Ontario Health

ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Robotic-Assisted Partial Nephrectomy for Kidney Cancer: A Health Technology Assessment

Key Messages

What Is This Health Technology Assessment About?

Partial nephrectomy (the removal of part of a kidney or a kidney tumour) is the gold standard surgical treatment for early kidney cancer because it preserves kidney function.

Surgical approaches for nephrectomy include open nephrectomy (an invasive procedure that involves a large surgical incision, or cut into the skin), laparoscopic nephrectomy (a minimally invasive procedure that involves several smaller incisions and the use of smaller surgical tools), and robotic-assisted nephrectomy (a minimally invasive procedure that involves the use of a robotic system operated by the surgeon). Laparoscopic nephrectomy is most often used for radical nephrectomy (the removal of an entire kidney), whereas robotic-assisted nephrectomy is most often used for partial nephrectomy. Although robotic-assisted nephrectomy is increasingly being adopted, whether it offers benefits over conventional surgical procedures remains unclear.

This health technology assessment looked at how safe, effective, and cost-effective robotic-assisted partial nephrectomy is for adults with kidney cancer. It also looked at the budget impact of publicly funding robotic-assisted partial nephrectomy and at the experiences, preferences, and values of people with kidney cancer, as well as those of surgeons who perform nephrectomy.

What Did This Health Technology Assessment Find?

Compared with open and laparoscopic partial nephrectomy, robotic-assisted partial nephrectomy may decrease estimated blood loss, shorten length of hospital stay, and reduce complications; however, this evidence was of low quality.

We did not perform a primary economic evaluation. Robotic-assisted partial nephrectomy may be more costly than open and laparoscopic partial nephrectomy; however, the published evidence was not generalizable to the Ontario context. Publicly funding robotic-assisted partial nephrectomy is estimated to increase costs to the province by about $1.58 million over 5 years.

People with lived experience of kidney cancer and surgeons both spoke favourably of robotic-assisted partial nephrectomy, particularly in terms of safety and quick recovery.

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Abstract

Background

Robotic-assisted surgery has been used in Ontario hospitals for over a decade, but there is no public funding for the robotic systems or the disposables required to perform robotic-assisted surgeries ("robotics disposables"). We conducted a health technology assessment of robotic-assisted partial nephrectomy for the treatment of kidney cancer (RAPN). Nephrectomy may be radical (the surgical removal of an entire kidney, nearby adrenal gland and lymph nodes, and other surrounding tissue) or partial (the surgical removal of part of a kidney or a kidney tumour). Partial nephrectomy is the gold standard surgical treatment for early kidney cancer. Our assessment included an evaluation of the effectiveness, safety, and cost-effectiveness of RAPN, as well as the 5-year budget impact for the Ontario Ministry of Health of publicly funding RAPN. It also looked at the experiences, preferences, and values of people with kidney cancer, as well as those of health care professionals who provide surgical treatment for kidney cancer.

Methods

We performed a systematic literature search of the clinical evidence to retrieve systematic reviews and selected and reported results from five reviews that were recent and relevant to our research questions. We used the Risk of Bias in Systematic Reviews (ROBIS) tool to assess the risk of bias of each included systematic review. We assessed the quality of the body of evidence reported in the selected reviews according to the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group criteria. We performed a systematic economic literature search. We also analyzed the 5-year budget impact of publicly funding robotics disposables for RAPN for people with kidney cancer in Ontario. To contextualize the potential value of RAPN for people with kidney cancer, we spoke with people with lived experience of kidney cancer who had undergone either open or robotic-assisted nephrectomy, and we spoke with urologic surgeons who perform nephrectomy.

Results

We included five systematic reviews in the clinical evidence review. Low-quality evidence from observational studies suggests that compared with open or laparoscopic partial nephrectomy, RAPN may decrease estimated blood loss, shorten length of hospital stay, and reduce complications (All GRADEs: Low). We identified five studies that met the inclusion criteria of our economic literature review. Most included economic studies found robotic-assisted surgical procedures to be more costly than open and laparoscopic procedures; however, the results from these studies were not applicable to the Ontario context. Assuming a moderate increase in the volume of RAPN procedures, our reference case analysis showed that the 5-year budget impact of publicly funding RAPN for people with kidney cancer would be $1.58 million. The budget impact analysis results were sensitive to surgical volume and the cost of robotics disposables. The people we spoke with who had lived experience of kidney cancer, as well as urologic surgeons, spoke favourably of RAPN and its perceived benefits over open and laparoscopic procedures.

Conclusions

RAPN may improve clinical outcomes and reduce complications. The cost-effectiveness of RAPN for people with kidney cancer is unknown. We estimate that the 5-year budget impact of publicly funding RAPN for people with kidney cancer would be $1.58 million. People we spoke with who had lived experience of kidney cancer and had undergone RAPN reported favourably on their experiences,

particularly in terms of the quick recovery, short hospital stay, and minimal pain. Conversely, those who had undergone an open procedure spoke of difficulties including pain, complications, and increased length of hospital stay. Surgeons emphasized the importance of RAPN being made available to people with kidney cancer because of the increased risks and complications associated with open partial nephrectomy.

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Objective

This health technology assessment evaluates the effectiveness, safety, and cost-effectiveness of robotic-assisted partial nephrectomy for adults with kidney cancer. It also evaluates the budget impact of publicly funding robotic-assisted partial nephrectomy and the experiences, preferences, and values of people with kidney cancer, as well as surgeons who perform nephrectomy for people with kidney cancer.

Background

Health Condition

Kidney cancer in adults involves malignant tumours arising from the renal parenchyma and renal pelvis. Renal parenchyma cancer is the most common form of kidney cancer. Cigarette smoking, obesity, and hypertension are well-established risk factors for kidney cancer.[1]

In Ontario, 2,904 cases of kidney cancer were diagnosed in 2020.[2]

Current Treatment Options

Conventional surgical approaches for nephrectomy include open nephrectomy (an invasive procedure that involves a large surgical incision) and laparoscopic nephrectomy (a minimally invasive procedure that involves several smaller incisions and the use of smaller surgical tools). Radical nephrectomy (the removal of an entire kidney, nearby adrenal gland and lymph node, and other surrounding tissue) is the standard of care for large and locally advanced kidney cancer, whereas partial nephrectomy (the removal of part of a kidney or a kidney tumour) is the preferred surgical treatment for early kidney cancer because it preserves renal function.

Partial nephrectomy is usually performed as an open surgery because laparoscopic partial nephrectomy requires advanced surgical skills, and the ergonomics required for this type of procedure are challenging for the surgeon. However, because of the large incision required for open surgical procedures, patients are at greater risk of postoperative pain and infection than with minimally invasive procedures. Further, open partial nephrectomy requires a flank incision, which increases the risk of a complication called flank bulge (a bulge on the back or side of the abdomen).

Health Technology Under Review

Robotic-assisted partial nephrectomy is a minimally invasive surgical procedure with the potential to improve clinical outcomes compared with open partial nephrectomy and to overcome the technical and ergonomic challenges of laparoscopic partial nephrectomy.

Regulatory Information

Four robotic surgical systems are currently licensed by Health Canada (Table 1).

Table 1: Robotic Surgical Systems Licensed by Health Canada

System	Manufacturer (location)	Device class	Licence number	Date of first issue
Da Vinci Si Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	81353	December 3, 2009
Da Vinci Xi Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	97378	July 27, 2016
Da Vinci X Surgical System	Intuitive Surgical, Inc. (Sunnyvale, CA)	IV	103348	July 26, 2019
Hugo robotic-assisted surgery system	Medtronic (Minneapolis, MN)	III	107066	December 3, 2021

Ontario Context

From fiscal year (FY) 2019 to FY 2021, 11 hospitals in Ontario performed more than 100 robotic-assisted surgical procedures. Five of these hospitals accounted for 72% of all robotic-assisted surgical procedures in Ontario (4,249 out of 5,926) (Discharge Abstract Database, Canadian Institute for Health Information, IntelliHealth Ontario, November 2022).

The existing robotic systems in Ontario have largely been purchased through charitable donations to hospital foundations. The costs of the disposables required to perform robotic-assisted surgical procedures and the maintenance costs of robotic systems are typically covered by a hospital's global budget or foundation funds. This funding arrangement is in keeping with that of other technologies used in the operating room.

Expert Consultation

We engaged with an expert in the specialty area of urology to help inform our understanding of aspects of the health technology and our methodologies and to contextualize the evidence.

Expedited Summary of the Clinical Evidence

Research Questions

- What are the clinical effectiveness and safety of robotic-assisted partial nephrectomy (RAPN) compared with laparoscopic partial nephrectomy (LPN) or open partial nephrectomy (OPN) in adults with kidney cancer?
- What are the clinical effectiveness and safety of robotic-assisted radical nephrectomy (RARN) compared with laparoscopic radical nephrectomy (LRN) or open radical nephrectomy (ORN) in adults with kidney cancer?

We included an evaluation of RARN as an indirect source of evidence for RAPN.

Appendix 1 provides the full methods for the clinical evidence summary.

Results

The clinical literature search retrieved 187 publications from the MEDLINE and Cochrane bibliographic databases published between January 1, 2017, and March 22, 2022 (Appendix 2). The grey literature search yielded one additional item. We identified nine systematic reviews that met our inclusion criteria (Appendix 3, Figure A1). Appendix 4 provides our risk-of-bias assessment of these studies using the Risk of Bias in Systematic Reviews (ROBIS) tool.[3]

The following sections present the results of the selected systematic reviews based on recency, study eligibility criteria, literature search, and risk-of-bias assessment. Appendix 1 provides the rationale for our selection of the included systematic reviews. All included systematic reviews comprised only nonrandomized observational studies (Appendix 5, Table A2).

Robotic-Assisted Versus Laparoscopic Partial Nephrectomy

Compared with LPN for small renal tumours (defined as tumours ≤ 4 cm in diameter), RAPN may result in a shorter length of hospital stay (GRADE: Low) and less estimated blood loss (GRADE: Low). There were no differences between RAPN and LPN in operative time, warm ischemia time, complications, renal function, or cancer-specific outcomes (GRADEs: Low to Very low). (Table 2).

Table 2: Outcomes of Robotic-Assisted vs. Laparoscopic Partial Nephrectomy for Small Renal Tumours

Outcome	No. and type of studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Operative time	3 observational studies	No difference	Very low
Estimated blood loss	4 observational studies	Favoured RAPN: less estimated blood loss	Low[c]
Warm ischemia time	4 observational studies	No difference	Very low
Major postoperative complications	3 observational studies	No difference	Low
Intraoperative complications	3 observational studies	No difference	Low
Length of hospital stay	4 observational studies	Favoured RAPN: shorter length of hospital stay	Low
Positive surgical margins	4 observational studies	No difference	Very low
eGFR	4 observational studies	No difference	Very low
Cancer-specific survival	4 observational studies	No difference	Very low
Overall recurrence	3 observational studies	No difference	Very low
CKD upstaging	2 observational studies	No difference	Very low

Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; RAPN, robotic-assisted partial nephrectomy.

[a]Numeric results were presented in graphics.

[b]GRADE ratings extracted from Tang et al.[4]

[c]The quality of the evidence for the outcome of estimated blood loss should have been graded low instead of moderate because of risk of bias and imprecision. The authors upgraded the quality of this outcome because of "parallel evidence on cystectomy which is consistent and comes from RCTs [randomized controlled trials]." However, robotic-assisted cystectomy is a different intervention from robotic-assisted nephrectomy; therefore, the outcome is not necessarily equivalent or comparable between the two procedures.

Source: Data extracted from Tang et al.[4]

Compared with LPN for large complex renal tumours (defined as tumours > 4 cm in diameter with a RENAL nephrometry score ≥ 7 based on size, depth, and anatomical location of the tumour[5]), RAPN may result in shorter warm ischemia time, shorter length of hospital stay, less decline in estimated glomerular filtration rate (eGFR), a lower rate of chronic kidney disease upstaging, and a lower rate of

conversion to radical surgery but a higher rate of positive surgical margins (all GRADEs: Low). There were no differences between RAPN and LPN in operative time, estimated blood loss, rate of conversion to open surgery, or complications according to the Clavien–Dindo Classification of Surgical Complications (all GRADEs: Low) (Table 3).

Table 3: Outcomes of Robotic-Assisted vs. Laparoscopic Partial Nephrectomy for Large Complex Renal Tumours

Outcome	No. of participants and studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Operative time	RAPN: 732 LPN: 680 8 observational studies	No difference MD: 0.70 (95% CI, −18.10 to 19.51)	Low
Estimated blood loss	RAPN: 732 LPN: 680 8 observational studies	No difference MD: 13.53 (95% CI, −5.77 to 32.83)	Low
Warm ischemia time	RAPN: 661 LPN: 606 7 observational studies	Favoured RAPN: shorter warm ischemia time MD: 3.02 (95% CI, 1.67 to 4.36)	Low
Length of hospital stay	RAPN: 637 LPN: 623 7 observational studies	Favoured RAPN: shorter length of hospital stay MD: 0.67 (95% CI, 0.35 to 0.99)	Low
Positive surgical margins	RAPN: 3,483 LPN: 1,500 8 observational studies	Favoured LPN: lower rate of positive surgical margins OR: 0.71 (95% CI, 0.53 to 0.96)	Low
eGFR decline	RAPN: 618 LPN: 566 6 observational studies	Favoured RAPN: less eGFR decline MD: 2.41 (95% CI, 1.22 to 3.60)	Low
CKD upstaging	RAPN: 206 LPN: 206 3 observational studies	Favoured RAPN: lower rate of CKD upstaging OR: 2.44 (95% CI, 1.54 to 3.60)	Low
Conversion to open surgery	RAPN: 496 LPN: 533 5 observational studies	No difference OR: 5.14 (95% CI, 0.88 to 29.97)	Low
Conversion to radical surgery	RAPN: 585 LPN: 571 6 observational studies	Favoured RAPN: lower rate of conversion to radical surgery OR: 4.33 (95% CI, 2.01 to 9.33)	Low

Outcome	No. of participants and studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Clavien–Dindo classification grades 1–5	RAPN: 806 LPN: 692 9 observational studies	No difference OR: 1.22 (95% CI, 0.95 to 1.57)	Low
Clavien–Dindo classification grades 1–2	RAPN: 806 LPN: 692 9 observational studies	No difference OR: 1.25 (95% CI, 0.96 to 1.63)	Low
Clavien–Dindo classification grades 3–5	RAPN: 806 LPN: 692 9 observational studies	No difference OR: 1.02 (95% CI, 0.61 to 1.71)	Low

Abbreviations: CI, confidence interval; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; LPN, laparoscopic partial nephrectomy; MD, mean difference; OR, odds ratio; RAPN, robotic-assisted partial nephrectomy.

[a]The reference group for the OR and MD was RAPN (vs. LPN). For example, an OR of 2.44 means LPN has a 2.44 times higher risk of CKD upstaging than RAPN; therefore, RAPN is favoured over LPN on this outcome.

[b]Observational studies started at a GRADE rating of low because of inherent limitations in study design (e.g., lack of randomization, lack of blinding). The Newcastle–Ottawa Scale scores of the included studies ranged from 6 to 8, indicative of intermediate to high quality. As such, we did not further downgrade any GRADE ratings.

Source: Data extracted from Lin et al.[6]

Robotic-Assisted Versus Open Partial Nephrectomy

Compared with OPN for renal tumours, RAPN may result in less estimated blood loss, shorter length of hospital stay, and fewer postoperative complications. There were no differences between RAPN and OPN in operative time, warm ischemia time, rate of positive surgical margins, pre- or postoperative eGFR, or intraoperative complications (all GRADEs: Low) (Table 4).

Table 4: Outcomes of Robotic-Assisted vs. Open Partial Nephrectomy for Renal Tumours

Outcome	No. of participants and studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Operative time	RAPN: 641 OPN: 886 5 observational studies	No difference WMD: 0.14 (95% CI, −0.33 to 0.61)	Low
Warm ischemia time	RAPN: 999 OPN: 1,024 6 observational studies	No difference WMD: 0.28 (95% CI, −0.13 to 0.69)	Low
Estimated blood loss	RAPN: 424 OPN: 518 4 observational studies	Favoured RAPN: less estimated blood loss WMD: −0.67 (95% CI, −1.07 to −0.28)	Low
Positive surgical margins	RAPN: 852 OPN: 670 5 observational studies	No difference OR: 1.04 (95% CI, 0.37 to 2.94)	Low
Preoperative eGFR	RAPN: NR OPN: NR 3 observational studies	No difference WMD: 0.11 (95% CI, −0.01 to 0.23)	Low
Postoperative eGFR	RAPN: NR OPN: NR 2 observational studies	No difference WMD: −0.11 (95% CI, −0.27 to 0.04)	Low
Postoperative length of hospital stay	RAPN: 247 OPN: 454 3 observational studies	Favoured RAPN: shorter length of hospital stay WMD: −1.09 (95% CI, −1.86 to −0.32)	Low
Intraoperative complications	RAPN: NR OPN: NR 2 observational studies	No difference OR: 0.13 (95% CI, 0.02 to 1.04)	Low
Postoperative complications	RAPN: NR OPN: NR 6 observational studies	Favoured RAPN: fewer postoperative complications OR: 0.51 (95% CI, 0.38 to 0.68)	Low

Abbreviations: CI, confidence interval, eGFR, estimated glomerular filtration rate; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; NR, not reported; OPN, open partial nephrectomy; OR, odds ratio; RAPN, robotic-assisted partial nephrectomy; WMD, weighted mean difference.

[a]The reference group for the OR and WMD was OPN (vs. RAPN).

[b]Observational studies started at a GRADE rating of low because of inherent limitations in study design (e.g., lack of randomization, lack of blinding). The Newcastle–Ottawa Scale scores of the included studies ranged from 6 to 8, indicative of intermediate to high quality. As such, we did not further downgrade any GRADE ratings.

Source: Data extracted from Ni and Yang.[7]

Robotic-Assisted Versus Laparoscopic Radical Nephrectomy

Compared with LRN for renal tumours, RARN may result in shorter length of hospital stay but longer operative time. There were no differences between RARN and LRN in estimated blood loss, blood transfusion rate, or complications (all GRADEs: Low) (Table 5).

Table 5: Outcomes of Robotic-Assisted vs. Laparoscopic Radical Nephrectomy for Renal Tumours

Outcome	No. of participants and studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Operative time	RARN: 511 LRN: 817 5 observational studies	Favoured LRN: shorter operative time MD: 37.44 (95% CI, 3.94 to 70.94)	Low
Estimated blood loss	RARN: 511 LRN: 624 5 observational studies	No difference MD: 2.18 (95% CI, −26.69 to 31.04)	Low
Blood transfusion rate	RARN: 10,869 LRN: 25,123 6 observational studies	No difference OR: 1.42 (95% CI, 0.97 to 2.06)	Low
Length of hospital stay	RARN: 8,528 LRN: 17,572 7 observational studies	Favoured RARN: shorter length of hospital stay MD: −0.84 (95% CI, −1.52 to −0.16)	Low
Overall complications	RARN: 8,627 LRN: 19,938 7 observational studies	No difference OR: 0.97 (95% CI, 0.73 to 1.27)	Low
Major complications (Clavien–Dindo classification grades ≥ 3)	RARN: 5,835 LRN: 19,367 5 observational studies	No difference OR: 0.95 (95% CI, 0.81 to 1.11)	Low
Intraoperative complications	RARN: 5,421 LRN: 1,717 4 observational studies	No difference OR: 1.01 (95% CI, 0.17 to 6.03)	Low
Postoperative complications	RARN: 10,617 LRN: 22,780 7 observational studies	No difference OR: 0.93 (95% CI, 0.70 to 1.23)	Low

Abbreviations: CI, confidence interval; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; LRN, laparoscopic radical nephrectomy; MD, mean difference; OR, odds ratio; RARN, robotic-assisted radical nephrectomy.

[a]The reference group for the OR and MD was LRN (vs. RARN).

Notes for Table 5 continued
[b]Observational studies started at a GRADE rating of low because of inherent limitations in study design (e.g., lack of randomization, lack of blinding). The Newcastle–Ottawa Scale scores of the included studies were 8, indicative of high quality. As such, we did not further downgrade any GRADE ratings.
Source: Data extracted from Crocerossa et al.[8]

Robotic-Assisted Versus Open Radical Nephrectomy

Compared with ORN in adults with kidney cancer, RARN may result in shorter length of hospital stay, less estimated blood loss, and fewer overall complications. There were no differences between RARN and ORN in operative time, blood transfusion rate, major complications, or perioperative death (all GRADEs: Low) (Table 6).

Table 6: Outcomes of Robotic-Assisted vs. Open Radical Nephrectomy for Renal Tumours

Outcome	No. of participants and studies	Summary of results[a]	Certainty of the evidence (GRADE)[b]
Operative time	RARN: 37 ORN: 49 2 observational studies	No difference MD: 43.04 (95% CI, −166.37 to 252.45)	Low
Estimated blood loss	RARN: 37 ORN: 49 2 observational studies	Favoured RARN: less estimated blood loss MD: −7.02 (95% CI −12.55 to −1.49)	Low
Blood transfusion rate	RARN: 390 ORN: 11,367 4 observational studies	No difference OR: 0.29 (95% CI, 0.04 to 2.19)	Low
Length of hospital stay	RARN: 390 ORN: 11,367 4 observational studies	Favoured RARN: shorter length of hospital stay MD: −3.06 (95% CI −4.97 to −1.16)	Low
Overall complications	RARN: 390 ORN: 11,367 4 observational studies	Favoured RARN: fewer overall complications OR: 0.56 (95% CI, 0.43 to 0.72)	Low
Major complications (Clavien–Dindo classification grades ≥ 3)	RARN: 61 ORN: 77 3 observational studies	No difference OR: 0.58 (95% CI, 0.14 to 2.45)	Low
Perioperative death	RARN: 359 ORN: 11,336 3 observational studies	No difference OR: 0.30 (95% CI, 0.05 to 1.80)	Low

Abbreviations: CI, confidence interval; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; MD, mean difference; OR, odds ratio; ORN, open radical nephrectomy; RARN, robotic-assisted radical nephrectomy.

[a]The reference group for the OR and MD was LRN (vs. RARN).

[b]Observational studies started at a GRADE rating of low because of inherent limitations in study design (e.g., lack of randomization, lack of blinding). The Newcastle–Ottawa Scale scores of the included studies were 8, indicative of high quality. As such, we did not further downgrade any GRADE ratings.

Source: Data extracted from Crocerossa et al.[8]

Ongoing Studies

We are aware of four randomized clinical trials (Appendix 6, Table A3) that are underway and have potential relevance to the research questions of this review.

Discussion

- No randomized controlled trials met our inclusion criteria
- All included systematic reviews were nonrandomized observational studies
- The evidence base for robotic-assisted nephrectomy was limited to short-term observational studies at risk of bias, particularly in patient selection
- Most studies were of small sample size with relatively short follow-up duration and focused on perioperative outcomes rather than long-term oncological outcomes such as survival and cancer recurrence
- Potential confounding factors, such as surgeon experience, tumour characteristics (e.g., size, complexity, anatomical location), and patient factors (e.g., baseline renal function) may have contributed to the heterogeneity of outcomes observed

Conclusions

- Low-quality evidence from observational studies suggests that compared with laparoscopic or open nephrectomy, robotic-assisted partial or radical nephrectomy may decrease estimated blood loss, shorten length of hospital stay, and reduce complications
- There are uncertainties regarding the existing evidence base for robotic-assisted nephrectomy because of methodological limitations and potential confounding factors

Expedited Summary of the Economic Evidence

Research Questions

- What is the cost-effectiveness of robotic-assisted partial nephrectomy (RAPN) compared with laparoscopic partial nephrectomy (LPN) or open partial nephrectomy (OPN) in adults with kidney cancer?
- What is the cost-effectiveness of robotic-assisted radical nephrectomy (RARN) compared with laparoscopic radical nephrectomy (LRN) or open radical nephrectomy (ORN) in adults with kidney cancer?

We included an evaluation of RARN as an indirect source of evidence for RAPN.

Appendix 1 provides the full methods for the economic evidence summary.

Results

The economic literature search retrieved 65 publications from the MEDLINE bibliographic database published between January 1, 2017, and March 21, 2022 (Appendix 2). We identified four studies that met the inclusion criteria: one prospective comparative study,[9] one retrospective longitudinal study,[9] and two retrospective observational studies[10,11] (Table 7; see also Appendix 3, Figure A2).

Table 7: Direct Comparison of Interventions

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator(s)	Results		
				Health outcomes	Costs	Cost-effectiveness
Wang et al, 2017, China[12]	Cost-effectiveness analysis Economic analysis based on a prospective match-paired comparative study Hospital perspective Time horizon: 5 y	Patients with moderate or highly complex renal tumours (RENAL score ≥ 7) (N = 380; RAPN = 190; OPN = 190)	RAPN vs. OPN	*Total operative time (mean), min* RAPN: 141.7 OPN: 148.5 *P* = .108 *Perioperative measures* Length of hospital stay (mean), d RAPN: 7.8 OPN: 9.2 *P* < .001 Estimated blood loss (mean), mL RAPN: 196.8 OPN: 240.8 *P* < .001 Intraoperative complications, % RAPN: 5.3 OPN: 7.4 *P* = .398 Postoperative complications, % RAPN: 15.8 OPN: 28.9 *P* = .002 Positive surgical margins, % RAPN: 1.6 OPN: 4.2 *P* = .221 *5-year cancer survival rate, %* RAPN: 95.1 OPN: 92.7 *P* = .48	*Direct costs*[a] RAPN: $11,872 OPN: $5,133 *P* < .001	Compared with OPN, RAPN was more costly and required longer operative time; there were no statistically significant differences between RAPN and OPN in positive surgical margins, oncological outcomes, or 5-y cancer survival rate Compared with OPN, RAPN was associated with improved perioperative outcomes: reduced length of hospital stay, reduced blood loss, and reduced postoperative complications

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator(s)	Results		
				Health outcomes	Costs	Cost-effectiveness
Camp et al, 2018, United Kingdom[9]	Cost-effectiveness analysis Economic analysis based on a retrospective longitudinal open-cohort study Hospital perspective Time horizon: 1 y	All adult patients undergoing PN included in the NHS Hospital Episode Statistics dataset between October 2008 and September 2014 (N = 4,175; RAPN = 610; LPN = 1,060; OPN = 2,505)	RAPN vs. LPN and OPN	*90-d readmission for wound-related complication, odds* RAPN: 0.003 LPN: 0.013 OPN: 0.02 *P* = .014 (RAPN–LPN) *P* = .013 (RAPN–OPN) *90-d readmission for postoperative infection, odds* RAPN: 0.018 LPN: 0.025 OPN: 0.045 *P* = .045 (RAPN–LPN) *P* = .003 (RAPN–OPN) *1-y readmission rate* RAPN: 0.928 LPN: 1.134 OPN: 1.628 *P* = .074 (RAPN–LPN) *P* = .001 (RAPN–OPN)	*Mean costs, 1 y following the intervention, £*[b] RAPN: £2,089.37 LPN: £2,225.05 OPN: £2,996.55 RAPN–LPN *P* = .973 RAPN–OPN *P* = .024 *Procedure cost* RAPN: £4,444 LPN: £4,356 *P* = .001 OPN: £5,024 *P* < .001	Compared with RAPN, procedural costs were statistically significantly higher for OPN and statistically significantly lower for LPN The frequency of postoperative complications was statistically significantly greater for OPN across all health outcomes, with the exception of gastrointestinal complications and neurological disorders Numbers of infections and pulmonary complications were significantly higher for LPN Compared with RAPN, 1-y readmission rates were higher for OPN
Gershman et al, 2020, United States[10]	Cost-effectiveness analysis Economic analysis based on a retrospective observational study Hospital perspective Time horizon not specified	Patients with nonurothelial renal cancer (N = 8,316; RARN = 4926, LRN = 3,390)	RARN vs. LRN	*Rate of any postoperative complication, %* RARN: 20.4 LRN: 27.2 *P* < .001 *Prolonged hospitalization, %* RARN: 7.1 LRN: 7.2 *P* = .81 *Prolonged hospitalization, RARN vs. LRN, multivariable analysis* OR: 1.29	*Total hospital costs (median)*[c] RARN: $16,207 LRN: $15,037 *P* < .001	In a multivariable analysis, compared with LRN, RARN was found to be independently associated with a reduction in perioperative complications, prolonged hospitalization, and higher total hospital costs

Author, year, country	Analytic technique, study design, perspective, time horizon	Population	Intervention and comparator(s)	Results		
				Health outcomes	**Costs**	**Cost-effectiveness**
				P = .007 *Perioperative blood transfusion rate* RARN: 5.6% LRN: 6.2% *P* = .27		
Sands et al, 2021, United States[11]	Cost-effectiveness analysis Economic analysis based on a retrospective observational study Hospital perspective Time horizon: 90 d	Patients undergoing radical nephrectomy for a renal mass (N = 194; RARN = 95, LRN = 99) Compared with patients who underwent RARN, patients who underwent LRN had more comorbidities (49.5% vs. 27.3%, *P* = .018)	RARN vs. LRN	*30-d readmission rate* RARN: 2.1% LRN: 11.1% *P* = .019 *90-d rate of any complications* OR: 1.10 *P* = .880 *Rate of positive surgical margins* RARN: 5.3% LRN: 1% *P* = .113 *Malignancy on final pathology* RARN: 93.7% LRN: 91.9% *P* = .635	*Variable costs*[a] RARN $2,310 more than LRN (*P* = .045) *Fixed costs* Not statistically significantly different *Procedural cost, mean* RARN $464 more than LRN when controlling for operative time (*P* < .001)	Compared with LRN, RARN was associated with longer operative time, higher supply costs, and higher overall hospitalization costs Compared with LRN, RARN was associated with statistically significantly fewer 30-d readmissions There were no statistically significant differences between RARN and LRN in rate of positive surgical margins, major complications, or 90-d rate of any complications

Note: Table is not comprehensive; some outcome measures have not been included.

Abbreviations: LPN, laparoscopic partial nephrectomy; LRN, laparoscopic radical nephrectomy; NHS, National Health Service; OPN, open partial nephrectomy; OR, odds ratio; PN, partial nephrectomy; RAPN, robotic-assisted partial nephrectomy; RARN, robot assisted radical nephrectomy.

[a]Currency and costing year unspecified.

[b]Costing year unspecified.

[c]In 2013 US dollars.

Robotic-Assisted Versus Laparoscopic Partial Nephrectomy

Camp et al[9] performed a retrospective longitudinal open-cohort study in the United Kingdom. They used routinely collected Hospital Episode Statistics data to compare 90-day complication rates, 1-year hospital activity, and costs following various types of partial nephrectomy. The study included 4,275 patients undergoing RAPN, LPN, or OPN between October 2008 and September 2014. This study found that compared with LPN, RAPN had higher procedural costs. However, total costs 1 year following LPN and RAPN were comparable. No statistically significant difference in hospital activity (e.g., outpatient visits, emergency admissions) was observed between RAPN and LPN.

Robotic-Assisted Versus Open Partial Nephrectomy

Wang et al[12] performed a retrospective matched-pair analysis of patients who underwent either RPN (n = 190) or OPN (n = 190) for a complex renal mass in China. All RPN procedures were performed at a hospital in Beijing with the da Vinci Surgical System by a single experienced, high-volume surgeon between 2007 and 2014. OPN procedures were performed retroperitoneally by three experienced surgeons in a hospital in Taiyuan during the same period. The authors found that compared with OPN, RAPN was more costly and required longer operative time. No statistically significant differences were observed in oncological outcomes (e.g., 5-year cancer survival rate, rate of positive surgical margins). However, compared with OPN, RAPN was found to be associated with improved perioperative outcomes, such as a shorter length of hospital stay, less estimated blood loss, and a lower rate of postoperative complications.

Camp et al[9] found that compared with OPN, RAPN had a lower total cost at the 1-year follow-up (mean: £2,996.55 vs. £2,089.37, P = .024) and lower complication-related costs at 90 days post-surgery. However, total cost did not include the cost of the procedure, which was £4,444 for RAPN, £5,024, for OPN, and £4,356 for LPN. Further, the total cost calculation was not adjusted for risks based on clinical indicators. The authors found that hospital activity was significantly lower in the year immediately following RAPN compared with OPN, driven in part by a reduction in postoperative complications requiring readmission, which contributed to reduced total costs.

Robotic-Assisted Versus Laparoscopic Radical Nephrectomy

Gershman et al[10] conducted a retrospective observational study of patients who underwent RARN or LRN for nonurothelial renal cancer in the United States between 2010 and 2013. The authors included 8,316 patients and conducted an independent data analysis and a multivariable analysis. They found that compared with LRN, RARN was independently associated with a reduction in perioperative complications but prolonged hospitalization and higher total hospital costs.

Sands et al[11] conducted a retrospective review of a data repository for patients who had undergone RARN (n = 95) or LRN (n = 99) for a renal mass. The authors compared both perioperative and oncological outcomes. They conducted a multivariate analysis of operative time, estimated blood loss, length of hospital stay, and rates of both overall and major 90-day complications, controlling for demographic data, Charlson Comorbidity Index scores, tumour size, and surgeon factors. The study also compared fixed, variable, and distinct procedural costs. The authors found that compared with LRN, RARN was associated with longer operative time, higher supply costs, and higher overall hospitalization costs. No statistically significant difference was found in rate of positive surgical margins or complications. However, there were fewer 30-day readmissions for the RARN cohort than for the LRN cohort.

Robotic-Assisted Versus Open Radical Nephrectomy

We did not identify any studies comparing RARN with ORN.

Discussion

- None of the included studies was conducted in Canada, and the health care resource use and costs in the settings reviewed could be very different from those in Ontario. Therefore, the results are not generalizable to the Ontario context
- We did not identify any model-based economic studies; all included studies are economic analyses based on observational studies
- Cost outcomes and time horizons varied across the included studies, making it difficult to compare results

Conclusions

- We did not identify any economic studies assessing the outcomes of RARN compared with ORN
- Three included studies found robotic-assisted surgical procedures to be more costly than open and laparoscopic procedures. Only one study found that compared with OPN, RAPN was associated with lower complication-related costs at 90 days and total costs at 1 year post-surgery; however, these costs were not adjusted for clinical risk factors and did not include relevant procedure costs

Expedited Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding robotic-assisted partial nephrectomy (RAPN) for adults with kidney cancer?

Methods

Analytic Framework

We estimated the budget impact of publicly funding RAPN using the cost difference between two scenarios: (1) current clinical practice without public funding for RAPN (the current scenario), and (2) anticipated clinical practice with public funding for RAPN (the new scenario). Figure 1 presents the budget impact model schematic.

RAPN is typically an inpatient procedure, and the costs are covered by the Ontario Health Insurance Plan. However, there is currently no public funding for robotic systems or the disposables required to perform robotic-assisted surgical procedures ("robotics disposables"). The existing robotic systems in Ontario have largely been purchased through charitable donations to hospital foundations. Hospitals with robotic systems manage the costs of robotics disposables from the hospital's existing global budget or hospital foundation funds. At the time of writing this report, there are no public funding allowances for the additional expenses associated with robotics disposables.

We explored the budget impact of publicly funding RAPN in the long term. Therefore, for simplicity, we assumed that there is no public funding for robotics disposables in the current scenario.

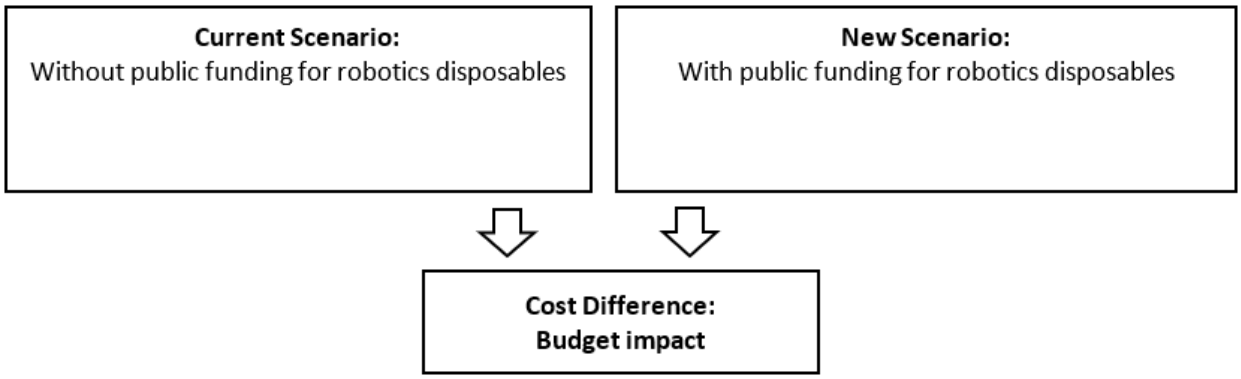

Figure 1: Schematic Model of Budget Impact

Flow chart describing the model for the budget impact analysis. The current scenario explores resource use and total costs without public funding for robotics disposables. The new scenario explores resource use and total costs with public funding for robotics disposables. The budget impact represents the difference in cost between the two scenarios.

Key Assumptions

- The total number of robotic systems in Ontario would stay relatively stable over the next 5 years. When a robotic system approaches the end of its service life, we assume it would be replaced; if a hospital currently does not have a robotic system, we assume the hospital would be unlikely to purchase one in the near future (because performing robotic-assisted surgical procedures requires both the equipment and the surgical expertise)
- Most RAPN procedures would be performed using the da Vinci Surgical System, and the market share of other robotic systems for RAPN would be limited over the next 5 years
- Public funding for robotics disposables would lead to a moderate increase in the total volume of robotic-assisted surgeries performed

Population

Our population of interest was people with kidney cancer undergoing RAPN. We searched administrative databases to understand the historical data for robotic-assisted surgeries in Ontario and predicted the surgical volumes in the current and new scenarios based on historical volumes.

Overview of Robotic-Assisted Surgeries in Ontario, Fiscal Years 2012 to 2021

We estimated the numbers of different types of robotic-assisted surgeries in Ontario for recent years using administrative data. We primarily searched the Discharge Abstract Database (DAD; Canadian Institute for Health Information [CIHI], IntelliHealth Ontario, November 2022) to identify inpatient robotic-assisted surgeries between fiscal years (FYs) 2012 and 2021. (Note: In this budget impact analysis, a fiscal year is expressed as the year in which reporting begins; for example, "FY 2012" means the fiscal year beginning April 1, 2012, and ending March 31, 2013.) We also searched the National Ambulatory Care Reporting System (NACRS; CIHI, IntelliHealth Ontario) to supplement our data. To understand recent trends in robotic-assisted surgeries, we analyzed the main diagnosis, principal intervention, and hospital for all robotic-assisted surgical procedures conducted in the province over the most recent 3 years (FY 2019 to FY 2021). Most robotic-assisted surgeries are inpatient procedures, and the statistics we report are based on inpatient data from the DAD, unless otherwise specified. Our main findings can be summarized as follows (see Appendix 7 for detailed findings):

- The overall volume of robotic-assisted surgeries (for all indications) increased over time, from 909 procedures in FY 2012 to 2,223 procedures in FY 2021 (Appendix 7, Table A4)
- The most common indications for robotic-assisted surgery were prostate cancer (45.7%), arthrosis of the knee (9.5%), endometrial cancer (7.9%), kidney cancer (5.8%), and lung cancer (5.4%) (Appendix 7, Table A5 [volumes by main diagnosis] and Table A6 [volumes by principal intervention]). Of note, robotic-assisted knee surgeries were not performed using the da Vinci Surgical System

Volumes of Robotic-Assisted Partial Nephrectomy, Fiscal Years 2012 to 2021

We searched the DAD to obtain the volumes of RAPN procedures performed between FY 2012 and FY 2021 in Ontario. (The Canadian Classification of Health Interventions [CCI] codes[13] used to identify these procedures can be found in Appendix 7, Table A7.) Table 8 presents the total volumes for this period, along with main surgical approach (as defined by CCI code[13]) and main diagnosis (as defined by

the International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada[14]).

As RAPN is generally an inpatient procedure, we searched only the DAD, which provides inpatient data, to obtain historical volumes.

Table 8: Total Volumes of Robotic-Assisted Nephrectomy, FY 2012–2021

Procedure	Volume, N	Main CCI (surgical approach): N (%)	Main diagnosis (ICD-10-CA): N (%)
Robotic-assisted nephrectomy	1,020	–	–
Excision partial, kidney[a]	899	1.PC.87.DA (laparoscopic) + 7.SF.14.ZX (robotic): 868 (96.6%)	Malignant neoplasm of kidney, except renal pelvis (C64): 713 (79.3%) Benign neoplasm of urinary organs (D30): 82 (9.1%)
Excision radical, kidney[b]	79	1.PC.91.DA (laparoscopic) + 7.SF.14.ZX (robotic): 74 (93.7%)	Malignant neoplasm of kidney, except renal pelvis (C64): 51 (64.6%) Malignant neoplasm of renal pelvis (C65): 10 (12.7%)
Excision total, kidney[c]	42	1.PC.89.DA (laparoscopic) + 7.SF.14.ZX (robotic): 40 (95.2%)	Malignant neoplasm of kidney, except renal pelvis (C64): 21 (50%) Malignant neoplasm of renal pelvis (C65): 6 (14.3%)

Abbreviation: CCI, Canadian Classification of Health Interventions; ICD-10-CA, International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada.

[a]Partial nephrectomy: surgical removal of part of a kidney or a kidney tumour.

[b]Radical nephrectomy: surgical removal of an entire kidney, nearby adrenal gland and lymph nodes, and other surrounding tissue.

[c]Total nephrectomy: surgical removal of an entire kidney.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table 9 presents the yearly volumes of robotic-assisted nephrectomies (i.e., total, partial, and radical) performed for any diagnosis, as well as the yearly volumes of RAPN procedures performed for kidney cancer (i.e., the population of interest), from FY 2012 to FY 2021. (Total nephrectomy is the surgical removal of an entire kidney; partial nephrectomy is the surgical removal of part of a kidney or a kidney tumour; and radical nephrectomy is the surgical removal of an entire kidney, as well as nearby adrenal gland and lymph nodes, and other surrounding tissue.[15]) In this period, 1,020 robotic-assisted nephrectomies were performed, about 900 of which were partial nephrectomy. In addition to those with a main diagnosis of kidney cancer, some people with benign neoplasm of urinary organs also received RAPN.

The volume of all robotic-assisted nephrectomies (i.e., total, partial, and radical) performed for any diagnosis and the volume of RAPN procedures performed for kidney cancer both increased rapidly between FY 2012 and FY 2021.

Table 9: Yearly Volumes of Robotic-Assisted Nephrectomy, FY 2012–2021

Fiscal Year	Volume of all robotic-assisted nephrectomy for any diagnosis, N[a]	Volume of robotic-assisted partial nephrectomy for kidney cancer, N[b]
2012	30	17
2013	59	43
2014	85	63
2015	88	62
2016	121	95
2017	98	72
2018	128	102
2019	142	115
2020[c]	101	83
2021	168	143
Total	**1,020**	**795**

[a] This is the volume of all robotic-assisted nephrectomies (i.e., total, partial, and radical).

[b] This volume includes the number of surgeries for which the main ICD-10-CA (International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada) code was C64 (malignant neoplasm of kidney, except renal pelvis) or D30 (benign neoplasm of urinary organs) and the intervention code was 1.PC.87.^^ (excision partial, kidney) + 7.SF.14.ZX (robotic).

[c] The COVID-19 pandemic likely affected the volume of robotic-assisted nephrectomies conducted in FY 2020.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Volumes of Robotic-Assisted Partial Nephrectomy in the Current Scenario

The current scenario considered current clinical practice without public funding for RAPN. With no public funding for robotics disposables, the volume of robotic-assisted surgical procedures in next 5 years will largely be affected by the availability of funding from hospitals' global budgets and foundations allocated to robotic-assisted surgeries, as well as by competing funding needs for inpatient health care services. However, given that we specifically evaluated the budget impact of providing public funding for RAPN, the total costs in the current scenario are zero over the next 5 years regardless of volume, because there is currently no public funding for robotics disposables. Therefore, for simplicity, based on historical volumes, we estimated the volumes of RAPN procedures in the current scenario without public funding for robotics disposables.

The volume of RAPN procedures for kidney cancer is increasing. In the reference case, we assumed that without public funding for robotics disposables, the volume would continue to increase at a rate of about 5% per year, from about 150 procedures in year 1 to 183 procedures in year 5, for a total of 831 procedures (Table 10).

Table 10: Volumes of Robotic-Assisted Partial Nephrectomy for Kidney Cancer in the Current and New Scenarios – Reference Case

Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Current scenario	150	158	166	174	183	831
New scenario	172	189	208	229	252	1,050

Volumes of Robotic-Assisted Partial Nephrectomy in the New Scenario

We consulted stakeholders and reviewed historical volumes to estimate the volumes of RAPN procedures in the new scenario (with public funding for robotics disposables). We expected that the volume would increase more rapidly with public funding because robotic-assisted surgeries have been shown to have some advantages (e.g., shorter length of hospital stay, less blood loss) over open and conventional laparoscopic procedures, patients generally prefer a minimally invasive surgical approach, and many surgeons prefer robotic-assisted procedures over conventional laparoscopic procedures. However, we also expected that hospitals would continue providing open and conventional laparoscopic surgeries in the future. Therefore, in the new scenario, we expected that the overall volume of robotic-assisted surgeries would increase moderately in the near future.

The volume of RAPN procedures has increased considerably in recent years. In the reference case, we estimated that the volume of RAPN procedures for kidney cancer (including benign neoplasm) in year 1 would be 20% higher than the volume in FY 2021 (143 × 120% = 172). In the subsequent 4 years, we estimated that the annual increase would be 10% higher than the previous year. In total, we estimated that 1,050 RAPN procedures would be conducted over the next 5 years in the new scenario (Table 10).

Resources and Costs

ROBOTIC SYSTEM COSTS AND CONTEXT

We obtained the costs of a robotic system from the manufacturer of the da Vinci Surgical System (email communication, Intuitive Surgical Canada Inc., September 2022). We also reviewed recent published literature and consulted clinical experts. The following summarizes our findings regarding the costs and context of the use of the da Vinci Surgical System in Canada:

- According to the Intuitive 2021 annual report,[16] the cost of the da Vinci Surgical System varied from $0.5 million USD and $2.5 million USD, depending on model, configuration, and geography. Annual service fees ranged from $80,000 USD to $190,000 USD
- An Australian hospital reported that the purchase cost of the da Vinci Xi Surgical System was $3.9 million AUD and that the cost for the sterilizing equipment was $150,000 AUD.[17] The da Vinci Xi Surgical System cost was close to the upper band of the cost reported in the Intuitive 2021 annual report[16]
- Presently, both the da Vinci Si (third generation) and Xi (fourth generation) Surgical Systems are used in Ontario. The da Vinci Si system was phased out of the Canadian market in 2019. The disposables, services, and support for this generation will not be available beyond 2024 (Intuitive Surgical Canada Inc., email communication, September 2022)

- Robotic systems other than the da Vinci Surgical System are used for robotic-assisted knee replacement surgeries in Canada.[18-20] Medtronic's Hugo robotic-assisted surgery system has received a Health Canada licence and is being used in Canada for hernia and colorectal surgeries.[21] The costs of these other robotic systems and their disposables are unknown

SCOPE OF BUDGET IMPACT ANALYSIS

In the budget impact analysis, we included the costs of robotic disposables. These costs are the direct costs related to the use of robotic systems. In the present analysis, for the new scenario, the Ontario Ministry of Health would be providing funding only for robotics disposables.

We did not include the following costs:

- Cost of the robotic system: We assumed that the robotic system would have been donated to or purchased by the hospital
- Operating room costs: Robotic-assisted surgeries have different operating room standards from those of conventional surgeries, such as the requirement for a larger operating room.[22] However, because we did not consider the cost of purchasing a robotic system for hospitals that do not currently have one, we did not consider the potential costs of upgrading the operating room
- Cost of annual maintenance/service: We did not include this cost because it is usually covered by the hospital's global budget

COST OF ROBOTICS DISPOSABLES

We obtained the cost of robotics disposables from the manufacturer of the da Vinci Surgical System (email communication, Intuitive Surgical Canada Inc., September 2022). The cost of robotics disposables can vary; for example, because surgeons may use different instruments for the same procedure and because a surgeon may use different instruments for total, partial, and radical robotic-assisted nephrectomy. The cost of robotics disposables may also vary because the disposables used may vary by diagnosis (e.g., malignant vs. benign neoplasm).

We arrived at an approximate cost for robotics disposables of $1,500.60 (2022 CAD) per procedure. This cost was based on the most common disposables used in robotic-assisted surgeries and included the costs of instruments (e.g., needle drivers, forceps, scissors) and accessories (e.g., drapes, seals, tip covers). However, we did not include the costs of stapling or a trocar (a device placed in the abdomen during laparoscopic surgery).

We conducted sensitivity analyses to capture the uncertainty of the cost of robotics disposables.

Internal Validation

The secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and several sensitivity analyses. Our reference case analysis represents the analysis with the most likely set of input parameters and model assumptions. Our sensitivity analyses explored how the results are affected by varying input parameters and model assumptions. We conducted the following scenario analyses for RAPN:

- **Scenario 1, all types of robotic-assisted nephrectomy (i.e., total, partial, and radical) for any main diagnosis:** In this scenario, we aimed to capture the use of robotic-assisted surgery in real-world clinical practice in Ontario, so we estimated the volumes of all types of robotic-assisted nephrectomy (i.e., total, partial, and radical) for any main diagnosis. In the current scenario, the volume of robotic-assisted nephrectomy is assumed to be 176 in year 1 (5% higher than in FY 2021: 168 × 1.05 = 176) and to increase 5% annually from years 2 to 5. In the new scenario, the volume in year 1 is 202 (20% higher than in FY 2021: 168 × 1.20 = 202), and the volumes in years 2 to 5 increase by 10% annually compared with the previous year (Table 11)
- **Scenario 2, slower increase in RAPN volumes for kidney cancer:** In the current scenario, the volumes of RAPN for kidney cancer are the same as those in the reference case. In the new scenario, the volume in year 1 is 157 (10% higher than in FY 2021), and the volumes in years 2 to 5 increase by 5% annually compared with the previous year (Table 11)
- **Scenario 3, varying RAPN volumes:** RAPN volumes may vary from current estimates for many reasons, including funding being limited to people with a diagnosis of malignant neoplasm of kidney (i.e., excluding people diagnosed with benign neoplasm), funding being provided for broader indications (i.e., additional main diagnoses) or procedures (i.e., also including total or radical nephrectomy), more people being referred for robotic-assisted surgery, and more hospitals purchasing robotic systems. For simplicity, we considered potential lower and higher volumes for any reason. In scenario 3a, we assumed a volume 10% lower than in the reference case. In scenario 3b, we assumed a volume 15% higher than in the reference case. We assumed that the volumes in both the current and new scenarios would increase proportionally to the corresponding volumes in the reference case
- **Scenario 4: varying costs of robotics disposables:** The costs of robotics disposables may vary, as discussed earlier. In scenarios 4a and 4b, we assumed that these costs were 25% higher and 50% higher, respectively, than those in the reference case (scenario 4a: $1,876 per procedure; scenario 4b: $2,250 per procedure). In scenario 4c, we assumed that the costs were 25% lower than those in the reference case ($1,125 per procedure)

Table 11: Volumes of Robotic-Assisted Nephrectomy – Scenario Analyses for Scenarios 1 and 2

Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Scenario 1: All types of robotic-assisted nephrectomy[a] for any main diagnosis						
Current scenario	176	185	194	204	214	973
New scenario	202	222	244	268	295	1,231
Scenario 2: Slower increase in RAPN volumes for kidney cancer						
Current scenario	150	158	166	174	183	831
New scenario	157	165	173	182	191	868

[a]Includes the volume of all types of robotic-assisted nephrectomy (i.e., total, partial, and radical).

Results

Reference Case

Table 12 provides the results of the budget impact analysis for RAPN. Since robotics disposables are not currently publicly funded, costs in the current scenario are zero. Therefore, for the new scenario, the budget impact is equal to the cost of the robotics disposables. Over 5 years, the total cost of robotics disposables for RAPN is $1.58 million.

Table 12: Budget Impact Analysis Results for Robotic-Assisted Partial Nephrectomy – Reference Case

	Budget impact, $ million[a,b]					
Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Current scenario[c]	0	0	0	0	0	0
New scenario	0.26	0.28	0.31	0.34	0.38	1.58
Budget impact	**0.26**	**0.28**	**0.31**	**0.34**	**0.38**	**1.58**

[a]In 2022 Canadian dollars.

[b]Some numbers may appear inexact due to rounding.

[c]Given that there is currently no public funding for robotics disposables, we assumed costs of zero for the current scenario. Therefore, in the new scenario, the budget impact is equal to the cost of the disposables.

Sensitivity Analysis

Table 13 summarizes the results of our scenario analyses for RAPN. The budget impact analysis results were sensitive to changes in surgical volume and the cost of robotics disposables.

Table 13: Budget Impact Analysis Results for Robotic-Assisted Partial Nephrectomy – Scenario Analysis

	Budget impact, $ million[a,b,c]					
Scenario	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
Reference case						
Budget impact	**0.26**	**0.28**	**0.31**	**0.34**	**0.38**	**1.58**
Scenario 1: All types of robotic-assisted nephrectomy for any main diagnosis						
Budget impact	0.30	0.33	0.37	0.40	0.44	1.85
Scenario 2: Slower increase in the volumes of RAPN for kidney cancer						
Budget impact	0.24	0.25	0.26	0.27	0.29	1.30
Scenario 3a: RAPN volumes 10% lower than in reference case						
Budget impact	0.23	0.26	0.28	0.31	0.34	1.42
Scenario 3b: RAPN volumes 15% higher than in reference case						
Budget impact	0.30	0.33	0.36	0.40	0.43	1.81
Scenario 4a: Cost of disposables 25% higher than in reference case						
Budget impact	0.32	0.35	0.39	0.43	0.47	1.97
Scenario 4b: Cost of disposable 50% higher than in reference case						
Budget impact	0.39	0.43	0.47	0.52	0.57	2.36
Scenario 4c: Cost of disposables 25% lower than in reference case						
Budget impact	0.19	0.21	0.23	0.26	0.28	1.18

[a]In 2022 Canadian dollars.

[b]Some numbers may appear inexact due to rounding.

[c]Given that there is currently no public funding for robotics disposables, we assumed costs of zero for the current scenario. Therefore, in the new scenario, the budget impact is equal to the cost of the disposables.

Discussion

We reviewed the volumes of robotic-assisted nephrectomy procedures (i.e., total, partial, and radical) conducted in Ontario between FY 2012 and FY 2021 and estimated the potential budget impact of publicly funding RAPN over the next 5 years. If robotics disposables are publicly funded, it is likely that the volume of robotic-assisted surgeries will increase. Thus, it will be necessary to understand the following impacts of expanding the use of robotic-assisted surgeries:

- Although funding for robotic systems was not the focus of this budget impact analysis, it will be necessary to plan for funding these systems in the long term. The manufacturer of the da Vinci Surgical System will not provide service or support for its third-generation system (da Vinci Si) beyond 2024. However, some hospitals are currently using this system; therefore, funding to replace these systems must be determined

- In addition to the da Vinci Surgical System, other robotic systems have entered the market and may expand the indications for robotic-assisted surgery over time. Because of existing market competition, it is expected that the prices of robotic systems and robotics disposables are unlikely to increase in the near future. However, given that the overall volume of robotic-assisted surgeries is likely to continue increasing, the total budget for robotic systems and robotics disposables may also increase
- Robotic systems have been used for an increasing number of indications in recent years. In Appendix 7, Table A8, we present the volumes of the less commonly performed robotic-assisted surgeries (i.e., all those except hysterectomy, nephrectomy, and radical prostatectomy) conducted between FY 2012 and FY 2021. Compared with hysterectomy, nephrectomy, and radical prostatectomy, there is greater uncertainty about the volumes of the less common surgeries, and these volumes are likely to be strongly affected by the funding status of robotics disposables. Therefore, guidance for the proper use of robotic systems for less common indications will be necessary
- From an economic perspective, the per-surgery attributable costs of capital investment for robotic systems and annual service fees for equipment maintenance would decrease with an increase in the volume of robotic-assisted surgeries performed. However, an increase in surgical volume would be associated with an increase in the cost of robotics disposables. Centralizing robotic-assisted surgeries within a few high-volume hospitals is one approach to increase the ratio of robotic-assisted surgical volume to number of robotic systems. But centralizing specialized surgical procedures is a complex process, affected by many factors beyond the scope of the present budget impact analysis. It would be difficult to determine the optimal number of robotic systems in Ontario, as well as the optimal volume of surgeries per system per year

Strengths and Limitations

Our study had the following strengths:

- We searched administrative databases to obtain the volumes of robotic-assisted surgeries conducted in Ontario between FY 2012 and FY 2021. These data reflect the real-world clinical use of robotic-assisted surgeries in Ontario
- We consulted several stakeholders to understand the current costs of robotics disposables and the current context of robotic-assisted surgery in Ontario

The following limitations should be noted when interpreting the findings of this analysis:

- A lack of high-quality clinical data prevented us from being able to quantify any potential savings of RAPN compared with open or laparoscopic partial nephrectomy
- This analysis did not address the impact of RAPN on the volumes of open or laparoscopic partial nephrectomy or on the volumes of alternative treatment options for kidney cancer

Conclusions

We expect that publicly funding the disposables required to perform robotic-assisted surgery would lead to a moderate increase in the volume of these surgeries conducted in Ontario. We estimate that the 5-year budget impact of publicly funding RAPN for people with kidney cancer would be $1.58 million.

Preferences and Values Evidence

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience with kidney cancer. In addition, this analysis aimed to examine patient, family, and caregiver preferences and perceptions of robotic-assisted partial nephrectomy (RAPN). This analysis also explored the preferences and values of health care professionals who provide surgical treatment for kidney cancer regarding the use of RAPN.

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. It includes the impact of the condition and its treatment on the person with the health condition, their family and other caregivers, and the person's personal environment. Engagement also provides insight into how a health condition is managed by the province's health system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature).[23-25] Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider to understand the impact of the technology in people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology or intervention we are exploring.

For this analysis, the preferences and values of people with lived experience kidney cancer and of health care professionals who provide surgical treatment for kidney cancer were examined via direct engagement. The initiative was led by the Patient and Public Partnering team at Ontario Health, and direct engagement with eligible participants was completed through telephone interviews and emailed responses.

Direct Patient Engagement

Methods

PARTNERSHIP PLAN

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people who have been directly affected by kidney cancer and their family members and caregivers. We engaged with participants via telephone interviews.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with kidney cancer, as well as the experiences of their families and caregivers.[26] The sensitive nature of exploring people's experiences of a health condition and their quality of life further supported our choice of methodology.

PARTICIPANT OUTREACH

We used an approach called purposive sampling,[27-30] which involves actively reaching out to people with direct experience of the health condition and health technology or intervention being reviewed. We approached a variety of community organizations, clinical experts, and community-based health programs in Ontario that support people affected by kidney cancer in an effort to increase the public's awareness of our engagement activity and to connect with people who would like to share their lived experiences.

Inclusion Criteria

We sought to speak with adults with lived experience of kidney cancer who had undergone or are planning to undergo partial nephrectomy. Participants did not have to have direct experience with RAPN.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

For this project, we spoke with 11 individuals with lived experience of kidney cancer, 10 of whom had experienced kidney cancer and nephrectomy and one of whom was a caregiver.

APPROACH

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 8) if requested. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 20 to 60 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[31] Questions focused on the impact of kidney cancer on participants' quality of life, their experiences with partial nephrectomy, and their perceptions of the benefits or limitations of RAPN. Appendix 9 provides the patient interview guide.

DATA EXTRACTION AND ANALYSIS

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[32,33] We used the qualitative data analysis software program NVivo[34] to identify and interpret patterns in the data. The patterns we identified allowed us to describe the impact of kidney cancer and partial nephrectomy on those interviewed.

Results

AWARENESS OF ROBOTIC-ASSISTED NEPHRECTOMY

There was variation among participants regarding their awareness of RAPN. Some had a good understanding of the procedure from information provided through the internet, TV shows, and other

media. Some were unaware of the availability of the procedure in Canada. Others had no awareness of the procedure or how it was performed.

> *I just thought of this big robot working on me.*

> *It was new to me before my diagnosis*. I wasn't really aware of it whatsoever.

A few participants who had conducted their own research about the potential benefits of RAPN sought out surgeons who performed this type of surgery or asked their surgeon for it.

> *I did my own research before*, [which] brought me to the robotic surgery. When I spoke to the doctor, I said I would really be inclined to go for robotic surgery If you think it's possible for me.

> *I specifically went to a surgeon that I know does robot*-assisted surgery because of that; that would have been my preferred option. So, I went specifically to ask for that.

For those who were unaware of RAPN, we provided information about the procedure verbally during the interview. Whether having been informed by their surgeon or by the interviewer, participants reported seeing RAPN as an innovative surgical procedure that could greatly benefit patients. Participants who had developed foundational knowledge of the procedure through independent research spoke about its benefits for the surgeon, including improved precision and visualization. Overall, participants reported a strong preference for RAPN over open partial nephrectomy (OPN) and laparoscopic partial nephrectomy (LPN). Key factors informing this preference included the technology's perceived clinical effectiveness and its minimal invasiveness.

> *I thought it was mechanical. I thought it was assisted*, and I thought it was a cutting-edge technology.

> *I am aware that it is being used* increasingly, that it [is] seen as a way to give the physician more precision. And that in some cases it allows remote surgery.

DECISION-MAKING

Most participants stated that they had conducted online research regarding their treatment options after being diagnosed with kidney cancer. They also spoke of the importance of the patient–doctor partnership and their comfort with their surgeon in guiding them toward the best surgical option for them. Participants emphasized the importance of having information about the surgical procedure they would be receiving, including its potential risks and benefits. All participants reported preferring a minimally invasive surgical option over an open procedure, citing recovery as one of the most significant factors of their decision-making.

> *It was what the surgeon felt was best for me. He's the professional. I had no clue. I told them*, "Just treat me like a family member." I just remember being very comfortable with both specialists.

> *It was just kind of trying to weigh out the risk of surgery now or surgery in the future. And we decided that the robotic surgery made the most sense just due to the fact that it was less invasive than open surgery. And so, if I'm going to be subject to more surgeries in my life . . .*

> *actually [robotic-assisted surgery]* would be the best situation for somebody in my unique situation.
>
> *We discussed the different forms of surgery and in* terms of robotic or open. How it was presented to me was both are effective, that open surgery would result in more scar, a longer time of recovery, [and] longer time in hospital. But the robotic one would be the opposite [of] that; it would be less scarring or would be less recovery. And [they said] that they would do their best to be able to do it robotically.

When asked about the importance of the reduced scarring associated with robotic-assisted nephrectomy, some mentioned that it wasn't an important factor in their decision-making and that it wouldn't have influenced their treatment decision. However, a few mentioned that it would have been a factor if they were younger. Others mentioned that the pain and risk of infection associated with scarring, rather than the scarring itself, did influence their decision-making.

> *I can say that the scarring is painful. So*, if there was less scarring, that would be something that would be an improvement to your overall well-being.
>
> *Once* upon a time, a long, long time ago, that may have been very important to me. No, that's irrelevant [now].
>
> *I think just for physical appearance*–wise, if you want to wear certain clothes, you don't want too many scars for bathing suits. I think if there's less of an open wound, the less chances of infection.

EXPERIENCE WITH OPEN NEPHRECTOMY

Mindset Before Surgery

Participants who had undergone open nephrectomy, either partial or radical, described their mindset before going into surgery and reported feeling nervous and anxious.

> *I mean the first time going* through any kind of, like, major cancer surgeries is heart-wrenchingly terrifying, right?
>
> *I was* terrified. I'd never had a huge invasive surgery like that before. . . . He [the surgeon] warned me that he was really going to have to slice me open from end to end. It wasn't going to be a standard nephrectomy–type of kind of incision . . . it was too big for that. Because of the fat on my belly, they would have to really increase the size of the incision in order to move that out of the way.

Recovery

Participants spoke of several factors relating to the invasive nature of open surgery that made recovery extremely challenging. These included postoperative pain, postoperative complications, the length of the incision and scarring, the length of hospital stay, the length of time off work, and caregiver burden.

Participants spoke about the immense postoperative pain they experienced after waking up from surgery, which for some lasted for days.

> *When I woke up from that initial surgery, I remember being in significant pain and having to wait a certain amount of time before I could have an increase in pain meds. It was a tough first few days.*
>
> *The first* five days, they really struggled to get his pain under control. He had a lot of nerve pain.

Participants also experienced postoperative complications, with hernia being the most common.

> *My husband did have a hernia after his second surgery*, and he still has it to this day. Nobody will touch it.
>
> *Because they cut into the stomach muscle wall, there's a hernia that developed.*

One participant experienced a complication known as a flank bulge (a bulge on the back or side of the abdomen) and described the negative impact of that on their quality of life.

> *I'm a woman. And if you imagine that* . . . hourglass shape, well, I have maybe a bit of an hourglass on one side and a bulge on the other side. That's because of how the surgery was done, in the open nature of that surgery. So that has plagued me ever since.

The large incision and scarring had long-term effects for some participants, particularly in terms of a negative impact on their self-esteem.

> *[The scar] twists around my body*, [and] it's very lengthy. It's profoundly impacted my life because I don't want to change at a gym or public beach, or I don't want to change around other people.
>
> *I think the bigger the cut, the more infection, the* [greater] chance of an infection.

All participants who had undergone open nephrectomy had a hospital stays of at least five days. In some cases, the hospital didn’t have available beds in the recovery room, so patients were put in the intensive care unit (ICU).

> *I was in hospital for five days* . . . despite it being a planned surgery. Postsurgery there weren't any rooms available, so I was stuck in ICU for 24 hours.
>
> *It was tough*; eight days is a long time to be in the hospital.

Participants also touched on the amount of missed work and the struggle they faced when they returned to work. One participant who was employed in a physically demanding job needed to be off work for an extended period.

> I had to take time off work, and even when I went back to work, it absolutely exhausted me to be at work. There were things like just because of where my incision was [that] even wearing a bra [or] putting any kind of work clothing on, it was going to rub that part of the scar.
>
> *He* was off work for 18 months before he started working again as a young guy.

Open nephrectomy also posed a substantial burden for caregivers, who had to take time off work to support the person who had had surgery as they recovered. Some caregivers experienced burnout because of the increased responsibilities placed on them.

> *My wife took a month off work. It just wasn't feasible taking care of two kids. She just* couldn't get the kids to daycare and school and get herself to work and take care of me all at the same time.

> *I had to scramble to get time off work* to be home with him for a month.

> *I slept in the chemo chair for three nights as a caregiver and had* multiple breakdowns because you're just exhausted.

EXPERIENCE WITH ROBOTIC-ASSISTED PARTIAL NEPHRECTOMY

Mindset Before Surgery

Participants who had undergone RAPN reported that knowing they were having a minimally invasive procedure allowed them to feel more relaxed. Most reported feeling comfortable and being well informed about the procedure and stated that they had gone into surgery feeling optimistic about achieving a full recovery. They attributed this mindset to their trust and confidence in the expertise of their surgeon. Participants also reported valuing efforts made by their surgical team to provide streamlined care.

> *There was not a lot of apprehension at all other than the slight normal thing of going under* [anaesthesia].

> *Naturally I was feeling a little* anxious, [but] I was feeling grateful that I could get this done and move on with my life.

> *I think that having the robotic surgery definitely made me feel a lot more at ease with the whole process. I understood that the incisions would be smaller [and that] the recovery would be easier. My stay in the hospital could potentially be shorter. My recovery would be shorter. All of these things made it a lot less stressful.*

Recovery

The recovery experiences of participants who had undergone RAPN, and one who had undergone LPN, contrast starkly with those of participants who had undergone open nephrectomy. Participants who had undergone a minimally invasive procedure all spoke of a positive recovery experience.

Most notably, they commented on the quick recovery time and even reported being surprised by how well they felt physically when they woke up from surgery. They also experienced minimal scarring and pain; some reported needing only over-the-counter pain medication. Participants reported experiencing no complications and short hospital stays. The most notable benefit that patients spoke about was the quick recovery time. Participants were surprised by how they good they felt physically after waking up from their surgery. Further, they were able to go back to their day-to-day lives with minimal constraints, the primary one being to avoid lifting or pushing heavy objects.

> *This is astounding* . . . I could walk unassisted. I just felt so amazingly good.

> *I had absolutely no pain from the moment I woke up. And I know they took off the liquid meds very quickly and put me on extra*-strength Tylenol.

> *T*he scars were obviously visible, but they're so tiny, there's nothing to them. But now they're just gone.

> *I went in early one day, had surgery early afternoon.* Then I was there that night, and then they kept me the next night, and I left the next morning.

> *I don't have any cancer in my life anymore* . . . I was back to normal so quickly.

Most participants reported being discharged after two to three days in hospital. All participants felt positive about the short hospital stay, citing their preference to recover in the comfort of their home.

> *I stayed two nights*; basically the day of the surgery, I stayed that night. They kept me another night. And the third day I was ready to go, and they discharged me that day.

> *I was out* of the hospital in a short period of time. I think it was probably about three or four days at the most.

BARRIERS

One key barrier to accessing RAPN that participants mentioned was a lack of awareness that the procedure can be performed minimally invasively and that RAPN is available.

> *I didn't know it was an option for me.*

Participants living outside large city centres mentioned geography as a barrier, particularly in terms of the out-of-pocket costs they incurred by having to travel to large city centres for treatment, such as hotel and parking costs. It was mentioned that such costs could be a barrier for people with lower socioeconomic status.

> *If patients are outside the m*ajor city *centres*, there would be a financial [barrier] because I guess the families that would come [would have to] stay in hotels or whatever, [and] the cost of transportation, [and] the back-and-forth of [seeing] the doctors.

> *It's more of a concern whe*n there's a long hospital stay because I don't live in Toronto. And so, then my poor husband has to go back and forth and back and forth.

Participants also mentioned having to miss work and the associated financial constraints as a barrier. A few participants who were retired and those who were employed but had sick time and vacation time available to them reported being grateful to be in those situations.

> *I'm taking so many days off to have presurgery meetings and scans and all of that. Those* really add up in terms of the time off that you can get.

> *That would be less hotel time for us, less missing work hours for my husband or whoever came with you [if one underwent RAPN]. That's more of a financial thing.*

RAPN was viewed favourably by all of those we interviewed. Participants emphasized the need for minimally invasive surgical options for patients. They stressed the importance of having it widely available.

> *I think that having the robotic surgery definitely made me feel a lot more at ease with the whole process. I understood that the that the incisions would be smaller, the recovery would be easier. My stay in the hospital could potentially be shorter. My rec*overy would be shorter. All of these things made it a lot less stressful.

One younger participant spoke about the lack of mental health support for families, especially for young children of parents undergoing cancer treatment.

Overall, robotic-assisted nephrectomy was viewed favourably by all of those we interviewed. Participants emphasized the need for minimally invasive surgical options and the importance of having it widely available.

Discussion

We engaged with people with lived experience of kidney cancer and nephrectomy. Participants spoke of their values and preferences regarding surgical treatment for kidney cancer, factors that affected their decision-making, and the impact of their treatment on their recovery and quality of life. All participants who had undergone RAPN spoke positively of that experience, whereas those who had experienced an open procedure described a number of recovery challenges. All participants viewed RAPN favourably and emphasized the importance of having minimally invasive surgical options made widely available.

There were a couple of limitations to this work. Only a few participants had experience with RAPN. There was also a lack of geographic representation among participants, most of whom lived in southern Ontario. However, we did have representation from both urban and rural perspectives, which provided robust narrative data.

Conclusions

RAPN was viewed favourably by all participants because of its minimally invasive nature. Participants emphasized the importance of a quick recovery, the reduced risk of postoperative complications, and a shorter hospital stay. Participants felt strongly that RAPN should be publicly funded.

Participants also emphasized the importance of awareness; that is, ensuring that people are made aware that minimally invasive surgery is an option for nephrectomy and that RAPN is available in Ontario. They also highlighted the importance of access, with geography, cost, and time mentioned as potential barriers to treatment for people who do not live near large city centres where treatment is provided, those unable to afford the out-of-pocket costs associated with treatment (e.g., hotels, parking), and those unable to take time off work without experiencing financial constraints.

Direct Provider Engagement

We engaged directly with health care professionals to provide contextual information from a clinical perspective on the use of RAPN in Ontario for people with kidney cancer.

Methods

PARTNERSHIP PLAN

The partnership plan for this health technology assessment focused on consultation to examine the experiences of urologic surgeons performing nephrectomies for people with kidney cancer. We engaged with participants via telephone interviews and emailed responses.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of urologic surgeons performing nephrectomy for people with kidney cancer.

PARTICIPANT OUTREACH

We used an approach called purposive sampling,[27-30] which involves actively reaching out to people with direct experience of providing treatment for the population and with the health technology being reviewed. We also used snowball sampling to identify additional contacts.

Inclusion Criteria

We sought to speak with urologic surgeons with experience performing nephrectomy for people with kidney cancer. Participants did not have to have direct experience with RAPN.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

We spoke with four urologic surgeons with experience performing nephrectomy for people with kidney cancer.

APPROACH

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, and the risks of participation. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 30 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions focused on the impact of the various surgical options for partial nephrectomy for people with kidney cancer (i.e., OPN, LPN, and RAPN) and participants' perceptions of the benefits and limitations of RAPN. The provider interview guide can be found in Appendix 10.

DATA EXTRACTION AND ANALYSIS

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting,

analyzing, and comparing information.[32,33] We used the qualitative data analysis software program NVivo[34] to identify and interpret patterns in the data.

Results

We spoke with urologic surgeons to understand their experiences of performing OPN, LPN, and RAPN for people with kidney cancer.

OPEN PARTIAL NEPHRECTOMY

Participants emphasized the invasive nature of OPN and mentioned that some patients opt for a laparoscopic radical nephrectomy (i.e., the removal of an entire kidney) to avoid an open surgery. OPN also requires a flank incision, which puts patients at risk of flank bulge, a very painful complication (described by one our participants in the Direct Patient Engagement section). Participants spoke about increased venous bleeding and the risk of substantial postoperative complications associated with an open procedure, including blood loss, blood clots, infection, hernia, chronic pain, longer hospital stay, and longer recovery time.

LAPAROSCOPIC PARTIAL NEPHRECTOMY

Participants mentioned that LPN is not commonly used because of the advanced surgical skill needed to perform this type of surgery, the risk of needing to convert from a laparoscopic to an open procedure, and the risk of total kidney removal. Further, the ergonomics involved in this type of surgery are challenging for the surgeon, as they sometimes need to contort their body depending on the location of the tumour. Participants also mentioned the longer ischemic time associated with this procedure compared to OPN and RAPN.

ROBOTIC-ASSISTED PARTIAL NEPHRECTOMY: SURGEON BENEFITS

All participants reported that RAPN provides benefits to both patients and surgeons. For patients, a key benefit is that the procedure is minimally invasive and safer than an open procedure. Regarding benefits to the surgeon, participants described various advantages based on their experience, including improved ergonomics (because the surgeon is seated during the procedure), thus leading to less fatigue and muscle strain. The wristed instruments allow for improved dexterity, precision, and suturing. Participants also mentioned the superiority of the three-dimensional imaging, which negates the need for tactile feedback. Improved mindset and confidence were highlighted as key benefits to surgeons when performing RAPN, owing to the benefits it provides over OPN and LPN.

ROBOTIC-ASSISTED PARTIAL NEPHRECTOMY: PATIENT BENEFITS

The surgeons we spoke with emphasized the advantages of minimally invasive procedures for patients. Because LPN is not performed often owing to its challenges and risks, the availability of RAPN makes it possible to offer patients a safe minimally invasive surgical option. And compared with OPN, RAPN allows patients to recover more quickly and experience much less pain, with patients typically needing minimal to no pain management. RAPN also allows for a shorter hospital stay than OPN, which is especially important consideration for those travelling long distances, as they can reduce their travel costs and time away from family and work. These advantages were reinforced by our participants in the Direct Patient Engagement section.

BARRIERS AND IMPLEMENTATION

Participants mentioned several barriers to accessing RAPN. Lack of funding was reported as the most prominent, as lack of funding limits the number of patients who can be treated with RAPN. Health human resources was also reported as a key barrier, especially in terms of the current nursing shortage in Ontario and specifically in terms of surgical nurses trained on the use of robotic systems. Training for current and new urologic surgeons is also lacking because of the unavailability of the technology. Participants also spoke about scheduling challenges, given that robotic systems are used for a number of procedures in addition to RAPN.

Surgeons mentioned two important logistical implementation considerations. First was the need for hospitals to have dedicated robotics teams, as this would allow for greater standardization and contribute to improved efficiency and outcomes. Second was ensuring that RAPN is implemented only in high-volume centres to ensure that surgeons and surgical staff maintain their proficiency in conducting robotic-assisted procedures. Concentrating robotic-assisted surgeries in high-volume centres would also allow surgical teams' skills to improve over time and increase their ability to take on more complicated cases.

EQUITY CONSIDERATIONS

RAPN is not available consistently across the province, creating an issue of geographic inequity that particularly affects people with lower socioeconomic status who cannot afford the out-of-pocket costs associated with travelling for treatment or the financial constraints imposed by taking time off work. Given the increased risk of surgical and postoperative complications associated with open partial nephrectomy, it is important to ensure that people with kidney cancer have equitable access to a safe, effective minimally invasive surgical option.

Discussion

We engaged with four urologic surgeons with experience conducting partial nephrectomies for people with kidney cancer. They either had direct experience with RAPN or were familiar with the technology. A key strength of this engagement was the inclusion of the perspectives of health care professionals who provide surgical treatment for kidney cancer in addition to those of people who have received this treatment. Assessing the perspectives of health care professionals allowed for rich narrative data on provider preference and values regarding RAPN.

Most participants had experience performing RAPN and spoke to the advantages of this technology over open and laparoscopic partial nephrectomy but also to the clinical, administrative, and operational barriers to providing RAPN. Participants spoke about the positive clinical outcomes of their patients who had received RAPN. They were also able to compare the experiences of patients who had received RAPN with those who had received open or laparoscopic partial nephrectomy. One participant who did not have direct experience with RAPN spoke about the perceived advantages that having access to RAPN would have for her practice and her patients.

Limitations to this work include our low participation rate and geography, with representation only from southern Ontario (three from Toronto and one from Ottawa). Further, we had no representation from other key members of the surgical team, such as surgical nurses or anaesthetists.

Conclusions

All participants were supportive of publicly funding RAPN and perceived RAPN as a beneficial alternative to open and laparoscopic partial nephrectomy. They emphasized the importance of RAPN being made available to people with kidney cancer because of the increased risks and complications associated with open partial nephrectomy. Participants noted that the main barrier to providing RAPN was funding, which currently limits the number of people who can receive this treatment. Other important barriers include health human resources, a lack of training because of the unavailability of the technology, and scheduling challenges. In terms of implementation, surgeons spoke of the need for hospitals to have dedicated robotics team and for robotic-assisted surgeries to be performed only at high-volume centres, both of which would improve standardization, efficiency, surgical team skill, and the ability of surgical teams to take on more complicated cases.

Conclusions of the Health Technology Assessment

Low-quality evidence from observational studies suggests that compared with open and laparoscopic partial nephrectomy, robotic-assisted partial nephrectomy may decrease estimated blood loss, shorten length of hospital stay, and reduce complications.

The cost-effectiveness of robotic-assisted partial nephrectomy for adults with kidney cancer is unknown. We estimate that the 5-year budget impact of publicly funding robotic-assisted partial nephrectomy for adults with kidney cancer would be $1.58 million.

People with lived experience of kidney cancer, as well as urologic surgeons, spoke favourably of robotic-assisted partial nephrectomy and its perceived benefits over open and laparoscopic procedures, particularly in terms of safety and quick recovery. Surgeons emphasized the importance of robotic-assisted partial nephrectomy being made available to people with kidney cancer because of the increased risks and complications associated with open partial nephrectomy.

Abbreviations

CCI: Canadian Classification of Health Interventions

CIHI: Canadian Institute for Health Information

DAD: Discharge Abstract Database

eGFR: estimated glomerular filtration rate

FY: fiscal year

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

ICD-10-CA: International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada

LPN: laparoscopic partial nephrectomy

LRN: laparoscopic radical nephrectomy

NACRS: National Ambulatory Care Reporting System

NICE: National Institute for Health and Care Excellence

OPN: open partial nephrectomy

ORN: open radical nephrectomy

RAPN: robotic-assisted partial nephrectomy

RARN: robotic-assisted radical nephrectomy

ROBIS: Risk of Bias in Systematic Reviews

Glossary

Adverse event: An adverse event is any noxious, pathological, or unintended change in a physical or metabolic function, revealed by signs or symptoms or a change in the results of laboratory tests, in any phase of a clinical study, whether or not the change is considered treatment related.[35] It may involve the exacerbation of a preexisting condition, intercurrent diseases, an accident, a drug interaction, or a significant worsening of the disease.

Budget impact analysis: A budget impact analysis is an evaluation of the financial impact of the introduction of a technology or service on the capital and operating budgets of a government or agency.[35]

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness analysis: A cost-effectiveness analysis is an economic evaluation consisting of comparing various options, in which costs are measured in monetary units, then aggregated, and outcomes are expressed in natural (nonmonetary) units.[35]

Equity: Unlike the notion of equality, equity is not about treating everyone the same way.[36] It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

Laparoscopic nephrectomy: Laparoscopic nephrectomy is a minimally invasive surgical procedure to remove all or part of a kidney that does not involve the use of a robotic system.

Market distribution: When evaluating more than two technologies, the market distribution is the proportion of the population that uses each technology.

Minimally invasive surgery: A minimally invasive surgery is a surgical procedure that is performed laparoscopically, meaning with the use of a thin tube with a video camera, which allows the surgeon to see inside the body. Compared with open (invasive) surgery, it involves several smaller surgical incisions and the use of smaller surgical tools.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration, monitoring, hospital stays) and costs associated with managing adverse events caused by treatments. This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Nephrectomy: Nephrectomy is a surgical procedure to remove an entire kidney, part of a kidney, or a kidney tumour.

Open nephrectomy: An open nephrectomy is an invasive surgical procedure to remove an entire kidney or part of a kidney. It involves a large surgical incision, or cut into the skin.

Partial nephrectomy: Partial nephrectomy is the surgical removal of part of a kidney or kidney tumour[15]; it allows for the preservation of renal (kidney) function.

Radical nephrectomy: Radical nephrectomy is the surgical removal of an entire kidney, nearby adrenal gland and lymph nodes, and other surrounding tissue.[15]

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Robotic-assisted nephrectomy: Robotic-assisted nephrectomy is a minimally invasive surgical procedure to remove all or part of a kidney that involves the use of a robotic system operated by the surgeon. It is most often used for partial nephrectomy (the removal of part of a kidney).

Robotic-assisted surgery: Robotic-assisted surgery is a minimally invasive surgical procedure that involves the use of a robotic system operated by the surgeon.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses include varying structural assumptions from the reference case.

Sensitivity analysis: A sensitivity analysis is a means for evaluating the robustness of a mathematical model by testing a plausible range of estimates of key independent variables to determine whether such variations result in meaningful changes in the model's results.[35]

Total nephrectomy: Total nephrectomy is the surgical removal of an entire kidney.[15]

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Evidence Methods

Clinical Evidence Methods

LITERATURE SEARCH

We performed a literature search on March 22, 2022, to retrieve studies published from January 1, 2017, until the search date. We used the Ovid interface to search MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials. A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. We used methodological filters to limit retrieval to systematic reviews, meta-analyses, health technology assessments, randomized controlled trials. The final search strategies were peer-reviewed using the PRESS Checklist.[37]

We created database auto-alerts in MEDLINE and monitored them biweekly from March 2022 to May 2022. We performed a focused grey literature search of the International HTA Database; the websites of Canadian, US, and UK health technology assessment agencies, and ClinicalTrials.gov. See Appendix 2 for our literature search strategies, including all search terms.

ELIGIBILITY CRITERIA

Studies

- Full-text publications in any language
- Studies published between January 1, 2017, and March 22, 2022
- Health technology assessments, systematic reviews, or randomized controlled trials

Population

- Adults with kidney cancer (renal tumours)

Intervention

- Robotic-assisted partial nephrectomy (RAPN) or robotic-assisted radical nephrectomy (RARN)

Comparators

- Laparoscopic partial nephrectomy (LPN) or laparoscopic radical nephrectomy (LRN)
- Open partial nephrectomy (OPN) or open radical nephrectomy (ORN)

Outcome Measures

- Estimated blood loss
- Blood transfusion rate
- Operative time
- Rate of positive surgical margins
- Warm ischemia time

- Length of hospital stay
- Cancer-specific survival rate
- Complications

LITERATURE SCREENING

A single reviewer conducted an initial screening of titles and abstracts using Covidence[38] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and selected eligible studies for inclusion.

DATA EXTRACTION

We extracted relevant data on the study characteristics and methods of all eligible systematic reviews, as well as the outcomes of the selected systematic reviews.

CRITICAL APPRAISAL OF EVIDENCE

We used the Risk of Bias in Systematic Reviews (ROBIS) tool[3] to assess the risk of bias in the identified systematic reviews. We used the review authors' quality measures as a guide or as reported by the authors if Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria were used.[39]

STUDY SELECTION

Robotic-Assisted Versus Laparoscopic Partial Nephrectomy

Four systematic reviews[4,6,40,41] reported results comparing RAPN with LPN. The risk of bias was high in three reviews[4,40,41] and low in one review.[6] We chose the systematic review by Tang et al[4] for outcomes in small renal tumours because it had the most recent literature searches and Lin et al[6] for outcomes in large complex renal tumours because of its low risk of bias.

Robotic-Assisted Versus Open Partial Nephrectomy

Six systematic reviews[4,7,40-43] reported results comparing RAPN with OPN. All were rated as being at high risk of bias. We chose the systematic review by Ni and Yang[7] because it had the most recent literature searches.

Robotic-Assisted Versus Laparoscopic Radical Nephrectomy

Two systematic reviews[8,44] reported results comparing RARN with LRN. Both reviews were rated as being at low risk of bias. We chose the systematic reviews by Crocerossa et al[8] because it had the most recent literature searches.

Robotic-Assisted Versus Open Radical Nephrectomy

We chose the systematic review by Croserossa et al,[8] which was the only review that reported results comparing RARN with ORN. Its risk of bias was rated as low.

Economic Evidence Methods

LITERATURE SEARCH

We performed a literature search on March 21, 2022, to retrieve studies published from January 1, 2017, until the search date. We used the Ovid interface to search MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials. A medical librarian developed the search strategy using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied. The final search strategies were peer-reviewed using the PRESS Checklist.[37]

We created database auto-alerts in MEDLINE and monitored them until May 1, 2022. We performed a focused grey literature search of the International HTA Database; the websites of Canadian, US, and UK health technology assessment agencies; and ClinicalTrials.gov. See Appendix 2 for our literature search strategies, including all search terms.

ELIGIBILITY CRITERIA

Studies

- English-language full-text publications
- Studies published between January 1, 2017, and March 21, 2022
- Cost–benefit analyses, cost-effectiveness analyses, cost-minimization analyses, cost–consequence analyses or cost–utility analyses

Population

- Adults with kidney cancer (renal tumours)

Intervention

- RAPN or RARN

Comparators

- LPN or LRN
- OPN or ORN

Outcome Measures

- Costs
- Health outcomes (e.g., quality-adjusted life-years, number of adverse events)
- Incremental costs and incremental effectiveness
- Incremental cost-effectiveness ratios

LITERATURE SCREENING

A single reviewer conducted an initial screening of titles and abstracts using Covidence[38] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists for any additional relevant studies not identified through the search.

Appendix 2: Literature Search Strategies

Clinical Literature Search

Search date: March 22, 2022

Databases searched: Ovid MEDLINE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <January 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to March 16, 2022>, Ovid MEDLINE(R) ALL <1946 to March 21, 2022>

Search strategy:

---

1 Robotic Surgical Procedures/ (12964)
2 Surgery, Computer-Assisted/ (20291)
3 Video-Assisted Surgery/ (2450)
4 Robotics/ (24685)
5 (((procedur* or surg* or techni* or excis*) adj5 (robot* or comput* assist*)) or (robot* adj3 assist*) or remote* surg*).ti,ab,kf. (37265)
6 (da vinci* or davinci or hugo* or versius* or ottava*).ti,ab,kf. (5828)
7 or/1-6 (73498)
8 exp Nephrectomy/ (36801)
9 nephrectom*.ti,ab,kf. (40949)
10 exp Kidney Neoplasms/su (19270)
11 ((kidney* or renal*) adj3 (adenoma* or adenocarcinoma* or cancer* or carcinoma* or carcinogenes#s or malignan* or metastas#s or neoplas* or oncolog* or tumo?r*) adj3 (surg* or excision* or operat*)).ti,ab,kf. (3037)
12 nephron sparing.ti,ab,kf. (2589)
13 or/8-12 (62648)
14 7 and 13 (2740)
15 ((robot* adj3 nephrectom*) or RAPN or RALPN).ti,ab,kf. (1608)
16 14 or 15 (2891)
17 (Systematic Reviews or Meta Analysis).pt. (155947)
18 Systematic Review/ or Systematic Reviews as Topic/ or Meta-Analysis/ or exp Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (298565)
19 ((systematic* or methodologic*) adj3 (review* or overview*)).ti,ab,kf. (275411)
20 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab,kf. (262063)
21 (evidence adj2 (review* or overview* or synthes#s)).ti,ab,kf. (46459)
22 (review of reviews or overview of reviews).ti,ab,kf. (1003)
23 umbrella review*.ti,ab,kf. (913)
24 GRADE Approach/ (79)
25 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).ti,ab,kf. (267545)

26 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus).ab. (295263)
27 cochrane.ti,ab,kf. (132294)
28 (meta regress* or metaregress*).ti,ab,kf. (12810)
29 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).ti,ab,kf. (16550)
30 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (37782)
31 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).ti,ab,kf. (32184)
32 or/17-31 (720437)
33 Clinical Trials as Topic/ (232871)
34 controlled clinical trials as topic/ (5697)
35 exp Randomized Controlled Trials as Topic/ (165789)
36 controlled clinical trial.pt. (187703)
37 randomized controlled trial.pt. (1107906)
38 Pragmatic Clinical Trial.pt. (4057)
39 Random Allocation/ (127457)
40 Single-Blind Method/ (54512)
41 Double-Blind Method/ (316787)
42 Placebos/ (60390)
43 trial.ti. (631740)
44 (random* or sham or placebo* or RCT*1).ti,ab,kf. (2676839)
45 ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (487425)
46 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (3555)
47 or/33-46 (3387185)
48 32 or 47 (3851613)
49 16 and 48 (416)
50 exp Animals/ not Humans/ (4975868)
51 49 not 50 (414)
52 limit 51 to english language [Limit not valid in CDSR; records were retained] (365)
53 limit 52 to yr="2017 -Current" (219)
54 53 use medall (143)
55 53 use coch (0)
56 53 use cctr (76)
57 remove duplicates from 53 (199)

Economic Literature Search

Search date: March 22, 2022

Databases searched: Ovid MEDLINE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <January 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to March 16, 2022>, Ovid MEDLINE(R) ALL <1946 to March 21, 2022>

Search strategy:

---

1 Robotic Surgical Procedures/ (12964)
2 Surgery, Computer-Assisted/ (20291)
3 Video-Assisted Surgery/ (2450)
4 Robotics/ (24685)
5 (((procedur* or surg* or techni* or excis*) adj5 (robot* or comput* assist*)) or (robot* adj3 assist*) or remote* surg*).ti,ab,kf. (37265)
6 (da vinci* or davinci or hugo* or versius* or ottava*).ti,ab,kf. (5828)
7 or/1-6 (73498)
8 exp Nephrectomy/ (36801)
9 nephrectom*.ti,ab,kf. (40949)
10 exp Kidney Neoplasms/su (19270)
11 ((kidney* or renal*) adj3 (adenoma* or adenocarcinoma* or cancer* or carcinoma* or carcinogenes#s or malignan* or metastas#s or neoplas* or oncolog* or tumo?r*) adj3 (surg* or excision* or operat*)).ti,ab,kf. (3037)
12 nephron sparing.ti,ab,kf. (2589)
13 or/8-12 (62648)
14 7 and 13 (2740)
15 ((robot* adj3 nephrectom*) or RAPN or RALPN).ti,ab,kf. (1608)
16 14 or 15 (2891)
17 economics/ (27481)
18 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (44067)
19 economics.fs. (441948)
20 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (534964)
21 exp "costs and cost analysis"/ (267513)
22 (cost or costs or costing or costly).ti. (137379)
23 cost effective*.ti,ab,kf. (186745)
24 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab,kf. (119358)
25 models, economic/ (11244)
26 markov chains/ or monte carlo method/ (44268)
27 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (24682)
28 (markov or markow or monte carlo).ti,ab,kf. (78218)
29 quality-adjusted life years/ (15943)

30 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (43259)
31 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (75339)
32 or/17-31 (1273396)
33 16 and 32 (155)
34 limit 33 to english language [Limit not valid in CDSR; records were retained] (143)
35 limit 34 to yr="2017 -Current" (65)
36 35 use medall (59)
37 35 use cctr (6)
38 35 use coch (0)
39 remove duplicates from 35 (65)

Grey Literature Search

Performed: March 30, 2022

Websites searched:
Alberta Health Evidence Reviews, Alberta Health Services, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, Health Technology Assessment Database, Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, and National Institute for Health and Care Excellence (NICE).

Keywords used:
robot, robot assisted surgery, robotic assisted surgery, robotic surgery, robotic surgeries, nephrectomy, nephrectomies, kidney, nephron, da vinci, davinci

Clinical results (included in PRISMA): 1

Economic results (included in PRISMA): 1

Appendix 3: PRISMA Flow Diagrams

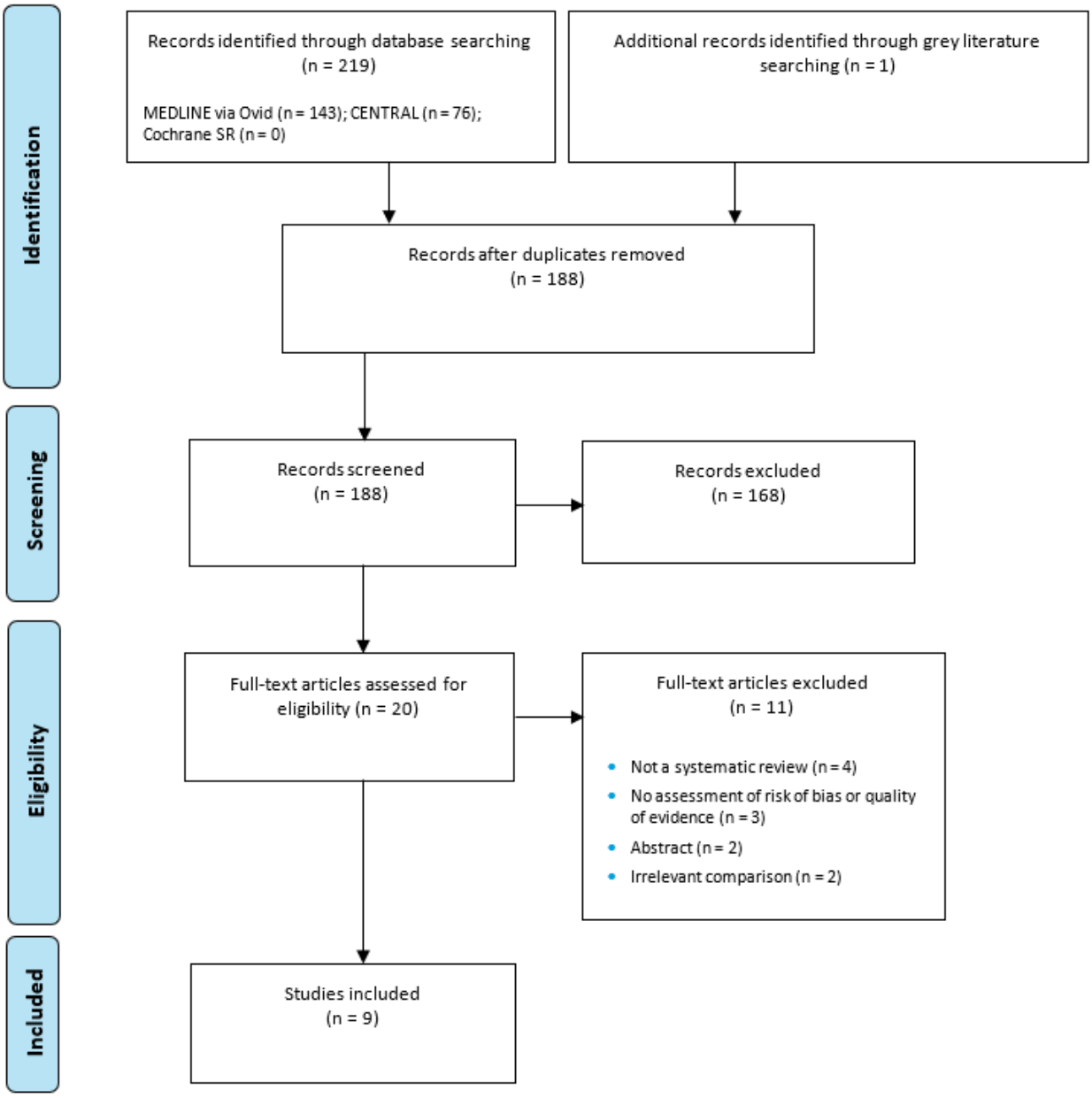

Figure A1: PRISMA Flow Diagram – Clinical Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 219 citations published between January 1, 2017, and March 22, 2022. We identified 1 additional eligible study from other sources. After removing duplicates, we screened the abstracts of 188 studies and excluded 168. We assessed the full text of 20 articles and excluded a further 11. In the end, we included 9 articles.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[45]

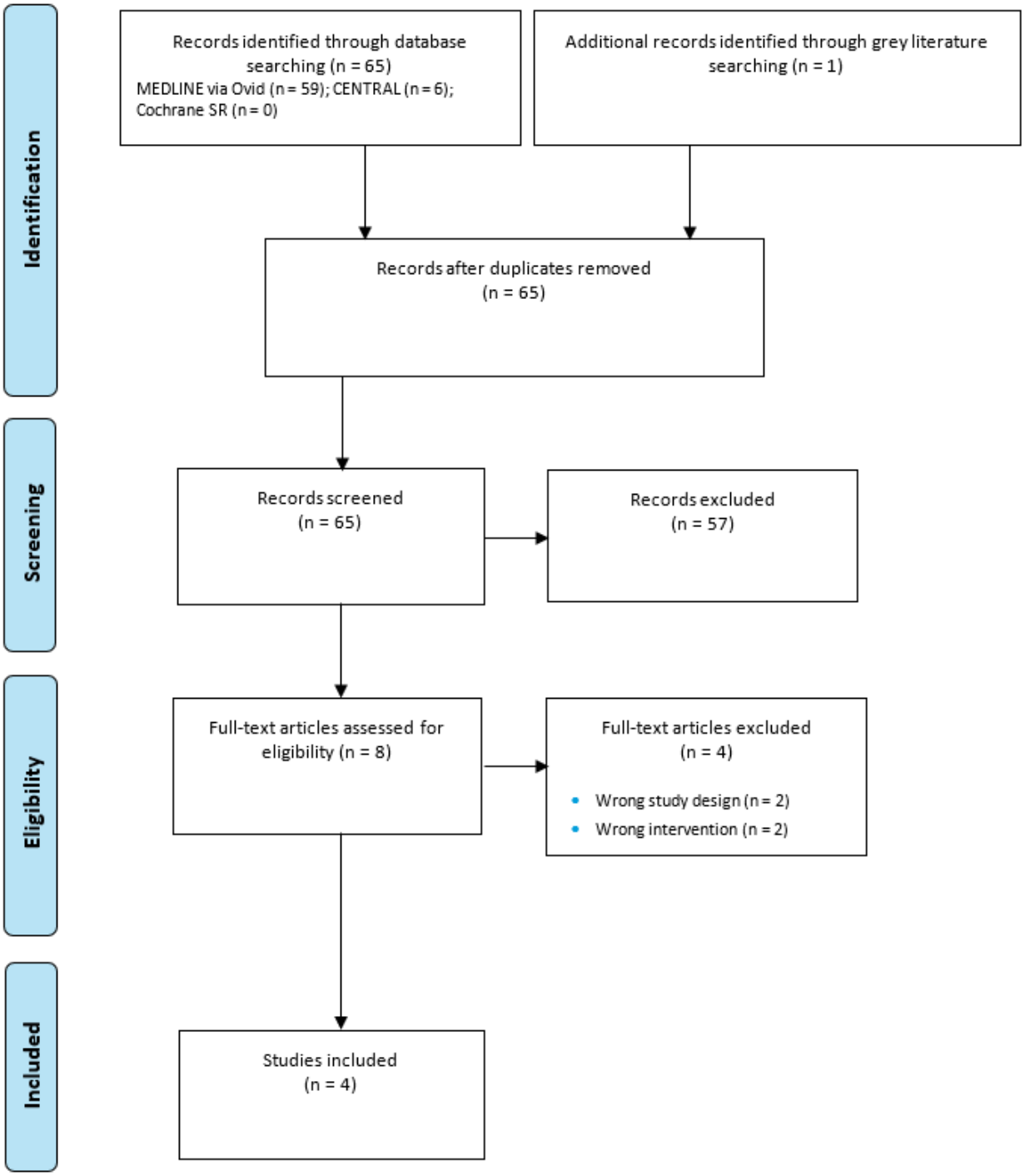

Figure A2: PRISMA Flow Diagram – Economic Search Strategy

PRISMA flow diagram showing the economic search strategy. The database search of the economic literature yielded 65 citations published between January 1, 2017, and March 21, 2022. We identified 1 additional eligible study from other sources. After removing duplicates, we screened the abstracts of 65 studies and excluded 57. We assessed the full text of eight articles and excluded a further four. In the end, we included four articles.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[45]

Appendix 4: Critical Appraisal of Clinical Evidence

Table A1: Risk of Bias in Systematic Reviews (ROBIS Tool)

	Phase 2				Phase 3
Author, year	Study eligibility criteria	Identification and selection of studies	Data collection and study appraisal	Synthesis and findings	Risk of bias in the review
Partial nephrectomy					
Alberta Health, 2017[40]	Low	High[a]	Low	Low	High
Lin et al, 2021[6]	Low	Low	Low	Low	Low
Maggard-Gibbons et al, 2019[41]	Low	Low	High[b]	Low	High
Ni and Yang, 2022[7]	High[c]	Low	Low	Low	High
Tang et al, 2021[4]	Low	Low	High[b]	Low	High
Tsai et al, 2019[42]	High[c]	Low	Low	Low	High
Xia et al, 2017[43]	High[c]	Low	Low	Low	High
Radical nephrectomy					
Crocerossa et al 2021[8]	Low	Low	Low	Low	Low
Li et al, 2020[44]	Low	Low	Low	Low	Low

Note: Possible risk-of-bias levels are low, high, and unclear.

[a]No description of literature search dates.

[b]The quality of the evidence for the outcome of estimated blood loss should have been graded low instead of moderate because of risk of bias and imprecision. The authors upgraded the quality of this outcome because of "parallel evidence on cystectomy which is consistency and comes from RCTs [randomized controlled trials]." However, robotic-assisted cystectomy is a different intervention from robotic-assisted nephrectomy; therefore, the outcome is not necessarily equivalent or comparable between the two procedures.

[c]Unclear whether objectives and eligibility criteria were predefined.

Appendix 5: Summary of Included Systematic Reviews

Table A2: Characteristics of the Included Systematic Reviews

Author, year, search end date	Population	Intervention	Comparator(s)	Outcomes	Studies included	Assessment of risk of bias/quality of evidence
Partial nephrectomy						
Lin et al, 2021[6] (inception to April 2020)	Patients diagnosed with localized renal tumours (clinical T1–T2) Complex tumours defined as masses with a RENAL score ≥ 7 or a maximum clinical tumour size > 4 cm	RAPN	LPN	Safety outcomes: conversion to open surgery, conversion to radical surgery, Clavien–Dindo classification grades 1–5, Clavien–Dindo classification grades 1–2, Clavien-Dindo classification grades 3–5) Effectiveness outcomes: operative time, estimated blood loss, warm ischemia time, length of hospital stay, positive surgical margins, eGFR decline, CKD upstaging	10 observational studies comparing RAPN vs. LPN	Quality of evidence: Newcastle–Ottawa Scale Level of evidence appraised according to the evidence evaluation criteria published by the Centre for Evidence-Based Medicine of the University of Oxford
Ni and Yang, 2022[7] (1997–2021)	Adults diagnosed with clinical T1 renal cell carcinoma	RAPN	OPN	Operative time, warm ischemia time, estimated blood loss, postoperative length of hospital stay, preoperative and postoperative eGFR, positive surgical margins, intraoperative and postoperative complications	7 observational studies comparing RAPN vs. OPN	Risk of bias: ROBINS-I tool Quality of evidence: Newcastle–Ottawa Scale

Author, year, search end date	Population	Intervention	Comparator(s)	Outcomes	Studies included	Assessment of risk of bias/quality of evidence
Tang et al, 2021[4] (January 2010–June 2019)	Adults with kidney cancer	RAPN	LPN and OPN	Intraoperative outcomes: estimated blood loss, intraoperative complications, surgery time, warm ischemia time	1 observational study comparing RAPN vs. LPN or OPN	Risk of bias: ROBINS-I tool Certainty of evidence: GRADE
				Postoperative outcomes: major complications, length of hospital stay	3 observational studies comparing RAPN vs. LPN	
				Functional and cancer-specific measures: eGFR rate, CKD upstaging, positive surgical margins, cancer-specific survival, overall rate of recurrence	3 observational studies comparing RAPN vs. OPN	
Radical nephrectomy						
Crocerossa et al, 2021[8] (January 2000–May 2020)	Adults with a diagnosis of kidney cancer, all tumour stages	RARN	LRN and ORN	Overall, major, intraoperative, and postoperative complications; operative time; estimated blood loss; transfusion; length of hospital stay; total hospital costs	2 observational studies comparing RARN vs. LRN and ORN 8 observational studies comparing RARN vs. LRN	Quality of evidence: Newcastle–Ottawa Scale

Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate, GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; LPN, laparoscopic partial nephrectomy; LRN, laparoscopic radical nephrectomy; OPN, open partial nephrectomy; ORN, open radical nephrectomy; RAPN, robotic-assisted partial nephrectomy; RARN, robotic-assisted radical nephrectomy; ROBINS-I, Risks of Bias in Nonrandomized Studies – of Interventions.

Appendix 6: Ongoing Studies – Clinical Evidence

Table A3: Ongoing Randomized Controlled Trials on Robotic-Assisted Nephrectomy for Kidney Cancer

ClinicalTrials.gov identifier	Title	Estimated enrollment	Estimated completion date
NCT04537247	A comparative study between open and robotic partial nephrectomy in treatment of high complex renal tumours	64	June 2023
NCT04534998	Robotic assisted vs. open partial nephrectomy (ROBOCOP)	50	March 2022
NCT04011891	Comparison of open vs. robotic partial nephrectomy (CONVERT)	30	November 2023
NCT03849820	Open vs. robotic-assisted partial nephrectomy (OpeRa)	606	March 2028

Appendix 7: Robotic-Assisted Surgical Volumes in Ontario

We used the Discharge Abstract Database and the National Ambulatory Care Reporting System (Canadian Institute for Health Information, IntelliHealth Ontario, November 2022) to identify robotic-assisted surgeries performed between fiscal years (FYs) 2012 and 2021.

A recent study by Muaddi et al[46] evaluated adverse events following robotic-assisted prostatectomy, hysterectomy, pulmonary lobectomy, and partial nephrectomy between 2008 and 2018 in Ontario.[46] We used a search strategy similar to that used by Muaddi et al[46] (i.e., we used the Canadian Classification of Health Interventions [CCI] codes), but we included all robotic-assisted procedures for people with a valid Ontario health card number (i.e., eligible to receive health care services covered by the Ontario Health Insurance Plan) and extended the search period to FY 2021. (Of note, the data we obtained were encrypted, meaning that no personal identifying information was available to us.) We identified robotic-assisted procedures through a combination of two codes: the "principal procedure code," which indicates the specific treatment (e.g., partial nephrectomy) a person received and the "all procedure code" of 7.SF.14.ZX, which indicates a robotic-assisted surgical approach.[13] Although other robotic systems have begun to be used for various procedures in Ontario in recent years, we understand that robotic-assisted partial nephrectomy is generally performed using the da Vinci Surgical System.

The total annual volumes in our searches were consistent with Muaddi et al.[46] The objective of the study by Muaddi et al[46] was to evaluate the surgical complications of four robotic-assisted procedures, whereas we aimed to understand the volumes of and indications for robotic-assisted surgeries in Ontario. Our data extraction methods differed slightly from those of Muaddi et al.[46] For example, Muaddi et al excluded patients with missing rural or income quintile status and patients at hospitals that performed fewer than 10 robotic-assisted procedures during the study period, but we did not make such exclusions. Further, we reported volumes by fiscal year, whereas Muaddi et al reported volumes by calendar year. As a result of these methodological differences, our results differed slightly from those of Muaddi et al.[46] However, given that our aim was to understand the overall trend in the use of robotic-assisted surgery in Ontario, we expect that the precision of our data was sufficient to meet our objective.

Table A4: Volumes of All Robotic-Assisted Procedures in Ontario, FY 2012–2021

Fiscal year	Volume
2012	909
2013	1,198
2014	1,376
2015	1,497
2016	1,570
2017	1,613
2018	1,791
2019	1,958
2020	1,745
2021	2,223
Total	**15,880**

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A5: Volumes of Robotic-Assisted Procedures by Main Diagnosis (N > 100), FY 2019–2021

ICD-10-CA code	Main diagnosis	Volume, N	Percent
C61	Malignant neoplasm of prostate	2711	45.7
M17	Gonarthrosis (arthrosis of knee)	562	9.5
C54	Malignant neoplasm of corpus uteri (endometrial cancer)	471	7.9
C64	Malignant neoplasm of kidney, except renal pelvis	345	5.8
C34	Malignant neoplasm of bronchus and lung	321	5.4
N13	Obstructive and reflux uropathy	156	2.6
C20	Malignant neoplasm of rectum	125	2.1
N85	Other noninflammatory disorders of uterus, except cervix	104	1.8

Abbreviation: ICD-10-CA, International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada.
Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A6: Volumes of Robotic-Assisted Procedures by Principal Intervention (N > 100), FY 2019–2021

CCI code	Principal intervention	Volume, N	Percent
1.QT.91.DA	Excise radical prostate using laparoscopic approach	2,617	44.2
1.PC.87.DA	Excision partial, kidney using apposition technique (e.g., suturing, stapling) and endoscopic (laparoscopic, laparoscopic-assisted, hand-assisted) approach	361	6.1
1.RM.89.AA	Excision total, uterus and surrounding structures – using combined laparoscopic and vaginal approach	317	5.3
1.RM.89.DA	Excision total, uterus and surrounding structures – using endoscopic (laparoscopic) approach	253	4.3
1.VA.53.LA-PN-N	Implantation of internal device, hip joint – dual component prosthetic device (femoral with acetabular)	207	3.5
1.GR.89.DA	Excision total, lobe of lung, using endoscopic approach (VATS)	163	2.8
1.GR.87.DA	Excision partial, lobe of lung, using endoscopic approach (VATS)	154	2.6
1.VG.53.LA-PP-N	Implantation of internal device, knee joint – TRI component prosthetic device	127	2.1
1.NQ.87.DE	Excision partial, rectum – colorectal anastomosis	115	1.9
1.VG.53.LA-PP-Q	Implantation of internal device, knee joint – TRI component prosthetic device, with combined sources of tissue (e.g., bone graft, cement, paste)	104	1.8

Abbreviations: CCI, Canadian Classification of Health Interventions; TRI, three components (i.e., femoral, tibial, and patellofemoral or a patellar button); VATS, video-assisted thoracoscopic surgery.

Source: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario), November 2022.

Table A7: Canadian Classification of Health Interventions Codes for Robotic-Assisted Nephrectomy

Procedure name	CCI code[a]
Robotic-assisted nephrectomy[b]	
Excision total, kidney	1.PC.89.^^ + 7.SF.14.ZX
Excision partial, kidney	1.PC.87.^^ + 7.SF.14.ZX
Excision radical, kidney	1.PC.91.^^ + 7.SF.14.ZX

Abbreviation: CCI, Canadian Classification of Health Interventions.

[a]The symbol "^^" refers to the use of any approach or technique (e.g., laparoscopic, open).

[b]We identified robotic-assisted procedures through a combination of two codes: the "principal procedure code," which indicates the specific treatment (e.g., nephrectomy) a person received and the "all procedure code" of 7.SF.14.ZX, which indicates a robotic-assisted surgical approach.[13]

Table A8: Volumes of Less Common Robotic-Assisted Procedures, FY 2012–2021

Fiscal year	Inpatient procedures except radical prostatectomy, hysterectomy, and nephrectomy	Outpatient procedures
2012	167	NA
2013	219	16
2014	301	41
2015	364	24
2016	355	27
2017	445	36
2018	503	45
2019	600	58
2020	631	70
2021	924	187
Total	**4,509**	**504**

Abbreviation: NA, not applicable.

Sources: Discharge Abstract Database (Canadian Institute for Health Information, IntelliHealth Ontario) (for inpatient procedures), November 2022; National Ambulatory Care Reporting System (Canadian Institute for Health Information) (for outpatient procedures), November 2022.

Appendix 8: Letter of Information

LETTER OF INFORMATION

Ontario Health

Ontario Health is conducting a review of **robot-assisted partial nephrectomy for kidney cancer**. The purpose is to understand whether this technology should be publicly funded in Ontario.

An important part of this review involves gathering perspectives of patients and caregivers of those who have been diagnosed with endometrial cancer and obesity and who may or may not have experience with robot-assisted partial nephrectomy.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 20-40 minutes of your time for a phone
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health staff. The interview will last about 20-40 minutes. It will be held over the telephone and with your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives on screening options in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however, no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After the project's completion, the records will be destroyed.

If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experiences.

IF YOU ARE INTERESTED, PLEASE CONTACT US BEFORE FEBRUARY 20, 2023:

Appendix 9: Patient Interview Guide

Patient Interview Guide: Robotic-Assisted Partial Nephrectomy

Care and Treatment Journey
History of cancer – type, diagnosis and background (general only)
How did you feel when diagnosed?
Post-diagnosis journey(Impact)
Wait times

Decision-Making
What treatment options were you offered?
Enough information going into surgery? Risks vs benefits?
How did you feel going into surgery? Concerns?
Mental health impacts
Why or why not are the below important to you:

1. Minimally invasive options (smaller cuts/incisions)
2. Reduction in hospital length of stay
3. Reduction of scarring
4. Reduction of infections
5. Reduction in post surgical complications

Robotic-Assissted Surgery Experience
Information given about robotic-assisted surgery
How was robotic-assisted surgery presented to you
Decision-making surrounding surgery
Access/barriers?-wait times, travel, out of pocket costs

Robotic-Assisted Surgery General Questions
Awareness of robotic assisted surgery
Comfort level
Preference (robotic vs conventional)
Procedure itself- pre and post op experience
Recovery-length of stay, post discharge (discharge information), readmission
Impact on qualify of life

Any equity/ethical concerns? (theoretically)
Any thing else you want to add?

Appendix 10: Provider Interview Guide

Robotic-Assisted Surgical Systems: Provider Interview Guide

Background Information

1. How long have you been practicing as a surgical specialist?
2. Where do you currently practice?
3. How often do you perform partial nephrectomies in patients with kidney cancer?

Robot-Assisted Surgery

4. What is your experience with robotic surgical systems to date?
   - Exposure to training?
   - Access to information about robotic systems?
   - How does robotic surgery compare to laparoscopic surgery for partial nephrectomies (e.g., health outcomes)?
     - How often do you perform the procedure with robot assistance versus laparoscopically?
     - Challenges
     - Benefits
   - How does robotic surgery compare to open surgery partial nephrectomies (e.g., health outcomes)?
     - How often do you perform the procedure with robot assistance versus open?
     - Challenges
     - Benefits

5. How would the public funding of robot-assisted partial nephrectomies impact your experience as a healthcare provider?
   - Enhanced continuity of care? Patient eligibility? Service provision?
   - Impact on workplace environment (e.g., efficiency, team dynamics, cognitive load, time spent engaging with patients)?
   - Barriers or concerns?
   - Equity or ethical considerations?

Conclusion

6. Is there anything else you would like to add or revisit?
7. Assisting with the recruitment of patients or other providers?
8. Do you have any questions for me?

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Ontario Health is committed to advancing equity, inclusion and diversity and addressing racism in the health care system. As part of this work, Ontario Health has developed an Equity, Inclusion, Diversity and Anti-Racism Framework, which builds on existing legislated commitments and relationships and recognizes the need for an intersectional approach.

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