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

Muskens, I.S.

Innovation in Neurosurgery

Evaluation of neurosurgical innovation, related ethics, and solutions

Innovation in Neurosurgery

Evaluation of neurosurgical innovation, related ethics, and solutions

Proefschrift

ter verkrijging van
de graad van Doctor aan de Universiteit Leiden,
op gezag van Rector Magnificus prof. mr. C. J. J. M. Stolker,
volgens besluit van het College voor Promoties,
te verdedigen op 1 april, 2021
klokke 16:15 uur

door

Ivo S. Muskens

geboren te Utrecht
in 1991.

Promotor: prof. dr. W.C. Peul

Copromotor: dr. mr. M.L.D. Broekman

Promotiecommissie:

Prof. dr. A.L. Bredenoord	UMC Utrecht
Prof. dr. M.M. Rovers	Radboud MC
Prof. dr. M.C. De Vries	
Prof. dr. M.J.H. Wermer	
Prof. dr. M.J.B. Taphoorn	

Keywords: Innovation, Neurosurgery, Ethics.

Financial support: None.

For my mother

Non viribus aut velocitate aut celeritate corporum res magnae geruntur, sed consilio auctoritate sententia
(It is not by muscle, speed, or physical dexterity that great things are achieved, but by reflection, force of character, and judgement)

Marcus Tulius Cicero (*De Senectute* 17)

Contents

Preface

Neurosurgery has come a long way during the past century as a result of continuous innovation. The quality of care provided by neurosurgeons today is the result of previous innovative neurosurgeons, including pioneers such as Dr. Harvey Cushing and Dr. Gazi Yaşargil, that wanted to provide better outcomes for their patients.[5, 8] There are endless examples of how neurosurgical innovation has resulted in improved patients' outcomes. These include microsurgical aneurysm clipping, awake resections, and epileptic surgery.[2, 3, 10, 13] These innovations are not limited to strictly surgical innovations and also include revolutions in imaging, new pharmaceuticals, radiation, and perioperative care.[1, 12, 14] As a result, neurosurgery in its current form would be unrecognizable to neurosurgeons a hundred years ago. Nevertheless, outcomes of many neurosurgical patients, and neuro-oncological patients in particular, remain poor and warrant further improvement.[11] This improvement will require continuous innovation and improvement of the innovation process.

Despite the need for continuous innovation, the manner of introduction of neurosurgical innovations has hardly changed over the last fifty years. Most neurosurgical innovations are introduced as an alteration of previous procedures or as a broadening of indications. Neurosurgeons may also be faced with a challenging case which forces them to innovate when no other options are available. Neurosurgical innovations may also only become apparent in retrospect. This is in stark contrast with pharmaceuticals, which have to be evaluated according to strict guidelines and receive official approval.[15] Not all neurosurgical innovations have been beneficial to patients and some have turned out to be downright detrimental to patients, such as the frontal lobotomy.[7] The manner in which neurosurgical innovation takes place may, therefore, be improved. In this thesis, several neurosurgical innovations, manners of outcome evaluation, related ethics, and potential manners for improvement of innovation are evaluated.

In **part I**, the current status of neurosurgical innovation will be evaluated. Several recent innovations such as the Woven Endobrigde device[6] (**chapter 1**), retreatment for intracranial aneurysms (**chapter 2**), and endoscopic endonasal meningioma resection (**chapter 3**) will be evaluated. **Chapter 4** will evaluate the applicability of randomized control trials (RCT) in neurosurgery as a manner of ethical innovation. This chapter describes what the advantages and disadvantages are of RCTs in neurosurgery.

Part II will focus on the ethical evaluation of neurosurgical innovation. **Chapter 5** describes the ethics related to oversight and regulation of medical devices introduction. Ethics related to conflicts of interest in neurosurgery are discussed in **chapter 6**. **Chapter 7** describes how procedural innovations may be introduced in an ethical manner. **Chapter 8** reviews the implications of the learning curve that comes with innovative surgery. Finally, respect for autonomy in emergency neurosurgery and

innovation in such a scenario is discussed in **chapter 9**.

Part III focuses on the applicability of available frameworks for neurosurgical innovation. **Chapter 10** describes the evaluation of the Idea, Development, Exploration, Assessment, Long-term study (IDEAL) Framework for neurosurgery and discusses how it may be applied in neurosurgery.[9] **Chapter 11** describes the applicability of the learning health systems (LHS) in neurosurgery for potential improvement of the current situation from both a practical and an ethical perspective.[4] This will provide insight into how neurosurgical innovation may be improved in both an ethical and practical manner and thereby improve patients' outcomes.

Ivo S. Muskens
The Hague, February 2021

References

1. Castillo M (2014) History and evolution of brain tumor imaging: insights through radiology. Radiology 273:S111-125

2. Dwivedi R, Ramanujam B, Chandra PS, Sapra S, Gulati S, Kalaivani M, Garg A, Bal CS, Tripathi M, Dwivedi SN, Sagar R, Sarkar C, Tripathi M (2017) Surgery for Drug-Resistant Epilepsy in Children. N Engl J Med 377:1639-1647

3. Eseonu CI, Rincon-Torroella J, ReFaey K, Lee YM, Nangiana J, Vivas-Buitrago T, Quinones-Hinojosa A (2017) Awake Craniotomy vs Craniotomy Under General Anesthesia for Perirolandic Gliomas: Evaluating Perioperative Complications and Extent of Resection. Neurosurgery 81:481-489

4. Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL (2013) An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics. Hastings Cent Rep Spec No:S16-27

5. Flamm ES (1999) Professor M. Gazi Yasargil: an appreciation by a former apprentice. Neurosurgery 45:1015-1018

6. Klisch J, Sychra V, Strasilla C, Liebig T, Fiorella D (2011) The Woven EndoBridge cerebral aneurysm embolization device (WEB II): initial clinical experience. Neuroradiology 53:599-607

7. Kucharski A (1984) History of frontal lobotomy in the United States, 1935-1955. Neurosurgery 14:765-772

8. Long DM (1999) Harvey Cushing at Johns Hopkins. Neurosurgery 45:983-989

9. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, Nicholl J, Balliol C, Aronson JK, Barkun JS, Blazeby JM, Boutron IC, Campbell WB, Clavien PA, Cook JA, Ergina PL, Feldman LS, Flum DR, Maddern GJ, Nicholl J, Reeves BC, Seiler CM, Strasberg SM, Meakins JL, Ashby D, Black N, Bunker J, Burton M, Campbell M, Chalkidou K, Chalmers I, de Leval M, Deeks J, Ergina PL, Grant A, Gray M, Greenhalgh R, Jenicek M, Kehoe S, Lilford R, Littlejohns P, Loke

Y, Madhock R, McPherson K, Meakins J, Rothwell P, Summerskill B, Taggart D, Tekkis P, Thompson M, Treasure T, Trohler U, Vandenbroucke J (2009) No surgical innovation without evaluation: the IDEAL recommendations. Lancet 374:1105-1112

10. Molyneux AJ, Birks J, Clarke A, Sneade M, Kerr RS (2015) The durability of endovascular coiling versus neurosurgical clipping of ruptured cerebral aneurysms: 18 year follow-up of the UK cohort of the International Subarachnoid Aneurysm Trial (ISAT). Lancet 385:691-697

11. Ostrom QT, Gittleman H, Fulop J, Liu M, Blanda R, Kromer C, Wolinsky Y, Kruchko C, Barnholtz-Sloan JS (2015) CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2008-2012. Neuro-Oncology 17:iv1-iv62

12. Puri N, Puri V, Dellinger RP (2009) History of technology in the intensive care unit. Crit Care Clin 25:185-200, ix

13. Spetzler RF, McDougall CG, Zabramski JM, Albuquerque FC, Hills NK, Russin JJ, Partovi S, Nakaji P, Wallace RC (2015) The Barrow Ruptured Aneurysm Trial: 6-year results. J Neurosurg 123:609-617

14. Stupp R, Mason WP, van den Bent MJ, Weller M, Fisher B, Taphoorn MJ, Belanger K, Brandes AA, Marosi C, Bogdahn U, Curschmann J, Janzer RC, Ludwin SK, Gorlia T, Allgeier A, Lacombe D, Cairncross JG, Eisenhauer E, Mirimanoff RO, European Organisation for R, Treatment of Cancer Brain T, Radiotherapy G, National Cancer Institute of Canada Clinical Trials G (2005) Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. N Engl J Med 352:987-996

15. Voelker R (2011) FDA ponders regulation and innovation. JAMA 305:1523-1524