

## Impact of Diabetes Mellitus on Urinary Continence Recovery after Radical Prostatectomy: a Systematic Review and Meta-Analysis

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**Purpose:** To evaluate the impact of diabetes mellitus (DM) on the recovery of urinary continence (UC) after radical prostatectomy (RP).

**Materials and Methods:** A systematic review of English articles was performed in August 2019, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Trials were identified in a literature search of PubMed, Embase, Cochrane Library and Web of Science using appropriate search terms. All comparative studies reporting diabetes mellitus, study characteristics, and outcome data including the relationship between diabetes mellitus and urinary continence data were included. Continence rates at different time after RP were compared. Odds ratio (OR) was used for the comparison and all the results were presented with 95% confidence intervals (CIs).

**Results:** Seven cohort studies comprising with 5944 participants were included, the percentage of DM patients was 8.7%. The results showed that DM decreased urinary continence rates at 12 months after RP (OR 0.54, 95%CI 0.36 to 0.81,  $p = 0.003$ ). The continence rates were not significantly different between DM and Non-DM groups at short-term (catheter removal, 3 months, 6 months) and long-term (>12 months). When stratified by the surgical approaches, the pooled results in patients who underwent robot -assisted radical prostatectomy (RARP) were similar to results of the overall analysis.

**Conclusion:** DM has an adverse impact on the recovery of UC during the intermediate-term after RP. Well-designed trials with strict control of confounders are needed to make results more comparable.

**Keywords:** urinary continence; diabetes mellitus; radical prostatectomy; prostate cancer; meta-analysis

### INTRODUCTION

Urinary incontinence (UI) is still the most important complication of radical prostatectomy (RP) with a negative impact on the quality of life<sup>(1)</sup>. The prevalence of postprostatectomy UI varies according to the definition applied<sup>(2)</sup>. Various factors that affect urinary continence (UC) recovery have been reported. In addition to surgeon experience and different surgical techniques, age, membranous urethral length, and some comorbidities might impact on continence recovery<sup>(3,4)</sup>. Diabetes mellitus (DM) is a chronic disease associated with some genitourinary complications<sup>(5)</sup>. Uropathy due to DM may cause voiding disorders by impairing the storage and outlet functions of the urinary tract<sup>(6)</sup>. DM is a very common comorbidity in prostate cancer patients who receive treatment of RP. However, there is a lack of evidence in terms of the relationship between DM and UC recovery after RP for prostate cancer patients. Our study was aimed to systematically review and meta-analyze studies reporting the impact of DM on the recovery of UC following RP.

### MATERIALS AND METHODS

#### Search Strategy

A literature search was performed in August 15, 2019 using PubMed, Embase, Cochrane Library, and Web of Science databases. Medical Subject Headings (MeSH) and related keywords were used in searching. A combination of search terms was used including [Title/Abstract] or [Topic (TS)]: “diabetes mellitus OR diabetes”, “prostatectomy OR prostatectomies OR radical prostatectomy” and “urinary incontinence OR incontinence OR Urinary continence OR continence”. The search was conducted with a language restricted to English publication. References for all of the original studies were also identified.

#### Inclusion criteria and Exclusion criteria

Inclusion criteria: (1) Men undergoing radical prostatectomy; (2) Postoperative continence assessment completed; (3) Original articles in English publication; (4) Full journal article published in a peer-reviewed journal; (5) DM was described; (6) A report of the relationship between DM and postoperative continence status.

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**Table 1.** Demographic and clinical data of DM and non-DM patients in different studies.

	Wille et al.	Teber et al.	Nilsson et al.	Mao et al.	Song et al.	Cakmak et al.	Manfredi et al.
	<b>2006</b>	<b>2010</b>	<b>2011</b>	<b>2015</b>	<b>2017</b>	<b>2019</b>	<b>2019</b>
Country	Germany	Turkey	Sweden	China	Korea	Turkey	Italy
Study period	1989~2003	1999~2008	2002~2006	2010~2013	2008~2013	2009~2014	2013~2017
Patients	742	2071	1179	446	186	312	1008
DM cases (%)	74(10)	135(6.5)	71(6.2)	34(7.6)	31(16.7)	99(31.7)	71(7.04)
Type of DM	Both	Type 2	NA	NA	NA	Type 2	NA
Age (years)	66 ± 6.5	NA	63 (36~77)	66.9 (41-82)	64.5 ± 7.6	63.3 ± 6.5 (DM), 61.3 ± 6.8 (Non-DM)	64.8 ± 6.8
Preoperative PSA, Mean	NA	NA	6.9 (0.4-117)	18.5 (0.17-150.4)	8.25 ± 9.11	9.8 ± 9.3 (DM), 9.7 ± 8.2 (Non)	10.31 ± 11.61
Gleason score							
≤6	NA	NA	822(71.2)	NA	33 (17.7)	198(63.5)	97 (9.6)
7	NA	NA	276(23.9)	NA	137 (73.7)	69(22.1)	763(75.7)
8-10	NA	NA	57(4.9)	NA	16 (8.6)	45(14.4)	148 (14.7)
Clinical stage							
T1	28(3.8)	NA	702 (60)	135 (30.3)	NA	192(61.5)	0a
T2	395(53)	NA	422 (36)	301 (67.5)	NA	120(38.5)	549 (54.5)
T3	306(41)	NA	55 (5)	10 (2.2)	NA	0	458 (45.5)
Surgical approach	RRP	LRP	RRP+RARP	RRP+LRP	RARP	RARP	RARP
Operation time(min)	NA	221 (134~395), 212 (138~394)	NA	NA	294.5 ± 88.9	NA	117.28 ± 26.05
EBL (mL)	NA	560 (200~2400), 600 (200~2500)	NA	NA	304.9 ± 217.5	133.3 ± 89.2 156.3 ± 158.3	250.75 ± 64.44
Nerve sparing(%)	129(17.4)	none, unilateral or bilateral	NA	0	104 (55.9)	270(86.5) Bilateral	Full 102(10.1) partial 408 (40.5)
other techniques	NA	BNS	NA	NA	NA	PR	TAR
Catheterization(days)	NA	7 (4~25) (DM)7 (7~25)	NA	NA	NA	9.6 ± 5.0 (DM) 9.7 ± 5.3	3.5 (3~6)
Hospital stay (days)	NA	10 (6~25) (DM)10 (5~30)	NA	NA	NA	3.8 ± 1.8 (DM) 3.8 ± 2.7	6 (4~8)
Definition of continence	≤1 pad in 24 h	≤1 pad in 24 h	≤1 pad in 24 h	≤1 pad in 24 h	0 pad in 24 h	≤1 pad in 24 h	≤1 pad in 24 h
Study quality (stars rating)	****	*****	****	****	****	****	****

**Abbreviations:** DM, diabetes mellitus; NA, not available; RRP, retropubic radical prostatectomy; LRP, Laparoscopic radical prostatectomy; RARP, robot-assisted radical prostatectomy; EBL, estimated blood loss; BNS, bladder neck sparing; PR, posterior reconstruction; TAR, total anatomical reconstruction.  
a Pathological stage was used.

Exclusion criteria: (1) Review articles and descriptive commentaries; (2) Animal studies; (3) Conference abstracts or poster publications; (4) Publication in a language other than English.

#### Data Extraction and Quality Assessment

After the removal of duplicates, two authors (Huang and Wang) screened all titles and abstracts independently to identify potentially relevant articles for eligibility. Subsequent full-text record screening was fulfilled independently by two authors (Huang and An). Any disagreements were resolved by a third reviewer by discussion (Liao). All included trials in our meta-analysis contained data as follows: (1) first author's name, published year, country; (2) sample size, age, prostate-specific antigen, Gleason score, type of surgical approach; (3) the proportion of patients with DM; (4) the definition, method of assessment, and the time points used for UC assessment.

Authors of the studies identified in our search were also contacted by email to provide clarification and/or additional data where necessary. Some studies have shown the OR and 95% CI but not the numbers of continence of each group, which could be calculated with the total continence rates and numbers of each group. The quality of each included study was assessed by the Newcastle-Ottawa scale (NOS), which is widely used and recommended by the Cochrane collaboration<sup>(7)</sup>. The scale instrument evaluates cohort studies based on three aspects: participant selection, comparability of study

groups, and assessment of outcome. A maximum of four, two, and three stars can be awarded for each category, respectively.

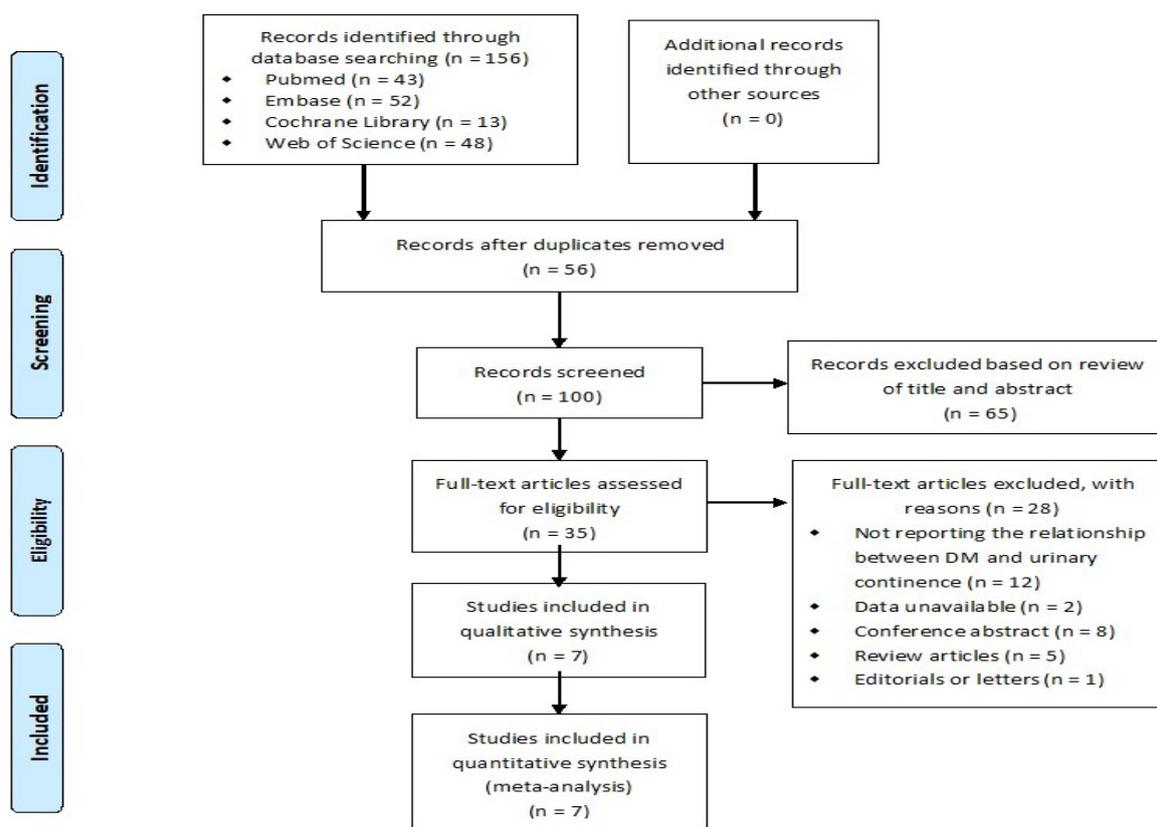
#### Statistical Methods

Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was used to perform this meta-analysis. Odds ratio (OR) was used for the comparison of dichotomous variables, and all the results were presented with 95% confidence intervals (CIs). Chi-square and *I*-square tests were employed to test the heterogeneity of different trials. A fixed-effects model (Mantel-Haenszel method) was applied to pool the trial results since no significant heterogeneity existed when  $p > 0.1$  and  $I^2 < 50\%$ . Significant heterogeneity was identified if  $p < 0.1$  and  $I^2 > 50\%$ , and a random-effects model which considered both within- and between-study variability was employed. Publication bias was assessed by funnel plots. A  $P < 0.05$  was considered statistically significant.

## RESULTS

#### Workflow of literature research

**Figure 1** presents the flow diagram for the study selection process. After primary literature search, 156 potentially relevant studies were found and 56 duplicate studies were excluded. Then, after screening the title and abstract, 65 studies were further excluded. Finally, 28 additional studies were removed by two authors accessing the full text independently. Therefore, 7 studies were included in this meta-analysis<sup>(8-14)</sup>.



**Figure 1.** Flow diagram for selection of the included trials reviewed.

### Study Characteristics

Seven included studies recruited 5944 participants. The percentage of DM patients was 8.7% (515/5944), from 6.2% to 31.7% in different studies. The demographics of enrolled patients and tumor characteristics are presented in Table 1. All seven studies were cohort studies (one prospective and six historical) representing seven different institutions from seven different countries. All studies were rated at 4-8 stars (of a maximum of 9 stars), according to the Newcastle-Ottawa Scale grading system (Table 1).

### Assessment and definition of UC or UI

All studies reported a definition of continence and the method of assessment used. Seven studies reported similar methods for the assessment of postoperative UC via direct patient questioning and/or the use of questionnaires about the perceived degree of UI, the absence of involuntary leakage and/or the use of pads. Continence status was additionally evaluated by physical examination with Valsalva or cough test at 3 months postoperatively in one study<sup>(9)</sup>. There was only one study that used both the 24-h pad weight test and the standard 1-h pad test for patients who were still incontinent at 12 and 24 weeks<sup>(14)</sup>. Continence was defined as the use of no or one safety pad per day, or incontinence was defined as the use of two or more pads per day in six studies. One study defined continence as no pad or protection<sup>(12)</sup>.

### Continence outcomes

Three trials reporting the UC data after catheter removal consisted of 1766 participants. The overall pooled

OR indicated that there was no significant association between DM and UC in patients who underwent radical prostatectomy (RP) (odds ratio [OR] 0.27, 95% confidence interval [CI] 0.02 to 4.64,  $p=0.37$ ) (Figure 2(a)). Four trials reporting the UC data at 3 months consisted of 2036 participants. The overall pooled OR indicated that there was no significant association between DM and UC in patients who underwent RP (OR 0.46, 95% CI 0.19 to 1.11,  $p=0.08$ ) (Figure 2(b)).

Three trials reporting the UC data at 6 months consisted of 1506 participants. All 3 trials were about robot-assisted radical prostatectomy (RARP). The overall pooled OR indicated that there was no significant association between DM and UC in patients who underwent RP (OR 0.38, 95% CI 0.13 to 1.08,  $p=0.07$ ) (Figure 2(c)). Four trials reporting the UC data at 12 months consisted of 1776 participants. No significant heterogeneity existed ( $I^2=47\%$  and  $P=0.13$ ) and a fixed-effects model was used. The overall pooled OR indicated that there was a significant association between DM and UC in patients who underwent RP (OR 0.54, 95% CI 0.36 to 0.81,  $p=0.003$ ) (Figure 2(d)). Same result was obtained while a random-effects model was used (OR 0.49, 95% CI 0.25 to 0.97,  $p=0.04$ ).

Four trials reporting the UC data at long-term (>12 months) consisted of 2474 participants. The time of assessment was not completely the same in each study, two were at 24 months (Teber et al. 2010 and Cakmak et al. 2019), one was at average 45 months (12~143 months) (Wille et al. 2006) and the other one was at average 2.2 years (1~5 years) (Nilsson et al. 2011). The

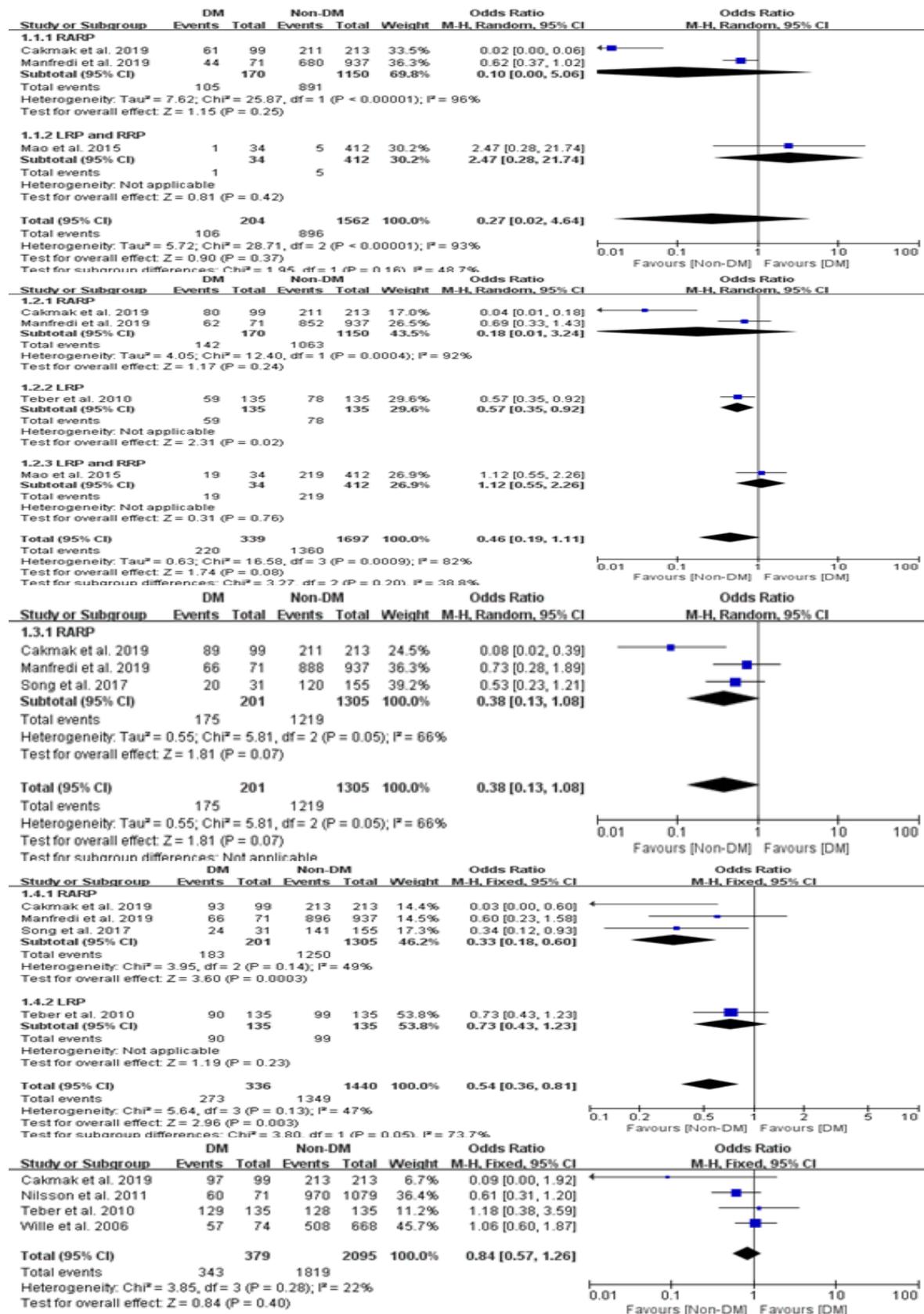
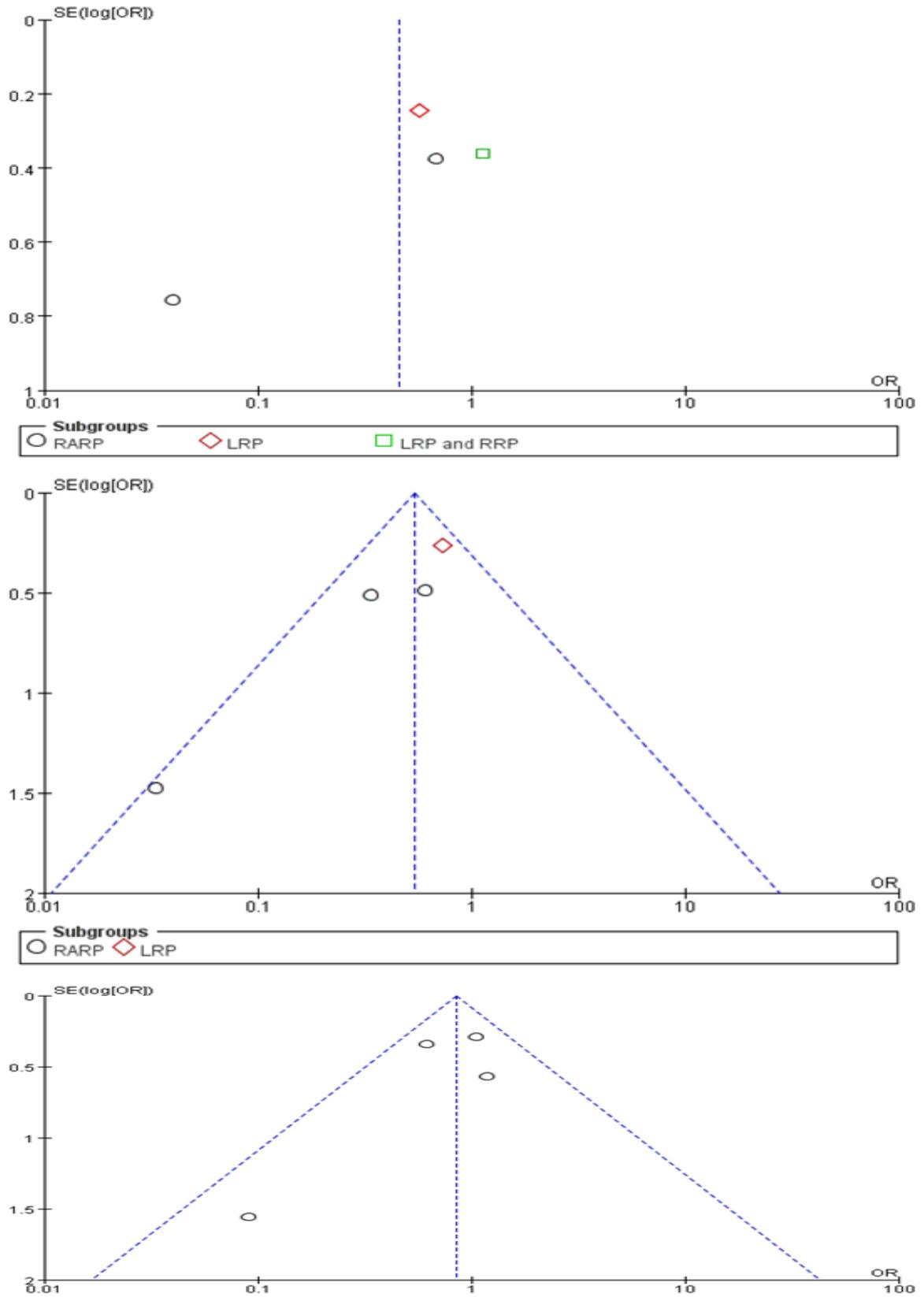


Figure 2. Forest plots comparing urinary continence rates between DM and non-DM men at catheter removal(a), 3 months (b), 6 months (c), 12 months (d) and long-term (>12 months) (e).



**Figure 3.** Funnel plots of urinary continence rates at 3 months (a), 12 months (b) and long-term (>12 months) (c). SE standard error, OR odds ratio.

overall pooled OR indicated that there was no significant association between DM and UC in patients who underwent RP (OR 0.85, 95% CI 0.57 to 1.26,  $p = 0.41$ ) (Figure 2(e)).

### Subgroup analysis

When stratified by the surgical methods including radical retropubic prostatectomy (RRP), laparoscopic radical prostatectomy (LRP), and RARP. There were three studies of RARP, one study of RRP, and one study of LRP. Two studies included 2 types of surgical approach (RRP+RARP, RRP+LRP), in which subgroup analysis was not performed. Because only one trial was included in each subgroup, so subgroup analysis was not performed at long-term (>12 months). In RARP subgroup, there was also a significant association between DM and UC at 12 months after RP (OR 0.33, 95% CI 0.18 to 0.60,  $p = 0.0003$ ), and no significant association at catheter removal (OR 0.10, 95% CI 0.00 to 5.06,  $p = 0.25$ ), 3 months (OR 0.18, 95% CI 0.01 to 3.24,  $p = 0.24$ ), 6 months (OR 0.38, 95% CI 0.13 to 1.08,  $p = 0.07$ ). In the LRP subgroup, there was a significant association between DM and UC at 3 months after LRP. In other subgroups, there were no significant associations between DM and UC after surgery.

### Publication Bias

The publication bias of our meta-analysis was assessed using funnel plots (Figure 3). No evidence of significant publication bias was found.

## DISCUSSION

At present, Diabetes mellitus (DM) is a major public health problem worldwide because of its frequency and the complications. With the rapid lifestyle changes, the prevalence of type 2 DM is steadily increasing in many countries<sup>(15)</sup>. As a result, the number of patients with both DM and prostate cancer is increasing, too. In addition to receiving curative therapy, patients with prostate cancer also need to maintain their quality of life (QOL). Urinary incontinence remains an important factor influencing the QOL after surgery<sup>(16)</sup>. Several studies have investigated the effect of factors on incontinence. Patient age, Body Mass Index (BMI), comorbidity index, lower urinary tract symptoms, and prostate volume were considered as the factors that affect the occurrence of incontinence<sup>(3,17)</sup>. However, the results obtained in these studies do not always support each other<sup>(18)</sup>. Currently, there is still a lack of data in terms of predictors of continence recovery after RP for prostate cancer patients. To the best of our knowledge, this study is the first meta-analysis with a focus on the relationship between DM and UC recovery after RP. Our results showed that patients with DM had lower continence rates than patients without DM at 12 months following RP, while there was no difference at short-term ( $\leq 6$  months) and long-term (>12 months). It could be understood that DM delayed continence recovery during the intermediate-term after RP. Postprostatectomy incontinence mainly depends on sphincter deficiency caused by operation and leads to stress type incontinence<sup>(19)</sup>. The persistent incontinence of patients that is seen within the first year may be related to the anatomic dysfunction related to the operation. Many patients continue to recover urinary function after 12 months<sup>(20)</sup>, which might be delayed by DM. While in the short-term after RP, DM might not be the predominant factor which in-

fluences the recovery of UC. In most studies included, other factors such as age, BMI, prostate volume, and surgical techniques had not been controlled, so it's hard to find the difference of continence between the two groups. Furthermore, some non-significant differences (non-significant  $p$ -value) might be due to the small sample size and the small number of studies.

Considering the efficacy of operative technology, subgroup analysis stratified by RRP, LRP, and RARP was performed. In subgroups, similar results showed that patients with DM had lower continence rates than patients without DM at 12 months following RARP. In other subgroups, the difference was not significant except patients with DM had lower continence rates than patients without DM at 3 months following LRP. It's possible that other main factors such as surgical techniques have a bigger impact<sup>(4)</sup>. In recent years, RARP has been the predominant surgical approach of RP, especially in some developed countries. Robotic technology allows surgeons to perform meticulous, precise, and accurate movements that are fundamental to preserve the key anatomic structures for urinary continence and potency. Basiri et al. performed a meta-analysis regarding UI between RLRP and LRP groups. The results revealed that the rate of UI was significantly lower after RLRP than LRP<sup>(21)</sup>. Ficarra et al. also found a better 12-month urinary continence recovery after RARP in comparison with RRP or LRP<sup>(22)</sup>. There are 3 studies in which the only surgical approach was RARP, while other subgroups only include one study in each category. Results of RARP subgroup analysis were similar to results of the overall pooled analysis, which further strengthened the conclusion of the impact of DM on continence recovery, regardless of the surgical approach used.

Various surgical steps of the procedure can influence the recovery of urinary continence. It was also showed that more techniques were used in later studies especially in RARP, including nerve sparing, posterior rhabdosphincter reconstruction, bladder neck sparing, etc. Posterior reconstruction for example, was popularized by Rocco for use in radical retropubic prostatectomy to support recovery of continence<sup>(23)</sup>, which was also later used in laparoscopic and robotic prostatectomy<sup>(24)</sup>. This procedure was recommended as a simple and fast technique to improve the recovery of continence in RARP. Furthermore, total anatomical reconstruction, a 'tension-free' anastomosis technique that aims to restore the anterior and posterior supports to the sphincter, conferred excellent results in the early recovery of urinary continence<sup>(14)</sup>.

There were different opinions about whether the duration of diabetes has an impact on continence. Teber et al. found that rates of continence in patients with DM for 5 or more years were significantly less than those in patients with DM for less than 5 years at 3, 12 and 24 months postoperatively<sup>(9)</sup>. However, another study showed that patients with a longer duration of diabetes ( $\geq 5$  years vs  $< 5$  years) had significantly more incontinence at the urethral catheter removal time, whereas no differences were detected in terms of urinary continence outcomes during the 1st, 3rd, 6th, 12th, 18th, and 24th months of follow-up times<sup>(13)</sup>.

There are several limitations of our study. Firstly, we did not include data from conference proceedings because generally this type of publication does not report a complete set of data, which is required for a meta-anal-

ysis. This choice might be considered a limitation of the study. Secondly, it is possible that other potential confounding factors were not adequately evaluated and could have influenced the reported outcomes, which included the participant preoperative parameters, the experience of surgeons, different kinds of techniques used by surgeons, and data collected and reported using different methods. Only one study used 1:1 randomly matched control for age, BMI, preoperative prostate specific antigen, clinical stage, presence of neoadjuvant hormonal therapy, measured prostate volume, and presence of previous abdominal surgeries<sup>(9)</sup>. Thirdly, with the development of society, RP techniques have changed and improved over time. The publication year of 7 studies included in this meta-analysis varied from 2006 to 2019, and the study periods ranged from 1989 to 2017. It is difficult to assess the potential difference in techniques in statistical models because the same surgical step can be performed using different techniques by various surgeons. Fourthly, in terms of the small sample size and the limited number of studies enrolled, the results may lack statistical power. Further studies need to be done. Fifthly, two different definitions of continence have been given in the literature and several ways of assessing continence have been used. The outcome could be affected by some degree of subjectivity. Moreover, preoperative urinary continence status was not reported in most studies, and continence recovery is not evaluated in all treated cases because some patients are lost at follow-up.

## CONCLUSIONS

In conclusion, this study indicated that DM had an adverse impact on the recovery of UC at 12 months (intermediate-term) in patients who underwent RP or RARP. However, there was no significant association between DM and UC at short-term (0~6 months) and long-term (>12 months) in patients with RP. The results should be confirmed by well-designed trials with strict control of confounders to make results more comparable.

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## CONFLICT OF INTEREST

The authors report no conflict of interest.

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