









Review

Role of pelvic drain and timing of urethral catheter removal following RARP: a systematic review and meta-analysis

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Objectives

To assess the clinical value of routine pelvic drain (PD) placement and early removal of urethral catheter (UC) in patients undergoing robot-assisted radical prostatectomy (RARP), as perioperative management such as the necessity of PD or optimal timing for UC removal remains highly variable.

Methods

Multiple databases were searched for articles published before March 2022 according to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement. Studies were deemed eligible if they investigated the differential rate of postoperative complications between patients with/without routine PD placement and with/without early UC removal, defined as UC removal at 2–4 days after RARP.

Results

Overall, eight studies comprising 5112 patients were eligible for the analysis of PD placement, and six studies comprising 2598 patients were eligible for the analysis of UC removal. There were no differences in the rate of any complications (pooled odds ratio [OR] 0.89, 95% confidence interval [CI] 0.78–1.00), severe complications (Clavien–Dindo Grade \geq III; pooled OR 0.95, 95% CI 0.54–1.69), all and/or symptomatic lymphocele (pooled OR 0.82, 95% CI 0.50–1.33; and pooled OR 0.58, 95% CI 0.26–1.29, respectively) between patients with or without routine PD placement. Furthermore, avoiding PD placement decreased the rate of postoperative ileus (pooled OR 0.70, 95% CI 0.51–0.91). Early removal of UC resulted in an increased likelihood of urinary retention (OR 6.21, 95% CI 3.54–10.9) in retrospective, but not in prospective studies. There were no differences in anastomosis leakage and early continence rates between patients with or those without early removal of UC.

Conclusions

There is no benefit for routine PD placement after standard RARP in the published articles. Early removal of UC seems possible with the caveat of the increased risk of urinary retention, while the effect on medium-term continence is still unclear. These data may help guide the standardisation of postoperative procedures by avoiding unnecessary interventions, thereby reducing potential complications and associated costs.

Keywords

pelvic drain, perioperative complication, prostate cancer, robot-assisted radical prostatectomy, urethral catheter

Introduction

Radical prostatectomy (RP) is a standard surgical treatment for localised and locally advanced prostate cancer (PCa) [1]. Today, robot-assisted RP (RARP) has replaced open and laparoscopic RP as the main technical approach [2,3]. RARP enables surgeons to dissect and suture with higher precision, facilitating a nerve-sparing approach and for the reconstruction of the vesicourethral anastomosis [4–6]. However, perioperative management, such as urethral catheter (UC) and pelvic drain (PD) management, have not adapted to the progress in surgical technique [7,8]. For example, it remains unclear whether there is still a need to keep the UC for 7 days postoperatively to avoid urine leakage in the setting of a meticulous running sutures for vesicourethral anastomosis.

Similarly, PD is still utilised to drain lymphatic fluid, blood, and/or urine after RP. However, the need for a routine PD placement after abdominal and/or pelvic surgery, including urological surgery, has recently been questioned [9–13]. Therefore, we decided to undertake this systematic review and meta-analysis to assess the need for routine PD placement and the safety of early UC removal in the perioperative management of patients undergoing RARP for PCa.

Methods

The protocol has been registered in the International Prospective Register of Systematic Reviews database (PROSPERO: CRD42022321736).

Search Strategy

This systematic review and meta-analysis was conducted according to the guidelines of the Preferred Reporting Items for Meta-Analyses of Observational Studies in Epidemiology Statement (Fig. S1) [14]. In March 2022, a literature search on PUBMED®, Web of Science™, and Scopus® databases was performed to identify studies assessing the clinical impact of PD placement or early removal of UC on postoperative complication rates in patients who had undergone RARP. The keywords used in our search strategy were as follows: (prostatectomy) AND (drain) OR (drainage) OR (urethral catheter). The detailed search strategy is described in Appendix S1. The primary outcome of interest was the rate of postoperative complications. Two investigators performed initial screening based on the titles and abstracts to identify eligible studies. Potentially relevant studies were subjected to a full-text review. Additionally, manual searches of reference

lists of relevant articles were also carried out to identify additional studies. Disagreements were resolved by consensus with co-authors.

Inclusion and Exclusion Criteria

Studies were included if they investigated patients with PCa who had undergone RARP (Patients), without routine PD placement (Interventions), compared to those with routine PD placement (Comparisons) to assess the postoperative complication rates (Outcome) in randomised controlled trials (RCTs), non-randomised observational, or cohort studies (Study design). Additionally, studies were also included if they investigated patients with PCa who had undergone RARP (Patients), with early removal of UC (Interventions), compared to those with standard removal of UC (Comparisons) to assess the postoperative complication rates (Outcome). Early removal of UC was defined as UC removal at postoperative Day (POD) 2–4, and standard removal of UC was defined as $\text{POD} \geq 5$. Studies lacking original patient data, reviews, letters, editorial comments, replies from authors, and case reports were excluded. All potentially relevant articles were listed in Appendix S2. References of all papers included were scanned for additional studies of interest.

Data Extraction

Data were extracted independently by two authors. The information regarding the first author's name, publication year, recruitment periods, number of patients, study design, information of surgeon, timing of UC removal, cystogram at UC removal, age, pathological stage, pelvic lymph node dissection (PLND), operation time, estimated blood loss, any complication, severe complication (Clavien–Dindo Grade \geq III), length of stay, details of postoperative complications (i.e., urinary retention, vesicourethral anastomotic leakage, lymphocele, ileus), early and delayed continence rates were extracted. All discrepancies were solved by consensus with co-authors.

Risk of Bias Assessment

The study quality and risk of bias were assessed following the Cochrane Handbook for Systematic Reviews of Interventions risk-of-bias tool (RoB version 2; Fig. S2) [15]. We also assessed the study quality and risk of bias following the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool, referring to the Cochrane Handbook for Systematic Reviews of Interventions (Table S1). Each bias domain and overall risk of bias were judged as 'Low',

‘Moderate’, ‘Serious’ or ‘Critical’ risk of bias. The risk-of-bias figure was created using Review Manager 5.3 Software (RevMan; The Cochrane Collaboration, Oxford, UK). The risk-of-bias assessment of each study was performed independently by two authors.

Statistical Analyses

Forest plots were applied to analyse and summarise the odds ratio (OR) and to describe the relationships between perioperative management and postoperative complications. Heterogeneity among the outcomes of included studies in this meta-analysis was assessed using Cochrane’s Q test and the I^2 statistic. When significant heterogeneity ($P < 0.05$ in the Cochrane Q test and/or a ratio $>50\%$ in I^2 statistics) was observed, we applied a random-effects model and investigated the reason for heterogeneity [16,17]. Otherwise, fixed-effects models for the calculation of pooled ORs for non-heterogeneous results were applied [18]. Funnel plots were used to assess publication bias (Figs S3 and S4). Subgroup analyses were conducted by study design, RCTs or observational studies. All analyses were conducted using Review Manager 5.3 (The Cochrane Collaboration, Copenhagen, Denmark), and the statistical significance level was set at $P < 0.05$.

Results

Study Selection and Characteristics

Our initial search identified 1966 records. After removing duplicates, 1371 records remained for screening the titles and abstracts (Fig. 1). After screening, we carried out a full-text review of 55 articles. According to our inclusion criteria, we finally identified 14 studies comprising 7710 patients eligible for meta-analysis [19–32]. Of the 14 studies, eight studies comprising 5112 patients were eligible for the meta-analysis of PD placement [25–32], and six studies comprising 2598 patients were eligible for the meta-analysis of UC removal [19–24]. The demographics of each included study are shown in Tables S1 and S2. The quality assessment of this meta-analysis was performed using the Assessment of Multiple Systematic Reviews 2 (AMSTAR2) checklist; overall confidence in the results of this review was ‘Moderate’ (Appendix S3) [33].

Differential Postoperative Outcomes between Patients Who Underwent RARP with/without Routine PD Placement

Perioperative outcomes are shown in Table 1 [25–32]. The pooled rates of patients who received PLND were 78% for both the routine and no PD placement groups.

Meta-Analysis of any or Severe (Clavien–Dindo Grade \geq III) Complications

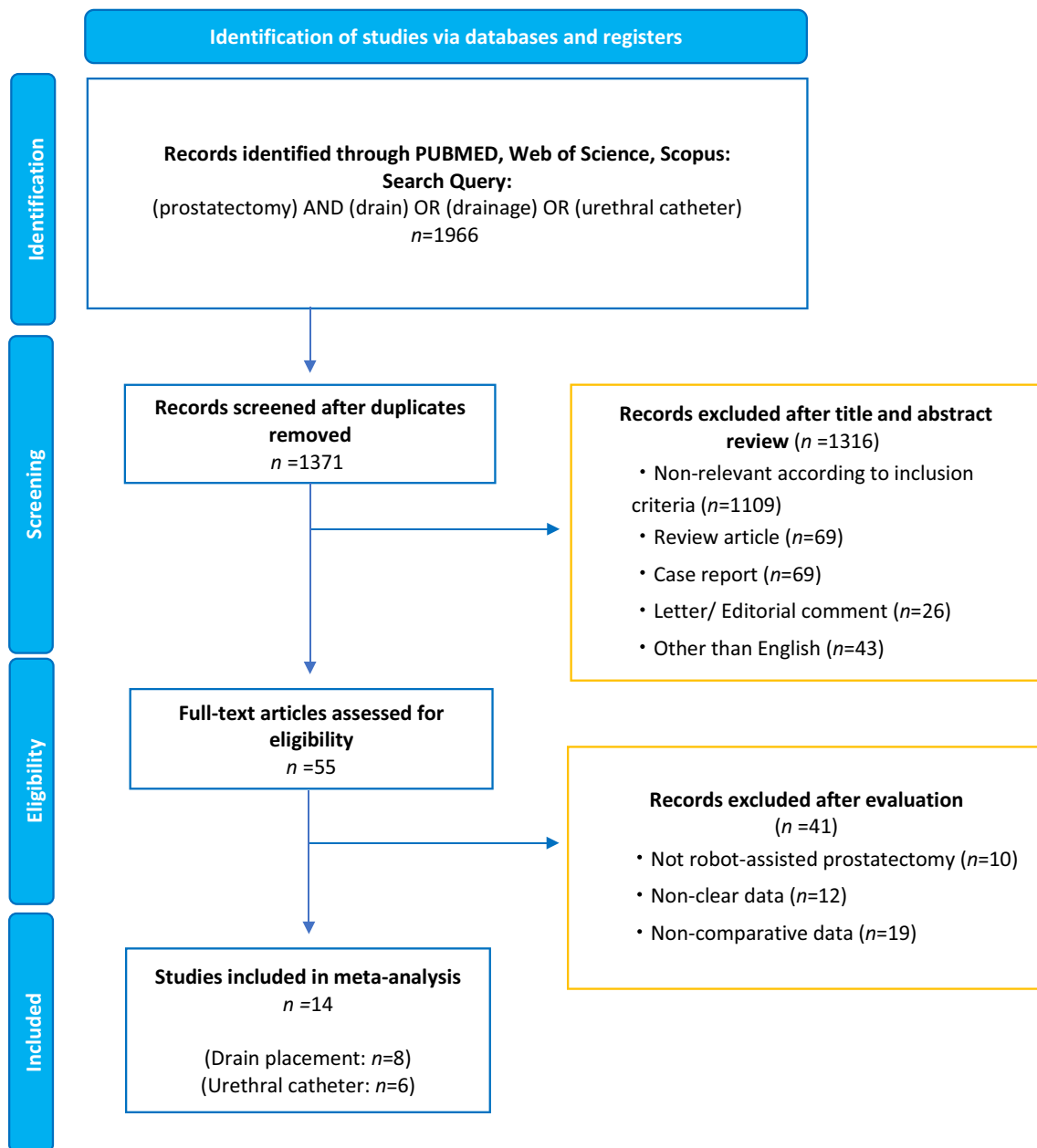
Five studies provided data on the incidence of any complication in patients who had undergone RARP with or without routine PD placement. The pooled rates of any complication were 15% (range 7.0–23%) in patients without routine PD placement and 16% (range 8.7–29%) in patients with routine PD placement. The Forest plot (Fig. 2A) revealed no statistical differences in the rates of any complication between patients with or without routine PD placement (pooled OR 0.89, 95% CI 0.78–1.00; $P = 0.06$). However, CIs included clinically meaningful differences. The Cochrane’s Q ($\chi^2 = 3.83$; $P = 0.43$) and I^2 ($I^2 = 0\%$) tests revealed no significant heterogeneity. Subgroup analysis among two RCTs also revealed no statistically significant differences in the rates of any complication between patients with or without PD placement (pooled OR 0.60, 95% CI 0.35–1.04; $P = 0.07$).

For severe complications (Clavien–Dindo Grade \geq III), four studies provided data. The pooled rates of severe complication were 3.8% (range 0–5.4%) in patients without routine PD placement and 3.9% (range 2.9–5.4%) in patients with routine PD placement. The Forest plot (Fig. 2B) revealed no differences in the rates of severe complications between patients with or without routine PD placement (pooled OR 0.95, 95% CI 0.54–1.69; $P = 0.87$). The Cochrane’s Q ($\chi^2 = 4.19$; $P = 0.24$) and I^2 ($I^2 = 28\%$) tests revealed no significant heterogeneity.

Meta-Analyses of any and Symptomatic Lymphoceles

Five observational studies provided data on the incidence of any lymphocele in patients who underwent RARP with or without routine PD placement. The pooled rates of any lymphocele were 5.5% (range 1.6–32%) in patients without routine PD placement and 7.3% (range 2.6–45%) in patients with routine PD placement. The Forest plot (Fig. 2C) revealed no differences in the incidence rates of any lymphocele between patients with or without routine PD placement (pooled OR 0.82, 95% CI 0.50–1.33; $P = 0.41$). The Cochrane’s Q ($\chi^2 = 2.46$; $P = 0.48$) and I^2 ($I^2 = 0\%$) tests revealed no significant heterogeneity.

For symptomatic lymphocele, five studies provided data. The pooled rates of symptomatic lymphocele were 1.2% (range 0–2.2%) in patients without routine PD placement and 2.1% (range 0.4–4.3%) in patients with routine PD placement. The Forest plot (Fig. 2D) revealed no differences in the rates of symptomatic lymphocele between patients with or without routine PD placement (pooled OR 0.58, 95% CI 0.26–1.29; $P = 0.18$). The Cochrane’s Q ($\chi^2 = 0.83$; $P = 0.84$) and I^2 ($I^2 = 0\%$) tests revealed no significant heterogeneity.

Fig. 1 The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow chart, detailing the article selection process.

Meta-Analysis of Ileus

Four studies provided data on the incidence of ileus in patients who had undergone RARP with or without routine PD placement. The pooled rates of ileus were 2.1% (range 0.5–2.3%) in patients without routine PD placement and 3.2% (range 0.8–3.5%) in patients with routine PD placement. The Forest plot (Fig. 2E) revealed that routine PD placement was associated with higher incidence rates of ileus (pooled OR 0.69, 95% CI 0.52–0.91; $P = 0.01$). The Cochrane's Q ($\chi^2 = 1.19$; $P = 0.76$) and I^2 ($I^2 = 0\%$) tests

revealed no significant heterogeneity. However, in contrast, the only RCT for this endpoint revealed no statistical differences in the rates of ileus between patients with or without PD placement (OR 2.13, 95% CI 0.19–23.93; $P = 0.54$).

Length of Hospital Stay (LOS)

Seven studies provided data on the LOS. However, this endpoint is highly affected by the different practice patterns between countries. In addition, the LOS was reported in different forms,

Table 1 Postoperative outcomes of included studies assessing outcomes in patients with or without routine pelvic drain placement.

Reference	Number of patients			PLND		Operation duration, min		Hospitalisation	
	All	No PD	PD	No PD	PD	No PD	PD	No PD	PD
Danuser et al., 2013 [26]	331 (205 RRP/ 126 RALP)	RRP: 73 RARP: 126	RRP7: 66 RRP1: 66*	All patients underwent ePLND		NA			
Musser et al., 2014 [31]	637	230	407	194 (84) [†]	333 (82) [†]	NA		>2 days 20 (8.7)	>2 days 149 (37)
Chenam et al., 2018 [25]	189	92	97	Limited: 16 (17) ePLND: 65 (71) 2424 (78) [†]	Limited: 11 (11) ePLND: 77 (79) 2739 (77) [†]	Median (IQR) 190 (169–217)	Median (IQR) 201 (180–224)	POD1: 82 (89) POD2: 8 (8.7) POD3: 2 (2.2)	POD1: 82 (85) POD2: 14 (14) POD3: 1 (1.0)
Kirmiz et al., 2020 [29]	6746	3112 (Selective use)	3544 (Regular use)	ePLND: 25 (74)	ePLND: 25 (74)	NA		>2 days 197/3112	>2 days 298/3544
Makifa et al., 2020 [30]	68	34	34	ePLND: 25 (74)	ePLND: 25 (74)	Median (range) 309 (197–471)	Median (range) 311 (176–452)	Median (range) 7 (6–11)	Median (range) 8 (6–12)
Huang et al., 2021 [27]	357 (only RARP)	125	232	86 (69) [†]	216 (93) [†]	Median (IQR) 158 (143–177)	Median (IQR) 199 (160–237)	Median (IQR) 1 (1–1)	Median (IQR) 1 (1–1)
Iwamoto et al., 2021 [28]	308	77	231	19 (25) [†]	111 (48) [†]	Median (IQR) 239 (177–352)	Median (IQR) 234 (138–398)	Median (IQR) 12 (9–25)	Median (IQR) 15 (9–48)
Porcaro et al., 2021 [32]	110	54	56	ePLND: 34 (63)	ePLND: 37 (66)	Median (range) 212.5 (170–310)	Median (range) 217 (150–335)	Median (range) 4 (3–8)	Median (range) 4 (4–8)

Values are described as number, number (%), or median. Minor complications are defined as Clavien–Dindo Grade I–II, severe complications are defined as Clavien–Dindo Grade III–V. ePLND, extended PLND; NA, not applicable; RRP, retropubic RP. *RRP1 and RRP7 is described as POD of PD removal after RRP. [†]The extent of PLND was not reported. [‡]Described as Clavien–Dindo Grade II–V.

e.g., as median with interquartile range (IQR) or range. Thus, we did not perform a formal meta-analysis for LOS.

Three studies provided data on the rates of LOS of >1 day. Musser et al. [31] reported that the rate of LOS of >1 day was significantly higher in the routine PD placement group (37%) than in the group without routine PD (8.7%, $P < 0.001$). Kirmiz et al. [29] reported that the rate of LOS >2 days was significantly higher in the routine PD placement group (8.4%) than in the group without routine PD (6.3%, $P = 0.001$). On the contrary, the only RCT conducted by Chenam et al. [25] revealed no statistical difference in the rate of LOS >2 days between patients with or without routine PD placement (15% vs 11%, $P = 0.35$).

Four studies reported the data on LOS as medians with IQRs or ranges [27,28,30,32]. All three observational studies reported that routine PD placement was significantly associated with a longer LOS, but the LOS varied widely depending on the country (median LOS ranging from 1 to 15 days) [27,28,30]. The only RCT that evaluated this outcome was conducted by Porcaro et al. [32], and revealed no statistically significant difference in the median LOS between the two groups (routine PD: 4 [range 3–8] vs no PD: 4 [range 4–8] days, respectively).

Differential Postoperative Outcomes between Patients Who Underwent RARP with/without Early UC Removal

The perioperative outcomes and demographics of included studies are shown in Table 2 [19–24] and Table S3.

Meta-Analysis of Urinary Retention

Six studies provided data on the incidence of urinary retention in patients who underwent RARP with or without early UC removal. The pooled rates of urinary retention were 7.0% (range 1.4–13%) in patients with early UC removal and 0.8% (range 0.3–8.1%) in patients without early UC removal. The Forest plot (Fig. 3A) revealed that early UC removal was associated with higher incidence rates of urinary retention compared to standard UC removal (pooled OR 6.21, 95% CI 3.54–10.89; $P < 0.001$). The Cochrane's Q ($\chi^2 = 10.7$; $P = 0.06$) and I^2 ($I^2 = 53\%$) tests revealed no significant heterogeneity. However, in contrast, subgroup analysis among two RCTs revealed no statistically significant differences in the rates of any urinary retention between patients with or without early UC removal (pooled OR 1.06, 95% CI 0.21–5.34; $P = 0.95$).

Meta-Analysis of Vesicourethral Anastomotic Leakage

Three studies provided data on the incidence of vesicourethral anastomotic leakage in patients who had undergone RARP with or without early UC removal. The pooled rates of vesicourethral anastomotic leakage were 5.9% (range 0.8–18%) in patients with early UC removal and 4.3% (range 0–8.15%) in patients without early UC removal. The Forest plot (Fig. 3B) revealed no differences in the rates of vesicourethral anastomotic leakage between patients with or without early UC removal. The Cochrane's

Any complications		Severe complications		All lymphocele		Symptomatic lymphocele		Ileus		
No PD	PD	No PD	PD	No PD	PD	No PD	PD	No PD	PD	
18/258 ¹	33/379 ²	12/258	11/379	RRP: 7/73 RARP: 4/126	RRP7: 4/66 RRP1: 8/66	RRP: 5/73 RARP: 1/126	RRP7: 0/66 RRP1: 5/66	NA	2/258 ¹	2/379 ²
16	26	5	5	NA	NA	2 (Minor: 2)	4 (Minor: 1, severe: 3)	2 (Minor: 1, severe: 1)	1 (Minor: 1)	
455	570	NA	NA	NA	NA	NA	NA	73	120	
38	35	NA	NA	10/31 (All minor)	13/29 (All minor)	NA	NA	NA	NA	
29	45	3	11	4	12	2	10	NA	NA	
NA	NA	NA	NA	12 (All minor)	29 (All minor)	0	1 (Severe)	1	8	
11	16	0	3	NA	NA	NA	NA	NA	NA	

Q ($\chi^2 = 0.57$; $P = 0.75$) and I^2 ($I^2 = 0\%$) tests revealed no significant heterogeneity.

Urinary Continence

Two studies provided data on the rates of urinary continence at 1 month after operation in patients who had undergone RARP with or without early UC removal. The pooled rates of urinary continence at 1 month after operation were 67% (range 63–71%) in patients with early UC removal and 57% (range 33–77%) in patients without early UC removal. The Forest plot (Fig. 3C) revealed no differences in the rate of early urinary continence between patients with or without early UC removal (pooled OR 0.62, 95% CI 0.13–2.95; $P = 0.55$). The Cochrane’s Q ($\chi^2 = 8.79$; $P = 0.003$) and I^2 ($I^2 = 89\%$) tests revealed significant heterogeneity.

These two studies also provided the outcomes of different measurements for urinary continence at 3 months after RARP; thus, we did not perform a formal meta-analysis. One study evaluated the continence rate [21], and the other study evaluated the International Consultation on Incontinence Questionnaire-Male Lower Urinary Symptoms (ICIQ-MLUTS) score at 1, 3, and 6 months after RARP [24]. Harke et al. [21] reported that no pad continence rates were 69% in patients who had their UC removed at POD5, while 80% in patients who had their UC removed at POD2. By contrast, Lista et al. [24] showed that the incontinence score of ICIQ-MLUTS at 3 months after RARP was significantly worse in patients who had their UC removed at POD3 compared to

patients who had their UC removed at POD5, while there was no difference in this score at 6 months after RARP between the two groups.

Urinary Function

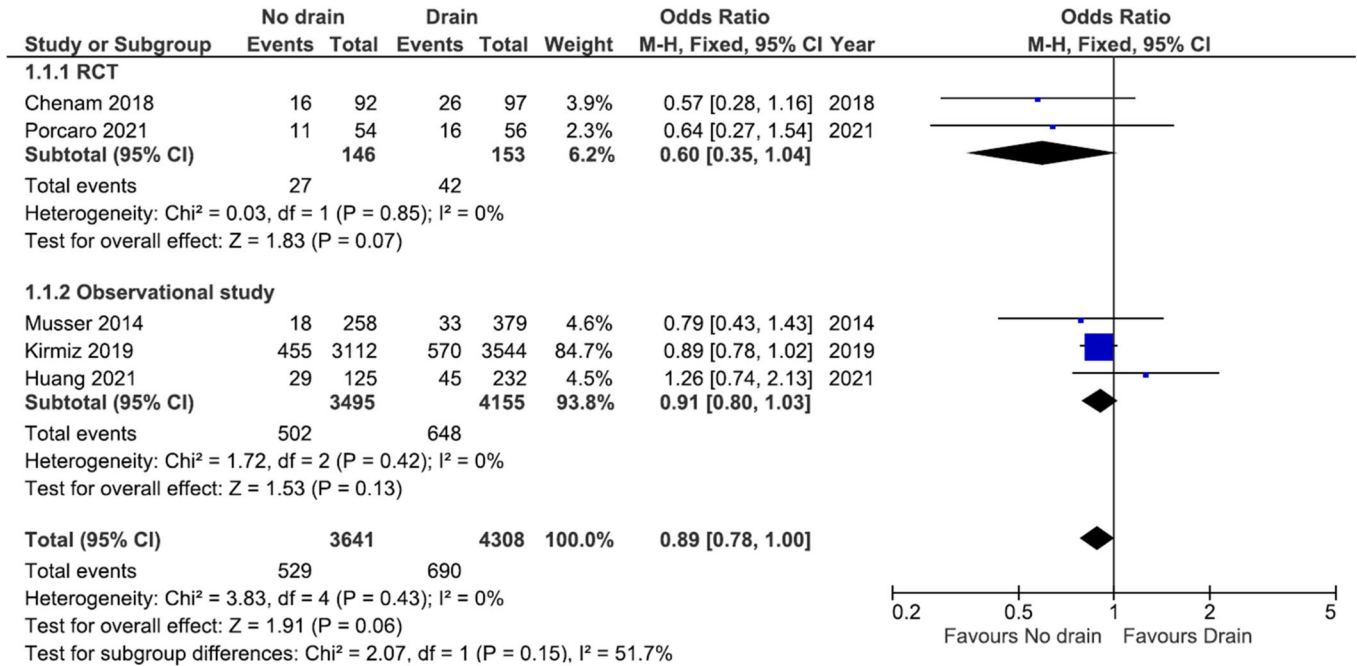
Two studies investigated the impact of early removal of UC on voiding parameters. Gratzke et al. [20], assessed the differential voiding parameters after UC removal in patients who had their UC removed at POD2 vs POD6. The authors reported that removal of the UC on POD6 was significantly associated with better maximum urinary flow rate (Qmax) (median [IQR] Qmax on POD2 10 [6–14] vs 21 [8–28] mL/s on POD6; $P < 0.001$) [20]. On the contrary, the authors reported that removal of UC on POD2 was significantly associated with better voided volume (median [IQR] voided volume on POD2 202 [146–315] vs 174 [131–307] mL on POD6; $P < 0.001$) [20]. On the other hand, Lista et al. [24], evaluated the differential voiding parameters at 30 days after RARP in patients who had their UC removed at POD3 vs POD5. The authors reported no difference in either median (IQR) Qmax, at 17 (5–35) on POD3 vs 18 (5–36) mL/s on POD5 ($P = 0.3$); or voided volume (median [IQR] on POD3 179 [14–467] vs 234 [36–596] mL/s on POD5; $P = 0.05$) at 30 days after RARP [24].

Discussion

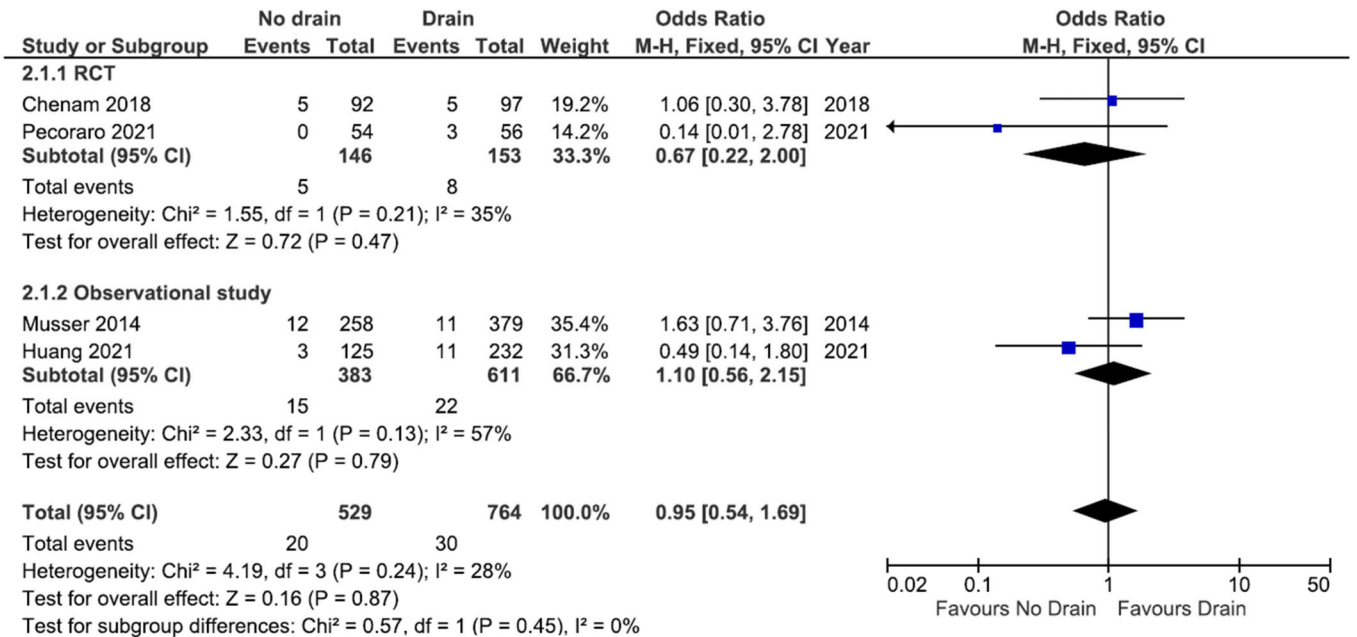
In this systematic review and meta-analysis, we found several significant findings regarding the perioperative management following RARP. First, our analyses revealed no differences in

Fig. 2 Forest plot showing association of postoperative complications with or without routine PD placement: (A) any complication, (B) severe complication, (C) any lymphocele, (D) symptomatic lymphocele, (E) ileus.

(A) Any complication



(B) Severe complication

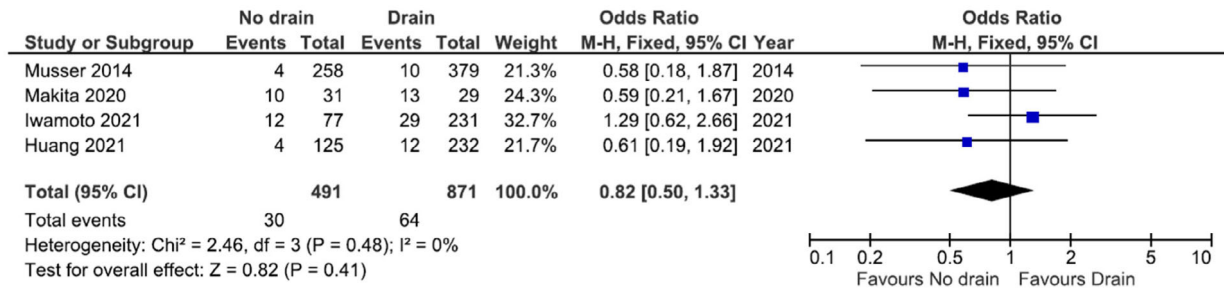


the incidence rates of all and severe complications and lymphoceles between patients who underwent RARP with or without routine PD placement. Second, although only one RCT revealed no difference in the incidence of ileus, our

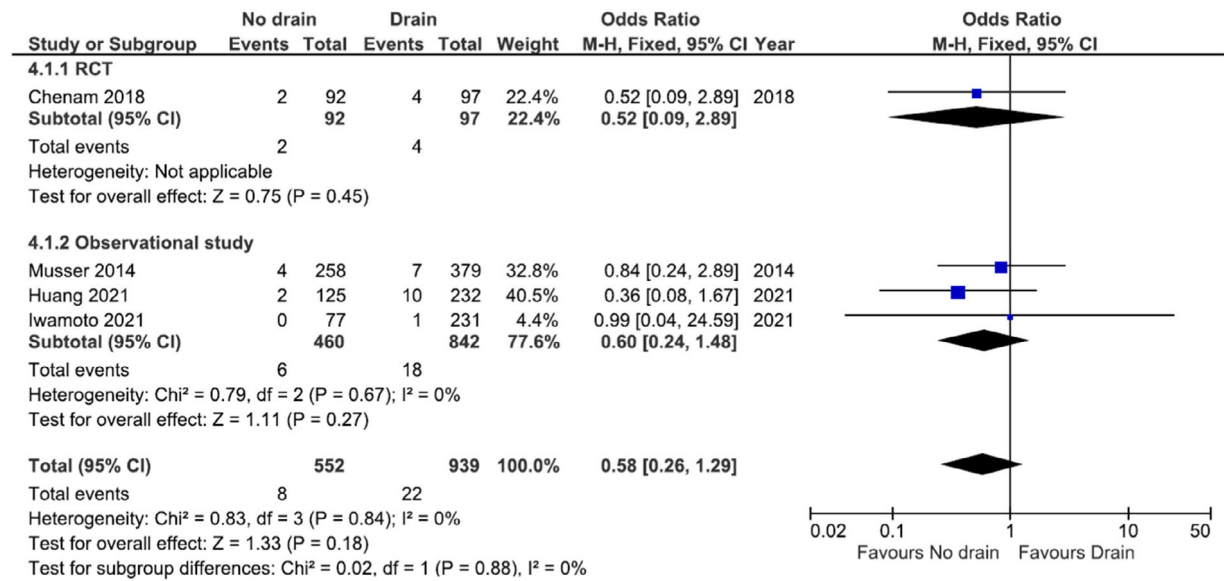
analysis, including observational studies, revealed that routine PD placement was associated with higher incidences of ileus in patients who had undergone RARP with routine PD placement compared to those without routine PD placement.

Fig. 2 Continued.

(C) Any lymphocele



(D) Symptomatic lymphocele



(E) Ileus

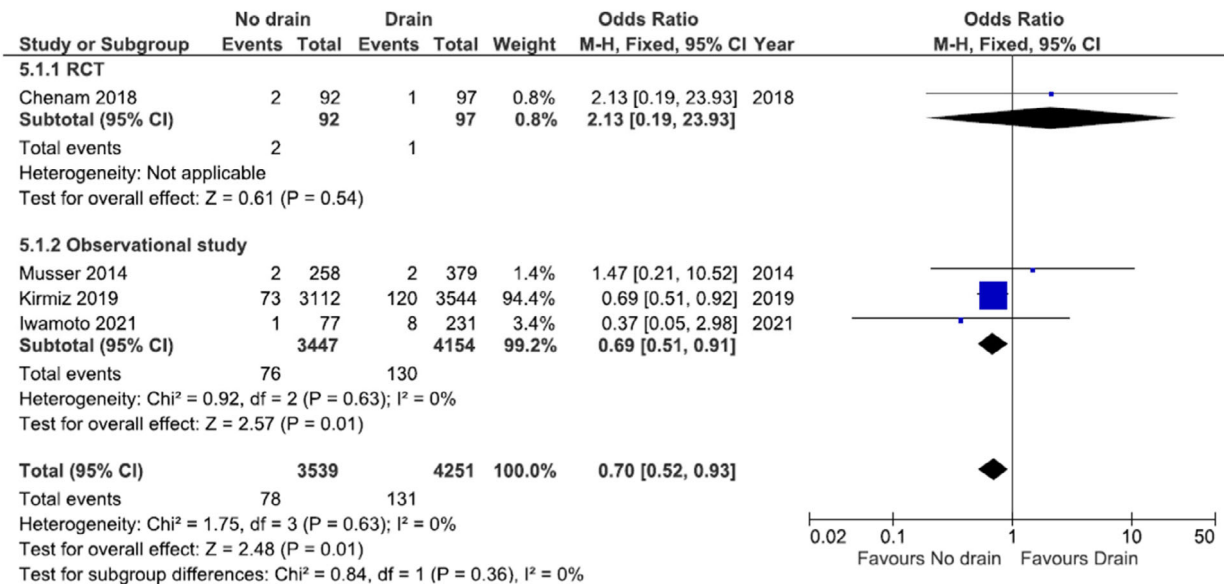


Table 2 Perioperative outcomes of included studies assessing outcomes in patients with or without early removal of urethral catheter.

Author	Number of patients			Retention		UTI		Anastomotic leakage	
	All	Early	Standard	Early	Standard	Early	Standard	Early	Standard
Khemees et al., 2013 [22]	1026	381 × POD3-4	645 × POD5	22/381	3/645	NA		3/380	6/646
Gratzke et al., 2016 [20]	74	37 × POD2	37 × POD6	4	3	NA		NA	
Alnazari et al., 2018 [19]	740	351 × POD4	389 × POD7	16	1	NA		7	
Lista et al., 2020 [24]	146	72 × POD3	74 × POD5	1	1	3	2	1	0
Lenart et al., 2020 [23]	425	194 × POD4	231 × POD7	25	5	11	16	34	35
Harke et al., 2021 [21]	198 (187)	TD5:64/SD5:63/SD2:60*		TD5: 2 SD5: 1 SD2: 2		NA			

Values are described as number, number (%), or *TD5, standard removal of urethral catheter at POD5; SD5, POD5 with suprapubic tube; SD2, POD2 with suprapubic tube. ePLND, extended PLND; NA, not applicable; POM, postoperative Month.

Third, in observational studies, early removal of UC was associated with higher rates of urinary retention, but not in the subgroup analysis of the two RCTs. In addition, there were no differences in the rates of anastomotic leakage and early continence between patients who underwent RARP with early vs standard removal of UC.

Since 1982, when Patrick Walsh proposed open retropubic RP, as a surgical approach for PCa, it has gained acceptance and widespread utility around the world [34]. Since then, the technique for the vesicourethral anastomosis has evolved from approximation to continuous suture. Recently, DaVinci® robot-assisted surgery has enabled surgeons to perform watertight anastomoses with a greater range of motion and a magnified three-dimensional high-definition view of the surgical field [35,36]. Two decades ago, in the open RP era, several clinical trials assessed the optimal duration of indwelling UC placement, comparing 7 vs 14 days with cystography confirmation of the absence of anastomotic urine leakage [37,38]. However, if the vesicourethral anastomosis is achieved in a watertight fashion, it has been demonstrated that the UC can be safely removed prior to POD7 [39,40]. In addition, the safety of omitting routine PD placement following RP has already been debated even in the open RP era [41,42]. The widespread use of RARP has ushered a rethinking of the standards after surgery for optimal perioperative management in order to decrease the burden and cost of unnecessary intervention, which might also lead to unnecessary complications.

Our analysis revealed no significant differences in the rates of all and severe complications, as well as lymphocele formation, between patients who had undergone RARP with or without

routine PD placement. In addition, most studies included demonstrated that omitting routine PD placement was associated with shorter hospitalisation compared to routine PD placement [27–31], leading to greater cost-effectiveness and treatment value.

Moreover, interestingly, we found that routine PD placement was associated with higher incidences of ileus in patients who had undergone RARP compared to those without routine PD placement. A large retrospective cohort study conducted by Kirmiz et al. [29] reported that routine PD placement was significantly associated with a higher rate of postoperative ileus on multivariable analysis. One explanation for this finding could be that PD placement may increase the usage of narcotic drugs to control the discomfort associated with the PD. Another explanation could be that the PD itself may directly cause some bowel irritation by lying adjacent to bowel. However, our analysis should be interpreted with care owing to being greatly affected by the result from a large cohort study conducted by Kirmiz et al. [29]. The only RCT which prospectively assessed the association of PD placement and postoperative ileus did not find any difference in the incidence of postoperative ileus, which might suggest a bias in the assessment of the impact of PD placement on the rates of postoperative ileus [25]. Therefore, as incidence rates of postoperative ileus are relatively low following RARP, RCTs with a higher number of patients are needed to draw a definitive conclusion.

Despite the comparable safety outcomes found in our study that suggest the feasibility of omitting routine PD placement in most RARP cases, selecting optimal candidates who should

Any complications		Severe complications		Hospitalisation, days		Continence at POM1		Continence at POM3	
Early	Standard	Early	Standard	Early	Standard	Early	Standard	Early	Standard
NA		NA		Retention Mean (SD): 1.0 (0.0) No retention Mean (SD): 1.02 (0.16) Median (IQR): 3 (3-4)		NA		NA	
36	36	0	2		Median (IQR): 6 (6-6)	NA		NA	
NA						0 Pad: 167/351 (14/16 in retention patients.)		0 Pad: 242/351 (15/16 in retention patients.)	
10	8	NA		Median (range): 4 (3-7)	Median (range): 6 (4-8)	Pad <1/day 51 (71)	Pad <1/day 57 (77)	NA	
NA						NA		NA	
						0 Pad TD5: 33% SD5: 41% SD2: 63%		0 Pad TD5: 69% SD5: 67% SD2: 80%	

have a PD placed (i.e., extended PLND) is of utmost of importance. Indeed, the rate and the extent of PLND differed across the included studies (Table 1). Only one of the included studies exclusively evaluated patients who underwent extended PLND [26]. This is a multi-arm study by Danuser et al. [26] that included patients who underwent retroperitoneal RP or RARP and showed comparable lymphocele rates between patients with or without PD. In addition, Chenam et al. [25] reported no differences in complication rates between limited vs extended PLND in patients who underwent RARP. Taken together, these findings support omitting routine placement of PD regardless of the extent of the PLND. However, further investigation is needed to identify the optimal patients who are likely to benefit from PD placement.

Regarding the timing of UC removal, our analyses revealed that early removal of UC was associated with higher rates of urinary retention among four observational studies, but not among two RCTs. Although acute urinary retention following RP seems to be a rare and minor complication, some previous studies have emphasised that acute urinary retention after UC removal is a potential risk for anastomotic stricture or bladder neck contracture in the open RP era [43,44]. However, Khemees et al. [22] reported that none of 25 patients with acute urinary retention developed anastomotic stricture or bladder neck contracture among a cohort of 1026 men who underwent RARP. As a rationale for the association between early UC removal and urinary retention, previous studies suggested that postoperative oedema, and/or increase in smooth muscle tone at the anastomosis, as well as haematoma as possible causes [22,45,46]. In addition, shorter

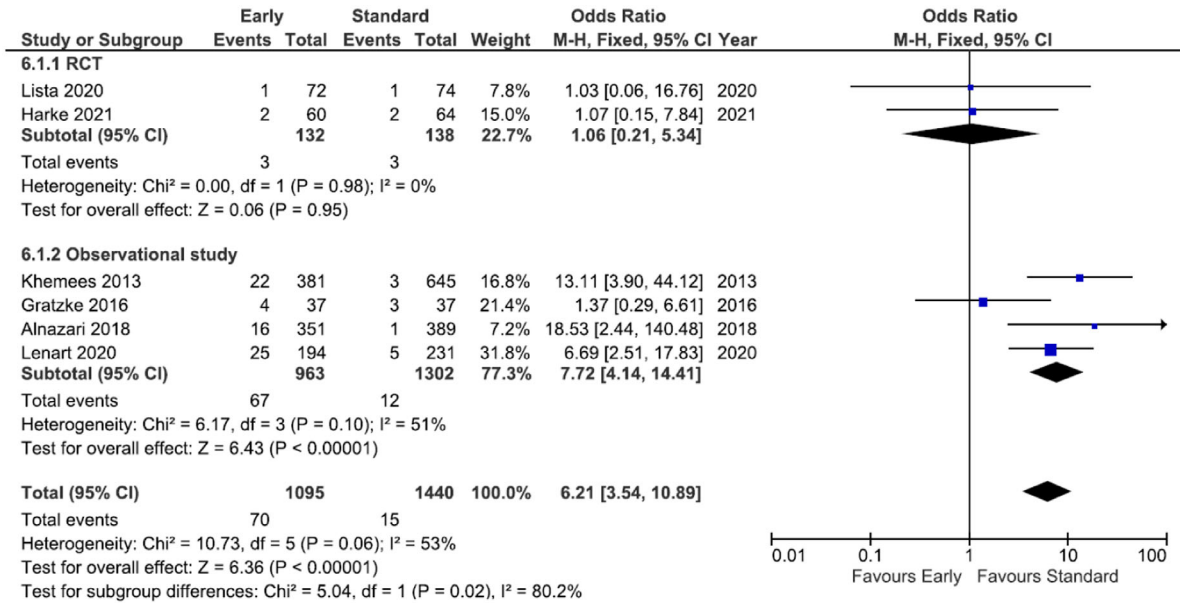
catheterisation theoretically increases the risk of anastomotic leakage, increasing the risk of subsequent anastomotic stricture. However, in our analyses, early UC removal following RARP was not associated with an increased risk of urinary retention among RCTs, and it was not associated with an increased risk of anastomotic leakage. Taken together, despite requiring careful assessment of the risk of urinary retention, early removal of UC seems to be safely feasible in patients who underwent RARP when a meticulous watertight anastomosis was achieved, and no other contraindications exist.

We also evaluated the impact of early UC removal on voiding outcomes. Our meta-analysis and systematic reviews revealed no differences between patients with or without early UC removal in the rate of continence, Qmax, and voided volume at 1 month after RARP. A recent RCT conducted by Harke et al. [21], assessing the long-term impact on urinary continence rates between early (POD2 with suprapubic tube) or standard (POD5 with/without suprapubic tube) UC removal revealed that early voiding significantly improved the continence rates at 1, 6 and 12 months after RARP. Taken together, at least, early UC removal seems not to worsen the functional outcomes. Further RCTs with a more significant number of patients are warranted to conclusively assess the impact of early UC removal on long-term urinary function.

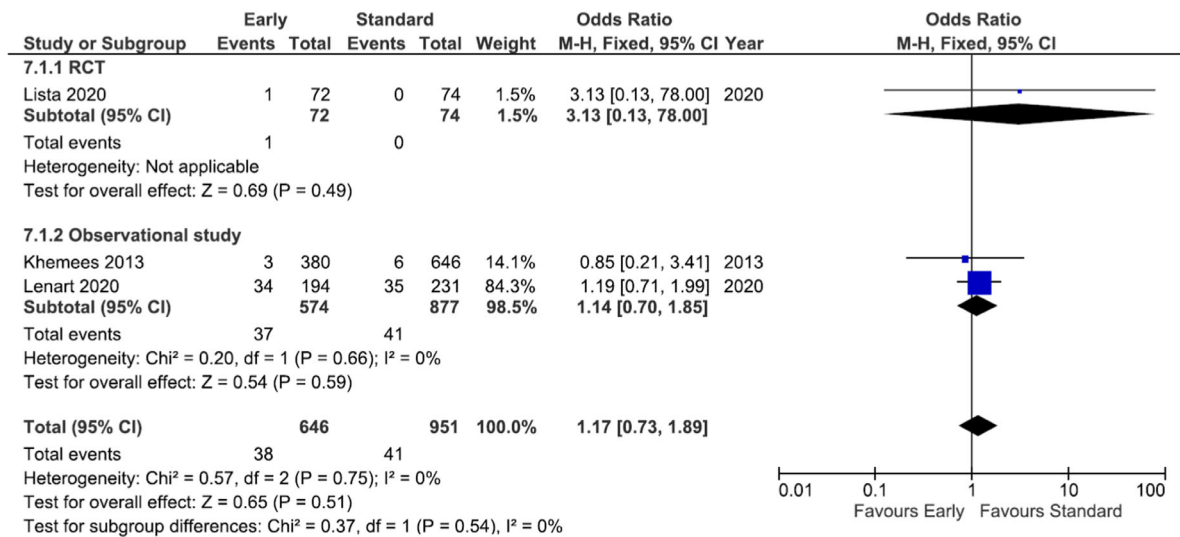
Despite these important findings regarding the clinical and functional impact of early UC removal following RARP, it remains unclear when the optimal timing for UC removal should be. Brassetti et al. [47] reported that 'super early' UC

Fig. 3 Forest plot showing association of postoperative complications and functional outcomes with early vs standard removal of UC: (A) urinary retention, (B) vesicourethral anastomotic leakage, (C) continence at 1 month after operation.

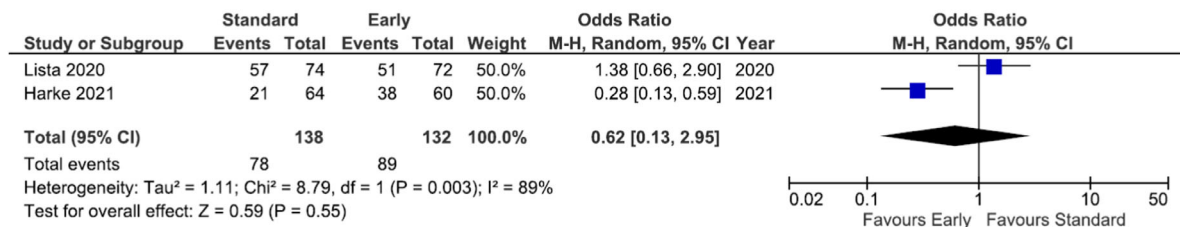
(A) Urinary retention



(B) Vesicourethral anastomotic leakage



(C) Continence at 1 month after operation



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removal was safe and feasible including 138 patients in a single-arm study. A prospective study conducted by Gratzke et al. [20] assessed the differential outcomes of early UC removal at POD2 vs POD6 following RARP without placement of a suprapubic tube. This study showed comparable outcomes between the two groups but suffered from a limited number of patients and a non-randomised study design [20]. The only RCT assessing the safety and functional outcomes of early UC removal at POD3 compared to POD5 showed no differences in perioperative complication rates, as well as functional outcomes, leading to a conclusion that early UC removal could improve health-related quality of life and be more cost-efficient [24]. To date, the safety, and equivalent functional outcomes of UC removal at POD3 has been proven by the RCT [24]; on the other hand, despite safety consensus regarding UC removal at POD2 being reported, RCTs with an adequate number of patients are warranted to reliably conclude the safety and functional value of early UC removal at POD2.

Our study has several limitations. First of all, the detailed principal or quality of procedures of RARP such as extended PLND, nerve-sparing, and vesicourethral anastomosis differed among studies depending on surgeon's experience and discretion; thus, procedural heterogeneity is inevitable. Specifically for the UC removal and consecutive outcomes, different techniques of vesicourethral anastomosis, as well as anatomical reconstruction, might affect the clinical or functional outcomes as a recent systematic review showed significant differences in continence rates, while there were no differences in anastomosis-related complications across the different reconstruction techniques [48]. To minimise bias due to retrospective studies, we analysed all outcomes of RCTs and observational studies separately. However, heterogeneity was detected in the analysis of continence at 1 month after operation, owing to a limited number of included studies for this analysis. Although the random effect model was used to address heterogeneity among the evaluated studies, these results should be interpreted with care. Second, most RCTs have a high risk of bias, mainly owing to their unblinded nature based on the procedural trial (i.e., the surgeon decided final eligibility for PD placement after vesicourethral anastomosis in one RCT) [25]. In addition, the two RCTs regarding early UC removal assessed the differential postoperative outcomes between UC removal at POD2–3 vs POD5 [21,24]. These slight time differences (i.e., 48 h difference) between the two groups compared to observational studies might underestimate the absolute differential complication rates. Therefore, our results, as well as results from each RCT should be interpreted with care. Further well-designed RCTs with adequate numbers of patients are warranted. Third, instead of UC, the suprapubic tube following RARP has been shown to reduce pelvic pain [49]. However, to date, no study has

assessed the impact of early removal of a suprapubic tube; therefore, further studies are needed. Fourth, only six of the 14 studies used the Clavien–Dindo classification for reporting complications. Furthermore, only one study reported the number of detailed complications stratified by the Clavien–Dindo classification, preventing the performance of subgroup analysis. Standardisation of reporting complications in urological surgery is another critical issue. Finally, as previously mentioned, we did not perform a formal meta-analysis for LOS in patients with or without routine PD placement owing to different practice patterns between countries and different forms of reporting. However, in our review, most studies showed that routine PD placement was significantly associated with a longer LOS. As it was reported that an enhanced recovery after surgery (ERAS) protocol reduced LOS and time to PD removal in RARP [50], incorporating non-routine PD placement with an ERAS protocol may provide optimal patient care in cost-saving environments.

Conclusions

Our analyses suggest that routine PD can safely be omitted following most RARP procedures. Routine PD placement was even associated with a higher risk of postoperative ileus in observational studies. However, further investigation with more patients is needed to clarify the optimal candidates who are most likely to benefit from PD placement. Early UC removal seems to be as safe as standard UC removal with postoperative functional outcomes; however, early detection of urinary retention is needed when UC is removed early. We hope that our findings will help guide the standardisation of the management of PD placement and UC removal following RARP, providing optimal patient care and cost-effective management.

Author Contributions

Takafumi Yanagisawa contributed to protocol/project development, data collection and management, data analysis, and manuscript writing/editing. Tatsushi Kawada contributed to data analysis and manuscript writing/editing. Hadi Mostafaei, Reza Sari Motlagh, Fahad Quhal, Ekaterina Laukhtina, Pawel Rajwa, Markus von Deimling, Alberto Bianchi, Maximilian Pallauf, and Benjamin Pradere contributed to manuscript writing/editing. Pierre I. Karakiewicz, Jun Miki, and Takahiro Kimura contributed to supervision and manuscript editing. Shahrokh F. Shariat contributed to supervision, protocol/project development/management and manuscript editing.

Acknowledgement

None.

Funding

No external funding provided. European Urological Scholarship Programme (EUSP) Scholarship of the European Association of Urology to Pawel Rajwa.

Disclosure of Interests

Takahiro Kimura is a paid consultant/advisor of Astellas, Bayer, Janssen and Sanofi. Shahrokh F. Shariat received follows: Honoraria: Astellas, AstraZeneca, BMS, Ferring, Ipsen, Janssen, MSD, Olympus, Pfizer, Roche, Takeda. Consulting or Advisory Role: Astellas, AstraZeneca, BMS, Ferring, Ipsen, Janssen, MSD, Olympus, Pfizer, Pierre Fabre, Roche, Takeda. Speakers Bureau: Astellas, AstraZeneca, Bayer, BMS, Ferring, Ipsen, Janssen, MSD, Olympus, Pfizer, Richard Wolf, Roche, Takeda. The other authors declare no conflicts of interest associated with this manuscript.

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Abbreviations: ERAS, enhanced recovery after surgery; ICIQ-MLUTS, International Consultation on Incontinence Questionnaire-male lower urinary symptoms; IQR, interquartile range; LOS, length of hospital stay; OR, odds ratio; PCa, prostate cancer; PD, pelvic drain; PLND, pelvic lymph node dissection; POD, postoperative Day; RCT, randomised controlled trial; (RA)RP, (robot-assisted) radical prostatectomy; UC, urethral catheter.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Search strategy for meta-analysis.

Appendix S2. The list of all potentially relevant articles ($n = 55$).

Appendix S3. AMSTAR2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both.

Fig. S1. PRISMA checklist 2009.

Fig. S2. Risk of bias assessment of the included randomised controlled trials.

Fig. S3. Funnel plot of association of postoperative complications with versus without routine pelvic drain placement: (A) any complication, (B) severe complication, (C) any lymphocele, (D) symptomatic lymphocele, (E) ileus.

Fig. S4. Funnel plot of association of postoperative complications or incontinence with early versus standard removal of urethral catheter: (A) urinary retention, (B) vesicourethral anastomotic leakage, (C) continence at 1 month after operation.

Table S1. Risk of bias assessment for non-RCTs (ROBINS-I).

Table S2. Study demographics of included studies assessing postoperative outcomes in patients with or without routine PD placement.

Table S3. Study demographics of included studies assessing outcomes in patients with or without early removal of UC.