Are there Safety Concerns with Robotic Surgery in Pediatrics?

There are certainly safety concerns with robotic surgery in pediatrics, just as there are safety concerns with open, laparoscopic and endoscopic surgery during the initial learning curve and mastery of the system. In addition, the popular media have given significant press to potential dangers with the robotic surgical system so a transparent discussion of potential risks is important to maintain our credibility.1

Evaluation of a new technology must involve an evaluation of the technology and the person using the new technology. The surgical robot essentially represents a new interface between the surgeon and the patient rather than a completely new form of operating. The U.S. Food and Drug Administration (FDA) approved the da Vinci Surgical System® in 2000 and urologists have established themselves as the principal users of this technology. Pediatric urologists immediately followed their adult colleagues in the use of the robot with several advantages to the technology including the ability to perform intricate suturing with a reduced learning curve. There are specific safety concerns with the application of the generic robotic system to the pediatric population. 1) The robot should be positioned so that the long arms do not come into contact with the patient’s body or face during the procedure, leading to mechanical trauma. 2) Less intra-abdominal working space combined with full-length adult instruments makes it challenging to judge the proper depth for the initial placement of the robotic arms to avoid injury to surrounding organs. 3) Learning proper patient positioning and padding is necessary to maximize surgical exposure and to prevent pressure injuries (see figure). 4) A lack of haptic feedback can lead to rougher tissue handling and ischemic damage to delicate structures. 5) The long working distance from the instrument’s articulation joint poses a risk to surrounding organs (eg iliac vessel and renal hilum) and the utmost diligence is required to avoid these injuries.

While these issues have not been formally addressed in the literature, we believe that they are worthy of consideration as potential risk factors for complications. We looked at a multicenter study to learn more about these complications of pediatric robotic surgery. In a recent series of 860 robotic surgeries conversion to open surgery occurred in 1.6% of patients.2

There are also operator independent concerns with the robot. Intuitive Surgical® addressed a problem with insulation in the monopolar scissors and there was a recent recall for needle drivers due to manufacturing issues.

In a recent analysis of FDA data Friedman et al reported on 565 robotic equipment failures reported to the FDA, although there were no reports that these failures led to adverse clinical outcomes.3 Despite these risks robotic surgery has become increasingly popular as a means to bridge the gap between open and endoscopic surgery.

In terms of patient outcomes the robot provides certain enticements. Multiple studies have demonstrated decreased blood loss, narcotic requirement and length of hospitalization with robotic compared to open procedures. In addition, many patients appear to appreciate the psychological benefit of knowing that their care involves robotics and the newest technology available. There are also benefits for families in that parents require less time off from work and the children are more comfortable postoperatively.

How then do we minimize the risk of complications unique to robotic surgery? An analogy to safety improvements in the airline industry is often presented. Checklists of equipment and procedural steps are useful, but the analogy comparing surgeons to pilots is not perfect. If a pilot flies a new plane and has difficulty with landing, it would be unfair to blame the plane’s yoke rather than the pilot’s training and skill. Similarly, a complication that occurs as a result of robotic surgery may be more applicable to the surgeon than the robot.

Appropriate training is the key to success. The learning curve is steep and requires training that many urologists in practice did not receive during residency. Training could be accomplished in various ways such as continuing medical education courses, workshops, one-on-one teaching courses, proctored training or simulation with a wet lab and mentorship. Learning is a gradual process that requires dedicated, passionate investment from the surgeon and organization. It is understood that procedures will take more time during the initial learning curve, but safe execution is more important than case length and the time requirement of robotic surgery will approach that of open surgery. Completion of appropriate training could one day lead to professional certification that may be required by hospitals to obtain robotic operating privileges.

We have several suggestions to improve the safety of robotics in the pediatric population. Safety starts in the clinic with thoughtful case selection. Patients should be counseled that conversion to open surgery is a possibility, and there should be no hesitation to convert to open surgery for safety concerns. Less complicated cases should be mastered before proceeding to more complex cases. The operating room should have a standard setup for pediatric patients with a dedicated team for every case. The dual console allows for safer training since the attending can see exactly what the resident sees while operating at all times. Residents should learn the procedures in a graduated fashion.

In the hands of a well trained and experienced robotic surgeon, there are no additional concerns about safety with only the introduction of the robotic interface. In fact, Orvieto et al recently reported on the safety of multiple pediatric robotic procedures with outcomes equivalent to those of open surgery.4

Much as the urology community had to integrate laparoscopy into practice a generation ago, robotic surgery requires another paradigm shift. We believe that embracing new technology and expanding its use benefit surgeon and patient by creating opportunities for innovation. Furthermore, we should insist on continuing to use this technology for many of its more radical promises. Once we fully know that the robot is safe we can consider true telesurgery where a surgeon can provide care in remote locations or in parts of the world where there are no experts available. What is radical and new one day may become standard of care within a just a few years.◆