Commonwealth of Massachusetts
Board of Registration in Medicine

Quality and Patient Safety Division

ADVISORY ON ROBOT-ASSISTED SURGERY

March 2013

Background

Over the last two years, the Quality and Patient Safety Division (QPSD) has received an increasing number of Safety and Quality Review (SQR) reports of patient complications associated with robot-assisted surgery. This advisory is issued to draw providers' attention to some of the potential issues involving robot-assisted surgery, to share some of the lessons learned by the reporting health care facilities, and to support health care facilities in the review and development of their systems for safe robotic-surgical practice. While some references are provided, this advisory does not include a comprehensive review of the literature; nor is it intended to provide specific recommendations for evidence-based practice.

Overview

Robot-assisted surgery has increased dramatically since its introduction in the mid-2000s. A majority of radical prostatectomies and increasing percentages of other urologic, gynecologic and colorectal surgeries are now performed using robots. While there are numerous single institution, procedure-specific studies describing robotic-surgical outcomes, large-scale, high quality, prospective studies of the risks and benefits of robotic surgery as compared to laparoscopic and open procedures have not been carried out.[1,2]

Robot-assisted surgeries have a number of technical advantages, such as an improved field of view and articulated instruments, but like any surgical procedure, they carry risks of complications and poor outcomes. Clinical studies and reviews of training guidelines discuss variable learning curves for surgeons, the need for significant mentoring, and greater risks associated with pursuing lengthier and more complex cases. [3,4,5]

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[1] ECRI Institute. Da Vinci Decisions. Health Devices 2013. Available at: https://www.**ecri**.org/. Accessed 3/04/13.

[2] Tracking the rise of robotic surgery for prostate cancer. NCI Cancer Bulletin 2011;8(16). Available at: http://www.cancer.gov/ncicancerbulletin/080911/page4. Accessed 3/04/13.

[3] Ghazi, A et al. Extraperitoneal robot-assisted radical prostatectomy using the standardized Martin classification. Urology 2013;81:324-333.

[4] Buchs NC, et al. Perioperative risk assessment in robotic general surgery. Arch Surg 2012;147(8):701-708.

[5] Zorn KC, et al. Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. J of Urol 2009;182:1126-32.

Case Examples

Case One: The patient underwent elective robot-assisted laparoscopic hysterectomy and bilateral salpingo-oophorectomy, performed by two attending surgeons. After removal of the uterus, excessive bleeding was noted. Intraoperative colorectal and urologic consults found a significant length of the sigmoid colon mesentery damaged from incorrect tenaculum placement, left ureter dissection and cautery injury along the pelvic sidewall. The patient required laparotomy, sigmoid resection, diversion ileostomy and bilateral ureteral stents.

Lessons Learned: The health care facility's internal review found that the injury was caused by a failure of the two attending surgeons to coordinate their actions and to confirm precise placement of the tenaculum prior to applying traction, and concluded that an alternative approach of laparotomy would have avoided the bowel injury. The complexity of the case and length of time of the surgery (5 hours) were considered to be a factor. The surgeons were directed in the future to carefully consider and match the pathology and anatomy, optimal operative approach and the technical skills of the team. The surgeons changed their practice patterns by limiting use of the robot to less complex procedures.

Case Two: A morbidly obese patient underwent a robot-assisted hysterectomy. Dense abdominal adhesions and other factors led to eventual conversion to laparoscopic and then open laparotomy. The patient spent 210 minutes in deep Trendelenburg prior to the open procedure. On the first postoperative day, she complained of bilateral arm pain, weakness and numbness, and was determined to have brachial plexus injuries.

Lessons Learned: The long operative time, steep Trendelenburg and patient obesity were felt to be factors contributing to the brachial plexus injuries. Following review of this case, the surgeon eliminated the use of shoulder braces in favor of alternative methods of restraint, and now uses a shallower degree of Trendelenburg to reduce pressure on the patients' shoulders. The surgical team now pays careful attention to the length of operative time and there is repositioning as needed, to prevent injuries due to positioning and restraints.

Case Three: The patient underwent robotic proctosigmoidectomy for refractory ulcerative colitis. Resected rectal tissue was inadvertently left in the abdomen and was not detected during visual sweep using the robot before closure. The surgeon realized the error later in day and the asymptomatic patient underwent successful corrective surgery the next day.

Lessons Learned: Review findings involved the fact that this was new technology being applied to a complex colorectal surgery. The surgeon was still refining the surgical process, and the use of a robot throughout a two-part procedure greatly increased the complexity, with multiple demands for attention upon the surgeon. A new role, "Robotic Resource RN," was implemented to improve pre- and perioperative communication within surgical team. The surgeon now uses a laparoscope for sweeping the abdomen rather than the robotic device.

Areas for Health Care Facility Systems Review

The adoption and evolution of new technology obligates health care facilities to re-evaluate their credentialing, and other quality and patient safety systems to ensure that they are adequate and current. The areas reviewed below provide some recommendations and references as starting points for internal discussions and review.

Training, proctoring, and assessment of proficiency.

- Guidelines set forth by SAGES-MIRA Robotic Surgery Consensus Group (Society of Gastrointestinal and Endoscopic Surgeons and the Minimally Invasive Robotic Association) and the American Urological Association (AUA) may be helpful in establishing robotic surgery credentialing protocols.[6,7] For example, AUA's credentialing Standard Operating Practices (SOP) include privileges for open procedure, on-line and instructor training, case observation, use of proctors, assistance by another urologist until comfortable with procedure, ongoing review of surgical outcomes and continuing CME.[7]

- Credentialing should be based on proven competency and proficiency, rather than the completion of a set number of cases. While recommended minimum numbers of cases vary in the literature, proficiency for an individual surgeon will depend on innate skill, previous experience, frequency of cases, and peer supported training systems.[1] Some health care facilities have established special committees to oversee robotic surgery privileging and are paying careful attention to ongoing competency assessment as a surgeon advances to more complex cases.

Patient selection and risk assessment.

- Patient selection and pre-operative risk assessment are complicated by evolving surgical skills and uses of robotic technology. Careful preoperative assessment of patient risk is critical for preventing perioperative complications.[8] Both the patient's comorbidities and the complexity of the robotic surgical case are important risk factors to be considered.[4, 6]

- Establishment of a multi-disciplinary special committee to monitor evolving surgical practices and outcomes, as noted for credentialing, may also be useful to develop "robotic surgery-specific" pre-operative assessment guidelines and protocols.

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[6] SAGES-MIRA Robotic Surgery Consensus Group. A Consensus Document on Robotic Surgery, Position Papers/Statements, 2007. Available at: http://www.sages.org/publication/id/ROBOT/. Accessed 3/04/13.

[7] American Urological Association. Standard Operating Practices (SOP) for urologic robotic surgery. Available at: http://www.auanet.org/content/residency/resident-education/SOP-Urologic-Robotic-Surgery.pdf Accessed 3/04/13.

[8] Massachusetts Board of Registration in Medicine, Quality and Patient Safety Division Advisory: Preoperative Assessment and Coordination of Care, 2013. Available at: http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/coordination-care.pdf. Accessed 3/04/13.

- Careful attention should be paid to the influences of direct to patient marketing and other factors that may introduce different dynamics into the patient selection process.[9,10]

Informed decision making.

- Risks for robot-assisted surgery should be thoroughly explained in the context of the patient's clinical condition, surgical options, pathology and anatomy. Patients should be advised on the experience of the surgeon in performing the recommended robotic procedure.

- Information on health care facility websites should be reviewed for completeness of information regarding both the risks and benefits of robotic surgery.[11,12]

Perioperative considerations.

- Proper patient positioning and restraint during surgery may avoid complications, such as brachial plexus injury, particularly in prolonged cases. A recommendation for reassessment of the need for prolonged deep Trendelenburg in all robotic cases has been made in the literature.[13]

- As with any medical device, health care facilities must assure careful oversight and maintenance of robotic equipment, and should carefully monitor the literature and other sources for any potential safety issues.[14,15]

- Adequate and ongoing training in robotic surgery for surgical support staff should be commensurate with advancing complexities of the surgery being performed. Health care facilities might consider the addition of personnel such as the "Robotic Resource RN" to improve perioperative communication.

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[9] Mirkin, JN et al. Direct-to-consumer internet promotion of robotic prostatectomy exhibits varying quality of information. Health Affairs 2012;31(4):760-769.

[10] Wright, JD et al. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. JAMA 2013;309(7):689-698.

[11] Jin LX, et al. Robotic surgery claims on United States hospital websites. J for Healthcare Quality 2011;33(6):48-52.

[12] Schiavone MB, et al. The commercialization of robotic surgery: unsubstantiated marketing of gynecologic surgery by hospitals. Am J Ob Gyn 2012;207:174.e1-7.

[13] Ghomi A, et al. Trendelenburg position in gynecologic robot-assisted surgery. J of Min Invasive Gyn 2012;19(4):485-89.

[14] Chen CC, et al. Malfunction of the daVinci robotic system in urology. Int J Urol 2012;19(8):736-40.

[15] Mues AC, et al. Robotic instrumentation failure: initial report of a potential source of patient injury. Urology 2011;77(1): 104-7.

- Education and guidelines to reinforce post-operative team awareness of potential complications, such as perforation, is recommended, particularly when robotic procedures are new to the facility or a surgical-medical unit.

Conclusion

Health care facilities should utilize a "systems approach," as they move into the emerging and expanding field of robot-assisted surgery. Developing innovative and adaptive credentialing, pre-operative assessment and other processes that reflect the evolving nature of the field will help to ensure adequate patient protection. As with any new technology, care should be taken that protocols are in place to ensure appropriate patient selection and the full explanation of risks and benefits for all surgical options. Education and guidelines for the perioperative and post-operative teams, particularly those personnel or units new to robotic surgery, are important steps for assuring that these surgeries are performed safely, and that there is prompt recognition and treatment of any patient complications.

If you have any questions about this advisory, please contact the QPSD at *jennifer.sadowski@state.ma.us* or *781 876-8296.*

Additional References

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