Original Article

Radical prostatectomy after previous transurethral resection of the prostate: a systematic review and meta-analysis

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Background: The influence of a previous transurethral resection of the prostate (TURP) on the outcomes of radical prostatectomy (RP) is still controversial. Therefore, we performed a meta-analysis to evaluate the perioperative, functional and oncological outcomes of RP with or without a previous TURP.

Methods: We conducted a computerized literature search of PubMed, Embase, and the Cochrane Library and included 15 retrospective studies evaluating RPs with or without a previous TURP in this meta-analysis.

Results: Fifteen studies, including 6,840 cases, were analyzed. RP after a previous TURP were related to smaller prostate volumes (WMD: −6.93 cm^3; 95% CI, −10.89 to −2.97; P<0.001), lower preoperative prostate-specific antigen (PSA) levels (WMD: −1.51; 95% CI, −2.49 to −0.53; P=0.002), longer operative times (WMD: 13.22 min; 95% CI, 4.55 to 21.89 min; P=0.003), more blood loss (WMD: 55.38 mL; 95% CI, 12.35 to 98.41 mL; P=0.01), higher overall complication rates (OR =1.98; 95% CI, 1.27 to 3.08; P=0.002), longer hospital stays (WMD: 1.16 days; 95% CI, 0.65 to 1.67; P<0.001), longer duration of catheter (WMD: 0.60 days; 95% CI, 0.56 to 0.64; P<0.001), higher positive surgical margin rates (OR =1.30; 95% CI, 1.09 to 1.55; P=0.004), lower complete continence rates at 3 months (OR =0.67; 95% CI, 0.56 to 0.81; P<0.001), 6 months (OR =0.52; 95% CI, 0.31 to 0.88; P=0.01), 12 months (OR =0.59; 95% CI, 0.46 to 0.74; P<0.001), and lower potency rates at 12 months (OR =0.62; 95% CI, 0.51 to 0.77; P<0.001). Subgroup analysis indicated that open RP after previous TURP could achieve better outcomes.

Conclusions: RP after a previous TURP leads to worse perioperative, oncological, and functional outcomes. For these patients an open procedure is recommended. Due to the low number of studies and known biases, further large-scale studies are needed to support this result.

Keywords: Prostatectomy; transurethral resection of the prostate (TURP); prostatic neoplasms; margins of excision

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Introduction

Prostate carcinoma is one of the leading causes of cancer-related deaths worldwide among older males. In 2017, approximately 164,690 American men were diagnosed with prostate carcinoma, and 29,430 will likely die from it, causing it to be a leading global health problem (1,2). It is generally considered that treatment with radical prostatectomy (RP) should be recommended for locally advanced prostate carcinomas (3,4). However, many older men undergo RP for locally advanced prostate carcinoma having had a previous transurethral resection of the prostate (TURP) (5), a standard surgical treatment for benign prostatic hyperplasia (BPH) (6). Some studies have shown that RP after a previous TURP was related to an increase in intraoperative

and postoperative morbidity (7), while other studies have indicated that a RP could be safely conducted after a TURP with uncompromising results (8,9). As such, the influence of a previous TURP on the outcomes of a RP is still controversial. Therefore, we performed this meta-analysis to evaluate the perioperative, functional, and oncological outcomes of a RP with or without a previous TURP.

Methods

This systematic review and meta-analysis was completed in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (10) and registered on PROSPERO (http://www.crd.york.ac.uk/ PROSPERO ID: CRD42019129277).

Search strategy

We conducted a computerized literature search of PubMed, Embase, and the Cochrane Library in February 2019. The MeSH terms and their combinations were searched in [Title/Abstract] as follows: Prostatic Neoplasms, transurethral resection of prostate, and prostatectomy. We made no limitations on the publication status, but only included studies which were reported in English. If two or more studies reported on the same population, we only included the most recent.

Inclusion and exclusion criteria

Inclusion criteria: (I) studies comparing RP with or without a TURP in full text; (II) studies containing detailed information of baseline characteristics, perioperative outcomes, oncological outcomes, and functional outcomes; and (III) studies containing adequate information on estimating relative risk (RR) or hazard ratio (HR) by 95% confidence interval (95% CI).

Exclusion criteria: (I) studies which reported mixed previous prostate surgery not confined to a transurethral resection of prostate; (II) studies not reported in English; and (III) letters to the editor, editorials, reviews, conference abstracts, case reports, and animal experimental studies.

Data extraction and outcomes of interest

Two reviewers assessed the titles and abstracts independently of all the studies, and any disagreements, were discussed and determined by a third senior reviewer. The outcomes contained four parts: baseline features, perioperative outcomes, oncological outcomes, and functional outcomes. Baseline features contained: age, prostate volumes, preoperative prostate-specific antigen (PSA) levels, body mass index (BMI), biopsy Gleason scores, and clinical stage ≥T3. Perioperative outcomes contained: operative times, estimated blood loss (EBL), blood transfusion rates, complication rates, hospital stay, and duration of catheter. Oncological outcomes contained: pathologic stage ≥T3, pathologic Gleason scores =7, pathologic Gleason scores >7, and positive surgical margin rates. Functional outcomes included: Complete continence rates at 3, 6, and 12 months and potency rates at 12 months. We defined a RP after a previous TURP as the TURP group and a RP without a previous TURP as the non-TURP group. Most studies defined 0 or 1 safety pads used per day as complete continence (5,8,11-15), except for Teber *et al.* and Yang *et al.* who defined 0 or 1 pads used per day as continence (16,17), and Pastore *et al.* who defined an ICIQ score of <6 as continence (18). Five studies used the International Index of Erectile Function (IIEF) questionnaire and the ability to have intercourse, regardless of whether medication was used or not, to assess erectile function (5,8,11,12,19). Two studies assessed erectile function only on the ability to have intercourse, regardless of whether medication was used or not (13,16). Only one study assessed erectile function through the ability to have intercourse without the use of medication (14).

Quality assessment and data synthesis

We evaluated the methodological quality of all the retrospective studies based on the Newcastle-Ottawa Scale (NOS) as recommended by the Cochrane Collaboration (20). A 0 to 9 score system was applied to judge each study, and a score of 7 to 9 was considered high quality (21). Ten of the 15 studies were considered high quality.

Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was used to conduct this meta-analysis. For continuous variables, such as operative time, we applied a weighted mean difference (WMD) for comparison. While for dichotomous variables, such as complication rates, an odds ratio (OR) was applied. Both comparisons were presented with 95% confidence intervals (CIs). For any studies reporting continuous data by means and range values, we used statistical algorithms to calculate the standard deviations (22). Statistical heterogeneity was evaluated using a chi-square test with a significance level set at P<0.10. The

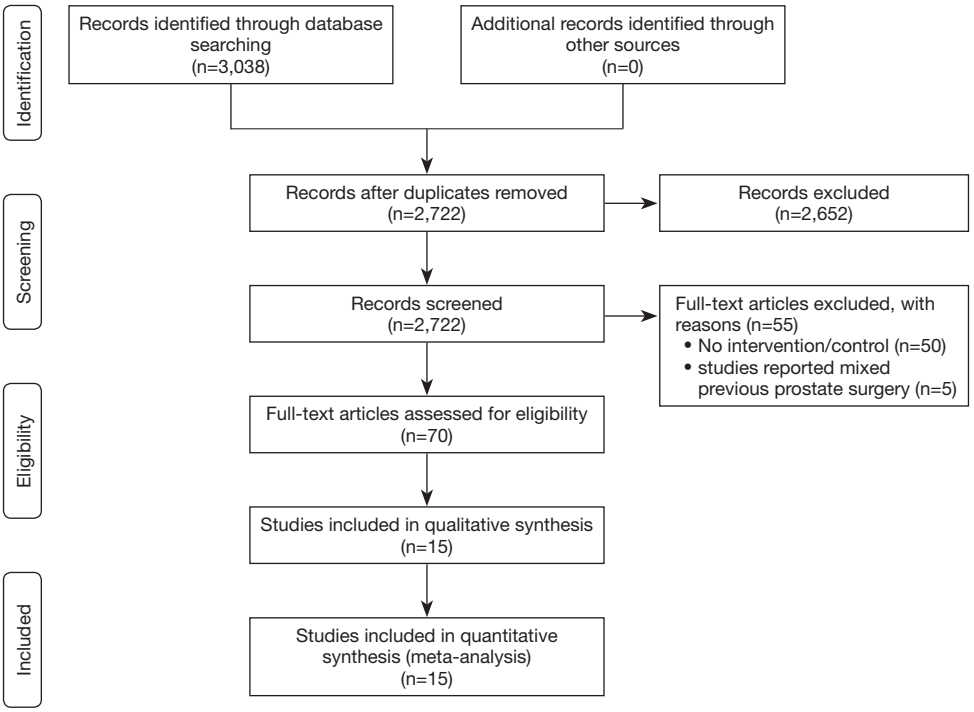

Figure 1 Flow diagram of studies identified, included, and excluded. From: Moher D, Liberati A, Tetzlaff J, *et al*. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6:e1000097.

heterogeneity was quantified by the I^2 statistic. If P>0.10 and $I^2 \leq 50\%$, heterogeneity was defined as low and a fixed-effects model was applied, alternatively, a random-effects model was applied (23). We conducted subgroup analyses to compare laparoscopic radical prostatectomy (LRP), robotic assisted laparoscopic radical prostatectomy (RARP), open prostatectomy (OP), and a mixed procedure of OP and RARP. Potential publication biases were detected using a Begg funnel plot (24).

Results

Characteristics of the included studies

Fifteen studies, including 6,840 cases (1,121 cases for the TURP group and 5,719 cases for the non-TURP group), met the inclusion criteria and were included in the analysis (*Figure 1*) (5,7,8,11-19,25-27). Study characteristics are summarized in *Table 1*. All 15 studies were retrospective case-controlled studies, and included 6 studies conducted by LRP (14-18,25), five studies conducted by RARP (7,8,12,13,27), three studies conducted by OP (11,19,26), and one study conducted by mixed procedure (5). The matching factors between the two groups were age, BMI, preoperative PSA levels, biopsy Gleason scores, prostate volumes, pathologic stage, and use of nerve sparing techniques.

Baseline features

The pooled data indicated that baseline features of age showed no significant differences between the two groups (*Figure 2A*). However, significantly lower prostate volumes (WMD: −6.93 mL; 95% CI, −10.89 to −2.97; P<0.001) and lower preoperative PSA levels (WMD: −1.51; 95% CI, −2.49 to −0.53; P=0.002) were found in the TURP group. Due to the large heterogeneities, random-effect models were applied (*Figure 2B,C*). Other baseline features including BMI, biopsy Gleason scores, and a clinical stage sparing d no significant differences (*Figure 3*).

Perioperative outcomes

Eleven studies, including 3,697 patients, reported on operative times and demonstrated significantly longer times in the TURP group (WMD: 13.22 min; 95% CI,

Table 1 Characteristics of included studies

Study	Level of evidence	Design	Method	Patients (n)		Matching	Follow-up (months): TURP/non-TURP1	Quality score
				TURP	Non-TURP			
Fragkoulis	3b	R	OP	35	35	1, 2, 3, 4, 5, 6, 7	12/12	8
Gupta	3b	R	RARP	26	132	2, 4, 5, 6	15.3/15.3	6
Hampton	3b	R	RARP	51	102	1, 2, 3, 4, 6, 7	0/0	7
Hung	3b	R	RARP	16	184	1, 2, 3, 4, 6, 7	12/12	7
Jaffe	3b	R	LRP	119	119	3, 4, 5, 6	0/0	6
Menard	3b	R	LRP	46	594	3, 4, 5	24/24	6
Palisaar	3b	R	OP	62	62	1, 2, 3, 4, 5, 6, 7	12/12	8
Paulson	3b	R	OP	33	106	4	120/120	5
Pompe	3b	R	Mixed	470	1,410	1, 3, 4, 5, 6, 7	12/12	7
Ramirez Backhaus	3b	R	LRP	19	136	1, 2, 3, 4, 5, 6, 7	15/15	7
Su	3b	R	RARP	49	2,644	2, 3, 4	12/12	6
Teber	3b	R	LRP	55	55	1, 2, 3, 4, 5, 6, 7	24/24	7
Yang	3b	R	LRP	35	35	1, 2, 3, 4, 6	57.6/57.6	7
Zugor	3b	R	RARP	80	80	1, 2, 3, 4, 5	13.5/13.5	7
Pastore	3b	R	LRP	25	25	1, 2, 4, 6	6/6	7

TURP, radical prostatectomy after previous transurethral resection of the prostate; non-TURP, radical prostatectomy without previous transurethral resection of the prostate; R, retrospective; RARP, robotically assisted laparoscopic prostatectomy; LRP, laparoscopic prostatectomy; OP, open radical prostatectomy; Mixed, a mixed procedure of open radical prostatectomy and robotically assisted laparoscopic prostatectomy. Matching: 1= age; 2= body mass index (BMI); 3= prostate specific antigen (PSA); 4= Gleason score; 5= prostate volume; 6= pathological staging; 7= nerve sparing technique.

4.55 to 21.89 min; P=0.003). A random-effects model was applied (I^2=83%; P<0.001, *Figure 4A*). Pooled data from 10 studies included EBL for 3,542 patients and showed more significant levels of blood loss in the TURP group as compared to the non-TURP group (WMD: 55.38 mL; 95% CI, 12.35 to 98.41 mL; P=0.01). A random-effects model was applied (I^2=83%; P<0.001, *Figure 4B*). Nine studies, including 3,041 patients, reported on transfusion rates and showed no significant differences between the two groups (OR =1.15; 95% CI, 0.83 to 1.59; P=0.39). A fixed-effects model was applied (I^2=0%; P=0.92, *Figure 4C*). Eight studies, including 3,368 patients, reported on complication rates and the pooled data showed significantly higher complication rates in the TURP group (OR =1.98; 95% CI, 1.27 to 3.08; P=0.002). A random-effects model was applied (I^2=59%; P=0.02, *Figure 5A*). Three studies, including 1078 patients, reported on the length of hospital stay and indicated a significant difference between the two groups (WMD: 1.16 days; 95% CI, 0.65 to 1.67 days; P<0.001). A fixed-effects model was applied (I^2=48%; P=0.15, *Figure 5B*). Six studies, including 3,040 patients, reported on the duration of catheter use and found a significant difference between the two groups (WMD: 0.60 days; 95% CI, 0.56 to 0.64; P<0.001). A fixed-effects model was applied (I^2=0%; P=0.50, *Figure 5C*).

Oncological outcomes

Pooled data indicated that the oncological outcomes of the pathologic stage ≥ T3, Gleason scores =7, and Gleason scores >7 showed no significant differences between the two groups (*Figures 6,7A*). Data from all 15 studies assessed the positive surgical margin rates of 6,840 patients, which showed significantly higher positive surgical margin rates in the TURP group than the non-TURP group (OR =1.30; 95% CI, 1.09 to 1.55; P=0.004) with no heterogeneity (I^2=0%; P=0.69), and a fixed-effects model was applied (*Figure 7B*).

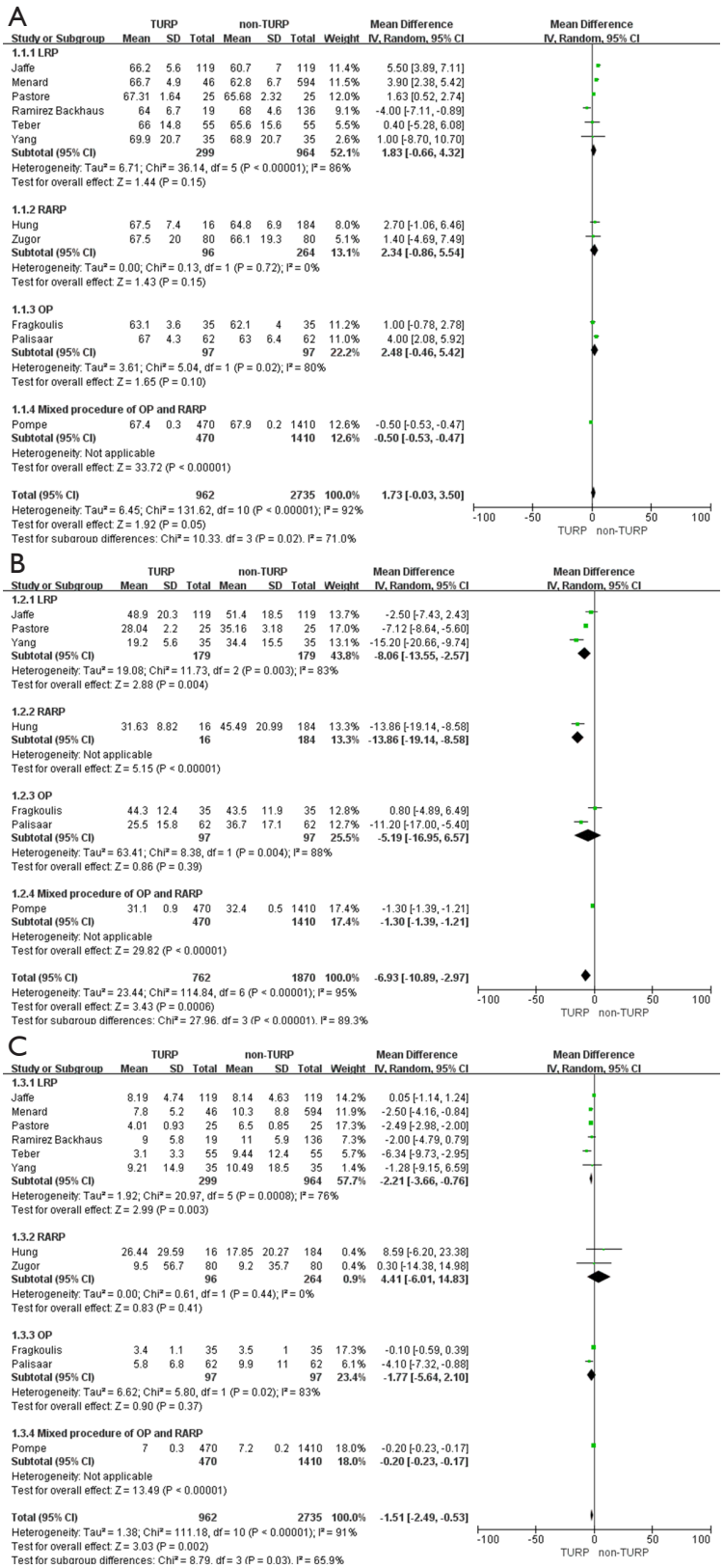

Figure 2 Forest plot for (A) age; (B) prostate volume; (C) preoperative PSA. PSA, prostate-specific antigen.

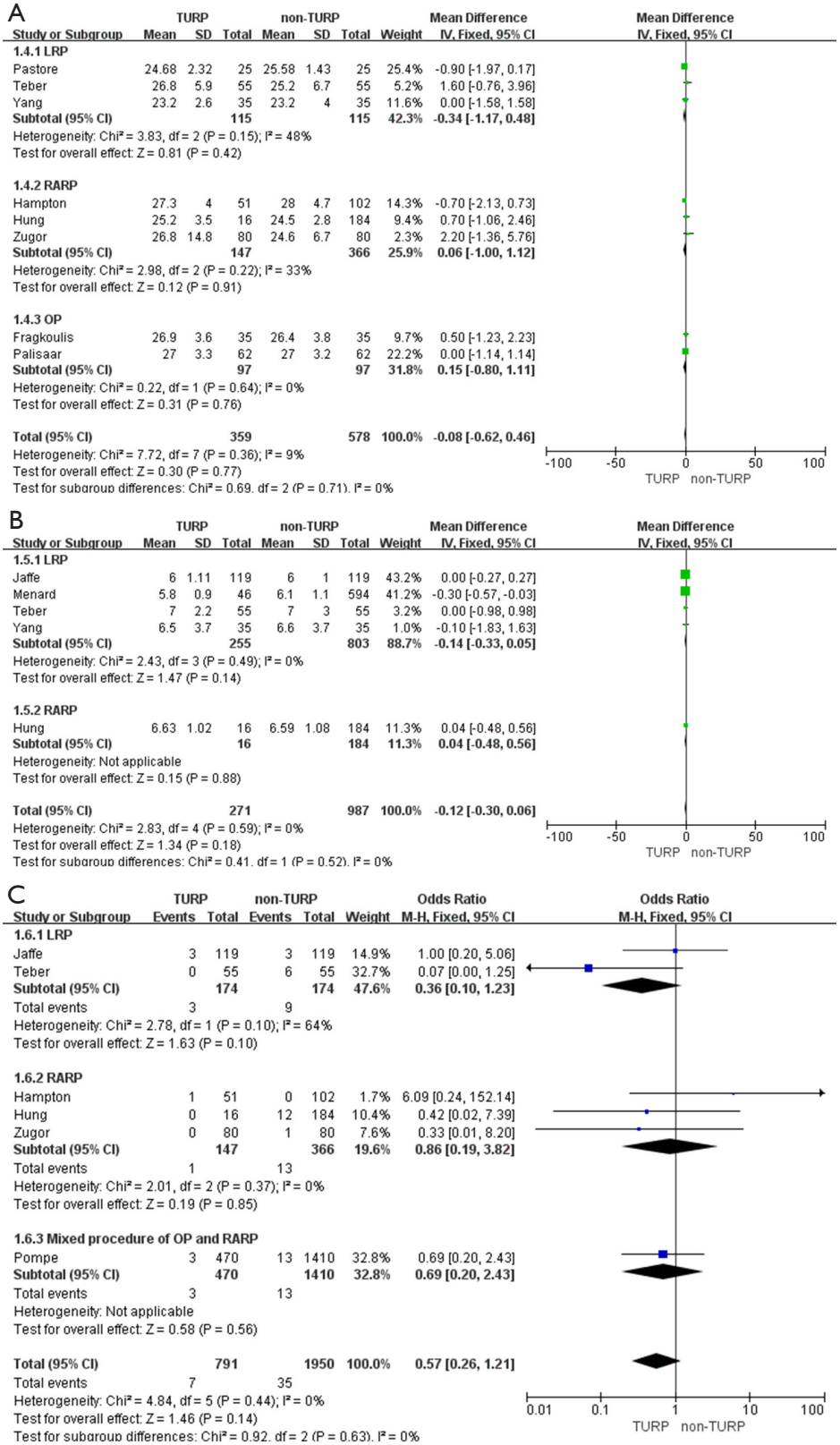

Figure 3 Forest plot for (A) BMI; (B) biopsy Gleason score; (C) clinical stage ≥ T3. BMI, body mass index.

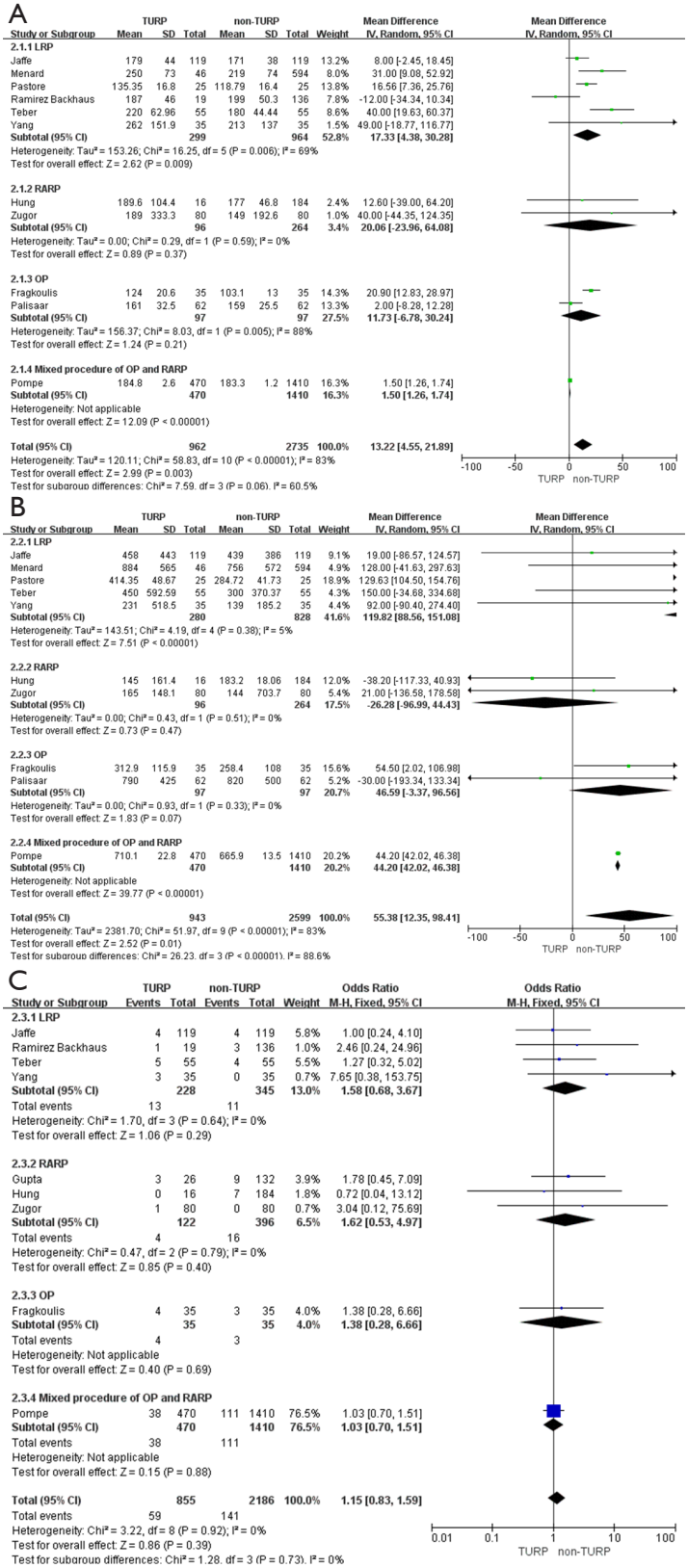

Figure 4 Forest plot for (A) operative time; (B) estimated blood loss; (C) blood transfusion rates.

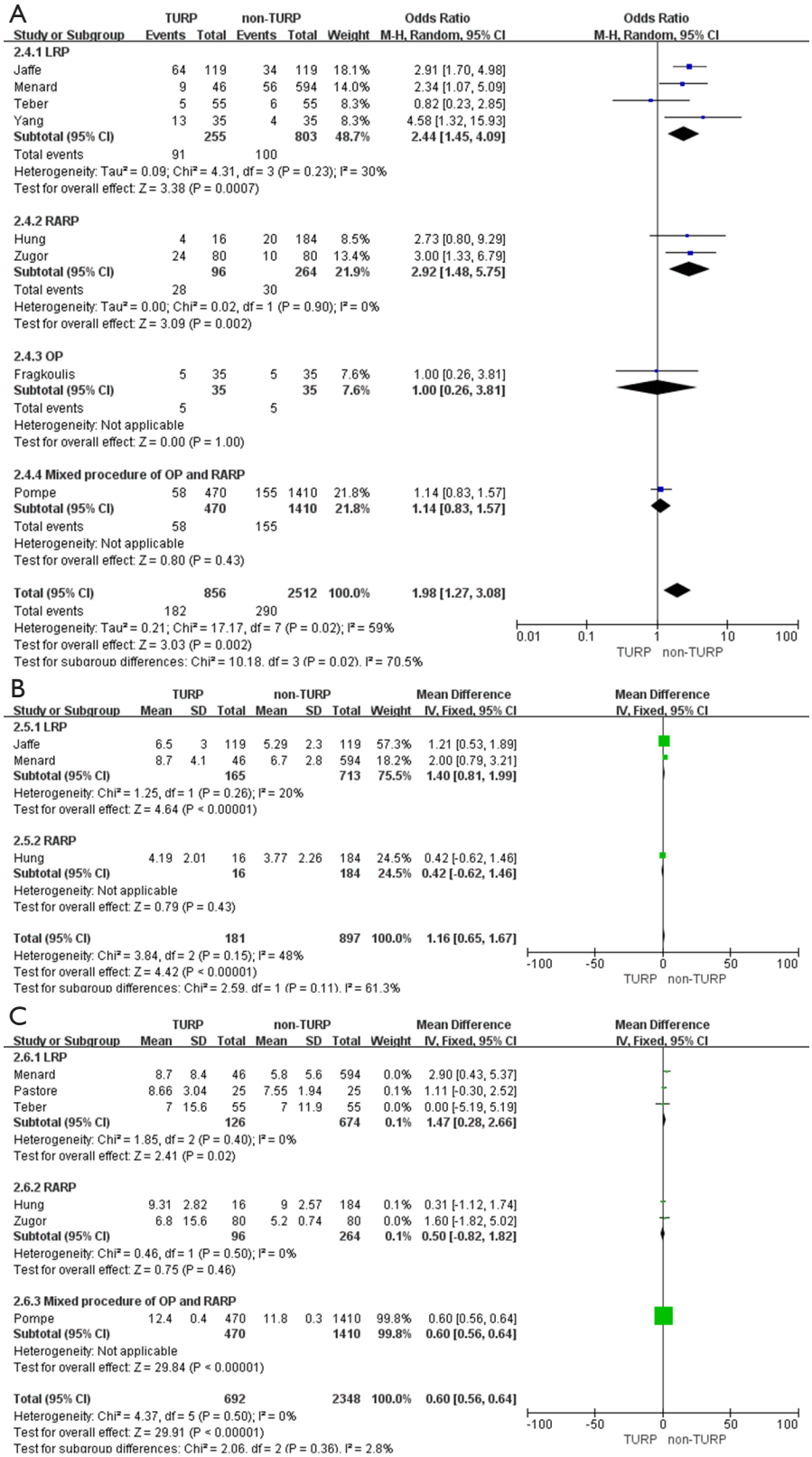

Figure 5 Forest plot for (A) complication rates; (B) hospital stay; (C) duration of catheter.

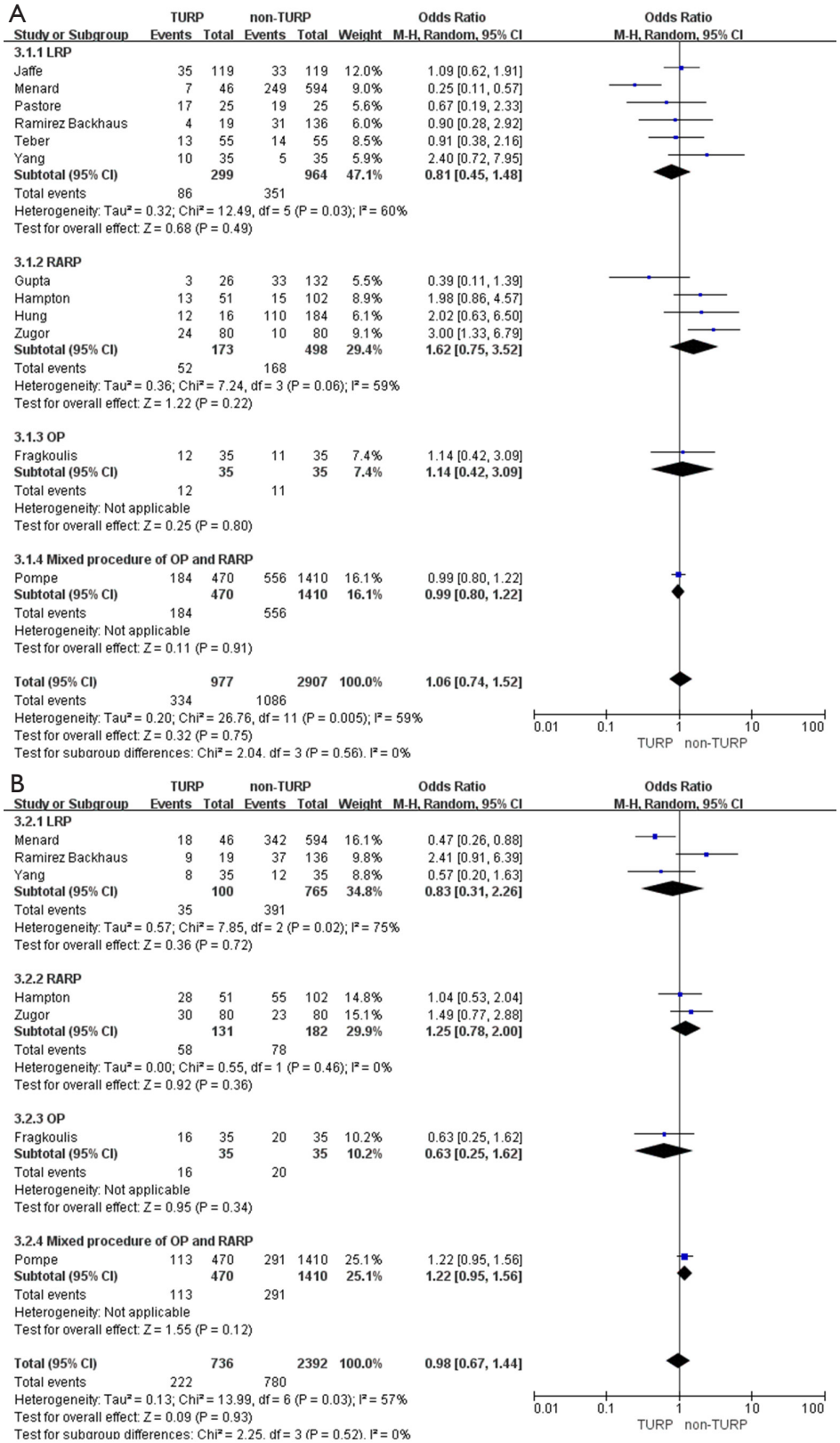

Figure 6 Forest plot for (A) pathologic stage ≥ T3; (B) pathologic Gleason score =7.

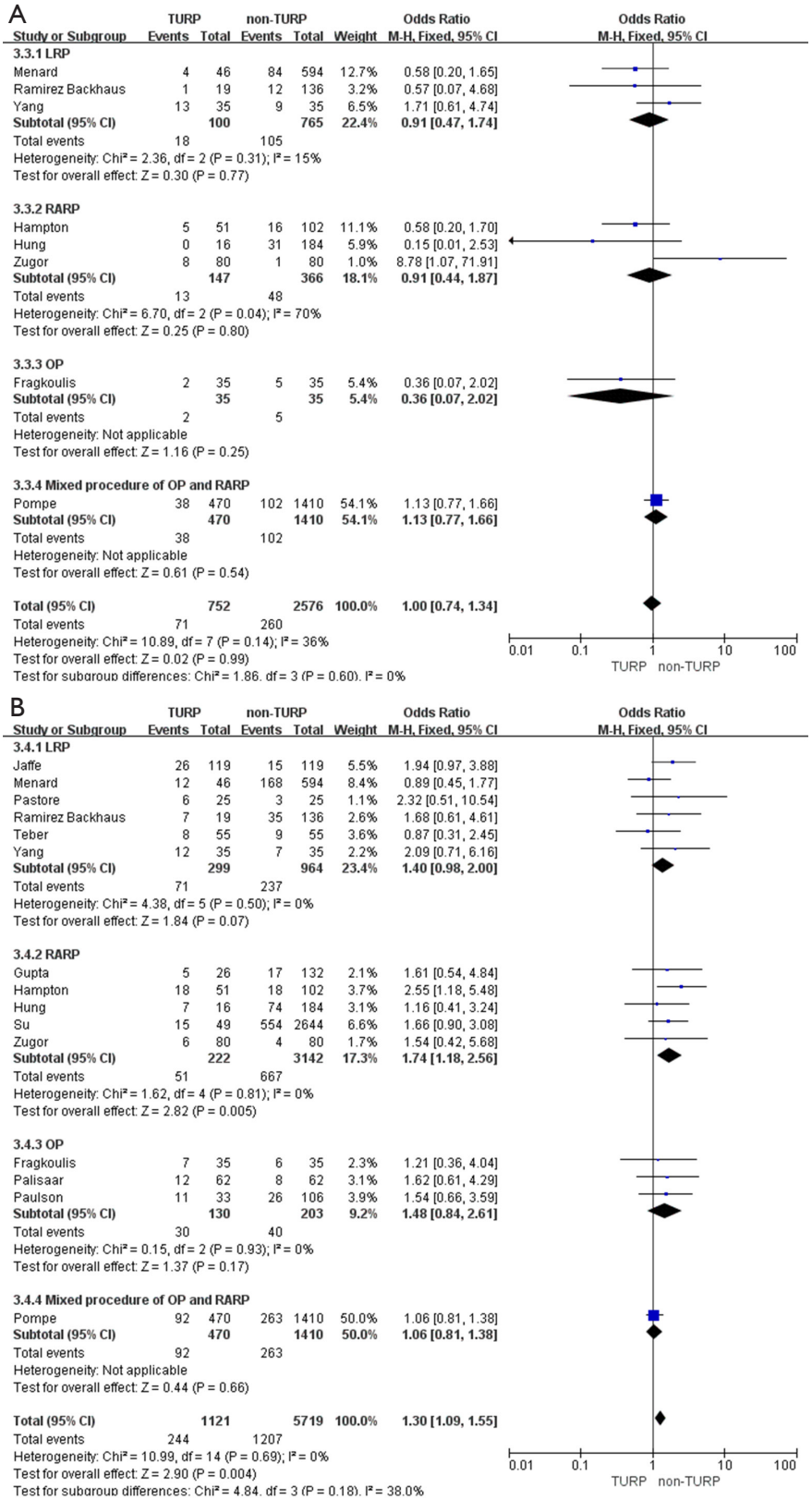

Figure 7 Forest plot for (A) pathologic Gleason score >7; (B) positive surgical margin rates.

Functional outcomes

Pooled data from seven studies assessed the complete continence rates at 3 months for 2,625 patients, which showed significantly lower continence rates in the TURP group (OR =0.67; 95% CI, 0.56 to 0.81; P<0.001). A fixed-effects model was applied (I^2=0%; P=0.84, *Figure 8A*). Pooled data from five studies assessed the complete continence rates at 6 months for 603 patients, which indicated significantly lower rates in the TURP group (OR =0.52; 95% CI, 0.31 to 0.88; P=0.01). A fixed-effects model was applied (I^2=0%; P=0.95, *Figure 8B*). Eight studies, including 3283 patients, evaluated the complete continence rates at 12 months and the pooled data showed significantly lower continence rates in the TURP group (OR =0.59; 95% CI, 0.46 to 0.74; P<0.001). A fixed-effects model was applied (I^2=0%; P=0.93, *Figure 9A*). Seven studies, including 2,371 patients, evaluated the potency rates at 12 months and the pooled data showed significantly lower rates in the TURP group (OR =0.62; 95% CI, 0.51 to 0.77; P<0.001). A fixed-effects model was applied (I^2=0%; P=0.95, *Figure 9B*).

Subgroup analyses

TURP group as compared with the non-TURP group in LRP

There were no changes in this subgroup as compared with the original analysis, except for no significant differences being found in the positive surgical margin rates (OR =1.40; 95% CI, 0.98 to 2.00; P=0.07, *Figure 7B*), continence rates (OR =0.61; 95% CI, 0.33 to 1.13; P=0.12), and erectile function (OR =0.65; 95% CI, 0.32 to 1.35; P=0.25) at 12 months (*Figure 9*). Only one study reported on continence rates at 6 months, and a subgroup analysis could not be conducted.

TURP group as compared with the non-TURP group in RARP

When compared with the original analysis, no significant differences in preoperative PSA levels (WMD: 4.41; 95% CI, −6.01 to 14.83; P=0.41, *Figure 2C*), operative times (WMD: 20.06 min; 95% CI, −23.96 to 64.08 min; P=0.37, *Figure 4A*), EBL (WMD: −26.28 mL; 95% CI, −96.99 to 44.43 mL; P=0.47, *Figure 4B*), duration of catheter (WMD: 0.50 days; 95% CI, −0.82 to 1.82; P=0.46, *Figure 5C*), complete continence rates at 3 months (OR =0.56; 95% CI, 0.31 to 1.01; P=0.06, *Figure 8A*), and complete continence rates at 12 months (OR =0.53; 95% CI, 0.24 to 1.19; P=0.12, *Figure 9A*) were found. Only one study reported on prostate volumes, biopsy Gleason scores, and hospital stay, and subgroup analyses could not be conducted.

TURP group as compared with the non-TURP group in OP

Compared with the original analysis, no significant differences in prostate volumes (WMD: −5.19 mL; 95% CI, −16.95 to 6.57 mL; P=0.39, *Figure 2B*), preoperative PSA levels (WMD: −1.77; 95% CI, −5.64 to 2.10; P=0.37, *Figure 2C*), operative times (WMD: 11.73 min; 95% CI, −6.78 to 30.24 min; P=0.21, *Figure 4A*), EBL (WMD: 46.59 mL; 95% CI, −3.37 to 96.56; P=0.07, *Figure 4B*), positive surgical margin rates (OR =1.48; 95% CI, 0.84 to 2.61; P=0.17, *Figure 7B*), complete continence rates at 12 months (OR =0.91; 95% CI, 0.40 to 2.09; P=0.83, *Figure 9A*), and potency rates at 12 months (OR =0.74; 95% CI, 0.31 to 1.79; P=0.50) were found between the two groups (*Figure 9B*). Only one study reported on biopsy Gleason scores, clinical stage ≥ T3, blood transfusion rates, complication rates, length of hospital stay, duration of catheter use, and continence rates at 3 and 6 months, and subgroup analyses could not be conducted.

Quality assessment and publication bias

The scores for the included studies are summarized in *Table 1*. If the study received a score ≥7, it was considered to be of high quality. Ten studies were evaluated as high quality. We used a funnel plot to assess the risk of publication bias. There was some asymmetry found (*Figures S1-S4*), indicating a publication bias.

Discussion

To the best of our knowledge, this systematic review and meta-analysis investigated the outcomes of a RP with or without a previous TURP for the first time. Pooled data showed that RP after a previous TURP led to worse outcomes, including perioperative, functional, and oncological outcomes. However, subgroup analyses indicated that open RP after a previous TURP could lead to better outcomes.

For the treatment management of patients with low or intermediate risk localized prostate carcinoma, a RP is believed to be a primary option (28). Whereas, for the management of BPH, a TURP is normally regarded as gold standard surgical treatment (6,29). As both BPH and prostate carcinoma share age as a risk factor, there is a 4% incidence of prostate carcinoma occurring following a

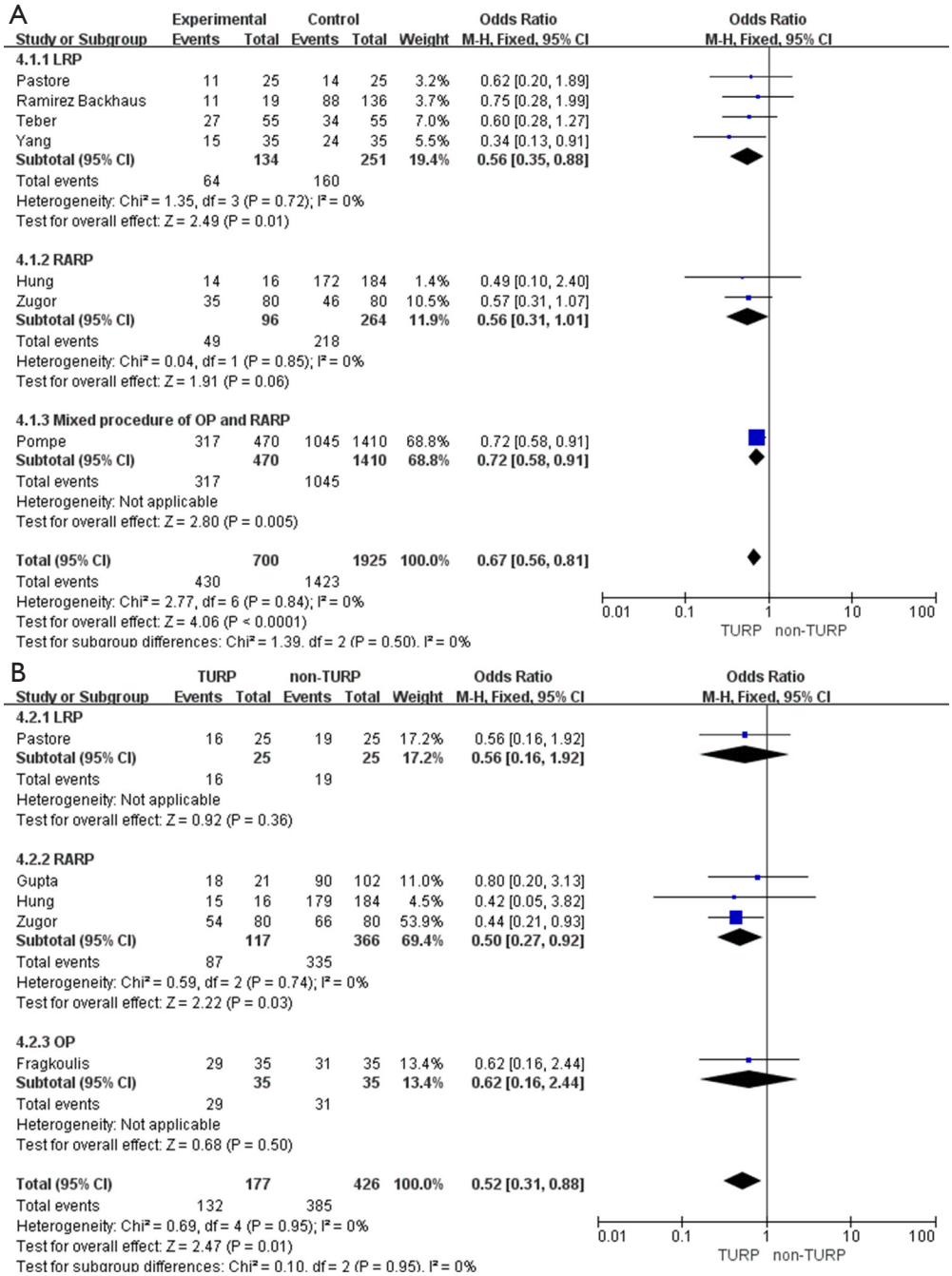

Figure 8 Forest plot for (A) continence rates at 3 months; (B) continence rates at 6 months.

TURP within a 7-year' follow-up (30). Furthermore, even after careful evaluation of PSA levels and a digital rectal examination (DRE), around 6.4% to 11.4% of patients who undergo a TURP because of bladder outlet obstruction could be diagnosed with an incidental prostate carcinoma (31-33). Unfortunately, studies investigating RP with or without a previous TURP have achieved conflicting results. Hampton *et al.* compared RPs in 51 patients with a previous TURP and 102 patients without a previous TURP, and concluded that patients who had received a previous TURP had higher positive margin rates (7). However, Zugor *et al.* performed a match-paired analysis with 160 patients

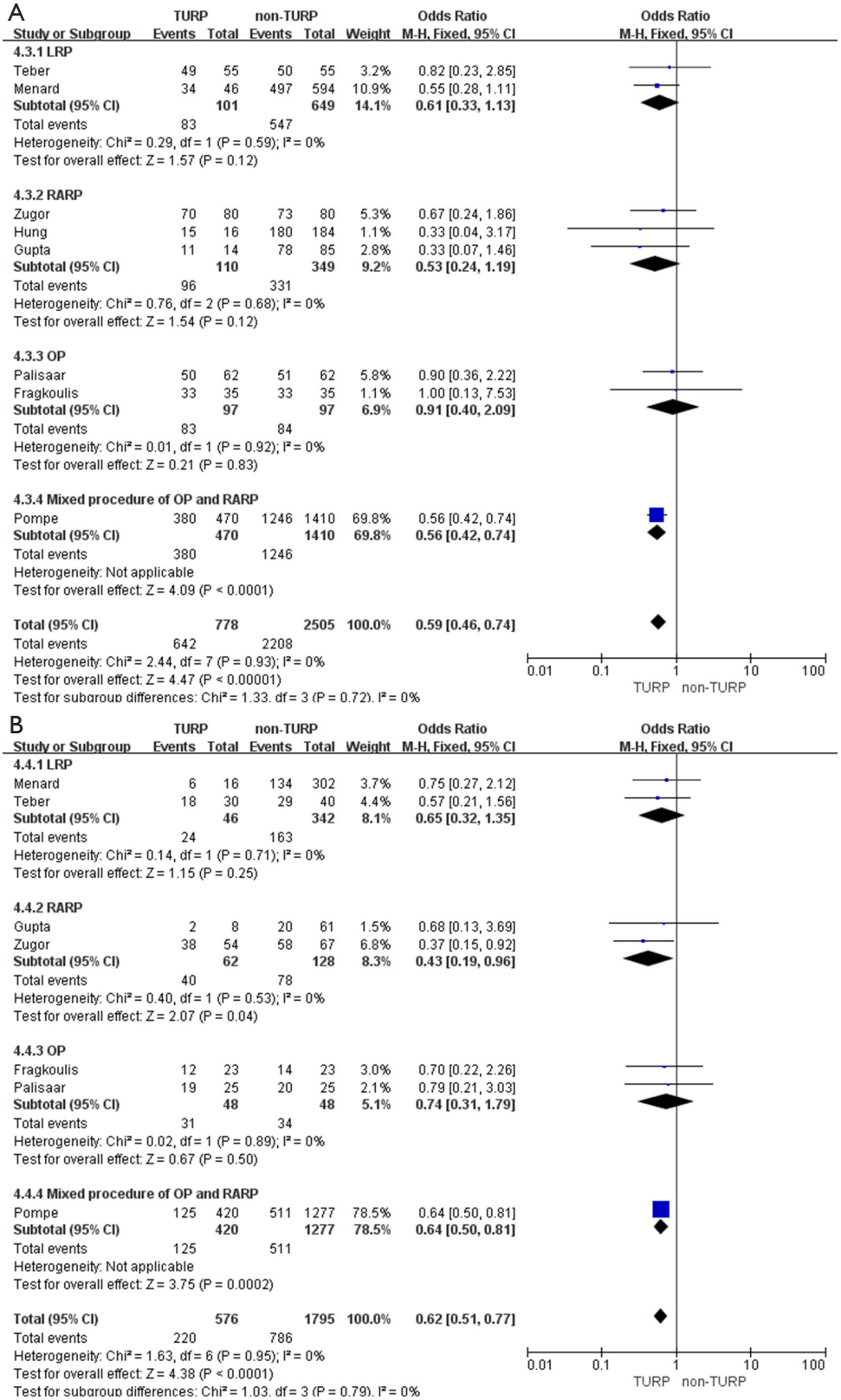

Figure 9 Forest plot for (A) continence rates at 12 months; (B) potency rates at 12 months.

and concluded that RP could be safely conducted after a previous TURP with the same functional and oncological outcomes (8). Additionally, Do *et al.* conducted RPs on 100 patients who had undergone a previous TURP, which led to promising and comparable perioperative, functional, and oncological outcomes (9).

This meta-analysis of 15 retrospective studies, including 6,840 patients, which compared a RP with or without a previous TURP, showed that a RP after a TURP compromised perioperative outcomes, had longer operative times, more blood loss, higher complication rates, longer hospital stays, and a longer duration of catheter use. Furthermore, it compromised oncological outcomes, resulting in higher positive surgical margin rates, along with functional outcomes, including lower complete continence rates after 3, 6, and 12 months of follow-up and lower erectile function after 12 months of follow-up. While subgroup analyses indicated that an open RP could eliminate these differences and achieve nearly uncompromised results.

There are concerns that previous TURP could change the prostate anatomy and make a RP more challenging (11) and cause difficulties mainly concentrated on resecting the posterior bladder neck and dissecting the posterior plane of the prostate (14). A possible explanation for the compromised results is that the infection of the prostate along with the capsular perforation and extravasation of irrigation fluid during a TURP could cause periprostatic inflammation and fibrosis (34,35). Additionally, after the removal of prostatic tissue, the prostatovesicular junction becomes floppy, which results in identification difficulties (12). Moreover, most of the patients underwent a previous TURP because of bladder outlet obstruction, which could thicken the bladder wall and make it difficult for urethrovesical anastomosis (17). Furthermore, for functional outcomes, identifying and preserving adequate residual urethral length are difficult as a result of the surrounding fibrosis, which may influence urethrovesical anastomosis and long-term continence. In addition, TURP can cause the internal sphincter mechanism to become deficient (17). Moreover, it is difficult to identify and preserve the neurovascular bundle because of periprostatic adhesions caused by periprostatic inflammation and fibrosis (11). However, subgroup analyses showed that an open RP could be safely and effectively performed after a previous TURP. One possible explanation is that OP can separate periprostatic inflammation and fibrosis subtly, and lead to better results.

Recently, Veccia *et al.* conducted a meta-analysis of LRP and RARP after previous bladder outlet surgery (BOS), and concluded that a minimally invasive RP after BOS led to worse outcomes (36). The authors recommended RARP for these patients. However, both their results and the results of this meta-analysis found no better outcomes in the RARP group. Also, they missed the study reported by Teber *et al.* (16). Another difference is that we only included RP after TURP. However, they included RP after TURP along with other BOS techniques, and as the authors stated, this was one of their limitations. There are also some studies which evaluated the outcomes of RP after other BOS techniques and led to conflicting results. For example, Eden *et al.* included 600 patients, 42 of which had undergone a previous BOS. The authors reported that previous prostate surgery resulted in similar operative times, blood loss, oncological outcomes, and functional outcomes (37). Suardi *et al.* evaluated the feasibility and safety of radical retropubic prostatectomy after holmium laser enucleation of the prostate (HoLEP) and concluded that a RP was feasible after a previous HoLEP (38). Martin *et al.* reviewed 510 patients, of which 24 patients had undergone previous treatment of the prostate, including transurethral microwave therapy, transurethral resection or incision of the prostate, photoselective vaporization, transurethral needle ablation, external beam radiotherapy, simple prostatectomy, open bladder neck reconstruction and brachytherapy. The authors concluded that a prostatic treatment history had no effect on perioperative outcomes during RARP (39). The reason for the contradictory results may be that different technologies have led to different changes in the prostate, periprostate, and bladder neck.

There are some limitations to this meta-analysis. Firstly, all the articles included were retrospective, and the number of patients was relatively small. As such, it cannot avoid selection and recall bias. Furthermore, Funnel plots indicated that there was a publication bias. Secondly, as a RP is a long learning curve surgery and the studies included were from all over the world, different surgeons and different centrals may have affected the outcomes. Thirdly, we could not include the time lapsed from TURP to RP within the meta-analysis, and obviously, different times could have influenced the outcomes. Finally, there was limited information on the oncological outcomes, and long-term follow-up of the patient's biochemical recurrence and overall survival are needed.

Conclusions

This meta-analysis suggests that RP after a previous TURP

leads to worse perioperative, oncological, and functional outcomes. For these patients, an open procedure should instead be recommended. Due to the low number of studies and the known bias, further large-scale studies are needed to support this result.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This article does not contain human participants or animals.

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Supplementary

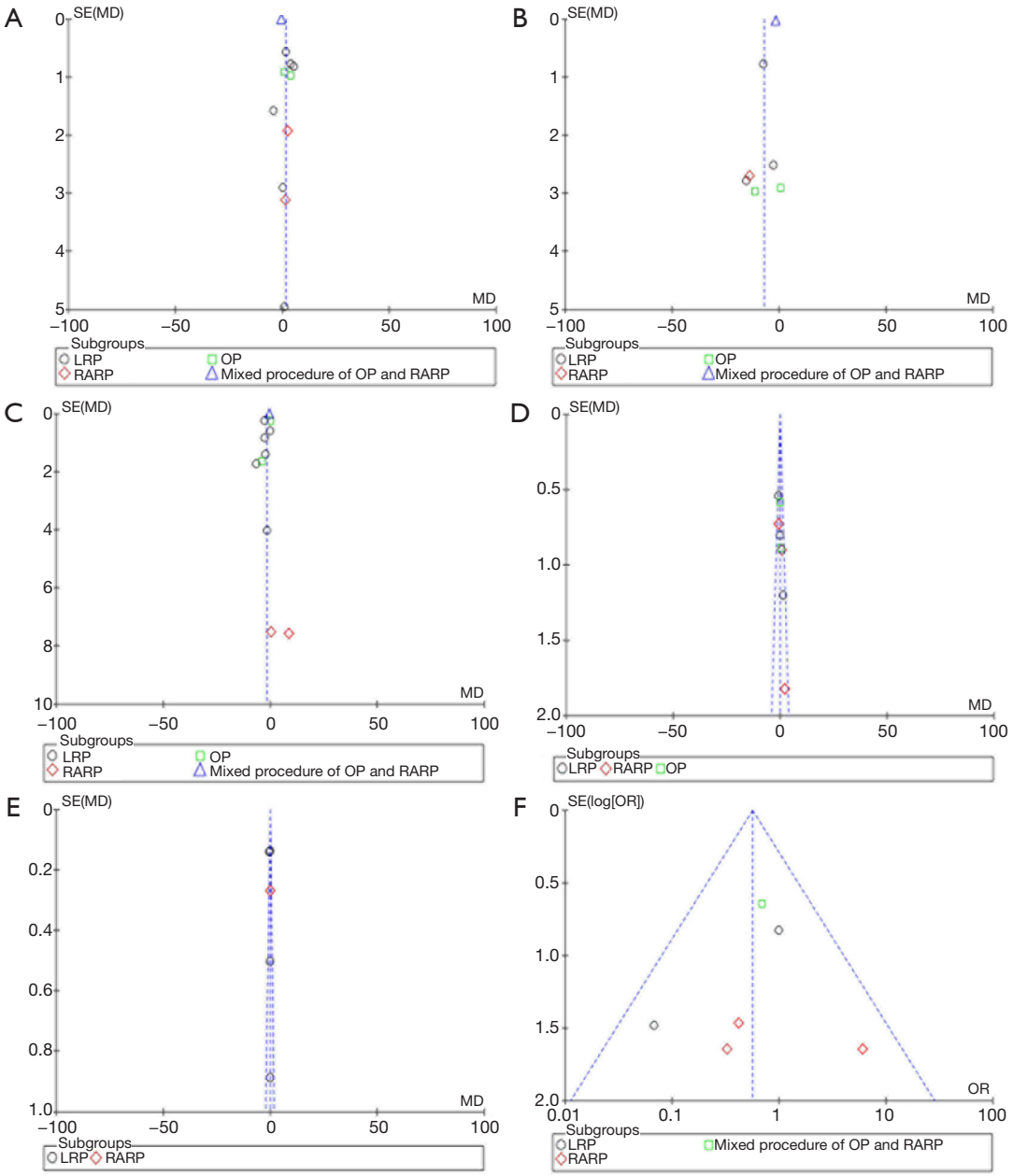

Figure S1 Funnel plots for (A) age; (B) prostate volume; (C) preoperative PSA; (D) BMI; (E) biopsy Gleason score; (F) clinical stage ≥ T3. BMI, body mass index.

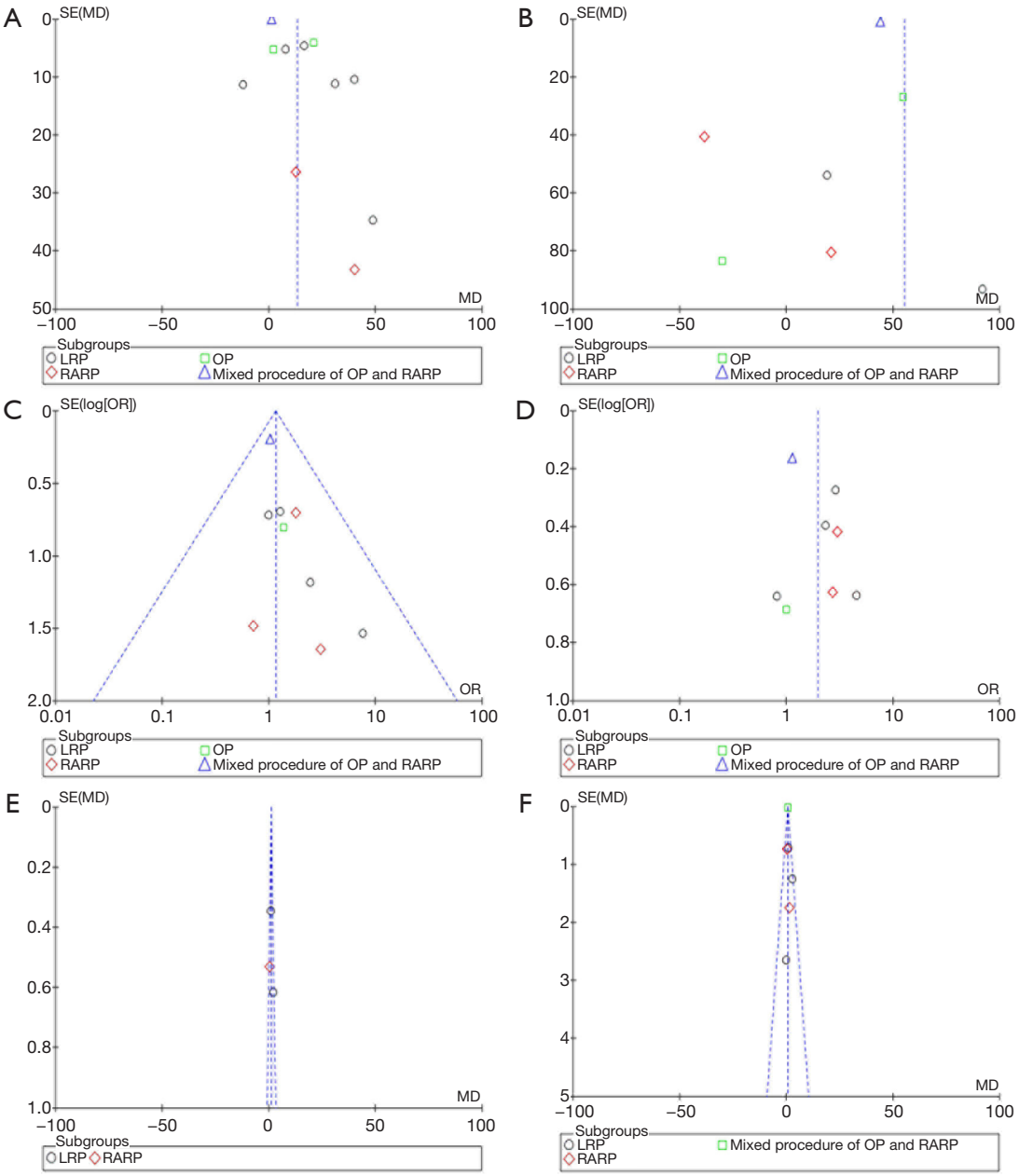

Figure S2 Funnel plots for (A) operative time; (B) estimated blood loss; (C) blood transfusion rates; (D) complication rates; (E) hospital stay; (F) duration of catheter.

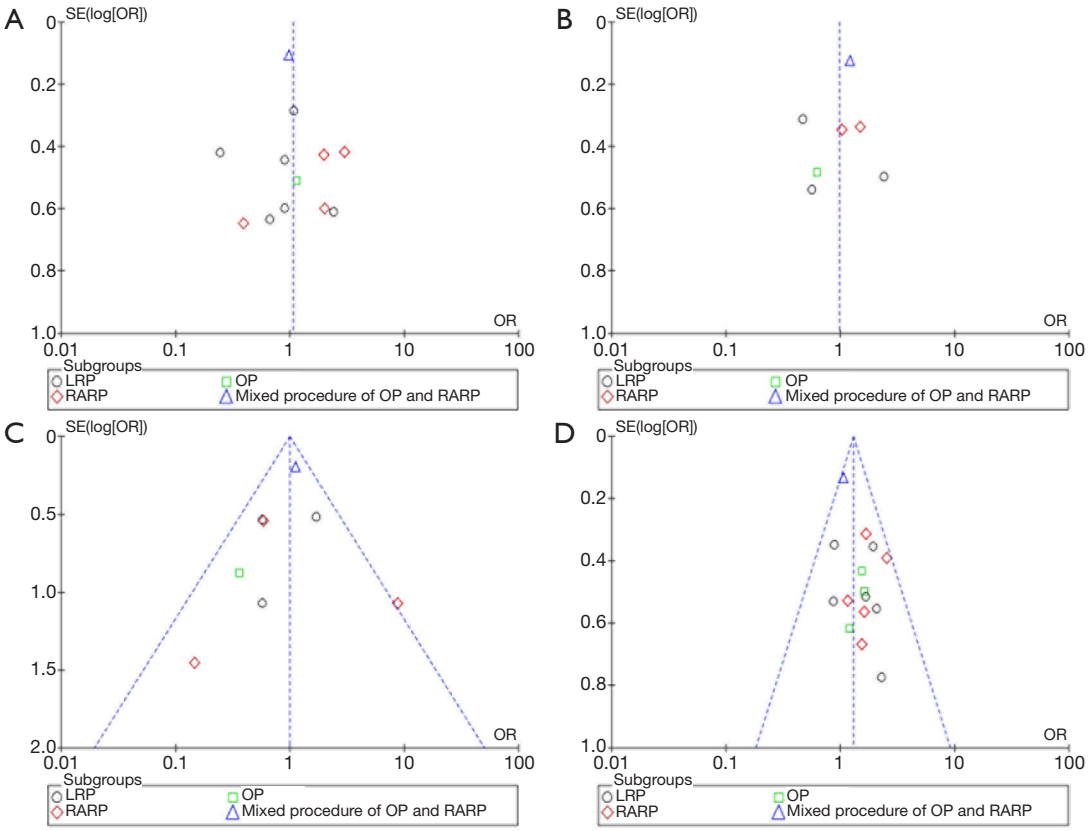

Figure S3 Funnel plots for (A) pathologic stage ≥ T3; (B) pathologic Gleason score =7; (C) pathologic Gleason score >7; (D) positive surgical margin rates.

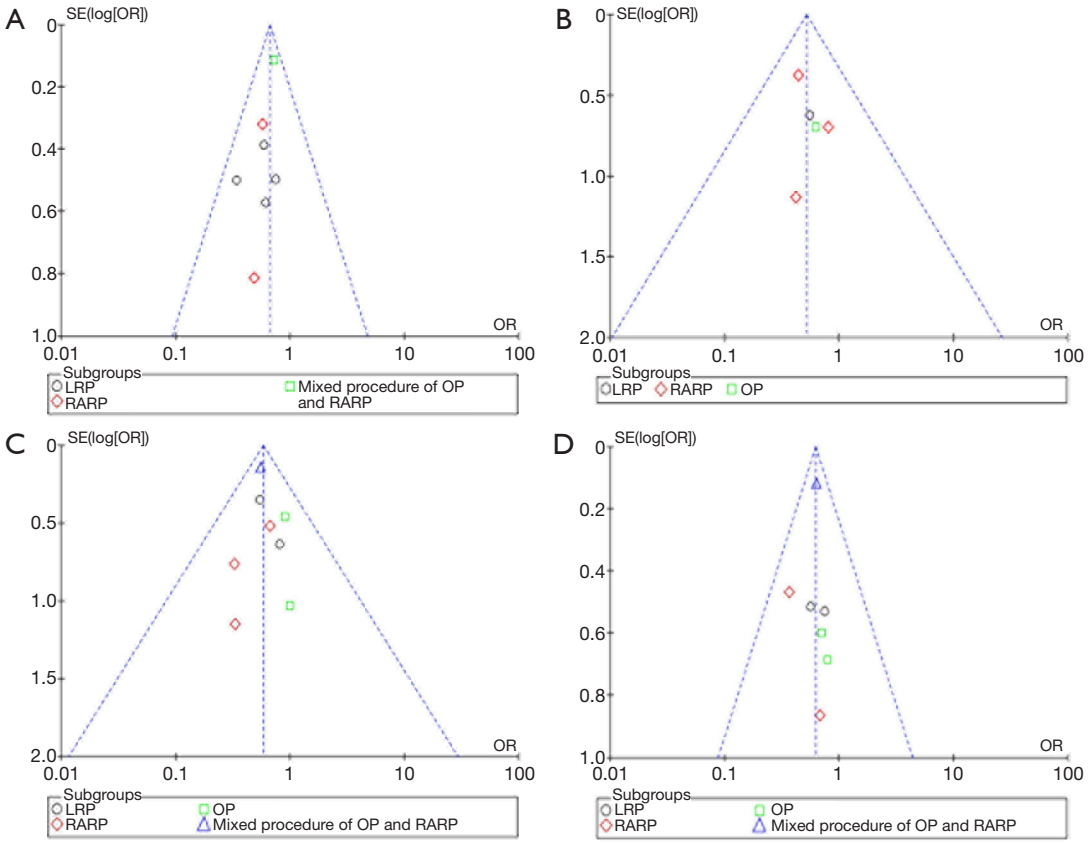

Figure S4 Funnel plots for (A) continence rates at 3 months; (B) continence rates at 6 months; (C) continence rates at 12 months; (D) potency rates at 12 months.