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REVIEW

Robot-assisted radical cystectomy with intracorporeal urinary diversion – The new 'gold standard'? Evidence from a systematic review

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KEYWORDS

Radical cystectomy;
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Robotics;
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ABBREVIATIONS

EORTC, European Organisation for the Research and Treatment of Cancer;
HR, hazard ratio;
HRQOL, health-related quality of life;

Abstract ***Objective:*** To investigate whether a totally intracorporeally radical cystectomy (RC) can be considered the new 'gold standard' in bladder cancer, as open RC (ORC) is the current 'gold standard' for surgical treatment of muscle-invasive and high-grade non-muscle-invasive bladder cancer. However, robot-assisted radical cystectomy (RARC) is becoming the preferred surgical approach in many centres as it seems to maintain the oncological control of open surgery whilst offering improved perioperative benefits.

Materials and methods: A review of the literature was conducted using the Pubmed/MEDLINE, ISI Web of Knowledge and Cochrane Databases to identify studies that included both ORC and RARC with intracorporeal and extracorporeal urinary diversion (UD) published up to July 2017.

Results: Evidence from four single-centre randomised controlled trials and now the multicentre Randomized Trial of Open versus Robotic Cystectomy (RAZOR) trial demonstrate the oncological equivalence of RARC to ORC. The only convincing evidence for the superiority of RARC is in the area of blood loss and transfusion rates. However, the UD procedure in these trials was performed extracorporeally and, to realise the full benefits of RARC, a totally intracorporeal approach is needed. Intracorporeal UDs (ICUDs) have been shown to be technically feasible

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(EC)(IC)UD, (extracorporeal) (intracorporeal)urinary diversion;
LOS, length of stay;
(N)MIBC, (non-) muscle-invasive bladder cancer;
RAZOR, Randomized Trial of Open versus Robotic Cystectomy;
(O)(RA)RC, (open) (robot-assisted)radical cystectomy;
RCT, randomised controlled trial

by a few expert centres and have demonstrated some improved short-term perioperative outcomes compared to extracorporeal UDs.

Conclusions: Although initial outcomes appear promising, RARC with ICUD is far from gaining 'gold standard' status. Further studies are needed to confirm that outcomes are reproducible widely. Furthermore, the benefits of a totally intracorporeal approach must be confirmed in randomised controlled trials.

Introduction

Open radical cystectomy (ORC) with extended pelvic lymph node dissection and urinary diversion (UD) is the current 'gold standard' management for muscle-invasive (MIBC) and high-grade non-muscle-invasive bladder cancer (NMIBC). However, the procedure is associated with considerable morbidity, with complication rates in the region of 30–70% [1]. As a result, there has been growing interest in the use of the robot to reduce the morbidity of the procedure. The last decade has seen an increase in the use of robot-assisted RC (RARC), which is now the standard of care in many institutions including our own. In the USA, it is estimated that the use of this approach has increased from 0.7% in 2002 to 18.5% in 2012 [2]. However, RARC is far from gaining widespread adoption due to concerns regarding cost-effectiveness, increased operative times, and the lack of long-term oncological and functional outcomes [3]. Short-term data from prospective randomised controlled trials (RCTs) have shown that RARC achieves similar oncological and functional outcomes as ORC and offers some improved perioperative outcomes but at a higher cost. Most of the morbidity of RC stems from the UD rather that the removal of the bladder itself; yet in the majority of RARCs, the UD is performed extracorporeally through a mini-laparotomy. Several institutions have demonstrated the feasibility of a totally intracorporeal UD (ICUD), which spares the patient a mini-laparotomy and thus offers the advantages of reduced intraoperative blood loss, bowel exposure, and postoperative pain [4]. In this invited review, we summarise the current evidence for RARC and ICUD with respect to oncological, perioperative and functional outcomes.

Material and methods

A review of the literature was conducted using the Pubmed/MEDLINE, ISI Web of Knowledge and Cochrane Databases to identify studies that included both ORC and RARC with ICUD and extracorporeal UD (ECUD) published up to July 2017. Only publications in English were considered. The following keywords were used in the databases: 'open radical cystectomy', 'robot-assisted radical cystectomy', 'intracorporeal', 'extracorporeal' and 'urinary diversion'. The list of generated articles was screened by title and abstract by N.L. and then relevant full papers were scrutinised (Fig. 1).

RARC

Oncological outcomes

The long-term oncological outcomes of ORC for MIBC are well established [5]. In contrast, despite almost two decades of robotic surgery, 5-year survival rates following RARC have only become available relatively recently. In the largest multi-institutional study to date, the International Robotic Cystectomy Consortium reported 5-year recurrence-free, cancer-specific and overall survival rates of 67%, 75% and 50%, respectively [6], which are comparable to ORC series [5,7,8].

To date, four single-centre RCTs have compared ORC and RARC [9–12]. Oncological outcomes from these trials have been reported using surrogate markers, namely surgical margin status and lymph node yield. None of these trials have shown a significant difference in the rate of positive surgical margins between modalities, which range from 0% to 15% for RARC and 0–10% for ORC [9–12]. Furthermore, although lymph node yields vary from trial to trial, there was no statistically significant difference in lymph node yield between RARC and ORC. Until recently, these studies provided the only evidence demonstrating the oncological equivalence of RARC to ORC. However, we now have preliminary results from the highly anticipated Randomized Trial of Open versus Robotic Cystectomy (RAZOR)

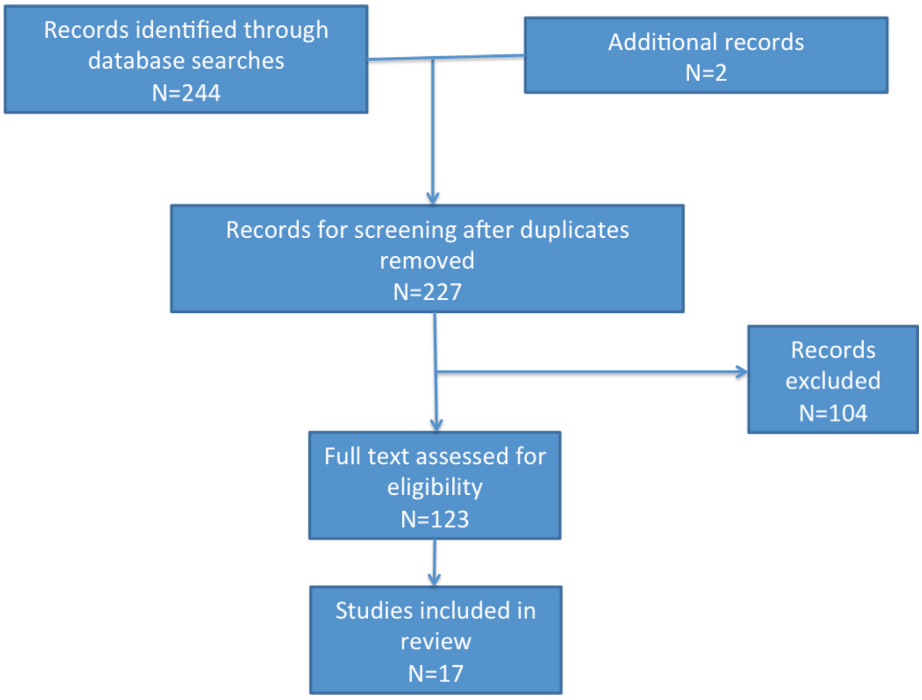

Fig. 1 Flowchart of literature search.

trial [13]. This is the first multi-institutional phase 3 prospective randomised trial assessing oncological outcome as a primary endpoint. Designed as a non-inferiority study, it provides level I evidence showing no significant difference in 2-year progression-free (71.8% vs 72.0%, hazard ratio [HR] 0.91, $P = 0.653$) and overall survival (80.2% vs 79.1%, HR 0.80, $P = 0.31$) between RARC and ORC. The study also confirmed the findings of single-centre trials, reporting no significant difference in the extent of lymph node dissection (23% vs 25% $P = 0.26$) and overall positive margin rates (17% vs 13%, $P = 0.27$).

Local recurrence rates are an important measure of the adequacy of RC. More than 80% of recurrences occur within the first 2 years of RC [14] and some argue that the use of the robot may compromise oncological clearance due to incomplete excision or tumour seeding secondary to the pneumoperitoneum [15]. Nguyen et al. [15] retrospectively compared recurrence patterns in 383 patients undergoing RC and found no difference in recurrences (local, distant, or any) between RARC and ORC, although they did note a higher frequency of peritoneal carcinomatosis (21% vs 8%) and extraperitoneal lymph node recurrences (23% vs 15%) in RARC patients. More recently, Collins et al. [16] reported early recurrence patterns in 717 patients undergoing RARC and ICUD at nine centres with a minimum follow-up of 12 months. Recurrence-free survival estimates at 3, 12, and 24 months were 95.9%, 80.2%, and 74.6%, respectively. Similar to ORC series, pelvic lymph nodes were the most common site of local recurrence and distant recurrences occurred most frequently in the lungs, liver, and bones [17]. The incidence of peritoneal carcinomatosis and port-site metastases was low, 0.7% and 0.3% respectively; of these patients, 80% had upstaging to non-organ confined disease postoperatively and four out of five presented with multiple metastases, leading the authors to conclude that recurrence is influenced by the biological aggressiveness of the tumour rather than surgical approach.

Perioperative outcomes

Early non-randomised comparisons of RARC with ORC suggested that the robotic approach was associated with improved perioperative outcomes, including reduced blood loss, complication rates, and length of stay (LOS) [18,19]. However, these findings are subject to selection bias, variation in healthcare systems, surgeon expertise, patients' performance status, and social circumstances. In contrast, data from single centre prospective randomised trials and now the multicentre RAZOR trial have shown that the only area where the robot offers a significant advantage across the board is for blood loss. Estimated blood loss was 363 vs 829 mL ($P < 0.001$) in the RAZOR trial and RARC patients required less frequent intraoperative (13.6% vs 33.6%, $P < 0.001$) and postoperative blood transfusions (25.6% vs 41.0%) [13]. This is most likely the result of improved visualisation and the tamponade effect of the pneumoperitoneum.

Operative times are consistently longer for the robotic approach, which range from 252 to 456 min for RARC and 210–329 min for ORC [9–12]. Time to flatus or bowel movement has not been consistently collected and variable results have been reported in trials. Nix et al. [9] reported a significant decrease in time to passage of first flatus ($P = 0.001$) and bowel movement ($P = 0.001$) with RARC. However, neither Parekh et al. [10] nor Khan et al. [12] were able to demonstrate any significant difference in return of bowel function between the two modalities. Trials have also failed to show a significant difference in LOS between ORC and RARC patients, although the RAZOR trial observed a trend towards a shorter stay with RARC.

For complication rates, Bochner et al. [11] found no difference between RARC and ORC for 90-day Clavien–Dindo all-grade complications by either intention-to-treat or per-protocol analyses, although when complications were considered by organ system, RARC was associated with fewer wound complications than ORC (3.3% vs 14.0%, $P = 0.04$). Similarly, Khan et al. [12] found no differences in 30-day complication rates (of any Clavien–Dindo grade) between RARC and ORC (70% vs 55%, $P = 0.50$). Additionally, comparisons of high-grade (Clavien–Dindo grade $>$ III) or 90-day complications did not reveal an advantage of RARC over ORC. These findings have been confirmed in the RAZOR trial, which also found no difference between RARC and ORC for Clavien–Dindo high-grade (grade $>$ III) complications.

However, when trying to draw conclusions about the complication rate of RARC, it must be noted that all patients in these trials underwent open urinary reconstruction. It is well known that the morbidity of this operation stems not from its extirpative component, but rather the UD. Because UD was performed extracorporeally with an open incision in both arms of these trials, we cannot truly evaluate whether RARC has reduced complications compared with ORC. A need exists for a RCT comparing complete ICUD RARC with ORC, and this is currently underway in the UK. Until these results are available, no firm conclusions can be made about complication rates.

Functional outcomes

The success of RC is not simply limited to tumour eradication; given the procedure's high morbidity, measuring health-related quality-of-life (HRQOL) outcomes is becoming ever more important. Data comparing functional outcomes between RARC and ORC are limited. Aboumohamed et al. [20] performed a retrospective comparison of HRQOL outcomes in patients undergoing RARC and ORC using the Bladder Cancer Index, a validated questionnaire assessing function and bother scores across urinary, bowel, and sexual domains. Questionnaires were completed at baseline and at regular intervals postoperatively for 2.5 years. RARC had comparable HRQOL outcomes to ORC at all postoperative time points and the type of UD did not appear to affect HRQOL.

Messer et al. [21] published the first prospective RCT evaluating HRQOL for ORC vs RARC. HRQOL in 40 patients was assessed using the Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index (FACT-VCI) at baseline, 3, 6, 9 and 12 months postoperatively. The questionnaire measures four domains of well-being (physical, social/family, emotional and functional) with additional questions on urinary, sexual, and bowel function and body image. No statistically significant differences were observed between HRQOL outcomes in the RARC and ORC groups, and HRQOL in both cohorts returned to baseline 3 months postoperatively. In the Bochner et al. [11] trial, HRQOL was assessed using the European Organisation for the Research and Treatment of Cancer (EORTC) quality of life questionnaire core 30 (QLQ-C30) at baseline, 3 and 6 months. Again, no difference between RARC and ORC was seen with respect to the change in HRQOL from baseline to 3 months or from 3 to 6 months.

Although these studies appear to show equivalence between RARC and ORC for HRQOL outcomes, there are some caveats. Firstly, in all studies, measurement of HRQOL was delayed until 3 months after surgery. The robotic approach promises quicker postoperative recovery; yet none of the trials provide data on early postoperative morbidity such as analgesic requirements or timing of oral intake [22]. Secondly, the assessment of HRQOL is not standardised between studies. The EORTC questionnaire used in the Bochner et al. [11] trial is not specific to bladder cancer and does not capture data on urinary continence or sexual function. Similarly, the Bladder Cancer Index, whilst being disease-specific, lacks the detail required to provide an accurate assessment of HRQOL across all types of UDs. Furthermore, current HRQOL questionnaires provide only a superficial assessment of continence and give no measure of parameters like pad usage or mucous leakage [3].

ICUD

At present, $<5\%$ of RARCs have an ICUD. Reasons for this are historical and relate to early experiences with laparoscopic ICUD. Not only was the UD procedure technically challenging, it was also associated with poor perioperative outcomes and high complication rates [23]. Many feared that the same difficulties would apply to a robotic approach and opted for an ECUD with the benefits of a familiar technique, shorter operative times, and the availability of a pre-existing extraction site. However, if the main driver of morbidity is the UD

procedure, it follows that a totally incorporeal approach should avoid the pitfalls of open surgery, i.e. the need for a laparotomy and increased bowel handling. This should mean a smaller incision, reduced blood and insensible fluid losses which should, in turn, result in a more rapid return of bowel function and shorter LOS. It should also, theoretically, lead to fewer ureteroenteric anastomotic strictures due to reduced mobilisation and handling of the ureters.

Ileal conduits were the UDs first to be attempted intracorporeally [24,25]. The largest series comes from Roswell Park, who describes the outcomes from a series of 100 patients undergoing RARC and intracorporeal ileal conduit UD [26]. The median operative time was 352 min and the authors reported an overall 90-day complication rate of 81%, comparable to open series [1,27]. Intracorporeal formation of orthotopic neobladders has also been attempted, with the largest series reported by the Karolinska Institute [28] and the University of Southern California in 132 patients [29]. The mean operative time was 7.5 h for the entire cohort. Overall, early and late complications were observed in 47% and 27.3%, respectively. Urological complications included five uretero-enteric anastomotic strictures, which compares favourably with stricture rates reported in historic open series [8,30]. Complete daytime and night-time continence (0–1 pad/day) was reported in 84% of the patients who had completed 6 months of follow-up. At 12 months, complete daytime and night-time continence was reported in 44/62 (74.2%) of men and two of three women.

Continent cutaneous ICUDs have also been shown to be feasible, although the technique is still in its early stages. Goh et al. [31] were the first to perform a totally intracorporeal modified Indiana pouch UD, reporting a 3 h UD operative time. There were no perioperative complications and, at the 1-year follow-up, the patient was reported to be doing well. Desai et al. [32], at the University of Southern California, have since published a limited series of 10 cases in which they report a median total operating time of 6 h and a mean hospital stay of 10 days. Early complications (Clavien–Dindo grade I–II) were observed in 30%, and 20% developed uretero-enteric anastomotic strictures. At the 1-year follow-up, all patients (with the exception of one who requested conversion to an ileal conduit) were fully continent and catheterising without difficulty.

The question of superiority over ECUD has been addressed by the International Robotic Cystectomy Consortium who retrospectively compared perioperative outcomes in 935 patients undergoing ICUD ($n = 167$) and ECUD ($n = 768$) following RARC [33]. The authors found no difference in operative times, blood loss or LOS. Although 90-day complication rates were not statistically significant, there was a trend towards fewer complications in the ICUD group (41% vs 49%, $P = 0.059$), who also had significantly fewer gastrointestinal complications (10% vs 23%, $P \leq 0.001$) and lower transfusion rates (7% vs 16%, $P = 0.02$). Overall, these patients had a lower risk (32%) of developing a postoperative complication at 90 days (odds ratio 0.68, 95% CI 0.50–0.94; $P = 0.02$) compared to those with an ECUD. Although these results are encouraging, with a mean follow-up of 16 months, it would be premature to draw conclusions about long-term oncological and functional outcomes. Furthermore, as data were only available for 87% of patients, it is possible that the complication rate was under-reported. However, with this said, complication rates during RARC have been shown to decrease with experience [34] and the same is likely to hold true for ICUD.

Cost analysis

Cost analysis is critical in determining whether the benefits of RARC truly justify the expense. A number of studies have compared the cost outcomes of RARC and ORC. The time period for evaluation of these costs varies between studies; some assess costs for the index hospital stay only, whilst others consider a 90-day postoperative period that is influenced by the cost of complications and re-admissions [35].

Smith et al. [36] performed a comparative cost analysis of 20 cases at their institution and found that the overall cost of RARC was $1640 (American dollars) more than ORC. Fixed and variable operating room costs were higher for RARC, primarily due to increased operative times, whereas ORC had higher variable hospital costs as a result of costs relating to blood transfusions and LOS. Fixed-hospital costs were similar for both modalities. In contrast, Lee et al. [37] performed a cost-identification analysis of three single institution series and demonstrated an overall cost decrease for RARC; although material costs were higher, these were counteracted by a significantly shorter LOS.

An analysis of the USA Nationwide Inpatient Sample comparing 1444 ORCs and 224 RARCs showed that RARC cost almost $4000 more than ORC ($P = 0.023$) [38]. Expanding on this study, Leow et al. [39] conducted a population-based cohort study of 34 672 ORCs and 2101 RARCs. Using propensity-matched scoring, the authors showed that RARC was associated with higher 90-day direct hospital costs ($31 007 vs $26 681; $P < 0.001$), which was mainly as a result of higher supply costs ($ 6041 vs $3638; $P < 0.001$). However, when a subgroup analysis of the highest volume surgeons (≥7 cases/year) and hospitals (≥19 cases/year) was performed, the cost difference between RARC and ORC was no longer statistically significant. More recently, Hu et al. [2] performed a propensity-matched comparison of 439 RARC and 7308 ORC patients using Surveillance, Epidemiology and End Results (SEER)-

Medicare linked data and showed that although there was no statistically significant difference in inpatient costs between the two modalities, RARC was associated with higher costs at 30- ($P < 0.01$) and 90-days ($P < 0.01$) postoperatively.

In the Bochner et al. [11] RCT, cost analysis was performed to compare both operating room and total inpatient costs. RARC and neobladder were shown to be $3920 more expensive on average ($19 231 vs $15 311, $P < 0.001$) than ORC, whilst the ileal conduit was cheaper overall but still more expensive when performed with the robot ($18 388 vs $16 648, $P > 0.05$). Further information on cost-analysis will come from the RAZOR trial. As yet, no data exist on the cost outcomes of a totally ICUD compared to an ECUD. However, as experience with both RARC and ICUD grows, it is anticipated that operative times and LOS will fall, thus reducing the overall costs of a robotic approach. Furthermore, the robotic technology is expensive because of the monopoly of one supplier, high installation and maintenance costs, and limited-use instruments. As the technology becomes cheaper this argument will become less relevant.

Conclusion

Are RARC and ICUD the new 'gold standard'? Not yet. We now have Level I evidence demonstrating the non-inferiority of RARC compared to ORC with regard to oncological outcomes. However, the only convincing evidence for superiority of RARC over ORC is in the area of blood loss and transfusion rates. To realise the full benefits of a RARC, a totally intracorporeal approach is needed. ICUDs have been shown to be technically feasible by a few high-volume centres of expertise and have shown some improved perioperative outcomes compared to ECUDs. However, if a totally intracorporeal RARC is to become the 'gold standard', these benefits must be confirmed in multicentre RCTs. Furthermore, cost will prove as significant a factor as patient outcome and, at present, the costs of RARC remain prohibitive for non-specialist centres. However, as overall experience with RARC and ICUD grows, it is anticipated that operative times and LOS will fall, thus improving cost effectiveness.

Conflict of interest

None.

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None.

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