Accessed May 2018]
11)
Agency for Healthcare Research and Quality 2008 New AHRQ study finds surgical errors cost nearly $1.5 billion annually Available from https://archive.ahrq.gov/news/newsroom/ press-releases/2008/surgerr.html [Accessed May 2018]
12)

Gupta S, Ahmed AK, Bi WL, Dawood HY, Iorgulescu B, Corrales CE, Dunn IF, Smith TR. Predicting Readmission and Reoperation for Benign Cranial Nerve Neoplasms: a Nationwide Analysis. World Neurosurg. 2018 Sep 24. pii: S1878-8750(18)32127-2. doi: 10.1016/j.wneu.2018.09.081. [Epub ahead of print] PubMed PMID: 30261394.

13) Reponen E, Korja M, Niemi T, Silvasti-Lundell M, Hernesniemi J, Tuominen H. Preoperative identification of neurosurgery patients with a high risk of in-hospital complications: a prospective cohort of 418 consecutive elective craniotomy patients. J Neurosurg. 2015 Sep;123(3):594-604. doi: 10.3171/2014.11.JNS141970. Epub 2015 May 1. PubMed PMID: 25932609.

14) Hanna S, Palmadottir V, Penar PL, Boyd JT. Pallidal stimulation-induced psychosis and suicidality in Parkinson's disease. Clin Park Relat Disord. 2022 Dec 17;8:100175. doi: 10.1016/j.prdoa.2022.100175. PMID: 36594072; PMCID: PMC9803938.

15) Sarnthein J, Stieglitz L, Clavien PA, Regli L. A Patient Registry to Improve Patient Safety: Recording General Neurosurgery Complications. PLoS One. 2016 Sep 26;11(9):e0163154. doi: 10.1371/journal.pone.0163154. eCollection 2016. PubMed PMID: 27669157.

16) Schiavolin S, Broggi M, Acerbi F, Brock S, Schiariti M, Cusin A, Visintini S, Leonardi M, Ferroli P. The Impact of Neurosurgical Complications on Patients' Health Status: A Comparison Between Different Grades of Complications. World Neurosurg. 2015 Jul;84(1):36-40. doi: 10.1016/j.wneu.2015.02.008. Epub 2015 Feb 18. PubMed PMID: 25701767.

17) Landriel Ibañez FA, Hem S, Ajler P, Vecchi E, Ciraolo C, Baccanelli M, Tramontano R, Knezevich F, Carrizo A. A new classification of complications in neurosurgery. World Neurosurg. 2011 May-Jun;75(5-6):709-15; discussion 604-11. doi: 10.1016/j.wneu.2010.11.010. PubMed PMID: 21704941.

18) Bombled C, André A, Jacquens A, Clarençon F, Degos V. Postoperative neurosurgery complication in 2017: A new window to take into account surgical ischaemic events. Anaesth Crit Care Pain Med. 2017 Aug;36(4):203-204. doi: 10.1016/j.accpm.2017.07.001. PubMed PMID: 28780988.

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