Guidelines on

Robotic- and Single-site Surgery in Urology

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1. METHODOLOGY

1.1 Introduction

In 2011, the EAU Guidelines Office formed a working group to evaluate the current literature and the level of evidence (LE) of keyhole and robotic assisted surgery in urological procedures.

The panel members are surgeons with particular expertise in performing the procedures discussed in this document. All have been trained in traditional open and laparoscopic surgical approaches. Robotic assisted surgery is performed as a routine procedure by two expert panel members on a daily basis.

This document will not address economic evidence for robotic surgery in a systematic fashion. Resource limitations made it impossible for the panel to perform a comparative cost analysis (laparoscopic vs. robot assisted surgery). Doing so within a European-wide setting is not possible because national health policies determine the costs of clinical care. An analysis suggests that robotic surgery is more expensive than open surgery and laparoscopic surgery in approximately 75% of cases, with any cost-saving benefits of robotic surgery being largely attributed to variation in hospitalisation costs (1). Also, since robotic surgical devices are currently offered by one producer only, costs may decline in the future if there is more competition in the market for machines or related consumables (2).

1.1.1 Definitions

The following definitions are used here:

1. Single-site surgery is one single incision, with the addition of a maximum of one instrument (port) not larger than 5 mm.
2. Robotic surgery is the use of console-based laparoscopic telemanipulators.

1.2 Evidence acquisition

1.2.1 Literature search

Searches were carried out in the Cochrane Library database of Systematic Reviews, the Cochrane Library of Controlled Clinical Trials, Medline, and Embase on the Dialog-Datastar platform. The controlled terminology of the respective databases was used and both MesH and EMTREE were analysed for relevant entry terms.

1.2.2 Inclusion criteria

Case reports, congress proceedings, editorials, reviews and letters to the editor were not included. Publications reporting from the same institution and cohort were limited to the most recent or largest study. An online systematic review of the literature, according to Cochrane recommendations, was performed in July 2012 and identified data from 1990 to 2012. Manuscripts in languages other than English were included if data were extractable; these manuscripts were selected for inclusion in analysis using the criteria mentioned above.

1.2.3 Quality of evidence

There is still an on-going learning curve with this technique. It was therefore difficult to draw strong conclusions from the data currently available for analysis. There is a lack of multicentre, randomised, controlled studies producing conclusive evidence supporting open- vs. laparoscopic surgery.

In the absence of high-quality data, the expert panel came to the conclusion that providing guidance on the use of robotic-assisted surgery may even be more important. Except for a few procedures for which more mature data exist, recommendations are therefore generally based on the panel's review of low-level evidence and expert opinion.

The only robotic system assessed in clinical studies is the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA). Most of the literature published discusses robotic assisted laparoscopic radical prostatectomy (RALP) and open radical prostatectomy (ORP). In renal cell cancer, bladder cancer and uretero-pelvic junction obstruction only limited research was done assessing this novel technique.

1.3 Level of evidence and grade of recommendation

References in the text have been assessed according to their level of scientific evidence (Table 1), and guideline recommendations have been graded (Table 2) according to the Oxford Centre for Evidence-based Medicine Levels of Evidence (3). Grading aims to provide transparency between the underlying evidence and the recommendation given.

Table 1: Level of evidence*

Level	Type of evidence
1a	Evidence obtained from meta-analysis of randomised trials.
1b	Evidence obtained from at least one randomised trial.
2a	Evidence obtained from one well-designed controlled study without randomisation.
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study.
3	Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports.
4	Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities.

**Modified from (3).*

It should be noted that when recommendations are graded, the link between the level of evidence (LE) and grade of recommendation (GR) is not directly linear. Availability of randomised controlled trials (RCTs) may not necessarily translate into a grade A recommendation where there are methodological limitations or disparity in published results.

Alternatively, absence of high level of evidence does not necessarily preclude a grade A recommendation, if there is overwhelming clinical experience and consensus. There may be exceptional situations where corroborating studies cannot be performed, perhaps for ethical or other reasons and in this case unequivocal recommendations are considered helpful. Whenever this occurs, it is indicated in the text as “upgraded based on panel consensus”. The quality of the underlying scientific evidence - although a very important factor - has to be balanced against benefits and burdens, values and preferences, and costs when a grade is assigned (4-6).

Table 2: Grade of recommendation*

Grade	Nature of recommendations
A	Based on clinical studies of good quality and consistency that addressed the specific recommendations, including at least one randomised trial.
B	Based on well-conducted clinical studies, but without randomised clinical trials.
C	Made despite the absence of directly applicable clinical studies of good quality.

**Modified from (3).*

1.4 Of note

As with all technical equipment, malfunctions may occur; conversion to open procedure may be necessary in that case.

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2. RENAL ROBOTICS - RADICAL NEPHRECTOMY, RECONSTRUCTIVE, AND PYELOPLASTY

2.1 Robotic radical nephrectomy (RRN)

Since its introduction in 1991, laparoscopic nephrectomy has been the gold standard for cases in which radical nephrectomy is indicated or nephron-sparing surgery is not possible (1). The first RRN was performed in 2000 (2). There are reports in the literature from 2001 for the use of robotic assisted surgery in donor nephrectomy and robot assisted laparoscopic nephrectomy (3,4).

Robotic radical nephrectomy is considered a safe procedure in selected cases. The reported complication rate of RRN in experienced hands is 18%, which is similar to the reported rate for laparoscopic radical nephrectomy (LRN) (5-9) (LE: 3; one prospective data evaluation). A longer operative time for RRN is reported, mainly due to the learning curve, robot dock time, and port placement. The use of the four-arm robot has been described to retract and position the kidney, independent of the assistant (10).

Few studies have evaluated the use of RRN due to the reduced advancement compared to standard laparoscopic surgery or non-robotic laparoscopic single site surgery (LESS), mainly due to the technical effort and additional cost per procedure and mostly not taking the initial costs for the robotic system into account. Robotic radical nephrectomy was performed either by a transperitoneal or retroperitoneal route. The available studies that compare RRN with LRN include cohorts of less than 50 patients (2,5,6,8,11).

Robotic assistance may be considered to be a 'technical over-treatment'. It should therefore be weighed against a standard laparoscopic approach depending on the individual case. However, RRN serves as a useful training setting for robotic partial nephrectomy (RPN) (9). One publication has reported higher complication rates for RRN (5).

2.2 Robotic partial nephrectomy (RPN)

If feasible, for renal tumours ≤ pT1b, nephron-sparing surgery is the preferred surgical approach because it conserves renal function and potentially increases overall survival (1). The first report of RPN was in 2004 (12) (LE: 3). There has been evaluation of triangulation, sliding clip technique (13), reduction of warm ischaemia time and zero ischaemia (14). Triangulation and localisation of tumours are important reasons why laparoscopic partial nephrectomy (LPN) is still a challenging procedure in most cases (15,16).

The reported mean tumour size is usually small (mean 2.9 cm) and accounts for well-selected cases in reported studies, which might not reflect the real-world setting. Tumours > 4 cm treated with RPN have been associated with higher complication rates of 26.7% (17). A retrospective series to date comparing LPN with RPN in 261 consecutive patients found in a matched cohort analysis (150 patients) no difference in operative time (197 vs. 200 minutes), warm ischaemia time (20.3 vs. 18.2), length of hospitalisation ($p = 0.84$), percent change in renal function ($p = 0.8$) or adverse events ($p = 0.52$). However, the mean blood loss was higher in RPN cohort (323 vs. 222 ml, $p = 0.01$) (18). One of the largest comparative studies retrospectively evaluated 381 patients who underwent LPN ($n = 182$) or RPN ($n = 199$). The conversion rate was significantly lower (1%) in the RPN group compared to the LPN cohort (11.5%). In addition, a higher decrease in percentage of eGFR was noted (-16% vs. -12.6%) (19).

In the largest single centre series to date, which consists of 400 patients undergoing RPN, there were a total of 11 intraoperative complications (2.7%). There were 61 cases (15.3%) of postoperative complications, which were mainly low grade (grades 3 and 4 in 3.2%) (20).

Robot assisted partial nephrectomy is a safe and viable alternative to LPN. It provides equivalent early oncological outcomes and comparable morbidity to a traditional laparoscopic approach. Robot assisted partial nephrectomy appears to offer no difference, with regards to hospital stay, intraoperative blood loss, operative time or conversion rate, and a shorter warm ischaemia time. However, the RPN series reported significantly less warm ischaemic time than with an LPN procedure, as reported by a recently published systemic meta-analysis on RPN vs. LPN (21).

Table 3 lists selected studies on RPN. Further investigations defining RPN effects on renal preservation and long-term oncological outcomes are needed.

Table 3: The outcomes of selected studies on robotic assisted partial nephrectomy compared to laparoscopic partial nephrectomy.

Author	N LPN RPN	OR time LPN RPN	EBL LPN RPN	TF rate LPN RPN	W-ischaemic LPN RPN	Complications LPN RPN	Hosp stay LPN RPN	Study design	LE
Aron, 2008 (22)	12 12	256 242	300 329	NA	22 23	NA	4.4 4.7	Retrospective, matched pair	3
Benway, 2009 (23)	118 129	174 189	196 155	2 1	28.4 19,7	12 11	2.7 2.4	Retrospective	3
Deane, 2008 (24)	11 11	289 228	198 115	NA	35 32	0 1	3.1 2.0	Retrospective	3
DeLong, 2010 (25)	15 13	253 352	NA	NA	39.9 29.7	NA	NA	Retrospective	3
Jeong, 2009 (26)	26 31	139 169	208 198	1 1	17 20	NA	5.3 5.2	Retrospective	3
Kural, 2009 (27)	20 11	226 185	387 286	2 0	35 27	2 1	4.2 3.9	Retrospective	3
Williams, 2011 (28)	59 27	221 233	146.3 179.6	NA	18.5 28.0		2.71 2.51	Prospective, single surgeon	3
Wang, 2009 (29)	62 40	156 140	173 136	1 2	25 19	8 6	2.9 2.5	Comparative, retrospective	3
Ellison, 2012 (30)	108 108	162 215	400 368		19.3 24.9		2.2 2.7	Retrospective	3
Pierorazio, 2011 (31)	102 48	192 152	245.1 122.4		18 14.1		NA	Retrospective	3
Seo, 2011 (32)	14 13	117 153	264.1 283.6		36.4 35.3		5.3 6.2	Retrospective	3
Long 2012 (19)	182 199	240.7 196.9	325.0 280.2	14.3% 12.1%	23.2 22.4	5.5% 3.0%	1.36 2.21	Retrospective	3

N = nephrectomy; LPN = laparoscopic partial nephrectomy; RPN = robotic partial nephrectomy; OR time = operating time; EBL = estimated blood loss; TF = transfusion rate; W-ischaemic = warm ischaemic; Hosp stay = hospital stay; NA = not available.

2.3 Robotics reconstructive renal surgery

Initial experience of laparoscopic pyeloplasty performed with the da Vinci robotic system matched to procedures performed with standard laparoscopic techniques dates back to 1999 (33). The robotic platform is well suited for reconstructive procedures due to the number of degrees of freedom, superior optics, and reduction of tremor. Operative time, perioperative outcome and success rates are similar for laparoscopic pyeloplasty (LPP) and robotic assisted laparoscopic pyeloplasty (RLPP). The mean suturing time for RLPP seems shorter. Complications for both procedures are infrequent. Success rates, as measured by diuretic scintirenography, are high for the conventional and robotic approach. Most data on pyeloplasty robotic surgery are from the paediatric literature (34).

A recent meta-analysis on open vs. LPP in children demonstrated a cosmetic advantage with comparable long-term results and function (35). For the comparison of LPP and RLPP data are sparse, a meta-analysis on these comparators used the data of 8 studies valid enough for consideration (36) and concluded that both techniques had no major differences with regards to OR time, postoperative urine leakage, and function.

2.4 Conclusions and recommendations on RPN and LPN

Conclusions on RPN and LPN	LE
Conclusive long-term data are not available.	
RPN and RRN are technically feasible.	
No comparable long-term data on oncological, safety and functional outcomes are available. However, based on short-term data and panel expertise, no significant differences are expected.	4
In ablative surgery, robotics will produce no better outcomes compared to laparoscopy.	
Possible benefit in reconstructive surgery, i.e. partial nephrectomy/pyeloplasty.	

Recommendations	GR
Use laparoscopy for simple or radical nephrectomy.	C
Use robotic assisted or laparoscopic surgery for partial or reconstructive renal surgery if technically feasible.	C
Use of minimal invasive techniques should not compromise nephron-sparing surgery in ≤ pT1b.	C

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3. LESS KIDNEY - RADICAL NEPHRECTOMY, PARTIAL NEPHRECTOMY, NEPHROURETERECTOMY, PYELOPLASTY AND (PARTIAL) ADRENALECTOMY

3.1 Terminology and technical principals

Laparoendoscopic single site surgery (LESS) was first suggested as a consensus nomenclature suggested by the Urologic NOTES Working Group in 2008. Laparoendoscopic single site surgery is now widely accepted as a general term for all new surgical procedures using one skin incision for access of camera and instruments, with or without an additional port of max 5 mm (1).

Advantages of this new approach regarding minimal invasiveness over conventional laparoscopy are in discussion, but not yet proven (2), and cosmesis seems to be driving this technology to a considerable extent (3,4). Since advantages of NOTES techniques over conventional laparoscopy are not yet proven, personal and institutional expertise should guide the selection of surgical treatment. The first urological report on nephrectomy in humans was reported by Raman et al. (5) in 2007.

Although all the published studies have used only one single skin incision, three different trocar settings were reported. Raman et al. described the use of adjacent 5-mm trocars, resulting in one centre of rotation with skin incisions connected at the time of specimen extraction, while most other authors used a single port system with three or four instrument channels. Both approaches resulted in the need to use articulating and bent instrumentation to achieve triangulation intracorporeally, despite trocars being adjacent to one another (6).

Another study group used a small c-shaped incision in the umbilical fold, which was stretched to maximum length prior to the placement of three conventional trocars through the rectus fascia in a straight line, resulting in enough space for triangulation with straight instruments (single incision triangulated umbilical surgery = SITUS) (2,7). This approach was confirmed by a laboratory experiment addressing the problem of clashing of crossed bent and articulating instruments resulting in a loss of precision and time in a laboratory setting. The authors of this experiment setting concluded that coordinative abilities and time for the trained tasks were optimal, using straight followed by bent instruments and worst with articulating instruments.
In 2009, Kaouk et al. (8) reported the first urological LESS procedures aided by the da Vinci system. In a multi-institutional analysis in 2011 of 1076 cases, the same author presented the use of this so called R(obotic)-LESS in 13% of all collected cases (9). Until then, there was no specific robotic platform for R-LESS on the market. Forced by positive reports concerning vision, limitation of instrumental movement, triangulation, suturing, etc.

using the conventional da Vinci System (11-13), several studies have demonstrated the innovative potential of novel robotic platforms (11,14). As in conventional laparoscopy, robotics has the potential to play a major role in LESS surgery.

3.2 Simple and radical nephrectomy

Laparoendoscopic single site nephrectomy was first described by Raman et al. in 2007 in three humans, without complications. Key steps of the new technology are shown in Table 3.

Table 4: Simple nephrectomy (SNX), radical nephrectomy (RNX)

Author	n SNX RNX	OR time SNX RNX	EBL SNX RNX	TF rate SNX RNX	Conversion SNX RNX	Hosp. stay SNX RNX	Incision length	Comments
Raman, 2008 (6)	2 1	Mean 133 min	Mean 30 mL	0 0	0 0	3 1	2-4.5 cm	First multitrocar study
Desai, 2008 (21)	1	3.4 h	100 mL		0	1		First single port study with curved instruments
Nagele, 2011 (7)	3 12	Mean 127 min	Mean 115 mL	n.c.	no	5	n.a.	First SITUS study
Kaouk, 2009 (8)	130 210	~161 ~158	~166 ~168			4.1 3.7		First robotic study

SNX = simple nephrectomy; RNX = radical nephrectomy; OR time = operating time; EBL = estimated blood loss; TF rate = transfusion rate; Hosp. stay = hospital stay; n.a. = not applicable.

There have been several comparative studies of LESS vs. conventional laparoscopy. A recent meta-analysis included 1,094 LESS nephrectomy cases and demonstrated a longer operative time and a higher conversion rate compared with conventional laparoscopic nephrectomy. However, LESS nephrectomy was associated with less postoperative pain, lower analgesic requirement, shorter hospital stay, shorter recovery time and a better cosmetic outcome. Furthermore, no significant differences were found in perioperative complications, estimated blood loss, warm ischaemia time, and postoperative serum creatinine levels of graft recipients (14).

3.3 Radical Nephroureterectomy

Nephroureterectomy using a single port inserted via Pfannenstiel incision was first reported by Ponsky et al. (16). Following LESS nephrectomy, the distal ureter was then resected through the 7.5 cm incision in two patients. The operating time (OR time) was 187 + 409 min, the estimated blood losses (EBL) were 50 mL and 200 mL, and the patients were discharged after 2 to 4 days. White et al. demonstrated 7 nephroureterectomies in his single centre 100 single port case series (17). Park et al. described a LESS nephroureterectomy mimicking an open bladdercuff technique in two patients with OR times of 385 and 285 min, EBLs of 100 and 350 mL, and discharge at day 3 without perioperative complications (18). Laparoendoscopic single site nephroureterectomy using an endoloop for en-bloc bladdercuff excision was published by Chung et al. in two patients, with OR times of 165 and 325 min and EBLs of 30 mL and 65 mL. One patient was discharged at day 3 and the other patient at day 7 (19). Kaouk et al. reported 39 nephroureterectomies in a multicentre, retrospective trial (9). To date, neither long-term oncological data nor comparative studies are available.

3.4 Pyeloplasty

In the mostly young patient population needing reconstructive surgery for ureteropelvic junction obstruction, cosmesis seems to be of great importance.

A matched cohort study was reported by Stein et al. with 16 patients in each arm (20). The mean follow-up was 13 months in LESS and 17 months in the laparoscopic approach. All patients in both groups experienced clinical resolution of their symptoms; no difference in perioperative variables was noted between the groups. The authors noted no benefit for LESS, except aesthetic advantages.

Desai et al. performed 17 cases of LESS pyeloplasty. The mean OR time was 236 min and the EBL was 79 mL. One case was converted to conventional laparoscopy, while all other cases were aided by a 2-mm additional instrument for suturing. Fifteen of 16 available postoperative imaging demonstrated no obstruction

(21). Another series with 28 patients receiving LESS was published by Best et al. in 2011. This series reported a complication rate of 25% within the first 30 days (22). Seventy-one per cent of all these complications were reported in the first 10 cases. The authors concluded that the surgical challenge of this procedure might translate into a higher complication rate for LESS compared to conventional pyeloplasty in the early learning curve for this procedure.

3.5 (Partial-)adrenalectomy

Whereas Hirano et al. reported an retroperitoneal adrenalectomy using a rectoscope without gas insufflation in 2005 (23), Castellucci et al. described the first, transperitoneal, supraumbilical, single incision adrenalectomy using thee ports in 2008 (24). Rane et al. reported results from a cumulative number of 59 functional adenomas, 28 pheocromocytomas and 15 miscellaneous in his review of LESS adrenalectomy (25). Rane et al. reported retroperitoneal and transperitoneal (umbilical, supraumbilical and subcostal) access.

Retroperitoneal access seems to have some advantages compared to transperitoneal access concerning body mass index (26) and avoidance of retraction of intraperitoneal organs (27). However, it is restricted by limited space resulting in an inability to use bent instruments and hampered triangulation. Agha et al. (28) compared 4 retro- and 4 trans-peritoneal adrenalectomies and concluded that both access techniques are safe and feasible in appropriate OR time.

Matched case control studies (26,29,30) showed a trend to longer OR time in LESS vs. conventional laparoscopy, but less postoperative pain and no significant difference in blood loss or complications. The first synchronous bilateral laparoendoscopic single site adrenalectomy in a patient with aldosterone-producing tumours was published by Jeong et al. with uneventful surgery and follow-up (29). Initial experience of transumbilical LESS surgery of partial adrenalectomy in patient with aldosterone producing adenoma was contributed by Yuge et al. in a patient with both-sided disease using a multiport and ultrasound scalpel (31).

3.6 Complications and conversions in LESS surgery of the upper urinary tract

A multicentre study by Irwin et al. reporting results from transumbilical LESS procedures of the upper urinary tract. A total of 13.3 % (125 patients) of all laparoscopic procedure were done via a LESS approach (32). Conversion, defined as additionally placed 5- or 10-mm trocars (single 2-mm ports for reconstructive surgery were not considered conversion), was necessary in 5.6% of all LESS procedures due to facilitated dissection and reconstruction and control of bleeding. No conversion to open surgery was necessary. Complications occurred in 15.2% of all cases. The authors concluded that LESS was technically feasible for upper tract procedures, but was associated with a higher complication rate than in major conventional laparoscopic series. Kaouk et al. reported a total of 3.3% of intraoperative complications (1.7% vascular, 0.5% bowel, 0.2% splenic and diaphragmatic injuries) and 9.5% postoperative complications in an 18-institution multinational series with 1076 patients (9). Postoperative complications were 3.3% Dindo-Clavien grade 1, 3.8% grade 2, 1.9% grade 3 and 0.4% grade 4. An additional port was used in 23% of all cases. Conversion rate was 20.8% (1% to open surgery) and the overall transfusion rate was 6.1%.

3.7 Conclusions and recommendations

Conclusions	LE
LESS surgical procedures of the upper urinary tract are technically feasible but demanding.	3
Long-term oncological data are not yet available.	
No proven or documented benefits over laparoscopic approach.	
Cosmesis is a reported advantage.	4

Recommendations	GR
LESS surgery should be favoured in cases where cosmesis is of paramount importance.	A
Only experienced laparoscopic surgeons should embark on this technique.	A

LESS = Laparoendoscopic single site

3.8 Laparoendoscopic single site partial nephrectomy

The cumulative surgical experience of LESS partial nephrectomy is low and very few centres are using this challenging technique (Table 4). A total of 12 publications were identified. The studies included case series (LE: 3b) and prospective cohort studies (LE: 2a). Because the number of patients treated with this technique is low, studies often report data from LESS partial nephrectomy together with results from LESS procedures for other causes, or in multi-institutional evaluations (9, 10). One multi-institutional study reported 190 cases of patients who received LESS partial nephrectomy (10). Another multi-institutional study reported on 137 patients out of a series of a total of 1076 patients (9).

In total, the results of the presented case series studies and multicentre studies (9,10) appear to match the findings of conventional laparoscopic approaches with regard to intraoperative and perioperative data. An observational study by Bazzi et al., which compared conventional laparoscopic vs. LESS partial nephrectomy, found a reduced mean use of postoperative analgesics in favour of LESS with no significant difference in the postoperative VAPS score (33). Long-term or intermediate-term follow-up is not available. In most cases, negative surgical margins could be achieved (21,34-37). One multi-institutional study demonstrated a positive surgical margin rate of 4.2% (10). Table 4 summarises these findings (9,17,21,34,38-42).

Table 5: LESS in partial nephrectomy

Authors	n / total	n / LESS PN	% / Robot LESS	Additional ports (%)	Diameter lesion (cm)	Estimated blood loss (EBL)	OT time (min)	BMI	WIT	Hospital stay (d)	Transfusion	Conversion
Aron, 2008 (34)	5	5	0.00	1/5 (20%)	3.00	150.00	270.00	23 [22;30]	20 [11;29]	3,00	0	0,00
Desai, 2009 (21)	100	6	0.00	6/6 (100%)	n.a.	525 [11-1000]	270 [240; 336]	25 [22;32]	n.a.	4 [2;22]	0	1 lap
Kaouk, 2009 (37)	7	5	0.29	1 Liver retraction	2.10	420±475 [50;1200]	160±25	27.5±1.1	16.00	3.2	1 (2 units)	1 lap
White, 2009 (17)	100	15	0.36	n.a.	3.01	422.00	196.00	n.a.	n.a.	4.5	4	2 offen
Cindolo, 2010 (38)	6	6	0.00	2 Suturing, 1 Liver retraction	1.85 [1;3,5]	201 [30; 550]	148 [115; 180]	26.35 [24;30]	n.a.	5.5 [3;10]	0,00	1 lap
Choi, 2011 (39)	171	3	0.95	1 Liver retraction	2.5	70.00	226.00	n.a.	29 [11;65]	4.3	n.a	1 open
Han, 2011 (40)	14	0	14/14 100%	n.a.	3.2 [1,2; 6,5]	200 [30;1850]	205 [140;365]	23.4 [21.2; 28.3]	30 [16;43]	4 [3;11]	11/14	2 open
Kaouk, 2011 (9)	127	127	n.a.	n.a.	n.a.	276.9 ± 294.3	208.3 ± 165.3	n.a.	18.4 ± 15.5z	1.6 ± 1.7	n.a.	n.a.
Cindolo, 2011 (41)	1	1	n.a.	n.a.	3.5	180	165	n.a.	0	6	n.a.	0,00
Rais-Bahrami, 2012 (42)	14	14	0	14.00	2.3 [0.7; 4.0]	293.3 [50; 1300)	167.3 [120; 267]	29.3 [23.9; 35.9]	14.7 [0; 37]	2.7 [2;5]	n.a.	1.00

BMI = body mass index; n.a. = not applicable; OT = operating time;WIT = warm ischaemia time.

Recommendations	LE	GR
LESS surgery or SITUS partial nephrectomy for renal cell cancer can provide an alternative surgical approach in experienced hands if all the factors involved in choosing open or laparoscopic partial nephrectomy are considered, especially with regard to warm ischaemia time (WIT) and organ sparing. Currently, LESS or SITUS practical nephrectomy are only advised as part of a clinical study.	2a, 3b	B
Open or conventional laparoscopic partial nephrectomy is mandatory for patients with tumours smaller than 4 cm.	1b	A

LESS = laparoendoscopic single site; SITUS = single-incision triangulated umbilical surgery

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4. ROBOTIC-ASSISTED RADICAL PROSTATECTOMY

4.1 Literature search

A comprehensive PubMed search was conducted on publications related to the robot-assisted radical prostatectomy (RARP). No time frame was used. Key words included ‘robot assisted radical prostatectomy’ or ‘robotic prostatectomy’ and one of the following: ‘oncological outcome’, ‘continence’ and ‘potency’. Additional relevant literature was retrieved from references outlined by the initially harvested manuscripts. Literature was limited to human studies only and manuscripts published in English. Due to the wide extent of the robotic prostatectomy literature (more than 1,300 articles), review was restricted to comparative studies and meta-analyses that compared robot-assisted with open and conventional laparoscopic approaches. Review manuscripts were also excluded.

4.2 Introduction

Since its introduction in 2000 by Binder and Kramer, RARP has been adopted by many institutes worldwide as the standard care for the management of localised prostate cancer (1). Currently, there is a lack of multicentred, randomised, control studies (LE: 1a) comparing RARP with the gold-standard open retropubic radical prostatectomy (ORP). Additionally, only two, single-institute, randomised studies have been published comparing RARP with the well-established alternative conventional laparoscopic radical prostatectomy (LRP). Thus, current guidelines are based mostly on simple cohorts and meta-analyses derived from large volume centres and non-randomised, single-institute, prospective studies, resulting in LE 2 and 3 data.

4.3 Oncological outcome

There are very little data on the long-term oncological outcomes of RARP (biochemical recurrence and disease-free survival). Until such evidence is available, positive surgical margin (PSM) will remain the most valid oncological parameter available to justify the oncological effectiveness of the robotic approach in comparison with alternative radical prostatectomy techniques.

Comparative studies between RARP and RR or LRP demonstrate varying PSM outcomes. The majority of such studies report equivalent or lower PSM rates for RARP than the other two approaches (Table 5). The two currently available, prospective, randomised studies, which compare RARP with LRP, found no differences in PSM between the two surgical groups (2,3) (LE: 2b). However, in the absence of large-scale, randomised, controlled trials, it is not possible to make a definite conclusion, regarding the superiority or not of RARP in cancer control.

Meta-analyses of published radical prostatectomy outcomes have reported equivalent or lower PSM rates than the gold-standard ORP and LRP (LE: 3a). Parsons and Bennett and Ficarra et al., in two meta-analyses of RARP studies published before 2006 and 2008, respectively, showed no significant differences in overall risk for PSM between ORP and LRP or RARP (4,5). In contrast, Coelho et al. in a comparative meta-analysis of ORP, LRP and RARP outcomes reported by high-volume centres (studies reporting population of more than 250 patients) revealed that RARP yielded a lower, overall, weighted, mean PSM rate than ORP and LRP (6). Finally, Novara et al. and Tewari et al, in two of the most recent meta-analysis on the subject reported similar PSM between RARP, ORP and LRP (7,8).

The biochemical recurrence-free survival for RARP is well documented for up to 5 years. Schroeck et al. have documented no significant difference in early (1 year) prostate-specific antigen (PSA) recurrence between RARP and ORP (9). Similarly, Barocas et al. and Krambeck et al. have reported equivalent 3-year biochemical recurrence-free survival rates between the two techniques (10,11). In addition, Drouin et al. in a retrospective evaluation of 239 patients treated via ORP, LRP or RARP showed no difference in the 5-year PSA-free survival rates between the different approaches (12). Finally, Magheli et al. reported an analysis using propensity score matching, in which 522 RARP cases were matched with an equal number of patients who had undergone LRP and ORP. A higher overall PSM rate was observed for the RARP group compared to ORP and LRP. However, there was no difference with respect to a 5-year biochemical recurrence-free survival between the three surgical groups (13).

Surgical expertise appears to be a crucial factor in oncological outcomes of RARP. The rates for both PSM and biochemical recurrence have been reported to decrease significantly with increasing experience (14,15). Nevertheless, the exact number of cases required for a surgeon to achieve to sustain acceptable oncological outcomes remains to be defined.

Table 6: PSM rates of RARP in comparison with other techniques

Author	n	Type of study	Overall PSM	LE
Porpiglia, 2012 (2)	60 (vs. 60 LRP)	Prospective randomised trial	26.6% NS	2a
Magheli, 2011 (13)	522 (vs. 522 ORP, vs. 522 LRP)	Retrospective matched pair comparison	19.5% Significantly higher than ORP and LRP	4
Di Pierro, 2011 (16)	75 (vs. 75 ORP)	Prospective trial	16% Significantly lower	2c
Asimakopoulos, 2011 (3)	64 (vs. 64 LRP)	Prospective randomised trial	NS	2a
Doumerc, 2010 (17)	212 (vs. 502 ORP)	Prospective trial	21.2% NS	2c
Williams, 2010 (18)	604 (vs. 346 ORP)	Retrospective cohort	7.7-13.5% Significantly higher	4
Ficcara, 2009 (19)	103 (vs. 105 ORP)	Prospective trial	21% NS	2c
Drouin, 2009 (12)	71 (vs. 83 ORP, vs. 85 LRP)	Retrospective cohort	17% NS	4
White, 2009 (20)	50 (vs. 63 ORP)	Retrospective cohort	22% Significantly lower	4
Laurila, 2009 (21)	94 (vs. 98 ORP)	Retrospective cohort	13% NS	4
Rocco, 2009 (22)	120 (vs. 240 ORP)	Prospective matched pair comparison	22% NS	4
Krambeck, 2009 (11)	294 (vs. 588 ORP)	Retrospective matched pair comparison	15.6% NS	4
Schroeck, 2008 (8)	362 (vs. 435 ORP)	Retrospective cohort	29% NS	4

Chan, 2008 (23)	660 (vs. 340 ORP)	Retrospective cohort	9.9-19% Significantly lower	4

PSM = positive surgical margin; RARP = robotic assisted radical prostatectomy; LE = level of evidence; LRP = laparoscopic radical prostatectomy;ORP = retropubic radical prostatectomy; NS = non-significant difference with compared approach.

4.4 Conclusions and recommendation on robotic radical prostatectomy

Conclusions	LE
RARP for localised prostate cancer is now a well-established surgical approach offering similar positive surgical margin rates with ORP and LRP.	2a
Long-term PSA-free survival of patients treated with RARP as documented for up to 5 years is comparable with other radical prostatectomy approaches.	3b
In the absence of level 1a data and very limited long-term data, a firm conclusion regarding the oncological superiority of the technique over other techniques cannot be drawn.	2a

Recommendation	GR
Robotic surgery does not improve oncological outcomes in comparison to ORP and LRP; surgical expertise is the crucial factor. Use of the robot is not recommended to improve surgical outcomes.	A

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4.6 RARP and urinary continence

As evidenced by numerous studies on RARP, there is a trend towards faster recovery of continence and higher overall continence rates in comparison to the gold standard ORP (Table 6). Nevertheless, this finding is questioned by the lack of randomised comparative studies between the two approaches. Coelho et al. in a well-documented meta-analysis of comparative studies between ORP, LRP and RARP revealed that RARP was associated with higher continence rates at 12 months' postoperatively. The weighted mean continence rate was 79%, 84.8% and 92% for ORP, LRP, and RARP, respectively (1). Similarly, Ficara et al. in the most recent meta-analysis on the subject calculated a statistically significant advantage in favour of RARP compared with both ORP and LRP in terms of 12-month urinary continence recovery (2). In contrast, two other meta-analyses including 3893 and 44,702 patients, respectively, did not confirm the superiority of RARP at 12-month continence recovery, with equal continence calculated for all three approaches (3,4).

Tewari et al. in a non-randomised, prospective, comparison between ORP and RARP demonstrated an earlier continence recovery for RARP (median time 44 vs. 160 days; $p < 0.05$) (5). Similarly, Ficcara et al., in a prospective study comparing ORP cases with RARP, demonstrated not only earlier recovery, but significantly higher continence rates at 1 year postoperatively after RARP (6). In addition, Rocco et al. in a matched-pair analysis of 120 prospectively evaluated RARP cases with a comparable population of ORP cases (n = 240) revealed superior continence rates for RARP at 6 and 12 months' postoperatively (93% and 97% vs. 83% and 88% for RARP and ORP, accordingly) (7).

In contrast, no significant difference in continence was reported in a larger matched-pair analysis, reporting equivalent 1-year urinary continence rates for RARP and ORP, respectively (8). More recently, Pierro et al. in a prospective trial comparing consecutive series of ORP and RARP cases (including learning curve cases) revealed that RARP was associated with a faster recovery of continence but not with higher overall continence at 1 year postoperatively (9).

The two, currently available, randomised controlled trials between LRP and RARP have reported conflicting results. Porpiglia et al. in a recent, randomised, controlled study between LRP and RARP reported higher continence rates after RARP (10). In contrast, Assimacopoulos et al. revealed no differences in continence rates between the two approaches (11). Similarly, other non-randomised studies have revealed controversial results (12,13,14).

Table 7: Continence outcomes of RARP in comparative studies.

Author	RARP cases	Type of study	Continence	Time of observation (mo)	LE
Tewari, 2003 (5)	200 (vs. 100 ORP)	Prospective trial	50% Higher than ORP	1.5	2c
Ficcara, 2009 (6)	103 (vs. 105 ORP)	Prospective trial	97% Significantly higher	12	2c
Rocco, 2009 (7)	120 (vs. 240 ORP)	Prospective mach pair comparison	97% Significantly higher	12	4
Kramberck, 2009 (8)	294 (vs. 588 ORP)	Matched pair analysis	92% NS	12	4
Di Pierro, 2011 (9)	75 (vs. 75 ORP)	Prospective trial	89% NS	12	2c
Porpiglia, 2012 (10)	60 (vs. 60 LRP)	Prospective randomised trial	95% Significantly higher	12	2a
Park, 2011 (12)	44 (vs. 62 LRP)	Retrospective cohort	94.4% NS	12	4
Hakimi, 2009 (13)	75 (vs. 75 LRP)	Retrospective cohort	93.3% NS	12	4
Ploussard, 2013 (14)	1009 (vs. 1377 LRP)	Prospective trial	83.6% Significantly higher	12	2c

RARP = robotic assisted radical prostatectomy; LE = level of evidence; ORP = retropubic radical prostatectomy; NS = Non-significant difference with compared approach; LRP = laparoscopic radical prostatectomy.

4.7 Conclusions and recommendations RARP and incontinence

Conclusions	LE
RARP for localised prostate cancer is a surgical approach offering high continence rates, at least comparable with ORP and LRP.	2a
Experienced robotic surgeons achieve good early continence results.	3b
There is a trend towards faster recovery of continence after RARP in comparison to ORP and LRP.	3b

Recommendations	GR
To achieve better early continence results, the use of robotic technique is recommended.*	C

**The expert panel would like to stress that a well-done laparoscopy or open procedure would produce similar results.*

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4.9 RARP and potency

The significant variation on reported potency rates after RARP can be explained by the fact that different studies entail varying population characteristics, different potency assessment and the use of different potency aids. The majority of comparative studies between RARP and ORP favour the robotic approach in terms of potency. Faster recovery of intercourse (with or without phosphodiesterase type 5 inhibitors), faster return to intercourse and higher overall potency rates at 1 year postoperatively have been documented by several studies (1-4). In addition, two well-documented meta-analyses revealed that RARP was associated with higher potency rates than ORP(5,6). In contrast, comparable potency rates between RARP and ORP at 1-year follow-up were reported in a large matched-pair analysis and an additional meta-analysis (7,8). Due to the lack of randomised comparative studies between RARP and ORP, it is not possible to make definite conclusions, regarding the superiority of RARP in terms of potency.

A direct comparison of RARP with LRP reveals a trend towards better potency outcomes for RARP. Asimacopoulos et al. and Porpiglia et al., in two, currently available, prospective, randomised studies comparing LRP with RARP, reported a significantly shorter time-to-capability for intercourse and a higher 12-month rate of capability for intercourse in the RARP arm and erection recovery, accordingly (9,10). Coelho et al. in a meta-analysis of high-volume comparative studies calculated weighted mean potency rates for patients who underwent unilateral or bilateral nerve sparing, at 12-month follow-up, of 31.1% and 54% for LRP, compared with 59.9% and 93.5% for RARP (5). In a recent meta-analysis, Ficarra et al. calculated a non-statistically significant trend in favour of RARP compared with LRP (6). Similarly, Plaussard et al. in a recent comparative investigation including 1,009 RARP and 1,377 LRP operations revealed higher potency rates in the RARP arm at both 6 and 12 months of follow-up (11). In contrast, comparable potency rates between RARP and LRP at 1-year follow-up were reported by other studies (12,13).

Table 8: Potency outcomes of RARP in comparative studies

Author	RARP cases	Type of study	Potency rates	Time of observation	LE
Tewary, 2003 (1)	200 (vs. 100 ORP)	Prospective trial	50% Significantly higher	6	2c
Di Pierro, 2011 (2)	75 (vs. 75 ORP)	Prospective trial	55% Significantly higher	12	2c
Ficcara, 2009 (3)	103 (vs. 105 ORP)	Prospective trial	81% Significantly higher	12	2c
Rocco, 2009 (4)	120 (vs. 240 ORP)	Prospective mach pair comparison	61% Significantly higher	12	4
Krambeck, 2009 (7)	294 (vs. 588 ORP)	Matched pair analysis	70% NS	12	4
Asimakopulos, 2011 (9)	64 (vs. 64 LRP)	Prospective randomised trial	77% Significantly higher	12	2a
Porpiglia, 2012 (10)	60 (vs. 60 LRP)	Prospective randomised trial	80% Significantly higher	12	2a
Ploussard, 2013 (11)	1009 (vs. 1377 LRP)	Prospective trial	57.7% Significantly higher	12	2c
Park, 2011 (12)	44 (vs. 62 LRP)	Retrospective cohort	54.5% NS	6	4
Hakimi, 2009 (13)	75 (vs. 75 LRP)	Retrospective cohort	76.5% NS	12	4

RARP = robotic assisted radical prostatectomy; LE = level of evidence; ORP = retropubic radical prostatectomy; NS = non-significant difference between compared groups; LRP = laparoscopic radical prostatectomy.

4.10 Conclusions and recommendations RARP and potency

Conclusions	LE
Potency assessment after radical prostatectomy has many limitations, which partly explains the wide variation in potency outcomes among different studies.	2a
RARP is not inferior to ORP and LRP for potency rates.	2a
There is a trend towards faster recovery of potency after robotic assisted laparoscopic radical prostatectomy (RALP) in comparison to ORP and LRP.	2a-3b

Recommendations	GR
To achieve better early potency results, the use of laparoscopy or robotic techniques are recommended.*	C
To achieve better early potency results, a cautery-free (i.e. athermal) technique during neurovascular bundle dissection is recommended.	A

**The expert panel would like to stress that a well-done ORP or LRP, compared to RARP would produce similar results.*

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5. ROBOTIC ASSISTED PELVIC LYMPH NODE DISSECTION AT THE TIME OF RADICAL PROSTATECTOMY

5.1 Introduction

Pelvic lymph node (LN) dissection (PLND) is considered the most reliable staging method to access LN involvement in clinically localised prostatic cancer (GR: B). The EAU 2011 guidelines on prostate cancer have recommended that nodal evaluation can be spared in patients with stage T2 or less, PSA < 10, a Gleason score ≤ 6 and < 50% positive biopsy cores, since these patients have < 10% risk of LN metastases (GR: B) (1). In contrast, PLND may increase staging accuracy and influence decision-making with respect to adjuvant therapy in the treatment of a subset of intermediate-risk cases and in all high-risk prostatic cancer cases (GR: B) (2).

5.2 Outcomes

Published outcomes of PLND during RARP demonstrate significant variability in both the number of harvested LNs and LN invasion rates. Multiple factors are responsible for the latter, including the different PLND indications used, different levels of surgical experience among robotic surgeons and different PLND resection templates followed in each institution. Different indications for PLND lead to different rates of nodal involvement; higher rates would be expected when PLND is offered only in high-risk patients and lower rates when PLND is regularly offered to all RARP cases. The EAU 2011 guidelines recommended that when PLND is indicated, an extended dissection template should be offered, including the removal of nodes overlying the external iliac artery and vein, the nodes within the obturator fossa cranially and caudally to the obturator nerve, and the nodes medially and laterally to the internal ileac artery (GR: C) (2). The more extended the LN yield, the higher the probability of detecting a LN invasion (3-5). Finally, rates for LN yield and LN invasion are surgeon-related. Siberstein et al., in a retrospective comparative study between open, laparoscopic and robotic PLND, revealed wide variations in median LN yield between surgeons. This variation was much greater than the variation of LN yield between the different surgical approaches (6).

Di Pierro et al., in a prospective trial comparing consecutive series of 75 open retropubic and 75 RARP, revealed a significant (p< 0.001) difference compared with robotic assistance in the number of retrieved LNs. RARP retrieved a median of 12 LNs (range 9-17) in contrast to an open technique retrieving 18 (range 12-23) nodes, respectively (7). Most available studies comparing robotic-assisted PLND with its open counterpart support the open approach and demonstrate a lower LN yield for robotic-assisted PLND (Table 8). The inferior LN retrieval of RARP is most likely related to the comparison of a well-established technique (e.g. open) with a newly introduced approach incorporating data during the learning curve. Recent reports on robotic-assisted PLND verified that robotic assistance itself does not limit a surgeon's ability to perform a complete extended pelvic lymph node dissection (8,9).

Table 9: Robot assisted PLND studies

Author	N	Type of study	LN yield (range of median)	lymph node involvement; (LNI)	LE
Siberstein, 2011 (6)	126 (vs. 126 open, vs. 78 laparoscopic)	Retrospective cohort	16 (11-21) Significantly lower than open and laparoscopic	13%	2b
Di Pierro, 2011 (7)	75 (vs. 75 open)	Prospective trial	12 (9-17) Significantly lower than open	12%	2b
Truesdale 2010 (10)	99 (vs. 217 open)	Retrospective cohort	6.35 (4.52) Borderline difference	1%	2b
Lalas, 2010 (11)	473 (vs. 343 open)	Retrospective cohort	7.1 (0-29) Significantly higher than open	1.1%	2b
Yee, 2010 (12)	32	Prospective case series	18 (12-28)	13%	2b

Cooperberg, 2010 (13)	562 (vs. 716 open)	Prospective case series	9.3 (5.4) Significantly lower than open	4.1%	2b
Yates, 2009 (14)	62 (vs. 61 open)	Retrospective cohort	3.3 Significantly lower than open	3.2%	2b
Feicke, 2009 (15)	99	Retrospective case series	19 (8-53)	16%	4
Polcari, 2009 (16)	60 (vs. 64 open)	Retrospective cohort	8.2 NS	3.3%	2b
Zorn, 2009 (17)	226 (vs. 471 open)	Retrospective cohort	12.5 (7-16) Significantly lower than open	7.8%	2b
Atung, 2006 (18)	40 (vs. 75 LRP)	Prospective case series	14.08 (9-24)	5%	4

LN = lymph node; LNI = lymph node involvement; LE = level of evidence; NS = non-significant difference between compared groups.

5.3 Conclusions and recommendations on root-assisted pelvic lymph node dissection

Conclusions	**LE**
The reported number of lymph nodes removed in laparoscopic and robotic series is lower than in open surgical series.	2a
However, the same extent of lymphadenectomy can be safely performed by all techniques of radical prostatectomy including RARP.	

Recommendation	**GR**
RARP, LRP and ORP achieve similar perioperative and oncological pelvic lymph node dissection outcomes so either technique can be used in lymphadenectomy.	A

RARP = robotic-assisted radical prostatectomy; LRP = laparoscopic radical prostatectomy; ORP = open retropubic radical prostatectomy.

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6. ROBOTIC-ASSISTED LAPAROSCOPIC SACROCOLPOPEXY

6.1 Introduction

Robotic-assisted laparoscopic sacrocolpopexy (RALS) has emerged as a minimally invasive option for the treatment of vaginal vault prolapse, aiming to provide a similar anatomical outcome with the open technique, in addition to limited morbidity and faster recovery time, both associated with laparoscopy. The literature on RALS is almost entirely limited to a few case series with short-term outcome data leading to a low level of evidence. In addition, there are three comparative studies; one study is a retrospective cohort study comparing RALS with an open approach, while the other two studies are small, randomised controlled studies, comparing RALS with laparoscopic sacrocolpopexy (1,2,3). Table 9 summarises the studies reporting RALS clinical outcomes.

Table 10: Clinical studies in robot-assisted laparoscopic sacrocolpopexy

Author	n	Type of study	LE
Geller, 2008 (1)	73 (vs. 105 open)	Retrospective cohort study	2b
Paraiso, 2011 (2)	40 (vs. 38 laparoscopic)	Randomised controlled trial	2b
Seror, 2012 (3)	20 (vs. 47 laparoscopic)	Randomised controlled trial	2b
Moreno, 2010 (4)	31	Prospective case series	2c
Gocmen, 2011 (7)	12	Retrospective case series	4
Kramer, 2009 (6)	21	Retrospective case series	4
Akl, 2009 (9)	80	Retrospective case series	4
Daneshgari, 2007 (10)	12	Retrospective case series	4
Elliott, 2006 (5)	30	Retrospective case series	4
Benson, 2010 (8)	12	Retrospective case series	4

LE = level of evidence.

6.2 Outcomes

As demonstrated by all published series, RALS is highly effective in restoring the apical vaginal vault defect. Cure rates of 95-100% are comparable with those using an open technique. Geller et al., in a retrospective cohort study comparing 73 RALS to 105 abdominal sacrocolpopexies, reported similar short-term vaginal vault support between the two techniques (1). In addition, Paraiso et al. and Seror et al., in two studies providing data from randomised trials, compared the outcomes of laparoscopic vs. RALS and demonstrated significant improvement in vaginal support and functional outcomes 1 year after surgery with no differences between the groups (2,3) (LE: 2b). The anatomical outcome of the procedure is considered durable. Nevertheless, the true durability of RALS still requires documentation, given that only a few studies report long-term results. No recurrence was evident in 31 cases, after a mean follow-up of 24.5 months, while one recurrence was reported in 30 other cases after a mean follow-up of 24 months in two studies providing long-term data (4,5).

6.3 Conclusion and recommendation robotic-assisted laparoscopic sacrocolpopexy

Conclusion	LE
RALS is safe and effective in restoring vaginal vault prolapse with durability evidenced up to 24 months.	2b

Recommendation	GR
Laparoscopic and robotic colpopexy should be considered standard treatment options for the restoration of apical vaginal vault defects.	A

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7. ROBOTIC-ASSISTED AND LESS CYSTECTOMY

7.1 Introduction

Open radical cystectomy (ORC) with PLND is the standard-of-care treatment for high-risk non-muscle-invasive and muscle-invasive urothelial carcinoma of the bladder (UCB), providing durable local cancer control (1-4). Even when performed by experienced surgeons, it is associated with significant morbidity, including bleeding, pain associated with the lengthy incision and prolonged abdominal wall retraction, and major fluid shifts related to prolonged exposure of the peritoneal surface. Additionally, visibility of the surgical field can be difficult in the deep pelvis and retrovesical space using the open approach (5-10). With the increasing adoption of robot-assisted laparoscopic techniques for prostate and kidney cancers, there has been growing interest in robot-assisted radical cystectomy (RARC). To date, there are only limited published data on robot-assisted or LESS simple cystectomy, which means we cannot make any evidence-based recommendations regarding their use. However, since simple cystectomy is usually not technically more difficult than radical cystectomy, the concepts discussed below regarding RARC should apply to simple cystectomy.

7.2 RARC Safety

It has been suggested that RARC results in less blood loss, reduced morbidity, improved convalescence, and earlier initiation of adjuvant systemic therapies (5,9,10). To date, there is no prospective randomised study, comparing the safety and complications of RARC to ORC. In the absence of randomised clinical trials, comparison to historical ORC series from high-volume centres is the only possible approach (Table 10). Taken together, complication rates of RARC in the literature range from 20-91% (Table 10). RARC has been suggested, in retrospective comparative studies, to result in a lower rate of postoperative complications than ORC. A recent population-based study comparing RARC to ORC confirmed these findings (10). However, these studies suffered from a retrospective uncontrolled design with significant selection bias. Risk factors associated with major complications after RARC are (11,12), age > 65 years, estimated perioperative blood loss > 500 mL and intraoperative intravenous fluid > 5000 mL. The cumulative data supports the finding that the perioperative and long-term safety of RARC is at least not inferior to that of ORC. However, the long-term oncological safety and efficacy of RARC are still under debate.

7.3 Oncological efficacy

Theoretically, RARC should be a safe procedure provided there is adherence to standard oncological principles. In the absence of long-term data, surgical factors, including quality-of-care indicators, such as the soft-tissue surgical margin rate and the extent of lymphadenectomy (13,14) have been used to assess the oncological safety of RARC (7,15,16). Herr et al. suggested benchmark recommendations of a positive soft-tissue surgical margin rate of < 10% and a lymph node yield of > 10-14, based upon the oncological outcomes of 16 experienced ORC surgeons (17). Although early RARC series met these benchmarks, these studies included lower-risk patients with a lower rate of extravesical disease and nodal metastasis (7,18-21).

In addition, early RARC cohorts seemed to select generally younger and healthier patients, often excluding patients with prior pelvic treatments (i.e. surgery and radiation). Indeed, generalisation from the largest, reported, single-centre RARC series (n = 100) is limited by its patient selection (22). Such selection biases in early RARC series have made it difficult to extrapolate their findings to the general bladder cancer population which is often older and iller. However, these early studies established RARC as a feasible and safe procedure when performed in selected patients. In the current phase of RARC evaluation, the inclusion criteria have been relaxed to include almost all candidates for RC.

In a comparison of 35 RARC consecutive cases and 35 ORC consecutive cases (no statistically significant differences in patient characteristics, tumour stage, and LN status), Richards et al. (23) reported the same median LN yield (15 vs. 16). There was also no difference in positive soft tissue surgical margin rates (one in the RARC group compared to three in the ORC group). Using a multi-institutional international RARC database, Hellenthal et al. found that 82.9% of 527 patients from 15 institutions underwent adequate lymphadenectomy, which was defined as having ≥ 10 LNs removed (24). This rate was comparable to rates of historical ORC series, even at specialised academic centres (1-3). Furthermore, the authors identified the surgeon's volume and sequential case number (two factors suggestive of the learning curve) were predictive of the probability of undergoing an adequate lymphadenectomy with RARC. However, there was no association between margin positivity (35/513 RARC cases, 6.8%) and sequential case number or institutional volume (25). Moreover, the soft tissue margin positivity rate was within the range of that of ORC series and standards proposed (17,26). Similarly to ORC series, advanced age, LN positivity, and advanced tumour stage were associated with an increased likelihood of a positive soft tissue surgical margin (26,27). Comparative retrospective studies confirmed these findings either in an unmatched (28) or in a matched study design (9). Finally, a small prospective randomised trial (n = 41) confirmed the non-inferiority of RARC to ORC with the primary endpoint of LN yield (mean of 19 vs. 18 LNs) (29). Although the sample size is small, the authors should be recognised for reporting the first prospective randomised controlled trial between RARC and ORC. Cumulatively, these data, similar to robot-assisted radical prostatectomy, support that RARC can achieve a similar oncological surgical quality to ORC, and that this depends more on the surgeon performing the surgery than the procedure used.

To date, early and mid-term oncological outcomes have been reported and are presented in Table 11 (28,30,31). Two-year, recurrence-free, cancer-specific and OS estimates (74%, 85%, and 79%, respectively) mirror those of large contemporary ORC series, suggesting an early oncological equivalency of RARC to ORC (1,2,4,32,33). Despite the potential perioperative benefits and promising surgical quality indicators, as well as the mid-term oncological control afforded by RARC, the long-term oncological efficacy of this relatively new technique has yet to be determined. Before widespread application of RARC, it needs to be further tested at high-volume centres within controlled clinical studies.

7.4 Learning curve

To date, there is no standard definition of what would be considered an adequate learning curve for RARC. A recent study from the International Robotic Cystectomy Consortium demonstrated that operative time, estimated blood loss, and lymph node yield are significantly associated with previous robot-assisted radical prostatectomy experience. Moreover, the authors defined a cut-off of 30 cases as sufficient for obtaining an adequate learning experience for RARC (34). The panel cannot establish the number of cases needed before to become proficient at performing RARC.

7.5 Diversion

Extracorporeal urinary diversion through a mini-laparotomy incision is to date the most widely used reconstructive approach. The intracorporeal technique has been shown to generate increased rates of major complications in retrospective mono-centric studies (35,36). Recently, Pruthi et al. compared the perioperative outcomes of 12 patients who underwent RARC with intracorporeal urinary diversion to 20 patients who underwent extracorporeal diversion (37). In this small sample size series, the intracorporeal technique was associated with a longer operative time. However, complication rates and length of stay were not different. The choice of urinary diversion depends on the skill and dedication of the surgeon. There is no recommendation that can be made, regarding the benefit of one over the other. However, the panel suggests it is best to start with extracorporeal urinary diversion in the early experience.

7.6 Cost-effectiveness

The rapid adoption of robot-assisted surgery for prostate cancer and other diseases has called into question whether the benefits of this technology justify the cost, as there is no clear evidence demonstrating superior clinical outcomes of these techniques over traditional surgical approaches (i.e. open or laparoscopy) (10,38,39). There are only few, small, single-centre studies on comparative costs of RARC vs. ORC (38-40). Similar to other diseases, RARC has been estimated to be more costly than ORC (i.e. approximately US$

1,600 difference per case in direct costs). A population-based study found that the inpatient cost difference exceeded the US$1600 figure (10).

However, RARC has been reported to result in potentially less perioperative complications and a shorter length of stay than ORC, thereby possibly lowering hospital costs (8,10,41). When perioperative complication costs were included in the cost-comparison analysis of RARC and ORC (40), Lee et al. found that RARC was indeed cheaper than ORC (83 vs. 103 consecutive cases, respectively). The generalisability of these single-institution analyses is limited as the data are from high-volume, tertiary care centres with significant robotic experience. The cost issue therefore remains unsettled.

7.7 LESS RC

Due to the lack of data available, we cannot recommend this approach, outside of properly designed clinical trials.

7.8 Conclusions robot-assisted radical cystectomy

Conclusions	**LE**
RARC is a feasible and safe approach with comparable perioperative and long-term complications to ORC.	1b
RARC can yield the same extent of lymphadenectomy than ORC.	1b
Initial RARC series had a high rate of positive soft tissue surgical margins. Experienced surgeons, however, can achieve similar margin rates, irrespective of the technique used.	1b
Short- and intermediate-term survival data from retrospective series suggest that the oncological efficacy of RARC is not inferior to that of ORC.	3
Urinary diversion can safely be performed extracorporeally or intracorporeally.	3

Table 11: Perioperative data and complications rates of robot-assisted radical cystectomy studies

Author	Year	Nb RARC	Gender	Mean Age (y)	BMI (kg/ m2)	ASA ≥ 3 (%)	Clinical stage NMIBC ≥ T3 (%)	OR Time (min)	Conversion rate (%)	EBL (mL)	Transfusion (%)	Length of stay (days)	Complications Overall (%)	Complications Clavien grade 1-2 (%)	Complications Clavien grade 3-4 (%)	Mortality(%)
Retrospective single centre studies																
Guru et al. [18]	2007	20	65%	70	26	30	25 5	442	5	555	0	10	20	10	10	5
Dasgupta et al. [19]	2008	20	85%	66	NA	55	45 5	330	0	150	5	10	-	-	10	-
Murphy et al. [20]	2008	23	87%	64.8	28.9	-	-	309	-	507	4	11.6	-	-	13	-
Pruthi et al. [22]	2010	100	73%	65.5	27.3	-	30 5	276	0	271	-	4.9	36	28	8	0
Jonsson et al. [30]	2011	45	84%	62	26	-	45 7	477	4	550	-	9	40	17	23	0
Khan et al. [42]	2011	50	88%	66	28.7	18	21 3	361	0	340	4	10	34	24	10	0
Torrey et al. [43]	2012	34	62%	68.7	29	80	-	510	-	504	-	12.9	91	76	15	3
Yuh et al. [44]	2012	196	83%	70.4	27.1	78	-	432	-	400	20	9	77	59	18	2
Retrospective comparative unmatched studies																
Wang et al. [7]	2008	33 RARC	88%	70	26.7	-	51 -	390	-	400	-	5	21	12	9	0
		21 ORC	62%	66	27.1	-	29 -	300	-	750	-	8	24	5	19	0
Ng et al. [8]	2010	83 RARC	78%	70.9	26.3	43	-	375	0	460	7	5.5	59	58	1	0
		104 ORC	71%	67.2	27.2	48	-	357	-	1172	-	8	41	30	11	4.8
Richards et al. [21]	2010	35 RARC	86%	65	27	89	-	530		350	17	7	60	40	20	3
		35 ORC	71%	66	26	77	-	420		1000	71	8	65	40	25	0
Retrospective comparative matched studies																
Styn et al. [9]	2012	50 RARC	-	66.6	29.8	54	-	454	-	350	2	9.5	66	47	19	0
		100 ORC	-	65.6	29.6	57	-	349	-	475	24	10	62	48	14	1
Yu et al. [10]	2012	103 RARC	91%	69	-	-	-	-	-	-	32	8	49	-	-	0
		8209 ORC	83%	69	-	-	-	-	-	-	38	8	64	-	-	2.5
Prospective randomized trial																
Nix et al. [29]	2010	21 RARC	70%	67	27.5	-	30 15	252	0	273	-	5	33	-	-	0
		20 ORC	85%	69	28.4	-	25 5	210	-	564	-	6	50	-	-	5

EBL= estimated blood loss; OR = operation; BMI = body mass index; ASA = American Society of Anesthesiologists; NMIBC = non-muscle invasive bladder cancer.

Table 12: Oncological outcomes of robot-assisted radical cystectomy studies

Author	Year	NB	Follow-up	Lymph node yield (%)	STSM (%)	RFS (%)	CSS (%)	OS (%)
Retrospective single centre studies								
Guru et al. [18]	2007	20	-	13	5	-	-	-
Dasgupta et al. [19]	2008	17	23	16	0	90 90 90	95 (f/u)	- - -
Murphy et al. [20]	2008	23	17	16	0	91 (f/u)	96 (f/u)	96 (f/u)
Pruthi et al. [22]	2010	100	21	19	0	85 (f/u)	94 (f/u)	90 (f/u)
Hellenthal et al.[24, 25]	2010 and 2011	527 and 513	-	17.8	6.8	-	-	-
Martin et al. [28]	2010	59	25	-	-	82 71 71	- - -	82 72 72
Jonsson et al. [30]	2011	45	25	19	2	84 (f/u)	92 86 86	-
Kauffman et al. [31]	2011	85	18	19	5	79 73	88 84	82 79
Retrospective comparative unmatched studies								
Wang et al. [7]	2008	33 RARC	-	17	6	-	-	-
		21 ORC	-	20	14	-	-	-
Richards et al. [21]	2010	35 RARC	-	16	3	-	-	-
		35 ORC	-	15	9	-	-	-
Retrospective comparative matched studies								
Styn et al. [9]	2012	50 RARC	-	14	2%	-	-	-
		100 ORC	-	15	1%	-	-	-
Prospective randomized trial								
Nix et al. [29]	2010	21 RARC	-	19	0%	-	-	-
		20 ORC	-	18	0%	-	-	-

STSM = soft tissue surgical margin; RFS = recurrence-free survival; CSS = cancer-specific survival; OS = overall survival.

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8. ABBREVIATIONS USED IN THE TEXT

This list is not comprehensive for the most common abbreviations

EAU	European Association of Urology
EBL	Estimated blood losses
GR	Grade of recommendation
LARP	Laparoscopic radical prostatectomy
LE	Level of evidence
LESS	Laparoendoscopic single-site
LN	Lymph node
LPN	Laparoscopic partial nephrectomy
LPP	Laparoscopic pyeloplasty
LRN	Laparoscopic radical nephrectomy
LRP	Laparoscopic radical prostatectomy
ORC	Open radical cystectomy
ORP	Open retropubic radical prostatectomy
PLND	Pelvic lymph node dissection
PSA	Prostate-specific antigen
PSM	Positive surgical margin
RALP	Robotic-assisted laparoscopic radical prostatectomy
RALS	Robot-assisted laparoscopic sacrocolpopexy
RARC	Robot-assisted radical cystectomy
RARP	Robot-assisted radical prostatectomy
RC	Radical cystectomy
RCT	Randomised controlled trial
RLPP	Robot-assisted laparoscopic pyeloplasty
RP	Radical prostatectomy
RPN	Robotic partial nephrectomy
RRN	Robotic radical nephrectomy
SITUS	Single-incision triangulated umbilical surgery
UCB	Urothelial carcinoma of the bladder
VAPS	Visual analogue pain scale
WIT	Warm ischaemia time

Conflict of interest

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