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ORIGINAL ARTICLE

Photoselective vaporization has comparative efficacy and safety among high-risk benign prostate hyperplasia patients on or off systematic anticoagulation: a meta-analysis

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Abstract

Purpose The necessity to cease anticoagulation before photoselective vaporization (PVP) surgery remains nonconsensual. We aimed at assessing the efficacy and safety of PVP among high-risk benign prostate hyperplasia (BPH) patients on or off anticoagulation.

Methods We systematically searched Pubmed, Embase, and Cochrane Library Central Register of Controlled Trials (CENTRAL). 2299 patients from 11 studies were eventually included. Newcastle–Ottawa Scale (NOS) was employed to assess the quality and risk of bias of each study. All statistical analyses were conducted with Review Manager v.5.3 software.

Results Ten parameters (operation time, laser time, blood transfusion, urethral stricture, urinary tract infection, reoperation, dysuria, capsule perforation, catheterization time, and re-catheterization) from patients on or off anticoagulant therapy were collected. The patients without anticoagulants performed better at catheterization time [MD − 0.54, 95% CI (− 0.82, − 0.26), $P = 0.96$, $I^2 = 0$] with a reduction of 0.54 day than those on anticoagulants. Significant statistical difference was not observed from other parameters. Subgroup analysis, grouped by the power output of PVP systems (80 W, 120 W and 180 W), consistently showed no statistical significant difference except at catheterization time in the 180-W PVP subgroup.

Conclusion PVP, a safe and effective option for high-risk BPH patients, work comparably regardless of anticoagulant therapy, despite non-anticoagulant patients have shorter catheterization time. It is implied that the use of anticoagulants might be unnecessary to stop for high-risk BPH patients undergoing PVP for the sake of safety, which certainly requires further investigations to confirm.

Keywords Photoselective vaporization (PVP) · Benign prostate hyperplasia (BPH) · Lower urinary tract symptom (LUTS) · Anticoagulant

Introduction

Low urinary tract symptoms (LUTS) are becoming increasingly common in patients benign prostate hyperplasia (BPH) [1]. It is estimated that more than 70% of males aged > 60 years are diagnosed with LUTS because of BPH [2]. Patients in this age group have higher risks of cardiovascular and neurological diseases, for which treatment with anticoagulants is often required [3]. The transurethral section of the prostate (TURP) has been established as a "good standard" procedure for the treatment of BPH [4]. In addition, photoselective vaporization of the prostate (PVP) is drawing increasing attention in this field due to its virtually bloodless tissue ablation [5, 6] and lower complication rates [6–11]. Accordingly, the European Association

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of Urology guidelines for the treatment of non-neurogenic male LUTS suggest that PVP is a safe option for high-risk patients treated with anticoagulants [12]. However, there is still no consensus regarding the safety of anticoagulation therapy in high-risk males undergoing PVP surgery. Several studies have compared the overall perioperative parameters and complications between patients treated with and without anticoagulation therapy [3, 13–22]. Importantly, PVP involves three different systems based on power output (80 W, 120 W, and 180 W) and variable efficacy [12].

To explore the impact of power output in patients treated with and without anticoagulation therapy undergoing PVP, we performed a subgroup analysis.

Methods

Search strategy

A search was conducted using PubMed, Embase, and Cochrane Library Central Register of Controlled Trials to assess the perioperative outcomes of PVP surgery in patients with benign prostatic hyperplasia receiving anticoagulant therapy up to 2 March, 2018. The search strategy employed boolean logic to incorporate discrepant concepts and synonyms. The search terms were the following: an anatomic filter for "benign prostatic hyperplasia" OR "BPH" OR "benign prostatic obstruction" OR "BPO," a treatment filter for "PVP" OR "vaporization" OR "laser" and a patient filter for "high risk" OR "anticoagulation" OR "anticoagulants" OR "platelet" OR "aspirin" OR "warfarin." Two independent investigators (KLN and LST) initially screened the article titles and abstracts.

Patients and study selection

We encompassed all prospective or retrospective cohort studies or randomized controlled trials reporting perioperative outcomes of PVP surgery. Studies that met the following criteria were selected: (1) studies were conducted in a homogenous group of patients with BPH; (2) at least one type of PVP was performed; (3) patients were at least grouped into anticoagulant and non-anticoagulant therapy groups; (4) the articles were full-length and peer-reviewed research articles; (5) at least one outcome was interested by our meta-analysis. The exclusion criteria were the following: (1) use of other laser therapies instead of PVP; (2) other types of high-risk patients rather than those with bleeding tendency; (3) comorbidity with other prostatic diseases; (4) non-English text, review articles or case reports. Discrepancies in the study inclusion criteria were resolved by consulting the corresponding author. In the selected studies, the average age of the patients was > 65 years. The patients were diagnosed with BPH and underwent PVP. The patients treated with continuous systemic anticoagulation therapy were compared with those without. Systemic anticoagulation therapy included the use of antiplatelet (i.e., aspirin or clopidogrel) and other anticoagulant agents (i.e., novel oral anticoagulant or warfarin) [18].

Data extraction and outcomes

The data from eligible studies were extracted by two independent reviewers who reached a consensus regarding discrepancies in the selection process. The baseline and characteristic data were collected on the following data points: (1) essential information, including the first author, the location of the study, year of publication, and the size of the cohort; (2) study characteristics, including age, gender, group size, and type of PVP.

The primary outcomes of interest were intraoperative parameters including operative time, laser time, and blood transfusion. The secondary outcomes were postoperative outcomes of catheterization time, and the rates of re-catheterization and reoperation. In addition, complications of capsule perforation, urethral stricture, urinary tract infection, and dysuria were included in the analysis. Furthermore, attempts were made to complement the missing data by contacting the first or corresponding author of these studies, as applicable.

Quality assessment

The Newcastle−Ottawa Scale (NOS) was used to assess the quality of the eligible studies [23]. This scale evaluates cohort studies through a total of eight items comprised of three major parts, including the study population selection (selection), comparability (comparability), and result (outcome). The NOS used the semi-quantitative principles of the star system to perform the quality assessment and the maximum score was 9 stars. The assessment of quality was performed by two independent reviewers. When the two reviewers encountered discrepancies in the results/outcomes, they resolved those through discussion.

Statistical analysis

The Review Manager software, version 5.3 (Cochrane Collaboration, Oxford, UK) was used to analyze the data. In terms of the continuous variables and the categorical variables, mean differences (MD) and odds ratios (OR) were calculated, respectively. Moreover, 95% confidence intervals (CI) were reported. For articles providing only the median, range, or inter-quartile range, algorithms were utilized to estimate the mean and standard deviations [24]. Heterogeneity among trials was tested using both I^2 test and Q test. An

$I^2 > 50\%$ or Q test reporting P values < 0.1 were considered to denote heterogeneity. When heterogeneity was detected, a random-effects model was utilized to calculate the pooled effect estimate; otherwise a fixed-effects model was used [25]. Sensitivity analyses were performed through the exclusion of one or more studies suspected of causing heterogeneity. The sensitivity analyses and subgroup analysis based on different power output (80 W, 120 W, and 180 W) were conducted to evaluate the variables reported by at least three studies.

Results

Literature search

Up to 2 March 2018, the literature search yielded 1017 articles, as shown in the PRISMA flowchart (Fig. 1). Of those, 798 articles were eliminated based on the titles and abstracts. The remaining 219 articles were deemed potentially relevant clinical trials for full-text review. Following the exclusion of 208 articles that did not meet the eligibility criteria, 11 articles (studies) were selected for data extraction and analysis.

Study characteristics

Tables 1 and 2 display the characteristics of the selected 11 studies, including 2299 patients published between 2008 and 2017. Three studies were prospective while the remaining eight studies were retrospective. The patients were divided into two groups: an anticoagulant group with continuous use of anticoagulants (i.e., warfarin, low-weight heparin, clopidogrel, dipyridamole, acetyl salicylic acid, and novel oral anticoagulant) and a control group. The mean study sample size was 210 patients (range 67–533; non-anticoagulant vs. anticoagulant = 142 vs. 68 patients) with the duration of follow-up ranging from 90 days to 5 years. The mean average age of patients in the non-anticoagulant and anticoagulant groups were 69.6 years and 74.4 years. The energy applied intraoperatively varied from 80-W PVP to 180-W

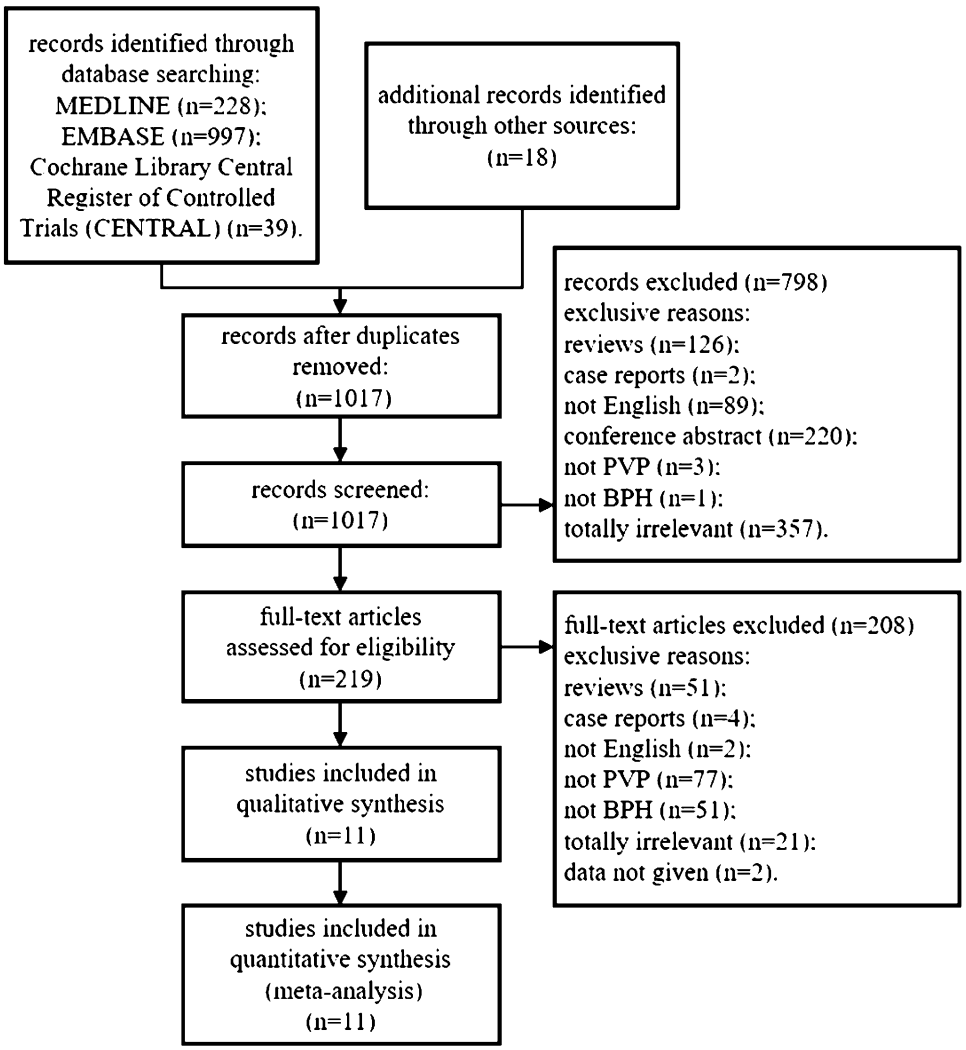


Fig. 1 PRISMA flow chart for study selection with excluding reasons

Table 1 Summary of study characteristics

First author	Year of publication	Location	Study type	Study duration	Intervention	Entire cohort		Non-anticoagulants		Anticoagulants		
						Size	Age	Size	Age	Size	Age	Drugs
Ruszat [19]	2007	Switzerland	Prospective	40 m	80-W PVP	208	na	92	68 ± 9	116	74 ± 9	Aspirin; coumarin; clopidogrel
Woo [22]	2008	Australia (multicenter)	Retrospective	11 m	120-W PVP	305	na	238	67.5 ± 9.5	67	73.9 ± 7.8	Aggregation inhibitor; warfarin; clopidogrel; acetyl salicylic acid
Karatas [17]	2010	Turkey	Prospective	6 m	80-W PVP	67	71.4 ± 9	58	na	9	na	Low molecular weight heparin
Chen [14]	2013	China	Retrospective	24 m	120-W PVP	120	82.8 ± 8.6	84	81.1 ± na	36	86.6 ± na	Aspirin; clopidogrel; coumarin derivatives
Choi [15]	2013	South Korea	Retrospective	3 y	120-W PVP	533	70.8 ± 8.1	411	70.3 ± 8.3	122	72.4 ± 7.5	Unknown
Shao [20]	2013	Taiwan	Retrospective	12 m	120-W PVP	89	72 ± na	66	71.7 ± na	23	73.0 ± na	Aspirin
Sohn [21]	2013	South Korea	Retrospective	12 w	120-W PVP	60	na	30	67.1 ± 5.8	30	71.3 ± 5.8	Unknown
Chen [13]	2013	Taiwan	Retrospective	24 m	na	156	na	72	66.2 ± 6.4	31	74.5 ± 7.5	Unknown
Lee [18]	2016	United States	Retrospective	2 y	180-W PVP	384	72 ± na	198	69.5 ± na	186	75 ± na	Aspirin; clopidogrel; other anticoagulation agents (I.E. warfarin)
Knapp [3]	2017	Australia	Prospective	90 d	180-W PVP	373	69.6 ± 9.0	272	67.6 ± 9	59	74.9 ± 10.3	Heparin; warfarin; clopidogrel; dipyridamol; new oral anticoagulant (NOAC)
Piotrowicz [16]	2017	Poland	Retrospective	5 y	120-W PVP	109	na	44	66.9 ± 6.5	65	68.3 ± 6.63	Acetylsalicylic acid; acenocoumarol

na not applicable, *pvp* photoselective vaporization

Table 2 Perioperative and postoperative characteristics of selected studies

First author	Study size		Non-anticoagulant vs anticoagulant																	
	Non-anticoagulant	Anticoagulant	Operation time (min)		Laser time (min)		Catheterization time (day)		Blood transfusion		Urethral stricture		Urinary tract infection		Reoperation		Dysuria		Recatheterization		Capsule perforation	
80-W PVP																						
Ruszat [19]	92	116	63 ± 29	67 ± 28	na	na	na	na	0	0	7	6	7	9	5	2	8	10	na	na	na	na
Karatas [17]	58	9	48.7 ± 12.6	52.5 ± 14.8	na	na	na	na	0	0	0	0	0	0	na	na	na	na	na	na	na	na
120-W PVP																						
Woo [22]	238	67	na	na	na	na	na	na	0	1	0	1	9	4	2	0	7	0	9	5	2	1
Chen [14]	84	36	na	na	na	na	na	na	0	0	1	0	3	2	6	2	13	5	1	1	1	0
Choi [15]	411	122	na	na	na	na	na	na	0	0	na	na	na	na	na	na	na	na	na	na	na	na
Shao [20]	66	23	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
Sohn JH [21]	30	30	24.9 ± 12.4	16.9 ± 6.1	na	na	na	na	na	na	0	0	0	0	na	na	na	na	na	na	na	na
Piotrowicz [16]	44	65	na	na	na	na	na	na	na	na	na	na	2	3	4	2	4	7	na	na	na	na
180-W PVP																						
Lee [18]	198	186	55 ± 30.7	60 ± 23.7	36 ± 34.8	39 ± 24.4	3.5 ± 2.2	4 ± 2.2	0	0	0	1	10	7	5	8	na	na	na	na	na	na
Knapp [3]	272	59	65.7 ± 4.0	61.4 ± 35.8	47.3 ± 26.2	44.9 ± 24.1	1 ± 0.7	1.5 ± 2.7	0	0	3	0	7	1	na	na	na	na	8	5	2	2
Unknown																						
Chen [13]	72	21	na	na	29.7 ± 12.4	33.7 ± 10.4	1.7 ± 1.2	2.3 ± 1	0	0	3	1	1	3	0	0	16	4	15	6	na	na

na not applicable, *pvp* photoselective vaporization

PVP. Of note, one trial employed HPS PVP; however, the consumed energy was not mentioned [13]. The results of the meta-analysis for intraoperative parameters (i.e., operation time, laser time, and blood transfusion), postoperative parameters (i.e., urethral stricture, urinary tract infection, reoperation, dysuria, capsule perforation, catheterization time, and re-catheterization) were summarized. Moreover, a subgroup analysis was conducted based on the consumed energy. Regarding the international prostate symptom score (IPSS) and maximum urine flow (Q_{max}), due to defects in the data, statistical analysis was not performed.

Quality assessment

The NOS for non-randomized studies was employed to evaluate the quality of the data and the risk of bias. The selection, compatibility, and outcome were assessed. Each study meeting one of the numbered items was awarded one star, with a possible maximum of nine stars awarded to a single study. Studies awarded at least seven stars were defined as "high quality" [26]. Table 3 displays a summary of the NOS scores of those 11 studies. According to these data, the selected studies were of high quality and relative low risk of bias.

Intraoperative parameters (i.e., operation time, laser time, and blood transfusion)

Figure 2a shows the results for the intraoperative parameters. Operation time was reported in five studies involving 1050 patients [3, 17–19, 21]. No significant statistical difference was observed between the patients treated with or without anticoagulant therapy (MD 0.17, 95% CI − 5.95 to 6.29, $P = 0.004$, $I^2 = 74\%$). In addition, 808 patients from three studies [3, 14, 18] were included in the comparison of laser time. There was no statistically significant difference reported (MD − 1.55, 95% CI − 5.51 to 2.41, $P = 0.23$, $I^2 = 33\%$). Blood transfusion was discussed in eight studies; however, it was not possible to perform an analysis since blood transfusion was carried out for only patients in 2041 patients (1/2041).

Postoperative parameters and complications (i.e., urethral stricture, urinary tract infection, dysuria, capsule perforation, reoperation, catheterization time, and re-catheterization)

The quantity of studies, population, and outcomes related to postoperative parameters and complications were as follows: Eight studies [3, 13, 14, 17–19, 21, 22] involving 1610 patients with urethral stricture (RR 1.04, 95% CI 0.49 to 2.22, $P = 0.62$, $I^2 = 0$), nine studies [3, 13, 14, 16–19, 21, 22] involving 1719 patients with urinary tract infection (RR 0.91, 95% CI 0.57 to 1.46, $P = 0.41$, $I^2 = 2\%$), six studies [13, 14, 16, 18, 19, 22] involving 1219 patients with reoperation (RR 1.31, 95% CI 0.68 to 2.50, $P = 0.89$, $I^2 = 0$), five studies [13, 14, 16, 18, 19, 22] involving 835 patients with dysuria (RR 1.13, 95% CI 0.69 to 1.82, $P = 0.89$, $I^2 = 0$), four studies [3, 13, 14, 22] involving 891 patients with re-catheterization (RR 0.61, 95% CI 0.35 to 1.05, $P = 0.95$, $I^2 = 0$), and three studies [3, 14, 22] involving 798 patients with capsule perforation

Table 3 Quality assessment by Newcastle–Ottawa Scale

Study	Year	Selection				Comparability		Exposure			No. of stars
		REC	SNEC	AE	DO	SC	AF	AO	FU	AFU	
Ruszat [19]	2007	*	*	*	*	*	*	*	*	*	9
Karatas [17]	2008	*	*	*	*	*	–	*	–	*	7
Woo [22]	2010	*	*	*	*	*	*	*	–	*	8
Chen [14]	2012	*	*	*	*	*	–	*	*	*	8
Choi [15]	2013	*	*	*	*	*	–	*	*	*	8
Shao [20]	2013	*	*	*	*	–	*	*	*	*	8
Sohn [21]	2013	*	*	*	*	*	*	*	*	*	9
Piotrowicz [16]	2013	*	*	*	*	*	*	*	–	*	8
Lee [18]	2016	*	*	*	*	*	–	*	*	–	7
Knapp [3]	2017	*	*	*	*	*	*	*	–	*	8
Chen [13]	2017	*	*	*	*	*	*	*	*	–	8

REC representativeness of the cohort, *SNEC* selection of the none posed cohort, *AE* ascertainment of exposure, *DO* demonstration that outcome of interest was not present at start of study, *SC* study cohort for age, *PSA level* prostate volume, *AF* study controls for other important factors, *AO* assessment of outcome, *FU* follow-up long enough for outcomes to occur ('long enough' is defined as 1 year), *AFU* adequacy of follow-up of cohort (≥ 80%)

*Means that the study is satisfied with the item, and "–" means not

(RR 0.55, 95% CI 0.15 to 2.09, $P=0.80$, $I^2=0$). None of these showed statistically significant differences, although re-catheterization approached statistical significance (RR 0.61, CI 0.35 to 1.05, $P=0.95$, $I^2=0$). Figure 2b shows the outcomes.

As Fig. 2c shows, the catheterization time was the only parameter with statistically significant differences between patients treated with and without anticoagulant therapy (MD − 0.54, 95% CI − 0.82 to − 0.26, $P=0.96$, $I^2=0$). This demonstrates that non-anticoagulant therapy leads to a reduction in the catheterization time (0.54 day) compared with anticoagulant therapy.

Subgroup analysis

We conducted a subgroup analysis according to the intraoperative PVP power output. Although it was not possible to complete this subgroup analysis due to a lack of data, the outcomes of the subgroup analysis were consistent with those of the overall analysis. No statistically significant difference was observed among these parameters except a reduction in catheterization time (0.51 day) in the non-anticoagulant therapy group in the 180-W PVP subgroup analysis [3, 18] (MD − 0.51, 95% CI − 0.85 to − 0.17, $P=0.94$, $I^2=0$) (Fig. 2c and Online Resource 1).

Sensitivity analysis

The heterogeneity was relatively high in terms of the operation time ($I^2=74\%$, $P=0.004$) and declined significantly ($I^2=13\%$, $P=0.33$) when the study conducted by Sohn [21] was removed (Fig. 3). All the other analyses are highly homogenous (Fig. 2a–c).

Discussion

Summary of main results

A total of 11 clinical trials involving 2295 patients and comparing the intraoperative and perioperative parameters of patients with BPH who underwent PVP and were treated with or without continuous anticoagulant therapy were included in this meta-analysis. Previously, Lee et al. [18] found that the administration of anticoagulants increased the risk of high-grade complications. However, the present data analysis did not reveal overall statistically significant differences in perioperative and postoperative parameters between these two groups of patients, except the shorter catheterization time observed in non-anticoagulant therapy patients (MD − 0.54, 95% CI − 0.82 to − 0.26), $P=0.96$, $I^2=0$) compared with that observed in anticoagulant therapy patients. This difference approached but failed to reach statistical significance.

The standard surgical treatment for BPH, TURP has several drawbacks (i.e., excessive bleeding and sexual dysfunction). Therefore, a few minimally invasive techniques have been introduced into this field. The LIFT and WATER studies reported the promising ability of prostatic urethral lift and aquablation, respectively, in preserving sexual function [27, 28]. Another option for the treatment of BPH is prostatic artery embolization (PAE), showing improvement in sexual function [29]. However, research regarding the impact of anticoagulant therapy in patients with BPH undergoing these new techniques is lacking. PVP was shown to be a good option for patients treated with anticoagulant therapy. Previous clinical studies demonstrated that perioperative morbidity, including sexual dysfunction, was not connected to the use of anticoagulants in males undergoing

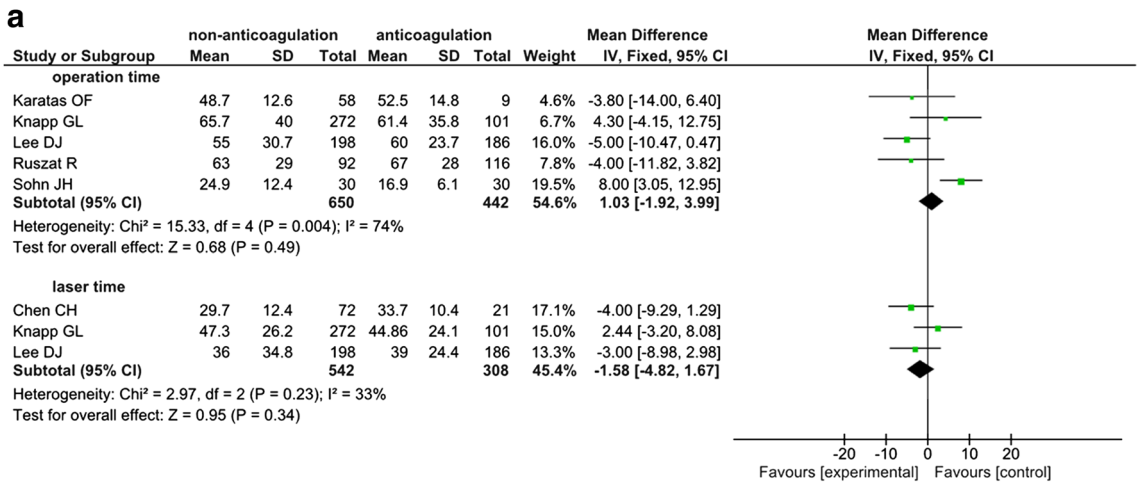


Fig. 2 **a** Forest Plot for intraoperative parameters. **b** Forest plot for postoperative parameters. **c** Forest plot for catheterization time

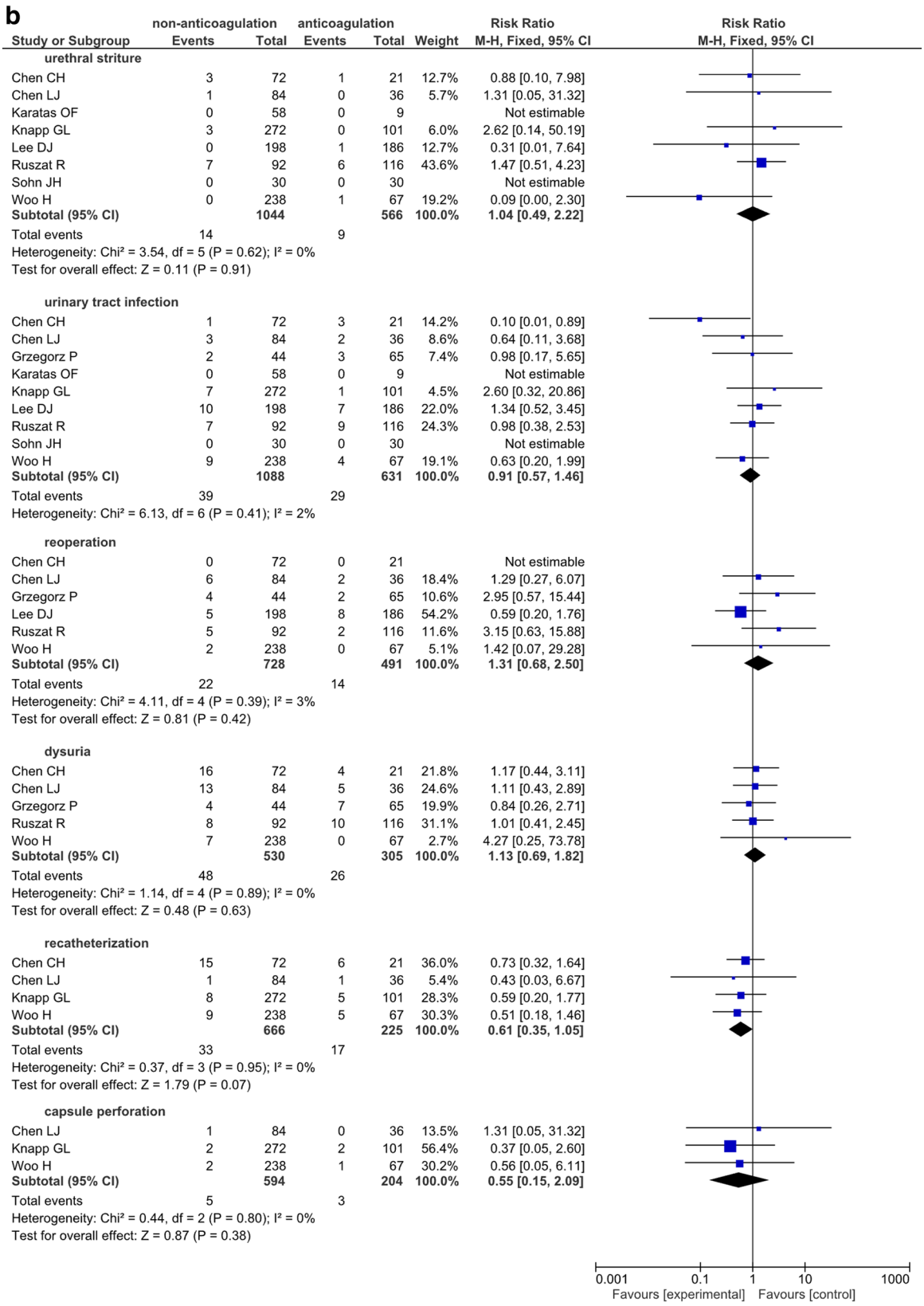
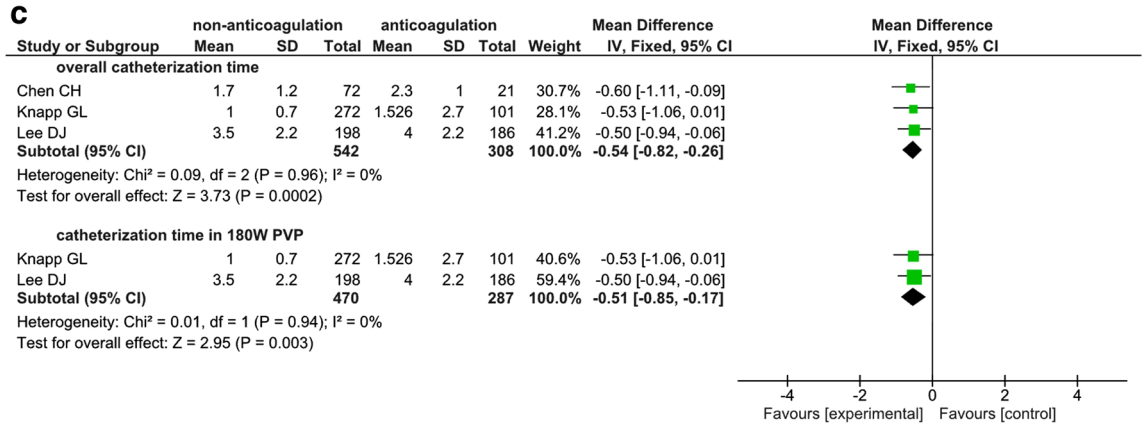


Fig. 2 (continued)



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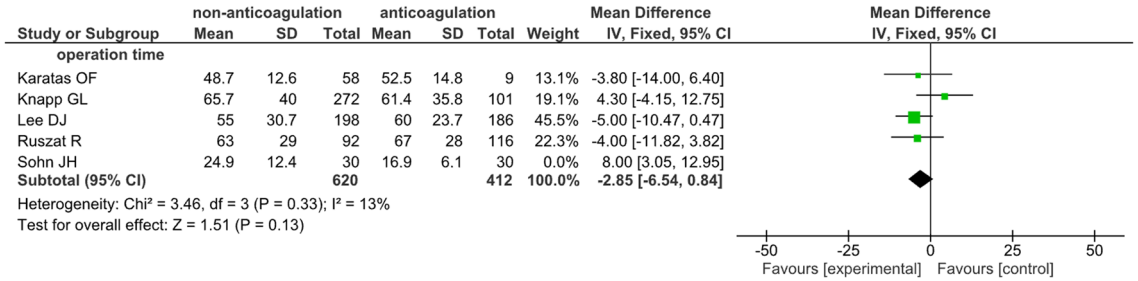

Fig. 3 Forest plot for heterogeneity analysis of operation time

PVP [30, 31]. In terms of bleeding and blood transfusion, studies reported that blood transfusion was required in 30% of patients with BPH treated with anticoagulation therapy after TURP [32]. Nevertheless, in the current analysis, only one patient (1/2041) in the anticoagulant therapy group (1/616) required blood transfusion. This finding suggests that PVP is not associated with intraoperative hemorrhage.

Research and clinical implications

It is believed that anticoagulants may increase the risk of excessive bleeding in patients requiring surgical intervention. Hence, the use of anticoagulants is discontinued preoperatively [33]. The present analysis confirmed that PVP surgery is safe for high-risk patients with BPH regardless of the administration of anticoagulant therapy. The low rate of blood transfusion and similar operation times diminish the concerns regarding bleeding and consequent enhanced complexity of the surgical process. Moreover, PVP may not be necessarily associated with the discontinuation of anticoagulation therapy in patients with comorbidities, particularly cardiovascular disease, requiring continuous anticoagulant therapy. Thus, other pre-existing diseases have a minimal risk of outbreak.

In terms of catheterization time, the results of the present analysis declared that the non-anticoagulant group had a better performance, an unsurprising finding considering that anticoagulation potentially increases the risk of bleeding and, consequently, may lead to longer catheterization time. The reduced 0.54 day of catheterization time observed in the non-anticoagulant group indicates that the continuous use of anticoagulant therapy in high-risk patients with BPH is linked to pain as a result of the catheterization. This finding supports the necessity for the preoperative discontinuation of anticoagulant therapy in relation to this specific parameter. However, additional clinical trials are required to confirm this conclusion, currently based on only three relevant studies. Moreover, due to the lack of studies focused on life quality (IPSS, Q_{max}, postvoid residual, etc.) in this field, we failed to evaluate these parameters between those two groups. In addition, provided that re-catheterization results nearly significantly favor anticoagulant group, a potential association between PVP, anticoagulation therapy, and catheterization-related parameters is awaiting exploration.

Strengths and limitations

The present meta-analysis was the first to demonstrate an association between anticoagulant therapy among patients with BPH and PVP. In spite of the limited number of clinical trials on this topic, we performed a systematic literature search, selected the relevant articles, and analyzed ten perioperative parameters, aiming to explore this association. Given that heterogeneity was found only in the operation time and the absence of publication bias, the results and conclusion of the present meta-analysis are reliable. This was affirmed by the fact that the subgroup analysis yielded consistent outcomes.

The limitations of this meta-analysis should be mentioned. First, eight of the 11 selected studies were retrospective while the remaining three studies were prospective cohort studies. This indicated that these were not high-level evidence studies, compromising the reliability of our conclusions. Second, functional outcomes, such as the IPSS, post-void residual, and Q_{max}, are not reported in the majority of these studies. This did not permit a comparison of the quality of life in these patients prior to and after PVP surgery. Third, the drugs used in these studies varied considerably. Various oral anticoagulants (e.g., warfarin, clopidogrel, aspirin, and heparin) were administered. Thus, it is difficult to standardize and divide the subgroup based on anticoagulant medications, leading to potential risk of bias because of the varying efficacy of these drugs. Finally, not all the studies were included in the analysis of each individual parameter since the data were not symmetrically presented in these articles, reducing the reliability of the present conclusions.

Conclusion

The present meta-analysis supports the notion that PVP is a safe and effective option for high-risk patients with BPH. Compared with the non-anticoagulant group, the continuous administration of anticoagulants in patients undergoing PVP may be related to complications such as excessive bleeding or enhanced surgery complexity, but at the same time alleviate the inconvenience caused by catheterization. Furthermore, it is not necessary to discontinue the use of anticoagulants in high-risk patients with BPH undergoing PVP. Future research, particularly focused on quality of life, to confirm and expand the conclusions of the present study is warranted.

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Author's contributions QW, LY: Project development, public funding. LST, KLN, LLQ, ML, XH: Data collection. XNZ, YXC, SQ: Data analysis, Manuscript writing/editing.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Not applicable as there are no study participants.

Research involving human participants and/or animals Not applicable as there are no human participants and/or animals.

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