Benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy: A meta-analysis

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Abstract
We performed a meta-analysis to evaluate the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy. A systematic literature search up to December 2021 was done and 19 studies included 5715 benign prostatic hyperplasia subjects at the start of the study; 1501 of them were on anticoagulant/antiplatelet therapy, and 4214 were control. We calculated the odds ratio (OR) and mean difference (MD) with 95% confidence intervals (CIs) to evaluate the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy by the dichotomous or continuous methods with a random or fixed-influence model. Anticoagulant/antiplatelet therapy had significantly higher bleeding complication (OR, 1.88; 95% CI, 1.36–2.60, P < .001), higher blood transfusion (OR, 2.15; 95% CI, 1.63–2.83, P < .001), lower operation time (MD, −3.53; 95% CI, −6.80–0.27, P = .03), higher catheterization time (MD, 0.30; 95% CI, 0.06–0.53, P = .01), longer length of hospital stay (MD, 0.82; 95% CI, 0.37–1.26, P < .001) and higher thromboembolic events (OR, 2.88; 95% CI, 1.26–6.62, P = .01) compared to control in benign prostatic hyperplasia subjects. Anticoagulant/antiplatelet therapy had a significantly higher bleeding complication, higher blood transfusion, lower operation time, higher catheterization time, longer length of hospital stay and higher thromboembolic events compared to control in benign prostatic hyperplasia subjects. Further studies are required.

KEYWORDS
anticoagulant, antiplatelet, benign prostatic hyperplasia, bleeding complication, blood transfusion
Key Messages

- we performed a meta-analysis to evaluate the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy
- anticoagulant/antiplatelet therapy had a significantly higher bleeding complication, higher blood transfusion, lower operation time, higher catheterization time, longer length of hospital stay and higher thromboembolic events compared to control in benign prostatic hyperplasia subjects. Further studies are required

1 | BACKGROUND

Benign prostatic hyperplasia is an illness that frequently occurs in men above 50 years of age. At 60 years of age up to 50% of men suffer from benign prostatic hyperplasia, and the rate increases with age. The men having lower urinary tract symptoms require drug management or surgical intervention. For pharmacological management, α1-adrenoceptor antagonists like tamsulosin could decrease lower urinary tract symptoms. Yet, the α1-adrenoceptor antagonist cannot stop the incidence of urinary retention or the necessity for surgery. Transurethral surgery of the prostate is the gold standard for the surgical treatment of benign prostatic hyperplasia in current years. Though illness after transurethral prostate surgery is still conflicting, especially bleeding, needing a blood transfusion, and late postoperative bleeding. With aging people and a high frequency of cardiovascular disease, the number of subjects needing anticoagulant or antiplatelet treatment is constantly increasing. With accumulative elderly people needing surgical operations for benign prostatic hyperplasia management and long-term use of anticoagulants, the treatment approaches of anticoagulant/antiplatelet treatment in the preoperative time continue to be conflicting. Many surgeons favour stopping anticoagulant/antiplatelet treatment and changing to low molecular weight heparin before surgery, while others carry on anticoagulant/antiplatelet treatment perioperatively. Lately, several laser methods have arisen as a replacement to transurethral surgery of the prostate comprising the holmium yttrium aluminium garnet neodymium, thulium laser and Potassium titanyl phosphate (also known as the Green-light), proposing new choices for subjects with benign prostatic hyperplasia. These laser surgeries give the benefit of haemostasis compared with transurethral surgery of the prostate and are real tools for benign prostatic hyperplasia. All types of lasers are considered appropriate and harmless for subjects having anticoagulants as suggested by European Association of Urology guidelines for the management of benign prostatic hyperplasia. Also, the European Association of Urology guidelines on the surgical management of benign prostatic hyperplasia choose 532-nm laser evaporation to be considered in subjects getting anticoagulant medicine or for those with a high cardiovascular risk. Though, the European Association of Urology guidelines did not discuss whether pre-operative anticoagulant treatment must be stopped irrespective of whether transurethral surgery of the prostate or laser technique is chosen. In addition, the National Institute for Health and Care Excellence guidelines did not require the perioperative treatment of subjects using anticoagulant/antiplatelet treatment. So, we did this meta-analysis depending on the present indication to evaluate the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy. We aimed to get good useful suggestions for clinical practice.

2 | METHODS

This meta-analysis is organised according to the epidemiology statement, after the established methodology.

2.1 | Study selection

The main objective of this study was to compare the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy using the following tools like odds ratio (OR), mean difference (MD), frequency rate or relative risk and confidence interval of 95%.

The search was not narrowed to English, and inclusion criteria were not restricted by study type or size. Studies with no correlation were exempted from the study, for example, editorials, review articles letters and commentary. Figure 1 exhibits the mode of analysis.

The article inclusion criteria were classified and integrated into the meta-analysis when.
1. The study was a randomised control trial, prospective study, or retrospective study.
2. The target population was benign prostatic hyperplasia subjects.
3. The intervention program was anticoagulant/antiplatelet therapy.
4. The study comprised comparisons between anticoagulant/antiplatelet therapy and control.

The next exclusion criteria were adopted among the intervention groups.
1. Studies that did not determine the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy.
2. Studies with management other than anticoagulant/antiplatelet therapy.
3. Studies that did not concentrate on the influence of comparative outcomes.

2.1.1 Identification

PICOS principle was the protocol for the search strategy and asserted the critical elements of PICOS as P (population): benign prostatic hyperplasia subjects; I (intervention/exposure): anticoagulant/antiplatelet therapy; C (comparison): anticoagulant/antiplatelet therapy and control; O (outcome): bleeding complication, blood transfusion, operation time, catheterization time, length of hospital stay and thromboembolic events; and S (study design): had no limitation. We conducted a systematic and brief search on MEDLINE/PubMed, Google Scholar, Embase, OVID and Cochrane Library until December 2021, by a combination of keywords and correlated words for anticoagulant, antiplatelet, benign prostatic hyperplasia, control, bleeding complication, blood transfusion, operation time, catheterization time, length of hospital stay and thromboembolic events as shown in Table 1. The selected studies were pooled in EndNote software to exclude the duplicates. In addition, a thorough screening on the title and abstracts were done to erase any data that did not show any influence of anticoagulant/antiplatelet therapy and control on the outcomes studied for benign prostatic hyperplasia subjects. Related pieces of information were collected from the remaining studies.

2.2 Screening

Subject-related and study-related data characteristics were considered for the collection and classification of data, and it was pooled into a standardised form. The categorization was made into the standard form like the surname of the first author, duration of the trial, place of practice, design of the study, subject type, sample size, categories, demography

| Database       | Search strategy                                                                 |
|----------------|---------------------------------------------------------------------------------|
| Pubmed         | #1 “anticoagulant”[MeSH Terms] OR “antiplatelet”[MeSH Terms] OR “benign prostatic hyperplasia”[All Fields] OR “bleeding complication”[MeSH Terms] OR “blood transfusion”[All Fields] OR “operation time”[All Fields] OR “catheterization time”[All Fields] OR “length of hospital stay”[All Fields] OR “thromboembolic events”[All Fields] OR “bleeding complication”[All Fields] OR “blood transfusion”[All Fields] OR “operation time”[All Fields] OR “catheterization time”[All Fields] OR “length of hospital stay”[All Fields] OR “thromboembolic events”[All Fields] #3 #1 AND #2 |
| Embase         | ‘anticoagulant’/exp OR ‘antiplatelet’/exp OR ‘benign prostatic hyperplasia’/exp OR ‘bleeding complication’/exp OR ‘blood transfusion’/exp OR ‘operation time’/exp OR ‘catheterization time’/exp OR ‘length of hospital stay’/exp OR ‘thromboembolic events’/exp #3 #1 AND #2 |
| Cochrane Library | #1 (anticoagulant):ti,ab,kw OR (antiplatelet):ti,ab,kw OR (benign prostatic hyperplasia):ti,ab,kw (Word variations have been searched) OR (bleeding complication):ti,ab,kw OR (blood transfusion):ti,ab,kw OR (operation time):ti,ab,kw OR (catheterization time):ti,ab,kw OR (length of hospital stay):ti,ab,kw OR (thromboembolic events):ti,ab,kw (Word variations have been searched) #3 #1 AND #2 |

**TABLE 1** Search strategy for each database
and treatment methodology, information source, method of evaluation (both qualitative and quantitative), statistical analysis and primary outcome evaluation. Methodological quality was assessed by the “risk of bias tool” adopted from Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. This meta-analysis recommended that if a trial with inclusion criteria is based on the standards mentioned earlier, any conflicts that arose during the data collection by two reviewers must be resolved through discussion and when necessary by the “corresponding author” to ensure the quality of the methodology. When there were different data from one study based on the evaluation of the relationship, we extracted them separately.

2.3 Level of risk of bias is counted in the assessment criteria

The level of risk was considered low if all quality parameters were met; it was considered moderate if one of the quality parameters was not met/or partially met; and was considered high if one of the quality parameters was not met/or not included. A reexamination of the original article was addressed for any inconsistencies.

2.4 Eligibility criteria

The main eligibility criteria concentrated on the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy. An evaluation of the influence of anticoagulant/antiplatelet therapy and control on the bleeding complication, blood transfusion, operation time, catheterization time, length of hospital stay and thromboembolic events in benign prostatic hyperplasia was conducted and the data were extracted forming a summary.

2.5 Inclusion

Studies reporting the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy were only included in the sensitivity analysis. In comparison, the impact of anticoagulant/antiplatelet therapy and control were considered as a subcategory of sensitivity analysis.

2.6 Statistical analysis

The dichotomous or continuous methods were used to compute the odds ratio (OR) and mean difference (MD) at a 95% confidence interval (CI) on a fixed-influence or random-influence model. First, the $I^2$ index range was established between 0%–100%, when the $I^2$ index scale for heterogeneity was indicated as no, low, moderate and high as 0%, 25%, 50% and 75%, respectively. Random-influence was considered if $I^2$ was $>50\%$, and if $<50\%$, as fixed-influence. The initial evaluation of the result was stratified, and in sub-group analysis a $P$-value $<.05$ was reported statistically significant. Egger regression test was used quantitatively and qualitatively to assess the publication bias (if $P \geq .05$) by inspecting funnel plots of the logarithm of odds ratios compared with their standard errors. The entire $P$-values were two-tailed. The statistical analysis and graphs were done by “Reviewer manager version 5.3” (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

3 RESULTS

A total of 3450 distinctive studies were found, of which 19 studies (between 1996 and 2021) satisfied the inclusion criteria and were comprised in the study. This meta-analysis study based on 19 studies included 5715 benign prostatic hyperplasia subjects at the start of the study; 1501 of them were on anticoagulant/antiplatelet therapy, and 4214 were control. All studies evaluated the safety of benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy. Thirteen studies reported data stratified to the bleeding complication, 9 studies reported data stratified to the blood transfusion, 11 studies reported data stratified to the operation time, 10 studies reported data stratified to the catheterization time, 10 studies reported data stratified to the length of hospital stay, and 4 studies reported data stratified to the thromboembolic events. The study results ranged from 23 to 880 benign prostatic hyperplasia subjects at the beginning of the study. The information of the 19 studies is shown in Table 2.

Anticoagulant/antiplatelet therapy had significantly higher bleeding complication (OR, 1.88; 95% CI, 1.36–2.60, $P < .001$) with no heterogeneity ($I^2 = 0\%$), higher blood transfusion (OR, 2.15; 95% CI, 1.63–2.83, $P < .001$) with no heterogeneity ($I^2 = 0\%$), lower operation time (MD, $-3.53$; 95% CI, $-6.80–0.27$, $P = .03$) with moderate heterogeneity ($I^2 = 65\%$), higher catheterization time (MD, 0.30 95% CI, 0.06–0.53, $P = .01$) with high heterogeneity ($I^2 = 91\%$), longer length of hospital stay (MD, 0.82; 95% CI, 0.37–1.26, $P < .001$) with high heterogeneity ($I^2 = 96\%$), and higher thromboembolic events (OR, 2.88; 95% CI, 1.26–6.62, $P = .01$) with no heterogeneity ($I^2 = 0\%$) compared to control in benign prostatic hyperplasia subjects as shown in Figures 2-7.
The stratified data did not examine the factors like age, gender and ethnicity between the two groups because no studies adjusted or outlined these factors. No publication bias ($P = .88$) was detected when the quantitative measurement was conducted using the Egger regression test and examination of the funnel plot. However, low methodological quality was observed in selected randomised control trials. No articles had

| Study            | Country   | Total | Anticoagulant/Antiplatelet | Control |
|------------------|-----------|-------|-----------------------------|---------|
| Ala-Opas (1996)  | Finland   | 82    | 40                          | 42      |
| Nielsen (2000)   | Denmark   | 53    | 26                          | 27      |
| Dotan (2002)     | Israel    | 40    | 20                          | 20      |
| Ruszat (2007)    | Switzerland | 163  | 71                          | 92      |
| Hori (2008)      | Japan     | 318   | 51                          | 267     |
| Tyson (2009)     | USA       | 75    | 38                          | 37      |
| Sohn (2011)      | Korea     | 60    | 30                          | 30      |
| Taylor (2011)    | Australia | 163   | 72                          | 91      |
| Desczaleaud (2011)| France   | 809   | 403                         | 406     |
| Ong (2015)       | Australia | 198   | 32                          | 166     |
| El Tayeb (2016)  | USA       | 1588  | 30                          | 1558    |
| Knapp (2017)     | Australia | 331   | 59                          | 272     |
| Eken (2018)      | Turkey    | 233   | 59                          | 174     |
| Piotrowicz (2018)| Poland    | 109   | 65                          | 44      |
| Meskawi (2019)   | USA       | 422   | 148                         | 274     |
| Tokatli (2021)   | Turkey    | 337   | 134                         | 203     |
| Deuker (2021)    | Canada    | 268   | 104                         | 164     |
| Abdel Aal (2021)| Egypt     | 34    | 24                          | 10      |
| Agarwal (2021)   | USA       | 432   | 95                          | 337     |
| Total            |           | 5715  | 1501                        | 4214    |

**Figure 2** A forest plot of the bleeding complication in benign prostatic hyperplasia subjects with the anticoagulant/antiplatelet therapy compared to the control
selective reporting or incomplete data, which proved that selected articles devoid of selective reporting bias.

4 | DISCUSSION

This meta-analysis study constructed on 19 studies included 5715 benign prostatic hyperplasia subjects at the start of the study; 1501 of them were on anticoagulant/antiplatelet therapy, and 4214 were control. Anticoagulant/antiplatelet therapy had a significantly higher bleeding complication, higher blood transfusion, lower operation time, higher catheterization time, longer length of hospital stay and higher thromboembolic events compared to control in benign prostatic hyperplasia subjects. However, the analysis of outcomes should be performed with consideration because of the low sample size of some of the selected studies found for the meta-analysis, 6 out of 19 studies with ≤100 subjects as sample size; recommending the need for other studies to confirm these findings or perhaps to significantly impact confidence in the influence evaluation.

Meta-analysis is a methodology adapted to statistically pool and study the findings from several independent randomised controlled trials. Transurethral surgery of the prostate is extensively used for the management of benign prostatic hyperplasia. Though, the subjects’ morbidity after the prostate transurethral surgery is considerably high because of intraoperative and postoperative bleeding and electrolyte condition. Because of the anticoagulant/antiplatelet therapy for atrial fibrillation, recurring thromboembolic illness, or prosthetic
FIGURE 5 A forest plot of the catheterization time in benign prostatic hyperplasia subjects with the anticoagulant/antiplatelet therapy compared to the control

FIGURE 6 A forest plot of the length of hospital stay in benign prostatic hyperplasia subjects with the anticoagulant/antiplatelet therapy compared to the control

FIGURE 7 A forest plot of the thromboembolic events in benign prostatic hyperplasia subjects with the anticoagulant/antiplatelet therapy compared to the control
heart surgery, the risk of bleeding problems related to surgery is higher in benign prostatic hyperplasia subjects; however, stopping anticoagulant/antiplatelet therapy prior to surgery might influence subjects to thromboembolism produced by the release of tissue thromboplastins. Different laser management choices are established for benign prostatic hyperplasia surgery for those subjects on anticoagulant/antiplatelet therapy e.g. photo-selective vaporisation of the prostate, holmium yttrium aluminium garnet neodymium. These laser managements appear to minimise bleeding through surgery. Mainly in subjects getting anticoagulant/antiplatelet therapy, these laser managements appear to have a promising safety profile. Both European Association of Urology guidelines and National Institute for Health and Care Excellence guidelines recommend that laser management could be safely given to subjects who have a high risk of bleeding. Though, regarding the perioperative handling of anticoagulant/antiplatelet therapy, the guidelines did not indicate if there is a necessity to stop or shift to low molecular weight heparin. So, many surgeons stopped anticoagulant/antiplatelet therapy and shifted to low molecular weight heparin in advance of surgery, while others did not stop anticoagulant/antiplatelet therapy perioperatively. Lately, Zheng et al lead a meta-analysis to evaluate the effectiveness and safety of photo-selective vaporisation of the prostate on high-risk subjects comprising subjects on anticoagulants. Though, their meta-analysis did not conduct subgroup analysis for individuals on anticoagulant/antiplatelet therapy. The frequency of bleeding problems and blood transfusions is a key parameter when assessing the safety of the surgery for benign prostatic hyperplasia subjects with anticoagulant/antiplatelet therapy. For perioperative anticoagulant/antiplatelet treatment, the regularly used process in the present practice comprised bridging management with low molecular weight heparin and continued therapy. One of the chief fears about bridging management is that it may raise the risk of thromboembolic events. Chakravarti et al used anticoagulants for 11 subjects undergoing transurethral surgery of the prostate by discontinuing warfarin and bridging with heparin preoperatively. They observed only one blood transfusion, but minor bleeding happened in 27% of the subjects. Descazeaud et al similarly determined that shifting to low molecular weight heparin preoperatively is better for benign prostatic hyperplasia subjects using anticoagulant/antiplatelet therapy. Between the studies for operation time and catheterization time, the synthesis of meta-analysis discovered similar outcomes between groups. These outcomes recommend that the use of anticoagulant/antiplatelet therapy through the perioperative period will not influence the quality of surgery.

This meta-analysis showed the relationship between the influences of anticoagulant/antiplatelet therapy compared with control in benign prostatic hyperplasia subjects. However, further studies are needed to validate these potential associations. Also, further studies are needed to deliver a clinically meaningful difference in the results. This was suggested in other meta-analyses which showed similar effects. This needs additional examination and clarification because no clear reasoning was found to clarify these outcomes. Well-designed clinical trials are also required to evaluate these factors with the blend of diverse ages, gender, and ethnicity; as our meta-analysis study could not answer whether these factors are related to the outcomes. In summary, Anticoagulant/antiplatelet therapy had a significantly higher bleeding complication, higher blood transfusion, lower operation time, higher catheterization time, longer length of hospital stay and higher thromboembolic events compared to control in benign prostatic hyperplasia subjects.

The limitations of the meta-analysis were as next: There may be a collection bias in this meta-analysis since several studies found were excluded from the meta-analysis. Though, the studies excluded did not satisfy the inclusion criteria of the meta-analysis. Furthermore, we could not decide if the results were linked to age, gender and ethnicity or not. The study designed to assess the relationship between the influence of anticoagulant/antiplatelet therapy and control on the outcomes of benign prostatic hyperplasia subjects was depending on data from former studies, which may result in bias brought by incomplete details. The meta-analysis was depending on 19 studies; 6 studies of them were small, \( \leq 100 \). Features comprising the age, gender, obedience, nutritional status and ethnicity of subjects were also likely bias-encouraging features. Several unpublished studies and lost data may result in a pooled influence bias. Subjects were using diverse chief pharmacological medicines, treatment schedules, doses and health care schemes. The length of anticoagulant/antiplatelet therapy and control treatment of the included studies was varying. The comprised studies did not sufficiently assess the hospital costs of the subjects studied, which is a vital result.

In conclusion, anticoagulant/antiplatelet therapy had a significantly higher bleeding complication, higher blood transfusion, lower operation time, higher catheterization time, longer length of hospital stay and higher thromboembolic events compared to control in benign prostatic hyperplasia subjects. However, the analysis of outcomes should be done with consideration because of the low sample size of some of the selected studies found for the meta-analysis; recommending the need for added studies to confirm these results or perhaps to significantly
influence confidence in the effect evaluation. More studies are essential to confirm these outcomes.

CONFLICT OF INTEREST
The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT
The datasets examined during the present study are obtainable from the corresponding author on reasonable request.

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How to cite this article: Ji X, Zhao Y, Zhang L, Liu Y. Benign prostatic hyperplasia wound after surgical removal in subjects on anticoagulant or antiplatelet therapy: A meta-analysis. Int Wound J. 2022;19(8):1990-1999. doi:10.1111/iwj.13799