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Robotic-Assisted Minimally Invasive Prostatectomy: OHTAC Recommendation

Ontario Health Technology Advisory Committee

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All reports prepared by the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OTHAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO's website for 21 days for public and professional comment. For more information, please visit: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit http://www.hqontario.ca for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by the Evidence Development and Standards branch of Health Quality Ontario or one of its research partners for the *Ontario Health Technology Advisory Committee* and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to Health Quality Ontario. It is possible that relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

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Background

Prostate cancer is the most common cancer among men, accounting for approximately 27% of all cancers in Canadian men in 2012. An estimated 26,500 new prostate cancer cases were expected in Canada in 2012. Prostate cancer treatment depends on the stage and grade of the disease. Surgery in the form of radical prostatectomy (RP) and radiotherapy are treatment options for localized prostate cancer, regardless of the risk category.

The Da Vinci surgical system is a robotic device utilized to perform minimally invasive surgery. The proposed advantages of this system include enhanced precision through the use of "wristed" instruments, three-dimensional imaging, and a surgeon's console that allows for tremor-free manipulation. This type of surgery has mostly been used for hysterectomy for endometrial and cervical cancers and for RP for the treatment of prostate cancer. Robotic-assisted minimally invasive surgery is associated with higher costs and requires training of surgeons and other personnel.

Due to a lack of Ontario-specific evidence on the effectiveness and complication rates for robotic-assisted radical prostatectomy (RARP), the Institute for Clinical Evaluative Sciences conducted a field evaluation[*] on behalf of the Evidence Development and Standards branch of Health Quality Ontario with the following objective:

- To describe the rates of major surgical complications and outcomes among patients who had RARP compared to those who had other forms of RP, including laparoscopic or open prostatectomy.

The field evaluation was a population-based, retrospective cohort study design, using a series of administrative databases. Primary outcomes included prostatectomy post-surgical complications (blood transfusions, upper urinary tract complications, stricture and bladder neck contracture, urinary fistula, ureteric injury, gastrointestinal stoma creation, peritonitis, and death) and other general health services outcomes (length of hospital stay and re-admission) within 1 year of follow-up post-prostatectomy. A composite outcome measure of post-operative adverse events included all of the outcomes listed above except length of hospital stay. A patient was considered to have experienced the composite outcome if he had at least one of the individual outcomes.

[*]In the absence of adequate evidence on the safety, efficacy, effectiveness, clinical utility, and/or cost-effectiveness of health interventions, OHTAC may initiate a field evaluation. Field evaluations evaluate health interventions in clinical settings in real-time to reduce uncertainty in estimates of effect and to find out how they work in Ontario. They allow patients to access interventions during the evaluation process (known as coverage with evidence development) and provide decision-makers with Ontario-specific evidence prior to making comprehensive funding commitments.

Conclusions

Primary results

- Patients who underwent robotic-assisted radical prostatectomy (RARP) had significantly fewer complications compared with those who had other forms of radical prostatectomy (RP). RARP patients required statistically significantly fewer blood transfusions (≤ 0.8% vs. 11.4%; $P < 0.001$) and had significantly fewer complications related to stricture and bladder neck contracture (4% vs. 12.1%; $P < 0.001$).
- The majority of the RP-related complications were rare and differences between groups were not statistically significant.
- RARP patients experienced shorter length of hospital stay compared with all other RP patients.
- The odds of having the composite outcome (at least one of the following prostatectomy post-surgical complications: blood transfusions, upper urinary tract complications, stricture and bladder neck contracture, urinary fistula, ureteric injury, gastrointestinal stoma creation, peritonitis, hospital readmission, and death) were 1.45 times higher for the all other RP group compared to the RARP group (24.3% vs. 7.7%, respectively; $P < 0.001$).
- Outcomes improved over the study period (April 1, 2005, to March 31, 2011), presumably as practitioners work through the "learning curve" and improve their skill with experience.

Primary conclusions

- The data confirm a gradual uptake of this technology in Ontario, in the absence of empirical, contextualized evidence.
- Men (aged 40 to 75 years) who had RARP for prostate cancer in Ontario had better surgical outcomes than those who had RP by other methods.

Limitations

- Administrative data lack clinical information, and the investigators could not completely account for selection bias and confounding by indication.
- Administrative data also do not include other clinical outcome data such as quality of life or more sensitive measures of sexual dysfunction and urinary incontinence.
- The study only identified *procedures* for sexual dysfunction and incontinence and did not measure the use of erectile dysfunction or incontinence medications. This limitation likely led to an underestimation of pre-existing and post-operative sexual dysfunction rates.

Decision Determinants

The Ontario Health Technology Advisory Committee (OHTAC) has developed a decision-making framework that consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* available at: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework.

Appendix 1 shows a summary of the decision determinants for this recommendation..

Based on the decision determinants criteria, OHTAC weighed in favour of the safety of RARP in making its recommendation. For prostate cancer, RARP leads to fewer surgical complications than radical prostatectomy (RP) by other methods.

OHTAC Recommendations

OHTAC Recommendations on Robotic-Assisted Minimally Invasive Prostatectomy

In 2010, the Ontario Health Technology Advisory Committee (OHTAC) recommended that a field evaluation be conducted on the effectiveness and safety of using robotic-assisted minimally invasive surgery for radical prostatectomy. In 2013, the Institute for Clinical Evaluative Sciences (ICES) reported to OHTAC on the results of this study.

1. The Ontario Health Technology Advisory Committee (OHTAC) recommends the establishment of a Provincial Steering Committee on robotic-assisted minimally invasive surgery. This Steering Committee will:
    a. Advise on the development of province-wide registries to systematically collect outcomes data associated with this technology (e.g., patient-reported outcome measures, functional and surgical outcomes), as coverage for evidence development (CED) given the uncertainty regarding the clinical and cost-effectiveness,
    b. Monitor key performance indicators associated with this technology, and
    c. Recommend training of surgeons on the use of this technology (e.g., mentorship, accreditation).

2. OHTAC recommends that the Provincial Steering Committee on robotic-assisted minimally invasive surgery be comprised of clinical experts (including experts on robotic-assisted minimally invasive surgery in gynecology), the Ontario Medical Association (OMA), the Ontario Hospital Association (OHA), and the Council of Academic Hospitals of Ontario (CAHO). The Provincial Steering Committee should report back to OHTAC.

Appendices

Appendix 1 – Decision Determinants

Evaluation of Criteria for Robotic-Assisted Minimally Invasive Prostatectomy

The evaluation of the four explicit criteria (overall clinical benefit, consistency with societal and ethical values, value for money, and feasibility of adoption into the health system) are reported in the Decision Determinants table (Table A1).

Table A1: Decision Determinants for Robotic-Assisted Minimally Invasive Prostatectomy

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/intervention likely to be (taking into account any variability)?	RARP allows for enhanced precision through the use of "wristed" instruments, three-dimensional imaging, and a surgeon's console that allows for tremor-free manipulation. The effectiveness of the procedure depends on the training and experience of the practicing surgeon. Outcomes improved over the study period, presumably as users gained experience.
	Safety How safe is the health technology/intervention likely to be?	Patients who underwent RARP had significantly fewer complications, according to a composite measure ($P < 0.001$). The odds of having the composite outcome were 1.45 times higher for the all other radical prostatectomy group compared to the RARP group. The majority of individual complications were rare and differences between groups were not statistically significant; however, RARP required statistically significantly fewer blood transfusions ($P < 0.001$) and had significantly fewer stricture and bladder neck contracture complications ($P < 0.001$). Bladder neck contractures require secondary procedures to correct.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	Prostate cancer is the most common cancer among men, accounting for approximately 27% of all cancers in Canadian men in 2012. An estimated 26,500 new prostate cancer cases were expected in Canada in 2012.
	Need How large is the need for this health technology/intervention?	There has been gradual uptake of this technology; however, the need is uncertain.
Consistency with expected societal and ethical values[a] How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	**Societal values** How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	There were no statistically significant differences between the RARP and all other radical prostatectomy groups with respect to procedures undergone for urinary incontinence ($P = 0.32$) and sexual dysfunction ($P = 0.67$). However, this secondary analysis does not account for more subtle clinical outcomes that may have demonstrated statistical differences between the comparison groups. Shorter LOSs after RARP reduce relative

Decision Criteria	Subcriteria	Decision Determinants Considerations
		hospitalization costs.
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Since centres with large surgical volumes may be best suited to managing the acquisition/operating and training/personnel costs associated with robotic surgery, use and access to RARP may be restricted in smaller centres or in less populated regions with smaller surgical volumes.[b] Use of minimally invasive surgery is consistent with societal trends towards reducing the physical impacts of health care interventions on patients.
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	In a comparison between RARP and all other radical prostatectomies performed in Ontario, mean LOS was significantly shorter in RARP patients ($P < 0.001$). Looking only at hospitals in which RARPs were performed (of which there were 3), the mean LOS did not significantly differ ($P = 0.38$) between the RARP and all other radical prostatectomy groups. This analysis was conducted to reduce possible heterogeneity in the sample arising from differences in RARP and non-RARP hospitals.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	Hospitals are the budget holders for the payment of robotic equipment and its maintenance. Analyses[b] have shown that the costs of acquiring, operating, and maintaining surgical robots lead to higher per-patient costs than the comparator group. Increasing the annual caseload can lower the incremental costs per patient for RARP (the mean incremental costs drop significantly during the first 200 procedures).[b]
	Organizational feasibility How organizationally feasible is it to implement the health intervention? (e.g., with respect to system enablers).	Some reports have recommended an operating room of at least 562 square feet to accommodate the staff, the robot, the anesthesia cart, the table, and a three-dimensional projection system.[b] A dedicated room for robotic surgery may be preferable to avoid moving and potentially damaging the robot. No standards for training or credentialing for robotic surgeons currently exist. Training of surgical staff may involve travel at a cost.

Abbreviations: LOS, length of hospital stay; RARP, robotic-assisted radical prostatectomy.

[a]The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

[b]Ho C, Tsakonas E, Tran K, Cimon K, Severn M, Mierzwinski-Urban M, Corcos J, Pautler S. *Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses* [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011) [cited 2011-09-20]. (Technology report no. 137). Available from: http://www.cadth.ca/en/products/health-technology-assessment/publication/2682

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