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Robotic-assisted Versus Laparoscopic Surgery: Outcomes from the First Multicentre, Randomised, Patient-blinded Controlled Trial in Radical Prostatectomy (LAP-01)

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Abstract

Background: The LAP-01 trial was designed to address the lack of high-quality literature comparing robotic-assisted (RARP) and laparoscopic (LRP) radical prostatectomy.
Objective: To compare the functional and oncological outcomes between RARP and LRP at 3 mo of follow-up.
Design, setting, and participants: In this multicentre, randomised, patient-blinded controlled trial, patients referred for radical prostatectomy to four hospitals in Germany were randomly assigned (3:1) to undergo either RARP or LRP.
Outcome measurements and statistical analysis: The primary outcome was time to continence recovery at 3 mo based on the patient's pad diary. Secondary outcomes included continence and potency as well as quality of life in addition to oncological outcomes for up to 3 yr of follow-up. Time to continence was analysed by log-rank test and depicted by the Kaplan-Meier method. Continuous measurements were analysed by means of linear mixed models.
Results and limitations: A total of 782 patients were randomised. The primary endpoint was evaluable in 718 patients (547 RARPs; full analysis set). At 3 mo, the difference in continence rates was 8.7% in favour of RARP (54% vs 46%, $p = 0.027$). RARP remained superior to LRP even after adjustment for the randomisation stratum nerve sparing and age >65 yr (hazard ratio = 1.40 [1.09–1.81], $p = 0.008$). A significant benefit in early potency recovery was also identified, while similar oncological and morbidity outcomes were documented. It is a limitation that the influence of different anastomotic techniques was not investigated in this study.
Conclusions: RARP resulted in significantly better continence recovery at 3 mo.

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Patient summary: In this randomised trial, we looked at the outcomes following radical prostate surgery in a large German population. We conclude that patients undergoing robotic prostatectomy had better continence than those undergoing laparoscopic surgery when assessed at 3 mo following surgery. Age and the nerve-sparing technique further affected continence restoration.

1. Introduction

Transient or persistent urinary incontinence after radical prostatectomy (RP) is a known adverse event of prostate cancer surgery that is considered to have a negative impact on patient quality of life [1]. While improvements in surgical techniques have increased early continence recovery in modern series compared with surgeries in the past, a significant percentage of RP patients still leak months after surgery. Robotic-assisted radical prostatectomy (RARP) is a surgical approach considered to offer optimal oncological and functional outcomes due to its magnified vision and high precision. Nevertheless, despite the wide diffusion of RARP in the management of localised and locally advanced prostate cancer, there is no convincing evidence from prospective comparative trials to support the superiority in functional results of RARP over laparoscopic RP (LRP) and open RP (ORP). Currently, there is only one randomised controlled trial (RCT) comparing RARP with ORP and two RCTs comparing RARP with LRP, which were limited by single-centre outcomes with patients operated on by a single surgeon (per approach) [2–4]. With regard to continence preservation, in the single RCT available comparing RARP with ORP, similar results were shown at 6 and 12 wk and at 6, 12, and 24 mo postoperatively [2–5]. By contrast, the two available RCTs (both enrolled a small number of cases) comparing RARP with LRP reported conflicting results. Asimakopoulos et al [3] focused on erectile function recovery, which did not reach statistical significance regarding continence at any follow-up time point between both surgical approaches (1, 3, 6, and 12 mo following surgery). However, a clear benefit of robotic assistance was shown in the RCT of Porpiglia et al [4,6], with higher continence rates at every time point in their study (upon catheter removal and at 48 h, and 1, 3, 6, and 12 mo after surgery), which was sustained for up to 60 postoperative months.

To close this gap of high-quality evidence in the available literature, we designed the first multicentre, randomised, comparative trial between RARP and LRP worldwide in an attempt to document differences in the early continence outcomes between the two techniques.

2. Patients and methods

2.1. Study design and participants

In this multicentre, randomised, patient-blinded controlled phase 3 trial, male patients referred for RP to four high-volume centres in Germany were randomised to undergo either RARP or LRP according to standard operating procedures in each department. All four departments employ both surgical approaches for RP on a regular basis. In total, 15 surgeons performed the procedures in this trial, with a mean of 51 procedures per surgeon (range 1–198, median 38). All surgeons, except one, were experienced in RARP and LRP, having performed over 150 procedures of each type. A few reasons for the difference in the number of surgeries performed by each surgeon are that they were involved in other surgeries on operation days, joined the trial later, or left the clinic during the trial period. The trial initiated patient recruitment in November 2014, and the last patient was randomised in April 2019. The inclusion and exclusion criteria are included in Supplementary Table 1.

Ethical approval was obtained from the ethical committees of all four participating centres, and written informed consent was obtained from all patients. The LAP-01 trial was registered with the U.S. National Library of Medicine clinical trial registry (clinicaltrials.gov; NCT number: NCT03682146) and with the German Clinical Trial registry (Deutsches Register Klinischer Studien; DRKS ID number: DRKS00007138).

2.2. Randomisation and masking

Randomisation to each study arm was computer based, and procedure assignment for each patient took place 1 d prior to surgery. Randomisation was stratified by age ($\leq$65 yr and $>$65 yr) and preoperative nerve sparing (none, unilateral, and bilateral) as well as trial site using a minimisation procedure with a random component [7].

The trial participants were randomly assigned in a 3:1 ratio to undergo RARP or LRP. Given that most German patients prefer to be operated on with robotic assistance, this particular design was chosen to improve trial recruitment. Patients were blinded with respect to the surgical method until the end of the 3-mo evaluation and extraction of the primary study outcome. Once the patients were informed about the type of procedure performed, patient-reported outcomes at 6 and 12 mo were obtained in the context of an open trial.

2.3. Procedures

Both RARP and LRP were performed in each department according to the centres' perioperative protocol for minimally invasive RP. A transperitoneal or an extraperitoneal approach was used based on the surgeon's preference, and pelvic lymph node dissection (PLND) was performed in all intermediate- and high-risk patients using the D'Amico criteria. A standardised extended PLND template was utilised in all lymph node dissections performed, with the upper margin being the common iliac artery. Preoperative nerve sparing was designed based on clinical criteria and modified during the procedure based on a frozen section protocol (evidence of bundle invasion was followed by further excision of the bundle on the affected side). The patients were discharged upon drain removal based on the surgeon's decision and local postoperative protocols. Pelvic floor training instructions were given to all patients.

The patients were assessed for functional and oncological outcomes upon admission for surgery and at 1, 3, 6, and 12 mo postoperatively, while long-term oncological outcomes (prostate-specific antigen) were collected additionally at 24 and 36 mo.

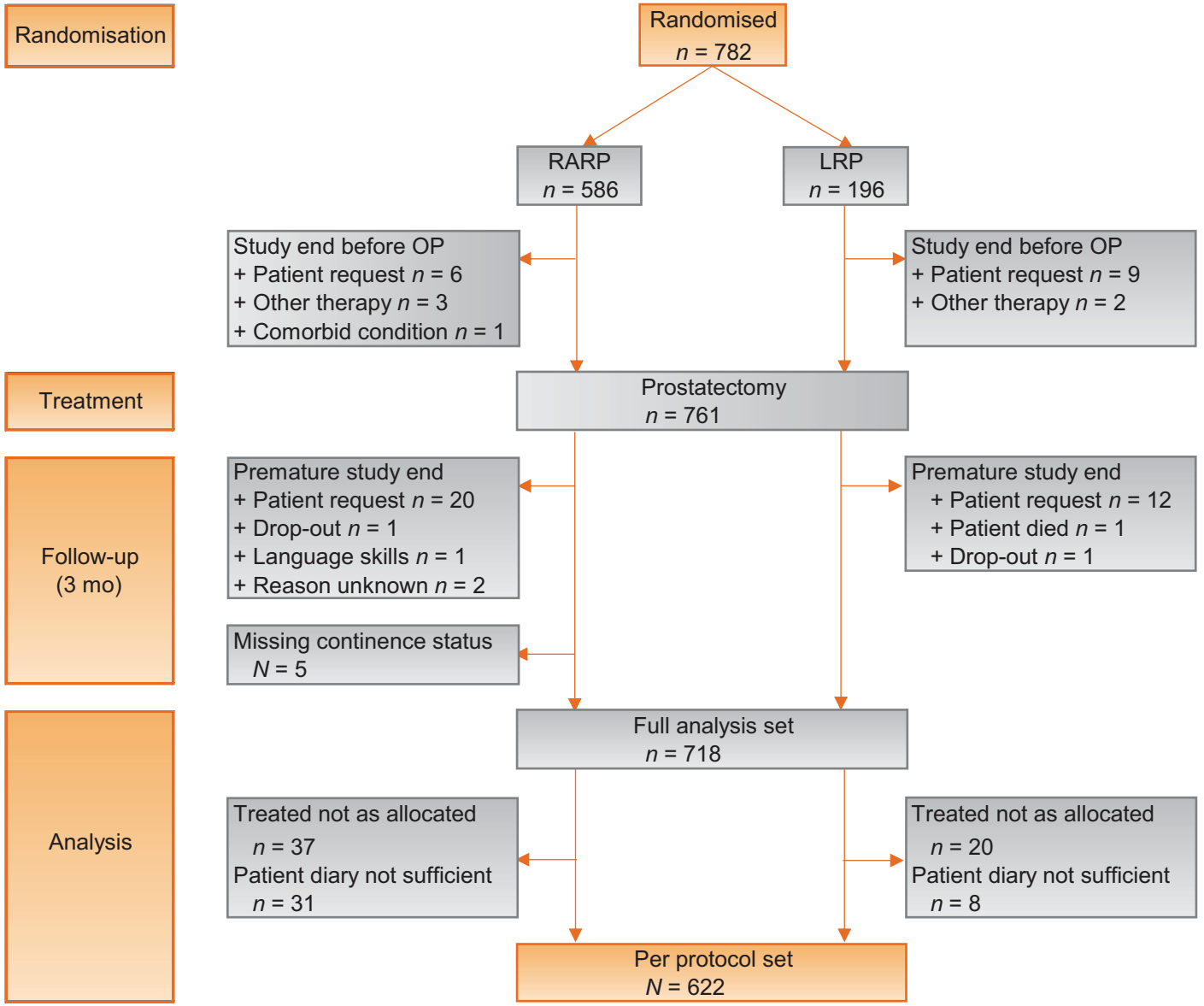

Fig. 1 – Flow chart of the trial.
LRP = laparoscopic radical prostatectomy; OP = operation; RARP = robotic-assisted laparoscopic radical prostatectomy.

Table 1 – Baseline characteristics and perioperative data

		RARP N = 547	LRP N = 171
Baseline characteristics (full analysis set)			
Sociodemographic data			
Age at surgery (yr), median (quartiles)		65 (59; 69)	65 (59; 70)
Body size (cm), median (quartiles)		177 (173; 181)	176 (172; 181)
Body weight (kg), median (quartiles)		84 (78; 93)	84 (77; 92)
BMI (kg/m^2), median (quartiles)		27.2 (25.2; 29,4)	27.0 (25.0; 29,1)
Karnofsky Index, median (quartiles)		100 (100, 100)	100 (100, 100)
Family status, number (%)			
Married		444 (81)	136 (80)
Smoker, *n* (%)		86 (16)	27 (16)
Urinary track medical history, *n* (%)			
History of urinary tract infection		14 (2.6)	8 (4.7)
Transurethral resection of bladder cancer		2 (0.4)	0 (0)
Transurethral resection of the prostate		13 (2.4)	6 (3.5)
Other interventions on the urinary tract		123 (23)	45 (27)
Primary disease: carcinoma of the prostate			
Diagnosis since (mo), median (IQR)		2.1 (1.5, 3.0)	2.0 (1.5, 3.0)
PSA, preoperative (ng/ml), median (IQR)		7.7 (5.6, 12.1)	8.1 (6.0, 11.0)
Gleason sum (preop), *n* (%)			
5	1 (0.2)		0 (0)
6	188 (34)		55 (32)
7	258 (47)		83 (49)
8	61 (11)		23 (13)
9	35 (6.4)		9 (5.3)
10	4 (0.7)		1 (0.6)
Planned nerve sparing, *n* (%)			
None	216 (39)		67 (39)
Unilateral	80 (15)		24 (14)
Bilateral	251 (46)		80 (47)
Diabetes mellitus	82 (15)		19 (11)
Renal failure, *n* (%)	86 (16)		25 (15)
GFR (ml/min), *n* (%)			
≥90	176 (32)		58 (34)
60–89	335 (62)		107 (63)
<60	32 (5.9)		6 (3.5)
Incontinence: no. of used pads, *n* (%)			
0	522 (96)		165 (98)
Safety pad	12 (2.2)		3 (1.8)
≥1 pad	7 (1.3)		0 (0.0)
Other comorbidities	121 (26)		34 (24)
Medication, *n* (%)			
Antidiabetics	69 (13)		14 (8)
Antihypertensives	315 (58)		100 (59)
Diuretics	36 (6.6)		14 (8.2)
Psychotropic drugs	8 (1.5)		4 (2.3)

	RARP N = 530	LRP N = 188	*p* value
Perioperative details (actual OP method) [a]			
Randomised, *n* (%)			
RARP	510 (93)	37 (6.8)	
LRP	20 (12)	151 (88)	
Access route, *n* (%)			
Transperitoneal	310 (58)	97 (52)	0.10
Extraperitoneal	220 (42)	91 (48)	
Nerve sparing (realised), *n* (%)			
None	201 (38)	77 (41)	
Unilateral	52 (9.8)	16 (8.5)	
Bilateral	277 (52)	95 (51)	
Lymphadenectomy, *n* (%)	404 (76)	142 (76)	
Anastomosis method, *n* (%)			
Continuous	522 (98)	11 (5.9)	<0.0001
Interrupted	8 (1.5)	177 (94)	
Rocco stitch, *n* (%)	516 (97)	89 (48)	<0.0001
Prostate weight (g), median (IQR)	48 (39, 61)	47 (38, 60)	
Blood loss (ml, median (IQR)	250 (150, 350)	210 (150, 300)	0.0068

Table 1 (*Continued*)

	RARP N = 530	LRP N = 188	*p* value
No. of blood conserves, median (IQR)	0	0	–
Duration of the op (min), median (IQR)	176 (144, 208)	169 (151, 195)	0.084
Anastomosis time (min), median (IQR)	19 (12, 30)	31 (25, 43)	<0.0001
Period of catheterisation (d), median (IQR)	6 (5, 7)	6 (5, 10)	0.23

BMI = body mass index; GFR = glomerular filtration rate; IQR = interquartile range; LRP = laparoscopic radical prostatectomy; OP = operative; PSA = prostate-specific antigen; RARP = robotic-assisted radical prostatectomy; RARP = robotic-assisted laparoscopic radical prostatectomy; SD = standard deviation.
[a] Patients are compared not by arm but by the actual method of surgery.

2.4. Outcomes

The primary outcome of the study was the assessment of time to continence restoration at 3 mo after removal of the urinary catheter, defined as no use of pads or use of a single safety pad within 24 h. A safety pad was defined as "no involuntary loss of urine, but a pad was still used". This was evaluated by an assessment of a pad diary completed daily by each patient from the time of catheter removal until restoration of continence.

Secondary outcomes included continence (pad use and International Consultation on Incontinence Questionnaire Short Form [ICIQ-SF] scores) and potency (International Index of Erectile Function [IIEF]-5 scores along with three specific questions as shown in Supplementary Table 2) function as well as quality of life assessments (European Organisation for Research and Treatment of Cancer quality of life questionnaire [EORTC-QLQ]-C30, EORTC-QLQ-PR25, and Hospital Anxiety and Depression Scale-Depression [HADS-D]) at 1, 3, 6, and 12 mo after surgery, in addition to oncological outcomes defined as positive surgical margins and biochemical recurrence at 3, 6, 12, 24, and 36 mo after surgery. As both surgical treatments are well established, no data monitoring committee was necessary. However, the data collection was exhaustively supervised by on-site and central statistical monitoring. We herein report the results after evaluation of the primary endpoint at 3 mo.

The statistical analysis is detailed in the Supplementary material.

3. Results

Between 2014 and April 2019, 782 patients were randomised to undergo RARP (*n* = 586) or LRP (*n* = 196). Twenty-one patients withdrew their consent before surgery, and a total of 761 patients underwent RP in the four participating centres. All operations were successful, and none were converted to open surgery. During the first 3 mo of follow-up, 38 patients were lost and five more patients had insufficient information on continence. As a result, the full analysis set (FAS) following good clinical practice included 718 patients (RARP: 547; see Fig. 1). Overall, 62 patients (including 57 from the FAS) were treated by a different technique than the one allocated (usually due to delay in availability of the robotic or laparoscopic operative rooms necessitating change of surgical approach). In 39 patients,

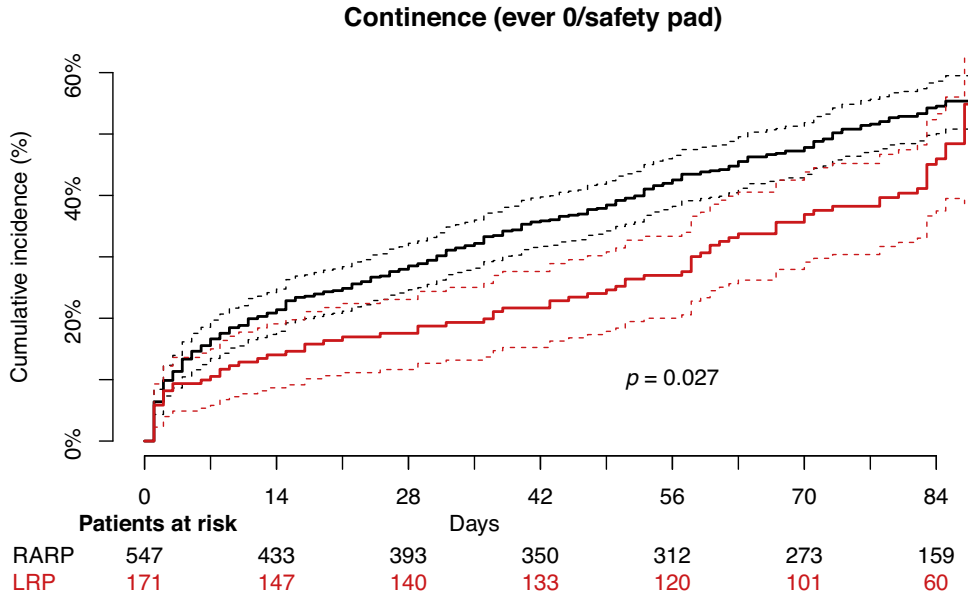

Fig. 2 – Kaplan-Meier curve with CI of 3-mo continence recovery (according to no pad/safety pad definition) after catheter removal. Black line represents RARP and red line LRP.
CI = confidence interval; LRP = laparoscopic radical prostatectomy; RARP = robotic-assisted radical prostatectomy.

the pad diary was missing, and continence could not be assessed from only the questionnaires, leaving 622 patients (511 RARPs) as the per-protocol set for sensitivity analysis (cf. Fig. 1). Demographic and baseline oncological characteristics of the FAS as well as perioperative data are presented in Table 1.

3.1. Primary outcome: continence recovery at 3 mo

At 3 mo of follow-up, no pad or safety pad use was reported by 54% of patients subjected to RARP versus 46% of LRP patients ($p = 0.027$; see Fig. 2). A more profound difference in favour of robotic assistance was evident in the patients subjected to bilateral nerve sparing, with 66% of RARP patients being continent compared with 50% of LRP patients ($p = 0.005$; see Table 2). The vast majority of incontinent patients reported a small amount of urine leak per day for both approaches, with only 9.3% of RARP patients and 15% of LRP patients reporting a moderate to large amount of urine loss. The differences in subjective assessment of urinary loss by the patients as documented by ICIQ-SF sum scores were also statistically significant between RARP and LRP at both 1 (9.40 ± 5.33 vs 11.0 ± 4.89; $p = 0.001$) and 3 mo (6.44 ± 5.01 vs 7.76 ± 5.05; $p = 0.003$) of follow-up and favoured robotic assistance. Quality of life as assessed by EORTC-PR25 was also better preserved by robotic assistance (Table 3).

Analysis of the per-protocol set was performed as a sensitivity analysis. The results of the primary and main secondary endpoints replicated the outcomes observed in the intention-to-treat analysis. The continence rate at 3 mo in the RARP arm was 11% higher than that in the LRP arm (56% vs 45%; $p = 0.010$), with the difference being even more profound in the patients subjected to bilateral nerve sparing (RARP: 66%, LRP: 49%; $p = 0.005$). RARP remained superior to LRP even after adjustment for the randomisation stratum nerve sparing and age >65 yr (hazard ratio [HR] = 1.48 [1.12–1.96]; $p = 0.005$).

As expected, age >65 yr and no nerve-sparing surgery decreased the chance for continence: age >65 yr HR = 0.69 (0.54–0.86), $p = 0.001$; no nerve-sparing HR = 0.56 (0.43–0.72), $p < 0.0001$; and unilateral (vs reference bilateral) nerve-sparing HR = 0.66 (0.44–0.98), $p = 0.038$.

Table 2 – Continence recovery at 3 mo; descriptive statistics and tests

		ITT: randomisation arm				*p* value	Effect measure
		RARP		LRP			
		N = 547		*N* = 171			Freq. diff. (95% CI)
Continence rates [a]							
Nerve sparing							
No		85	40%	26	41%	0.90	
Unilateral		27	52%	7	44%	0.78	
Bilateral		185	66%	45	50%	0.005	
Total		297	54%	78	46%	0.027	8.7% (0.1–17%)
Number of pads [b]							*A* (Stoch. super.) [c]
0		158	30%	29	17%	0.001	0.58 (0.53–0.63)
Safety pad		112	21%	33	20%		
1		99	19%	42	25%		
≥2		159	30%	63	38%		
ICIQ-SF							
1. How often do you leak urine	Never	130	25%	27	16%	0.016	0.56 (0.51–0.61)
	About once per week or less often	88	17%	23	149%		
	2 or 3 times a week	55	10%	22	13%		
	About once daily	47	8·9%	15	9·1%		
	Several times a day	192	36%	72	44%		
	All the time	15	2.8%	6	3.6%		
2. How much urine do you leak	None	133	25%	30	18%	0.010	0.56 (0.50–0.61)
	Little	341	65%	111	67%		
	Moderate	41	7.8%	18	118%		
	Large	8	1.5%	7	4.2%		
		Mean ± SD		Mean ± SD			
3. Overall, how much does leaking urine interfere with your everyday life?		2.44 ± 2.64		3.08 ± 2.72		0·004	0.57 (0.52–0.63)
ICIQ sum		6.44 ± 5.01		7.76 ± 5.05		0·003	0.58 (0.52–0.63)

CI = confidence interval; ICIQ-SF = International Consultation on Incontinence Questionnaire Short Form; ITT = intention to treat; LRP = laparoscopic radical prostatectomy; RARP = robotic-assisted radical prostatectomy; SD = standard deviation; Stoch. Super. = stochastic superiority.

[a] Continence rates following pad diary.

[b] Number of pads following 3-mo questionnaire.

[c] *A*: probability of stochastic superiority.

Table 3 – Results of the EORTC-PR25 and IIEF questionnaires at 3 mo

	Baseline (preop)		3 mo		*p* value
	RARP	LRP	RARP	LRP	For interaction [a]
EORTC-PR 25					
Urinary symptoms	16 (14.6–17.4) [b]	16.8 (14.3–19.2)	28.5 (27.1–29.9)	32 (29.5–34.5)	– [c]
Sexual activity	49 (46.7–51.4)	48.8 (44.6–53.1)	65.0 (62.6–67.4)	64.8 (60.6–69.1)	–
Sexual function	66 (64.4–67.7)	67 (64–69.9)	49.1 (47.1–51.1)	46.9 (43.2–50.7)	–
Incontinence aid [d]					
Question 8: patients with continence aid	28 (5.3%)	2 (1.2%)	288 (52.7%)	104 (60.8%)	–
IIEF					
IIEF sum	14.4 (13.8–15.0)	15.0 (14.0–16.0)	4.7 (4.1–5.3)	3.8 (2.8–4.9)	0.026
Residual erectile function	3.4 (3.3–3.4)	3.5 (3.3–3.6)	2 (1.9–2.1)	1.8 (1.6–2.0)	0.051

EORTC = European Organisation for Research and Treatment of Cancer; IIEF = International Index of Erectile Function; LRP = laparoscopic radical prostatectomy; RARP = robotic-assisted radical prostatectomy.
[a] A *p* value for interaction in a linear model with repeated measurements adjusted by the randomisation strata.
[b] 95% confidence intervals.
[c] The nonsignificant interaction term time × arm was removed from the model.
[d] PR-25 contains only one question (8) on continence aid answered only by patients who use pads.

3.2. *Secondary analyses of continence*

Continence, as documented by the number of pads and ICIQ-SF scores, also reflected that the patients in the RARP arm had improved continence outcomes at 3 mo compared with the LRP patients (Table 2). Measures of stochastic superiority ($A = 0.56–0.58$) indicated that an RARP patient, from a randomly chosen pair of RARP and LRP patients, had a probability between 56% and 58% of using fewer pads, leaking urine less often, having a lower leak amount, and having less interference from incontinence with daily life than an LRP patient.

3.3. *Oncological outcomes and potency recovery*

No significant differences in early oncological outcomes between RARP and LRP were documented in this trial. Both techniques demonstrated comparative positive surgical

Table 4 – Oncological outcomes

	Actual OP method		*p* value
	RARP *N* = 530	LRP *N* = 188	
PSA preop (ng/ml), median (IQR)	7.71 (5.63, 11.9)	8.10 (5.99, 11.7)	
Tumour stage, *n* (%)			
pT1c	1 (0.2)	0 (0)	
pT2a	25 (4.7)	13 (7)	
pT2b	5 (0.9)	0 (0)	
pT2c	309 (58)	101 (54)	
pT3a	120 (23)	45 (24)	
pT3b	64 (12)	27 (14)	
pT4	4 (0.8)	1 (0.5)	
Gleason sum, *n* (%)			
6	87 (16)	30 (16)	
7	356 (67)	117 (62)	
8	51 (9.6)	25 (13)	
9	35 (6.6)	15 (8.0)	
10	0 (0)	1 (0.5)	
Positive surgical margins, *n* (%)			
RX	2 (0.4)	0 (0)	0.19
R0	426 (80)	162 (86)	
R1	101 (19)	26 (14)	
Lymph node invasion, *n* (%)			
N0	355 (67)	132 (70)	0.38
N1	41 (7.8)	9 (4.8)	
NX	131 (25)	47 (25)	

IQR = interquartile range; LRP = laparoscopic radical prostatectomy; OP = operative; PSA = prostate-specific antigen; RARP = robotic-assisted radical prostatectomy.

margins (19% for RARP and 14% for LRP; $p = 0.19$) and lymph node invasion rates (7.8% for RARP and 4.8% for LRP; $p = 0.38$; Table 4).

In terms of potency recovery, at 3 mo following surgery, 18% and 6.7% of patients, subjected to nerve-sparing (bilateral or unilateral) RARP and LRP, respectively, reported erections sufficient for intercourse ($p = 0.007$; Supplementary Table 2). The superiority of robotic assistance in erectile function recovery was also documented by the outcomes of the IIEF questionnaire (Table 3). As demonstrated by the IIEF sum scores in Supplementary Table 3, the significant estimate −1.54 for the interaction term indicated that, on average, the IIEF sum score in the LRP group decreased by 1.54 points more than that in the RARP group ($p = 0.026$). Nevertheless, no significant difference in sexual function and sexual activity was documented by the EORC-PR25 questionnaire between the two techniques at 3 mo. As expected, bilateral and unilateral nerve sparing enhanced erectile function recovery, as documented by the positive mean estimates of 1.95 and 3.19, respectively, as opposed to age >65 yr, which was negatively associated (−2.53) with potency restoration ($p < 0.001$). However, assessment of potency recovery was not consistent across the various tools used.

3.4. *Safety: complications after surgery*

The patients in the LRP arm had an increased rate of complications (Clavien-Dindo classification): 87 patients (15%) in the RARP arm and 41 (21%) in the LRP arm developed complications of any grade ($p = 0.097$). Most complications were of low grade. One patient in the LRP group (0.5%) died due to necrotising pancreatitis followed by septic shock. Details on complications are presented in Supplementary Table 4.

4. Discussion

Traditionally, conventional LRP and RARP have been considered to deliver similar short- and long-term continence outcomes, based on numerous studies documenting similar results or marginal differences [8]. According to the 2019 update of the European Association of Urology guidelines, physicians should inform their patients that no surgical approach (ORP, LRP, or RARP) has clearly shown superiority in functional or oncological results [9].

This is the first study providing level 1 evidence revealing that robotic assistance enhanced the early recovery of continence compared with the laparoscopic approach. At 3 mo following surgery, a significant difference of 8.7% (0.1%, 17%) was evident ($p = 0.027$; cf. Fig. 2). The 3-mo continence rates in this trial (54% for RARP and 46% for LRP) are lower than those in the majority of the RP literature. In the robotic arm of two previously conducted RCTs, at 3 mo of follow-up, Asimakopoulos et al [3] reported no-pad continence in 69% of patients, while Porpiglia et al [4,6] reported no pad or safety pad use in 80% of patients. Accordingly, in the laparoscopic arm of the two RCTs, Asimakopoulos et al [3] reported no-pad continence rate in 63%, and Porpiglia [4] reported no pad or safety pad use in 61.6%. Both RCTs enrolled a small number of cases with a low statistical power comparing RARP and LRP in controlled settings. The study by Asimakopoulos et al [3] cannot be directly compared with the current study due to various reasons: inclusion of a highly selected group with only cT1 and cT2, Gleason ≤7, single-surgeon results, inclusion of only bilateral nerve sparing, and a small patient number, which is not representative of the real situation of the German clinics. A potential explanation of these deviations in the 3-mo continence rates is also that our study represented an unselected population including patients with preoperative incontinence. In addition, a significant percentage of our FAS population (60 patients; 8.4% up to 3 mo) underwent early adjuvant or salvage radiotherapy, a factor known to affect postoperative continence negatively. In addition, 39% of the FAS population underwent wide excision surgery with no nerve preservation, since high-risk patients represented more than half of our patients, and extended PLND was undertaken in 76% of the FAS. Both wide excision surgery and pelvic lymphadenectomy are factors known to affect continence recovery [10,11].

Surgical experience plays a major role in the functional and oncological outcomes of RP [12,13]. Especially in the case of urinary continence after RARP, functional improvements do not reach a plateau even after 100 patients, suggesting continuous refinement of the technique [13]. As a result, trials comparing different surgical techniques are affected by the individual performance of operating surgeons. While randomisation in this trial was not stratified based on surgical experience, the multicentre nature of the study design, including operations performed by 15 different surgeons with various levels of clinical experience, diminishes the effect of individual surgical performance.

A strength of this study is that apart from being patient blinded, it was based on multiple patient-reported assessment tools. It has been well documented that there is a large discrepancy between patient and surgeon perceptions of postoperative functional outcomes following prostate cancer surgery [11,14].

In this study, three different patient-reported tools (pad diary, ICIQ-SF, and EORTC-PR25) were used for the assessment of continence to ensure that the conclusions drawn by the study can be of clinical importance for men subjected to RP. To obtain very detailed outputs, we used the pad dairy up to 12 wk where the patient recorded how many pads he used each day. We used these data as the primary source of continence in comparison with other studies that used only a single entry for every follow-up. In addition, we defined the continence criteria with constituent pad usage in 3 consecutive days. This is stricter than the criteria in almost all studies. We consider it a strength of the study that we also provide data distinguishing between zero pads, safety pad, and one pad. The uniformity in the results drawn by the analysis of each individual component of assessment reinforced the conclusions drawn by this trial.

It is a limitation that different anastomosis techniques have been used in the study. The influence of different

anastomotic techniques [15,16], such as continuous versus interrupted suture, posterior reconstruction (Rocco stitch), bladder neck sparing, and ventral reconstruction, have not been in focus of this study and was not investigated. Every surgeon carried out the anastomotic techniques that he was performing every day (best practice of care). Urethrovesical anastomosis was performed using a continuous running suture in 98% of robotic procedures, while an interrupted suturing technique was followed in the vast majority (94%) of laparoscopic patients. In addition, posterior reconstruction using a Rocco stitch was employed in 97% of robotic versus 48% of laparoscopic procedures. We performed a subgroup analysis of all patients with Rocco stitch (laparoscopic vs robotic), which showed a significant difference in continence rate favouring the RARP arm (p = 0.007). Another potential limitation is that surgeons who performed most of the procedures were more experienced in the laparoscopic technique. However, despite this, there was improved continence in the RARP arm, which further validates the findings.

Early potency recovery was found to be superior in the RARP arm of this trial, with 18% of RARP and 6.7% of LRP patients who underwent nerve-sparing procedures regaining erections sufficient for intercourse. It should be stressed that the power of the study was calculated based on continence and not on potency, and randomisation was not stratified based on preoperative potency status. Furthermore, a standardised penile rehabilitation protocol was not applied to all patients. These factors should be taken into consideration before drawing firm conclusions related to potency. At 3 mo following surgery, only 44% of robotic and 35% of laparoscopic patients reported the use of pharmacological supporting agents (PDE5 inhibitors, intracavernous injections, and intraurethral alprostadil). However, the analysis of different potency assessment tools did not provide a consistent picture.

5. Conclusions

Patient-blinded continence outcomes following RP revealed that RARP resulted in superior early continence recovery at 3 mo to that with the laparoscopic approach. Age and the nerve-sparing technique during surgery further affected continence restoration. Erectile function recovery was also found to be improved with robotic assistance, while no difference was evident in perioperative morbidity and early oncological outcomes.

***Author contributions*:** Jens-Uwe Stolzenburg 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.

Study concept and design: Holze, Stolzenburg, Neuhaus, Mende.
Acquisition of data: Holze, Neuhaus.
Analysis and interpretation of data: Mende, Holze (interpretation: Stolzenburg).
Drafting of the manuscript: Stolzenburg, Holze, Kyriazis, Mende.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Mende, Holze.
Obtaining funding: Holze, Stolzenburg.
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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.eururo.2021.01.030.

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