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**Full Title:**

# Robotic-Assisted Radical Cystectomy with Intracorporeal Urinary Diversion versus Open: Early Australian Experience

**Short Title:**

RARC-ICUD vs. ORC: Australian Experience

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## Abstract

### Background

To describe our initial Australian single-surgeon experience with robotic-assisted radical cystectomy (RARC) and intracorporeal urinary diversion (ICUD) and to compare the outcomes with open radical cystectomy (ORC).

### Methods

Between January 2014 and June 2016, consecutive patients diagnosed with muscle invasive and high-risk non-muscle invasive bladder cancer undergoing radical cystectomy were included. Treatment modalities included either RARC with ICUD or ORC. ICUD consisted of either intracorporeal ileal conduit or orthotopic neobladder formation. Prospectively collected perioperative and oncological outcomes were analysed.

### Results

26 RARC and 13 ORC were performed. Median operating times were 362 min and 240 min for RARC and ORC, respectively ($p$ = <0.001). Estimated blood loss for RARC was 300 ml compared with 500 ml for ORC ($p$ = 0.01). Post-operative haemoglobin drop was less in the RARC cohort (20% vs. 24%, $p$ = 0.03). There was no statistical difference in overall 90-day complication rates (81% vs. 62%, $p$ = 0.25) and 90-day major complication rates (19% vs. 23%; $p$ = 0.67) between the RARC and ORC groups, respectively. Positive surgical margins for RARC were 4% and 8% for ORC ($p$ = 1.0).

### Conclusions

Early results demonstrate that the safe introduction of RARC with ICUD in Australia is potentially feasible without compromising peri-operative and oncological outcomes. Future randomised trial with larger numbers will be required for further analysis in the Australian setting.

## Introduction

Primary bladder cancer is a serious worldwide issue with an estimated 425,000 new cases and 165,000 deaths occurring worldwide in 2012.[1] In Australia, it is the 8$^{th}$ and 18$^{th}$ most common cancer in men and women, respectively. Over 1000 Australians die from bladder cancer each year with a mortality rate of 4.6 per 100,000 individuals.[2]

Open radical cystectomy (ORC) with regional lymph node dissection is currently the gold standard treatment for muscle invasive bladder cancer (MIBC) and selected high-risk non-MIBC.[3] It is associated with the greatest reduction in risk of disease related mortality.[4] Due to the high morbidity associated with ORC, there has been a growing trend towards minimally invasive surgery due to its potential for reduced morbidity and hospital stay without compromising oncological endpoints.[5-7] These include techniques such as laparoscopic radical cystectomy (LRC) and robotic-assisted radical cystectomy (RARC).

The first laparoscopic simple cystectomy was described in 1992 by Parra et al.[8] Subsequently, the first few cases of LRC with urinary diversion was described by Puppo et al. and Sánchez de Badajoz et al. in 1995.[9,10] The uptake by surgeons performing these procedures was hindered by its long operative times, poor ergonomics and steep learning curve.[11] The development and implementation of the robotic platform eliminated the cumbersome ergonomics and steep learning curve which plagued LRC. Following the first RARC by Menon et al. in 2003, multiple studies worldwide have confirmed functional and oncological safety of RARC in the treatment of MIBC and high-risk non-MIBC.[12-16]

Recent systematic reviews by Novara et al. and Yuh et al. from the Pasadena Consensus Panel have also highlighted that contemporary data demonstrates RARC is equivalent to ORC in regards to pathological, early oncological and functional outcomes as well as complication rates.[6,17]

The aim of this initial Australian experience is to compare the clinicopathological outcomes of RARC with intracorporeal urinary diversion (ICUD) to ORC performed by the same surgeon and whether a robotic cystectomy program can be safely instituted in the Australian and New Zealand surgical environment.

## Patients and Methods

Between January 2014 and June 2016, a total of 39 consecutive patients underwent radical cystectomy with urinary diversion by either RARC or ORC by a single surgeon in Melbourne, Australia. Indications for curative radical cystectomy were either MIBC, high-risk non-MIBC or extensive non-MIBC not controlled by transurethral resection and intravesical therapies. One patient underwent RARC for high-grade ductal prostate cancer.

A prospective database was maintained for all patients, which included detailed demographic data, operative details, peri-operative and pathological outcomes. The Charlson

Comorbidity Index was used to assess preoperative comorbidities. The Clavien classification system was used to report post-operative complications. Overall 90-day complications include Clavien grade I-V while major complications only consist of Clavien grade III-V. The joint American Joint Committee on Cancer and Union for International Cancer Control TNM staging is used for pathological classification. Statistical analysis used for the comparison of continuous data was Student's *t*-test for parametric data and Mann-Whitney *U*-test for nonparametric data. Fisher's exact test was used for comparing categorical data between two groups.

As standard practice of radical cystectomies, men underwent the removal of the prostate while women underwent the removal of the uterus and cervix. The pelvic lymph node dissection boundaries were the level of the common iliac bifurcation superiorly; genitofemoral nerve laterally; bladder medially; lymph node of Cloquet inferiorly. Urinary diversions consisted of both orthotopic and ileal conduit techniques. For all robotic-assisted cases within this cohort, intracorporeal urinary diversion was performed.

All procedures were performed by the same surgeon (PD) with training and post-fellowship experience in robotic pelvic surgery. RARC cases were performed at one of the two sites in Melbourne (Royal Melbourne Hospital and Epworth Richmond) with availability of the robotic platform. The majority of ORC cases were performed at the Western General Hospital, where the robot platform was not available. Five patients underwent ORC where the robotic platform was available during the initial learning curve: one patient had received prior pelvic radiotherapy for anal cancer; one patient had undergone prior robotic assisted radical prostatectomy; two patients were unable to tolerate the steep Trendelenberg due to airways disease and one patient had a large ventral incisional hernia that required concomitant open surgical repair. One further patient underwent ORC due to robotic failure. The treatment modality was otherwise based on the site of surgery and the availability of the robotic platform. Cancer staging was not actively factored in the selection of surgical modality.



## Results

RARC group had 26 patients while the ORC group had 13 patients. Between the two cohorts, there were no significant differences in age, body-mass index (BMI), Charlson Comorbidity Index score, prior bacillus Calmette-Guérin therapy, and neoadjuvant chemotherapy.

Median operating time was significantly shorter in ORC than RARC (240 min vs. 362 min, $p < 0.001$). Median estimated blood loss (EBL) was 300 ml for RARC compared to 500 ml for ORC ($p = 0.01$). There were two intra-operative transfusions in the ORC group, but none in the RARC group. Including intra-operative and post-operative events, 8% of the RARC cohort and 31% of the ORC cohort required transfusions ($p = 0.15$). The median percentage of haemoglobin drop, measured in post-op/pre-op haemoglobin level, was 20% in the RARC cohort and 24% in the ORC cohort ($p = 0.03$). Hospital length of stay (LOS) was similar in both groups, 8 days for RARC and 10 days for ORC ($p = 0.54$). There were no conversions to ORC for any RARC patient.

In the RARC cohort, majority of urinary diversions were ileal conduits compared to orthotopic neobladders; 81% and 15% respectively. One RARC patient did not undergo a urinary diversion. This patient had previously undergone left nephro-ureterectomy for upper tract urothelial carcinoma and underwent concurrent laparoscopic right nephro-ureterectomy and RARC. All 13 patients in the ORC group underwent an ileal conduit formation.

The overall 90-day (81% vs. 62%, *p* = 0.25) and major 90-day (19% vs. 23%; *p* = 0.67) complication rates were similar between the RARC group compared to the ORC group, respectively. Overall, there were 38 complications in 21 patients, with 7 major complications in 5 patients in the RARC group. In comparison, there were 16 complications in 8 patients, with 5 major complications in 3 patients in the ORC group. There was one intra-operative complication in the ORC group and none in the RARC group.

ORC had a higher median lymph node yield than RARC (25 vs. 18, p = 0.21). There was no difference in the positive surgical margin rate between RARC and ORC (4% vs. 8%; *p* = 1.0).

## Discussion

RARC provides the surgeon with enhanced surgical field visualisation and operative ergonomics leading to improved dexterity and control. Despite this, there are low adoption rates due to the technical complexity of the procedure and steep learning curve. It is reported that less than 15% of radical cystectomies are performed robotically in the United States.[18] The primary objective of this series is to compare the peri-operative and post-operative outcomes between both RARC and ORC performed by a single surgeon across tertiary referral centres in Melbourne, Australia.

In our series, ICUD was performed in all robotic cases. When RARC was originally described by Menon et al.[12], an extracorporeal urinary diversion (ECUD) was performed. Many centres worldwide still utilise ECUD techniques for RARC due to the technical complexities of ICUD.[6] Results from the International Robotic Cystectomy Consortium demonstrated that patients that underwent ICUD compared to ECUD had lower 90-day mortality rates, lower 30-day and 90-day readmission rates, as well as fewer complications within 30 days of surgery.[19] Additionally, Ahmed et al. also reported that patients undergoing ICUD also had fewer gastrointestinal complications and postoperative infections which is likely due to reduced bowel handling and exposure.[19]

A large systematic review by Novara et al. analysed the perioperative outcomes and complications following RARC. Their review of 93 studies demonstrated the mean operative time for RARC with intracorporeal ileal conduit formation was 340 min (range: 292-660 min) while intracorporeal neobladder formation was 420 min (range: 420-450 min).[6] Our RARC median operative time was comparable at 362 min. In comparison, our ORC median operative time was significantly shorter by 122 min (p = 0.001). This is consistent with other RARC vs. ORC studies by Bochner et al.[20] and Nix et al.[21] where a mean difference in operative time favouring ORC was 127 min and 42 min, respectively. This difference is most likely accounted for by the required robotic setup and docking time as well as the learning curve associated with RARC. It has previously been described by Hayn et al.[22] and Collins et al.[23] that a reduction in operative time is associated with greater experience in RARC. This similar difference between open and robotic procedures was also noted with the adoption of robotic-assisted radical prostatectomies.[24] Even within the early learning curve of this series, overall operative time for neobladder diversion decreased from 600 to 375 minutes, with similar improvement seen for ileal conduit diversion.

Median EBL was favourably lower for RARC when compared to ORC (300 ml vs. 500 ml, p = 0.01). EBL for the RARC was similar at 300 ml (interquartile range [IQR]: 150 ml, 400 ml) when compared to the reported mean of 270 ml (range: 200-1118 ml) for intracorporeal ileal conduits and 480 ml (range: 225-500 ml) for intracorporeal neobladders in the systematic review by Novara et al.[6] For ORC, a large study at Memorial Sloan-Kettering Cancer Center of 1142 consecutive patients treated with ORC had a median EBL of 1000 ml.[25] Our EBL for ORC compared well with a median of 500 ml. Additionally, our RARC transfusion rates of 8% was also comparable with the reported 14.7% and 7% for intracorporeal ileal conduits and neobladders, respectively.[6] Our ORC transfusion rate was 31%, which is encouraging in comparison to 41.6-67% in the literature.[25-27] LOS of 8 days for RARC and 10 days for ORC is equivalent to available published data.[6,19,25]

For radical cystectomies and more specifically in newly developed procedures with only short- and intermediate-term follow up data available, PSM and lymph node yield have been used as surrogate markers for quality of surgical resection. More recently, 5-year oncological outcomes have been published by early adopters of RARC which report that survival outcomes are dependent on similar surgical parameters as ORC.[28] Patients with PSM have been shown to have higher incidence of progression to local recurrence and metastases as well as shorter survival.[29-31] The PSM rate in the RARC group was 4% compared to the reported 5.6% in the literature.[17] For ORC, a large study of 1589 patients with bladder cancer demonstrated a PSM rate of 4.2%, where in our ORC group it was 8%.[29]

It has been described that the greater number of lymph nodes removed during pelvic lymph node dissection decreases local recurrence rates whilst improving disease survival rates.[31-33] The Pasadena Consensus Panel for RARC recommends that the lymphadenectomy template should be the same between both RARC and ORC; which is the case in our series where an extended lymph node dissection was performed to the proximal level of the bifurcation of the iliac vessels.[15] We achieved a median yield of 18 (IQR: 15, 21) and 25 (IQR: 16, 28) for RARC and ORC, respectively (p = 0.21). The reported yield in a systematic review was 19.[17] It has also been reported that lymph node yields are affected by the RARC learning curve and that yields improve with higher volume of cases.[22]

The International Robotic Cystectomy Consortium reported overall 90-day complication rates for RARC of 48% while 90-day major complication (Clavien grade III-V) rates were 19%.[34] Our RARC complication rates were higher for 90-day overall rates at 81% while it was equivalent at 19% for 90-day major complication rates. The higher overall complication rates in our series could be due to initial learning curve of RARC. Collins et al. reported a significant decrease in overall complications with greater experience.[23] The open series by Shabsigh et al. experienced overall 90-day complication rates of 64% and major complications of 13%.[25] This is similar to our rates of 62% and 23%, respectively. When comparing the RARC and ORC groups in our series, there is no clear difference for both 90-day overall and major complication rates. This was similarly found in the trials by both Bochner et al. as well as Khan et al.[20,35]

The main limitation of this study is the small series of patients. This is due to the low number of patients with MIBC and high-risk NMIBC in whom radical cystectomy is indicated. In order to provide the best overview comparison between RARC and ORC, every consecutive patient undergoing radical cystectomy was included despite the location of the procedure whether it be in the public or private setting. Prior publications have suggested the minimum number for RARC proficiency is 20-30 cases.[22,36] Therefore, this series with 26 cases over a 30 months period only documents the early part of the learning curve for RARC. The current international series of literature is predominantly based on data from ultra-high volume centres in which Australian and New Zealand centres are not able to match. As access to the robotics platform is limited in the Australian and New Zealand public sector, accrual of cases to meet RARC proficiency is a challenge and will be a hurdle in the uptake of RARC for most surgeons. Due to this, we would recommend that only high-volume Australian and New Zealand centres consider undertaking the implementation of RARC. Another factor impeding the uptake for RARC may be the initial and ongoing costs for the robotics platform. Publications have shown that when factoring in the indirect costs in high-volume tertiary centres, RARC may provide cost benefits over ORC[37,38]; however, focused Australian and New Zealand cost-analysis studies are required. Furthermore, the cases were not randomised. However, recent publications of randomised trials have shown robotic surgery to be at least as good as open surgery with respect to functional and oncologic outcomes, but with lower blood loss, lower transfusion rates and less pain post-operatively.[20,35,39] RARC at our institution commenced in January 2014 and it is therefore too early to document oncologic outcomes such as 5-year recurrence and survival rates. We plan to publish this data in the fullness of time.

## Conclusion

Despite growing literature and uptake of RARC worldwide, it is still in its infancy in Australia; unlike robotic-assisted prostatectomies which have been adopted into many centres. This is likely due to a small number of surgeons who have had the opportunity to acquire the robotic proficiency and skills to attempt such a technically challenging procedure. This series highlights that the safe introduction of RARC with ICUD is feasible in Australia in a tertiary institution with a team of supportive staff. With increasing experience and the implementation of a structured enhanced recovery care pathway, we are likely to witness further improvement in operative times and LOS. Future series will require a higher number of cases with longer follow-up for further assessment of long-term oncological outcomes.

## Disclosure Statement

No authors have any conflicts of interests to disclose.

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**Table 1 – Demographic and pre-operative characteristics**

| | Robotic | Open | *p*-value |
|---|---|---|---|
| Patients, n | 26 | 13 | |
| Age, yr, median (IQR) | 70 (63,76) | 75 (68,81) | 0.13 |
| Body mass index, kg/m$^2$, mean ± SD | 28 ± 4 | 27 ± 5 | 0.36 |
| Gender | | | |
| Male, n (%) | 21 (80) | 10 (77) | |
| Female, n (%) | 5 (19) | 3 (23.1) | |
| Charlson Comorbidity Index, median (IQR) | 2 (2,3) | 2 (2,4) | 0.16 |
| Pre-op eGFR, median (IQR) | 78 (69,88) | 84 (51,88) | 0.23 |
| Pre-op Hb, median (IQR) | 143 (132,157) | 136 (123,144) | 0.06 |
| Prior bacillus Calmette-Guérin therapy, n (%) | 2 (8) | 2 (15) | |
| Neoadjuvant chemotherapy, n (%) | 1 (4) | 0 (0) | |
| Clinical stage, n (%) | | | |
| T0 | 1 (4) | 0 (0) | |
| Ta | 2 (8) | 4 (31) | |
| Tis | 5 (19) | 0 (0) | |
| T1 | 9 (35) | 1 (8) | |
| T2 | 8 (31) | 8 (62) | |
| T3 | 0 (0) | 0 (0) | |

| | | |
|---|---|---|
| T4 | 0 (0) | 0 (0) |

**Table 2 – Intra-operative details, post-operative and pathological outcomes**

| | Robotic | Open | *p*-value |
|---|---|---|---|
| Urinary diversion type, n (%) | | | |
| No diversion | 1 (4) | 0 (0) | |
| Ileal conduit | 21 (81) | 13 (100) | |
| Neobladder | 4 (15) | 0 (0) | |
| Operative time, min, median (IQR) | 362 (315,390) | 240 (230,285) | 0.001 |
| Estimated blood loss, ml, median (IQR) | 300 (150,400) | 500 (250, 600) | 0.01 |
| Hb levels | | | |
| Pre-op, median (IQR) | 144 (132,157) | 136 (123,144) | 0.06 |
| Post-op, median (IQR) | 116 (107,125) | 93 (90,107) | 0.0005 |
| Post-op/Pre-op Hb drop, %, median (IQR) | 20 (13,22) | 24 (21,30) | 0.03 |
| Conversion to open, n (%) | 0 (0) | N/A | |
| Hospital length of stay, d, median (IQR) | 8 (7,11) | 10 (7,12) | 0.54 |
| Transfusions, n (%) | | | |
| Intra-operative | 0 (0) | 2 (15) | 1 |
| Total (intra and post-operative) | 2 (8) | 4 (31) | 0.15 |
| 90-day complications, total/patients (%) | | | |
| Overall, Clavien I-V | 38/21 (81) | 16/8 (62) | 0.25 |
| Major, Clavien III-V | 7/5 (19) | 5/3 (23) | 0.67 |

| | | | |
|---|---|---|---|
| Highest grade post-op complication, n (%) | | | |
| Clavien I | 5 (19) | 3 (23) | |
| Clavien II | 11 (42) | 2 (15) | |
| Clavien IIIa | 3 (12) | 1 (8) | |
| Clavien IIIb | 1 (4) | 1 (8) | |
| Clavien IVa | 1 (4) | 0 (0) | |
| Clavien IVb | 0 (0) | 1 (8) | |
| Positive surgical margins, n (%) | 1 (4) | 1 (8) | 1 |
| Lymph node yield, median (IQR) | 18 (15,21) | 25 (16,28) | 0.21 |
| Pathological T stage, n (%) | | | |
| T0 | 7 (27) | 2 (15) | |
| Ta | 2 (8) | 2 (15) | |
| Tis | 5 (19) | 3 (23) | |
| T1 | 4 (15) | 0 (0) | |
| T2 | 2 (8) | 0 (0) | |
| T3 | 5 (19) | 6 (46) | |
| T4 | 1 (4) | 0 (0) | |
| Pathologic N stage, n (%) | | | |
| $N_0$ | 24 (92) | 11 (85) | 0.59 |

| | | |
|---|---|---|
| $N_1$ | 2 (8) | 2 (15) |