

Evaluating trends in radical prostatectomy approach and 30-day complication rate in Ontario from 2010–2019Nickan Motamedi¹, Andrew McClure¹, Nicholas Power¹, Stephen Pautler¹, Lilian Gien¹, Blayne Welk¹, Jacob McGee¹¹London Health Sciences Centre, London, ON, Canada

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ABSTRACT

Introduction: Radical prostatectomy (RP) for prostate cancer has changed over the years with the advent of minimally invasive (MIRP) approaches, which includes robotic-assisted RP (RARP). The MIRP approaches have been shown to reduce complication rate, but there remain barriers to adoption. The objective of this study was to quantitatively describe the trend in the RP approach in Ontario, and to assess the trend in complication rates.

Methods: We conducted a population-based, retrospective cohort study including all men who underwent RP for prostate cancer in Ontario from 2010–2019. We used administrative data from Ontario’s health databases to gather surgical

KEY MESSAGES

- Through the 2010s in Ontario, Canada, there was a shift in radical prostatectomy approach from open to robotic technique, with over 1/3 of cases now being done robotically.
- Minimally invasive radical prostatectomy portends a lower complication rate, driven by lower transfusion rate, although open procedure now has better outcomes than earlier in the decade.
- Surgeon volume is among the most significant predictive factors of 30-day complication rate.

outcome data. Our primary outcomes were the annualized frequency of RP by surgical approach and annualized 30-day composite complication rate.

Results: In total, 22 118 patients were included in the analysis over the study period. There was a trend away from retropubic (RRP) frequency over the study period (80.3% of cases in fiscal year [FY] 2010 to 55.6% in FY 2018) and towards RARP approach (6.8% of cases in FY 2010 and 36.7% in FY 2018). The most common complication was blood transfusion at 6.26%, which saw a downtrend over the study period (7.96% FY 2010, 3.47% FY 2018). The odds ratio for 30-day complication for open RP compared to MIRP was 1.74 (95% confidence interval 1.57–1.92, $p < 0.001$).

Conclusions: In Ontario, there has been a steady shift away from RRP and towards RARP. Minimally invasive approaches portend a significantly lower complication rate, likely driven by a lower blood transfusion rate.

INTRODUCTION

Radical prostatectomy (RP) is the surgical intervention for prostate cancer, with approximately 8000 men undergoing the procedure in Canada each year^[1] Traditionally, this procedure has been done via open techniques, with open RP (ORP) including retropubic (RRP) or perineal (PRP) approaches. The advent of laparoscopic surgery allowed for the pioneering of the laparoscopic approach (LRP), and later with the commercial availability of the Da Vinci robot in 2000, the robotic-assisted RP (RARP).^[2] These two approaches collectively offered minimally-invasive RP (MIRP), with many studies investigating the benefits of MIRP over ORP. The most clear and consistent evidence summarized in a 2017 Cochrane review suggests that MIRP offers a lower complication rate, predominantly from reduced bleeding and blood transfusion requirement, as well as shorter length of stay in hospital compared to ORP.^[3] Of particular interest is how the complication rate is affected, as patients who suffer perioperative complications contribute to increasing healthcare utilization and cost in the form of re-admission or hospitalization and re-operation. On the other hand, up front procedure cost and surgical procedure time are limitations of the MIRP, and specifically the popular RARP, compared to the ORP. Other factors affecting the complication rate that have been described include age, obesity, and surgeon volume.^[4–6]

Nevertheless, in the United States, RARP in particular has quickly become popular for its patient and provider advantages. According to national insurance data sources, RARP was the choice approach for just 1.9% of RPs in 2002, increasing to 29.5% in 2008, and accounting for over 65% of all RPs in 2017.^[7,8] Accordingly, studies utilizing National Surgical Quality Improvement Program (NSQIP) data sources have acknowledged that this transition resulted in an overall reduction in the RP complication rate, again primarily driven by a reduction in need for blood transfusion.^[9] Ontario data would suggest that the adoption of the MIRP has not been as rapid as in the United States. The Canadian Institute for Health Information (CIHI) published

a report demonstrating tremendous heterogeneity in RARP delivery among the provinces, with only Ontario, Alberta, Quebec, and British Columbia using RARP as an approach at the time (Saskatchewan, Nova Scotia, and Manitoba have since adopted it as well).^[1] Nationally, only 19% of RPs were done robotically by 2013, ranging from less than 10% in BC to nearly 60% in Alberta, and Ontario and Quebec both at approximately 20%.^[1]

Since the CIHI report, there have been two studies published by the same working group describing trends in robotic surgery volume and complication rate in Ontario compared to alternative approaches using propensity score matching.^[10,11] These studies did include RARP among other robotic surgeries, but could not focus on key details such as quantifying factors that affect complication rate. The objective of this study was to quantitatively describe the trend in the radical prostatectomy approach in the last decade in Ontario, and to assess the trend in complication rates of the different RP approaches. Our secondary aim was to quantitatively describe the impact of various factors affecting RP complications.

METHODS

Study design and data sources

We conducted a population-based retrospective cohort study including all men who underwent radical prostatectomy for prostate cancer in the province of Ontario, Canada (population approximately 14.4 million in 2018) from April 1, 2010 to March 31, 2019.^[12] We excluded non-Ontario residents, men who were less than 18 or greater than 75 years old, did not have a confirmed diagnosis of prostate cancer within 5 years of surgery, had a non-urologist listed as surgeon, or who had a history of total or radical cystectomy, renal transplant, or received pelvic radiation within the last 10 years. We also excluded patients if they underwent abdominal perineal resection or other bowel resection on the same date as the RP or if we were unable to identify a billing record associated with the procedure. Subjects were followed up to 30-days post-operatively to measure 30-day complication rate. Our look-back window for exclusions was up to 10 years.

All Ontario residents have access to universal health care through the Ontario Health Insurance Plan (OHIP), with all insured services captured in administratively-linked databases. Patient demographic data was obtained using the Registered Persons Database (RPDB); comorbidity, patient characteristic, and complication data was obtained using the CIHI Discharge Abstract Database (DAD) and Same Day Surgery (SDS) databases; prostate cancer diagnosis was confirmed using Ontario Cancer Registry (OCR); surgeon data, reoperation data, obesity demographics, and identification of concurrent procedures was obtained using the OHIP database; pelvic radiation history was captured using the Cancer Activity Level Reporting database (ALR); some demographic data was gathered using three ICES derived cohort databases (ODD, HYPER, COPD). These datasets were linked using encoded identifiers and analyzed at ICES Western. ICES is a prescribed entity under section 45 of Ontario's Personal

Health Information Protection Act. Consequently, informed consent and approval from a Research Ethics Board were not required for this study.

Outcome definitions

Our primary outcome was the annualized 30-day composite complication rate of RP. To build the composite complication list, we categorized complications into cardiac, pulmonary, neurologic, venous thromboembolism (VTE), wound, transfusion, rectal injury or colostomy, fistula, urinary tract, or ureteric injury complications. The complete list of CCI and ICD-10 codes used to identify the complications can be found in Supplement 1. We intentionally used a broad spectrum of complications, in an attempt to capture as many complications related to RP as possible. Several previous studies examining complications were considered in an attempt to increase the generalizability of the data, and those with complications that could be captured within the population-based data were included.^[4,5,9,13,14] Notable omissions were incontinence and erectile dysfunction, as these cannot be assessed at 30 days postoperatively.

Baseline variables

Patient age, comorbidity information (including obesity with BMI ≥ 40 , diabetes, hypertension, chronic obstructive pulmonary disease, and composite Charlson Index score), centre of surgery, rurality and income quintile, surgical approach (highlighted separately), surgeon volume, and centre volume were obtained. The comorbidities were obtained using a 1 year look back window, and 3-year look back window for obesity. As BMI is not captured by our administratively-linked datasets, we identified obesity using the obesity premium rider for billing surgical procedures in OHIP database, where patients with BMI ≥ 40 qualify. For surgeon volume and centre volume, we identified thresholds for high and low volume surgeons and centres independently, as there is no standard threshold in the literature. To define high volume surgeons, we tallied each surgeon's case volume in each year, identified the number of cases required to define a 90th percentile case-volume surgeon in each year (range: 36-22 cases/year), and then chose the lower end of that range and applied it to all years to standardize the case threshold. Thus, a high-volume surgeon was one who performed at least 22 RPs in a year at some point during the study period. This methodology preserved the original case volume data, and ensured that some high-volume surgeons are not mischaracterized in the low volume group in some years. The same procedure was applied to define high volume centre (defined as 65 cases/year).

Analysis

We compared baseline characteristics for men who did and did not experience a complication from RP using standardized differences (SD). For large cohorts, SDs have been shown to better reflect clinically important differences than p-values obtained by independent samples t-test.^[15] With this method, we used $SD \geq 0.2$ as a clinically meaningful indicator of between group difference, as differences up to this threshold are still considered to be small.^[15] A 2-sided Cochran-Armitage test of trend was done to compare trends in 30-day complication rate for each surgical approach to RP. We used logistic regression modeling defining the effects of age,

obesity, surgeon volume, and minimally-invasive approach on complication rate, as these have been identified as important factors in the literature. We elected to analyze age and surgeon volume as continuous variables to elucidate the per-year and per-case effect on complication rate, as this provides a more scalable interpretation of the effect. All analyses were performed using SAS EG version 7.15 (SAS Institute, Cary, NC, USA).

RESULTS

Our initial cohort consisted of 24 099 patients. After applying exclusions criteria, 2771 were excluded leaving us with a final cohort of 22 118 who remained included for analysis Table 1.

Baseline characteristics are shown in Table 2. In the comparison between those with no complications and complications, variables that had an $SD \geq 0.2$ included median age (63 years vs 64 years, $SD=0.2$), Charlson comorbidity score median (0 vs 1, $SD=0.21$), and high-volume surgeon (53.5% vs 40.7%, $SD=0.26$). Median (IQR) surgeon and institution volume was 22 (13-52) and 65 (38-183) cases/year respectively. The number of cases stratified by surgical approach is shown separately to highlight the annual trend.

Table 1 shows the proportion of RP by surgical approach by each fiscal year. Over the 9-year study period, the majority of RPs were done via retropubic approach (66.3%), followed by robotic-assisted (23.7%), laparoscopic (6.7%), and perineal approach (3.3%). This 9-year period happens to define the increase in popularity of RARP, as in FY 2010-2011 only 6.8% of RPs were done via this approach, while in FY 2018-2019 it had reached 36.7%. This compares to the decreasing trend by retropubic approach, with 80.3% in FY 2010-2011 down to 55.6% in FY 2018-2019. Laparoscopic approach (10.3% to 4.6%) and perineal approach (2.6% to 3.1%) had smaller absolute changes.

The overall composite complication rate of the cohort was 2471/22 118 (11.17%), and is shown in Table 3. The most common complication category was need for blood transfusion (6.26%), followed by wound-related (5.38%), urinary tract infection (2.13%), cardiac (1.59%), and rectal (0.66%), with the others being rare, or accounting for less than 0.5% respectively. There was a downtrend that was most notable in transfusion rate (7.96% FY 2010-2011; 3.47% FY 2018-2019), while the wound complication rate along with the others remaining stable.

Table 4 presents the composite complication rate by surgical approach annually. Complication rates for retropubic approach (12.70 % overall; range 10.57% to 14.49%) and robotic (7.47% overall; range 6.35% to 8.89%) remained relatively stable year over year, while perineal (12.29% overall; range $\leq 6.85\%$ annual complications to 17.98%) and laparoscopic (8.56% overall; range $\leq 5.4\%$ to 14.95%) had greater fluctuations year over year, likely due to their small numbers. Overall, minimally-invasive approaches had fewer complications. The unadjusted odds ratio for 30-day complication for open RP compared to MIRP was 1.74 (95% CI 1.57-1.92, $p<0.001$). A 2-sided Cochran-Armitage test of trend for the composite complication rate for each approach is shown, with retropubic approach trending towards significantly fewer complications ($p<0.001$). Other trends were not significant.

The logistic regression analysis is shown in Table 5. A priori predictors based on our literature review were statistically significant, with increasing age associated with a higher complication rate (OR 1.03 [1.02-1.04 95% CI], $p < 0.001$), while protective associations included surgeon volume (OR 0.994 [0.993-0.996 95% CI], $p < 0.001$), and minimally-invasive approach (OR 0.71 [0.63-0.80 95% CI], $p < 0.001$). Obesity was not statistically significantly associated with composite complication rate (OR 1.31 [0.97-1.78 95% CI], $p = 0.0838$).

DISCUSSION

This study clearly illustrates the trend away from open RP and shift to RARP that is consistent with Muaddi et al (2022).^[11] Despite the trend, this study demonstrates that Ontario's most recent figure of 36.7% robotic-assisted approach in FY 2018-2019 remains lower than the United States and United Kingdom, where RARP trends over 60%.^[7,8] Our study demonstrated a reduction in complication rate over the study period, as illustrated in Table 4, from 13.24% in FY 2010-2011 to 9.04% in FY 2018-2019. The main drivers of complication rate were blood transfusion and wound complications.

The complication rate decline mirrors the rise in robotic approach, which portends a lower complication rate than open approaches. The only complication that appreciably declined year over year was the transfusion rate. While this would suggest that the transition to more RARP would account for the declining complication rates, it must be acknowledged that RRP trended towards significantly fewer complications over the study period as well. We hypothesize that a higher proportion of cases are being done by high volume surgeons, which could lead to fewer transfusions by this approach and contribute to the global trend of lower complication rate in RP.

Our study also confirmed that minimally-invasive approach (OR 0.71) is a protective factor against complication. Surgeon volume (OR 0.994) and age (OR 1.04) were analyzed as continuous variables, hence have smaller odds ratios, but are also important as they can be scaled. Using our results, the complication rate odds ratio for a surgeon who does one case per month ($0.994^{12} = \text{OR } 0.930$) and the surgeon who does one per week ($0.994^{52} = \text{OR } 0.731$) can be defined, which numerically defines the value of RP done by higher volume surgeons. Previous literature has categorized surgeon volume as "high" or "low" based on various thresholds or quartiles, where there is no agreed definition.^[5,6] In treating surgeon case volume as a continuous variable, this study defines the quantifiable importance to additional case volume, which previous studies such as Muaddi et al (2022) may not have accounted for.^[10] Obesity was not a statistically significant predictor of subsequent complication.

This study has limitations with regards to data sourcing. Many complications are not easily captured in administrative data, as the purpose of the data collection is not for clinical research purposes. For example, urinary tract infections are likely underestimated, as our databases would only capture those that are diagnosed in hospital or health facilities; outpatient urine studies, diagnoses, and treatments would not be captured. As such, our complication rate is potentially underestimated. From the baseline data, obesity is likely underestimated as the

obesity premium is only applied to BMI 40 and above, excluding many obese individuals. This may explain why demographically obesity is commonly associated with increased complications, but was not statistically significant in our study when adjusted for independently.

CONCLUSIONS

In Ontario, there has been a steady shift away from RRP and towards RARP in the last decade. RRP remains the most popular approach in Ontario, and RARP now accounts for over one third of cases. Minimally invasive approaches including RARP in Ontario portend a significantly lower complication rate, and this is likely driven by a lower blood transfusion rate, though the RRP complication rate has also independently declined over the decade. Future studies should examine the cost-effectiveness of the current shift to RARP, as well as barriers to implementation.

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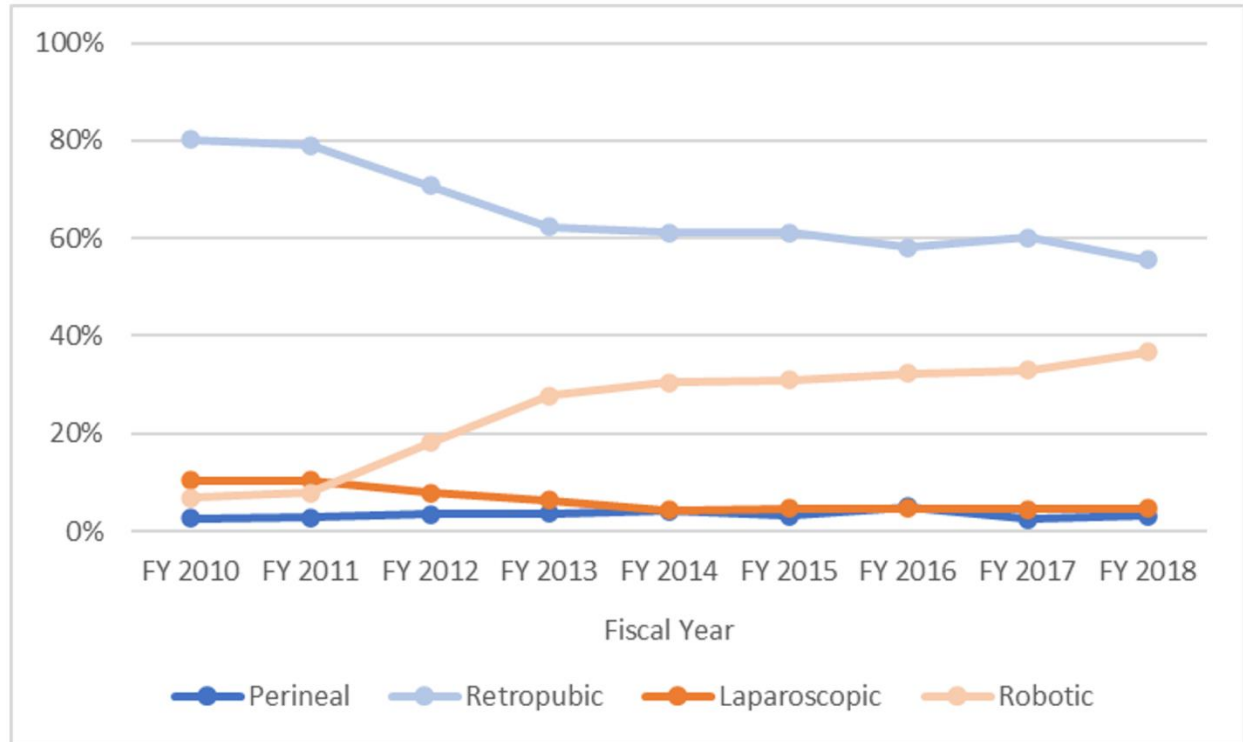
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FIGURES AND TABLES

Figure 1. Annualized proportion of radical prostatectomies done by each surgical approach.

Exclusion criteria	Number excluded	Number included
Initial Cohort	N/A	24 099
Data cleaning	15	24 084
Non-Ontario resident	6	24 078
Age <18 or >105 years	311	23 767
No cancer within 5 years of index	790	22 977
No matching OHIP record	1366	22 401
Total/radical cystectomy	113	22 288
Pelvic radiation therapy	133	22 155
Renal transplant	7	22 148
Concurrent procedure/Not by a urologist	30	22 118
TOTAL	2771	22 118

Variable	Value	Overall cohort	No complication	Complication	SD
		N=22 118	n=19 647 (88.9%)	n=2471 (11.1%)	
Age	Mean (SD)	62.49±6.44	62.35±6.43	63.58±6.44	0.19
	Median	63 (58–67)	63 (58–67)	64 (60–68)	0.2
Morbid obesity (BMI ≥40)	Yes	2.0%	2.0%	2.3%	0.02
Diabetes	Yes	16.6%	16.2%	20.2%	0.1
Hypertension	Yes	52.1%	51.4%	57.2%	0.12
COPD	Yes	12.7%	12.3%	15.1%	0.08
Charlson comorbidity score	Median (IQR)	0 (0–2)	0 (0–2)	1 (0–2)	0.21
	0	94.8%	96.6%	80.9%	0.51
	≥1	5.2%	3.4%	19.1%	
Center of surgery	Academic	44.1%	45.0%	37.3%	0.16
	Community	55.9%	55.0%	62.7%	0.16
Stage	1	8.8%	8.9%	8.3%	0.02
	2	50.4%	50.6%	49.0%	0.03
	3	31.5%	31.4%	32.7%	0.03
	4	3.7%	3.5%	5.2%	0.09
	Missing	5.6%	5.7%	4.7%	0.04
Income	Quintile 1	13.3%	13.1%	14.7%	0.05
	Quintile 2	18.2%	18.1%	18.8%	0.02
	Quintile 3	19.9%	19.8%	20.3%	0.01
	Quintile 4	22.3%	22.4%	21.3%	0.03
	Quintile 5	26.1%	26.3%	24.6%	0.04
	Missing	0.2%	0.2%	0.2%	0
Surgeon volume	High volume	52.0%	53.5%	40.7%	0.26
Institution volume	High volume	49.8%	50.5%	44.3%	0.12

Table 3. Annualized composite complication rate

Outcome	By fiscal year									Overall rate
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	
	n=2939	n=3007	N=2529	n=2291	n=2156	n=2260	n=2321	n=2248	n=2367	
Composite complication rate	13.24%	12.30%	11.19%	11.00%	11.22%	10.80%	10.17%	10.72%	9.04%	11.17%
Cardiac	1.74%	1.83%	1.27%	1.13%	1.72%	2.08%	1.38%	2.05%	1.10%	1.59%
Pulmonary	0.24%	0.27%	≤5*	0.39%	≤5*	≤5*	≤5*	0.36%	≤5*	0.24%
Neurologic	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	0.10%
Venous thromboembolism	0.41%	0.30%	NR	0.48%	≤5*	0.49%	0.56%	0.67%	0.38%	0.42%
Wound	5.44%	4.56%	5.02%	5.54%	5.52%	5.75%	6.16%	5.56%	5.15%	5.38%
Transfusion	7.96%	6.75%	6.21%	5.11%	4.55%	3.85%	3.15%	3.47%	3.42%	6.26%
Rectal	0.68%	0.47%	0.95%	0.70%	0.42%	0.71%	0.78%	0.67%	0.63%	0.66%
Fistula	≤5*	0.20%	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	0.12%
Urinary tract infection	2.18%	2.03%	1.46%	2.27%	2.27%	2.21%	2.37%	2.31%	2.15%	2.13%
Ureteric injury	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	≤5*	0.09%

*≤5 indicates that there was 5 or fewer occurrences, and the value or percentage cannot be published to preserve anonymity. NR: not reportable.

Table 4. Annualized 30-day composite complication rate for each surgical approach

Approach	Fiscal year									Overall	Test of trend p
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018		
Perineal	10.53%	13.41%	17.98%	11.76%	14.77%	11.43%	14.04%	≤5*	≤5*	12.29%	0.135
Retropubic	14.49%	13.26%	12.42%	13.24%	12.81%	12.00%	11.93%	11.83%	10.57%	12.70%	<0.001
Laparoscopic	8.58%	7.99%	8.16%	NR	≤5*	14.95%	8.26%	10.20%	7.27%	8.56%	0.659
Robotic	6.50%	8.05%	6.35%	6.47%	8.52%	7.71%	6.68%	8.89%	7.36%	7.47%	0.386

*≤5 indicates that there was 5 or fewer occurrences, and the value or percentage cannot be published to preserve anonymity. NR: none recorded.

Table 5. The effects of age, obesity, surgeon volume, and minimally invasive approach on composite complication rate

Variable	OR	95% CI	p
Age (per year)	1.03	1.02–1.04	<0.001
Obesity	1.31	0.97–1.78	0.0838
Surgeon volume (per case)	0.994	0.993–0.996	<0.001
Minimally invasive approach	0.71	0.63–0.80	<0.001

CI: confidence interval; OR: odds ratio.