Protocol: Ethical Aspects of Robot-Assisted Surgery. A systematic Review

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Review Question

Background

Commercial surgical robots have been in clinical use since the mid-1990s (1–4). They are increasingly used in general surgery, pediatric surgery, gynaecology, urology, cardiothoracic surgery or otorhinolaryngology with a special emphasis on minimally invasive surgery (5,6). It can be expected that recent developments in robotics and software (e.g. the use of artificial intelligence and machine learning) will lead to increased development and use of such devices.

The term robotic surgery encompasses any "surgical technology that places a computer-assisted electromechanical device in the path between the surgeon and the patient" (5). The range of devices includes so-called remote telepresence manipulators as well as image-guided robotics in varying degrees of autonomy. Surgical robots focus on aiding and improving human capacities or aim at surpassing limitations in manual treatment. Surgical robotic devices can offer many benefits, such as improving precision, accuracy and outcome for the patient or increasing

control and comfort for the surgeon. At the same time, these technologies raise a variety of ethical challenges that need to be addressed (7–9). These include, among others, the protection of patient well-being and avoidance of harm which may occur through procedural disadvantages such as aseptic problems or lack of haptic feedback (10). Equally noteworthy are questions regarding the distribution of responsibilities among surgeons, devices and manufacturers (10,11). From a patient perspective informed consent and trust in robotic surgery need to be considered (12,13). In addition, questions such as cybersecurity, data protection and privacy which are connected to the digital nature of the devices, may occur and ethical problems surrounding the surgical procedure and the involved stakeholders or the role of manufacturers and designers need to be considered (14,15). These include far-reaching effects such as risks resulting from market monopolization due to the very limited number of providers being able to develop such systems as well as potential ethical responsibilities of the creators of such devices.

Objectives

Given a future perspective bending towards an increased use in more complex scenarios, it is noteworthy that in-depth ethical consideration of the different dimensions of robotic surgical procedures is still rather rare. Clear guidelines and standards with a focus on ethical aspects are largely missing. Arguments and debates often lack interconnectedness. Against this background, this review aims to provide a comprehensive overview of the ethical issues in robotic surgery. We understand a systematic review to be a method that can be adapted (16) to review ethical literature starting from "a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included"(17). Accordingly, the research questions are:

1. What are the ethical issues, discussions, debates and perspectives around current robotic surgery?

2. What ethical issues are related to which technical properties of current devices?

Searches

For a comprehensive search strategy, a preliminary search will be conducted in PROSPERO, PubMed, CINHAL, ProQuest, ScienceDirect, IEEE Xplore, Philosophers' Index and Cochrane Database of Systematic reviews to a) identify overlapping work such as similar systematic reviews, b) to determine potential relevancy of sources and c) to retrieve relevant background literature. The search strategy is, then, developed through the identification of key concepts and MesH terms as well as iterative refinement of free-text search terms.

The following databases will be included in the final search.

- PubMed
- Google Scholar
- EMBASE
- CINHAL
- Philosopers' Index
- IEEE Xplorere
- Web of Science (Core Collection)
- Scopus

In addition, screening of cited references of the included studies will be conducted in Web of Science. The selection of databases is based on the recommendations for a comprehensive search by Bramer et al. (18) which are complemented with specialized databases.

Search strategy

An exemplary search string in PubMed displays as follows:

((robotic surgical procedures[MeSH Terms] OR surgical[tiab] OR surgery[tiab] OR minimally invasive[tiab] OR laparoscopy[tiab] OR micro[tiab]) AND (robot*[tiab] OR robotic[tiab] OR robot assisted[tiab] OR robot-assisted[tiab])) AND (ethics[MeSH Terms] OR ethic*[tiab] OR ethical*[tiab] OR moral*[tiab])

It will be based on the respective MesH Terms (where possible) or any iteration of terms denoting surgical practices together with robotics and ethics. Wildcards will be used to shorten the search string where possible.

Types of studies being included

We will include all types of articles irrespective of data type that include perspectives of experts or stakeholders about ethical dimensions of robotic surgery. Non-empirical studies, books, book chapters, commentaries, letters and editorials, previous reviews, dissertations and conference proceedings will be included.

Condition or domain being studied

The field of interest is defined by two key concepts

Key Concept 1: robotic surgical procedure

Robotic surgery is defined as any surgical intervention that adds a computer-technology enhanced device to the interactions between a surgeon and their patient during a surgical operation (5). Computer-enhanced devices are to be distinguished from mechanical devices and manipulators based on their complexity and digital (electronic) data processing (3). Based on the definition used in current legislation and technical standardization documents, these devices can be described as "actuated mechanisms programmable in two or more axes with a degree of autonomy, moving within its environment, to perform intended tasks"(3,19) for one or more of the specific medical purpose(s) (19). They can also be defined as Robotically Assisted Surgical Equipment, that is, a Medical Electrical Equipment/System that incorporates a programmable actuated mechanism intended to facilitate the placement or manipulation of Robotic Surgical Instruments (17). "The mechanical structures typically include a combination of

surgical instruments and robotic bodies" (19). These can include mono-, micro, or electrosurgical blades, milling or drilling equipment, endoscopic equipment etc. The robot body facilitates placement, and manipulation of surgical instruments (19).

Available devices essentially correspond to autonomy levels 0 and 1 according to Yang et al. (14,20). Devices on level 0 include

> "tele-operated robots or prosthetic devices that respond to and follow the user's command. A surgical robot with motion scaling also fits this category because the output represents the surgeon's desired motion."(14)

Devices on level 1 provide

> "some mechanical guidance or assistance during a task while the human has continuous control of the system. Examples include surgical robots with virtual fixtures (or active constraints)[…]."(14)

We use this subdivision as an important clarification of this key concept and to distinguish factual and practically relevant from rather hypothetical ethical problems that have to be considered at higher levels of autonomy and with which we do not want to be concerned with at this stage of work.

Key Concept 2: ethical issues

There is no generally agreed-upon definition or description of an ethical issue (21). From a very general perspective, the term describes a state in which the moral implications of a given situation cannot be determined without much reservation or no consensus regarding morally adequate conduct can be reached (21,22). This may include unclear harms or risks as well as unclear or undetermined benefits and chances. In addition, ethical issues can occur if commonly accepted moral principles should have been considered in a specific situation, but were not (23). Besides this rather conceptual approach, ethical issues can also be defined based on related concepts indicating the above-named state (21). This

includes, for example, moral conflict, moral roles, moral dilemmas, moral uncertainty or difficult choices as perceived by a person involved or on basis of expert judgment. Finally, emotional and psychological states can be used to determine whether something is an ethical issue (21). This includes for example the concept of moral distress or emotional discomfort which can be grounded in unclear or conflicting moral obligations.

Criteria for exclusion

none

Methods of Review

Title, Abstract and Full-Text Screening

Retrieved records will be managed using Colandr (http://www.colandrapp.com) for title, abstract and full-text screening. All retrieved records will be independently screened in each stage by two authors. In case of conflict, the reviewers will discuss until a consensus is reached. In case no consensus can be reached a third independent reviewer will be consulted. Causes for exclusion will be documented.

Quality Assessment

Two authors will independently assess the quality of all included studies. A modified 6Qs approach as outlined by Mertz et al. (24) will be used.

Data Extraction

Two authors will independently extract study data using standardized extraction forms. These will include:

- Bibliographic details
- Type of article
- Aims
- Device(s) specifically addressed
- Description of devices (i.e. purpose, function etc.)

- Methods
- Normative Background
- Findings
- Key conclusions
- Implications for practice
- Future research directions

Synthesis

A synthesis is conducted using an approach by Strech et al. (23) modified for the analysis of ethical issues specifically connected to certain instances of technology. The aim is to develop a spectrum of ethical issues based on the extracted data to the fullest extent possible as well as to map out connections between specific properties of robotic surgical procedures and certain ethical problems. The data is analysed using a grounded theory approach (25). Extracted data is, first, openly coded by two authors in order to identify, label and build a set of primary concepts that describe the ethical issues and positions surrounding them. The generated codes are discussed within the review team to develop a common understanding of the analysed material and to validate the existing codes. Secondly, categories are built through axial coding to help to determine connections and relations between primary concepts. Finally, categories are selectively integrated into each other and refined through recoding.

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