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European Association of Urology

Guidelines

EAU Guidelines on Robotic and Single-site Surgery in Urology

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Abstract

Context: This is a short version of the European Association of Urology (EAU) guidelines on robotic and single-site surgery in urology, as created in 2013 by the EAU Guidelines Office Panel on Urological Technologies.
Objective: To evaluate current evidence regarding robotic and single-site surgery in urology and to provide clinical recommendations.
Evidence acquisition: A comprehensive online systematic search of the literature according to Cochrane recommendations was performed in July 2012, identifying data from 1990 to 2012 regarding robotic and single-site surgery in urology.
Evidence synthesis: There is a lack of high-quality data on both robotic and single-site surgery for most upper and lower urinary tract operations. Mature evidence including midterm follow-up data exists only for robot-assisted radical prostatectomy. In the absence of high-quality data, the guidelines panel's recommendations were based mostly on the review of low-level evidence and expert opinions.
Conclusions: Robot-assisted urologic surgery is an emerging and safe technology for most urologic operations. Further documentation including long-term oncologic and functional outcomes is deemed necessary before definite conclusions can be drawn regarding the superiority or not of robotic assistance compared with the conventional laparoscopic and open approaches. Laparoendoscopic single-site surgery is a novel laparoscopic technique providing a potentially superior cosmetic outcome over conventional laparoscopy. Nevertheless, further advantages offered by this technology are still under discussion and not yet proven. Due to the technically demanding character of the single-site approach, only experienced laparoscopic surgeons should attempt this technique in clinical settings.
Patient summary: This work represents the shortened version of the 2013 European Association of Urology guidelines on robotic and single-site surgery. The authors systematically evaluated published evidence in these fields and concluded that robotic assisted surgery is possible and safe for most urologic operations. Whilst laparoendoscopic single-site surgery is performed using the fewest incisions, the balance between risk and benefit is currently unclear. The evidence to support the conclusions in this guideline was generally poor, but best for robotic assisted radical prostatectomy. As such, these recommendations were based upon expert opinion, and further high-quality research is needed in this field.

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1. Introduction

This paper summarises the European Association of Urology (EAU) guidelines on robotic and single-site surgery in urology published in 2013 [1]. It supplements the other EAU guidelines and focuses on level of evidence (LE) evaluation of the current literature as well as on clinical recommendations established by the EAU Guidelines Office Panel on Urological Technologies regarding robotic and single-site surgery in urology.

2. Methodology and evidence acquisition

2.1. Literature search

An extensive online systematic review of the literature was conducted in July 2012 identifying data regarding robotic and single-site surgery in urology. 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. Retrieved papers were assigned a LE. Panel recommendations were graded (grade of recommendation [GR]) following the system currently used by the EAU Guidelines Office.

2.2. Inclusion criteria

Case reports, congress proceedings, editorials, and reviews were excluded. Cohorts derived from the same institution were restricted to the most recent or largest study. In the case of robotic prostatectomy due to the wide availability of low level literature, review was limited to comparative studies and meta-analyses comparing robotic assistance with open and laparoscopic approaches.

2.3. Quality of evidence

Currently, there is a lack of multicentre randomised controlled studies leading to a high LE regarding robotic versus open versus laparoscopic surgery. In addition, due to the relative recent adaptation of robotic technology in most of the reporting institutes, robotic outcomes are mostly considered to be within each surgeon's learning curve. As a result, it was difficult for the guidelines panel to extract strong conclusions from the data currently available for analysis. Apart from a few procedures documented by more mature data, the guidelines panel recommendations on robot-assisted approaches were generally based on the panel's review of low-level evidence and expert opinion.

3. Robotic surgery in urology

3.1. Robot-assisted nephrectomy

3.1.1. Robot-assisted radical nephrectomy

Robot-assisted radical nephrectomy (RRN) was introduced in 2000 [2], but the limited benefit offered with the approach has slowed its widespread adoption. The main limitations of the approach are the increased technical effort associated with robot docking time and the considerably higher cost per procedure, without significant improvement in clinical outcomes compared with standard laparoscopic surgery or nonrobotic laparoendoscopic single-site surgery (LESS).

RRN performed either by a transperitoneal or retroperitoneal route and robot-assisted donor nephrectomy are considered safe procedures as evidenced by the few published cohorts on the subject [2–9]. Despite a study reporting higher complication rates in the initial cases of RRN (compared with pure laparoscopic and hand-assisted laparoscopic nephrectomy), complication rates up to 18% for RRN have been reported, which is similar to the reported rates for laparoscopic radical nephrectomy (LRN) [3–6].

Data on the direct comparison of RRN with LRN are limited and include cohorts of <50 patients [2–6]. Similar perioperative outcomes were reported in most of the comparative studies (LE: 3), including only one prospective evaluation. Nevertheless, a longer operative time for RRN is commonly reported, mainly due to the learning curve and time necessary for robot docking.

Based on the preceding information, robotic assistance may be considered a technical overtreatment for radical nephrectomy. Its use should therefore be weighed against a standard laparoscopic approach depending on the individual case. However, RRN can still be a useful training setting for robot-assisted partial nephrectomy (RPN) [6].

3.1.2. Robot-assisted partial nephrectomy

According to the current EAU guidelines on renal cell cancer, nephron-sparing surgery, if feasible, is the preferred surgical approach for renal tumours ≤pT1b [10]. Since the first report on RPN in 2004 [11], there has been extensive evaluation of various technical aspects of the robotic procedure including instrument triangulation, the sliding clip technique, reduction of warm ischaemia time, and zero ischaemia techniques [11–13].

The outcomes of RPN are generally comparable with conventional laparoscopic partial nephrectomy (LPN). A single-surgeon matched cohort study retrospectively matching 75 RPNs with 75 LPNs cases found no difference in operative time, warm ischaemia time, length of hospitalisation, percentage change in renal function, or adverse events. However, mean blood loss was higher in the RPN cohort (323 vs 222 ml) [14]. Similarly, one of the largest comparative studies retrospectively evaluating 199 RPNs versus 182 LPNs found no significant differences in perioperative parameters, apart from a significantly lower conversion rate noted in the RPN group (1% vs 11.5% for LPN). In addition, there was less of a decrease in the estimated glomerular filtration rate for RPN (12.6% vs 16% for LPN) [15].

A recently published systemic meta-analysis on RPN versus LPN incorporating data from 717 patients (313 RPN vs 404 LPN) reported a significantly lower warm ischaemia time in the RPN arm. There were no significant differences between the two groups in all other examined perioperative parameters [16].

Complication rates associated with RPN are comparable with LPN, although it should be noted that the mean tumour size in the reported series is usually small, mainly due to case selection. Tumours >4 cm treated with RPN have been

Table 1 – The outcomes of selected studies on robot-assisted partial nephrectomy compared with laparoscopic partial nephrectomy

Study	N LPN RPN	OR time LPN RPN	EBL LPN RPN	TF rate LPN RPN	W-ischaemia LPN RPN	Complications LPN RPN	Hospital stay LPN RPN	Study design	LE
Aron et al. [19]	12	256	300	NA	22	NA	4.4	Retrospective, matched pair	3
	12	242	329		23		4.7		
Benway et al. [20]	118	174	196	2	28.4	12	2.7	Retrospective	3
	129	189	155	1	19.7	11	2.4		
Deane et al. [21]	11	289	198	NA	35	0	3.1	Retrospective	3
	11	228	115		32	1	2.0		
DeLong et al. [22]	15	253	NA	NA	39.9	NA	NA	Retrospective	3
	13	352			29.7				
Jeong et al. [23]	26	139	208	1	17	NA	5.3	Retrospective	3
	31	169	198	1	20		5.2		
Kural et al. [24]	20	226	387	2	35	2	4.2	Retrospective	3
	11	185	286	0	27	1	3.9		
Williams et al. [25]	59	221	146.3	NA	18.5	–	2.71	Prospective, single surgeon	3
	27	233	179.6		28.0		2.51		
Wang et al. [26]	62	156	173	1	25	8	2.9	Comparative, retrospective	3
	40	140	136	2	19	6	2.5		
Ellison et al. [27]	108	162	400	–	19.3	–	2.2	Retrospective	3
	108	215	368		24.9		2.7		
Pierorazio et al. [28]	102	192	245.1	–	18	–	NA	Retrospective	3
	48	152	122.4		14.1				
Seo et al. [29]	14	117	264.1	–	36.4	–	5.3	Retrospective	3
	13	153	283.6		35.3		6.2		
Long et al. [15]	182	240.7	325.0	14.3%	23.2	5.5%	1.36	Retrospective	3
	199	196.9	280.2	12.1%	22.4	3.0%	2.21		

EBL = estimated blood loss; LE = level of evidence; LPN = laparoscopic partial nephrectomy; N = nephrectomy; NA = not available; OR time = operating time; RPN = robotic partial nephrectomy; TF = transfusion rate; W-ischaemia = warm ischaemia time.

associated with high complication rates of up to 26.7% [17]. In the largest single-centre series to date, entailing data from 400 RPN patients, there was a total of 11 intraoperative complications (2.7%). Postoperative complications occurred in 15.3% of cases (61 patients); only a few were high-grade complications (grades 3 and 4 in 3.2%) [18].

Taking these experiences into consideration, RPN is a safe and viable alternative to LPN (Table 1). It provides equivalent early oncologic outcomes and comparable morbidity to a traditional laparoscopic approach. RPN appears to offer no difference to LPN in the duration of hospital stay, intraoperative blood loss, operative time or conversion rate, and warm ischaemia time. Further evaluation of the effect of RPN on renal preservation and long-term oncologic outcomes is needed.

3.1.3. Conclusions and recommendations on robot-assisted radical nephrectomy and robot-assisted partial nephrectomy

Conclusions and recommendations on RRN and RPN are shown in Table 2.

3.2. Robotics reconstructive renal surgery

Robotic assistance can significantly aid reconstructive procedures due to delicate robotic arm manoeuvrability, three-dimensional vision, and tremor control. Initial experience with robot-assisted laparoscopic pyeloplasty (RLPP) dates back to 1999 and followed the standard technique described for laparoscopic pyeloplasty [30]. Currently, most of the robotic pyeloplasty literature is in paediatric patients [31]. In the adult population, operative time, perioperative outcomes, and success rates are comparable for RLPP and conventional laparoscopic pyeloplasty (LPP) [32,33], although a reduced suturing time for RLPP is regularly reported. Complications for both procedures are rare. A meta-analysis of comparative studies of RLPP and LPP retrieved

Table 2 – Conclusions and recommendations on robot-assisted radical nephrectomy and robot-assisted partial nephrectomy

Conclusions on RRN and RPN	LE
Conclusive long-term data are not available.	–
RRN and RPN are technically feasible.	–
No comparable long-term data on oncologic, safety, and functional outcomes are available. However, based on short-term data and guidelines panel expertise, no significant differences are expected.	4
In ablative surgery, robotics will produce no better outcomes compared with laparoscopy.	–
Possible benefit exists in reconstructive surgery (ie, partial nephrectomy/pyeloplasty).	–
Recommendations	**GR**
Use laparoscopy for simple or radical nephrectomy.	C
Use robot-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.	C

GR = grade of recommendation; LE = level of evidence; RPN = robot-assisted partial nephrectomy; RRN = robot-assisted radical nephrectomy.

only eight studies valid enough for consideration. It was concluded that both techniques had no major differences with regard to operation time, postoperative urine leakage, and success rates [34].

3.3. Robot-assisted radical prostatectomy

Less than 10 yr following its introduction by Binder and Kramer, robot-assisted radical prostatectomy (RARP) has gained widespread acceptance and has become part of the standard armamentarium in the management of prostate cancer [35]. However, due to the relatively recent introduction of the approach, there are very few studies with long-term data and very few high-quality comparative studies of RARP, open radical prostatectomy (ORP), and standard laparoscopic radical prostatectomy (LRP).

3.3.1. Robot-assisted radical prostatectomy and oncologic outcomes

There is very little data on the long-term oncologic outcomes of RARP. Comparative studies between RARP and ORP or LRP have demonstrated varying outcomes for positive surgical margins (PSMs). Most of such studies reported equivalent or lower PSM rates for RARP than for the other two approaches (Table 3). The two currently available prospective randomised studies (LE: 2b) that compare RARP with LRP found no differences in PSMs between the two surgical groups [36,37].

Meta-analyses of published RARP outcomes have reported equivalent or lower PSM rates than ORP and LRP (LE: 3a). Two earlier meta-analyses of RARP studies published in 2006 and 2008 showed no significant differences in overall risk for PSMs between ORP and LRP or RARP [38,39]. Similarly, two of the most recent meta-analyses reported similar PSMs for all radical prostatectomy approaches [40,41]. In contrast, a comparative meta-analysis of studies performed by high-volume centres (studies reporting on >250 patients) revealed that RARP yielded a lower overall weighted mean PSM rate than ORP and LRP [42].

The biochemical recurrence–free survival for RARP is well documented for up to 5 yr. No significant differences in early (1 yr) and 3-yr prostate-specific antigen (PSA) recurrence between RARP and ORP have been reported [43–45]. In addition, a retrospective evaluation of 239 patients treated via ORP, LRP, or RARP showed no difference in the 5-yr PSA-free survival rates among the different approaches [46]. 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, revealed a higher overall PSM rate for the RARP group compared with the ORP and LRP groups. However, there was no difference with respect to 5-yr biochemical recurrence–free survival between the three surgical approaches [47].

Surgical expertise significantly affects the oncologic outcomes of RARP like any surgical therapy. Both PSM and biochemical recurrence–free survival rates have been reported to improve with increased experience [48,49]. Nevertheless, the exact number of cases required for a surgeon to achieve and sustain acceptable oncologic outcomes remains to be defined.

Table 3 – Positive surgical margin rates of robot-assisted radical prostatectomy in comparison with other techniques

Study	*n*	Type of study	Overall PSMs, %	LE
Porpiglia et al. [36]	60 (vs 60 LRPs)	Prospective randomized trial	26.6 NS	2a
Magheli et al. [47]	522 (vs 522 ORPs vs 522 LRPs)	Retrospective matched-pair comparison	19.5 Significantly higher than ORP and LRP	4
Di Pierro et al. [50]	75 (vs 75 ORP)	Prospective trial	16 Significantly lower	2c
Asimakopoulos et al. [37]	64 (vs 64 LRP)	Prospective randomized trial	NS	2a
Doumerc et al. [51]	212 (vs 502 ORPs)	Prospective trial	21.2 NS	2c
Williams et al. [52]	604 (vs 346 ORPs)	Retrospective cohort	7.7–13.5 Significantly higher	4
Ficcara et al. [53]	103 (vs 105 ORPs)	Prospective trial	21 NS	2c
Drouin et al. [46]	71 (vs 83 ORPs vs 85 LRPs)	Retrospective cohort	17 NS	4
White et al. [54]	50 (vs 63 ORPs)	Retrospective cohort	22 Significantly lower	4
Laurila et al. [55]	94 (vs 98 ORPs)	Retrospective cohort	13 NS	4
Rocco et al. [56]	120 (vs 240 ORPs)	Prospective matched-pair comparison	22 NS	4
Krambeck et al. [45]	294 (vs 588 ORPs)	Retrospective matched-pair comparison	15.6 NS	4
Schroeck et al. [43]	362 (vs 435 ORPs)	Retrospective cohort	29 NS	4
Chan et al. [57]	660 (vs 340 ORPs)	Retrospective cohort	9.9–19 Significantly lower	4

LE = level of evidence; LRP = laparoscopic radical prostatectomy; ORP = retropubic radical prostatectomy; NS = nonsignificant difference with compared approach; PSMs= positive surgical margins; RARP = robot-assisted radical prostatectomy.

Table 4 – Conclusions and recommendation on the oncologic outcome of robot-assisted radical prostatectomy

Conclusions	LE
RARP for localized prostate cancer is now a well-established surgical approach offering positive surgical margin rates similar to ORP and LRP.	2a
Long-term PSA-free survival of patients treated with RARP as documented for up to 5 yr is comparable to other radical prostatectomy approaches.	3b
In the absence of level 1a data and very limited long-term data, a firm conclusion regarding the oncologic superiority of RARP over other techniques cannot be drawn.	2a
Recommendation	**GR**
Robotic surgery does not improve oncologic outcomes; surgical expertise does.	A

GR = grade of recommendation; LE = level of evidence; LRP = laparoscopic radical prostatectomy; ORP = open radical prostatectomy; PSA = prostate-specific antigen; RARP = robot-assisted radical prostatectomy.

Table 5 – Conclusions and recommendations on incontinence outcomes of robot-assisted radical prostatectomy

Conclusions	LE
RARP for localized prostate cancer is a surgical approach offering high continence rates, at least comparable to 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 with ORP and LRP.	3b
Recommendations	**GR**
To achieve better early continence results, the use of robotic technique is recommended.*	C

GR = grade of recommendation; LE = level of evidence; LRP = laparoscopic radical prostatectomy; ORP = open radical prostatectomy; RARP = robot-assisted radical prostatectomy.
* Robotic surgery does not improve oncologic outcomes; surgical expertise does.

3.3.2. Conclusions and recommendations on the oncologic outcomes of robot-assisted radical prostatectomy

Conclusions and recommendations on the oncologic outcomes of RARP are shown in Table 4.

3.3.3. Robot-assisted radical prostatectomy and urinary continence

Numerous studies on RARP reveal a trend towards faster recovery of continence and a potentially higher overall continence rates compared with the gold standard ORP, but there is a lack of randomised comparative studies between the two approaches to support this finding. Two recent well-documented meta-analyses of comparative studies between ORP, LRP, and RARP showed that RARP was associated with higher continence rates at 12 mo postoperatively [42,58]. In contrast, two other large-scale meta-analyses, including 3893 and 44 702 patients, respectively, did not confirm the superiority of RARP, reporting similar 12-mo continence recovery rates for all three approaches [38,59].

An earlier continence recovery for RARP was documented by two prospective nonrandomised studies comparing ORP with RARP [53,60]. In addition, a matched-pair analysis of 120 prospectively evaluated RARP cases with a comparable population of ORP cases presented superior continence rates for RARP at 6 and 12 mo postoperatively [56]. In contrast, no significant difference in continence was reported in a larger matched-pair analysis, reporting equivalent 12-mo urinary continence rates for RARP and ORP, respectively [45]. More recently, 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 yr postoperatively [50].

The two currently available RCTs between LRP and RARP reported conflicting results. In a recent RCT comparing LRP and RARP, Porpiglia et al. reported higher continence rates after RARP [36]. In contrast, Asimakopoulos et al. revealed no differences in continence rates between the two approaches [37]. Other nonrandomised studies have revealed similarly controversial results [61–63].

3.3.4. Conclusions and recommendations on the potency outcomes of robot-assisted radical prostatectomy

Conclusions and recommendations on the potency outcomes of RARP are shown in Table 5.

3.3.5. Robot-assisted radical prostatectomy and potency

A significant variation in reported potency rates after RARP can be largely attributed to the fact that different studies entail varying population characteristics, different potency assessment, and the use of different potency aids. Most of the 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) and higher overall potency rates at 1 yr postoperatively have been documented [41,50,53,56]. Two meta-analyses verified that RARP was associated with higher potency rates than ORP [42,64]. In contrast, comparable potency rates between RARP and ORP at 1-yr follow-up were reported in a large matched-pair analysis and an additional meta-analysis [45,59]. Due to the lack of randomised comparative studies between RARP and ORP, it is not possible to reach 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. The two currently available prospective randomised studies comparing LRP with RARP reported a significantly shorter time to capability for intercourse and a higher 12-mo rate of capability for intercourse in the RARP arm and erection recovery [36,37]. A meta-analysis of high-volume comparative studies calculated weighted mean potency rates for patients who underwent unilateral or bilateral nerve sparing at 12 mo of follow-up of 31.1% and 54%, respectively, for LRP, compared with 59.9% and 93.5%, respectively, for RARP [42]. A nonstatistically significant trend in favour of RARP versus LRP was also reported in a recent meta-analysis [64]. Similarly, a recent comparative investigation, including 1009 RARP and 1377 LRP operations, revealed higher potency rates in the RARP arm at both 6 and 12 mo of follow-up [63]. In contrast, comparable

Table 6 – Conclusions and recommendations on potency outcomes of robot-assisted radical prostatectomy

Conclusions	LE
Potency assessment after radical prostatectomy has many limitations, which partly explain 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 RARP 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 (ie, athermal) technique during neurovascular bundle dissection is recommended.	A

GR = grade of recommendation; LE = level of evidence; LRP = laparoscopic radical prostatectomy; ORP = open radical prostatectomy; RARP = robot-assisted radical prostatectomy.
* Robotic surgery does not improve oncologic outcomes; surgical expertise does.

Table 7 – Conclusions and recommendations on robot-assisted pelvic lymph node dissection

Conclusions	LE
The reported numbers of lymph nodes removed in laparoscopic and robotic series are lower than in open surgical series.	2a
The same extent of lymphadenectomy can be safely performed by all radical prostatectomy techniques including RARP.	–
Recommendation	**GR**
RARP, LRP, and ORP achieve similar perioperative and oncologic PLND outcomes, so all techniques can be used for lymphadenectomy.	A

GR = grade of recommendation; LE = level of evidence; LRP = laparoscopic radical prostatectomy; ORP = open radical prostatectomy; RARP = robot-assisted radical prostatectomy.

potency rates between RARP and LRP at 6 mo and 1 yr of follow-up were reported by other studies [61,62].

3.3.6. *Conclusions and recommendations on the potency outcomes of robot-assisted radical prostatectomy*

Conclusions and recommendations on the potency outcomes of RARP are shown in Table 6.

3.4. *Robot-assisted pelvic lymph node dissection*

3.4.1. *Evidence for robot-assisted pelvic lymph node dissection*

According to the EAU guidelines on prostate cancer, nodal evaluation could be spared in patients with stage ≤T2, PSA <10, a Gleason score ≤6, and <50% positive biopsy cores because these patients have <10% risk of lymph node (LN) metastases (GR: B). In contrast, pelvic lymph node dissection (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). 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) [65].

Published outcomes of PLND during RARP demonstrate significant variability in both harvested LNs and LN invasion rates. This variability may be caused by several factors including different levels of surgical experience among surgeons, different PLND resection templates followed in each institution, and different PLND indications used in each series. Rates for LN yield are surgeon related. 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 in LN yield between the different surgical approaches [66]. 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. In addition, the more extended the LN yield, the higher the probability of detecting a LN invasion [67–69].

A prospective trial comparing consecutive series of 75 ORPs and 75 RARPs revealed a significant difference compared with robotic assistance in the number of retrieved LNs. RARP retrieved a median of 12 LNs (range: 9–17) in contrast to the open technique that retrieved 18 LNs (range: 12–23) [50]. Most available studies comparing robot-assisted PLND with its open counterpart support the open approach and demonstrate a lower LN yield for robot-assisted PLND. The inferior LN retrieval of RARP is most likely due to the comparison of a well-established technique (open or laparoscopic) with a newly introduced approach (RARP) incorporating data during the learning curve. Recent reports on robot-assisted PLND verified that robotic assistance itself does not limit a surgeon's ability to perform a complete PLND [70,71].

3.4.2. *Conclusions and recommendations on robot-assisted pelvic lymph node dissection*

Conclusions and recommendations on robot-assisted PLND are shown in Table 7.

3.5. *Robot-assisted laparoscopic sacrocolpopexy*

3.5.1. *Evidence on robot-assisted laparoscopic sacrocolpopexy*

Robot-assisted laparoscopic sacrocolpopexy (RALS) has emerged as a minimally invasive option for the treatment of vaginal vault prolapse. 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 [72–78]. In addition, there are only three comparative studies comparing RALS with the open or laparoscopic approach [79–81].

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 [79]. Prospective trials (LE: 2b) comparing the outcomes of laparoscopic versus RALS demonstrated significant improvement in vaginal support and functional

Table 8 – Conclusion and recommendation on robot-assisted laparoscopic sacrocolpopexy

Conclusion	LE
RALS is safe and effective in restoring vaginal vault prolapse with durability demonstrated up to 24 mo.	2b
Recommendation	**GR**
Laparoscopic and robotic colpopexy are safe and efficient options for the restoration of apical vaginal vault defects.	A

GR = grade of recommendation; LE = level of evidence; RALS = robot-assisted laparoscopic sacrocolpopexy.

outcomes at 1 yr after surgery with no differences between the groups [80,81]. The anatomic outcome of the procedure is considered durable. Nevertheless, the true durability of RALS still requires further evidence because only a few studies have reported long-term results. One long-term study reported no recurrence in 31 cases after a mean follow-up of 24.5 mo; another study reported one recurrence in 30 other cases after a mean follow-up of 24 mo [72,73].

3.5.2. *Conclusions and recommendations on robot-assisted laparoscopic sacrocolpopexy*

Conclusions and recommendations on RALS are shown in Table 8.

3.6. *Robot-assisted radical cystectomy*

There is growing interest in robot-assisted radical cystectomy (RARC) because of its potential to help the surgeon in performing this complex operation.

3.6.1. *Robot-assisted radical cystectomy safety*

To date, there are no prospective randomised studies comparing the safety and complications of RARC with open radical cystectomy (ORC). However, the cumulative data so far suggest that the perioperative and long-term safety of RARC is at least not inferior to that of ORC. Complication rates of RARC range from 20% to 91% (Table 9). In addition, retrospective comparative studies have suggested that RARC results in less blood loss, reduced morbidity, improved convalescence, and earlier initiation of adjuvant systemic therapies [82–84]. These findings have been confirmed by a recent population-based study comparing 224 RARCs with 1444 ORC cases [84]. However, in general, these studies have suffered from a retrospective uncontrolled design with significant selection bias. The lack of a high LE and the absence of RARC series with long-term follow-up means it is not possible to form definite conclusions regarding the long-term safety and efficacy of RARC.

3.6.2. *Robot-assisted radical cystectomy oncologic efficacy*

In the absence of long-term data, quality-of-care indicators such as the positive soft tissue surgical margin rate and the extent of lymphadenectomy have been used to assess the oncologic safety of RARC [85–87]. Early RARC series demonstrated that the procedure is feasible and safe, leading to satisfactory oncologic results in terms of both PSM rates and LN yield. Nevertheless, these studies included lower-risk patients with a lower rate of extravesical disease and nodal metastasis [85,88–92]. In addition, early RARC cohorts seemed to select for generally younger and healthier patients, often excluding patients with prior pelvic treatments (ie, surgery and radiation). Such selection biases in early RARC

Table 9 – Perioperative data and complications rates of robot-assisted radical cystectomy studies

Study	RARC cases	OR time, min	Conv, %	EBL, ml	TRF, %	Complications: Overall, %	Complications: CG 1–2, %	Complications: CG 3–4, %	Mortality, %
Retrospective single-centre studies									
Guru et al. [88]	20	442	5	555	0	20	10	10	5
Dasgupta et al. [89]	20	330	0	150	5	–	–	10	–
Murphy et al. [90]	23	309	–	507	4	–	–	13	–
Pruthi et al. [92]	100	276	0	271	–	36	28	8	0
Jonsson et al. [100]	45	477	4	550	–	40	17	23	0
Khan et al. [111]	50	361	0	340	4	34	24	10	0
Torrey et al. [112]	34	510	–	504	–	91	76	15	3
Yuh et al. [113]	196	432	–	400	20	77	59	18	2
Retrospective comparative unmatched studies									
Wang et al. [85]	33 RARC	390	–	400	–	21	12	9	0
	vs 21 ORC	300	–	750	–	24	5	19	0
Ng et al. [114]	83 RARC	375	0	460	7	59	58	1	0
	vs 104 ORC	357	–	1172	–	41	30	11	4.8
Richards et al. [91]	35 RARC	530		350	17	60	40	20	3
	vs 35 ORC	420		1000	71	65	40	25	0
Styn et al. [83]	50 RARC	454	–	350	2	66	47	19	0
	vs 100 ORC	349	–	475	24	62	48	14	1
Yu et al. [84]	103 RARC	–	–	–	32	49	–	–	0
	vs 8209 ORC	–	–	–	38	64	–	–	2.5
Prospective randomized trial									
Nix et al. [99]	21 RARC	252	0	273	–	33	–	–	0
	vs 20 ORC	210	–	564	–	50	–	–	5

CG= Clavien grade; Conv = conversion to open surgery; EBL= estimated blood loss; OR time = operation time; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy; TRF = transfusion rate.

series have made it difficult to extrapolate their findings to the general bladder cancer population, which is often older with significant comorbidities.

No significant differences in PSM rates and median LN yield were evidenced in a comparative study incorporating data from 35 RARC versus 35 ORC consecutive cases with similar patient characteristics, tumour stage, and LN status [91]. Hellenthal et al., using a multi-institutional international RARC database, found that 82.9% of 527 patients subjected to RARC underwent adequate lymphadenectomy (defined as having $\geq$10 LNs removed) [93]. The authors demonstrated that 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 PSMs, identified in 6.8% of total cases and sequential case number or institutional volume [94]. The soft tissue margin positivity rate was within the range of that of ORC series and current standards [95,96]. Similarly to ORC series, advanced age, LN positivity, and advanced tumour stage were associated with an increased likelihood of PSMs [96,97]. Comparative retrospective studies confirmed these findings [83,98]. Finally, a small prospective RCT confirmed the noninferiority of RARC to ORC with the primary end point of LN yield (mean of 19 LNs vs 18 LNs, respectively) [99].

To date, early and midterm oncologic outcomes have been reported [99,101,102] (Table 10). The 2-yr recurrence-free, cancer-specific, and overall survival estimates (74%, 85%, and 79%, respectively) mirror those of large contemporary ORC series, suggesting an early oncologic equivalency of RARC to ORC [102–106].

Cumulatively, these data support the conclusion that RARC can achieve a similar oncologic surgical quality to ORC, and that this depends more on the surgeon performing the surgery than the technology used. The long-term oncologic efficacy of this relatively new technique, however, has yet to be determined.

3.6.3. *Robot-assisted radical cystectomy learning curve*

The learning curve for RARC has not yet been properly documented. A study from the International Robotic Cystectomy Consortium demonstrated that operative time, estimated blood loss, and LN yield are significantly associated with previous RARP experience. The authors defined a cut-off of 30 cases as sufficient for obtaining an adequate learning experience for RARC [107]. Based on the limited data, the guidelines panel could not define the number of cases needed to become proficient at performing RARC, and further investigation is necessary.

3.6.4. *Robot-assisted radical cystectomy diversion*

To date, extracorporeal urinary diversion through a mini-laparotomy incision is the most widely used reconstructive approach. The intracorporeal technique has been shown to generate increased rates of major complications in retrospective single-centre studies [108,109]. In contrast, a recent small case series compared the perioperative outcomes of 12 RARC cases with intracorporeal urinary diversion to 20 patients who underwent RARC and

Table 10 – Oncologic outcomes of robot-assisted radical cystectomy studies

Study	Cases	F/u, mo	LN yield, %	STSM, %	RFS, %	CSS, %	OS, %
Retrospective single-centre studies							
Guru et al. [88]	20	–	13	5	–	–	–
Dasgupta et al. [89]	17	23	16	0	90	95 (f/u)	–
					90		–
					90		–
Murphy et al. [90]	23	17	16	0	91 (f/u)	96 (f/u)	96 (f/u)
Pruthi 2010 [92]	100	21	19	0	85 (f/u)	94 (f/u)	90 (f/u)
Hellenthal et al. [93,94]	527 and 513	–	17.8	6.8	–	–	–
Martin et al. [98]	59	25	–	–	82	–	82
					71	–	72
					71	–	72
Jonsson et al. [100]	45	25	19	2	84 (f/u)	92	–
						86	
						86	
Kauffman et al. [101]	85	18	19	5	79	88	82
					73	84	79
Retrospective comparative unmatched studies							
Wang et al. [85]	33 RARC	–	17	6	_	–	–
	vs 21 ORC	–	20	14	–	–	–
Richards et al. [91]	35 RARC	–	16	3	–	–	–
	vs 35 ORC	–	15	9	–	–	–
Retrospective comparative matched studies							
Styn et al. [83]	50 RARC	–	14	2%	–	–	–
	vs 100 ORC	–	15	1%	–	–	–
Prospective randomized trial							
Nix et al. [99]	21 RARC	–	19	0%	–	–	–
	vs 20 ORC	–	18	0%	–	–	–

CSS = cancer-specific survival; f/u = follow-up; ORC = open radical cystectomy; OS = overall survival; RARC = robot-assisted radical cystectomy; RFS = recurrence-free survival; STSM = soft tissue surgical margin.

Table 11 – Conclusions and recommendation on robot-assisted radical cystectomy

Conclusions	LE
RARC is a feasible and safe approach with perioperative and long-term complications comparable to ORC.	1b
RARC can yield the same extent of lymphadenectomy as ORC.	1b
Initial RARC series had a high rate of positive soft tissue surgical margins; however, experienced surgeons can achieve similar margin rates, regardless of the technique used.	1b
Short- and intermediate-term survival data from retrospective series suggest that the oncologic efficacy of RARC is not inferior to that of ORC.	3
Urinary diversion can safely be performed extracorporeally or intracorporeally.	3
Recommendation	**GR**
Robotic surgery does not improve oncologic outcomes; surgical expertise does.	A

GR = grade of recommendation; LE = level of evidence; ORC = open radical cystectomy; RARC = robot-assisted radical cystectomy.

extracorporeal diversion. The series found that the intracorporeal technique was associated with a longer operative time but comparable complication rates and length of stay [110].

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 guidelines panel suggests it is best to start with extracorporeal urinary diversion in the early experience.

3.6.5. *Conclusions on robot-assisted radical cystectomy*

Conclusions on RARC are shown in Table 11.

3.7. *Panel comments regarding the cost of robotic surgery*

Resource limitations made it impossible for the guidelines panel to perform a comparative cost analysis (open vs laparoscopic vs robot-assisted surgery). Doing so within a European-wide setting was not possible due to national health policies determining grossly the costs of clinical care. It has been suggested 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 largely attributed to variation in hospitalisation costs [115]. In addition, the only robotic system assessed in clinical studies and currently available is the da Vinci surgical system (Intuitive Surgical, Inc, Sunnyvale, CA, USA). Costs may decline in the future once there is market competition for machines and/or related consumables [116].

3.8. *Robotic malfunction*

Robotic malfunction was reported in 3.5% of a series of 400 da Vinci robotic urologic operations. In a Web-based survey of urologists performing RARP, 56.8% of responding surgeons had experienced an irrecoverable intraoperative malfunction [117,118]. Conversion to the conventional laparoscopic or open procedure may be necessary in these cases.

4. Laparoendoscopic single-site surgery in urology

4.1. *Terminology and technical principles*

LESS is the general term for all surgical procedures performed by one single skin incision for the introduction of camera and instruments, with or without an additional maximum port of 5 mm [119]. The advantages offered by this approach are still in discussion and not yet proven. The superior cosmetic outcome offered by LESS seems to be the main advantage and the primary reason for using this technology [120,121].

The first report on LESS in urology for human patients was in 2007 by Raman et al., who performed three LESS nephrectomies using a single transumbilical incision [122]. Various trocar settings have been used to try and minimise the reduction of instrument triangulation, which is the main limitation of LESS. Most studies have used a single-port system with three or four instrument channels. Another approach is single-incision triangulated umbilical surgery with straight instruments. This uses a small C-shaped incision in the umbilical fold that can be 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 [123,124]. The use of adjacent 5-mm trocars, resulting in one centre of rotation with skin incisions connected at the time of specimen extraction, has also been described. Due to the fact that trocars are adjacent to one another, the use of articulating and bent instrumentation significantly aids intracorporeal triangulation facilitating LESS [125,126].

In 2009, the first robot-assisted LESS (R-LESS) was reported by Kaouk et al. [127], who later reported the use of R-LESS in 13% of cases in a multi-institutional analysis in 2011 of 1076 LESS cases [128]. Until then, inspired by positive results concerning vision, instrumental movement, triangulation, suturing, and so on, using the conventional da Vinci system, several novel robotic platforms have been developed that show potentially promising results [129–132]. As in conventional laparoscopy, robotics has the potential to play a major role in LESS surgery.

4.2. *Simple and radical laparoendoscopic single-site surgical nephrectomy*

The most widely adopted LESS operations in urology are simple and radical LESS nephrectomies. The feasibility and safety of this minimally invasive approach have been well documented.

There are several comparative studies on LESS versus conventional laparoscopic nephrectomy. A recent meta-analysis including 1094 LESS nephrectomy cases demonstrated a longer operative time and a higher conversion rate for LESS 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. No significant differences were found in perioperative complications, estimated blood loss, warm ischaemia time, and postoperative serum creatinine levels [133].

4.3. Radical nephroureterectomy

Definitive conclusions cannot be made about the use of LESS radical nephroureterectomy because of the minimal research published so far, including the lack of long-term oncologic data and comparative studies with the open or laparoscopic approach.

The feasibility of radical nephroureterectomy using a single port inserted via Pfannenstiel incision was first reported by Ponsky et al. [134]. Following LESS nephrectomy, the distal ureter was resected through the 7.5-cm incision in two patients. Since then, there have been positive results in small case series including 39 radical nephroureterectomies in a multicentre retrospective trial of LESS in urology [128,135–137]. Further documentation of LESS radical nephroureterectomy is awaited. The possibility to perform a template LN dissection using LESS and its role in the disease in general remains to be determined.

4.4. Laparoendoscopic single-site surgical partial nephrectomy

4.4.1. Evidence on laparoendoscopic single-site surgical partial nephrectomy

Cumulative surgical experience with LESS partial nephrectomy (LESS-PN) is limited because only a few centres are using this challenging technique. Most reported outcomes of LESS-PN are from small case series, with intraoperative and perioperative data similar to that of conventional laparoscopic approaches. A prospective comparison of conventional laparoscopic versus LESS-PN reported comparable perioperative outcomes for both approaches, apart from postoperative analgesic use, which was reduced in the case of a single-site operation [138]. Most LESS-PN series have reported negative surgical margins [125,139–142]. In contrast, a positive surgical margin rate of 4.2% was reported in a recent multi-institutional study incorporating data from 190 LESS-PN cases [143]. There is a lack of intermediate- and long-term follow-up data on LESS-PN.

4.4.2. Recommendations on laparoendoscopic single-site surgical partial nephrectomy

Recommendations on LESS partial nephrectomy are shown in Table 12.

Table 12 – Recommendations on laparoendoscopic single-site partial nephrectomy

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

GR = grade of recommendation; LE = level of evidence; LESS = laparoendoscopic single-site; PN = partial nephrectomy.

4.5. Pyeloplasty

The cosmetic outcome following reconstructive surgery for ureteropelvic junction obstruction is a key surgical parameter for an operation that is usually performed in a younger patient population. Pyeloplasty is an excellent indication for single-site surgery because of the tendency of LESS to minimise postoperative scars.

A small matched cohort study comparing LESS pyeloplasty with standard laparoscopic technique reported no difference in perioperative variables between the groups, except for cosmetic appearance in the LESS arm [144]. Desai et al. included 17 cases of LESS pyeloplasty in their cumulative LESS experience report. One case was converted to conventional laparoscopy; all other cases were aided by a 2-mm additional instrument during suturing. Overall, 15 of 16 available postoperative images demonstrated no obstruction during follow-up [125].

High complication rates of up to 25% have been reported in the initial cases of LESS pyeloplasty series. This finding has been attributed to the stiff learning curve of the approach, which is challenging even for an experienced laparoscopic surgeon. The vast majority of complications have been reported during the initial 10 cases. After this learning curve threshold, the complication rate appears to be similar to that of standard laparoscopic pyeloplasty [145].

4.6. Laparoendoscopic single-site surgical adrenalectomy

A variety of approaches to LESS adrenalectomy with different advantages and disadvantages have been described since this approach was first used in 2005 [146–154]. Comparative studies of LESS versus conventional laparoscopic adrenalectomy reported no significant differences in blood loss or complications but less postoperative pain in the LESS adrenalectomy group [149,155].

4.7. Laparoendoscopic single-site surgical cystectomy and laparoendoscopic single-site surgical prostatectomy

Both LESS radical prostatectomy and radical cystectomy are considered feasible in selected cases [156,157] but only as part of a properly designed clinical trial due to the lack of mature data on its use.

4.8. Conversions and complications in laparoendoscopic single-site surgery

When performed by experienced surgeons in selected cases, LESS surgery is considered safe with conversion and complication rates similar to those obtained with a multiport laparoscopic approach. A multicentre study of 125 urinary tract urothelial carcinoma transumbilical LESS procedures reported conversion in 5.6% of all LESS procedures, which was defined as additionally placed

Table 13 – Conclusions and recommendations on laparoendoscopic single-site urologic surgery

Conclusions	LE
LESS surgical procedures of the upper urinary tract are technically feasible but demanding.	3
Long-term oncologic data are not yet available.	–
No proven or documented benefits exist over the laparoscopic approach.	–
Cosmesis is a reported advantage.	4
Recommendations	**GR**
LESS should be favoured in cases where cosmesis is of paramount importance.	A
Only experienced laparoscopic surgeons should embark on this technique.	A

GR = grade of recommendation; LE = level of evidence; LESS = laparoendoscopic single-site.

5- or 10-mm trocars. Single 2-mm ports for reconstructive surgery were not considered conversion. The main reasons for introducing additional ports were to assist dissection or reconstruction and control bleeding. No conversion to open surgery was reported. In the same series, complications occurred in 15.2% of all cases [158]. In an additional large multi-institutional worldwide series of LESS in urology with 1076 patients, the overall conversion rate was 20.8%. Of this, 15.8% of patients were converted to reduced-port laparoscopy, 4% to conventional laparoscopy/robotic surgery, and 1% to open surgery. A total of 3.3% of intraoperative complications and 9.5% mostly low-grade postoperative complications were also documented [128].

4.9. *Conclusions and recommendations on laparoendoscopic single-site urologic surgery*

Conclusions and recommendations on LESS urologic surgery are shown in Table 13.

Author contributions: Axel S. Merseburger had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition of data: Merseburger, Herrmann, Shariat, Kyriazis, Nagele, Traxer, Liatsikos.
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