

Transition From Open To Robotic-Assisted Radical Prostatectomy In The Public Sector In Victoria: A Single-Centre Comparison Of 100 Consecutive Cases

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Citation

M Basto, K Chow, L Marvelde, S Azer, J Duthie, A J Costello, J Goad, D G Murphy. *Transition From Open To Robotic-Assisted Radical Prostatectomy In The Public Sector In Victoria: A Single-Centre Comparison Of 100 Consecutive Cases*. The Internet Journal of Urology. 2014 Volume 12 Number 1.

Abstract

Objective

- To compare peri-operative, pathological and short-term oncological outcomes, as well as complications of patients undergoing radical prostatectomy (RP) during the transition phase from open radical prostatectomy (ORP) to robotic-assisted radical prostatectomy (RARP) in a public hospital.

Patients and methods

- 100 consecutive patients having undergone RP by either ORP (n=50) or RARP (n=50) between July 2007 to November 2011 at Peter MacCallum Cancer Centre (PMCC) in Melbourne, Australia were identified. A prospective database was maintained for RARP patients while ORP data was retrospectively collected.
- Detailed demographic, staging, peri-operative, pathological, complication and short-term oncological outcomes were collected prospectively and retrospectively analysed.

Results

- There was no difference in demographic characteristics between the cohorts with respect to age, prostate specific antigen (PSA) or D'Amico classification.
- Mean operative time was 213.6 (± 36.9) minutes with ORP compared to 242.5 (± 83.4) minutes with RARP ($P=0.45$).
- Median length of stay was reduced from five days (IQR 4-6) with an open approach to one day (IQR 1-1) with the robotic approach ($P<0.001$) and mean estimated blood loss was reduced from 766mLs (± 279.1) to 193mLs (± 117.4) in the ORP and RARP cohorts respectively ($P<0.001$). Blood transfusion rate was 6% in the open group (6% vs. 0%, $p=0.24$).
- Minor Clavien complication (I-II) rate was 34% for ORP compared to 22% for RARP ($p=0.24$), the difference primarily accounted for by the 6% transfusion rate with the open approach. Major complications (III-V) occurred in 2% of the open group and 4% of the robotic cohort, with no Clavien IV or V complications. Delayed complications (>90 days) occurred in three patients with an open approach and four patients with a robotic surgical approach.
- Although the estimated risk for biochemical recurrence (BCR) and oncological failure (OF) was about half for patients who underwent RARP (BCR HR = 0.45; OF HR = 0.52), with the current sample size and length of follow-up (26.7 months for ORP and 14.0 months for RARP) BCR and OF were not statistically different between RARP and ORP.

Conclusions

- The transition from ORP to RARP in the Victorian public sector has resulted in significant improvements in length of stay and estimated blood loss. Additionally, minor complications secondary to reduced blood transfusion rates, and oncological outcomes including risk of BCR and OF seemed to be reduced for patients who underwent RARP however differences were not statistically significant.

INTRODUCTION

Prostate cancer (PCa) remains by far the commonest non-cutaneous malignancy in Australian men and the incidence is increasing. Every year around 22,000 men are diagnosed with PCa in Australia, these figures are expected to rise to 25,000 by the year 2020(1). With stage migration due to

increased use of PSA testing, the majority of newly diagnosed cases are localised and suitable for surveillance or treatment with curative intent(2). Radical prostatectomy remains the gold standard for the surgical management of localised prostate cancer.

Robotic-assisted radical prostatectomy using the da Vinci©

surgical system (Intuitive Surgical Ltd, Sunnyvale, CA, USA) is now the dominant approach for radical prostatectomy in the USA and in many other regions(3). Although no randomised controlled trials exist to support the superiority of the robotic-assisted approach, numerous large systematic reviews and meta-analyses have demonstrated that when compared to an open surgical approach, RARP offers shorter hospital stay, less blood loss, and at least comparable complication and PSM rates(4-7). Moreover, improved recovery of erectile function(8) and urinary continence(9) have also been reported. Outcomes reported from Australian centres reflect the international literature(10) including comparisons with prior open experience in the private sector(11).

Robotic surgery was introduced to Australia in 2003 and now accounts for the majority of radical prostatectomies performed in the private sector in Victoria, Australia's second most populous State, where six da Vinci© surgical systems have been installed. However, robotic surgery had not been available in the public sector in Victoria until a surgical robot was installed at the PMCC in July 2010. Since that time, all patients suitable for radical prostatectomy have been offered RARP as part of an Academic Robotic Cancer Surgery Program.

The aim of this study is to compare peri-operative, pathological and short-term oncological outcomes as well as complications of patients undergoing RP during the transition phase from ORP to RARP in this academic comprehensive cancer centre.

PATIENTS AND METHODS

Patients

100 consecutive patients having undergone RP by either an open or robotic surgical approach were identified at PMCC. A prospective database was maintained of all patients undergoing RARP from July 2010 to July 2011 (n=50) and a retrospective data collection of ORP patients was undertaken for the period between July 2007 and November 2011 (n=50). Of the patients who underwent an open approach, 42 occurred prior to the introduction of the da Vinci© robot in July 2010 and eight thereafter. Both cohorts were under the care of three consultant urological surgeons. This study was approved by the PMCC Human Research Ethics Committee (HREC).

Detailed demographic data, operative details and

postoperative outcomes including pathological findings, complications and oncological outcomes were collected. For patients not followed up at PMCC, external records were sought in consultation with the surgeon and obtained from other metropolitan hospitals.

Definitions and statistical analysis

Risk stratification was completed using the D'Amico classification system(12) and complications up to 90 days post-operatively were classified utilising the Clavien grading system(13).

Biochemical recurrence (BCR) was defined as PSA \geq 0.2ng/mL. Oncological failure (OF) was defined as BCR or the start of salvage therapy. In time to event analyses, BCR and OF were defined as the date of surgery to the first date at which these criteria were met. In patients whom BCR or OF were not observed their recurrence or failure free time was censored at the date of last follow up.

Some patients (ORP n=4; RARP n=2) did not have BCR but started salvage therapy due to a higher potential for local recurrence. Factors contributing to this decision included a combination of positive surgical margin status, extra-capsular extension and/or high initial or increasing post-operative PSA which has not yet met the 0.2ng/mL criteria. For these patients recurrence free time was censored at the start date of salvage therapy. One patient in the open surgery group was lost to follow-up and it was not possible to establish whether BCR &/or OF occurred following surgery. This patient was therefore excluded from both time-to-event analyses.

Statistical significance of differences between treatment groups was determined using Fisher's Exact test for categorical variables and Wilcoxon rank sum test for continuous variables. Length of stay was tested using Poisson regression. Time to biochemical recurrence and oncological failure were analysed using the Kaplan-Meier method with Cox regression modelling to compare groups. Reverse Kaplan-Meier method was used to estimate median follow up. All analyses were performed in R Version 2.15.0 (R Development Core Team, 2009)(14). Time-to-event analyses were performed using the package 'survival'. P<0.05 was considered to indicate statistical significance.

RESULTS

Demographic and perioperative outcomes

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Demographics and perioperative outcomes of the study population are illustrated in table 1. As shown, there was no difference in demographic characteristics between the ORP and RARP groups in regard to age (p=0.25), PSA (p=0.10) or D’Amico risk category (p=0.35). The mean operative time was 29 minutes less with an open approach however this difference was not statistically significant (P=0.45).

Table 1
Demographic and perioperative outcomes

Characteristic	ORP (n=50)	RARP (n=50)	P-value
Age, years			0.22
Mean ± SD	58.4 ± 6	59.7 ± 5.4	
Median (IQR)	58.5 (54 - 62.5)	60 (56.3 - 63)	
PSA, ng/mL			0.10
Mean ± SD	8.8 ± 10.8	6.6 ± 3.84	
Median (IQR)	6.85 (5.3 - 9.3)	5.8 (4.6 - 7.2)	
D’Amico risk score (n, %)			0.27
Low	14, 28%	16, 32%	
Intermediate	22, 44%	27, 54%	
High	14, 28%	7, 14%	
Operative time, mins			0.45
Mean ± SD	213.6 ± 36.9	242.5 ± 83.4	
Median (IQR)	212.5 (190 - 240)	210 (191.3 - 256.3)	
Hospital stay, days			<0.001
Mean ± SD	5.3 ± 2.2	1.6 ± 1.6	
Median (IQR)	5 (4 - 6)	1 (1-1)	
Estimated blood loss, mls			<0.001
Mean ± SD	766 ± 279.1	193 ± 117.4	
Median (IQR)	725 (600 - 1000)	150 (100 - 287.5)	
Blood transfusion (n, %)	3 (6%); 8 units	0	0.24
Conversion to open (%)	N/A	0%	

ORP, open radical prostatectomy; RARP, robotic-assisted radical prostatectomy; SD, standard deviation; IQR, Inter-quartile range; PSA, prostate specific antigen

RARP resulted in a significant four day reduction in the median length of hospital stay; five days (IQR=4-6) with an open approach compared to one day (IQR=1-1) with the robotic surgical approach (P<0.001). 80% of all RARP patients were discharged by post-operative day one and 90% by day two. There was a significant reduction in mean estimated blood loss (EBL) of 573mLs with the robotic approach (P<0.001). Rate of blood transfusion was less with RARP however not significantly so (6% ORP V 0% RARP, P=0.24). No conversions to an open surgical approach occurred with RARP.

Pathological outcomes

PSM rates by pathological stage are illustrated in Table 2 for each group. There was no statistical difference in PSM rates between the cohorts overall (ORP 40% vs. RARP 30%, P=0.4) nor when analysed separately by pathological stage. The total PSM rate for pT2 tumours is 32% in the open compared to 19% in the robotic group. For pT3 tumours, PSMs were noted in 56% of all ORP patients and 53% of RARP patients. There was one patient in the robotic group with a pT4 tumour but a negative surgical margin.

Table 2
Positive surgical margins by pathological stage

Pathological stage	PSM				P-value
	ORP		RARP		
	n	%	n	%	
Total	20/50	40	15/50	30	0.4
pT2	11/34	32	6/32	19	0.26
pT3	9/16	56	9/17	53	>0.99
pT4	0	0	0/1	0	>0.99

PSM, positive surgical margin; ORP, open radical prostatectomy; RARP, robotic-assisted radical prostatectomy; pT, AJCC/UICC pathological tumour stage

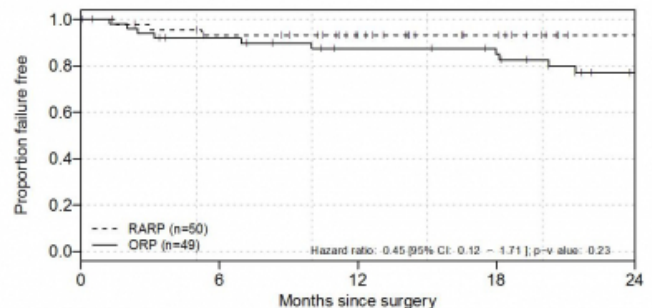
Oncological outcomes

Both time to BCR and OF were analysed. Some patients who do not experience BCR still go on to have some form of adjuvant or salvage therapy. Hence in this setting, OF is a more sensitive reflection of initial treatment failure. Figures 1 and 2 illustrate these time to event outcomes. One patient was excluded in the OF analysis as we were unable to ascertain oncological follow-up.

Ten of the 49 patients who had open surgery had BCR compared to three of the 50 patients who had robotic surgery (Figure 1), with a median time to follow up of 26.0 months (95% CI [24.0 – 36.0 months]) and 13.1 months (95% CI [12.4 – 16.5 month]) respectively. Follow-up was not long enough to estimate median time to BCR. Although the risk for BCR for patients with robotic assisted surgery was less compared to patients who had open surgery (HR=0.45, 95% CI [0.12 – 1.71]), this difference was not statistically significant (z= -1.44, df=1, P=0.23).

Figure 1

Kaplan-Meier curves for time to biochemical recurrence (defined as PSA >=0.2) for patients who had open (n = 49) or robotic assisted (n = 50) radical prostatectomy.

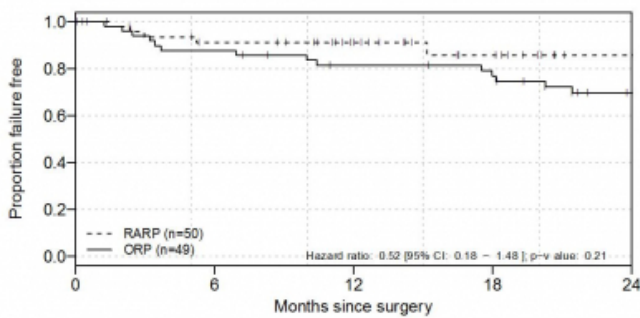


Fifteen of the 49 patients in the open surgery group had oncological failure as compared to five out of 50 patients in the robotic assisted surgery cohort (Figure 2), with a median time to follow up of 26.7 months (95% CI [24.0 – 36.6

months]) and 14.0 months (95% CI [12.4 – 16.6 month]) respectively. Again follow-up was not long enough to estimate median time to oncological failure. Although the risk for oncological failure was almost halved for the patients who had robotic assisted surgery compared to the patients who had open surgery (HR=0.52, 95% CI [0.18 - 1.48]), this difference was not statistically significant (z = -1.54, df = 1, p = 0.21).

Figure 2

Kaplan-Meier curves for time to oncological failure (Defined as PSA \geq 0.2 or the start of salvage therapy) for patients who had open (n = 49) or robotic assisted (n = 50) radical prostatectomy.



Complications

ORP resulted in a greater number of minor Clavien complications (I-II) compared to RARP (34% V 22%, p=0.24) (Table 3). Major complications (III-V) were comparable between the groups with one radiologically guided drainage of an abdominal collection required in each group (Clavien 3a, 2%) and one reoperation to re-do the vesico-urethral anastomosis at day two post-operative in the robotic group (Clavien 3b, 2%).

Table 3

Clavien grading system for short-term complications up to 90 days

Clavien grade	ORP n (%)	Comments	RARP n (%)	Comments	P-value
I-II	17 (34%)	Analgesia, PRBC, antibiotics, urine leak*, prolonged DT removal for high output	11 (22%)	Urine leak*, antibiotics, analgesia	0.24
IIIa	1 (2%)	1x Radiologically guided drainage of an abdominal collection	1 (2%)	1x Radiologically guided drainage of an abdominal collection	>0.99
IIIb	0		1 (2%)	1x Reoperation re-do vesico-urethral anastomosis (POD2)	0.53
IV-V	0		0		

ORP, open radical prostatectomy; RARP, robotic-assisted radical prostatectomy; PRBC, packed red blood cells; DT, drain tube; POD, post-operative day
 *Urine leak noted on imaging and managed conservatively

Three delayed complications were noted in the ORP group; two cystoscopy and dilatations for membranous strictures at four months and three years and one advanced urethral sling

(AUS) insertion at two years. There were four late complications that occurred in the RARP group; two cystoscopy and dilatations for strictures at eight and nine months, one AUS and one cystoscopy with a view to AUS insertion in the future.

DISCUSSION

In this study we compared the peri-operative, pathological and short-term oncological outcomes as well as complications during the transition from ORP and RARP at a single Australian institution in the public health sector. It is accepted there are significant improvements in perioperative parameters including length of hospital stay, estimated blood loss and blood transfusion rates with a robotic approach(15). Although some studies have shown lower PSM rates with RARP compared with ORP(16), larger systematic reviews and meta-analyses have shown comparable PSM rates between groups(4, 7, 17). Similarly there are no significant differences in complications rates except that accounted for by a reduction in blood transfusion rate in the robotic group(15).

The Australian series’ mimic this international experience with lower mean blood loss, length of stay and transfusion rates(18, 19). Cathcart et al. (2011) noted a trend towards higher PSM rates in RARP for surgeons still within their learning curve with equivalence once this was overcome. Boris et al. (2007) documented the transitional experience of a single surgeon’s last 100 ORPs (50 retropubic, 50 perineal) to the first 50 RARPs in a similar study methodology to our own, showing improved perioperative outcomes, improved PSM rates in organ confined disease and comparable functional outcomes.

A randomised controlled trial is currently underway at the Royal Brisbane Hospital in Australia, comparing open and robotic surgical techniques in terms of clinical and cost effectiveness(20). As of September 2013, 269 men had been randomised; 133 to RARP and 136 to ORP with good retention rate over two years follow-up(21). In the Australian setting where open surgery is still the most common approach to RP, this RCT holds significant promise to shape prostatectomy patterns of care in Australia in the future.

Contemporary data from a population-based prostate cancer registry in Victoria has demonstrated of 2385 patients undergoing RP between 2008-2012, those performed in a public hospital were 24% more likely (p=0.006) to have a

positive surgical margin than those undergoing RP in a private hospital(22). Much of this difference is likely to be due to surgeon experience as robotic surgery was not widely available in the public system at the time of this study. It is not known if the addition of a robotic-assisted approach to the public system would on its own help close this gap between PSMs in the public and private system in Victoria, Australia. Moreover, the multivariate analysis from the same prostate cancer registry data demonstrated that men undergoing RARP were also 31% less likely to have a PSM compared to the open approach ($p=0.002$)(22).

Our institution transitioned directly from ORP to RARP, without a laparoscopic approach to radical prostatectomy. The RARP series represents our initial experience at this centre under the care of one experienced fellowship-trained robotic surgeon and one surgeon who was transitioning from ORP to RARP. In addition, the majority of RARP cases were undertaken with significant trainee input (up to 80% of each case), as part of a modular training program. Similarly, senior trainees were involved in the majority of ORP cases in this series. Opinions vary as to how this might impact patient outcomes, however there is evidence to show that patients treated at residency and fellowship teaching institutions were less likely to experience postoperative complications and prolonged length of hospital stay(23).

The 50 ORP patients were collected over a 4.5-year period at a rate of approximately 12 cases per year. In contrast 50 RARP cases were undertaken in the first year after installation of the da Vinci© system which likely reflected a change in referral patterns and an overall push towards robotic prostatectomy as seen internationally. This volume had increased to 120 robotic cases per annum by the third year of the program.

Perioperative outcomes including length of hospital stay and estimated blood loss were significantly improved ($P<0.001$) during the transition from open to robotic prostatectomy. Additionally, oncological outcomes with RARP are at least comparable to ORP, and mimic that of international series in observing a possible reduction in BCR and OF with RARP(17).

This evaluation was potentially limited by a relatively short time to follow-up, particularly in the RARP group. Our study did not capture functional recovery of urinary continence and potency nor entail a cost comparison, however a health and economic impact evaluation is now

underway for all patients undergoing RARP at our institution. If we compare these two groups, one would anticipate a substantial decrease in per-patient direct costs given the significant reduction in length of hospital stay (median 4 days) and blood transfusion rates. Whether these savings are still over-shadowed by the cost of the robotic device and maintenance is yet to be seen. A commitment to a higher volume of robotic procedures is likely to counteract this to some extent(24-26).

In conclusion the transition from ORP to RARP in the Victorian public sector has resulted in significant reductions in length of hospital stay and estimated blood loss. It has also led to a significant increase in the volume of radical prostatectomies being undertaken at our institution. PSM rates, minor complications attributable to reduced blood transfusion rates and oncological outcomes including risk of BCR and OF were lessened with RARP however no differences were statistically significant.

Few comparative data are available from Australia however large RARP case series' from the private sector reflect that of international literature. Further collaboration is necessary between Australian institutions to decrease sample size bias, along with further comparative assessment of functional, longer-term oncological and economic outcomes.

ACKNOWLEDGEMENTS

Thank you to the generous philanthropists who enabled the establishment of the Academic Robotic Cancer Surgery Program at Peter MacCallum Cancer Centre in Melbourne, Australia. Thank you to Emma Birch our robotic nurse co-ordinator and Kath Schubach Urology Nurse Practitioner.

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