Perioperative, oncological and functional outcomes of the first robotic prostatectomy program in Quebec: Single fellowship-trained surgeon's experience of 250 cases

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See related article on page 333.

Cite as: *Can Urol Assoc J* 2013;7(9-10):316-32. http://dx.doi.org/10.5489/cuaj.319
Published online October 7, 2013.

Abstract

Background: Robotic-assisted radical prostatectomy (RARP) is being increasingly done in Canada. Despite this, the Canadian literature lacks publications on the oncologic and functional outcomes of RARP. The objective of this study is to report the longest single surgeon experience in the province of Quebec.

Methods: We collected prospective data from 250 consecutive patients who underwent RARP by a single fellowship trained surgeon (AEH) from October 2006 to October 2012. Mean follow-up was 28 months (range: 1-72). The D'Amico risk stratification distribution was 34% in low-risk, 48% in intermediate-risk and 18% in high-risk groups.

Results: The mean operation time (±SD) was 194 ± 60.6 minutes, and estimated blood loss 318 ± 179 mL. The transfusion rate was only 0.4%. All procedures were completed robotically. The mean hospital stay was 1.2 days, and 88% of patients were discharged on postoperative day 1. The mean catheterization time was 7 days (range: 6-13). There were 2% major (Clavien III-IV) and 7.2% minor (Clavien I-II) postoperative complications, and no mortalities. On final pathology, 76% of patients were organ-confined and 70% specimen-confined. Pathological Gleason sum ≥7 accounted for 86%. Return of urinary continence (0-pads) at 3, 6, 12, and 24 months was 73.3%, 83.5%, 92.3%, 96.5%, respectively. Potency rate (successful penetration with or without medication) at 6, 12, and 24 months was 49.3%, 85%, and 95.3%, respectively. Operative time and positive surgical margin (PSM) in organ-confined disease (pT2) decreased significantly after 50 cases. Seventeen patients (6.8%) had no undetectable prostate-specific antigen (PSA) at first visit (PSA <0.1 ng/mL). Of remaining 233 patients, biochemical recurrence (PSA >0.2 ng/mL) was 4.7% (11 patients), and another 3.4% (8 patients) received early salvage radiotherapy (rising PSA, but <0.2 ng/mL). No patients with undetectable PSA required salvage treatments within 6 months postoperatively.

Conclusions: Our results compare favourably with high-volume RARP programs, despite mainly intermediate- to high-risk disease. Initial learning curve was estimated to be 50 cases. Fellowship training was instrumental in achieving adequate functional and oncological outcomes, while maintaining low complications rate.

Introduction

Prostate cancer is the most common non-skin cancer in Canadian men with an incidence of 121 cases/100 000 per year, and an estimated 26 500 new cases diagnosed in 2012.[1] Surgical management of prostate cancer includes radical retropubic prostatectomy (RRP), perineal prostatectomy (PR), laparoscopic radical prostatectomy (LRP) and robotic-assisted radical prostatectomy (RARP). About 69% to 85% of prostatectomies are performed robotically in the United States.[2] Although RARP has not been widely adopted in Canada, there is a growing pool of expertise and interest. There are presently 19 operational daVinci surgical systems (Intuitive Surgical Inc.) in Canada (personal communication via email, Daniel Minogue from Minogue Medical Inc., February 14, 2013).

Beside its known minimal invasive advantages, RARP has been shown in recent meta-analyses to improve functional outcomes when compared to open or laparoscopic prostatectomy with at least similar oncological outcomes.[3-5] Urinary incontinence and erectile dysfunction remain the most feared and bothersome side effects following prostatectomy.[6] Unfortunately, very few Canadian centres have reported functional and/or oncological outcomes of radical prostatectomy and most radical prostatectomies are being performed via the traditional open technique.[7] The only published RARP series is by Fuller and Pautler on 305 patients.[8] Therefore, the purpose of this study is to expand the Canadian robotic prostatectomy literature by reporting a single surgeon experience of RARP with complete accounts of functional and oncological outcomes, along with complications and learning curve.

Methods

Between October 2006 and October 2012, 250 RARPs were performed by a single fellowship-trained surgeon (AEH) at Hôpital du Sacré-Coeur de Montréal (HSCM), using a 3-arm daVinci system and one assistant. Data were collected and maintained prospectively in a comprehensive database encompassing over 170 fields per patient-case. All men were followed at similar intervals (1, 3, 6, 9, 12 months, and then every 6 months for 5 years, and yearly thereafter) by the same surgeon. Patients were not preselected; any patient who was a surgical candidate was offered RARP.

Surgical technique

We used the athermal robotic technique of prostatectomy described during the surgeon's training,[9] with few modifications. The urethral catheter was removed on postoperative day 7 without cystogram. A Jackson-Pratt (JP) drain was routinely placed and removed on postoperative day 1.

Data collection

Patient demographics and baseline parameters were collected, including prostate-specific antigen (PSA), Gleason score, clinical stage, International Prostate Symptoms Score (IPSS) and Sexual Health Inventory for Men (SHIM). Detailed intraoperative data and postoperative complications (<30 days) were recorded on a standardized data collection sheet. Postoperatively PSA values, International Prostate Symptom Score (IPSS), Sexual Health Inventory for Men (SHIM) and Erection Hardness Score (EHS) (Table 1) scores were collected at each visit.

Continence

Continence was assessed by a modified question added to the IPSS score *"How many pads per 24 hours on average did you use in the past month for urinary incontinence: 0, 1 security liner, 1 pad, 2 pads, 3 pads, 4 or more pads."* We used a strict definition of 0 pads.

Potency

Patients who had a SHIM score of 22 to 25 and underwent bilateral nerve sparing were included in potency analysis. Potency was defined as the ability to penetrate, with a SHIM score of 17 or more (with at least a score of 3 on question number 2) and/or EHS ≥3 with or without phosphodiesterase type 5 inhibitors (PDE5-I).

Surgical margin

Positive surgical margin (PSM) was defined as the presence of cancer at the inked margin.

Biochemical recurrence

Biochemical recurrence (BCR) was defined as PSA >0.20 ng/mL in patients who had an undetectable PSA (<0.10 ng/mL) at first visit. We advocated the use of early salvage radiotherapy, particularly in patients with pT3 or pT2+ (PSM) and a rising PSA, before PSA reached 0.20 ng/mL.

Results

Demographics

Median patient age was 60.2 ± 6.1 years (range: 41-74), median body mass index 27.9 ± 4.8 kg/m^2 (range: 19.5-46), and median follow-up 28 ± 16.4 months (range: 1- 72). Median PSA at time of diagnosis was 7 ± 5.9 ng/mL (range: 0.7-26.4) and transrectal ultrasound (TRUS) prostate volume 35.8 ± 15.5 mL (range: 12-101). Preoperative Gleason sum 7 or more accounted for 59.2% and clinical stage T2-T3 for 37.6% (Table 2). D'Amico risk stratification distribution was 34% in low-risk, 48% intermediate-risk and 18% high-risk groups.

Operative data

Median operative (OR) time was 194 ± 60.6 minutes with a zero conversion rate. Estimated blood loss (EBL) was 318 ± 179 mL and only 1 patient (0.4%) required blood transfusion. Average catheterization time was 7 days (range: 6-13). Mean hospital stay was 1.2 days and 88% of patients were discharged on postoperative day 1 (Table 3).

Complications

There were a total of 5 (2%) major postoperative complications. Of these 5 patients, 2 (0.8%) had pulmonary embolism (Clavien IVa) within 1 month of surgery and successfully treated with anticoagulation. Two other patients (0.8%) had myocardial infarction (Clavien IVa), one treated medically and the other underwent coronary artery bypass surgery. The fifth patient had incisional hernia (Clavien IIIb).

All 5 patients had fully functional recovery. Intraoperatively, within the first 25 cases, there was 1 rectal injury (Clavien IIIb), which was identified and closed primarily with no further consequences (JP drain and antibiotics for 1 week). There was no perioperative mortality. There was 1 urinary leak that resolved spontaneously with prolonged

Table 1. Erection Hardness Score	
Score	Description
1	Penis does not enlarge
2	Penis is larger but not hard enough for penetration
3	Penis is hard enough for penetration but not completely hard
4	Penis is completely hard and fully rigid.

drainage and catheterization (Table 4).[10] There was 1 case of anastomotic stricture that required endoscopic incision, and another case of anastomotic clip migration with stone formation that required endoscopic removal, both beyond the perioperative period (>90 days).

Pathological data

The mean specimen weight was 47.1 ± 15.4 g (range: 22-133). On final pathology, 34% were non-organ confined (≥pT3). Pathological Gleason sum 7 or more accounted for 86%, including 10% Gleason 8 to 10. Overall PSM rate was 30%. The PSM was 25.7% in pT2 and 43.3% in pT3 disease (Table 5).

Functional outcomes

The rate of urinary continence recovery (0-pads) was 42.3% at 1 month, 73.3% at 3 months, 83.5% at 6 months, 92.3% at 12 months and 96.5% at 24 months (Table 6).

There were 77 patients with preoperative SHIM scores between 22 and 25 who were included in potency analysis. Potency rate (successful penetration with or without medication) was 49.3% at 6 months, 85% at 12 months and 95.3% at 24 months. Of note, 214 patients (85.6%) had bilateral nerve sparing and 27 patients (10.8%) had unilateral nerve sparing. Only 9 patients (3.6%) had bilateral wide excision of neurovascular bundle. The questionnaire return rates by patients were 91.6%, 78%, 82.8%, 83.6%, 82.4%, 81.5% at 1, 3, 6, 12, 18 and 24 months, respectively.

Biochemical recurrence

There were 17 patients whose PSA did not reach undetectable levels at first visit (PSA <0.1 ng/mL) and were treated with androgen deprivation therapy (ADT) ± radiotherapy. Of the remaining 233 patients, 11 (4.7%) had BCR (PSA >0.2 ng/mL) at mean follow-up of 26.1 months and required either radiotherapy alone or in combination with ADT. In addition, there were 8 cases (3.4%) that were electively referred for early salvage radiotherapy for rising PSA that did not reach 0.2 ng/mL. BCR-free rate at 12 months was 95.8%. There were no patients with undetectable PSA who required salvage treatments within 6 months postoperatively.

Table 2. Demographic and preoperative characteristics of 250 patients		
Variable	Mean ± SD	Range/rate
Age (years)	60.2±6.1	41-74
BMI (kg/m^2)	27.9±4.8	19.5-46
Preoperative PSA (ng/mL)	7±5.9	0.7-26.4
Prostate volume (mL)	35.8±15.5	12-101
Gleason sum (n, %)		
G6	102	40.8%
G7	127	50.8%
G8	16	6.4%
G9	5	2%
Clinical stage (n, %)		
T1a/1b	1	0.4%
T1c	155	62%
T2a	86	34.4%
T2b	6	2.4%
T3	2	0.8%

SD: standard deviation; BMI: body mass index; PSA: prostate-specific antigen.

Learning curve

OR time deceased significantly after the first 50 cases by an average of 80 minutes. Mean OR time for consecutive quintile (50 patients) was 260 ± 65 minutes, 190 ± 50 minutes, 170 ± 45 minutes, 170 ± 32 minutes, and 180 ± 64 minutes (Table 7). We performed only 1 case per day until 58th case, and then we routinely operated on 2 patients per day. In addition, after the 35th case we got a stable bedside surgical nurse assistant.

PSM in organ-confined disease (pT2) per consecutive quintiles were 36.1%, 17.1%, 27.9%, 23.6%, and 23.6%, respectively. There was a significant improvement after 50 cases (Table 7).

Discussion

We report the longest single surgeon experience of RARP in the province of Quebec, with complete accounts of perioperative, functional and oncological outcomes. There is a paucity of Canadian prostatectomy experience in the medical literature, of any surgical approach. We compare our

Table 3. Operative data	
Mean operation time (robot time) ± SD (min)	194 ± 60.6
Mean operation time (skin to skin) ± SD (min)	224 ± 60
Conversion rate (%)	0
Mean blood loss ± SD (mL)	318 ± 179
Transfusion rate, n (%)	1 (0.4%)
Mean catheterization time, range (days)	7.1 (6-13)
Mean hospital stay ± SD (days)	1.23 ± 0.73

SD: standard deviation.

Table 4. Perioperative complications (<30 days)

	n (%)	Clavien classification[10]
Intraoperative		
Inferior epigastric injury	3 (1.2)	IIIb
Bladder and/or urethral tear	3 (1.2)	IIIb
Rectal Injury	1 (0.4%)	IIIb
Postoperative		
Pulmonary embolism	2 (0.8%)	IVa
Myocardial infarction	2 (0.8%)	IVa
Incisional hernia	1 (0.4%)	IIIb
Wound infection	2 (0.8%)	II
Urinary tract infection	2 (0.8%)	II
Arrhythmia	1 (0.4%)	II
Epididymo orhchitis	1 (0.4)	II
Pelvic hematoma	1 (0.4%)	II
Hematuria	3 (1.2%)	I
Acute renal failure	2 (0.8%)	I
Ileus	2 (0.8%)	I
Neuromuscular	2 (0.8)	I
Urinary leak	1 (0.4%)	I
Reynaud's phenomenon	1 (0.4%)	I

Table 5. Pathological characteristics of 250 cases

Pathological stage (n, %)		
pT2a	55	22%
pT2b	135	54%
pT3a	44	17.6%
pT3b	13	5.2%
pT3c	3	1.2%
Pathological Gleason sum (n, %)		
G5	1	0.4%
G6	34	13.6%
G7	190	76%
G8	15	6%
G9	9	3.6%
G10	1	0.4%
Prostate weight ± SD, range (g)	47.1±15.4	22–133
Overall PSM (fraction, %)	75/250	30%
PSM pT2 (fraction, %)	49/190	25.7%
pT2a	11/55	20%
pT2b	38/135	28.1%
PSM pT3 (fraction, %)	26/60	43.3%
pT3a	13/44	29.5%
pT3b	12/13	92.3%
pT3c	1/3	33.3%

SD: standard deviation; PSM: positive surgical margin.

results with available functional and oncological outcomes reported from Canadian centres.

Urinary incontinence is the most bothersome side effect following prostatectomy and is a major source of patient anxiety early on the postoperative period.[6,11] We used a strict definition of 0-pads to report the rate of urinary continence. The early continence rate at 3 months was 73.3%, which improved to 92.3% at 12 months and 96.5% at 24 months. Fuller and Pautler reported a 70% no-pad use at 1 year.[8] The University of Alberta group reported continence rates post-RRP of 57% at 3 months, and 85% at 12 months (definition of incontinence, <8 g of urine loss on the pad test per day).[12] In another prospective study from the same group, 239 patients were studied (172 RRP and 67 LRP). According to the 24-hour pad test, 13% of RRP patients and 17% of LRP patients remained incontinent at 1 year.[13] In a recent systematic review and meta-analysis on urine incontinence after RARP from high-volume centres worldwide, the weighted mean rate of urine continence at 12 months was 84% (range: 69-96) using the no-pad definition.[4]

In the era of PSA screening, younger patients with good functional status are being diagnosed with prostate cancer.[14] Therefore, all efforts are made to preserve quality of life in the postoperative period. In the current cohort, 85.6% of patients had bilateral and 10.8% unilateral nerve sparing. The potency rate was 49.3% at 6 months, 82% at 12 months and 95.3% at 24 months. Coelho and colleagues performed a meta-analysis on potency after RARP from pooled literature of centres of excellence.[15] Weighted mean potency rates were 61.1%, 71.2% and 94% at 6, 12 and >18 months, respectively. In a population-based study from a Quebec-wide RRP cohort between 1988 and 1996, Karakiewicz and colleagues studied 2227 men without erectile dysfunction before surgery. Of these men, only 25% reported erections of adequate firmness for intercourse.[16] To our knowledge no other Canadian series reported erectile function outcomes after prostatectomy.

In this cohort we report low complication rates. There were a total of 23 postoperative complications: 2% major, 7.2% minor and 0.8% required further intervention. Fuller and Pautler recorded 70 complications in 350 RARP cases: 7.5% major, 15.4% minor and overall 5.2% required further intervention.[8] Our mean hospital stay of 1.2 days matches large RARP series in the United States, but was significantly lower than in a reported Canadian series of LRP (3.4 days)[17] and RARP (3 days).[8]

Overall the PSM rate was 30%, subdivided into 25.7% for pT2 and 43.3% for pT3 disease. Fradet and colleagues

Table 6. Return of urinary continence (0-pads or 1-security liner) after RARP

Time (months)	0-pads (%)	1-security liner (%)
1	42.3%	51.5%
3	73.3%	80.0%
6	83.5%	87.4%
12	92.3%	93.7%
18	95.1%	96.1%
24	96.5%	97.0%

RARP: robotic-assisted radical prostatectomy.

Table 7. The effect of learning curve on operation time and positive surgical margin

Quintiles	Mean operation time ± SD (min)	Overall PSM, fraction (%)	PSM in pT2, fraction (%)
First 50 cases	260±65	19/50 (38%)	13/36 (36.1%)
Second 50 cases	190±50	13/50 (26%)	6/35 (17.1%)
Third 50 cases	170±45	14/50 (28%)	12/43 (27.9%)
Forth 50 cases	170±32	13/50 (26%)	9/38 (23.6%)
Fifth 50 cases	180±64	16/50 (32%)	9/38 (23.6%)

SD: standard deviation; PSM: positive surgical margin.

from Quebec City reported an overall PSM rate of 34.5% in 1712 RRP.[18] Corcoran and colleagues reported a 24.4% PSM rate in 1514 patients who underwent RRP from a combined series of University of British Columbia and University of Melbourne.[19] In our series, PSM rate is in part due to a higher rate during the initial experience and because most patients fall in the intermediate- (48%) and high-risk (18%) groups. Furthermore, we adopted an aggressive nerve-sparing approach, which may have contributed to PSM. After the first 50 cases, the PSM rate in pT2 was 23.4%, which is comparable to published literature after initial experience,[20-22] and lower than in population-based studies.[23] Fuller and Pautler reported an overall PSM rate of 16.1% in their cohort of low- to intermediate-risk RARP, with 10.2% for pT2 and 32% for pT3.[8] In Ontario, the median province-wide PSM rate for pT2 disease was 33% among 43 hospitals, with RRP volumes ranging 12 to 625, with no differences between community and teaching hospitals.[23] The University of Toronto group reported an overall 20.8% PSM in 1268 men who underwent RRP between 1992 and 2008.[24]

In this cohort we met all goals established by Cancer Care Ontario guidelines on radical prostatectomy, namely positive margin rate of <25% for pT2 disease, a mortality rate of <1%, rates of rectal injury of <1% and blood transfusion rates of <10%.[25]

As with any new robotic program, we encountered several challenges at the beginning of our experience. Patel and colleagues reported few major challenges during their initial experience which were related to lack of haptic feedback, inexperience with the robot-assisted laparoscopic approach, and the remoteness of the surgeon from the patient.[26] In our experience, these difficulties were not encountered as the primary surgeon (AEH) had formal fellowship training in robotic prostatectomy. The main challenges included the inexperience of the ward staff in the RARP care, the anesthetic team's unfamiliarity with the procedure, the scarce case scheduling, the changing bedside assistant until the 35th case, the longer setup and turnover times, and the alterations in surgical technique to optimize outcomes with only 1 assistant on a 3-arm robot. Efficiency was reached after 50 cases and the mean OR time deceased by an average of 80 minutes. In addition, the PSM rate in organ-confined disease (pT2) improved significantly after 50 cases. This improvement in PSM rate and OR concurs with the experience of other groups.[27,28] The learning curve for prostate cancer recurrence after radical prostatectomy is even longer and was estimated at 250 cases.[29] These daunting figures are best appreciated in a broader context. For example, of the 2861 RRPs performed in Quebec between 1988 and 1993, on average 80% were by urologists using this surgery 12 times or less annually.[30]

Our results compare favourably with RARP centres of excellence (Table 8),[20,27,31-41] despite initial difficulties and operating mainly on patients with intermediate- to high-risk disease.

Table 8. Functional and oncological outcomes in contemporary series of open, laparoscopic and robotic-assisted radical prostatectomy

Series	Technique	n	Mean FU (months)	PSM (%)	Intercourse at 1 year (%)	Pad-free at 1 year (%)	BCR at 1 year (%)
Rabbani et al.[32]	Open	225	12	NA	42	NA	NA
Schover et al.[33]	Open	240	52	NA	NA	NA	NA
Guillonneau et al.[34]	Lap	550	36	16.7	66	82	14
Hoznek et al.[35]	Lap	134	12	25	5.6	86	11
Rassweiler et al.[36]	Lap	438	12	30	NA	90	13.2
Stolzenburg et al.[37]	Lap	70	12	21	33 (6 mo)	90 (6 months)	NA
Hara et al.[38]	Lap/open	52	6	NA	NA	NA	NA
Ahlering et al.[20]	RARP	60	9	17	33 (9 mo)	76 (3 months)	NA
Patel et al.[27]	RARP	200	9.7	21	NA	98	5
Bentas et al.[39]	RARP	40	15	30	22	84 (15 months)	NA
Menon et al.[40]	RARP	200	7.9	6	68	90	4
Tewari et al.[41]	RARP	530	12	9	78	98	4
Kaul et al.[31]	RARP	154	12	6.4	96	97	0
Present study	RARP	250	28	30	85	92.3	4.2

FU: follow-up; PSM: positive surgical margin; BCR: biochemical recurrence; Lap: laparoscopy; RARP: robotic-assisted radical prostatectomy. *Table reproduced with permission.[31]

Conclusion

Our results compare favourably with high-volume RARP programs, despite mainly intermediate- to high-risk disease. Initial learning curve was estimated to be 50 cases. Fellowship training was instrumental in achieving adequate functional and oncological outcomes, while maintaining low complications rate.

Acknowledgment: Ministry of higher education in Saudi Arabia for providing scholarship to Dr. Naif Al-Hathal in support of his fellowship training.

Competing interests: None declared.

This paper has been peer-reviewed.

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