Editorial Commentary

Is robotic-assisted surgery a step in the right direction for routine inguinal hernia repair?

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Until now, the latest technical novelty in inguinal hernia surgery, robotic-assisted repair, has spread without any evidence of its efficacy or safety from randomized clinical trials. In March 2020, however, Prabhu and colleagues (1) from the Cleveland Clinic in the US published the results of what they call a randomized pilot study. The reason for describing it as a "pilot" study was a lack of reliable data for the expected outcome of robotic-assisted surgery compared to conventional laparoscopic inguinal hernia repair. Nevertheless, they designed a multicenter single-blinded protocol conforming to most CONSORT criteria including a total of 102 patients (54 in the conventional laparoscopic arm and 48 in the robotic-assisted arm). Thus, with a strict study design and surgeons experienced in both methods, as applied by the Cleveland group, one can assume that most clinically relevant differences would become manifest in the outcome measures.

Another obvious reason for describing this trial as a pilot study is the difficulty in choosing an appropriate main outcome variable that would reveal a significant and clinically relevant improvement in results. This is underlined in an editorial by Jacob Rosenberg (2) published in this Journal in December 2019, commenting on a Chinese observational comparative study on conventional laparoscopic and robotic-assisted rectal resection surgery (3). No relevant advantage regarding complications or conversion rates could be identified for robotic-assisted surgery in that study. With this in mind, it is relevant to spend a few minutes on recapitulating the history of inguinal hernia surgery research on quality improvement, and subsequent changes in main outcome parameters over the past three decades.

Inguinal hernia may be regarded as a chronic disorder with surgery being the only cure. In the beginning, repeated recurrence was the expected course after surgery.

However, consequent standardization and quality control has reduced the recurrence rates. According to data from the Swedish and Danish national hernia databases the 2-year cumulative recurrence rates were less than 2% (4,5).

Improved surgical quality and individual audit of surgeons, as well as the introduction of reinforcement mesh (i.e., the Lichtenstein technique) contributed to this development.

A consequence of these low recurrence rates was that studies on hernia repair with recurrence as the main outcome variable became difficult to design and carry out. Such studies required the inclusion of thousands of patients to achieve acceptable power. This led to a paradigm shift where randomized trials adopted new main outcome variables. Long-term pain has become one of the most common of these. Depending on the definition of pain and when its estimation is performed, up to 30% of patients claim some degree of pain the past week and more than 5% suffer from pain that interferes with daily activities (6). Several instruments for standardized measurement of pain such as the Inguinal Pain Questionnaire (7) and Carolinas

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Comfort Scale (8) dedicated to inguinal hernia surgery, have been developed. Many studies have been performed using such questionnaires with long-term pain as the main outcome variable.

The introduction of minimally invasive laparoscopic techniques initially showed higher recurrence rates, but more recent studies have shown outcomes similar to those of open repair techniques. More importantly, several randomized studies have shown the laparoscopic techniques totally extraperitoneal (TEP) and transabdominal preperitoneal (TAPP) to have lower risk for long-term pain than the Lichtenstein technique, even when this is performed under local anesthesia (9). Minimizing the use of disposable instruments leads to comparable procedural costs for open and laparoscopic inguinal hernia repair (10).

Following continual quality improvement over three decades, the laparoscopic technique has become the recommended procedure for repair of inguinal hernia based on superior results in three main parameters: recurrence rate, long-term pain and healthcare economy (11). The potential ability to show the superiority of a novel technique using any of these outcome variables is limited. Thus, a new technique such as robot-assisted minimally invasive surgery must show superiority in other outcome variables, or create a new dimension in abdominal wall surgery.

One potential, until now rarely explored, parameter is surgical ergonomics (12). Many superspecialized inguinal hernia surgeons perform the repetitive procedure many times each day several days a week. It is a well-known fact that repetitive dissection using laparoscopic instruments and handling of the camera are ergonomically straining for the surgeon. Despite this, few well-designed studies on the topic have been made. However, several studies with different designs addressing several questions on the subject have been published over the past decade. When sampling the best of these studies, however, the conclusions drawn differ considerably. No significant ergonomic benefit using the robotic-assisted technique was seen in a recent meta-analysis (13), while a clear statement that robotic-assisted surgery is superior ergonomically was made in a review published in a journal profiled in robotic-surgery (14). The authors of the latter article deemed meta-analyses inappropriate due to the degree of heterogeneity in the studies available. A weakness of many of these studies is that complaints arising from the hands and fingers are not as easily assessed by some evaluation tools. Training programs focused on ergonomics in the robotic environment and ergonomically orientated technique developments were pointed out as key factors for improvement in the review (14). This was also stressed in a questionnaire study addressing surgeons that use robotic techniques, where 56% claimed they had problems due to poor ergonomics (15). There are few well-designed studies assessing the physiologic consequences of poor ergonomics. Lee *et al*. published a study using electromyography for assessment of physical workload, and the NASA Task Load Index Scale (NASA-TLX) instrument for assessment of mental workload (16) [as used by Prabhu (1)]. That study revealed a relationship between the degree of surgeons' expertise and positive experience of improved ergonomics. This suggests that high-volume surgeons experience greater ergonomic advantage using robotics compared to that seen in Prabhu's study (1) where a volume of only 25 procedures was required for inclusion.

Improved surgical ergonomics has been the main argument for investment in expensive robotic equipment. For this reason, the results of the first randomized trial comparing robotic and laparoscopic repair of inguinal hernia (1) are disappointing. No ergonomic benefits were observed when using the Rapid Upper Limb Assessment (RULA) tool. Rather the opposite; the authors detected an increase in mental workload using the NASA-TLX scale. Increased mental workload using the same instrument, has been shown to influence the quality of surgery (17) and hamper the transfer of simulator-acquired skills to clinical practice (18).

The obvious need for high surgical volumes introduces another important conflict of ambitions. Inguinal hernia surgery is a major component in the surgical training of residents, and sufficient skill in inguinal hernia surgery is mandatory for all surgeons involved in emergency care. This conflict in ambitions already became apparent when conventional laparoscopy was introduced at the expense of open inguinal hernia repair. However, laparoscopy has become standard for surgery on almost all organ systems, and this has facilitated the establishment of laparoscopic inguinal hernia surgery.

On the other hand, the relatively uncomplicated inguinal hernia repair procedure may serve as an excellent training ground for abdominal wall surgeons to acquire reasonable skills in robotic-assisted surgery. In the future, robotic-assisted surgery may well be a useful tool adding complementary dimensions when performing complicated abdominal wall reconstructive procedures and surgery for chronic pain. This may well include recurrent inguinal hernia when performing re-do procedures after a previous posterior repair. In such cases the robot may provide new

technical/surgical opportunities as further magnification, more versatile instruments and the possibility for a more exact dissection compared to the classic laparoscopic technique.

If it is to survive, surgical healthcare economy needs high volumes, and this in turn could warrant costly investments in robotic equipment. Prabhu (1) verified the demands on resources that robotic surgery had already been observed i.e., increased duration of surgery and increased device-associated procedure costs (19,20). One of these studies (19) pointed out the decrease in duration of postoperative care (22 min less) in the robotic group due to less pain. This advantage, however, was not reproduced in the randomized trial by Prabhu (1).

From the point of view of surgical ergonomics and mental workload/frustration, the study by Prabhu and colleagues (1) is welcome. Until now, published studies comparing laparoscopic and robotic-assisted minimally invasive inguinal hernia surgery have come to questionable conclusions based on discrete poorly controlled advantages using the robotic technique. Usually no data on the impact on healthcare economy are provided; information that is most important for decisionmakers. In a very recent American multicenter trial by LeBlanc and colleagues, they were unable to show any differences in relevant outcomes when comparing open, laparoscopic and robotic inguinal hernia repair (21). In contrast to Prabhu's pilot randomized study, LeBlanc describes their failure to perform a randomized trial. They found that the increase in cost per procedure does not provide any advantage regarding surgical ergonomics, rather an increase in mental workload. Even if a hospital owns a robot and there is time available in the operation program, the cost of primary inguinal hernia repair is higher when using the robot compared to conventional laparoscopic repair. It is striking that the first randomized trial to be published (Prabhu *et al*.) appears when the new technique has already spread widely throughout general surgical practice. There are usually many explanations and arguments for not delaying the introduction of a new technique before randomized trials have shown its worth. In this respect the review article by Wilson published 2006 in the *BMJ* is highly relevant (22). A common quote is that many surgeons consider it unethical to perform a randomized trial comparing a new technique with older established methods. Afterthought, however, may arise years later when it is seen that resources consumed have not given the returns hoped for in terms of value to the healthcare system.

With our current knowledge and the robotic equipment available today, it seems unlikely that a new randomized trial will be able to show superiority in favor of the robotic-assisted technique in routine inguinal hernia repair. Any supposed niche for robotic-assisted inguinal hernia surgery must be motivated by other considerations that compensate for the increased demand on resources. It is possible that surgeons at hernia repair centers, focused on optimal ergonomics in a high production environment, may appreciate the benefits of the robotic-assisted technique for inguinal hernia repair. As for many of the surgical procedures where robotic-assisted techniques are used, the study by Prabhu (1) points out surgical ergonomics and mental workload/frustration as key parameters for improvement.

Future technical developments leading to improved less expensive robots may well rub the balance between costs and gains in robotic-assisted inguinal hernia surgery.

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