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Holmium laser enucleation of the prostate in benign prostate hyperplasia patients with or without oral antithrombotic drugs: a meta-analysis

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Abstract

Background The continuous intake of antithrombotic drugs during holmium laser enucleation of the prostate (HoLEP) remains nonconsensual. We aim to pool those controversial evidence and provide practical guidance of oral antithrombotics on HoLEP for benign prostate hyperplasia (BPH).

Method PubMed, Embase and CENTRAL database were systematically searched up to June 2019 for trials on patients with and without oral antithrombotics undergoing HoLEP. Number of events and mean value with standard deviation were, respectively, extracted for dichotomous and continuous parameters. Subgroup analyses of anticoagulation and antiplatelet were also performed. All statistical analyses were conducted with Review Manager v.5.3 software. Newcastle–Ottawa Scale (NOS) was used to assess the quality of selected trials.

Result Nine studies with 5528 patients were eventually selected, and patients included were generally older than 65 years. It revealed that the non-antithrombotic group had a lower rate of blood transfusion (OR 0.21, 95% CI 0.10–0.45, $P<0.0001$), bladder tamponade (OR 0.30, 95% CI 0.13–0.69, $P=0.004$) and acute urine retention (OR 0.52, 95% CI 0.30–0.89, $P=0.02$). Operation time was also shorter (MD − 10.31, 95% CI − 12.76 to − 7.85, $P<0.00001$) in the non-antithrombotic group, but the heterogeneity was considerable ($I^2=75\%$). Subgroup analyses were generally consistent with the primary analysis except the non-anticoagulation and anticoagulation group having similar operation time (MD 6.66, 95% CI − 7.15 to 20.48, $P=0.34$).

Conclusion The current study confirmed that continuous intake of antithrombotic drugs could significantly increase the risk of bleeding and blood transfusion, bladder tamponade and acute urine retention.

Keywords Benign prostate hyperplasia (BPH) · Holmium laser enucleation of the prostate (HoLEP) · Antithrombotic · Perioperative safety

Introduction

Benign prostate hyperplasia (BPH) with lower urinary tract symptoms (LUTS) is prevalent among 60–70% males aged over 60 years [1, 2]. For decades, transurethral section of the prostate (TURP) and open prostatectomy (OP) have been established as the standard treatments for BPH [3, 4]. However, despite the widespread adoption, those two techniques are also commonly associated with multiple complications, in particular bleeding and blood transfusion [5, 6]. Therefore, holmium laser enucleation of the prostate (HoLEP), one of the minimal invasive surgical options for BPH, was introduced as the alternative to TURP and OP [7]. Evidence has indicated that HoLEP could cause less blood loss, shorter hospitalization and shorter catheterization regardless

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of the prostate size, although it also required longer operation time [8–11].

For patients with BPH in this age group, cardiovascular diseases are also commonly diagnosed, for which oral antithrombotic drugs (oral anticoagulants or antiplatelet drugs) are often required [12]. Several studies have investigated the safety of antithrombotic therapy during HoLEP and reported various outcomes. However, so far, no consensus of the intake of antithrombotic drugs has been reached. Hence, the current meta-analysis aims to pool those evidences and provide relevant clinical guidance.

Method

Study selection

We systematically searched PubMed, Embase, and CENTRAL for trials assessing the impact of intraoperative antithrombotic drugs use on patients undergoing HoLEP surgery for BPH up to June 2019. The searching terms include: anatomic filter for "benign prostate hyperplasia", "BPH", "benign prostatic obstruction" OR "BPO", treatment filter for "holmium laser enucleation" OR "HoLEP", patient filter for "anticoagulation", "anticoagulant", "antiplatelet" OR "antithrombotic".

All retrospective, prospective cohort studies and randomized controlled trials were assessed for possible inclusion: (1) patients must be treated with HoLEP for BPH; (2) patients must be divided into either antithrombotic group (continuous intake of oral antithrombotic drugs) or non-antithrombotic group (naïve to or discontinuation of oral antithrombotic drugs). (3) At least one outcome of our interest should be assessed and analyzable corresponding data of antithrombotic and non-antithrombotic groups should be presented. The exclusion criteria were: (1) Other techniques instead of HoLEP were used for BPH; (2) No bridging low-molecular-weight heparin (LMWH) was administrated by the non-antithrombotic group; (3) Overlapping data of antithrombotic and non-antithrombotic group were provided; (4) Review articles or case reports. Two members in our team independently screened the articles.

Statistical analysis

Data of study characteristics including publication year, country, design, cohort size, age, and antithrombotic drugs were collected. The primary outcome was the evaluation of safety of being on or off antithrombotic therapy, for which pooled odds ratio (OR) with 95% confidential interval (CI) blood transfusion, bladder tamponade (defined as a case of emergency in which the bladder is filled with formations of big blood clots [13, 14]), stress incontinence, urinary tract infection, urethral stricture, acute urine retention, re-hospitalization and retreatment were calculated. The secondary outcome was other intraoperative and postoperative parameters including operation time, hemoglobin (Hb) decrease and hospitalization time. Mean value and standard deviation were extracted, and pooled mean difference (MD) with 95% CI was calculated accordingly. Inter-study heterogeneity was assessed using I^2 test and an $I^2 > 50\%$ was regarded to denote heterogeneity. Subgroup analyses of above parameters were performed on the basis of antithrombotic drugs—studies were divided into anticoagulation subgroup (intake of anticoagulants only) and antiplatelet subgroup (intake of antiplatelet drugs only), which were then compared with the non-antithrombotic group separately. All above statistical analyses were conducted by RevMan 5.3 software. Quality of included studies was assessed by the Newcastle–Ottawa Scale (NOS) and the maximal score was 9 for a single study [15].

Result

Study characteristics

33 articles were initially identified up to June 2019 and 17 were excluded based on title and abstract (Fig. 1). The remaining 16 articles were full-text reviewed to assess for potential eligibility and 7 articles were eliminated for reasons shown in the PRISMA flowchart. Eventually, 9 retrospective studies with 5528 patients were selected for data extraction and pooled analysis [16–24]. All of the studies were published between 2009 and 2019, and seven were published within past 3 years (Table 1). The mean follow-up duration lasted from 2 to 19.4 months and the mean or median age of patients was generally above 65 years. Baseline prostate volume was presented in five trials and no significant difference was observed between the antithrombotic and non-antithrombotic group.

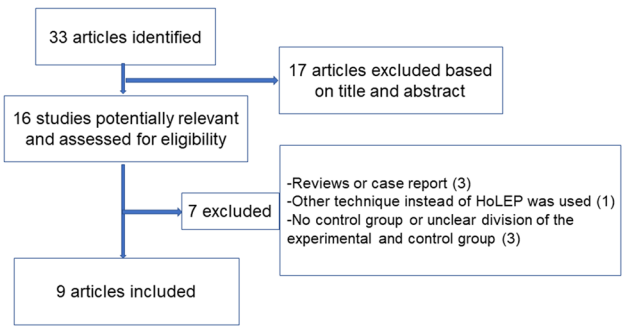

Fig. 1 PRISMA flowchart of study selection

Table 1 Summary of study characteristics

Study	Country	Design	Follow-up (months)	Cohort size	Non-antithrombotic		Antithrombotic group 1			Antithrombotic group 2			NOS
					Age	Prostate volume	Age	Prostate volume	Drugs	Age	Prostate volume	Drugs	
Bishop 2013	Australia	Retrospective	12 months	125	71.7	NA	75.1	NA	Aspirin; clopidogrel; dipyridamole; warfarin	–	–	–	7
Becker 2019	Germany	Retrospective	3 months	2027	70	70	75	65	Rivaroxaban, apixaban, dabigatran	–	–	–	8
Boeri 2019	Italy	Retrospective	2 months	166	68	87	69	85	Aspirin; clopidogrel; dipyridamole	68	84	Warfarin	9
Sun 2017	China	Retrospective	12 months	1052	70.8/71.6[#]	67.5/73.8[#]	72.4	77.7	Aspirin and clopidogrel	69.7	75.8	Aspirin or clopidogrel	9
Tyson 2009	US	Retrospective	3 months	62	65.2	49.9	69.4	65.0	Aspirin	70.6	50.3	Coumadin	8
Matsuoka 2017	Japan	Retrospective	19.4 months/12.8 months*	54	70.3	61.5	73.5	50	Aspirin; warfarin; clopidogrel; ticlopidine	–	–	–	8
Neuville 2018	France	Retrospective	NA	140	69.3	NA	73.8	NA	Aspirin; clopidogrel; ticagrelor	74.2	NA	Anti-vitamin K; LMWH	7
Elzayat 2016	Canada	Retrospective	12 months	81	NA	NA	NA	NA	Unknown; LMWH	–	–	–	7
Tayeb 2016	US	Retrospective	6 months	1674	NA	NA	NA	NA	Aspirin, Plavix, Aggrenox, Pradaxa, Lovenox, Coumadin	–	–	–	8

NA not applicable, *LMWH* low-molecular-weight heparin, *NOS* Newcastle–Ottawa scale

[#]Non-antithrombotic patients were categorized into two groups in Sun's and Tayeb's study: 1. Patients without any antithrombotic therapy; 2. Patients receiving antithrombotic therapy but ceasing preoperatively

*Follow-up in Matsuoka's study: Non-antithrombotic vs antithrombotic

Antithrombotic drugs varied in those studies. One study used only anticoagulants [17], while another study used only antiplatelet therapy and divided the non-antithrombotic group into two single antiplatelet and dual antiplatelet subsets [20]. Patients in the other seven studies were administrated both anticoagulants and antiplatelet drugs. Notably, three studies differentiated the patients into anticoagulation and antiplatelet subgroups [16, 19, 23], but the other four studies did not indicate it clearly [18, 21, 22, 24]. The quality assessment showed that all of the selected studies were ranked as high quality.

Safety

Data of safety from the anticoagulation and antiplatelet groups were combined. Figure 2 displayed that the non-antithrombotic group had a lower rate of blood transfusion (OR 0.21, 95% CI 0.10–0.45, $P<0.0001$), bladder tamponade (OR 0.30, 95% CI 0.13–0.69, $P=0.004$) and acute urine retention (OR 0.52, 95% CI 0.30–0.89, $P=0.02$). No significant difference was observed with regard to stress incontinence (OR 0.76, 95% CI 0.44–1.32, $P=0.33$), urinary tract infection (OR 0.84, 95% CI 0.53–1.34, $P=0.46$), urethral stricture (OR 2.09, 95% CI 0.40–10.81, $P=0.38$). Furthermore, the two groups had a similar rate of re-hospitalization (OR 0.67, 95% CI 0.25–1.85, $P=0.44$) and re-operation (OR 0.93, 95% CI 0.40–2.17, $P=0.86$).

Other intraoperative and postoperative parameters

For continuous parameters, data of anticoagulation and antiplatelet subgroup were extracted and compared with the non-antithrombotic group separately if applicable. Figure 3 presented that the non-antithrombotic group had shorter operation time (MD −10.31, 95% CI −12.76 to −7.85, $P<0.00001$), but Hb decrease (MD −0.24, 95% CI −1.24 to 0.75, $P=0.63$) and hospital stay (MD 0.01, 95% CI −0.08 to 0.09, $P=0.90$) after surgery were similar between the two groups.

Subgroup analysis

Both of the comparisons of anticoagulation versus non-antithrombotic (OR 0.21, 95% CI 0.05–0.87, $P=0.03$) and antiplatelet versus non-antithrombotic (OR 0.09, 95% CI 0.02–0.48, $P=0.005$) confirmed that the cessation of anticoagulants or antiplatelet drugs could significantly reduce the rate of blood transfusion. Moreover, it also confirmed that no significant difference was reached between the two groups regarding stress incontinence, urinary tract infection and re-hospitalization (Fig. 4).

In terms of operation time, the subgroup analysis consistently showed that the non-antiplatelet group operated more shortly (MD −11.22, 95% CI −13.72 to −8.71, $P<0.00001$), while the anticoagulation subgroup found no difference was observed (MD 6.66, 95% CI −7.15 to 20.48, $P=0.34$). Additionally, the subgroup analysis for Hb decrease and hospital stay was also consistent with the above outcomes (Fig. 5).

Discussion

The aged population with BPH on antithrombotic therapy commonly has a higher risk of intraoperative bleeding during TURP and required a higher rate of blood transfusion [25, 26], but the discontinuation of antithrombotic drugs may increase the risk of thromboembolic events. Although the intake of antithrombotic medicine has been proved to be safe among BPH patients undergoing photoselective vaporization (PVP) [27], another type of minimal invasive alternative to TURP, its safety during HoLEP still remained unclear. Despite several trials have investigated the efficacy and safety of HoLEP among BPH patients on antithrombotic drugs and compared it with non-antithrombotic group, the pooled evidence was lacking.

Therefore, the current study included 9 trials involving 5528 patients and performed a systematic review and meta-analysis of the impact of continuous intake of antithrombotic drugs during HoLEP, and revealed that, compared to the non-antithrombotic group, the antithrombotic group did not only require more blood transfusion and longer operation time, but also had a higher risk of bladder tamponade and acute urine retention. The higher blood transfusion rate was actually not surprising, since one of the risks of antithrombotic therapy was bleeding and the consequent higher risk of bladder tamponade and acute urine retention also looked feasible.

Bleeding complication was common during traditional surgeries, and the antithrombotic drugs would obviously increase the potential risk of it, so the management of old patients with high risk of cardiovascular disease undergoing surgery has been a critical and difficult problem for clinicians. By pooling all the available data from relevant clinical trials, our study revealed that continuous antithrombotic therapy could increase the risk of bleeding during HoLEP. Subgroup analyses also confirmed this conclusion by showing both anticoagulation and antiplatelet would increase the necessity of blood transfusion. However, the blood transfusion rate (4.0%) was still lower than in TURP (6.4%) and OP (14%) [9, 28, 29], although it was even lower among antithrombotic patients undergoing PVP (0.2%) [27]. Previously, Cornu et al. performed a meta-analysis and claimed that the mean Hb drop was 0.9 g/L after HoLEP [9], data from trials in the current study were slightly higher and comparable. Interestingly, we also found Hb decrease during

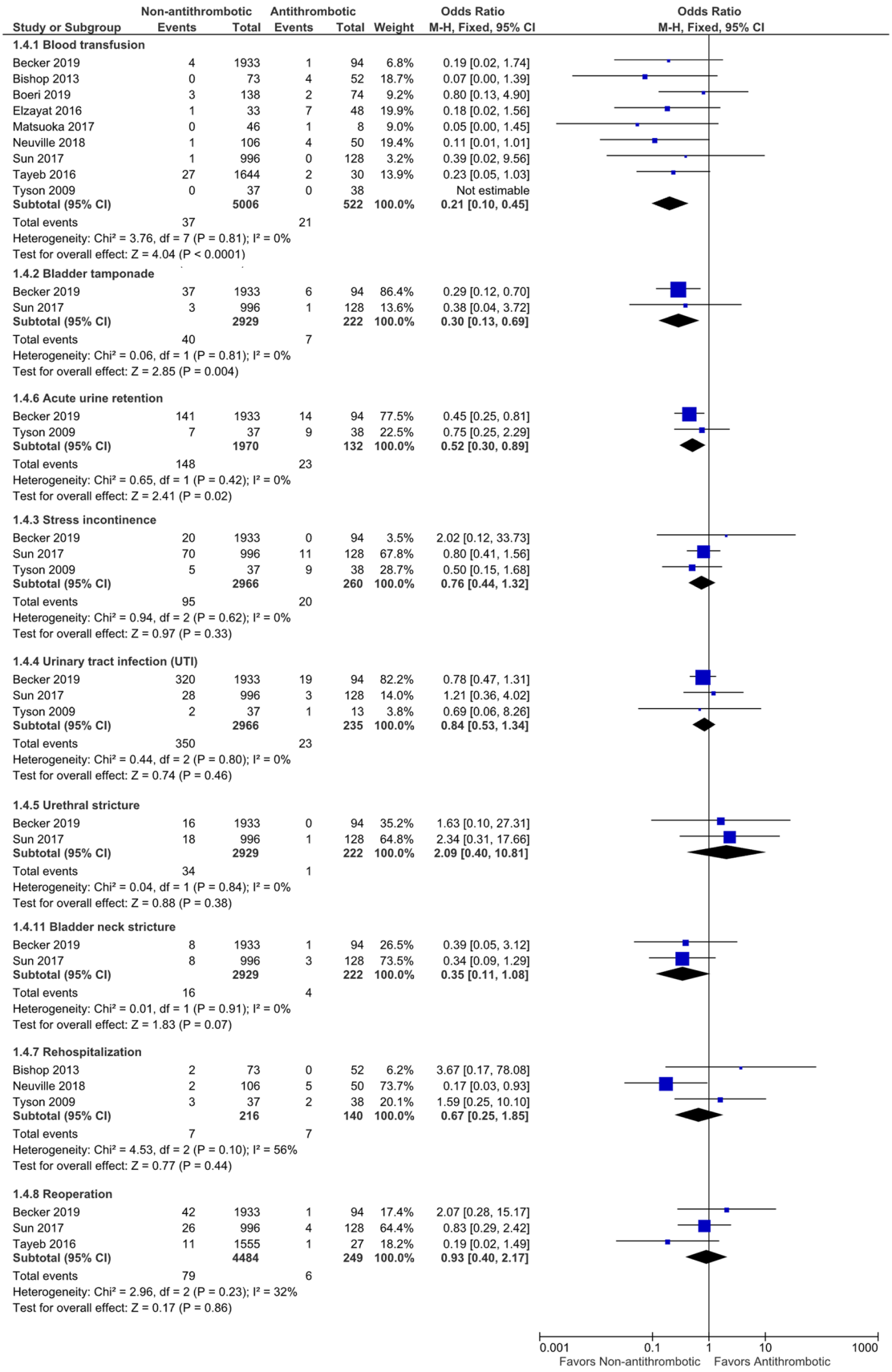

Fig. 2 Evaluation of perioperative complications

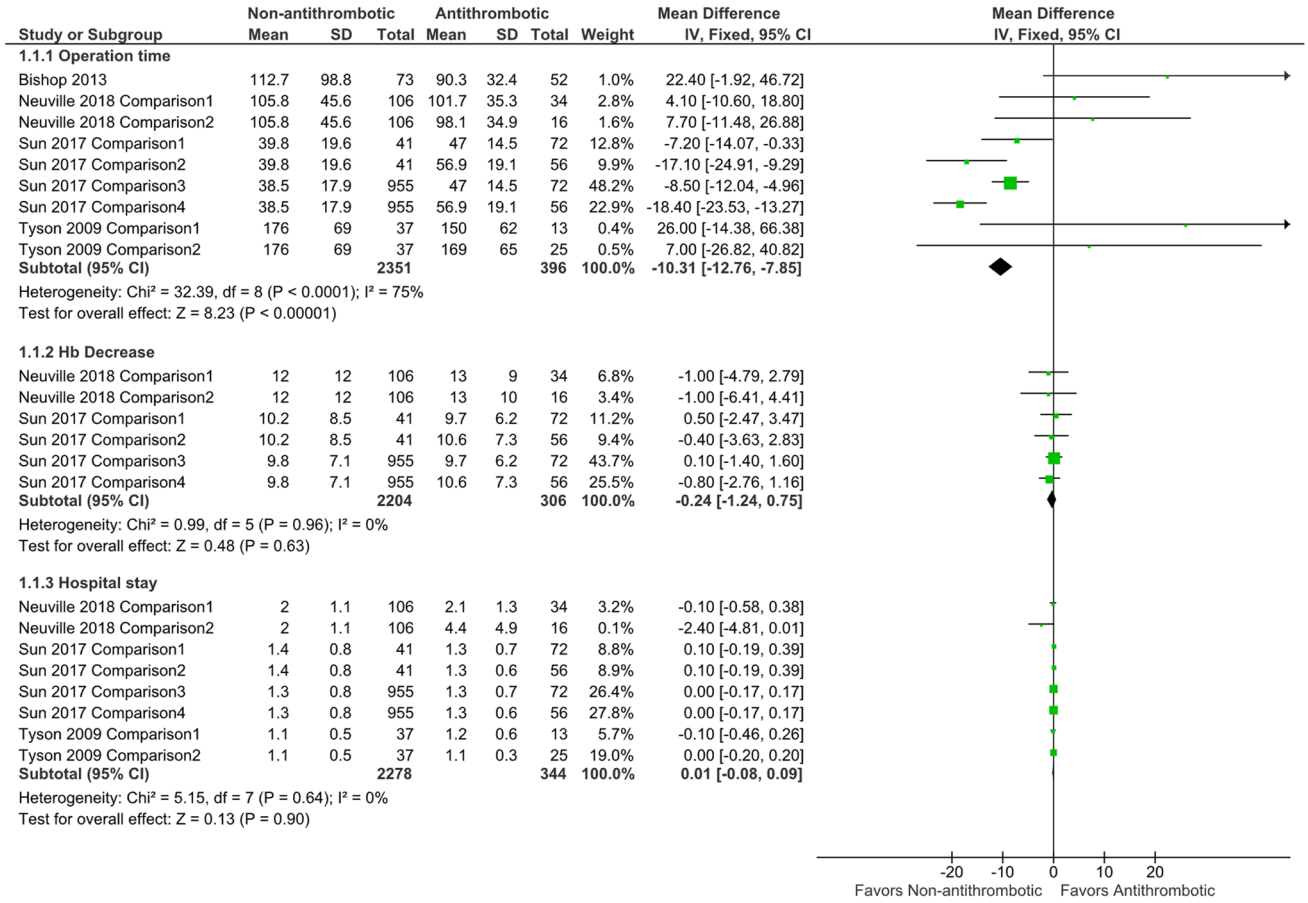

Fig. 3 Evaluation of continuous perioperative parameters

HoLEP was similar between the two groups, given that the antithrombotic group had a higher risk of bleeding, and another three selected trials supported this conclusion [16, 17, 24].

Published evidence has showed that the operation time was similar between the group with and without antithrombotic therapy during PVP [27]. However, the pooled outcomes in our study indicated that patients on antithrombotic therapy needed longer operation time, for which a reasonable explanation was that a quite small number of antithrombotic patients in the PVP series required blood transfusion (1/616) and the blood transfusion rate was similar between the groups with and without antithrombotic treatment (1/616 versus 0/1245), while antithrombotic patients had a much higher rate of blood transfusion rate (21/522 vs 37/5006) in the present HoLEP series. Notably, considerable inter-study heterogeneity was observed for the analysis of operation time. Sensitivity analysis was conducted and we found heterogeneity disappeared ($I^2 = 0$) after Sun's study was excluded. Actually, it's worth mentioning that, out of the seven trials presenting data of operation time—three were not available for quantitative analysis [16, 17, 24], only Sun declared that the antithrombotic group required longer operation time, while other studies found no significant difference [20]. Consequently, the authors thought it's hard to draw a conclusion regarding the comparison of operation time between the antithrombotic and non-antithrombotic groups. More trials are needed and it would be helpful for researchers to present relevant data in a uniform standard for the convenience of further analysis.

Catheterization time was another important parameter to evaluate new transurethral techniques for BPH. Michielsen has reported that the average catheterization time for monopolar and bipolar TURP was 1.77 days and 1.79 days [28]. Only one of the selected studies reported mean catheterization time, which was 1.9, 2.2 and 2.6 days for anticoagulation, antiplatelet and non-antithrombotic groups, respectively [19]. Tyson also claimed no significant difference was found. Three other included trials confirmed the similarity of catheterization time between the two groups with and without antithrombotic therapy by presenting median values. Nevertheless, Boeri and his colleagues declared the antithrombotic group had slightly longer postoperative catheterization ($P = 0.01$) [16]. Interestingly, the meta-analysis

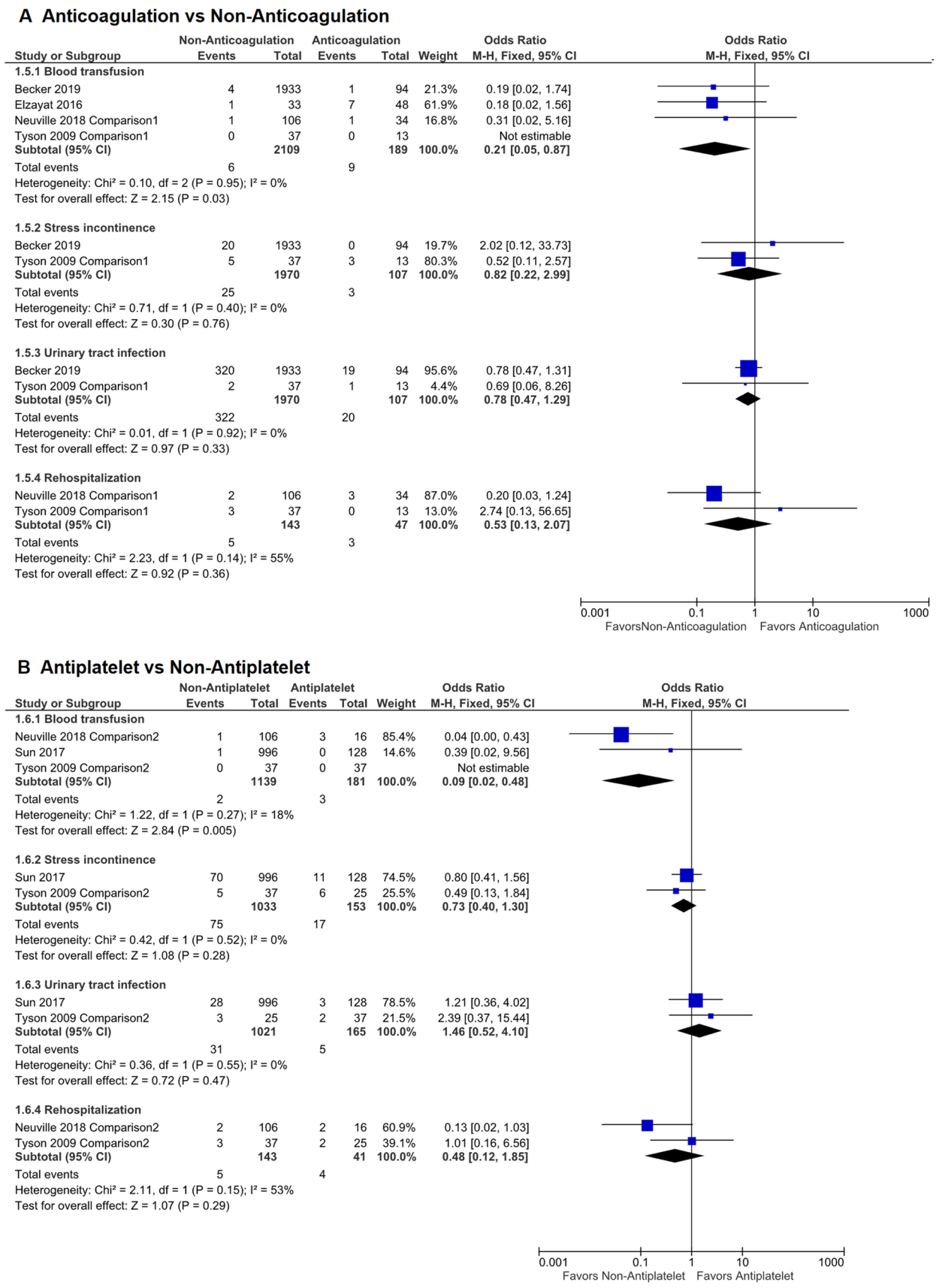

Fig. 4 Subgroup analysis of perioperative complications

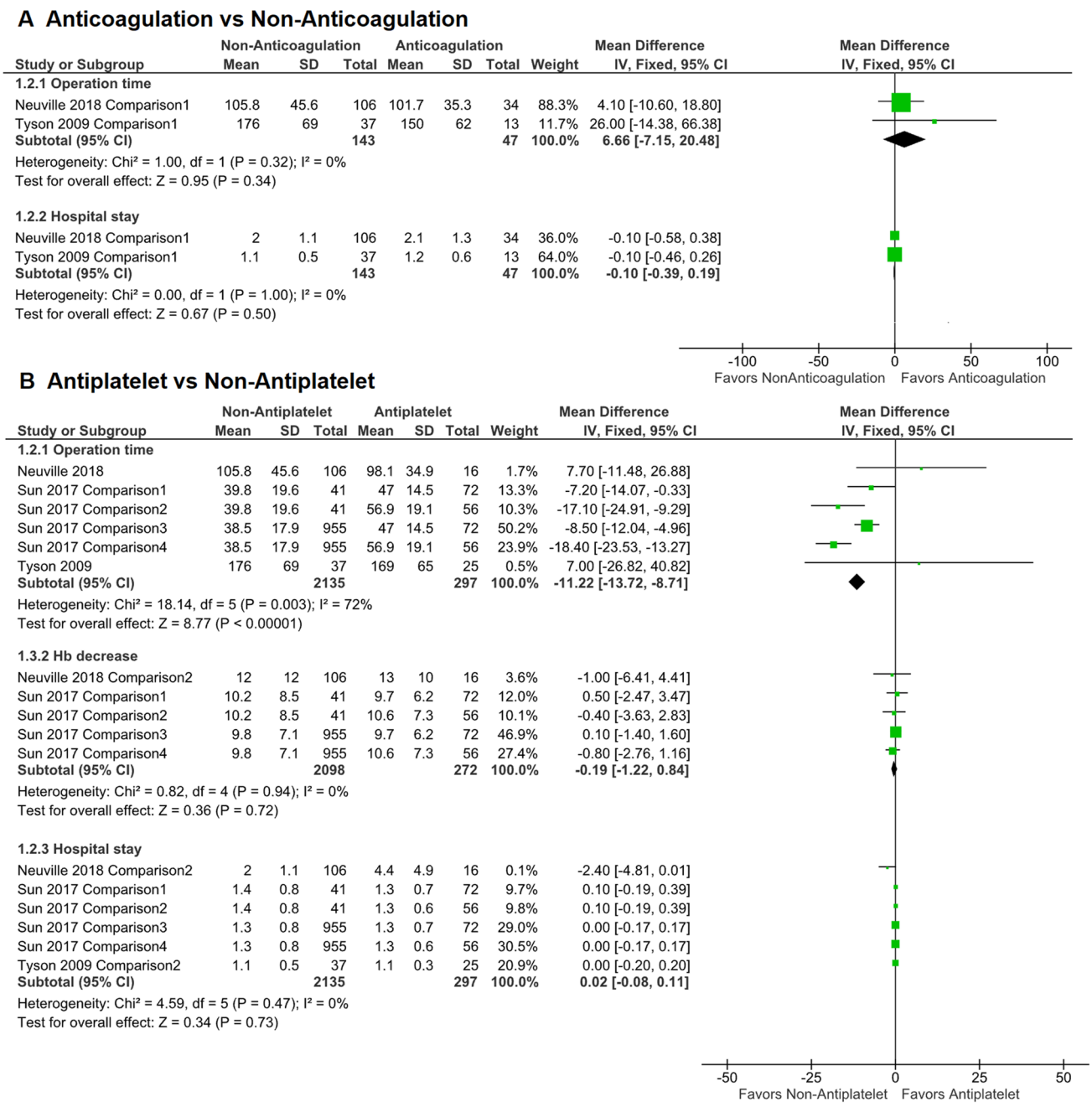

Fig. 5 Subgroup analysis of continuous perioperative parameters

of PVP also showed the antithrombotic group experienced longer catheterization time [27].

Functional outcomes and life quality after surgery have drawn increasing attention. One of the advantages of HoLEP over TURP and OP was the improved functional outcomes [9]. Although several studies have declared similar postoperative International Prostatic Symptom Score (IPSS), maximum urine flow rate (Qmax) and postvoid residual (PVR) between the antithrombotic and non-antithrombotic group [16–18], these data were either not enough or not available for quantitative analysis. Moreover, the follow-up duration of those reported functional outcomes was disparate, which made the analysis even more difficult and implied the demands of more future trials focusing on the impact of antithrombotic therapy on functional outcomes as well as a uniform reporting standard.

To our knowledge, the current meta-analysis was the first to demonstrate the impact of antithrombotic therapy among patients undergoing HoLEP. By systematically searching and including all relevant comparative trials, we hoped that

the consensus on this topic could be reached. Another advantage of our study was the performance of subgroup analysis based on the type of antithrombotic drugs, and the consistent outcomes of subgroup analysis made our conclusion more solid. Nonetheless, limitations should be mentioned before interpreting the current study. First, given no randomized controlled trials on this topic have been conducted, all the studies included were designed as retrospective. Second, as mentioned before, analysis of functional outcomes was lacking. Third, follow-up duration varied among studies and bias could be potentially caused. Last, inter-study heterogeneity was considerable in some analyses, even although we have performed a sensitivity analysis to rule out the source of heterogeneity.

Conclusion

The current study revealed that continuous intake of antithrombotic drugs during HoLEP could increase the risk of bleeding complication and blood transfusion, which was consistent with the outcomes from both the anticoagulation and antiplatelet subgroups. Moreover, higher rate of bladder tamponade and acute urine retention were also observed in the antithrombotic group. It's also implied that future researches should report outcomes in a uniform standard and more trials focused on functional outcomes are warranted.

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Authors' contributions QW, JZA, LY: project designation, public funding; XNZ, XH, HX: literature search and screening; XNZ, LP, DHC: data collection; XNZ, LP, DHC: data analysis, manuscript writing/editing; All the authors read and approved the final version.

Compliance with the ethical standard

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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