

Robotic prostatectomy: The new standard of care or a marketing success?

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Restlessness and discontent are the first necessities of progress.
(Thomas Edison, 1847-1931)

Technology has been the driving force behind advances in the past century, during which time unheralded progress has been made, from space travel to daily living to surgery. The establishment of minimally invasive surgery (MIS) and robotic surgery has challenged traditional approaches and dramatically changed the way patients view surgery. Not since the invention of the resectoscope by Stern and McCarthy in 1931 have urologists seen such a transformation in the way they perform surgery.

In 2009, a patient with suspected localized prostate cancer is faced with a myriad of treatment options, but few randomized trials demonstrate the superiority of any one particular choice over another, with the exception of open radical prostatectomy (ORP) over watchful waiting.¹ Despite the proven benefits of ORP, this treatment is associated with significant morbidity, which has led urologists to modify their techniques to minimize the impact on their patients' quality of life while maintaining excellent cancer-control rates.² This modification has led to a search for less invasive techniques with decreased blood loss, less perioperative pain, shorter hospital stay and quicker return to normal activity.

Over the past 10 years, MIS techniques have been developed to provide a less invasive approach to treat prostate cancer.^{3,4} Through the experience of skilled surgeons, we have been able to identify the benefits of laparoscopic radical prostatectomy. However, the learning curve was often long and painstaking, which made the transferability of the skill set difficult.⁵ Recognizing the benefits of the laparoscopic radical prostatectomy and its surgical challenges, urologists have identified the possible use of a surgical robot to help in this technically demanding procedure.

The first robotic-assisted laparoscopic radical prostatectomy (RALP) with the daVinci Surgical System® (Intuitive Surgical, Inc., Sunnyvale, CA) was performed by Binder and colleagues in 2000.⁶ The assistance of robotic technology was introduced to overcome the challenging limitations of laparoscopic radical prostatectomy and to allow the surgeon a smooth transition from ORP to MIS. The

benefits of robotic technology include magnified, high-definition 3D vision, wristed instrumentation with 7 degrees of freedom of motion, lack of tremor and comfortable surgeon ergonomics. With this instrument there is significant potential to provide the surgeon with the ability to dissect and reconstruct in very challenging locations, such as the pelvis.

As of October 2008, there are 1032 da Vinci robotic systems in service worldwide, with 776 (75%) located in the United States, 171 (17%) in Europe and 85 (8%) in remaining areas.⁷ Canada is one of the "remaining areas," with 9 operational units throughout the country. Since the acquisition of the 2 daVinci S systems in September 2007 in the Capital Health Region (Edmonton, AB), until March 2009, 481 patients underwent radical prostatectomy with 371 (77%) selecting RALP.⁷

Over the past 25 years, ORP has evolved into one of the most common urological procedures, with a recognized but acceptable complication rate and excellent cancer-control data. Using the anatomical depiction of nerve-sparing radical prostatectomy by Walsh and colleagues,^{8,9} we can determine that the goals of surgery for men with prostate cancer have been to improve the triad of outcomes: surgical margins, erectile function and urinary continence. Has RALP met the standards of ORP?

Most of the published data on RALP originates from 4 main academic sites: University of Central Florida (Orlando, FL),¹⁰ Henry Ford Hospital (Detroit, MI),¹¹ University of California Irvine (Irvine, CA)¹² and JW Goethe University (Frankfurt, Germany).¹³ With a combined reported series of over 5000 patients, these centres have published margin status, continence data and erectile function results comparable to large ORP series. In addition, RALP series have demonstrated decreased blood loss and transfusion rates, decreased hospital stay and decreased postoperative narcotic use compared to ORP.¹⁴ The limitations of current RALP published series include short-term follow-up of biochemical failure rates and a lack of consistent reporting of continence and sexual functional data.

In contrast to the reports of the major centres performing RALP, Hu and colleagues¹⁵ compared utilization, complication and salvage rates for minimally invasive radical

prostatectomy against those of ORP in a cohort of men from the United States Medicare and Medicaid Services nationwide database. The authors reported an advantage for the MIS approach in terms of lower perioperative complications and shorter mean length of hospital stay, but these results also show significantly higher rates of anastomotic stricture and more than 3 times the likelihood of requiring salvage therapy within 6 months of their surgery.

Significant limitations of this study have been identified, which brings into question the interpretation of the usage of this retrospective database for an accurate assessment of outcomes post-RALP. Issues include the lack of stratification of patients in regard to preoperative risk characteristics, the inability to separate procedures on the basis of robotic-assisted versus pure laparoscopic procedures, and the inability to identify indications for institution of salvage therapy.¹⁶ It is possible that the high complication and salvage rates reported in the combined MIS group may represent the recent adoption of new techniques and the learning curve with higher initial complications, and may not be representative of experienced surgeons in high-volume centres.¹⁷

Similar to reports with ORP, many smaller initial series of RALP emphasize the importance of the significant surgical learning curve required to improve outcomes and decrease complications. As demonstrated by several authors, appropriate patient selection, high case volume and surgeon experience contribute to the differences in functional and oncological outcomes after prostate cancer surgery.^{18,19}

Prostate cancer patients are well-educated and informed, with access to information from around the world, which has led to a dramatic shift in patients selecting RALP over ORP. Internet access to the latest techniques and aggressive marketing by industry have had a huge impact on the practice of medicine and the ability of appropriate clinical trials to evaluate new technology. In a 1000-patient survey reported by Patel and colleagues,²⁰ patients chose RALP based upon a perceived decreased morbidity (54%), potential improved outcomes (37%), decreased blood loss (57%) and less postoperative pain (31%). This survey identifies the needs that are most important to patients when choosing the type of surgery for their prostate cancer.

Can the Canadian health-care system afford RALP? Most of the robotic systems in Canada have been purchased primarily through foundations and private support, with a current price tag of \$2.3 million (U.S.). The per-case cost in our institution (Royal Alexandra Hospital, Edmonton, AB) is \$2800 (Cdn.), compared with the cost of ORP at \$450. The overall cost per case is understandably higher secondary to depreciation and service contracts, which may add an additional \$1000 per case.²¹ This total cost (approximately \$3800 per case) is roughly equivalent to the cost of a joint replacement surgery. Obviously, cost issues remain an area of concern; however, if we take into account the benefits experi-

enced by patients (faster recovery, shorter hospitalization and return to normal activity), then these cost issues, even in a publicly funded system, will undoubtedly be accepted.

Worldwide marketing and patient demands have driven RALP as a minimally invasive surgical option for men with localized prostate cancer. Unfortunately no randomized clinical trials are available to support the use of RALP; however, large case series do strongly support the equivalency of RALP versus ORP, and, based upon RALP's general acceptance into current clinical practice, it is unlikely that any significant randomized trial will be feasible in the future. As long-term follow-up matures, the limitations of RALP will be clarified in terms of biochemical failure rates, functional outcomes and cost-effectiveness analysis. Common issues to both ORP and RALP, including surgeon experience, case volume and patient selection, may have a bigger impact on outcomes than just the way surgery is performed.

Even though urologists may disagree about the process whereby robotic-assisted surgery has been introduced into clinical practice and some continue to doubt the data, for those who have made the transition from ORP to RALP the technical precision of the same operation and the rapid recovery of patients will be the evidence.

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