Innovation in neurosurgery: Evaluation of neurosurgical innovation, related ethics, and solutions

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Summary

In this Ph.D. thesis, *Innovation in Neurosurgery*, the current status of neurosurgical innovation, related ethics, and potential manners of improvement are discussed. Neurosurgical innovation has brought about a tremendous improvement in outcomes for patients. Nevertheless, many patients still face a poor prognosis when presented with a diagnosis that warrants a neurosurgical intervention. Further improvement of outcomes will require continuous innovation. This thesis shows that manner of innovation in neurosurgery has hardly changed over the past decades, which results in ethical challenges but also offers opportunities.

Part I showed that many neurosurgical innovations and medical devices were not introduced systematically. Furthermore, knowledge of long-term outcomes is generally limited. **Chapter 1** described that the Woven EndoBridge (WEB) device might show promising results, but also that long-term consequences remain unknown and warrant careful use of this device. **Chapter 2** described that retreatment for intracranial outcomes is associated with relatively poor outcomes for all available retreatment modalities. **Chapter 3** showed that endoscopic endonasal meningioma resection is not superior to traditional transcranial microscopic surgery. Most of the identified studies are retrospective in nature, may suffer from selection bias, and are generally of low quality. This lack of high-quality data is typical for most neurosurgical research. In **chapter 4**, the potential of the randomized control trial (RCT) was evaluated for applicability in neurosurgery. **Chapter 4** showed that many RCTs in neurosurgery are of low quality and are poorly registered. RCTs in neurosurgery may be significantly improved through registration of study protocols, complete follow-up, and improved design.

In **part II** specific ethical issues related to neurosurgical innovation were evaluated. **Chapter 5** described the various ethical issues that arise during the introduction of innovative medical devices due to current regulation. These ethical issues are very relevant as neurosurgeons use many medical devices during every neurosurgical procedure. Collaborations between neurosurgeons and medical device manufacturers are an absolute necessity for producing effective new medical devices but may result in conflicts of interest (COI) for the parties involved. There is no law that requires disclosure of COIs to patients. **Chapter 6** described that neurosurgeons have an ethical obligation to provide adequate disclosure to patients regarding potential COIs. This disclosure should be standardized and involve a description of personal experience with the device and financial interests. Medical journals must also continue to demand adequate disclosure of COIs when publishing papers describing experience with medical devices. This disclosure will provide the readership with the ability to appraise the described findings adequately. **Chapter 7** showed that no framework or oversight is in place for ethically sound operative innovation. This chapter described a framework where the severity of oversight for operative innovation increases with

the increased ethical risk a particular surgical innovation may bring. It is suggested that communication among peers and that collaboration between all parties involved will be essential for the ethical introduction of operative procedures. Operative innovation also naturally comes with a learning curve (**chapter 8**). There is currently no clear definition of the learning curve in innovative surgery. A focus on soft skills and communication with patients is necessary for ethically sound handling of the learning curve that comes with surgical innovation. Innovation may also happen in an emergency setting which holds important implications related to informed consent due to limited time to discuss treatment options and potential outcomes (**chapter 9**).

Part III focused on potential ways to improve the ethical situation of innovation in neurosurgery. **Chapter 10** described the feasibility and applicability of the Idea, Development, Exploration, Assessment, Long-term study (IDEAL) Framework for the ethical and systematic introduction of novel surgical procedures for neurosurgery. **Chapter 10** showed that the widely applied WEB device and the endoscopic endonasal approach for anterior skull base meningiomas were not introduced according to the IDEAL Framework. The neurosurgical patient population lends itself poorly for innovation that follows the IDEAL Framework. Low incidence of the disease, interpatient variability, and lack of equipoise make an RCT, the gold standard upheld by the IDEAL Framework, generally hard to conduct. Alternative trial designs and registries could form an alternative and provide relevant answers when feasible. In **chapter 11** the feasibility and ethical justification of the LHS for neurosurgery were discussed. The focus on learning may also place unnecessary ethical risks on patients. Furthermore, the data collection on a large scale may compromise the respect for autonomy and forms a major ethical risk. On the other hand, continuous learning and large-scale data collection may also significantly improve patients' outcomes due to research on a larger scale and improved access to quality data on rare diseases. It will require the collaboration of all parties involved to introduce LHS ethically into neurosurgery.

The **general discussion** described a framework for ethical and systematic neurosurgical innovation based on improved data collection, research quality, and valuation of innovation. Introduction of an electronic medical record system that collects high-quality data will help achieve these goals. Education of the neurosurgical community about research methodology and soft skills may improve research quality. Finally, all parties involved that innovate in systematic and ethical innovation fashion and thereby improve patient outcomes create value, which needs to be adequately rewarded. All these measures will require dedication from all parties involved as well as adequate funding.

In conclusion, ethical and systematic neurosurgical innovation requires dedication from all parties involved and needs to be adequately rewarded. Overall, we owe it to our patients to improve their outcomes through ethical innovation.