HIGH SCHOOL EDITION
Journal of Student Research
Volume 11 Issue 4 (2022)

The Impact of Surgical Advancement of Transoral Robotic Surgery on the Safety of Patients

Nikita Rammohan[1]

[1]Thousand Oaks High School, USA

ABSTRACT

Transoral robotic surgery (TORS) is a relatively new technological advancement in the surgical field of otolaryngology. However, there are many concerns of affordability, safety, patient expectations, and consent. This paper examines how the new surgical technology comes with a price many hospitals cannot afford, potentially compromising patient safety to gain a return on their investment. We analyze patient's expectations as a reason for risking their safety because there are certain cosmetic standards patients adhere to and opt for minimally invasive procedures, but put themselves in harm's way. We detail out the topic of informed consent, whereby surgeons cannot perform surgery and limit patients' treatment options. Finally, this paper also examines the role of the FDA in ensuring the safety and efficacy of the TORS technology.

Transoral robotic surgery

Transoral robotic surgery (TORS) is a new technological advancement in the surgical field of otolaryngology. However, there are many concerns of affordability, safety, patient expectations, and consent. New surgical technology comes with a price many hospitals cannot afford, so they consider compromising patient safety to gain a return on their investment.

Patient's expectations also risk their safety because there are certain cosmetic standards patients adhere to and opt for minimally invasive procedures but put themselves in harm's way. They also have certain expectations of the level of skill of the surgeon operating, but the learning curve associated with novel technology can reduce the surgeon's competency during such procedures. When the surgeon does not have enough training or is yet to overcome the learning curve, they cannot outline all of the risks and outcomes, making informed consent nearly impossible to obtain. Without informed consent, surgeons cannot perform surgery, limiting patients' treatment options.

Though TORS is an important surgical advancement that can give patients a more viable treatment option for head and neck injuries, cost, learning curve and patient expectations compromise safety of patients and puts them in danger of robotic malfunctions.

The Cost and Return on Investment for Hospitals

The cost of robotic surgery technology compared to funding of hospitals pushes surgeons to perform more surgeries and overlook any complications to turn a profit. Spillman and Sade (2014), researchers in the Department of Obstetric Oncology and Surgery, argue because robotic equipment is costly, surgeons would need to perform more operations and receive more training. If more focus is put on training for this type of operation in order to gain a return, surgical residents will not have enough training for the more commonly performed traditional procedures, which does not bode well for patients, surgeons, and hospitals. Sullins (2014), professor of philosophy at Sonoma State University, claims due to their need to break even, hospitals under report incidents and malfunctions. Without knowing the true dangers of robotic surgery, patients could opt for this technique and suffer consequences of

hospital's lack of disclosure. According to Angelos (2014), researcher in the Department of Surgery and Surgical Ethics University of Chicago Medicine, new surgical techniques most often require more operative time, resulting in greater loss of profit. If operation times for robotic surgery increase, there is less of an opportunity to fit in more surgeries and the hospital is less likely to gain a return. This economic risk of the technology's use often leads to hospitals overlooking patient safety in an effort to break even.

The Role of the FDA

The Food and Drug Administration (FDA) plays a key role in safety and approval of all TORS technology and equipment. Sullins (2014), argues whenever there is a new study involving surgical technology or debate of safety, the FDA creates a full analysis of both sides. Without this full analysis, many ethical issues could go unnoticed, increasing risk of malfunction as well as increased liability for hospitals and surgeons due to lack of disclosure of complications. According to Ferrarese et al. (2016), researchers at the Department of Clinical Medicine and Surgery at University of Naples, the FDA has a thorough multi-step check before approving new technology. With this, the risk of safety issues and possible technological complications arising, patients being harmed, and liability of hospitals, surgeons, and manufacturers reduces. Angelos (2014), addresses that during robotic-assisted surgeries in which there is a malfunction in robotic equipment, surgeons oftentimes troubleshoot the operation by varying the planned procedure. In 2008, 9 out of 189 procedures resulted in patient injury due to malfunction and surgeon incompetence (Ferrarese et al., 2016). Due to these surgical techniques not having to be approved by the FDA and the separation in training, patients are at risk of unforeseen complications. The FDA's role in the safety of patients is important, but their inability to review surgical innovations gives patients a false understanding of their safety during surgery.

Patients' Expectations of New Techniques

Patients undergoing TORS have certain expectations and understandings of their surgery, causing complications in safety and liability. Sullins (2014), claims patients opt for minimally invasive techniques such as robotic surgery due cosmetic benefits such as scar size. Because patients have certain expectations of the cosmetic results of robotic surgery, they overlook risks disclosed to them and compromise their safety. Sharkey and Sharkey (2013), roboticist and economic sociologist at Chicago Booth University, argue patients are often unaware of the novelty of technology in robotic surgery and their expectations can alter the status of their consent. Without a full understanding of risks of robotic surgery, the patient is at risk for complications that can arise from malfunctions, leaving hospitals, surgeons, and manufacturers liable. According to Sullins (2014), the learning curve involved in innovation results in surgeons not knowing the extent of risks involved in robotic surgery. A lack of knowledge and a patient's expectation that their surgeon knows what they are doing, puts them at risk for undisclosed dangers. Patient's cosmetic wants and lack of disclosure regarding the learning curve make obtaining full informed consent difficult.

Informed Consent

Informed consent plays a crucial, but complicated role in performing TORS. Siqueira-Batista et al. (2016), researchers in bio and medical ethics, argue informed consent is hard to obtain due to privacy and confidentiality issues seen with technology. Many fear that because technology is involved, their privacy is compromised. If patients are not comfortable enough to give informed consent, the surgeon cannot operate, leaving them with a limited number of effective treatments. According to Giannoukas et al. (2010), researchers in surgery and medical ethics, "provision of adequate information, and maintenance of confidentiality are all of paramount importance". In order to obtain informed consent, a surgeon must provide information on the details of surgery,

technology, outcomes and techniques used, while maintaining full confidentiality. Trust is the basis of informed consent and if a surgeon breaks that trust, they, the hospital, and manufacturer are liable. Sullins (2014), claims when a malfunction occurs, surgeons have to be innovative during surgery to fix complications. When they change course of action during surgery, it is hard to know whether or not they have the patient's consent to do so. Without firm informed consent, surgeons and hospitals could be liable for saving the patient from complications caused by the robot. With the status and role of informed consent changing, these aspects must be considered to avoid liability.

Discussion

Though the FDA does thorough multi-step checks of new surgical technology, they do not do enough to address safety concerns involved in innovation mid-surgery in the event of a malfunction. That and the level of understanding patients have as well as their reluctance to consent creates cause for concern. It is now up to the FDA, hospitals, and surgeons to address safety concerns associated with TORS robotic surgery before allowing it to be a viable option for treatment and put the lives of their patients over their own gain.

Conclusion

Ultimately, concerns associated with TORS and safety issues being debated, overshadow advancements in technology for treatment of otolaryngological injuries that would otherwise be considered untreatable in traditional surgery. The issue of safety and liability has become too apparent for hospitals, surgeons, and manufacturers to ignore and the option of TORS should not be available until the debate of safety is further resolved. Hospitals using high cost of robotic technology as an incentive to push surgeons to perform more surgeries they are underprepared for, will continue to endanger the lives of patients.

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