Complications following robot-assisted radical prostatectomy in a prospective Canadian cohort of 305 consecutive cases

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Abstract

Background: Robot-assisted radical prostatectomy (RARP) has emerged in the last decade as an alternative to open radical prostatectomy for men with localized prostate cancer. The increased cost of this technique has been justified by its ability to reduce blood loss, and to provide improved vision, less postoperative pain and more rapid recovery from surgery, while maintaining satisfactory oncological and functional outcomes. Given the increasing diffusion of robotic surgical technology within Canada and its associated high capital and operating costs, we review the clinical outcomes and complications from 305 consecutive cases performed at our Canadian institution.

Methods: A consecutive cohort of 305 patients with a mean follow-up of 30 months was analyzed with institutional ethics approval. All patients were treated and reviewed postoperatively by a single surgeon (SP). The primary aim of the study was to assess the incidence and type of complications associated with RARP in a Canadian setting. Our prospective database captured preoperative, intra-operative and postoperative data and was maintained by an individual independent of the robotic program. We report complications categorized according to the Clavien system. Multiple complications seen in an individual were recorded separately for the purposes of our analysis.

Results: Between April 2005 and October 2010, 305 patients underwent RARP at our institution. A total of 70 complications were identified, with 47 (67.1%) requiring only conservative or pharmacological management (Clavien I-II). Twenty-three patients were found to have a major complication (Clavien III-V). Of the 16 who required intervention under general anesthesia, 3 required emergency treatment and the remaining patients underwent elective surgery.

Conclusions: RARP has been incorporated at our institution with an acceptably low rate of intra-operative and postoperative complications. We have found that the database was effective in providing patients with outcome-related information, which in turn helped us gain patient consent with regard to the institution-specific risks of RARP.

Introduction

Prostate cancer remains the most common cancer diagnosed in Canadian men, with an estimated 24 600 cases newly diagnosed in 2010.[1] The lifetime risk of Canadian men being diagnosed is between 12% and 16%.[2]

The DaVinci surgical system (Intuitive Surgical, Sunnyvale, CA) was approved by the United States Food and Drug Administration in 2000 and has been widely adopted within the United States as the preferred technique for radical prostatectomy. The increased cost of robot-assisted radical prostatectomy (RARP) when compared with open radical prostatectomy (ORP) has been justified in terms of its ability to reduce blood loss and to provide improved vision, less postoperative pain and more rapid recovery following surgery, while maintaining satisfactory oncological and functional outcomes.[3]

Since Health Canada approved the use of robotic surgery in March 2001,[4] its adaptation has been less rapid in Canada. This is likely a result of differences in the health care delivery model. Most radical prostatectomies in Canada continue to be performed via the traditional open approach.

Our institution (Division of Urology, Western University, London, Ontario) was the first in Canada to perform radical prostatectomy with the DaVinci surgical robot in 2004.[5] Given the increasing diffusion of the technology within Canada and its associated high capital and operating costs, we review the clinical outcomes and complications from 305 consecutive cases performed by a single surgeon.

Methods

A prospective database of outcomes related to RARP has been maintained at our institution since the inception of the robotic program. Patients provided informed consent following institutional ethical approval from Western University (13086E). Information was recorded on standardized data

collection forms. Our database captured preoperative, intra-operative and postoperative data for 305 consecutive patients. Patients were treated and reviewed postoperatively by a single surgeon (SP). The primary aim of the study was to assess the incidence and type of complications associated with RARP in a Canadian setting.

The technique of RARP has been thoroughly described.[6] With the exception of one case performed extraperitoneally early in our series, surgery was performed at our institution via a transperitoneal antegrade approach with early division of the bladder neck. Pneumoperitoneum was achieved in all cases via an open Hasson technique[7] and all ports were inserted under direct vision. A bilateral pelvic lymph node dissection was performed for all patients, except for those with low-risk disease as defined by the D'Amico criteria.[8,9] Patients with high-risk disease, as defined by the D'Amico criteria, or with gland volumes more than 150 cm^3 are not offered RARP at our centre.

All patients were followed up at our institution with the exception of 2 patients who opted to follow-up with their urologist out-of-province due to the travel associated with follow-up at our centre. Complications were recorded during surgery and postoperatively on an inpatient and outpatient basis by the attending surgeon. With regard to continence and sexual health outcomes, we used validated, self-reported questionnaires (UCLA Prostate Cancer urinary function and Sexual Health Inventory for Men [SHIM-IIEF-5]). These were administered at the time of each follow-up appointment. A data manager independent of the robotic program reviewed patient records to capture complications related to surgery.

We reported complications categorized according to the Clavien system (a standardized method).[10] Complications are assigned a grade of I to V (Table 1). Multiple complications seen in an individual patient were recorded separately for our analysis.

Table 1. Clavien classification of surgical complications

Clavien	Definition
I	Any deviation from the normal postoperative course without the need for pharmacologic/ surgical/ radiological intervention (antiemetics, analgesics, antipyretics, diuretics, electrolytes allowed)
II	Complication requiring pharmacological treatment
III	Complication requiring surgical/ endoscopic/ radiological intervention
IIIA	Intervention without general anaesthesia
IIIB	Intervention under general anaesthesia
IV	Life-threatening complication requiring ICU management
IVA	Single organ dysfunction
IVB	Multi-organ dysfunction
V	Patient mortality

ICU: intensive care unit. Adapted from Hasson HM. *Am J Obstet Gynaecol* 1971.[7]

Results

Between April 2005 and October 2010, 309 consecutive patients underwent RARP at our institution. Of these, 2 patients did not consent to having their information stored in our prospective database. All patients were followed up at our institution, except for 2 patients who opted for follow-up out-of-province due to the travel time of getting to our centre. This represents the largest single surgeon series in Canada to date, with a mean follow-up of 30 months.

We collected preoperative patient data (Table 2). Demographic data are representative of a typical cohort of patients with localized low- to intermediate-risk prostate cancer, with a mean age of 59.9 years (standard deviation [SD]±7) and body mass index (BMI) of 27.8 kg/m^2 (SD±3.8).

With regard to oncological data (Table 3), the figures are within the expected range for patients presenting with screen detected, localized prostate cancer. The mean preoperative prostate-specific antigen (PSA) was 6.9 ng/mL (SD±3.2). Twenty-eight per cent of patients had Gleason 7 disease on biopsy; the remaining patients were classified as Gleason 6. Information regarding margin status was stratified according to pathological stage (Table 3). The overall positive margin rate was 16.1%, taking into consideration patients with both pT2 and pT3 disease.

Based on an analysis of the intra-operative variables, we found a mean operation time (defined as the time from the first incision until closure is complete) of 198 mins (SD±40). Mean estimated blood loss (EBL) was 200 mL (SD±343) and one intra-operative transfusion was required.

In total, 3 cases were converted to ORP. The first two cases occurred early in our series (case 2 and 10) due to failure to progress and the third was due to a technical failure of the robot requiring replacement parts which were not immediately available. In all cases, the operation was completed by an open retropubic technique by the primary robotic surgeon (SP). No complications beyond the need to convert were identified in these three patients.

A total of 269 patients had data on continence status at 12 months postoperatively. To date, 2 patients (0.7%) have required surgical management of severe and persistent stress type urinary incontinence. One patient underwent insertion

Table 2. Patient data

Patient variable	Mean (±SD)
Age (yrs)	59.9 (±7)
BMI (kg/m^2)	27.8 (±3.8)
Estimated Prostate Volume	41.5 (±17.7)
Pre-treatment PSA (ng/mL)	6.9 (±3.2)
Mean operative duration (mins)	198 (±40)
Mean length of stay (days)*	3 (±2)

*Includes day of surgery. BMI: body mass index; SD: standard deviation.

Table 3. Pathological and oncological and surgical outcomes		
Post-treatment Gleason score	3+2	1
	3+3	127
	3+4	147
	4+3	28
	3+5	2
Pathological staging	T2a	30
	T2b	4
	T2c	181
	T3a	72
	T3b	17
	T4	1
Positive surgical margins	pT2	22 (10.2%)
	pT3	27 (32%)

of an artificial urinary sphincter (American Medical Systems, Minnesota, MN) and the other required an Advance sling (American Medical Systems, Minnesota, MN). Both men regained complete continence. Of the remaining patients, 246 (91.4%) required one pad or less at 12 months. Seventy percent of patients had discontinued the use of pads by one year following surgery.

Nerve sparing was performed bilaterally in 177 patients and unilaterally in a further 67. At the time of surgery, 30 patients were found to have a median lobe and a further 4 had undergone prior transurethral resection of the prostate. Five patients had a pre-existing urethral stricture which was dilated prior to indwelling catheter (IDC) insertion at the beginning of the case.

A total of 70 complications (Table 4) were identified in this series of 305 cases, with 47 (67.1%) requiring only conservative or pharmacological management (Clavien I or II). Twenty-three patients (7.5%) had a major complication (Clavien III-V) requiring further intervention. One-third of the Clavien grade III complications could be managed under local anesthesia or light sedation. Three patients underwent meatal dilation for symptomatic postoperative meatal stenosis. One patient required flexible cystoscopy and replacement of the IDC over a guidewire after the catheter was inadvertently removed. One patient required bladder irrigation for catheter blockage due to small blood clots and another developed acute urinary retention after catheter removal on postoperative day 14.

Of the 16 patients requiring intervention under general anesthesia, three required emergency treatment and the remaining patients underwent elective surgery. One patient required laparotomy for ongoing hemodynamic instability and high drain output related to an unrecognized trocar injury to the right inferior epigastric artery. After identifying and oversewing the bleeding vessel, this patient made an otherwise uneventful recovery. There were a total of 12 incisional hernias in our series; six of these hernias required repair due to associated symptoms. Two patients developed incarcerated hernias: one involving omentum at the 8-mm robotic port at the left lower quadrant and the other involving herniation of small bowel through the supraumbilical specimen retrieval port. This second patient required laparotomy and small bowel resection on postoperative day 30. One patient required oversewing of a small bowel serosal tear caused at the time of surgery by the Hem-o-Lok (Teleflex Medical, Research Triangle Park, NC) clip applier. This was recognized intra-operatively and managed robotically. Five patients were found to have bladder neck contractures due to migrated clips, 3 of which were Hem-o-Lok and the remainder Titanium Weck clips (Teleflex Medical, Research Triangle Park, NC). Each of these patients presented with difficulty voiding and high post-void residual urine volumes; each of these patients was managed with cystoscopy, bladder neck incision and clip removal.

There were no complications (Clavien IV) requiring intensive care management. There was, however, one death 6 months postoperatively due to a myocardial infarction.

Discussion

The widespread availability of PSA testing has led to an overall stage migration for men presenting with prostate cancer. As a result, younger men are presenting, in most cases, with low- to intermediate-risk disease. Although these patients are more amenable to cure, they are also more averse to the complications associated with the therapeutic options available. In addition to achieving continence, potency and cancer control, patient satisfaction is also affected by perioperative complications and positive surgical margins.[11] When counselling such patients, the provision of accurate information is essential. This information should incorporate local data rather than extrapolating complication rates from large, high volume, international centres. This is particularly the case in Canada, where access to RARP remains restricted in a predominately publically funded health care system due to high acquisition and ongoing maintenance costs. In addition, the proposed benefits of RARP, including less postoperative pain, quicker recovery and less blood loss, need to be demonstrated in a Canadian context.

In light of the above information, a prospective database was created for our robotic program; this was done with the approval of an institutional ethics board. The outcomes from this single-surgeon series of 305 cases serve as the basis for discussion with patients at our institution who present with localized prostate cancer and are contemplating RARP. The information provided in this report is an accurate reflection of all the complications in our series. Reporting bias has been minimized by the use of a data manager who was not involved in the management of any of the study patients.

Several investigators have described the short-term

Table 4. Complications

Clavien grade	Details	Number	Total
I	Transient neuropathy	3	23
	Asymptomatic hernia	6	
	ATN (NSAID-related)	1	
	Anastomotic leak	12	
	Migrated clip (spontaneous passage)	1	
II	Balanitis	1	24
	Ileus	11	
	Wound infection	2	
	UTI	7	
	DVT (3/12 post op)	1	
	Guillian-Barre syndrome	1	
	Delirium tremens	1	
IIIa	Meatal stenosis	3	6
	Catheter replacement	1	
	Urinary retention	1	
	Bladder washout	1	
IIIb	Bulbar stricture (post XBRT)	1	16
	Incisional hernia	6	
	Artificial sphincter	1	
	Advance sling	1	
	IEA bleed – laparotomy	1	
	Migrated cip with bladder neck contracture	5	
	Serosal tear	1	
IV		0	0
V	MI (6/12) postoperative	1	1

ATN: acute tubular necrosis; NSAID: nonsteroidal anti-inflammatory drugs; UTI: urinary tract infection; DVT: deep vein thrombosis; XBRT: external beam radiation therapy; IEA: inferior epigastric artery; MI: myocardial infarction.

complications in the context of RARP.[12-16] With a mean follow up of 30 months, we have captured not only immediate postoperative complications, but also complications which typically present later, with equal potential to cause morbidity. Of particular note in this regard is the finding of 12 incisional hernias in our cohort of patients. Data with regard to the incidence and predisposing factors for incisional hernia in our series has been published previously.[17] Six of the 12 hernias required repair to date, with 2 on an emergency basis. One patient presented with a herniated section of omentum which became evident on drain removal. The second case occurred one month following surgery. The patient presented with symptoms consistent with small bowel obstruction and was found on subsequent computed tomography to have herniation of small bowel through a defect at the supraumbilical port site. This patient underwent laparotomy and small bowel resection. Recovery in both cases was otherwise uneventful. A further 4 patients underwent elective mesh herniorraphy. It is now routine practice to close the supraumbilical port with a non-absorbable suture in an interrupted fashion. The 8-mm ports are closed at the skin level with running subcuticular polyglactin (Vicryl, Ethicon Inc., Cornelia, GA). No attempt is made to close the peritoneal or fascial defect created by the 8-mm ports.

One patient required laparotomy and oversewing of the inferior epigastric artery (IEA) after presenting with symptoms of ongoing blood loss immediately postoperatively. We advocate insertion and removal of all ports under direct vision to identify and manage this complication intra-operatively if it occurs. In many cases, the anatomical landmarks for the IEA can be effectively identified prior to port insertion and therefore avoided.

There were 5 cases of erosion of clips at the level of the urethro-vesical anastomosis with resultant bladder neck contracture (BNC). In a published series of two cases,[18] it was suggested that such permanent clips be avoided in close proximity to the anastomosis. In recognition of these cases, we have altered our technique and now use small titanium clips on the pedicle tissue, avoiding the peri-urethral area. All patients who developed BNC underwent bladder neck incision with concurrent clip removal.

Our mean operative duration of 198 minutes compares favourably with those reported in contemporary series from large, high volume centres.[19] Our results incorporate the initial experience of RARP at our centre and confirm that

satisfactory outcomes in terms of length of surgery can be achieved at lower volume centres. Mean estimated blood loss was 200 mL and also compares favourably. There were 2 transfusions required in our series. One was administered intra-operatively and the second was in the context of postoperative bleeding from the IEA.

Margin data is often omitted in series of postoperative complications. We concur with the results from a recent paper by Patel and colleagues that a positive margin in the context of pathological T2 (pT2) disease constitutes a complication.[11] In particular, a positive margin increases the likelihood of requiring adjuvant or salvage therapies, such as androgen deprivation therapy or radiotherapy.[20] In the longer term, these secondary therapies may be to the detriment of functional outcomes, in particular continence and erectile function. Adjuvant radiotherapy has been associated with a higher rate of bladder neck contracture post-radical prostatectomy.[21]

Although a positive margin rate of 22% was seen in our first 50 cases, the overall pT2 positive margin rate in our series was 10.2% (Table 3); this compares favourably with the outcomes from large international open and robotic series.[12-16] In our last 150 cases, the rate declined to 2%, demonstrating the potential for ongoing improvement in this regard. The study is limited by the absence of patients with high-risk disease which may have influenced positive margin rates. We advocate monitoring rates of positive surgical margins throughout the learning curve as a means of ensuring appropriate change in surgical technique.[19] Due to variation in the rehabilitation strategies used at our institution for management of post-prostatectomy erectile dysfunction (ED), we have not included data on rates of postoperative ED in this study. We do acknowledge that there may be an interaction between the extent of nerve sparing, margin status and subsequent erectile function.

Our series provides an accurate summary of immediate and delayed complications observed during the largest single surgeon series in Canada to date. Although the numbers are small by international standards, we propose that the series remains relevant both in a Canadian setting and also internationally as the technology disseminates rapidly into lower volume community centres.

Conclusions

RARP has been incorporated at our institution with an acceptably low rate of intra-operative and postoperative complications. We report intermediate-term outcome data from our prospective database of 305 patients. The database has served as an effective means of informing patients with regard to the expected outcomes of surgery using hospital and surgeon-specific information.

Competing interests: None declared.

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