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Posterior musculofascial reconstruction after radical prostatectomy: an updated systematic review and a meta-analysis

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To evaluate the influence of posterior musculofascial plate reconstruction (PR) on early return of continence after radical prostatectomy (RP); an updated systematic review of the literature. A systematic review of the literature was performed in June 2015, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and searching Medline, Embase, Scopus and Web of Science databases. We searched the terms posterior reconstruction prostatectomy, double layer anastomosis prostatectomy across the 'Title' and 'Abstract' fields of the records, with the following limits: humans, gender (male), and language (English). The authors reviewed the records to identify studies comparing cohorts of patients who underwent RP with or without restoration of the posterior aspect of the rhabdosphincter. A meta-analysis of the risk ratios estimated using data from the selected studies was performed. In all, 21 studies were identified, including three randomised controlled trials. The overall analysis of comparative studies showed that PR improved early continence recovery at 3–7, 30, and 90 days after catheter removal, while the continence rate at 180 days was statistically but not clinically affected. Statistically significantly lower anastomotic leakage rates were described after PR. There were no significant differences for positive surgical margins rates or for complications such as acute urinary retention and bladder neck stricture. The analysis confirms the benefits at 30 days after catheter removal already discussed in the review published in 2012, but also shows a significant advantage in terms of urinary continence recovery in the first 90 days. A multicentre prospective randomised controlled trial is currently being conducted in several institutions around the world to better assess the effectiveness of PR in facilitating an earlier recovery of postoperative urinary continence.

Keywords

radical prostatectomy, posterior musculofascial reconstruction, posterior rhabdosphincter reconstruction, urinary incontinence, urinary continence, early continence

Introduction

Urinary incontinence and erectile dysfunction are the two major disadvantages of radical prostatectomy (RP). According to the European Association of Urology 2015 guidelines on prostate cancer [1], mean continence rates at 12 months range from 89 to 100% for patients treated with robot-assisted RP (RARP) to 80–97% for patients treated with retropubic RP. The mean potency recovery rates at 12 months range from 55 to 81% for patients treated with RARP to 26–63% for patients treated with retropubic RP.

In an effort to attain better functional results after RP, in 2001, Rocco et al. [2] described a technique for reconstruction of the posterior aspect of the rhabdosphincter, based on studies of the rhabdosphincter itself [3]. In 2006, it was reported that posterior reconstruction (PR) shortens incontinence time after RP [4]. In 2007, the application of the restoration of the posterior aspect to transperitoneal laparoscopic RP (LRP) was described [5]. In 2011, Coelho et al. [6] described a modified PR of the rhabdosphincter applied to RARP.

Since the original description, the rhabdosphincter reconstruction technique has spread worldwide, with mixed results. In 2012, Rocco et al. [7] published a systematic review of the literature on posterior musculofascial reconstruction after RP, suggesting that PR can improve early return of continence within the first 30 days after RP

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($P = 0.004$) and reduce the incidence of leakage on cystogram ($P = 0.050$).

The strength of the recommendations derived from this meta-analysis was limited by the high heterogeneity between studies: different continence definitions in each analysed study, several modifications to the original surgical technique, and different surgical approaches [open RP (ORP), LRP, RARP]. Moreover, the small sample size of many of the selected studies was another important limitation of the published review.

Since then, several other trials have been published, mainly studying the effect of PR in RARP and LRP. Consequently, based on the recommendation of the Cochrane Collaboration to update systematic reviews at least every 2 years [8], we elected to update our previous meta-analysis of the literature in the field of PR of the rhabdomyosphincter.

Materials and Methods

Literature Search and Study Selection

The present study is a systematic review of the literature conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [9]. A systematic and critical analysis of Medline, Embase, Scopus and Web of Science databases was carried out in June 2015, by three authors (A.A.C.G, F.A.M, G.C.) separately, applying the following key terms: posterior reconstruction prostatectomy, double layer anastomosis prostatectomy. The search was conducted across the 'Title' and 'Abstrac't fields of the records, with the following limits: humans, gender (male), and language (English). Only full-text articles were considered, while abstracts were not included. We decided not to include data from congress abstract proceedings, as they usually lack the completeness of data required.

Of articles found, the ones selected were those in which cohorts of patients who underwent RP (regardless if performed as ORP, LRP or RARP) were compared according to the execution or not of PR of the rhabdomyosphincter, and in which the continence outcomes at defined intervals (3–7, 30, 90 and 180 days after the catheter removal) were reported.

In the present meta-analysis, we assessed the following key aspects of each study: the patients' population, the study design, the definition used to assess the continence recovery, the data collection, if a variant of the PR defined as a 'Rocco Stitch' was performed, the rate of continence recovery (at 3–7, 30, 90 and 180 days after the catheter removal), the rate of urinary anastomotic leakage diagnosed at the postoperative cystogram, the rate of positive surgical margins (PSM), and the rate of postoperative complications potentially related to the PR of the rhabdomyosphincter (i.e. bladder neck stenosis or urinary retention). In case of studies reporting data not adequate for meta-analysis more information was directly requested from the authors.

All the data were collected in a single database and the quality control of the collection was performed on a random sample representative of the 20% of the totality of the studies included in the meta-analysis.

We assessed the methodological quality of studies using the Newcastle–Ottawa quality assessment scale for cohort

Fig. 1 Literature analysis and data acquisition.

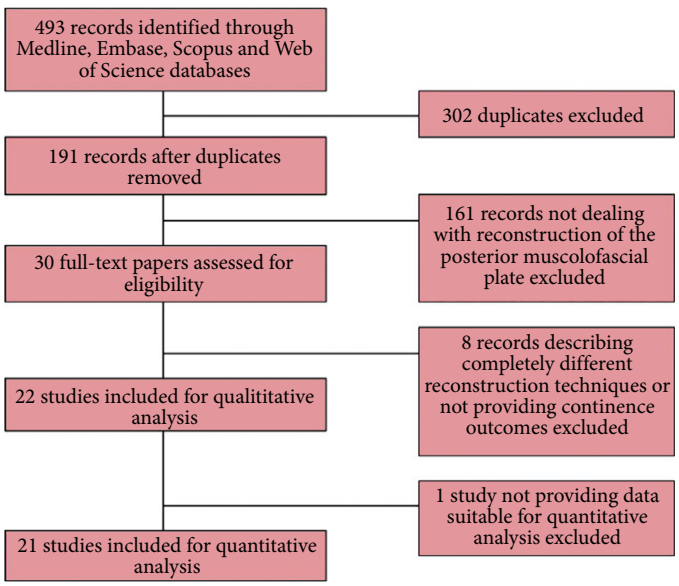


Table 1 Newcastle–Ottawa scale for risk of bias and quality assessment of the included observational studies.

Reference	Selection	Comparability	Outcome	Total score
Rocco et al. [4]	***	*	**	6
Rocco et al. [3]	***	*	**	6
Rocco et al. [5]	****	**	**	8
Tewari et al. [10]	****	*	**	7
Nguyen et al. [12]	***	*	**	6
Krane et al. [13]	****	**	**	8
Kim et al. [14]	****	**	**	8
Joshi et al. [15]	****	**	**	8
Coelho et al. [6]	****	**	**	8
Brien et al. [17]	****	**	**	8
Atug et al. [18]	****	**	**	8
Sano et al. [20]	****	**	**	8
Simone et al. [21]	****	**	**	8
Gondo et al. [22]	****	**	**	8
You et al. [23]	****	**	**	8
Anceschi et al. [24]	***	*	**	6
Ito et al. [25]	***	*	**	6
Daouacher and Waldén [26]	****	**	**	8

Table 2 Urinary continence in patients undergoing RP, with or without PR of the rhabdosphincter, at 3–7, 30, 45–75, 90, 180 days and 1 year after removal of the urinary catheter.

Reference	Study design	LoE	Surgical approach	PR, *n*		Continence definition	Method used to evaluate postoperative continence recovery	3–7 days	
				Yes	No			PR	No PR
Rocco et al. [4]	Retro.	4	ORP	161	50	0–1 pad/day	ICIQ – Short Form – telephone interview	72.0 $P < 0.001$	14.0
Rocco et al. [3]	Retro.	4	ORP	250	50	0–1 pad/day	Medical Examination, Pad test, ICIQ – Short Form	62.4 $P < 0.001$	14.0
Rocco et al. [5]	Pro.	2b	LRP	31	31	0–1 pad/day	External interviewer	74.2 $P < 0.001$	25
Tewari et al. [10]	Retro.	4	RARP	182	214	0–1 pad/day	External interviewer	38.4 $P < 0.001$	13.5
Menon et al. [11]	Pro. – random.	1b	RARP	59	57	0–1 pad/day, leakage ≤30 g/day		1 day – 34 2 days – 46 7 days – 54 $P > 0.1$	1 day – 26 2 days – 49 7 days – 51
Nguyen et al. [12]	Retro.	4	LRP and RARP	32	30	0–1 pad/day	Telephone interview/ questionnaire about the no. of pad used	34.0 $P = 0.007$	3.0
Krane et al. [13]	Retro.	4	RARP	34	37	0–1 pad/day	Medical examination	–	–
Kim et al. [14]	Retro.	4	RARP	25	25	0 pad/day	EPIC	24.0 $P = 0.540$	36.0
Joshi et al. [15]	Pro.	2b	RARP	53	54	0 pad/day, no leakage	EORTC questionnaire, QLQ-C30, Prostate Cancer Module	–	
Coelho et al. [6]	Pro.	2b	RARP	473	330	0 pad/day	EPIC	28.7 $P = 0.045$	22.7
Sutherland et al. [16]	Pro. – random.	1b	RARP	47	47	0–1 pad/day	EPIC: pad weight in 24 h	–	–
Brien et al. [17]	Retro.	3b	RARP	31	58	Pre- and postoperative RAND-UCLA score	RAND-UCLA QoL and AUA symptom scores	–	–
Atug et al. [18]	Retro.	4	RARP	125	120	0 pad/day	– –	71.2 $P < 0.001$	23.3
Hurtes et al. [19]	Pro. – random.	1b	RARP	39	33	0 pad/day, no leakage	UCLA-PCI scoring system	–	–
Sano et al. [20]	Pro.	2b	LRP	25	23	0–1 pad/day	– –	–	–
Simone et al. [21]	Retro.	4	LRP	155	125	0–1 pad/day	EPIC	–	–
Gondo et al. [22]	Retro.	4	RARP	160	39	0–1 pad/day	Medical examination	– –	–
You et al. [23]	Retro.	4	RARP	28	31	0–1 pad/day	ICIQ	–	–
Anceschi et al. [24]	Retro.	4	LRP	52	54	0 pad/day, no leakage	ICIQ and SF36 questionnaire	19.0 $P = 0.657$	22
Ito et al. [25]	Retro.	4	LRP	19	13	0 pad/day	UCLA-PCI scoring system	–	–
Daouacher and Waldén [26]	Pro.	2b	LRP	99	99	0–1 pad/day	IPSS	–	–

EORTC, European Organisation for Research and Treatment of Cancer; EPIC, Expanded Prostate Cancer Index Composite questionnaire; ICIQ, International Consultation on Incontinence questionnaire; LoE, level of evidence; PCI, Prostate Cancer Index; Pro., prospective; QLQ-C30, Quality of Life Core 30; QoL, quality of life; Random., randomised; Retro., retrospective; SF36, Short Form (36) 36-item Health Survey; UCLA, University of California, Los Angeles.

% Continence recovery after catheter removal at									
30 days		45–75 days		90 days		180 days		1 year	
PR	No PR	PR	No PR	PR	No PR	PR	No PR	PR	No PR
78.8 $P < 0.001$	30.0%	–	–	86.3% $P < 0.001$	46.0	–	–	96.0% $P = 0.132$	90.0%
74.0 $P < 0.001$	30.0	–	–	85.2 $P < 0.001$	46.0	–	–	94.0 $P = 0.301$	90.0
83.8 $P < 0.001$	32.3	–	–	92.3 $P = 0.25$	76.7	–	–	–	–
82.6 $P < 0.001$	35.2	–	–	91.3 $P < 0.001$	50.2	97.1 $P < 0.001$	62.0	–	–
80.0 $P > 0.1$	74.0	–	–	–	–	–	–	–	–
56.0 $P = 0.006$	17.0	–	–	–	–	–	–	–	–
–	–	85.0% $P = 1$	86.0%	–	–	–	–	–	–
72.0 $P = 1.000$	68.0	–	–	84.0 $P = 0.730$	76.0	96.0 $P = 1.00$	96.0	–	–
		–	–	75.0 $P = 0.391$	69.0	51.0 $P = 0.686$	43.0	–	–
51.6 $P = 0.016$	42.7	–	–	91.1 $P = 0.908$	91.8	97.0 $P = 0.741$	96.3	–	–
–	–	–	–	63 $P = 0.07$	81	–	–	–	–
–	–	–	–	64.0 $P = 0.05$	50.0	69.0 $P = 0.27$	62.0	–	–
72.8 $P < 0.001$	49.1	–	–	80.8 $P = 0.518$	76.6	84.8 $P = 0.509$	80.8	91.2 $P = 0.596$	88.3
26.5 $P = 0.047$	7.1	–	–	45.2 $P = 0.016$	15.4	65.4 $P = 0.609$	57.9	–	–
44.0 $P < 0.001$	0.0	–	–	60 $P = 0.049$	30.4	72 $P = 0.230$	52.2	88.0 $P = 0.022$	56.5
80.0 $P = 0.037$	68.8	–	–	93.6 $P = 0.026$	82.4	98.8 $P = 0.026$	93.6	–	–
75.6 –	20.5	– –	–	–	–	–	–	–	–
57.2 $P < 0.001$	35.5	–	–	89.2 $P = 0.092$	71.0	92.8 $P = 0.104$	87.5	94.5 $P = 0.142$	92.1
69 $P = 0.028$	37	–	–	86.0 $P = 0.006$	54.0	67.0 $P > 0.25$	70.0	73.0 $P > 0.82$	72.0
21.1 $P = 0.625$	7.7	31.6 $P = 0.195$	7.7	68.4 $P = 0.005$	15.4	84.2 $P = 0.001$	23.1	84.2 $P = 0.401$	69.2
33 $P = 0.007$	16	–	–	66.0 $P = 0.002$	44.0	81.0 $P = 0.034$	67.0	92.0 $P = 0.024$	80.0

studies, as recommended by the Cochrane collaboration. The instrument uses a star system to evaluate observational studies based on three criteria: participant selection, comparability of study groups, and assessment of outcome or exposure. A maximum of four, two, and three stars can be awarded, respectively, for each category. Studies awarded >6 stars were considered to be of high quality.

Statistical Analysis

Risk ratio (RR) was used in reporting the six dichotomous outcomes analysed in the study: urinary continence, PSM, urinary leakage on cystogram, acute urinary retention (AUR), and stenosis of the new bladder neck.

Heterogeneity between studies was assessed using the I^2 statistics. Pooled estimates were calculated with fixed-effect model (Mantel–Haenszel method) when there was no significant evidence of heterogeneity; otherwise, the random effect model (DerSimonian–Laird method) was used. The significance of the overall treatment effect was tested by the z-test. Meta-analysis results were graphically represented using forest plots.

Data were evaluated on an intention-to-treat basis as far as possible. The presence of publication bias was evaluated using funnel plots and the arcsine test was used to test funnel plot asymmetry.

All analyses were undertaken using R 3.2.3 (R Core Team 2015; R Foundation for Statistical Computing, Vienna, Austria) with the meta package.

Results

Systematic Literature Search Results

In all, 493 articles dealing with the PR after RP were found: 90 on Medline, 189 on Embase, 101 on Scopus, and 113 on the Web of Science database. Of these, 191 articles were identified after the removal of duplicates, with 161 articles excluded because they were not focused on the PR of the rhabdomyosphincter. Eight studies were excluded because the techniques of PR were different from the original, or for the absence of an adequate assessment of continence recovery. Finally, of the 22 studies defined eligible for the qualitative analysis, one was excluded because of a lack of standardised reporting of the continence recovery outcome (Fig. 1), leaving 21 studies [3–6,10–26].

Description of Included Studies and Quality Assessment

All the 21 studies included were divided according to the levels of evidence defined by Phillips et al. [27]:

1 Three studies were defined as randomised controlled trials (RCT) reaching the level of evidence 1b.
2 Five studies were defined as non-randomised controlled trials reaching the level of evidence 2b.
3 One study was defined as retrospective with a contemporary cohort of patients reaching the level of evidence 3b.
4 12 studies were defined as retrospective with an historical cohort of patients reaching the level of evidence 4.

Table 1 [3–6,10,12–15,17,18,20–26] summarises the quality scores of the studies and the risk of bias assessment.

Meta-Analysis of Urinary Continence

Table 2 [3–6,10–26] shows the outcomes of urinary continence in the studies included in the meta-analysis, at 3–7, 30,45–75 90, 180 days and 1 year after removal of urinary catheter in patients undergoing RP (ORP, LRP or RARP) with or without PR of the rhabdosphincter. Table 3 [3–6,10–26] summarises the different surgical techniques used in the studies comprised in the meta-analyses.

Of the 21 papers considered in the meta-analysis, five studies did not show any significant advantage in terms of postoperative urinary continence secondary to the PR of the sphincteric complex. However, most publications have shown, although with different levels of evidence, a significant advantage associated with the PR of the sphincter for postoperative urinary continence at different time intervals.

The combined analysis of all studies, regardless of the surgical approach, showed an overall statistically significant advantage in the rate of postoperative urinary continence in favour of the application of the technique of PR at 3–7 days after catheter removal (RR 1.90, 95% CI 1:25–2:90; $P = 0.003$; Fig. 2), at 30 days after catheter removal (RR 1.77, 95% CI 1.43–2.20; $P < 0.001$; Fig. 3) and at 90 days after catheter removal (RR 1.32, 95% CI 1.10–1.59; $P = 0.003$; Fig. 4). A smaller but still significant advantage in terms of urinary continence associated with PR at 180 days after catheter removal emerged (RR 1.13; 95% CI 1.02–1.26; $P = 0.025$; Fig. 5). Heterogeneity between studies was high for all the time intervals, ranging from an I^2 of 83.8 to 90.5%.

A subgroup analysis by study type (RCT, observational prospective and retrospective) of RR for urinary continence was performed (Figs 2–5). For the RCTs, the pooled RRs at 3–7, 30, 90 and 180 days were 1.07 (95% CI 0.75–1.51), 1.69 (95% CI 0.46–6.27), 1.48 (95% CI 0.41–5.32), 1.13 (95% CI 0.70–1.82), respectively. For the prospective studies the RRs were 1.81 (95% CI 0.81–4.01), 1.95 (95% CI 1.09–3.49), 1.22 (95% CI 0.93–1.58), 1.15 (95% CI 0.91–1.45), respectively. For the retrospective studies the RRs were 2.21 (95% CI 1.27–3.85), 1.86 (95% CI 1.39–2.49), 1.38 (95% CI 1.14–1.68), 1.13

Table 3 Comparison of the different surgical techniques employed.

Reference	Surgical techniques used to improve urinary continence	Inclusion of Denonvilliers' fascia in PR	Suspension of posterior bladder wall to the posterior musculofascial plate
Rocco et al. [4]	PR	Yes	Yes
Rocco et al. [3]	PR	Yes	Yes
Rocco et al. [5]	PR	Yes	Yes
Tewari et al. [10]	PR Anterior reconstruction with preservation of pubo-prostatic ligaments	Yes	Yes
Menon et al. [11]	PR	Yes	No
Nguyen et al. [12]	PR	Yes	No
Krane et al. [13]	PR	No	Yes
Kim et al. [14]	PR	Yes	Yes
Joshi et al. [15]	PR	Yes	No
Coelho et al. [6]	PR Periurethral suspension	Yes	No
Sutherland et al. [16]	PR	Yes	Yes
Brien et al. [17]	PR	Yes	Yes
Atug et al. [18]	PR Urethral suspension	Yes	Yes
Hurtes et al. [19]	PR Periurethral suspension	Yes	Yes
Sano et al. [20]	PR	Yes	Yes
Simone et al. [21]	PR	Yes	No
Gondo et al. [22]	PR Approximation of the Santorini venous plexus to the anterior bladder wall	Yes	Yes
You et al. [23]	PR	Yes	Yes
Anceschi et al. [24]	PR	Yes	Yes
Ito et al. [25]	PR	Yes	No
Daouacher and Waldén [26]	PR Preservation of pubo-prostatic ligaments	No	No

(95% CI 0.97–1.33), respectively. Subgroup differences were not statistically significant at each of the four time intervals. Heterogeneity between studies was high or medium–high in all the study subgroups ($I^2 > 70\%$).

A subgroup analysis of continence by surgical approach (LRP vs RARP; studies considering ORP or both LRP and RARP were excluded) was also performed (Figs 6–9). For LRP the pooled RRs at 3–7, 30, 90 and 180 days were 1.60 (95% CI 0.49–5.21), 1.93 (95% CI 1.20–3.12), 1.58 (95% CI 1.17–2.13), 1.16 (95% CI 0.95–1.43), respectively. For RARP the RRs were 1.75 (95% CI 1.06–2.87), 1.60 (95% CI 1.20–2.12), 1.21 (95% CI 0.94–1.55), 1.12 (95% CI 0.94–1.34), respectively. Subgroup differences were not statistically significant at each of the four time intervals. Heterogeneity between studies was high in all the study subgroups ($I^2 > 75\%$).

The above analysis shows a statistically significant advantage in terms of urinary continence at 30 and 90 days when LRP is used, and at 3–7 and 30 days when RARP is used.

Meta-Analysis of PSM

Table 4 [3–6,10,18,19,23–25] shows the percentage of PSM estimated by the studies included in the meta-analysis. The overall meta-analysis of data in the various studies showed a rate of PSM comparable in the group of patients undergoing PR and in the group of patients undergoing standard RP (RR 1.04, 95% CI 0.82–1.31; $P = 0.804$; Fig. 10). Heterogeneity between studies was very low ($I^2 = 0\%$, $P = 0.939$). Subgroups analysis by type of study did not show significant differences between the pooled estimates ($P = 0.664$).

Meta-Analysis of Urinary Leakage on Cystogram

The meta-analysis of the data reported in the literature showed a statistically significant advantage on the reduction of the risk of peri-anastomotic urinary leakage at postoperative cystogram in the group of patients treated with PR compared with the group of patients not undergoing PR (RR 0.43, 95% CI 0.25–0.75; $P = 0.006$; Fig. 11). Heterogeneity between studies was very low ($I^2 = 0\%$, $P = 0.624$). Subgroups analysis by type of study did not show significant differences between the pooled estimates ($P = 0.930$).

Meta-Analysis of Complications

We tried to evaluate complications that could be related to the specific technique, such as urethral stenosis due to an increased number of sutures in the area, but we found no data in the literature concerning this point.

Of all the trials included in the meta-analysis, six papers also reported information about the rate of AUR episodes in the comparison groups [3,4,6,14,15,24]. From the meta-analysis of these studies there was no statistically significant evidence to suggest any certain increased risk of AUR secondary to the PR of the sphincter (RR 1.36, 95% CI 0.63–2.95; $P = 0.937$; Fig. 12).

Three studies reported information on the detection of stenosis of the new bladder neck [3,4,15]. The meta-analysis of the RRs of these studies did not show a significant

Fig. 2 Forest plot of RR for urinary continence at 3–7 days after surgery, stratified by type of study: RCT, observational prospective and retrospective.

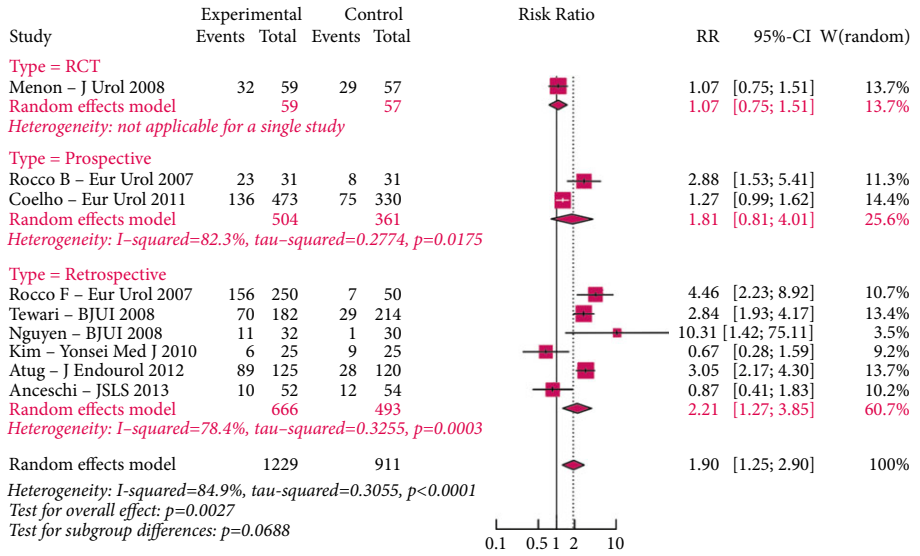
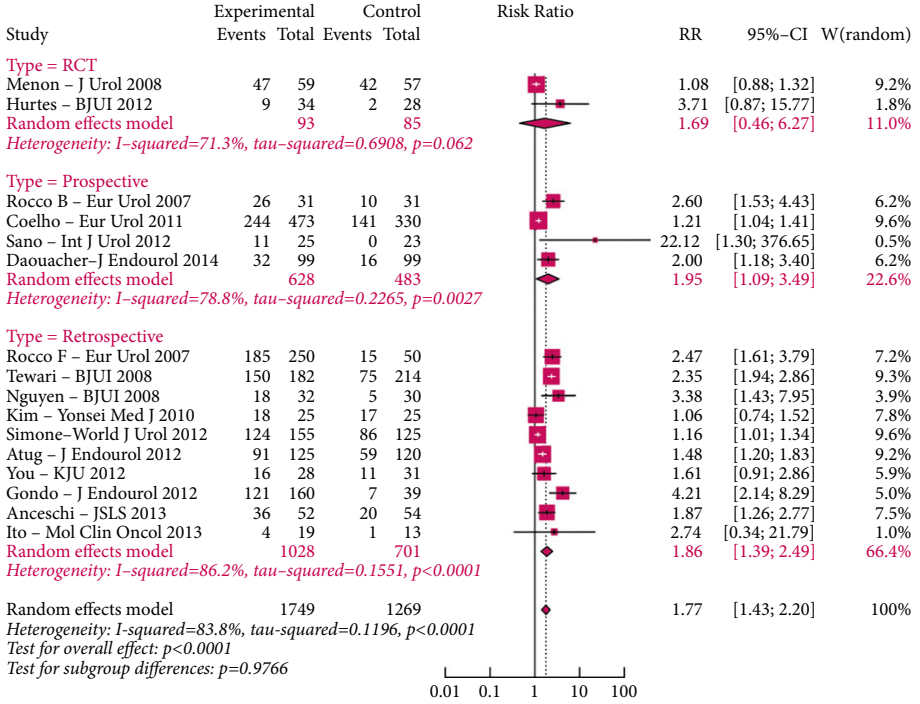


Fig. 3 Forest plot of RR for urinary continence at 30 days after catheter removal, stratified by type of study: RCT, observational prospective and retrospective.



difference between rates of stenosis of the new bladder neck in the two groups (RR 0.67, 95% CI 0.20–2.31; P = 0:526; Fig. 13).

Publication Bias

Funnel plots for urinary continence at the four time intervals are shown in Fig. 14. Although funnel plot asymmetry tests did not detect any significant asymmetry, visual inspection suggests that we cannot exclude the presence of a certain amount of bias.

Publication bias was also investigated for the rate of PSM. The funnel plot (not shown) evidenced a good symmetry, all study outcomes were within the 95% CIs, and the P value of the asymmetry test was P = 0.826.

Fig. 4 Forest plot of RR for urinary continence at 90 days after catheter removal, stratified by type of study: RCT, observational prospective and retrospective.

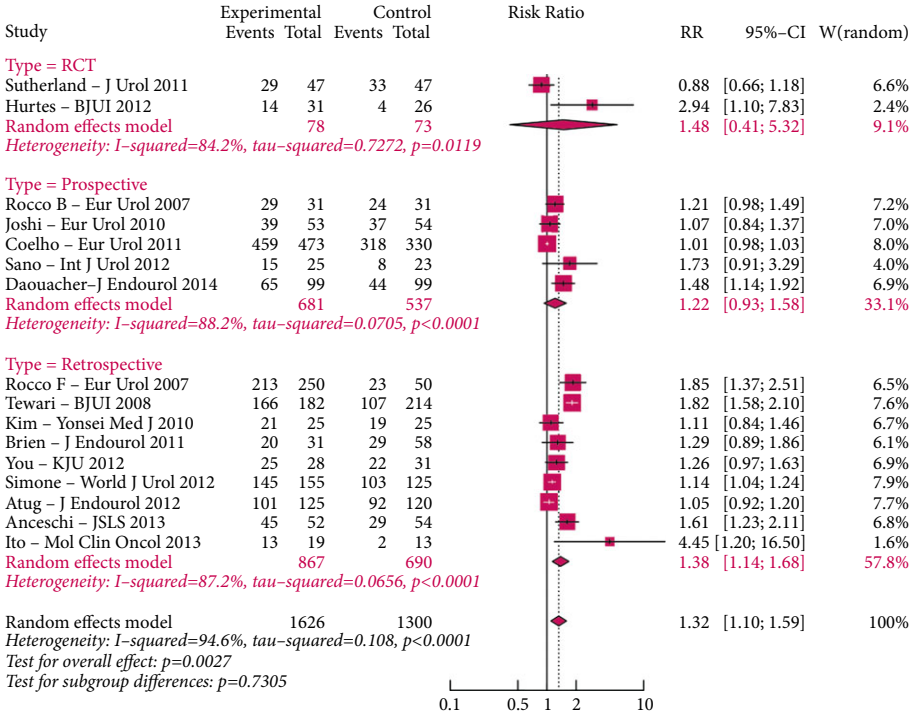


Fig. 5 Forest plot of RR for urinary continence at 180 days after catheter removal, stratified by type of study: RCT, observational prospective and retrospective.

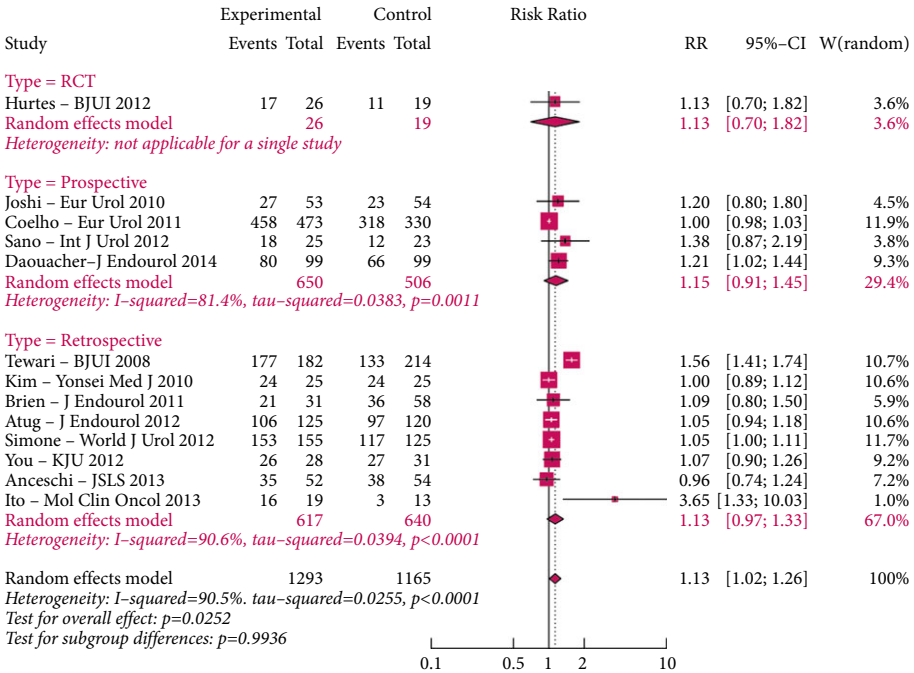


Fig. 6 Forest plot of RR for urinary continence at 3–7 days after catheter removal, stratified by surgical approach: ORP, LRP, and RARP.

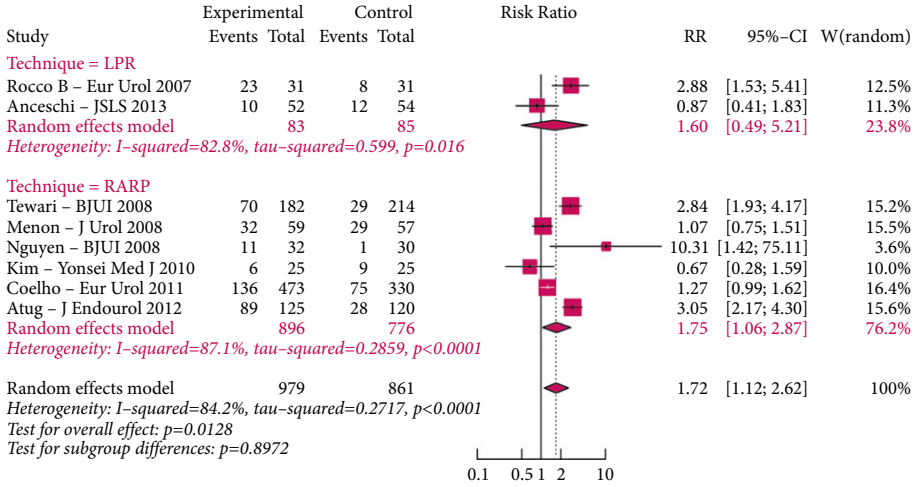
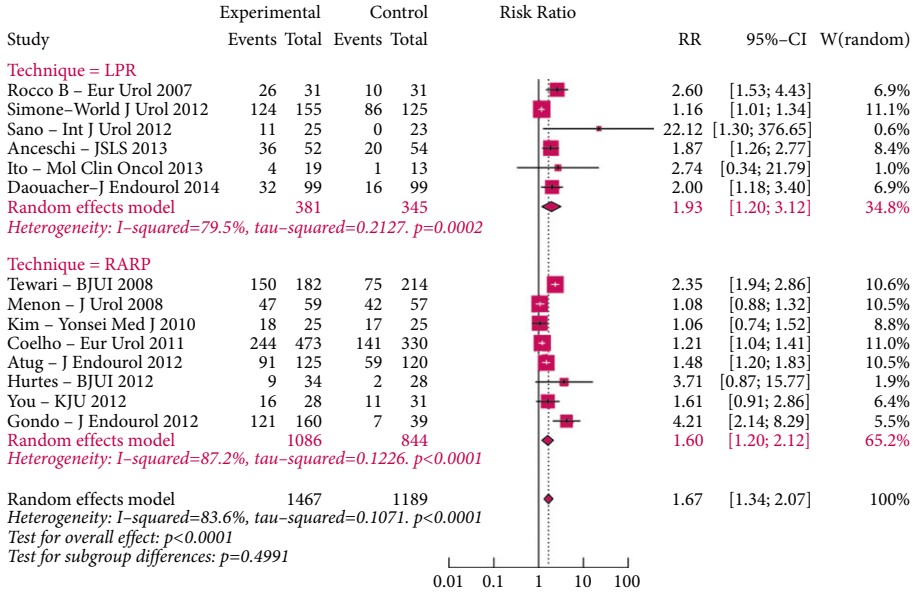


Fig. 7 Forest plot of RR for urinary continence at 30 days after catheter removal, stratified by surgical approach: ORP, LRP, and RARP.



Discussion

The PR of the rhabdosphincter was proposed nearly 15 years ago, first for ORP, then LRP, and finally RARP [2–4,6], and several studies to date have presented different outcomes and versions of the described technique. We know that >50% of robotic surgeons in Europe are now using this technique when performing RARP [28].

In 2012, Ficarra et al. [29] reported a significant advantage in terms of earlier continence when PR was performed in the robotic setting. In their study, Ficarra et al. [29] included only robotic studies focused on PR, also including other technical nuances such as anterior suspension suture. Differently from the Ficarra et al. [29] study, we published a meta-analysis in 2012 [7] investigating the role of PR only, but including ORP, LRP and RARP series. We found a significant advantage associated with PR for postoperative urinary continence at 3–7 days ($P = 0.030$) and 30 days ($P = 0.004$) after the removal of the catheter. No significant differences in the levels of urinary continence between the two comparison groups were apparent at 90 and 180 days ($P = 0.18$ at 90 days, $P = 0.66$ at 180 days).

The results obtained in our present meta-analysis are in agreement and also indicate that PR seems to be associated

Fig. 8 Forest plot of RR for urinary continence at 90 days after catheter removal, stratified by surgical approach: ORP, LRP, and RARP.

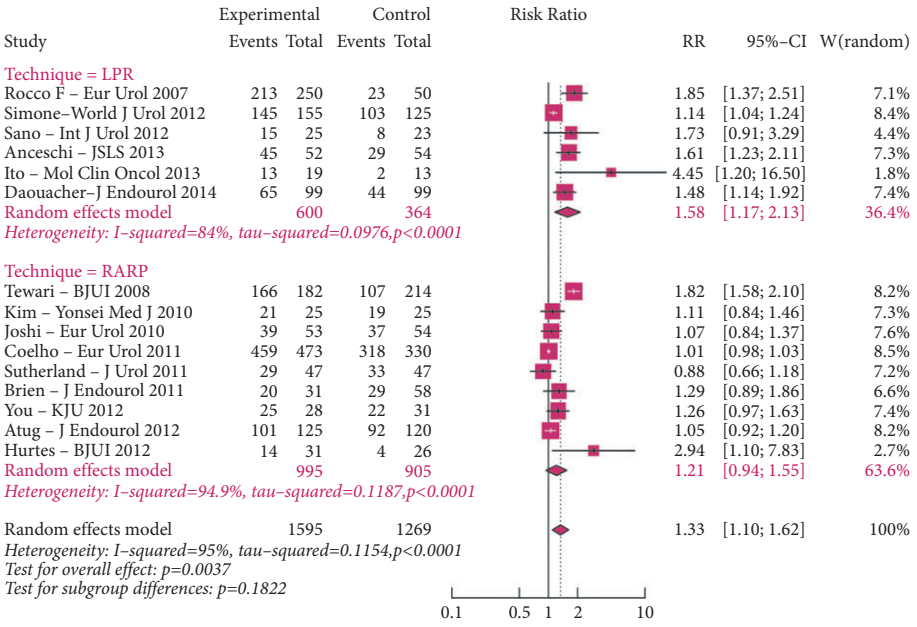
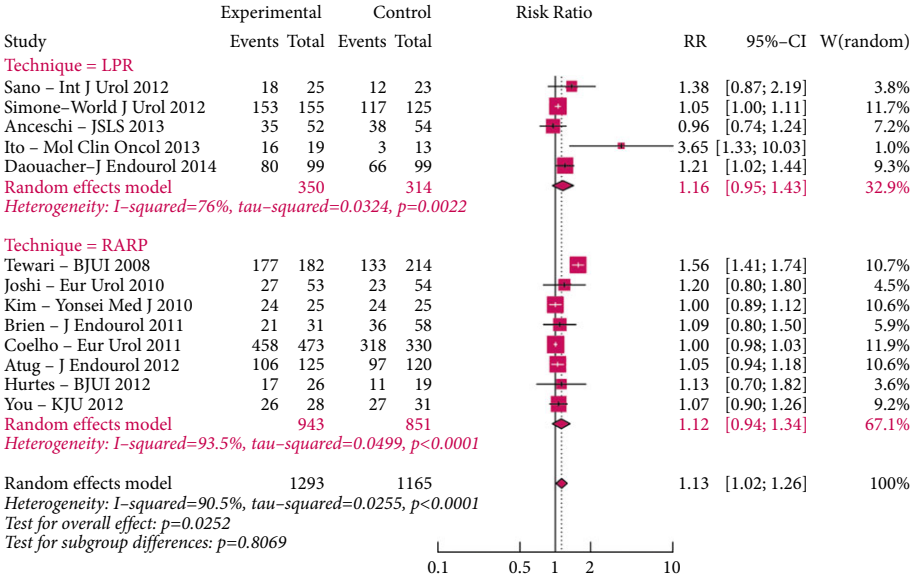


Fig. 9 Forest plot of RR for urinary continence at 180 days after catheter removal, stratified by surgical approach: ORP, LRP, and RARP.



with a lower incidence of cystographic leakage, probably as PR allows a greater hold of the vesicourethral anastomosis through a better approximation of the structures involved in the anastomosis.

All the published studies showed no statistical significant increase in the risk of postoperative complications (such as stenosis of the new bladder neck or AUR) in patients treated with PR.

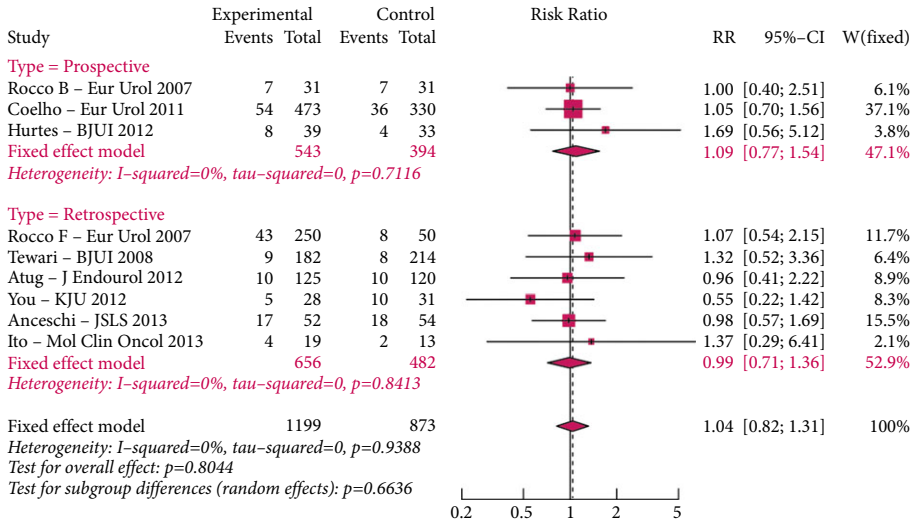
For cancer outcomes, the application of the technique of PR does not appear to be associated with an increased risk of PSM at final pathological analysis.

For postoperative urinary continence, the present meta-analysis indicates an advantage of PR regardless of the surgical approach (ORP, LRP and RARP): a significant benefit at 3–7 and 30 days from surgery and, unlike the findings of the previous meta-analysis, even at 90 days after

Table 4 Percentage of PSM estimated in the studies included in the meta-analysis.

Reference	No. of patients		Overall PSM, *n* (%)		PSM in pT2 patients, *n/N* (%)		PSM in pT3 patients, *n/N* (%)	
	No PR group	PR group	No PR group	PR group	No PR group	PR group	No PR group	PR group
Rocco et al. [4]	50	161	8 (16.0)	30 (18.6)				
Rocco et al. [3]	50	250	8 (16.0)	43 (17.2)	(6.0)	(7.6)	(10)	–
Rocco et al. [5]	31	31	7 (22.5) *P* = 1	7 (22.5)	3/21 (14.2) *P* = 0.34	1/19 (5.3)		
Tewari et al. [10]	214	182	8 (3.7)	9 (4.9)				
Coelho et al. [6]	330	473	36 (11.0) *P* = 0.912	54 (11.4)	18/262 (6.8) *P* = 0.832	28/393 (7.1)	18/63 (28.5) *P* = 0.672	–
Atug et al. [18]	120	125	(8.3) *P* = 0.920	(8.0)				
Hurtes et al. [19]	33	39	4 (12.1) *P* = 0.460	8 (20.5)				
You et al. [23]	31	28	10 (32.2) *P* = 0.223	5 (17.8)				
Anceschi et al. [24]	54	52	(33) *P* = 0.490	(32)	(25) *P* = 0.714	(26)	(30) *P* = 0.629	(29)
Ito et al. [25]	13	19	2 (15.3) *P* = 0.687	4 (21.0)				

Fig. 10 Forest plot of RR for rate of PSM, stratified by type of study: RCT, observational prospective and retrospective.



catheter removal. In addition, a smaller but still statistically significant advantage in terms of urinary continence was associated with PR at 180 days after catheter removal.

Performing a meta-analysis stratified by surgical approaches, a significant benefit was found for urinary continence at 30, 90 and 180 days when the PR is applied in the course of a LRP; a significant advantage at 3–7, 30 and 90 days when applied in the course of RARP was also found, but at 180 days this advantage was not statistically significant.

There are some limitations of the present study. Firstly, we did not include data from congress abstract proceedings because generally this type of publication does not report a complete set of data, which is required for a meta-analysis. This choice might be considered a limitation of the study. In the present meta-analysis, there are clues (in some cases quite obvious) of an asymmetry of the funnel plots; therefore the presence of publication bias cannot be excluded. The heterogeneity is quite high and this may have implications for the ability to extend the results to other populations. As already discussed in the previous meta-analysis [7], one of the main limitations is that the different authors who published their experience with this technique found different or even contrasting results for post-RP urinary continence, the main outcome examined. To explain the rate of heterogeneity found among these studies, some factors, which had already been mentioned in the previous study, will be briefly listed here. First, it must be recognised that several different definitions of continence have been given in the literature for post-RP outcomes and several ways of assessing continence

Fig. 11 Forest plot of RR for risk of peri-anastomotic urinary leakage at postoperative cystogram, stratified by type of study: RCT, observational prospective and retrospective.

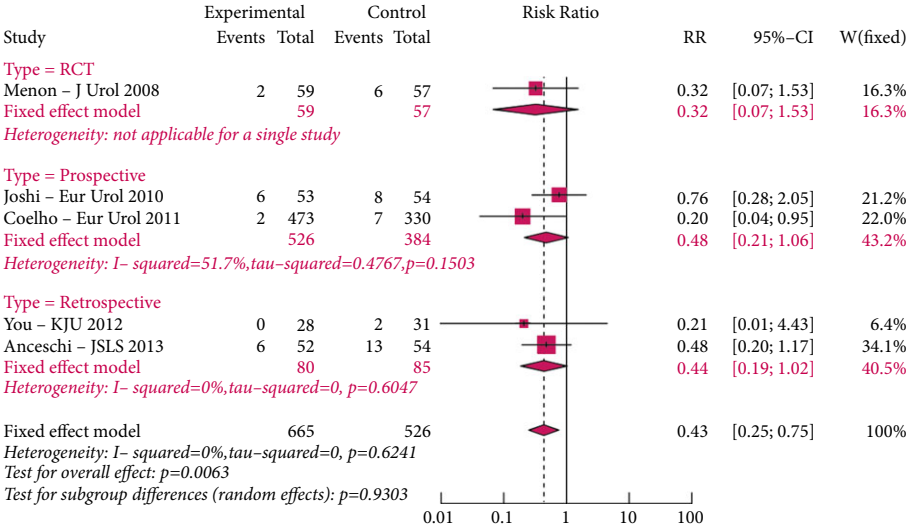


Fig. 12 Forest plot of RR for risk of AUR secondary to the PR of the sphincter, stratified by type of study: RCT, observational prospective and retrospective.

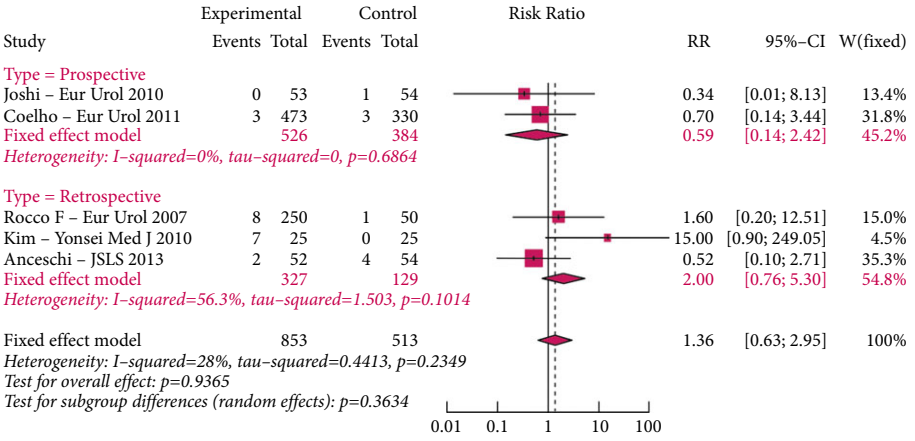
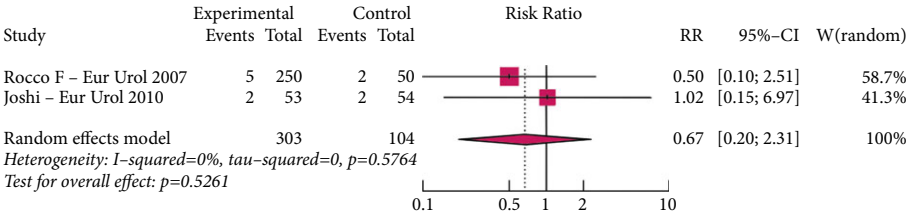


Fig. 13 Forest plot of RR for risk of stenosis of the new bladder neck secondary to the PR of the sphincter.



have been used. In addition, due to the fact that continence is self-reported by the patient, this outcome can be affected by a certain degree of subjectivity. Second, only a subset of the studies considered in the meta-analysis used the PR technique as originally described in 2006; several variations have been developed by different authors. Third, differences in terms of surgical approach (ORP, LRP and RARP) may have a significant role in justifying different results for post-RP urinary continence. In particular, Joshi et al. [15] argued that, using a robotic approach, the better preservation of the structures involved in the continence recovery process might reduce the apparent benefit of the PR; this hypothesis seems

Fig. 14 Funnel plots for urinary continence at 3–7, 30, 90 (3 months) and 180 days (6 months) after catheter removal with *P* values of the test for funnel plot asymmetry.

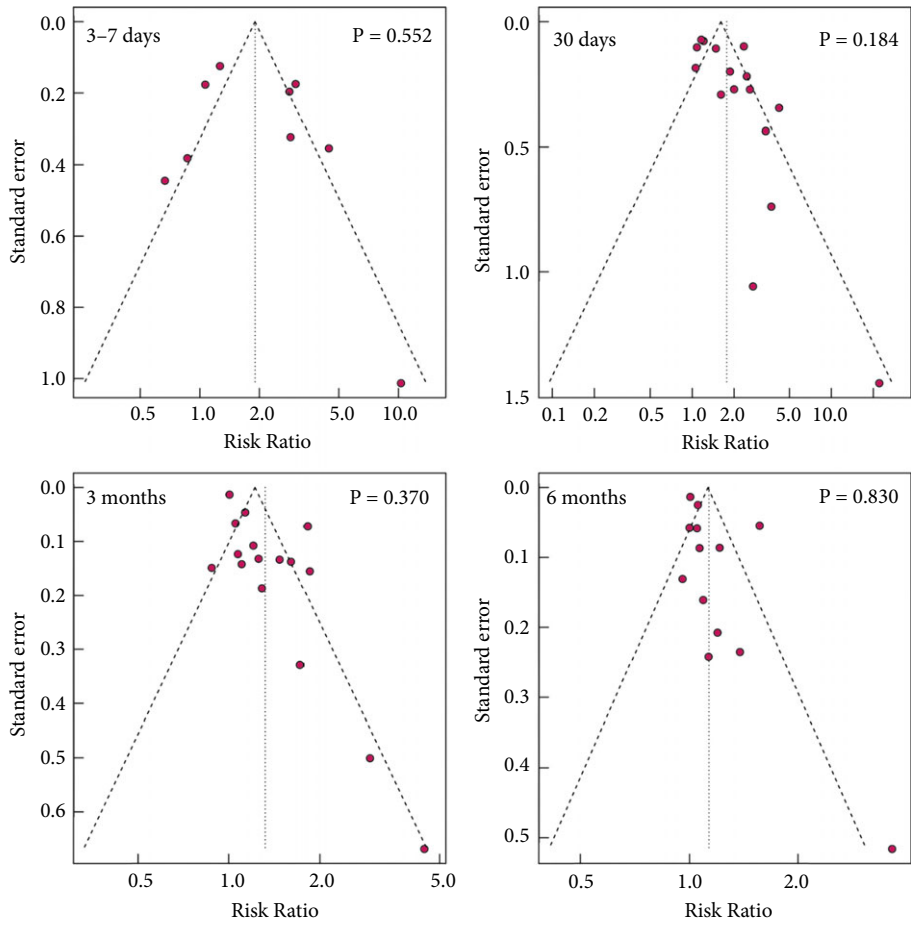


Table 5 Design of the prospective multicentre randomised controlled study 'NCT01809522'.

Title	Does the posterior reconstruction of the rhabdosphincter improve early recovery of continence after robotic-assisted radical prostatectomy? (PRR) A multicenter randomized controlled trial
Study design	A Phase III open-label prospective international multicentre randomised controlled study
Target population	Patients with clinically localised prostate cancer undergoing definitive treatment with RARP. Total number: 1 500 patients; Competitive enrolment, with minimum of 125 and maximum of 250 patients per centre
Objectives	
Primary	Evaluation of efficacy of PRR (vs no PRR) on early recovery of continence in prostate
Secondary	Evaluation of perioperative parameters of RALP with and without PRR Comparison of other functional outcomes Evaluation of the quality of life

to be supported by the results of our present study, where a reduced advantage of PR in the robotic setting compared with laparoscopy was evidenced. Lastly, some methodological aspects of the studies can affect their ability to detect significant differences; study design and sample size being two of the most relevant.

To better assess the effectiveness of the PR in facilitating an earlier recovery of postoperative urinary continence, an international prospective multicentre randomised controlled study is ongoing (ClinicalTrials.gov Identifier: NCT01809522; Table 5).

Conclusions

The PR of the sphincter is used by many surgeons in several centres around the world to improve one of the main adverse effects of RP, i.e. urinary incontinence. The PR technique is easily reproducible, quickly executed, and it does not appear to be associated with an increased risk of perioperative complications, but it appears to be associated with a reduction of peri-anastomotic urinary leakages.

Our present analysis confirms the benefits already discussed in the review published in 2012 [7], evidencing a significant advantage for urinary continence recovery in the first 90 days after RARP and also subsequently (at 180 days) after LRP. An advantage in terms of lower leakages at cystography is

also reported. No significant increase in PSM or complications is reported while using the PR. However, further high-quality, unbiased studies are required to allow firm conclusions to be drawn. To better assess the effectiveness of the PR in facilitating an earlier recovery of postoperative urinary continence, a multicentre randomised controlled trial is ongoing.

Conflicts of Interest

The authors declare no conflicts of interest, including specific financial interests or relationships or affiliations relevant to the subject matter or materials discussed in the manuscript.

The nature of the study and the dissemination worldwide of the surgical technique investigated make the study free from any ideological conflict of interest, although the creators of the surgical technique in question are in the list of the Authors of the current study.

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Abbreviations: AUR, acute urinary retention; PR, posterior reconstruction; PSM, positive surgical margins; RCT, randomised controlled trial; (L)(O)(RA)RP, (laparoscopic) (open) (robot-assisted) radical prostatectomy; RR, risk ratio.