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Review

Delayed versus standard ligature of the dorsal venous complex during laparoscopic radical prostatectomy: A systematic review and meta-analysis of comparative studies

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ABSTRACT

Purpose: To evaluate current views on comparing delayed ligature of the dorsal venous complex (D-DVC) with standard ligature of the dorsal venous complex (S-DVC) for safety, urinary control and oncological outcomes during laparoscopic radical prostatectomy.

Methods: A comprehensive searching of PubMed, Web of science, Embase and the Cochrane Library was made and then we performed a meta-analysis, including all randomized controlled trials (RCTs) and retrospective studies, to evaluate the two different techniques.

Results: Two RCTs and six retrospective studies containing 1822 cases (222 cases from RCTs and 1600 cases from retrospective studies) were identified. Although D-DVC was related to more blood loss (WMD: 7.30 mL; 95% CI, 2.43 to 12.16; p = 0.003), the blood transfusion rate between the two groups showed no significant difference (OR = 1.93; 95% CI, 0.55 to 6.73; p = 0.31), and patients in the D-DVC group could benefit from a shorter operative time (WMD: −30.83 min; 95% CI, −53.32 to −8.35; p = 0.007). Positive apical margin events were significantly less in the D-DVC group (OR = 0.39; 95% CI, 0.22 to 0.71; p = 0.002). As for urinary control, there were no differences in continence rates after 3 months (OR = 1.64; 95% CI, 0.98 to 2.73; p = 0.06) and 12 months (OR = 1.00; 95% CI, 0.63 to 1.57; p = 0.99) of follow-up. However, there was a significantly higher continence rate after 6 months of follow-up in the D-DVC group (OR = 1.46; 95% CI, 1.02 to 2.11; p = 0.04).

Conclusions: Standard and delayed approaches to DVC are equally safe and result in similar urinary control. The delayed approach could decrease the positive apical margin rate. However, further large-scale prospective studies are needed to investigate and compare the prognosis and long-term functional outcomes between the two approaches.

1. Introduction

For the surgical management of localised prostate cancer, laparoscopic (LRP) and robotically assisted laparoscopic prostatectomy (RARP) are becoming the established approaches [1]. During these surgeries, the management of the dorsal venous complex (DVC) is vital for controlling bleeding, recovering urinary continence, and ensuring precise apical dissection [2]. In order to control bleeding, it is generally believed that an early suture ligation of the DVC before cutting is the standard approach (S-DVC) [3]. However, this carries risk of injuring the urethra, hurting the external sphincter and decreasing the functional urethral length [4]. Also, it has been proposed that standard ligature of the DVC (S-DVC) has the potential to increase the positive apical margin rate [5].

As a consequence, many surgical modifications of radical prostatectomy have been raised, including delayed ligature of the dorsal venous complex (D-DVC). The standard approach (S-DVC) is to ligate the DVC before dissecting the apex. However, the delayed approach firstly transects the DVC and the apex of prostate, and then selectively suture ligates the DVC. This approach is named delayed ligature of the DVC (D-DVC) or selective ligature of the DVC [3]. As Sasaki et al. reported, delayed ligature of the DVC is simple and can be easily performed [6]. Also, Lei et al. and Porpiglia et al. reported that the D-DVC group could achieve a better early urinary control and a similar positive surgical margin rate [7,8]. Guru et al. and Antonelli et al. believed that D-DVC could lead to a lower apical surgical margin rate [3,5]. However, Woldu

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et al. reported that D-DVC achieved similar urinary control and apical margin status with higher blood loss (122 mL versus 112 mL) [9]. Kawakami et al. and Richman et al. reported that preliminary ligation of the DVC could lead to an excellent oncological outcome [10,11]. As the results are controversial, we therefore systematically performed this meta-analysis to evaluate the safety, urinary control and oncological outcomes of delayed ligature of the DVC (D-DVC) compared with standard ligature of the DVC (S-DVC).

2. Materials and methods

We conducted this study protocol based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [12] and Assessing the Methodological Quality of Systematic Reviews (AMSTAR) [13].

2.1. Literature-search strategy

We did a computerized literature search of PubMed, Web of science, Embase and the Cochrane Library in October 2018. The used search terms and their combination strategies were as followed [Title/Abstract]: santorini plexus, OR dorsal vein complex, OR dorsal venous complex, OR dorsal vascular complex, OR vascular pedicles, OR deep venous complex, OR prostatic pedicles and prostatectomy. There were no other search restrictions. We reviewed all abstracts and review articles relating to this topic and by manual search, we identified references for all of the original studies. We used the most recent or the most complete report when two or more reports containing the same population were published.

2.2. Inclusion and exclusion criteria

We included all the randomized controlled trials (RCTs) and the retrospective comparative studies without restriction to languages that met the following selection criteria: studies that compared delayed ligature of the DVC (D-DVC) and standard ligature of the DVC (S-DVC) in laparoscopic prostatectomy; studies that contained significant information about operation time, estimated blood loss, blood transfusion rate, continence rates after 3, 6 and 12 months of follow-up and positive apical margin rate; studies that provided adequate information for estimating relative risk (RR) or hazard ratio (HR) by a 95% confidence interval (95% CI). While we excluded editorials, letters to the editor, review articles, case reports, conference abstracts and animal experimental studies.

2.3. Data extraction and outcomes of interest

Two of the authors extracted and summarised data independently from the included studies. When there was a disagreement, it was determined by the adjudicating senior author. The outcomes were divided into four parts, including: baseline characteristics, perioperative outcomes, oncological outcomes and urinary control. Perioperative outcomes were subdivided into estimated blood loss (EBL), blood transfusion rates and operation time. Oncological outcomes referred to pathologic stage, postoperative Gleason score and the positive apical margin rate. Urinary control was compared between D-DVC and S-DVC groups after 3, 6 and 12 months of follow-up. As shown in Table 1, most of the studies included measured urinary control by Expanded Prostate Cancer Index Composite (EPIC) urinary function scores and by pad use, except for Porpiglia et al. who used the International Continence Society (ICS) male short form [8]. Also, most studies defined no pad used per day as continence, except that Otsuki et al., who defined no more than one pad used per day as continence [14].

2.4. Quality assessment and statistical analysis

Based on the Newcastle-Ottawa Scale recommended by the Cochrane Collaboration [15], a score system of 0–9 was used to judge each retrospective study. When a score of 7–9 was defined as high-quality, four retrospective studies were of high methodological quality. Based on the Cochrane risk of bias tool, RCTs getting six or more scores were regarded as high quality, and two RCTs were of high methodological quality.

Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) and Stata/SE 12.0 were used to perform this meta-analysis. We used weighted mean difference (WMD) for the comparison of continuous variables, and odds ratio (OR) for dichotomous variables. We presented all the results with 95% confidence intervals (CIs) and we calculated standard deviations by using the statistical algorithms when the studies reported continuous data as means and range values [16]. We evaluated statistical heterogeneity using chi-square test with a significance set at $p < 0.10$ and quantified the heterogeneity using the I^2 statistic. We measured the degree of heterogeneity according to the value of I^2 ($I^2 < 25\%$: no heterogeneity; $I^2 = 25\%–50\%$: moderate heterogeneity; $I^2 > 50\%$: large heterogeneity). If there was a large heterogeneity between studies, we used the random-effects model and if not, we used the fixed-effects model. We assessed publication bias by Begg funnel plot [17,18] and we conducted a sensitivity analysis by the leave-one-out cross validation.

3. Results

Two RCTs [3,8] and six retrospective studies [4,5,7,14,19] containing 1822 cases (222 cases from RCTs and 1600 cases from retrospective studies) met the inclusion criteria and were included in the final analysis (Fig. 1). All of the publications included were full-text articles. Consistency between the two reviewers was 100% for study selection and 95% for quality assessment of studies.

3.1. Characteristics of eligible studies

Table 1 shows the characteristics of the included studies, which contains two RCTs with a small sample (level of evidence: 1b; level of evidence: 2b) [3,8] and six retrospective studies comparing consecutive series of patients (level of evidence: 3b) [4,5,7,14,19]. As for operation methods, six studies were about robotically assisted laparoscopic prostatectomy (RARP) [3–5,7,9,14]and two studies were about laparoscopic prostatectomy (LRP) [8,19]. The baseline features of the patients included six parts: the age, the prostate volume, the prostate-specific antigen (PSA), the body mass index, the preoperative Gleason score and the clinical stage. Among the eight studies, five studies achieved a balance among all six parts. Also, we performed a meta-analysis of all these baseline characteristics. The pooled data showed no significant differences in all of these factors except for the age, which showed a significantly older age in the D-DVC group (WMD: 1 year; 95% CI, 0.30 to 1.69; $p = 0.005$) and a fixed model was used (Supply 1-2.

3.2. Methodological quality of included studies

Two RCTs used true randomization and provided details about allocation concealment and blinding method. However, no suitable protocol for treatment assignment was adopted by the retrospective studies, which means that the physician's will could have influenced the allocation. The baseline features for most of the patients included could achieve a balance. The perioperative data and the length of follow-up were provided by all the studies. Most of the studies did not adequately describe the way in which missing data was dealt with and the intention-to-treat analysis.

Table 1
Characteristics of included studies.

Study	Level of evidence	Design	Method	Patients, no		Matching	Definition of continence	Follow-up, mo. D-DVC/S-DVC	Quality score
				D-DVC	S-DVC				
Xu et al.	3b	R	LRP	180	53	1,2,3,4,5,6	EPIC, ICIQ, no pad	12	7
Tufek et al.	3b	R	RARP	50	50	1,2,3,4,5,6	No pad	3.5/7	7
Lei et al.	3b	R	RARP	240	303	2,3,4,6	EPIC, No pad	12	6
Woldu et al.	3b	R	RARP	126	118	NC	No pad	3	7
Guru et al.	3b	R	RARP	145	158	1,3,4,5,6	NC	NC	6
Otsuki et al.	3b	R	RARP	62	115	1,2,3,4,5,6	No or one pad	6	7
Porpiglia et al.	2b	RCT	LRP	30	30	1,2,3,4,5,6	ICIQ, No pad	12	RCT
Antonelli et al.	1b	RCT	RARP	81	81	1,2,3,4,5,6	EPIC, No pad	6	RCT

D-DVC = delayed ligature of the DVC; S-DVC = standard ligature of the DVC.
R = retrospective; RCT = randomized controlled trail; LRP = laparoscopic prostatectomy; RARP = robotically assisted laparoscopic prostatectomy; NC = data not clear; EPIC = The Expanded Prostate Cancer Index Composite; ICIQ = International Consultation on Incontinence Questionnaire.
Matching: 1 = age; 2 = prostate volume; 3 = prostate-specific antigen; 4 = body mass index; 5 = gleason score; 6 = clinical stage.

3.3. Outcomes

3.3.1. Perioperative outcomes

The pooling data from the five studies that assessed operative time in 1341 patients showed a significantly shorter operative time in the D-DVC group than the S-DVC group (WMD: −30.83 min; 95% CI, −53.32 to −8.35; p = 0.007) (Fig. 2 A). There was a heterogeneity between these studies (I^2 = 97%; P < 0.001) and a random-effects model was used. Although estimated blood loss (EBL) for the five studies in 1341 patients showed more blood loss in the D-DVC group (WMD: 7.30 mL; 95% CI, 2.43 to 12.16; p = 0.003), with a moderate heterogeneity (I^2 = 40%; p = 0.16) (Fig. 2 B), blood transfusion rates for the five studies including 1301 patients showed no significant differences between the two groups (OR = 1.93; 95% CI, 0.55 to 6.73; p = 0.31), with no heterogeneity (I^2 = 0%; p = 0.94) (Fig. 2 C). A fixed-effects model was used in these two figures.

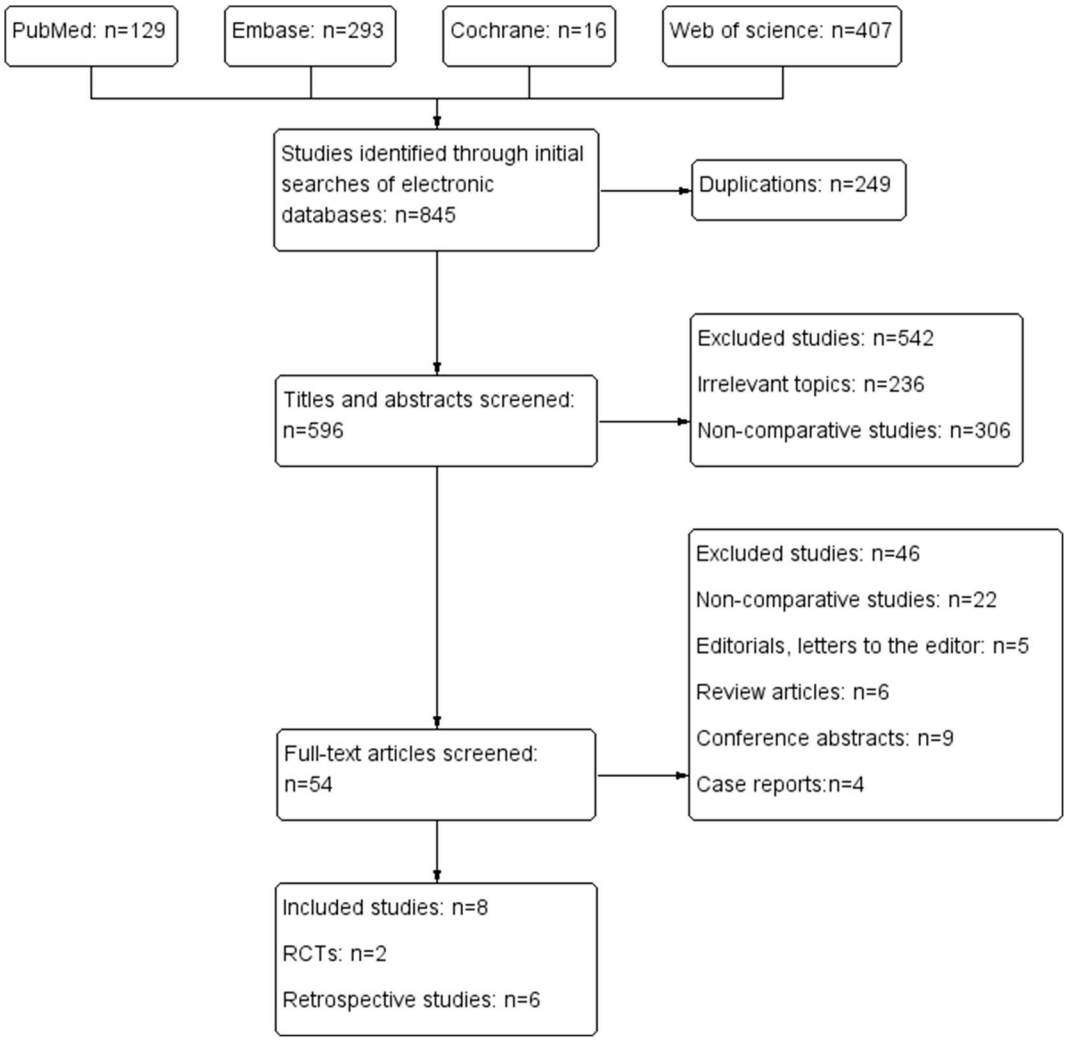

Fig. 1. Flow diagram of studies identified, included, and excluded.

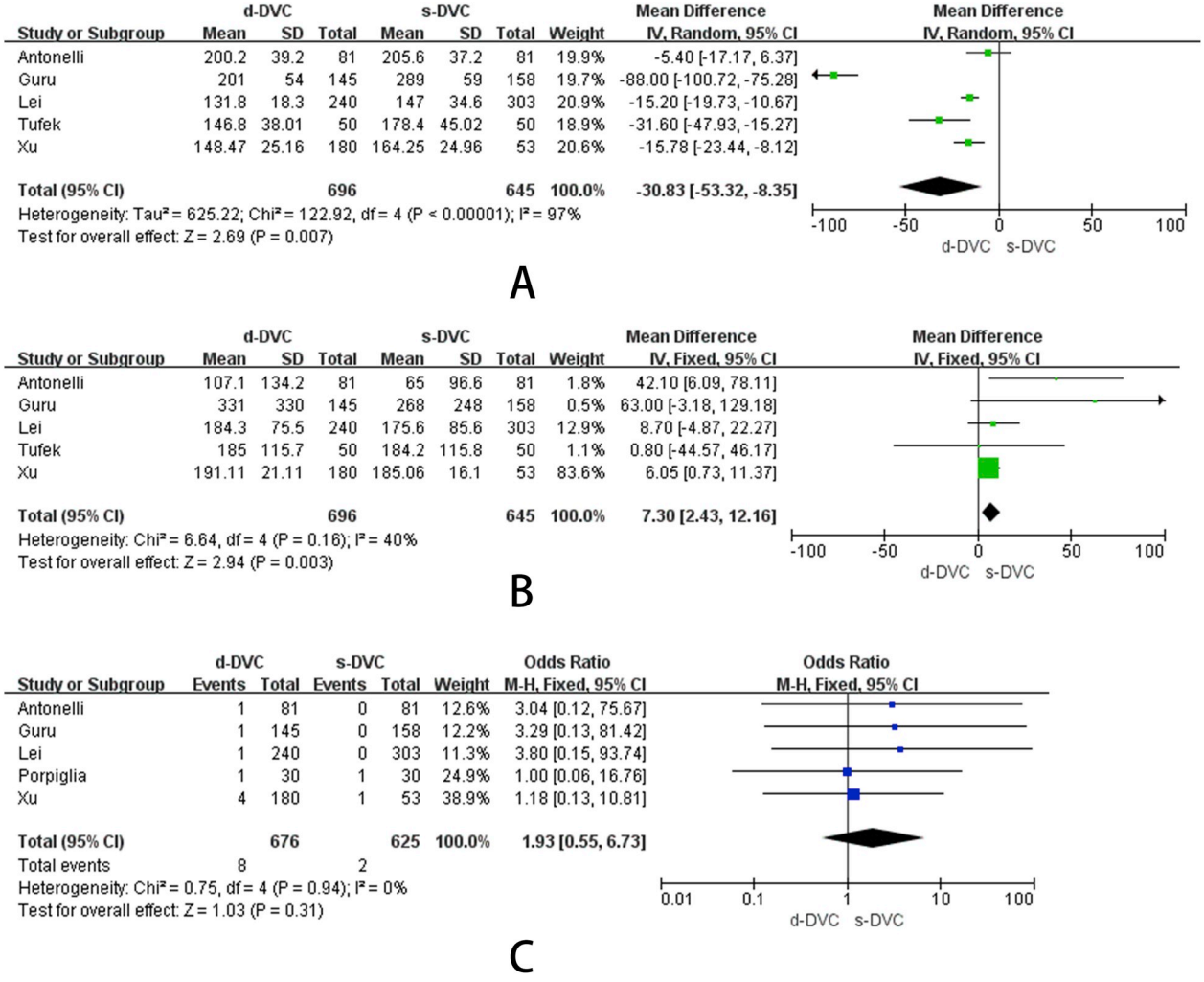

Fig. 2. Forest plot for (A) operative time; (B)blood loss; (C) blood transfusion rates.

3.3.2. Oncological outcomes

Seven studies including 1578 patients reported pathologic T2 and T3 stage and showed no significant difference between the two groups (OR = 0.87; 95% CI, 0.67 to 1.12; p = 0.27 and OR = 1.14; 95% CI, 0.88 to 1.48; p = 0.32) (Fig. 3 A–B). There was no heterogeneity between these studies and a fixed-effects model was used. Three studies including 393 patients reported postoperative Gleason score and showed no significant difference between the two groups (OR = −0.07; 95% CI, −0.32 to 0.19; p = 0.61) (Fig. 3 C). There was a moderate heterogeneity between these studies (I^2 = 36%; p = 0.21) and a fixed-effects model was used. Seven studies including 1616 patients reported positive apical margin events and showed significant difference between the two groups (OR = 0.39; 95% CI, 0.22 to 0.71; p = 0.002) (Fig. 3 D). There was no heterogeneity between these studies (I^2 = 0%; p = 0.88) and a fixed-effects model was used.

3.3.3. Urinary control

Five studies including 790 patients evaluated the continence rates after 3 months of follow-up. The pooled data showed no significant difference between the two groups (OR = 1.64; 95% CI, 0.98 to 2.73; p = 0.06) with a moderate heterogeneity (I^2 = 49%; p = 0.10) (Fig. 4 A), and a random-effects model was used. Four studies including 632 patients evaluated the continence rates after 6 months of follow-up and the pooled data showed a difference between the two groups (OR = 1.46; 95% CI, 1.02 to 2.11; p = 0.04) (Fig. 4 B). There was no heterogeneity (I^2 = 3%; p = 0.38), so a fixed-effects model was used. Three studies including 568 patients evaluated the continence rates after 12 months of follow-up and no difference was observed (OR = 1.00; 95% CI, 0.63 to 1.57; p = 0.99) (Fig. 4 C). A fixed-effects model was used as there was no heterogeneity (I^2 = 0%; p = 0.57). All the results are summarised in Table 2.

3.3.4. Sensitivity analysis and publication bias

To assess the stability of the meta-analysis results, we performed sensitivity analysis (Fig. 5-6, Supply 3-7) by leave-one-out cross validation. As the sensitivity analysis showed, the overall OR of the continence rates after 3 months of follow-up changed after removing the study reported by Antonelli et al. [3], which showed that D-DVC group had a better continence rate (Fig. 5). The continence rates at 6 months changed after removing the studies reported by Antonelli et al. Porpiglia et al., and Xu et al. reported [3,8,19], which showed that there was no difference between the two groups (Fig. 6).

Fig. 7 shows the funnel plots for the comparison of the positive apical margin rate and that there was no obvious asymmetry, indicating no obvious publication bias (Supply 8-13).

4. Discussion

This meta-analysis comparing D-DVC and S-DVC during laparoscopic radical prostatectomy (LRP) showed that D-DVC is safe, with shorter operative times, but more blood loss despite a similar blood transfusion rate when compared with S-DVC. As for urinary control,

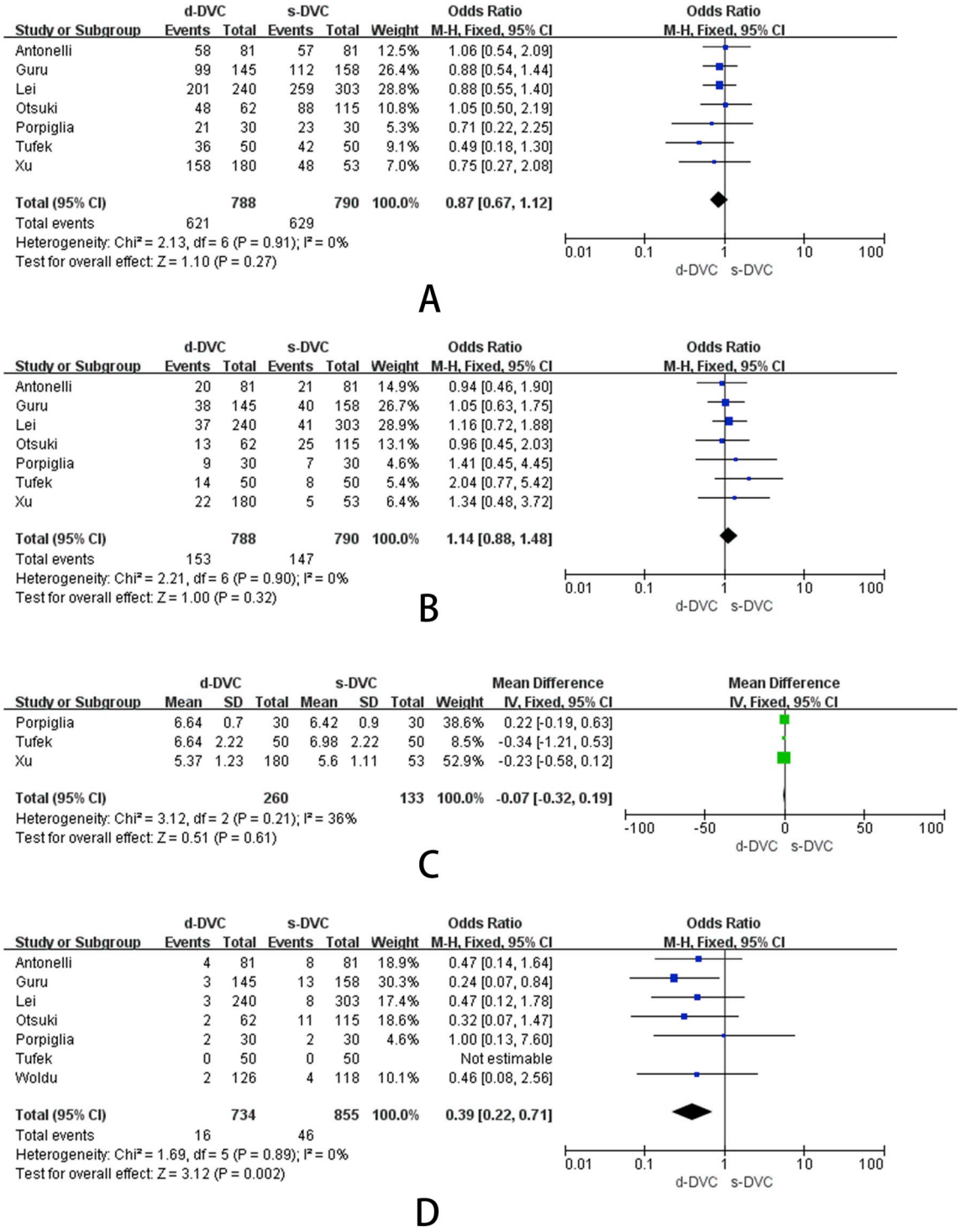

Fig. 3. Forest plot for (A) pathologic T2 stage rates; (B) pathologic T3 stage rates; (C) postoperative Gleason score; (D) positive apical margin rates.

there was no apparent difference between these two groups, with similar continence rates after 3 and 12 months of follow-up and a slightly higher continence rate in the D-DVC group at 6 months. Remarkably, with similar pathologic T stage and postoperative Gleason score, significant differences in the positive apical margin rate were demonstrated, indicating that D-DVC could achieve better cancer control.

Before the application of a new procedure, ensuring the safety of patients is the first and most important task. Giovanni Domenico Santorini, an Italian anatomist, was the first to mention the DVC [20] and it was latter to be found to contain a mixed component of veins, arteries, sphincteric muscle fibres etc. [6]. As bleeding is a major perioperative complication in radical prostatectomy and the primary source of bleeding comes from the dorsal vein complex, control of the dorsal vein complex is of vital important [21]. In order to minimize blood loss, an early ligature of the DVC and followed by transection became the standard technique (S-DVC) [22]. However, various surgical modifications to control DVC have been studied over the years, including: vascular stapling device for DVC control, athermal division and delayed suture ligation of the DVC [1,7], and as this meta-analysis showed, delayed suture ligation of the DVC did not increase the risk of

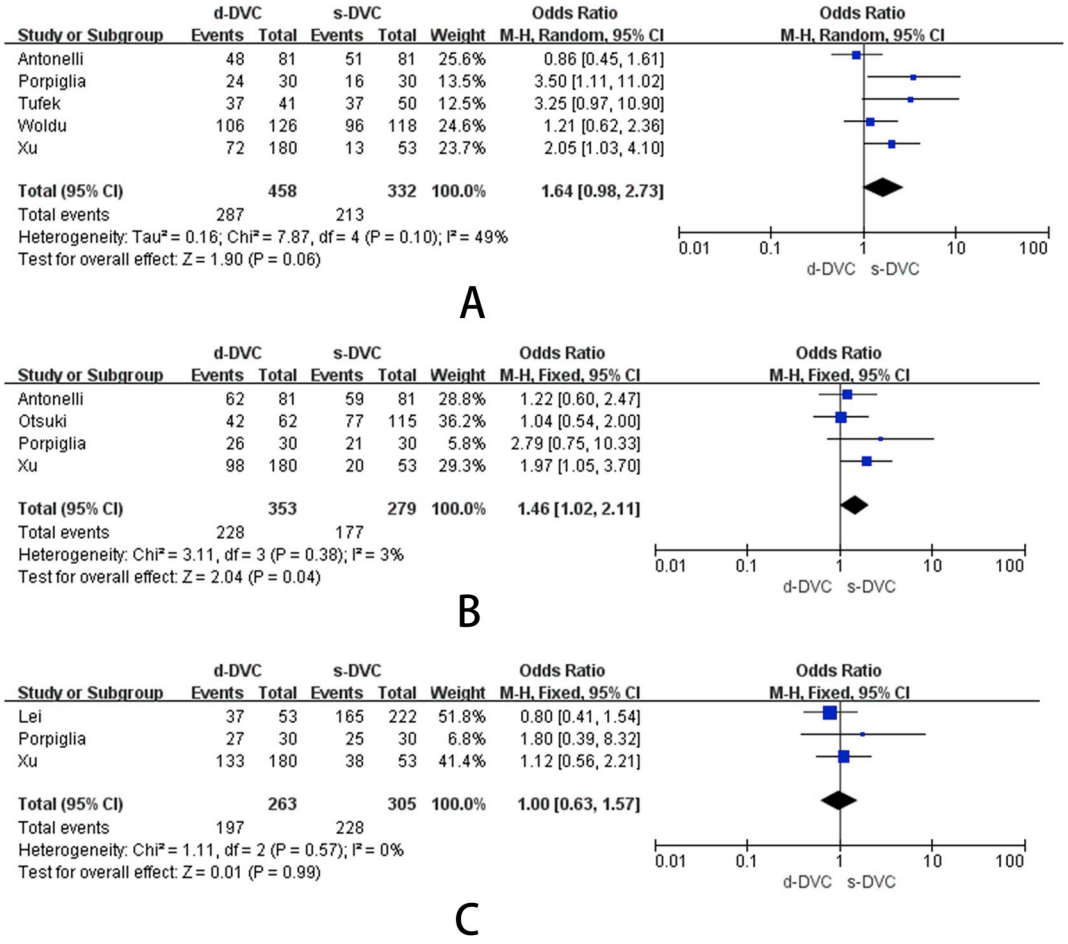

Fig. 4. Forest plot for (A) continence rate after 3 months of follow-up; (B) continence rate after 6 months of follow-up; (C) continence rate after 12 months of follow-up.

bleeding. The reason for this may be that in laparoscopic radical prostatectomy (LRP) or robotically assisted laparoscopic prostatectomy (RARP), bleeding from the vein can be controlled by increasing the pneumoperitoneum pressure of CO_2 and coagulating which could well control the artery [8]. Whereas, during open prostatectomy, bleeding can only be well controlled by standard ligation of the DVC. LRP and RARP have wrongly inherited this approach [3,22] and this is the root of the problem. As for operative time, the D-DVC group was significantly shorter than S-DVC group due to the decrease in surgical steps, which could decrease the burden on multiple organs, such as the heart and lungs [19].

Urinary control had similar results between the two groups. As for continence rates after 6 months of follow-up, there was a difference between the two groups. However, this was not significant with a p value equalling 0.04, and it was only included four articles [3,8,14,19]. Moreover, as the sensitivity analysis indicated, this figure was unstable and only when the study reported by Otsuki et al. was excluded [14], was a difference identified. Also, two of the remaining articles were performed purely laparoscopically [8,19]. An assumption is raised nowadays that an early suture of the DVC could delay functional recovery as a result of damaging the sphincter or neurovascular bundles [22,23]. However, worse early continence rates were only shown on

Table 2
Results of meta-analysis comparison of delayed ligature of the DVC (D-DVC) and standard ligature of the DVC (S-DVC).

Outcome of interest	Studies no.	D-DVC no.	S-DVC no.	WMD/OR (95% CI)	P value	Study heterogeneity			
						$\chi 2$	df	I^2,%	P value
operative time	1341	696	645	−30.83 (−53.32 to −8.35)	0.007	122.92	4	97	< 0.001
estimated blood loss	1341	696	645	7.30 (2.43–12.16)	0.003	6.64	4	40	0.16
blood transfusion rates	1301	676	625	1.93 (0.55–6.73)	0.31	0.75	4	0	0.94
pathologic T2 stage	1578	788	790	0.87 (0.67–1.12)	0.27	2.13	6	0	0.91
pathologic T3 stage	1578	788	790	1.14 (0.88–1.48)	0.32	2.21	6	0	0.90
postoperative Gleason	393	260	133	−0.07 (−0.32 -0.19)	0.61	3.12	2	36	0.21
positive apical margin	1616	734	882	0.39 (0.22–0.71)	0.002	1.76	5	0	0.88
continence rate at 3 mo	790	458	332	1.64 (0.98–2.73)	0.06	7.87	4	49	0.10
continence rate at 6 mo	632	353	279	1.46 (1.02–2.11)	0.04	3.11	3	3	0.38
continence rate at 12 mo	568	263	305	1.00 (0.63–1.57)	0.99	1.11	2	0	0.57

D-DVC = delayed ligature of the DVC; S-DVC = standard ligature of the DVC; WMD/OR = weighted mean difference/odds ratio; df = degrees of freedom; CI = confidence interval.

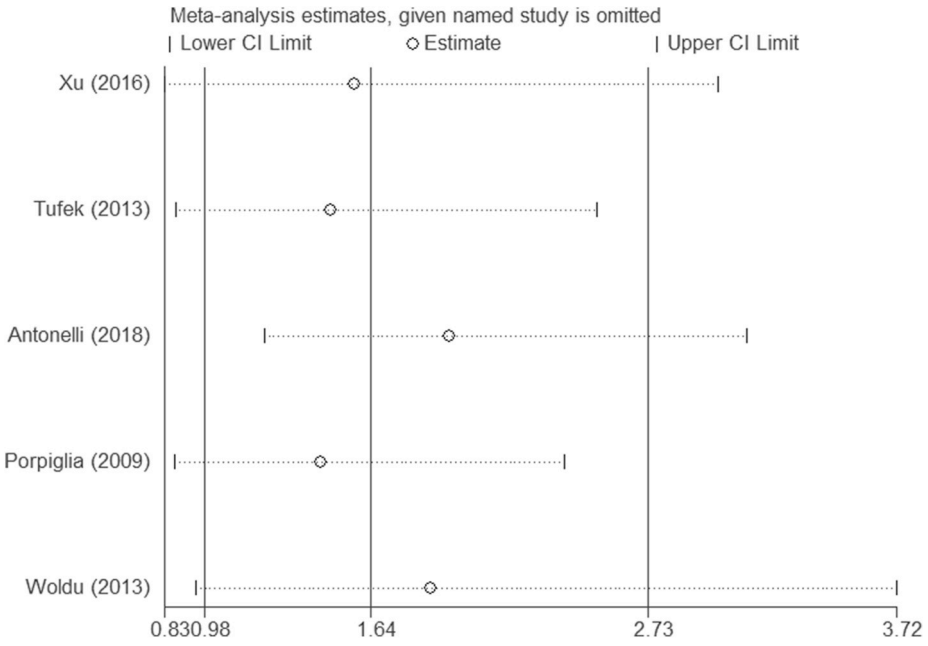

Fig. 5. Sensitivity analysis for the continence rate after 3 months of follow-up.

purely laparoscopic prostatectomies for the standard approach [3,8,19,24], probably as a result of a less accurate suture and the surgeons were the vital factor, not the technique [3].

The pooled data of the significant lower positive apical margin rate suggested that D-DVC may achieve better cancer control than S-DVC. It is known that positive surgical margins (PSM), preoperative serum PSA > 10 ng/mL, Gleason score ≥7, lymph-node metastasis, and seminal-vesicle involvement, are related to higher rates of biochemical, local or systemic progression [25]. Between the factors above, PSM is the sole risk factor that is affected by the surgical technique and the surgeon [26]. As studies suggested, positive surgical margins were significantly affected by modified surgical technique, especially when the technique tried to improve dissection at the apex [25]. Ahlering et al. and Wu et al. respectively reported that using an endovascular stapler in ligating the DVC could decrease apical PSM rates [27,28]. The common point between their studies and the studies this meta-analysis included, was that all of them avoided suture ligation of the DVC before apical dissection was performed. Although, there was a difference in Tufek et al. who used a vascular bulldog clamp to control the DVC before dividing it [4]. There were some possible reasons why control of the DVC after dividing it had lower positive apical margin rates, including that the higher mobility of the prostate and approaching the apex of prostate from all angles in the case of D-DVC could improve precision during apical dissection [3,29]. By improving circumferential visualization of the apex of the prostate, the membranous urethra and their anatomic intersection the surgeons could dissect the apex and the neural scaffold surrounding it more precisely [29]. Suturing the DVC had the risk of bunching the tissue and could alter apical anatomy, causing higher PSM rates [22]. Fear of increased blood loss and dislocation of the ligation suture could cause surgeons to incise too close to

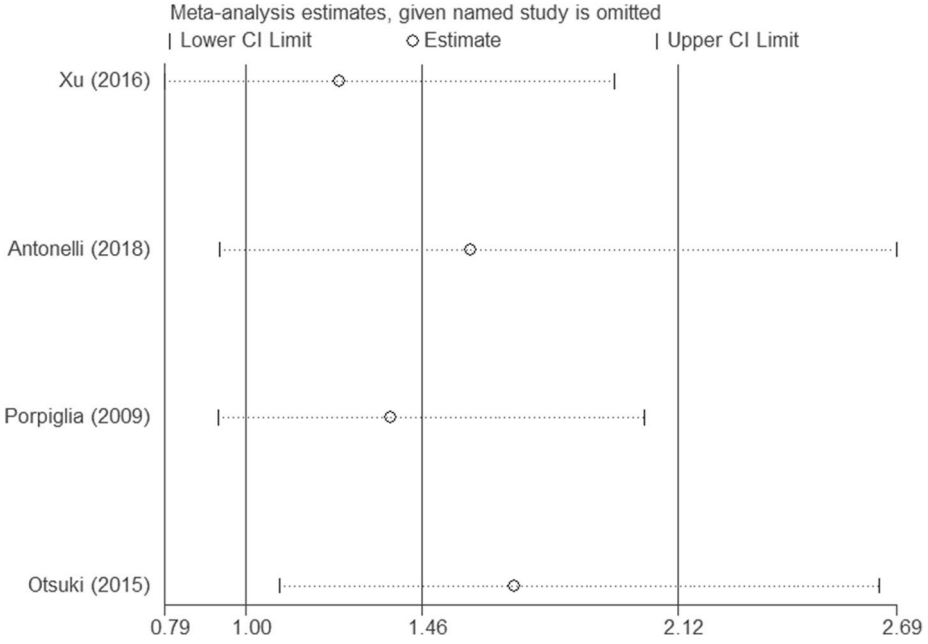

Fig. 6. Sensitivity analysis for the continence rate after 6 months of follow-up.

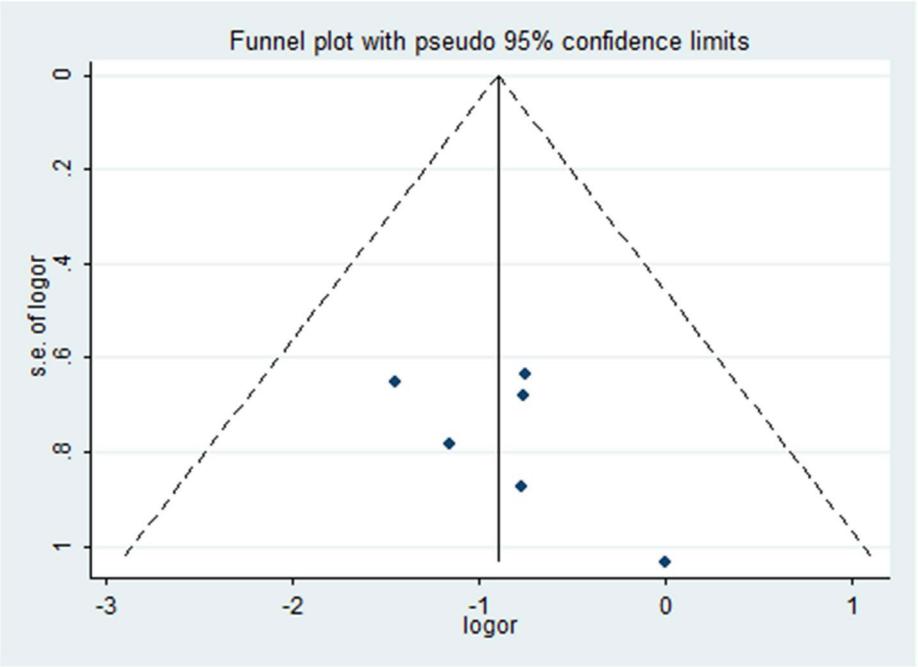

Fig. 7. Funnel plots for the positive apical margin rates.

the apex of prostate and compromise the apical margin [4,22,29].

The following limitations of this meta-analysis should be taken into consideration. First of all, this meta-analysis only included eight articles and the main articles were retrospective, except for two randomized controlled trials of small sample sizes. It could increase the risk of bias because of insufficient random sequence generation and blinding. As the sensitivity analysis showed, the results of continence rates included in this meta-analysis were not stable and further large-scale prospective studies are still needed. Secondly, the definitions of continence were different between the studies, like Otsuki et al. who defined no more than one pad used per day as continence, while others defined no pad used. Thirdly, although this meta-analysis indicated that patient and disease factors, such as Gleason score and tumour stage, had no differences, surgical margins at the apex could be affected by many other factors, including apical tissue biopsy and quality of pathological evaluation, which could not be analysed in the article. Fourthly, because the follow-up time was short, the oncological outcome only included positive apical margin rate and urinary control only included continence rate. Further studies should be made to compare the biochemical recurrence rate, overall survival rate and potency rate between these two approaches. Finally, the surgeries within the studies were carried out in different clinical centres with different protocols and varying levels of surgical expertise. Obviously, different levels of surgical experience could largely influence the outcomes.

5. Conclusion

The results from this meta-analysis suggest that standard and delayed approaches to DVC are equally safe and can achieve similar urinary control. The delayed approach could decrease positive apical margin rate. Considering the limitations, further large-scale prospective studies are needed to investigate and compare the prognosis and long-term functional outcomes between these two approaches.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Data statement

No additional unpublished data are available.

Ethical approval

Not applicable.

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Author contribution

Huihuang Li: project development; Data collection; Manuscript writing.
Jinbo Chen: Data collection and analysis.
Yu Cui: Data collection.
Peihua Liu: Data collection.
Zhenglin Yi: Data analysis.
Xiongbing Zu: project development.

Competing interests

The authors have declared no conflicts of interest.

Guarantor

Prof. Xiongbing Zu.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.06.015.

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