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

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The ethics of the learning curve in innovative surgery - a systematic review

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***Introduction**: Surgical innovation is essential for improving patient outcomes, but it inherently exposes patients to an increased risk of complications while surgeons master both the procedure and the associated peri-operative care. The purpose of this paper is to evaluate and discuss the literature on the ethics of learning curves in innovative surgery. **Methods**: PubMed and Embase were systematically evaluated for ethical discussions about mastering technical competencies, skills assessment, informed consent, and professional requirements for surgical innovation. Possible manners of addressing the learning curve in an ethical fashion were also evaluated. **Results**: The search strategy yielded 1681 articles of which 38 were included. These articles discussed ethics or the definition of "learning curve", how to deal with the learning curve regarding technical skills, mechanisms of oversight, and professional duties. Most studies included in this paper mainly focus on the technical aspects that are inherent to innovative surgical procedures and rarely discuss other professional requirements. Furthermore, there appears to be no consensus on a definition of the learning curve in an innovative setting. **Conclusions**: To address the learning curve associated with surgical innovation in a morally sound way, the literature shows that surgeons need to meet*

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various mainly technical requirements. We suggest that a broader view that incorporates both technical and professional requirements from the surgeon is necessary. Furthermore, we deem it essential to create a "safe" learning culture within innovative medical centers to minimize associated risks for patients.

Introduction

Without innovation throughout the years, surgical care would be nearly unrecognizable compared to the modern and technologically advanced field that is practiced today. In particular, surgical outcomes have been tremendously improved by the introduction of new techniques and procedures such as use of the bipolar cautery, microsurgery, and, more recently, endoscopic surgery.[38, 42, 46] Clearly, just because a new technique is innovative does not mean it is an improvement over standard practice, and many innovations come with ethical challenges. During the fledgling stages of the implementation of an innovative procedure, the associated learning curve presents one such challenge. Almost by definition, many surgeons may be relatively inexperienced with a brand-new procedure, and their patients may face increased risks of complications as a result. How to balance these risks with the potential benefit of better outcomes for future patients warrants further examination.

Learning curves in surgical innovation can broadly be divided into three phases. The first phase is the performance of a surgical procedure for the very first time.[8] In emergency situations, the surgeon might try something entirely new since reasonable alternatives or an established standard of care are unavailable.[12] This is in contrast to elective procedures, in which there is more time to prepare and practice the new procedure. In the elective setting, the ethical questions surrounding learning curves are therefore perhaps even more challenging since there is the possibility of opting for an established procedure rather than the novel one.

The second phase of learning curves is when an innovative procedure seems to be beneficial to the patient, but still needs further evaluation in order to prove its safety and efficacy.[21] A prospective trial with some type of randomization would be the preferred method to evaluate its efficacy and safety. To conduct a valid trial, however, all surgeons would ideally have the same proficiency level, which is not always feasible. For instance, equal proficiency could be achieved via a form of training before surgeons perform the new procedure, but this may not always be logistically possible. The third and final phase occurs when the innovative procedure has been proven to be beneficial and safe but has not been implemented outside of the initial centers.[37]

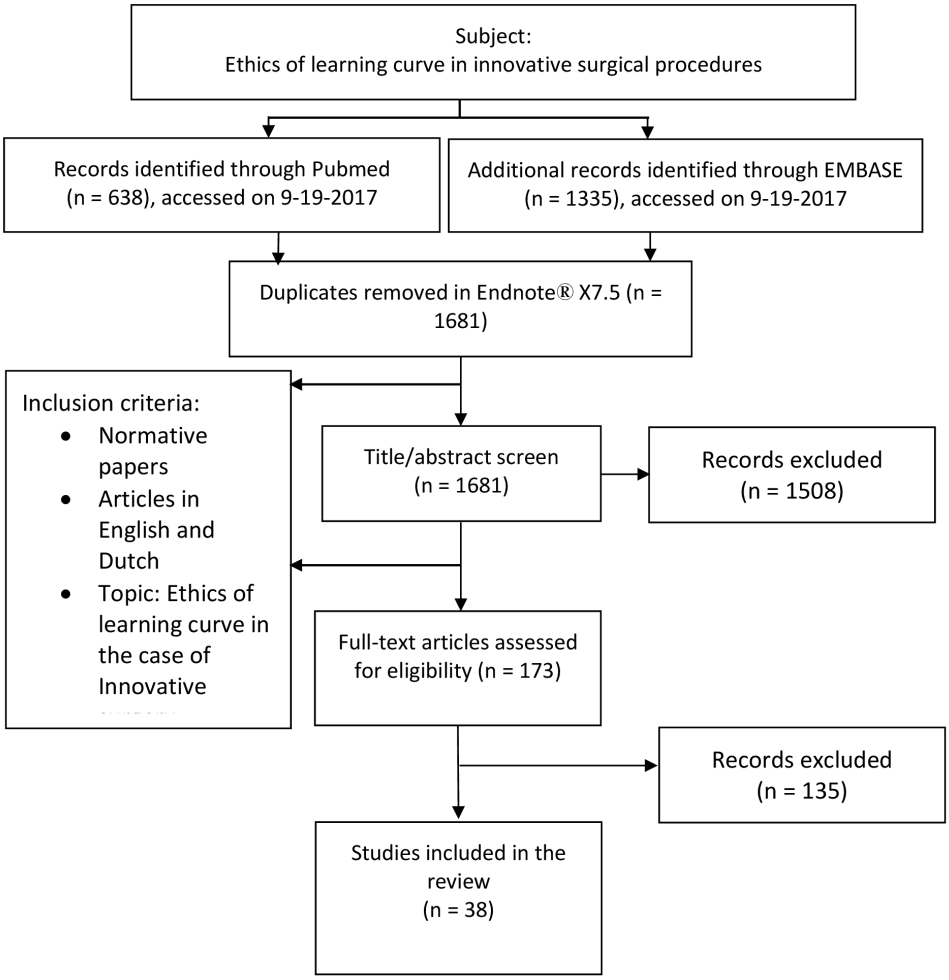
Each stage of innovation comes with unique considerations about the influence of learning curves on patient outcomes. In this systematic review, we evaluate the literature, address the ethical challenges of the learning curve in each phase, and describe methods of evaluation and management of surgeons' progress along learning curves.

Methods

This review sought to answer the following question: "What are the main ethical challenges of the learning curve phenomenon inherent in innovative surgery?"

This study is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[33] PubMed and Embase databases were searched on September 19th 2017. The search strategy was drafted with help from a librarian and is described in **Supplementary table 8.2**. Additional references were identified by hand searching of bibliographies of the retrieved papers. This review is restricted to published literature and language was restricted to English and Dutch. The search was not limited by date of publication.

Figure 8.1: Flowchart



The available title and abstracts of the retrieved studies were screened by two authors, and full texts of the potentially suitable articles were read by two authors. Only studies that provided recommendations, or express an opinion, point of view,

or statement regarding the ethics of learning curve in innovative surgery were included. The resulting flowchart is depicted in **Figure 8.1**. Disagreements were solved by discussion or consultation of the writing team if necessary.

Results

After screening of 1681 titles and abstracts, 38 papers that assessed the learning curve phenomenon were included. These articles discussed ethics or the definition of "learning curve", how to deal with the learning curve regarding technical skills, mechanisms of oversight, and professional duties. The findings are described in the following paragraphs by phase of innovation, starting with the (lack of a) definition of the learning curve.

Learning curves: lack of a clear definition

In the literature, there seems to be no uniform definition of "learning curve" as it applies to innovative procedures.[20, 30, 36] Some have described it as the gradual increase of knowledge and skill that comes with the repeated performance of the innovative procedure and peri-operative patient care.[20, 30, 36] Others define "learning curve" as the gained knowledge and experience that is necessary for successful performance of the surgical procedure.[37]

The influence of learning curves is recognized in several different phases and settings of innovative surgery.[8] Others discussed learning curves only in the setting of performing radically new procedures, such as during the first phase discussed above.[18, 26, 34] Interestingly, only three papers have described how evaluation of learning curves should be incorporated in a research setting, which would apply to the second phase of learning curves.[10, 21, 37] Most authors describe the influence of a learning curve during the third, or implementation phase of the innovative procedure.[3, 4, 23, 32]

In the literature, opinions about learning curves vary greatly. They range from the opinion that they are an unavoidable part of surgical innovation[20, 24] to the view that learning curves are a serious problem that needs to be addressed.[3-5, 14, 18, 20, 23, 31, 32, 47] Some have even described learning curves as a menace to patient safety, although this is not the typical stance taken by authors on this subject.[35]

Managing learning curves

Since innovative surgery is by definition initially performed by surgeons with little to no experience with the procedure in question, the associated learning curve could have unforeseen consequences. For instance, surgeon inexperience could confound and complicate evaluation and interpretation of patient outcomes.[14, 21, 24, 45] Furthermore, in the case of adverse outcomes, it could result in reduced patient trust in the surgeon.[20] Since the scope of the risks of innovative procedures cannot always be fully defined, it is difficult, and in some cases impossible, for the surgeon to completely explain the risks associated with the procedure to the patient.[4] From an educational standpoint, since the attending surgeon in these cases has not completely mastered the procedure, surgical training of residents who are participating may not be completely effective.[18, 30] Approaches for managing these and other aspects of

learning curves in surgical innovation have been described by various authors (**Table 8.1**).[1, 3-5, 8, 11, 13, 14, 18-21, 23, 24, 26, 28-32, 34-37, 44, 45, 47]

Table 8.1: Technical and professional requirements for each phase of innovation

Phase of innovation	*Goal*	*Professional requirements*
Pre-clinical phase	Maximum preparedness for first procedure	• Train through simulation (e.g. cadaveric or computer models etc.) • Evaluate relevant literature and operative videos • Shadow experts
Clinical phase	Independent performance of the procedure	• Involve mentor for guidance • Review video post-operatively • Disclosure of relative inexperience during the informed consent procedure
Post-clinical phase	Maintain and enhance skills	• Participate in mentoring programs • Share experiences and learn from mistakes (e.g. at a conference) • Evaluate personal experience and outcomes with peers • Present personal outcomes in a transparent fashion

Training and technical competency

One of the main professional requirements for surgeons is to be technically capable of performing the procedure. Various methods of training have been proposed in the literature to ensure the technical competency of surgeons performing innovative procedures.[3, 8, 14, 18-20, 26, 31, 32, 34, 37, 45, 47] There are three different time periods when training is appropriate which somewhat correspond to the aforementioned phases of learning curves: the preclinical phase, which involves preparation prior to the procedure, the clinical phase, in which the procedure actually takes place, and the post-clinical phase, in which proficiency of the surgeon is maintained.[37]

Pre-clinical phase

The purpose of the pre-clinical phase of training is to attempt to mitigate the potential negative effects on patient safety of a surgeon's inexperience with a new procedure. In this phase, both cognitive and technical training are essential. In order to achieve adequate preparation, the use of in vivo, in vitro, computer, and cadaver models have been suggested in order to simulate human anatomy during training.[6, 16, 18-20, 32, 34, 37, 41] If possible, the surgeon could also study existing literature and operative videos of similar cases.[26, 36, 37] Finally, gaining first-hand experience from experts, for instance, by visiting an expert center or by doing a fellowship, is suggested to a valuable tool to understand more nuanced aspects of the new procedure.[8, 18, 19, 26, 32, 36]

Clinical phase

The clinical phase of training is comprised of the actual repeated performance of the new procedure, and it begins as soon as the first procedure is done by a surgeon. It has been suggested that, ideally, the first procedure is performed with involvement of a mentor (i.e. a surgeon with greater experience).[18, 19, 26, 43] Although it is not always possible in the case of very new procedures, mentors could answer questions that may arise and offer guidance via back-and-forth communication.[31, 32] Alternatively, some have suggested that reviewing operative videos may be sufficient in certain cases, such as when a new procedure is a slight variation on a familiar one.[18] It has been suggested that an innovative procedure is only cost-effective when carried out with a high case-volume, partially due to the fact that learning curves can influence outcomes.[22] Others have also described possible statistical methods for assessing when a surgical apprentice has gained sufficient experience with innovative procedure.[39] The ultimate goal is for the surgeon to be able to perform the procedure independently, but this could be aided by expert review, when possible, as a final step before full independent performance of the procedure.[8]

Post-clinical phase

After having gained enough experience to successfully perform the new procedure independently, it is vital to maintain and enhance these skills. Some have suggested that this should be carried out in a mentoring program.[18] In any case, it is essential for the surgical community to share gained experience and patient outcomes, perhaps through conferences with this specific aim.[31, 40] By learning from mistakes, identifying problems, and describing risks and limitations of the procedure based on experiences of a broad group of surgeons, outcomes could be improved more quickly and efficiently.[31] This continued improvement and expansion of accumulated knowledge comprises the post-clinical phase of training, with the hope that this knowledge could be used to develop more accurate training modules to assist in the earlier phases of training.[31]

Assessment of the learning curve

There appears to be no standardized method to assess learning curves of innovative procedures. Several ways to monitor learning curves, however, have been described in the literature, including the formation of regulatory entities.[8, 13, 25, 30] Some have suggested that a single expert surgeon may be sufficient for adequate oversight, whereas others have argued that regional, multidisciplinary committees overseeing surgeon progress at multiple institutions would be better.[8, 13, 30, 36] The goals of these committees could be to define standardized requirements for appropriate training, to review fledgling innovative procedures, and to provide accreditation.[8, 36, 44] Others have suggested using the learning curve cumulative simulation, a statistical method aimed at identifying the number of procedures necessary to become competent surgeon.[9, 40]

Additional professional requirements

Physicians are not only expected to be technically skilled experts but also to possess other professional characteristics, such as high standards for ethical conduct. The learning curve associated with innovative surgeries calls for at least

the following two ethical requirements: 1) obtaining adequate informed consent from patients and 2) honest communication of technical competency with peers.[1, 4, 5, 8, 14, 18, 19, 21, 24, 26, 28, 29, 31, 32, 34, 35, 37, 44, 45, 47]

During the informed consent process, transparent communication is essential in order to provide patients with accurate information about the relative inexperience of the surgeon performing the procedure.[1, 4, 5, 14, 20, 24, 26, 28, 29, 32, 35, 47] This information could include a description of the success rate of the surgeon or other quantitative or qualitative forms of describing outcomes, both positive and negative.[1, 18] This disclosure becomes even more important when the surgeon performs the procedure for the first time.[7, 17, 32]

Some view it as an obligation of the surgeon to evaluate their personal outcomes and reflect on their own skill and performance when deciding whether to perform an innovative procedure.[1, 18, 20, 26, 30] This could be aided by keeping detailed records of outcomes with adequate follow-up, which then can be used to improve the training of other surgeons as well as allowing for a more informed self-assessment.[1, 5, 18, 20, 21, 26, 31, 32, 37, 44]

Discussion

In this review, the literature regarding the ethics of the learning curve during surgical innovation was evaluated. Most publications that were included in this synthesis focused on the ethical challenges associated with the technical aspects of a learning curve. The literature does not provide a uniform definition of a surgeon's learning curve for novel procedures, although such a definition would be helpful to facilitate the discussion about said learning curves. We suggest that a definition should incorporate the necessity for the surgeon to master a procedure, which inherently comes with steps that must be taken to progress to the desired skill level. Others have provided a practical alternative definition of the learning curve: a problem that arises when surgeons other than the original innovator start performing the procedure.[4] Whether or not this is the case, the experience of the primary investigator certainly could guide the learning process of other surgeons attempting to master the innovative procedure.[37] One could even argue that the learning curve that attending surgeons face when performing an innovative procedure is similar to residents gaining experience with established procedures, which comes with simulation, mentoring, and supervision. As a result, the learning curves of residents could provide valuable insights that are also applicable to innovative surgery.

There are several essential differences, however, between a resident's learning curve and the learning curve of a fully trained surgeon that performs innovative procedures. First, potential complications and outcomes of the procedures performed by the residents are relatively well-defined and the responsible attending surgeon is well-prepared to take over the procedure if something goes wrong. Furthermore, during the training of residents, the whole surgical team is experienced with the procedure, is familiar with potential complications, and has previously been involved in the training of residents. Conversely, during an innovative procedure, not only the surgeon but also the peri-operative team is inexperienced and unaware of the possible consequences, confounding and impeding the learning process which is more

systematic for residents.

Consequences of learning curves

In the case of performing a radically new procedure, adequate preparation by the whole peri-operative team involved is necessary in order to manage the surgical learning curve. This is especially important since no earlier experience is available to guide decision-making intra- and peri-operatively, which may be considered routine for established procedures. In this scenario, frameworks such as the IDEAL (Idea, Development, Exploration, Assessment, Long-term follow-up) framework may prove helpful, as it describes clear steps that should be taken during development and implementation of innovative procedures.[21] This could be further aided by pre- and post-clinical training, which we deem as imperative to ensure patient safety by minimizing risks. Since each innovative procedure is unique, it requires a carefully tailored training program in order to achieve maximum preparedness. This could be attained through various forms of simulations and/or direct mentoring by an expert surgeon.

Informed consent procedure

The most important aspects of an adequate informed consent procedure with regard to the learning curve are a transparent presentation of the experimental nature of the procedure and the known risks, benefits, and alternatives associated with the procedure.[4] Furthermore, a surgeon should describe his or her relative (in)experience, which we see as an absolute necessity in order to meet the requirements of adequate informed consent: disclosure, decisional capacity, patient understanding of the information, voluntariness, and consent.[47] In reality, however, perhaps out of fear that the disclosure might confuse or distress the patient, present informed consent procedures probably do not meet these criteria.[5] According to a survey among patients and surgeons, honest, descriptive disclosure of the risks and benefits and disclosure of whether the surgeon is performing the procedure for the first time appears to be the best approach.[27]

With regard to preparing for the procedure, most publications focus on meeting technical requirements and regulations for performing the procedure to ensure patient safety. Although some authors do acknowledge that non-technical skills, such as communicative skills, are also important, none provide clear recommendations on how to implement those in the case of innovative surgery. These ”soft skills”, however, may be of key importance when it comes to involving patients in innovation and acquiring adequate informed consent. These skills range from interpersonal skills (e.g. teamwork and communication), cognitive skills (e.g. situational awareness and decision-making) and personal resource skills (e.g. coping with stressful situations).[15] Furthermore, it has been suggested that surgical care is currently too heavily focused on technical skills and achievement and that there should be increased focus on these so-called soft skills, which might better be called professional skills.[2] We believe that this broader view on surgical care is especially important in the case of innovative surgery. Finally, as innovative surgeons will undoubtedly be faced with multiple ethical challenges involving both their professional and personal values, adequate training is necessary to ensure both technical and non-technical competency.

Learning curve assessment

Currently, there is no standard way to assess learning curves of innovative procedures. Even though we think that specific oversight bodies as described above could play a role, an interesting different approach could be critical self-evaluation by the surgeon before, during, and after performing an innovative procedure. This could be done together with an expert or mentor for added insight. A proper understanding of a surgeon's own limitations is also warranted, despite the possibility that this could result in the decision to stop performing the innovative procedure. In this method, characterized by self-reflection, a surgeon's errors and past complications are acknowledged, evaluated, and form a basis for future improvement. One efficient way of achieving this may be through patient databases that help promote adequate follow-up of all outcomes in order to evaluate not only safety but also progression of the surgeon along the learning curve. In the best-case scenario, these databases may even shorten the learning curve and result in prevention of adverse events.

As stated before, transparent communication among performing surgeons is necessary for safe surgical innovation. As outcomes of the procedure may be viewed as a reflection of a surgeon's performance or technical skill, however, many surgeons may be hesitant to openly communicate this information with their peers. Therefore, a key element in improving assessment of the innovative learning curve is the creation of a safe and 'learning' environment in which adverse events can be openly discussed. In this scenario, surgeons may be more willing to share adverse events and negative experiences with their peers, which otherwise may be downplayed or avoided altogether, again shortening the learning curve. Hierarchies within hospitals or academic medical centers may limit communication among peers and should therefore not be influenced by open communication of adverse events in surgical innovation.

Overall, self-reflection, verifiability, and honesty among surgeons form the foundations of this safe environment. As most surgeons follow the mantra "rather mistaken than in doubt" in the real world, however, this may be difficult to achieve.[5] Especially in regard to maintaining patient safety, but also in order to adequately evaluate the learning curve in innovative surgeries, we deem it essential to create a "safe" learning culture within innovative medical centers.

Conclusion

In order to address the learning curve associated with surgical innovation in a morally sound way, the performing surgeon needs to meet various professional requirements. We suggest that a broader view, however, is necessary - one which incorporates a professional attitude from the surgeon while managing and progressing along his or her own learning curve. In the end, it is an ethical necessity to incorporate self-reflection, verifiability, and honesty into a safe culture that promotes continuous learning in an open environment throughout the entire process of surgical innovation.

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Table 8.2: Search strategy

Search engine	*Search syntax*
PubMed	(((Innovative Therapy[MeSH Terms]) OR Invent*[Title/Abstract]) OR Innovat*[Title/Abstract]) AND (((((((Surgical procedures, Operative[MeSH Terms]) OR Surger*[Title/Abstract]) OR Surgical[Title/Abstract]) OR Operative procedur*[Title/Abstract]) OR Operative [Title/Abstract]) OR Operation[Title/Abstract]) OR Operations[Title/Abstract]) AND ((((Ethic*[Title/Abstract]) OR Bioethic*[Title/Abstract]) OR Moral*[Title/Abstract]) OR Ethics[MeSH Terms])
Embase	('experimental therapy'/exp OR 'experimental surgery'/exp OR innovat*:ab,ti OR invent*:ab,ti OR experiment*:ab,ti) AND ('surgery'/exp OR 'surgical technique'/exp OR 'experimental surgery'/exp OR 'surger*':ab,ti 'surgical':ab,ti OR 'operative procedur*':ab,ti OR 'operation':ab,ti OR 'operative':ab,ti OR 'operations':ab,ti) AND ('bioethics'/exp OR 'medical ethics'/exp OR 'ethical theory'/exp OR 'moral*':ab,ti OR 'ethic*':ab,ti OR 'bioethic*':ab,ti)