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REVIEW ARTICLE

Suprapubic tube compared with urethral catheter drainage after robot-assisted radical prostatectomy: A systematic review and meta-analysis

Mei-xuan Li [a,b,c,1], Peng Cheng [e,1], Liang Yao [c,d], Hui-juan Li [a,b,c], Yang-qin Xun [a,b,c], Pei-jing Yan [c,d], Cai-wen Han [d,f], Cun-cun Lu [b,c], Wen-bo He [a], Meng Wang [a], Rong Liu [g], Tian-kang Guo [d,**], Ke-hu Yang [b,c,*]

[a] School of Public Health, Lanzhou University, Lanzhou, China
[b] Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China
[c] Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, China
[d] Gansu Province People's Hospital, Lanzhou, China
[e] Department of Orthopedics, The Second Hospital of Lanzhou University, Lanzhou, China
[f] School of Clinical Medical Sciences, Gansu University of Traditional Chinese Medicine, Lanzhou, China
[g] The Second Department of Hepatobiliary Surgery, Chinese PLA General Hospital, Beijing, China

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Bladder drainage

Summary This meta-analysis aimed to compare the effectiveness of the suprapubic drainage and urethral catheterization after robot-assisted radical prostatectomy (RARP). PubMed, EMBASE, Cochrane Library and China Biology Medicine disc were systematically researched from their inception to December 2017. We selected randomized controlled trials, cohort studies comparing suprapubic tube with urethral catheter drainage in RARP patients. A meta-analysis was performed using R software, and a random-effects model was used to pool the effect size. Ten studies met eligibility criteria (N = 1248), including 3 RCTs, 3 prospective studies and 4 retrospective studies. Suprapubic drainage was associated with a reduction in the penile pain (39.64% [44 of 111]) compared with the UC group (62% [106 of 171]) (pooled RR 0.57, 95%

* Corresponding author. Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, 199 Donggang West Road, Lanzhou, China.
** Corresponding author. Department of General Surgery, Gansu Province People's Hospital, 204 Donggang West Road, Lanzhou, China.
E-mail addresses: 2370632263@qq.com (T.-k. Guo), kehuyangebm2006@126.com (K.-h. Yang).
[1] Co-first author.

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CI 0.31 to 1.02, $P = 0.05$). However, two groups showed similarity in the overall pain (Postoperative days 1—3: pooled MD −0.26, 95% CI 1.34 to 0.83, $P = 0.64$; Postoperative days 6—7: pooled MD −0.50, 95% CI −1.54 to 0.54, $P = 0.34$), urinary incontinence (pooled RR 0.80, 95% CI 0.56 to 1.15, $P = 0.23$), bladder neck contracture (pooled RR 0.77, 95% CI 0.39 to 1.53, $P = 0.45$), urinary retention (pooled RR 0.88, 95% CI 0.29 to 2.70, P = 0.82), anastomotic stricture (P = 0.15), urethral stricture (P = 0.84) and bacteriuria (P = 0.40). The present meta-analysis showed that suprapubic drainage may be associated with less penile pain, but there was no conclusive evidence that suprapubic drainage was advantaged in other outcomes. Due to the low quality and small quantity of the available comparative studies, more high-quality randomized trials are needed to provide stronger evidence of the benefits of the two routes.

1. Introduction

As a result of increasing rates of clinically localized disease and adoption of minimally invasive surgical techniques, the number of radical prostatectomy (RP) has rapidly increased with almost 80,000 surgeries performed annually in the United States and a 25-fold increase in other countries since the adoption of prostate specific antigen (PSA) screening.[1,2] RP is considered the gold standard for treatment of prostate cancer,[3] and over the last several years robot-assisted radical prostatectomy (RARP) has continued to gain preeminence globally.[4] The demand for RARP has increased because it better defined surgical anatomy and improved surgical maneuverability.[5]

However, there is still a controversial issue about drainage routes after RARP. Two commonly used routes for bladder catheterization in RARP are suprapubic region and urinary passage. UC is a traditional way used for bladder drainage and can prevent anastomotic stricture.[6] But plenty of patients complained about discomfort caused by their urethral catheterization (UC) during postoperative catheterization periods. Two randomized clinical trials (RCTs) and several prospective studies have shown the UC-associated discomfort, especially penile pain is a common postoperative complaint expressed by the patients.[7—13] Some primary studies indicated that the use of SPT could replace UC for postoperative drainage after RARP.[11,13—17] It has been shown to provide bladder drainage that is comparable to UC with potentially less penile pain and discomfort.

The original studies got inconsistent conclusions on whether SPT can replace UC, a randomized clinical trial[18] found no significant difference ($P = 0.4$) in postoperative pain, catheter related bother and treatment related satisfaction in a small sample ($N = 58$) of patients receiving either SPT or UC after RARP. They concluded that the SPT might be an unnecessary additional procedure that offers no benefit for patients, thus they stopped offering it to their patients.

These heterogeneous results make it difficult to draw conclusions on the effectiveness of SPT for RARP, used as an add-on or alternative to UC. This meta-analysis aims, therefore, to clarify such uncertainty with an emphasis on postoperative pain, urinary incontinence, bladder neck contracture, urinary retention, anastomotic stricture, urethral stricture, bacteriuria.

2. Methods

2.1. Search strategy and selection criteria

2.1.1. Search strategy

The systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[19] Following databases were systematically researched: PubMed, EMBASE, Cochrane Library and China Biology Medicine disc (CBM), with the restrictions of humans from their inception to December 2017. We did free texts terms and Mesh searches for "prostatic neoplasms", "prostatic cancer", "Prostatectomy", "robot*", "telerobotics" "Computer-Assisted", "remote operations", We also did keyword research for "suprapubic catheter", "urethral catheter", "transurethral catheterization", "suprapubic tube", "transurethral tube". In addition, we checked reference lists of relevant reviews for additional studies to ensure comprehensive data collection. (Specific search strategy was summarized in appendix 1). Finally, we transferred all relevant titles and abstracts to Endnote Web for selection.

2.1.2. Selection criteria

Two authors (HJ-L and YQ-X) independently screened all titles and abstracts of retrieved citations, evaluated potential full texts, and determined eligibility. Disagreements were resolved through discussion and consensus, or by consulting a third member (L-Y) of the review team. Studies were eligible for inclusion had to follow the following criteria: (1) Conducted on human subjects. (2) Focused on patients only with robot-assisted radical prostatectomy. (3) Suprapubic tube compared with urethral catheterization. (4) The study included at least one quantitative outcome data (overall pain, penile pain, urinary incontinence, bladder neck contracture, urinary retention, anastomotic stricture, urethral stricture, bacteriuria.) We excluded review articles, editorials, comments, and non-relevant topic studies.

2.2. Data extraction and quality assessment

Two reviewers (MX-L and CW-H) independently extracted the relevant data from all the included studies using a standardized, predesigned extraction form in Microsoft Excel 2010. The extracted information included study characteristics (First author, Country, Year of publication, Study design, The number of study participants, Age, Body Mass Index (BMI), Time for removal of UC and SPT, Continence definition, Follow-up time, Operative time, Pain assessed tools) and outcomes (overall pain, penile pain, urinary incontinence, bladder neck contracture, urinary retention, anastomotic stricture, urethral stricture, bacteriuria). If information was unclear or missing, we contacted the original authors by e-mail.

Two authors (MX-L and CC-L) independently assessed the quality of included studies. RCTs were evaluated using the Cochrane Collaboration's tool,[20] focusing on Randomization, Allocation concealment, Blinding of participants and outcome assessment, Incomplete outcome data and reporting bias. Non-RCT were evaluated according to criteria developed by the Newcastle—Ottawa Scale (NOS)[21] which is widely used for cohort study assessment. The items included: Representativeness of the SPT and UC, Ascertainment of exposure, Demonstration that outcome of interest was not present at start of study, Comparability of cohorts on the basis of the design or analysis, Assessment of outcome, Whether follow-up was long enough for outcomes to occur, Adequacy of follow up of cohorts. Any disagreement was resolved via discussion among the author group.

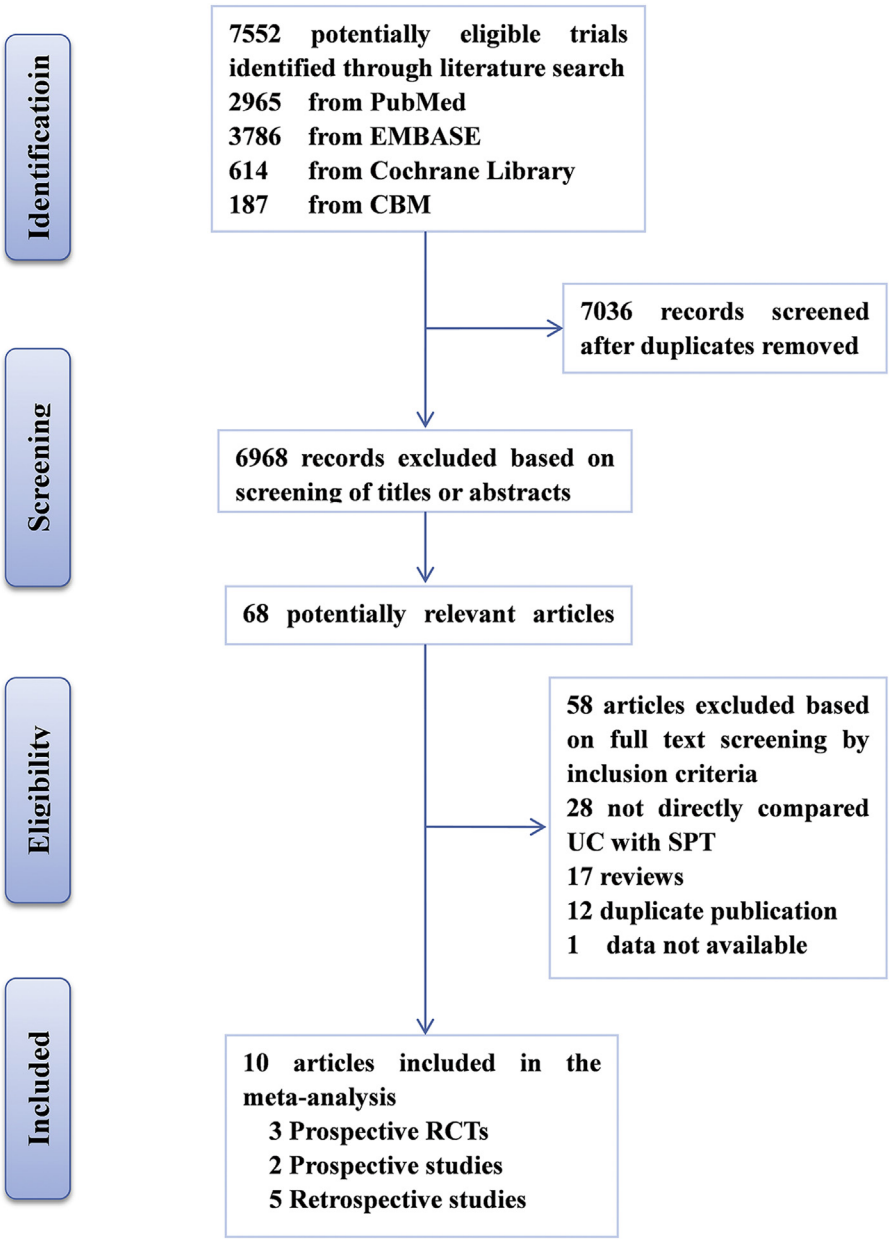

Figure 1 Flowchart of the meta-analysis.

Table 1 Characteristics of studies included in the meta-analysis.

First author	Country	Study design	No.of patients		Age, years median/mean		BMI,kg/m^2 median/mean	
			UC	SPT	UC	SPT	UC	SPT
Martinschek[13] 2016	Germany	Prospective RCT	35	27	62.99	64.97	NA	NA
Monica[6] 2015	US	Retrospective	94	65	64 (57–69)	62 (56–67)	28 (26–31)	27 (25–31)
Harke[11] 2016	Germany	Prospective RCT	80	80	63.1 (45–76)	62.3 (45–74)	26.2 (20.9–38)	25.6 (16.3–36)
krane[29] 2012	US	Retrospective	202	50	58 (41–76)	60 (46–75)	28 (19–41)	27 (19–38)
Afzal[28] 2015	US	Retrospective	174	51	63.7 ± 7.0	61.9 ± 6.9	29.6 ± 4.0	29.7 ± 5.0
Sandip[18] 2014	US	Prospective RCT	29	29	57.7 ± 8.6	60.0 ± 6.4	29.0 ± 4.0	28.8 ± 3.3
Tewari[26] 2008	US	Prospective	10	20	60.8 (52.8–67.3)	60.0 (55.8–66.3)	26.1 (22.9–33.2)	27.3 (23.1–34.2)
Yang[12] 2015	China	Prospective	10	10	68.5 (61 ± 74)	64.6 (49 ± 74)	25.16 (22.14 ± 29.35)	23.83 (19.26 ± 27.97)
Galfano[25] 2016	Italy	Prospective	65	124	65	65	NA	NA
Morga[27] 2014	US	Retrospective	57	36	NA	NA	NA	NA

UC: urethral catheter; SPT: suprapubic tube; NA: not available; POD: postoperative days; RCT: randomized controlled trial.

And studies achieving six or more points were considered to be of high quality.

2.3. Statistical analysis

This meta-analysis was performed using the R software (R x64 3.4.2, The Cochrane Collaboration, oxford, UK). Guidance was sought from the Cochrane handbook as well as some high quality articles[22,23] from published journals to provide the framework for the statistical analysis. Dichotomous variables were evaluated using risk ratio (RR) with 95% confidence intervals (95% CIs). Continuous variables were analyzed using mean differences (MDs) and 95% CIs. When studies reported on medians, ranges or P values for continuous variables, statistical algorithms were used to derive the appropriate means and standard. A random effects model was used for pooling studies, because it takes into account the almost inevitable natural variation inherent between studies, especially great use for conducting surgical research.[24] That is because surgical populations are inherently heterogeneous, patients have different levels of comorbidities, and surgeons often undertake similar procedures in different ways, introducing unavoidable clinical heterogeneity. Meta-analyses of binary variables were performed using the Mantel-Haenszel method, and those of continuous variables were conducted using the inverse variance method. Heterogeneity was assessed through Cochran Q test and I^2 tests. Subgroup analyses were conducted according to time of overall pain [postoperative day (POD) 1–3, POD 6–7] and study type (RCT and non-RCT) were performed.

3. Results

3.1. Literature search

The literature search yielded 7552 reports, of which 516 were excluded because of duplication, and 6968 were excluded on the basis of title or abstract that was irrelevant to the topic, and 58 were excluded from the remaining 68 literatures after reading the full text. Therefore, data from ten studies, of which 3 randomized controlled trials,[11,13,18] 3 prospective trials[12,25,26] and 4 retrospective studies[6,27–29] were included in this systematic review. Of a total 1248 men, 482 were distributed to SPT group and 766 were distributed to UC group. The results of the search are summarized in Fig. 1.

3.2. Study characteristics

The baseline and general characteristics of the included studies were extracted and listed in Table 1. The 10 studies were all published in English between 2008 and 2016, and the study samples ranged from 20 to 252 participants. Six studies[6,18,26–29] were performed in US, two studies[11,13] were performed in Germany, one study[25] were performed in Italy, and one study[12] were performed in China. Studies measured pain with VAS or NRS or ASA scale.

3.3. Quality assessment results

The summary of risk of bias in the non-RCTs are shown in Table 1, RCTs are shown in Table 2. In the evaluation of the RCTs, random sequence generation was unclear in all three trials, concealment of allocation to group were unclear in two trials,[13,18] one study[11] was rated as low risk. With regard to blinding, only one study[18] reported that they did not blind patients, other two studies[11,13] were unclear. Outcome data and selective reporting bias were considered as low risk in all three trials, because of objective outcome measures or patient reported outcomes using valid and reliable questionnaires. With regard to non-RCTs, all studies achieved six or more points, which were considered to be of high quality.

3.4. Postoperative pain

3.4.1. Overall pain

Postoperative pain in the original studies included overall pain and penile pain. 8 trials reported the overall pain, however, 3 trials[6,11,27] measured pain with NRS or ASA scale and did not report SDs, so could not be included in meta-

Time for removal of UC and SPT		Continence definition	Follow-up, months		Operative time, minutes		Pain assessed tools	Quality score
UC	SPT		UC	SPT	UC	SPT		
NA	NA	NA	12	12	NA	NA	VAS	8
POD7—10	POD9—10	NA	>3	3.6	177 (157—204)	230 (220—247)	questionnaire	RCT
POD 5	NA	0-1pad/day	22	22	151	152	NRS	RCT
POD7	POD 7	0-1pad/day	7	7	171	165	VAS	7
POD8	POD 6—9	0-1pad/day	1.5	1.5	NA	NA	NA	6
POD7	POD 7	NA	12.8	12.8	199.1 ± 36.0	224.1 ± 28.5	VAS	RCT
POD 7	POD 7	0-1pad/day	6	6	NA	NA	questionnaire	8
POD 7	POD 7	NA	3	3	102 (70 ± 120)	105 (80 ± 160)	VAS	8
POD 7	POD 7	NA	12	12	NA	NA	VAS-NAS	7
POD 7-10	POD 9-11	NA	2.8	2.8	173.8	223.1	questionnaire	6

analysis. Two of them concluded that patients in the SPT group had significantly less overall pain compared to the UC group,[11,27] while one of them[6] reported that there was no difference between the two groups. The other 5 trials[12,13,18,25,29] were included in the meta-analysis, of which pain was measured with VAS and data was reported by the mean ± SD. In POD 1—3, a random-effect meta-analysis yielded MD of −0.26 (95% CI −1.34 to 0.83, $P = 0.64$). In POD 6—7, a random-effect meta-analysis yielded MD of −0.50 (95% CI: −1.54 to 0.54, $P = 0.34$). No difference was in the two groups between RCTs and non-RCTs (Figs. 2 and 3). The test for heterogeneity was significant ($I^2 > 90\%$).

3.4.2. Penile pain

Only four trials[6,12,26,27] addressed penile pain as a specific outcome, but one study[12] reported the data using continuous variables. The study reported that SPT group had significantly less penile pain in POD 3 and POD 7 (mean VAS: 0.9 vs 2.2, $P < 0.001$ at POD 3; 0.1 vs 1.4, $P = 0.002$ at POD 7). We just pooled the other three studies,[6,26,27] which reported their data with binary variables. A random-effect analysis was performed. In RCT group, no difference was found between SPT and UC (pooled RR 0.46, 95% CI 0.14 to 1.50, $P > 0.05$, $I^2 = 73\%$). The result of non-RCT group was consistent with RCT group (pooled RR 0.61, 95% CI 0.24 to 1.56, P > 0.05). On the whole, SPT was associated with a significant reduction in the penile pain (39.64% [44 of 111]) compared with the UC group (62% [106 of 171]) (pooled RR 0.57, 95% CI 0.31 to 1.02, $P = 0.05$, $I^2 = 47\%$; Fig. 4).

3.5. Postoperative complications

3.5.1. Urinary incontinence

Six studies[11,13,25,26,28,29] specifically reported on the urinary incontinence in each group. Urinary incontinence was measured by pad usage within a year of surgery. The RCT group and non-RCT group showed similar results. There was no significant difference between the SPT group (10.36% [49 of 473]) and the UC group (17.06% [72 of 422]) (pooled RR 0.80, 95% CI: 0.56 to 1.15, $P = 0.23$, $I^2 = 0$) (Fig. 5).

3.5.2. Bladder neck contracture

Six trials[6,12,26—29] reported specific data for the bladder neck contracture associated with each intervention. Overall, no significant difference was found between SPT group (13.9% [52 of 374]) and the UC group (21% [85 of 405]) (pooled RR 0.77, 95% CI 0.39 to 1.53, $P = 0.45$) (Fig. 6).

3.5.3. Urinary retention

Four trials[13,25,28,29] provided sufficient data about urinary retention. Both RCT group and non-RCT group indicated that there was no significant difference between the SPT group (2.48% [10 of 404]) and the UC group (3.4% [11 of 324]) (pooled RR 0.88, 95% CI 0.29 to 2.70, $P = 0.82$, $I^2 = 33\%$) (Table 3).

3.5.4. Urethral stricture

Three trials[11,12,29] reported urethral stricture. There was no significant difference between the SPT group (0.37% [1 of 271]) and the UC group (0.72% [1 of 138]) (pooled RR 1.32, 95% CI 0.08 to 20.7, $P = 0.84$) (Table 3).

3.5.5. Anastomotic stricture

Five trials[6,11,13,25,29] reported anastomotic stricture. In RCT group, no difference between SPT and UC (pooled RR 0.18, 95% CI 0.01 to 4.24), which was similar to non-RCT group. Overall, there was no significant difference between the SPT group (0% [0 of 476]) and the UC group (0.95% [3 of 316]) (pooled RR 0.20, 95% CI 0.02 to 1.76, $P = 0.15$, $I^2 = 0$) (Table 3).

3.5.6. Bacteriuria

Only two trials[11,29] addressed bacteriuria as a specific outcome. A random-effect analysis was performed, there was no significant difference was found between the SPT group (2.3% [6 of 261]) and the UC group (6.3% [8 of 128]) (pooled RR 0.61, 95% CI 0.19 to 1.96, $P = 0.40$) (Table 3).

Table 2 Risk of bias assesment (RCTs).

作者	年份	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Harke	2016	unclear risk	low risk	unclear risk	unclear risk	low risk	low risk	low risk
Martinschek	2016	unclear risk	unclear risk	unclear risk	unclear risk	low risk	low risk	low risk
Sandip	2014	unclear risk	unclear risk	high risk	low risk	low risk	low risk	low risk

3.6. Subgroup analysis

The subgroup analyses did not show any significant differences within subgroups based on overall pain, urinary incontinence, urinary retention, urethral stricture, anastomotic stricture, bacteriuria.

4. Discussion

Our systematic review and meta-analysis demonstrated that SPT might be more comfortable than UC after RARP, with a possible advantage concerning penile pain. While there was no significant difference between the groups about overall pain, urinary incontinence, bladder neck contracture, urinary retention, anastomotic stricture, urethral stricture, bacteriuria.

A previous Cochrane review[30] had discussed SPT versus UC in patients, they found that there was insufficient evidence to determine whether SPT was effective than UC. However, the scope of the Cochrane review was broad, including studies on both male and female populations, and they did not consider specific diseases. This could introduce unavoidable clinical and statistical heterogeneity, which may influence reliability of results. So it is necessary and important to assess whether SPT can replace UC in the context of specific diseases. We performed the meta-analysis to discuss the two drainage routes for patients after RARP.

The primary postoperative parameters evaluated to compare SPT with UC were postoperative pain included overall pain and penile pain. All trials used pain scoring systems, with the number of patients and days of pain being recorded in a systematic manner. 8 eligible trials provided overall pain data, of which 2 trials[6,27] measured pain with ASA scale, 1 trial[11] measured with NRS scale. 5 trials[12,13,18,25,29] measured with VAS scale, so we just pooled the five trials. Subgroup analysis was performed according to the time of pain (POD 1—3 and POD 6—7) and study type respectively, the data collected from the comparative studies presented no significant difference between the groups. There was obvious heterogeneity, indicated by the I^2 test. It may because surgical populations are inherently heterogeneous, patients have different levels of comorbidities, and surgeons often undertake similar procedures in different ways, introducing unavoidable statistical and clinical heterogeneity.[31]

With regard to penile pain, only four trials[6,12,26,27] addressed penile pain as a specific outcome. The four studies reached a consistent conclusion that using of SPT was associated with a significant reduction in the penile pain compared with the UC group. However, although all of them used pain scoring systems, one study[12] expression of continuous variables, three studies[6,26,27] reported their data using binary variables. This may lead to statistical heterogeneity. It is difficult to draw robust conclusions from such a small sample and we must confirm the conclusion in larger studies in the future.

Urinary continence is also one of the common complications, we found there was no significant difference between the SPT and the UC group, presumably as any factors that may have influenced early continence will probably

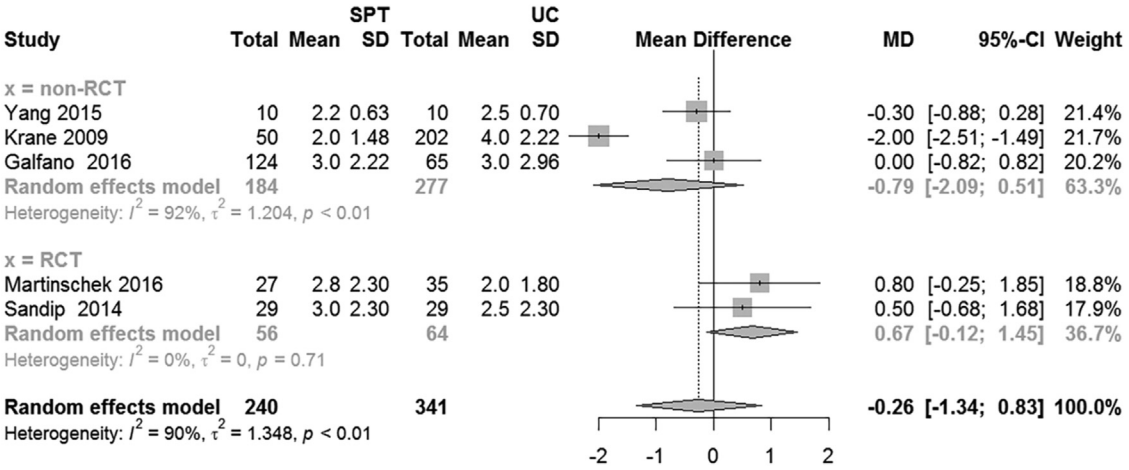

Figure 2 Forest plot of overall pain in POD 1—3.

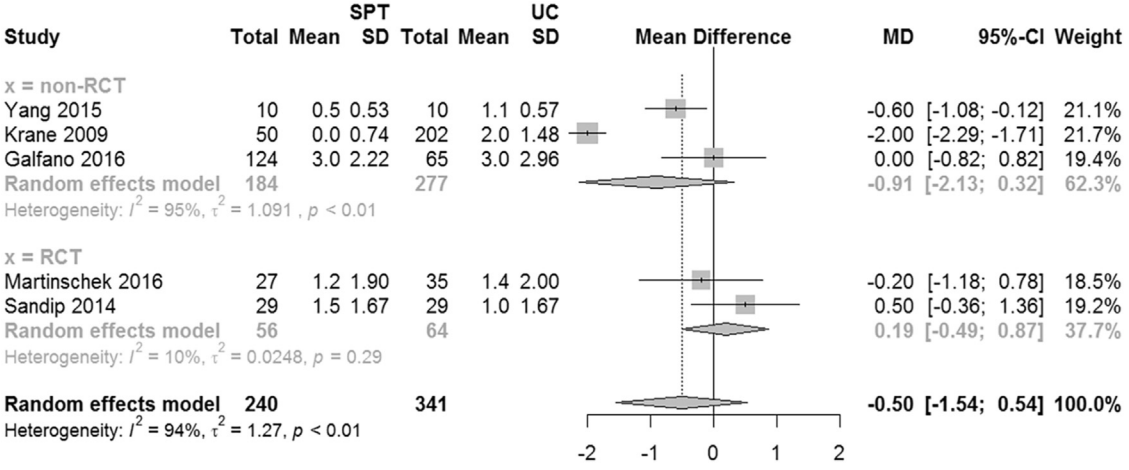

Figure 3 Forest plot of overall pain in POD 6—7.

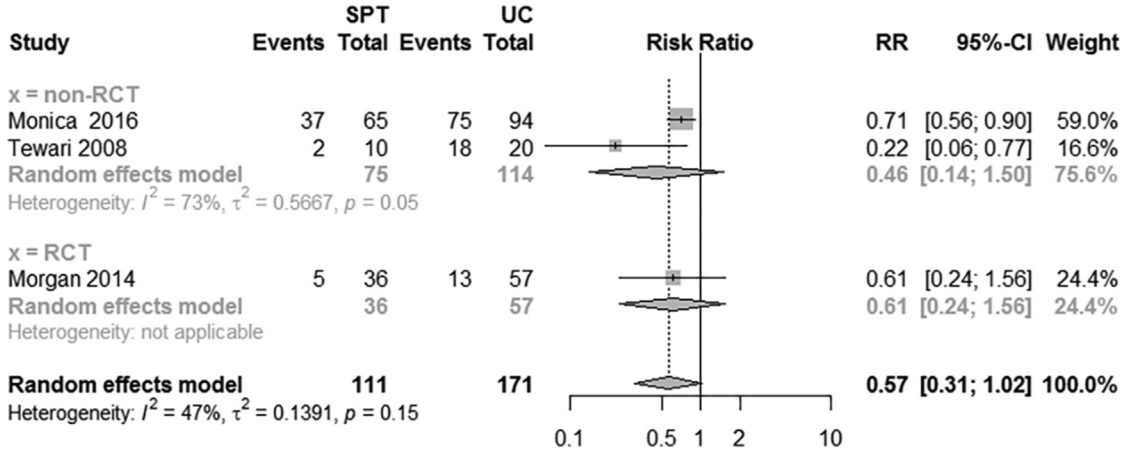

Figure 4 Forest plot of penile pain.

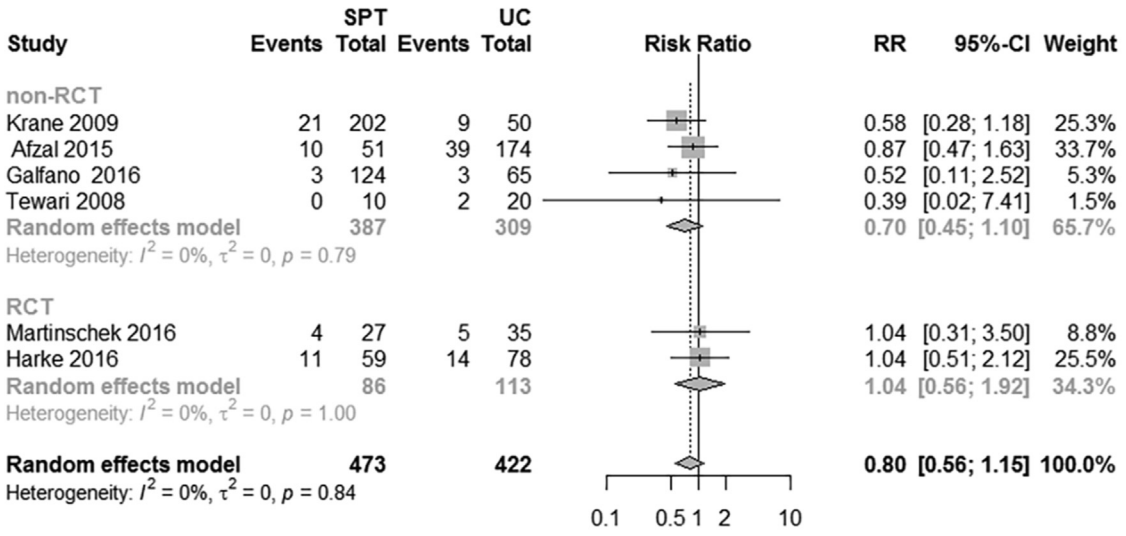

Figure 5 Forest plot of urinary incontinence.

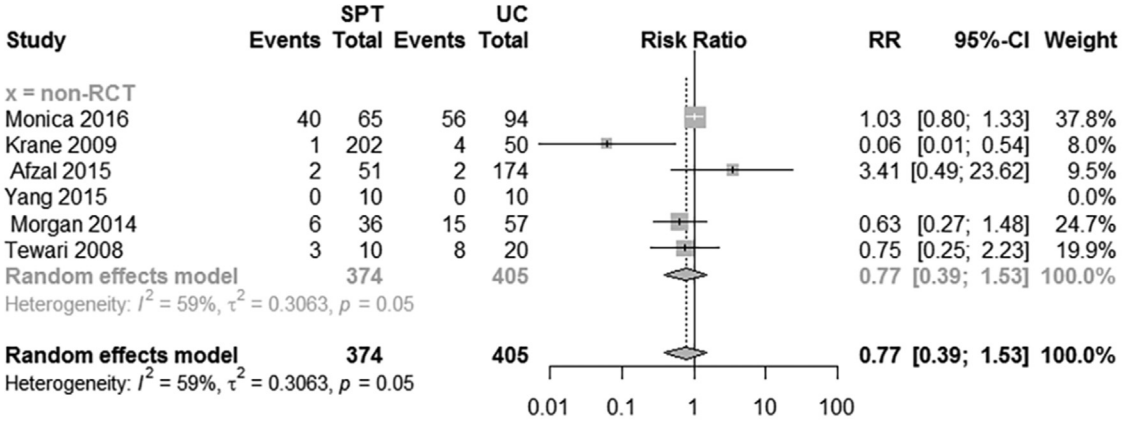

Figure 6 Forest plot of bladder neck contracture.

Table 3 Other outcomes studied comparing SPT with UC.

Outcomes	No. of studies	No. of patients (SPT/UC)	MD/OR	95% CI	P-Value	I^2, %
Overall pain (POD1-3)	5	240/341	−0.26	−1.34 to 0.83	0.64	90
Overall pain (POD6-7)	5	240/341	−0.5	−1.54 to 0.54	0.34	94
Penile pain	4	111/171	0.57	0.31 to 1.02	0.05	47
Urinary incontinence	6	473/422	0.8	0.56 to 1.15	0.23	0
Bladder neck contracture	6	374/405	0.77	0.39 to 1.53	0.45	59
Urinary retention	4	404/324	0.88	0.29 to 2.70	0.82	33
Urethral stricture	3	271/138	1.32	0.08 to 20.7	0.84	0
Anastomotic stricture	5	476/316	0.2	0.02 to 1.76	0.15	0
Bacteriuria	2	261/128	0.61	0.19 to 1.96	0.40	0

SPT: Suprapubic tube; UC: urethral catheter; POD: postoperative day; OR: odds ratio, MD mean difference; CI: confidence interval.

have subsided. Urinary incontinence was measured by pad usage within a year of surgery. However, the trials we included measured urinary continence in different periods, and lack of standard definitions or criteria of continence and potency. These could introduce unavoidable clinical and statistical heterogeneity, which may influence reliability of results.

In addition, other parameters including urinary retention, bladder neck contracture, urethral stricture, bacteriuria and anastomotic stricture were also no significant difference between the two groups. The postoperative complications are always related to many other ingredients such as preoperative patient characteristics, surgeon experience, surgical technique, and methods used to

collect and report data. They are the most common disease after surgery, but a lot of original researches did not report the complications after SPT or UC, it is unclear if this is because the complications did not occur or were simply not reported. So it intuitively seems improbable to get a more reliable conclusion. The trials included in this review reported a wide range of outcomes, to guide future trials should report core outcomes (eg, postoperative pain, bacteriuria, urinary continence and so on) and use standardized measures.

Some studies have been to explore the new way to take the place of the traditional postoperative bladder drainage. A trial[32] found clean intermittent catheterization was better than indwelling UC in reducing bacteriuria and urinary tract infection rates. Minimally invasive surgical techniques may reduce the need for prolonged catheterization in most cases, so intermittent urethral catheterization or non catheterization may be reasonable options. One study[33] reported no significant difference in bacteriuria rates between SPT and clean intermittent self-catheterization, but intermittent urethral catheterization may increase pain, frustration and difficultly.[34] Where prolonged postoperative catheter is required, SPT appears to reduce infective morbidity while avoiding repeating potentially painful catheter insertions[33] and minimizing nursing workload. Future studies should explore the non catheterization option, particularly in combination with minimally invasive procedures.

4.1. Strengths and limitations

The strengths of this study are as follows: (1) All of the studies we've included have been published in recent years; (2) the detailed data collection and extraction of all related studies; (3) the rating of the quality of the included studies; (4) the subgroup analysis was performed according to the time of postoperative pain and study type respectively; (5) the detailed reporting of results from the meta-analysis of all extracted outcomes.

This study has several limitations. Firstly, there was a significant paucity in high quality studies, most of the included studies were non-RCTs, which could be challenged to interpret the results. Secondly, the blinding assessment of outcomes was rare performed, we should pay more attention to blinding of assessor or patients. Thirdly, the included studies were too small to make publication bias and heterogeneity analyses, and the heterogeneity in several outcomes may hamper the straight forward comparability of results.

5. Conclusions

The data from the present meta-analysis showed that no route for bladder drainage in RARP is clearly superior. SPT may be associated with less penile pain. However, there was no conclusive evidence that SPT was advantaged in terms of overall pain, urinary incontinence, bladder neck contracture, urinary retention, anastomotic stricture, urethral stricture, bacteriuria. Due to the low quality and small quantity of the available comparative studies, further high-quality, more RCTs are needed to provide stronger evidence of the benefits of this method.

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Conflicts of interest

None.

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Appendix A. Supplementary data

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