Technological innovation

- Recent Advances in Microfluidic Impedance Detection: Principle, Design and Applications
- Decoding meningioma prognosis with multi-omics: macrophage diversity, immune-CNV interplay, and novel SPP1-targeted strategies
- Glioportal: a comprehensive transcriptomic resource unveiling ligand-mediated mesenchymal transition in glioblastoma
- Fluorescence-Guided Surgery for Gliomas: Past, Present, and Future
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- Single-cell transcriptome sequencing reveals new epithelial-stromal associated mesenchymal-like subsets in recurrent gliomas
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- Mission and Future of World Federation of Interventional and Therapeutic Neuroradiology (WFITN)

Technological innovation has advanced the efficacy of spine surgery for patients; however, these advances do not consistently translate into clinical effectiveness. Some patients who undergo spine surgery experience continued chronic back pain and other complications that were not present before the procedure. Defects in healthcare value, such as the lack of clinical benefit from spine surgery, are, unfortunately, common, and the US healthcare system spends $1.4 trillion annually on value defects.

Padula et al. in an article, examine how avoidable complications, post-acute healthcare use, revision surgery, and readmissions among spine surgery patients contribute to $67 million of wasteful spending on value defects. Furthermore, they estimated that almost $27 million of these costs could be recuperated simply by redirecting patients to facilities referred to as centers of excellence. In total, quality improvement efforts are costly to implement but may only cost about $36 million to fully correct the $67 million in finances misappropriated to value defects. The objective of this article is to present an approach to eliminate defects in spine surgery, including a center of excellence framework for eliminating defects specific to this group of procedures [1)]

Innovation

Surgical innovation is different from the introduction of novel pharmaceuticals. To help address this, in 2009 the IDEAL Collaboration (Idea, Development, Exploration, Assessment, Long-term follow-up) introduced the five-stage framework for surgical innovation. To evaluate the framework feasibility for novel neurosurgical procedure introduction, two innovative surgical procedures were examined: the endoscopic endonasal approach for skull base meningiomas (EEMS) and the WovenEndobridge (WEB device) for endovascular treatment of intracranial aneurysms.

The published literature on EEMS and WEB devices was systematically reviewed. Identified studies were classified according to the IDEAL framework stage. Next, studies were evaluated for possible categorization according to the IDEAL framework.

Five hundred seventy-six papers describing EEMS were identified of which 26 papers were included. No prospective studies were identified, and no studies reported on ethical approval or patient informed consent for the innovative procedure. Therefore, no clinical studies could be categorized according to the IDEAL Framework. For WEB devices, 6229 articles were screened of which 21 were included. In contrast to EEMS, two studies were categorized as 2a and two as 2b.

The results of this systematic review demonstrate that both EEMS and WEB devices were not introduced according to the (later developed in the case of EEMS) IDEAL framework. Elements of the framework such as informed consent, ethical approval, and rigorous outcomes reporting are important and could serve to improve the quality of neurosurgical research. Alternative study designs and the use of big data could be useful modifications of the IDEAL framework for innovation in neurosurgery [2)].

Although the call for evidence based practice in surgery is increasingly high on the agenda, most surgeons feel that the format of the randomized controlled trial is not suitable for surgery. Innovation in surgery has aspects of, but should be distinguished from both research and clinical care and raises its own ethical challenges.To answer the question “What are the main ethical aspects of surgical innovation?”, Broekman et al systematically searched PubMed and Embase. Papers expressing an opinion, point of view, or position were included, that is, normative ethical papers.

They included 59 studies discussing ethical aspects of surgical innovation. These studies discussed 4 major themes: oversight, informed consent, learning curve, and vulnerable patient groups. Although all papers addressed the ethical challenges raised by surgical innovation, surgeons hold no uniform view of surgical innovation, and there is no agreement on the distinction between innovation and research. Even though most agree to some sort of oversight, they offer different alternatives ranging from the formation of new surgical innovation committees to establishing national registries. Most agree that informed consent is necessary for innovative procedures and that surgeons should be adequately trained to assure their competence to tackle the learning curve problem. All papers agree that in case of vulnerable patients, alternatives must be found for the informed consent procedure.

They suggest that the concept of the learning health care system might provide guidance for thinking about surgical innovation. The underlying rationale of the learning health care system is to improve the quality of health care by embedding research within clinical care. Two aspects of a learning health care system might particularly enrich the necessary future discussion on surgical innovation: integration of research and practice and a moral emphasis on “learning activities.” Future research should evaluate whether the learning health care system and its adjacent moral framework provides ethical guidance for evidence-based surgery [3)].

Deep brain stimulation (DBS) for neuropsychiatric disorders needs to be investigated in proper research trials. However, there are rare circumstances in which DBS could be offered to psychiatric patients as a form of surgical innovation, therefore potentially blurring the lines between these research trials and health care.

Bell et al discuss the conditions under which surgical innovation may be accepted as a practice falling at the frontiers of standard clinical care and research per se. However, recognizing this distinction does not settle all ethical issues.

The article offers ethical guideposts to allow clinicians, surgical teams, institutions, and institutional

review boards to deliberate about some of the fundamental issues that should be considered before surgical innovation with psychiatric DBS is undertaken. They provide key guiding questions to sustain this deliberation. Then the review the normative and empirical literature that exists to guide reflection about the ethics of surgical innovation and psychiatric DBS with respect to general ethical questions pertinent to psychiatric DBS, multidisciplinary team perspectives in psychiatric DBS, mechanisms for oversight in psychiatric DBS, and capacity and consent in psychiatric DBS. The considerations presented here are to recognize the very specific nature of surgical innovation and to ensure that surgical innovation in the context of psychiatric DBS remains a limited, special category of activity that does not replace appropriate surgical research or become the standard of care based on limited evidence [4].

1)
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4)
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