Evaluation of the short-term cessation and early initiation of antithrombotic therapy in high-risk patients undergoing HoLEP procedure for large prostates (> 100 mL): A critical evaluation

Muhammed Ibis[1] and Zafer Tokatli[2]

[1]Affiliation not available
[2]Medicana International Ankara Hospital, Ankara, Turkey

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Abstract

What is Known and Objective: Currently, the safety and efficacy of Holmium Laser Enucleation of Prostate (HoLEP) in patients with large prostates (>100 ml) who are at high risk for Thromboembolic Events (TE) and receiving Antithrombotic Therapy (AT) are controversial. This study aims to characterise the safety and efficacy of the HoLEP in patients with large prostates (>100ml) at high risk for TE resuming AT in the early post-operative period.

Methods: We have reviewed retrospective data for 378 patients with large prostates treated with the HoLEP for symptomatic benign prostatic hyperplasia between December 2016 and July 2020. One hundred thirty-four of the patients had been receiving AT. Antiplatelet (AP) therapy was maintained. Patients taking vitamin K antagonists and new oral anticoagulants stopped taking the drug 5 and 2 days before the HoLEP, respectively. Postoperatively, anticoagulants (AC) were resumed within 24 hours. In patients receiving AT, we have determined "pre-operative, peri-operative, and post-operative" parameters, functional outcome, and adverse events for the 3 months after the operations. Subsequently, we have compared the results of 203 patients without AT.

Results and Discussion: Patients receiving AC and AP were older (p=0.015) and had a higher median ASA score (p<0.001). Objective-voiding parameters (Qmax, PVR) and urinary symptoms (IPSS, QoL) improved in the three groups (p<0.001). Median enucleation and morcellation efficiencies were 1.58 (IQR:0.87-3.13) and 5 (IQR:1-8.08), median catheterisation and hospitalisation time was 2 days (IQR:2-3) and 3 days (IQR:3-4), respectively. The peri-operative results were similar in the three groups. Overall, one patient in the AP group required blood transfusion at 4 days postoperatively due to clot retention and significant haemoglobin decrease (p=0.216). There was no adverse TE in any patient within the 3-months postoperatively.

What is new and Conclusion: In cases with large-sized prostates posing a high risk of bleeding as well as TE, the HoLEP procedure could be applied without leaving AP agents in a safe and highly efficient manner. Additionally, this procedure could be performed following the cessation of AC treatment with the chance of a quite early initiation of these agents to limit properly the potential risk of TE.

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WHAT IS KNOWN AND OBJECTIVE

Benign Prostatic Hyperplasia (BPH) is one of the most common urological diseases in elderly male patients. Associated lower urinary tract symptoms (LUTS) are the primary cause of decreased health-related Quality of Life (QoL) in these cases. [1]

Several endoscopic surgical alternatives such as resection, ablation, incision, vaporisation, and enucleation with mechanical morcellation have been described and applied in the relief of LUTS secondary to small-medium size BPH in patient's refractory to medical treatment or those developing BPH-related complications. Despite that, endoscopic management of large prostates (>100 ml) constituted a real challenge for

endo-urologists in this aspect. Especially, bleeding risk may limit the endoscopic treatment alternatives use, particularly in patients with large-volume prostates receiving antithrombotic (antiplatelet-anticoagulant) therapy.[2, 3]

Accumulated data so far have shown that it has increased the incidence of use of antithrombotic agents in cases at older ages and these patients have multiple comorbidities, which may increase the risk of a thromboembolic event (TE). Because of the high risk of TE, antithrombotic therapy (AT) has always been continued during minor surgeries and also AT was advised to be continued as soon as bleeding control is achieved, if AT was planned to be discontinued. Regarding this critical issue, guidelines state anti-platelet therapy should be started again in high-risk patients as soon as possible (within 48 hours if possible) after surgery. Similarly, coumadin should be restarted at 24 hours postoperatively in such patients (e.g., with prosthetic heart valves).[4]

HoLEP is a size-independent technique, enabling the complete removal of enlarged adenomas through a safe and anatomic dissection made between the adenoma(s) and surgical capsule associated with a lower risk of intraoperative bleeding. Published data on this aspect showed that the HoLEP procedure could reveal similar or better post-operative clinical outcomes along with lower complication rates than open prostatectomy or other endoscopic therapies. It has therefore become the new gold standard technique to treat BPH/LUTS, especially in large-volume prostates.[5, 6] Long-term data have been emerging to exhibit that this enucleation procedure has durable results with lower retreatment rates.[3, 7]

Last but not least, in the light of the clear risk of post-operative bleeding after the treatment alternatives above coupled with the increased risk of TE thanks to relatively longer cessation of anticoagulant (AC) therapy, the HoLEP procedure may give the advantages of the continuation of antiplatelet (AP) agents and immediate initiation of AC agents if stopped, because of the effective and safe tissue removal particularly in large-volume prostates.

This current study has aimed to evaluate the efficacy and safety of the HoLEP procedure in cases with large prostates with a social emphasis on the discontinuation besides the early initiation of AC and AP agents to limit the risk of associated TE.

METHODS

This retrospective study included 378 patients presenting with LUTS and large prostate. They underwent the HoLEP procedure between December 2016 and July 2020. Based on the use of AT agents, patients were divided into three groups. While patients receiving acetylsalicylic acid and platelet aggregation inhibitors were grouped as AP, patients receiving new oral anticoagulants (NOAC) and Vitamin K antagonists were grouped as AC. Afterwards, patients who did not receive AT were in the last one as the non-treatment (NT) group. Patient characteristics, perioperative, and postoperative outcomes were recorded properly in all cases.

For this study, we prepared a protocol as regards the use of antithrombotic therapy in patients who underwent the HoLEP, after detailed consultation with the responsible cardiologist. This protocol, prepared in line with the ESC and EAU guidelines, aimed to reduce the risk of TE reported during and after the HoLEP procedure in patients with large prostates receiving AT therapy.[4, 8] Patients receiving vitamin K antagonists stopped taking the medication for 5 days before the HoLEP and no alternative antithrombotic therapy was initiated. However, in high-risk patients, such as patients with mechanical prostatic heart valves or CHADS-VASc Score >3, Vitamin K antagonists had been stopped 5 days ago and bridged with a therapeutic dose of low molecular weight heparin (LMWH). Patients were treated with a therapeutic dose of LMWH and a vitamin K antagonist combination until the target INR value was reached immediately after the surgery. Patients taking NOAC stopped taking medication 2 days before surgery. The treatments of the patients who received vitamin K antagonist and NOAC were resumed within 24 hours postoperatively. In the AP group, the AP treatment of the patient who received single antiplatelet therapy was not discontinued. However, the

patients who received both acetylsalicylic acid and P2Y12 inhibitors were operated under acetylsalicylic acid treatment after the discontinuation of P2Y12 inhibitors. In these patients, P2Y12 inhibitors therapy was started within 24 hours postoperatively. In patients who underwent surgery, INR was <1.7. Pharmacological prophylaxis, such as LMWH, was not applied to the patients in the NT group.

Respectively, the difference between the Haemoglobin (Hb) values measured one day before the surgery and the values measured after 12 hours and 1 week the operation was defined as "haemoglobin decrease within 12 hours after surgery" and "haemoglobin decrease at 1-week postoperatively". As we started the AC treatment 24 hours after the procedure and the drop in Hb levels could show the dilutional changes, we thought that the effect of AC treatment might be quite limited for the changes in Hb levels noted after 12 hours. To start the potential effect of AC management on post-operative Hb changes, we focused on the Hb levels detected 1-week after the procedures. The enucleation and morcellation efficiency were calculated as the ratio of the removed tissue volume to the enucleation-morcellation time. Functional data were obtained from the post-op follow-up records of 337 patients referring to our clinic for the 3rd-month post-operative follow-up evaluation. Because the data for 41 patients was not available, their relevant recordings were excluded from the evaluation.

A single surgeon performed all the surgeries in the present study. Prostate adenomas were enucleated as two or three lobes' techniques depending on the prostate morphology (with/without a huge median lob). The equipment included a 100W Holmium laser (Versapulse, Lumenis Inc., Santa Clara, CA, USA), 550-um end-firing flexible fibre, a 26fr continuous flow laser resectoscope (Karl- Storz, Germany), 26fr nephroscope, and morcellator (Versacut; LumenisInc). The standard laser setting was adjusted as 1.2J and 50Hz.

We performed all statistical analyses with the SPSS 25.0.0.1 software (IBM Corp., Armonk, NY, USA) with the Mann-Whitney U, Kruskal–Wallis test, chi-squared test, and Wilcoxon signed-rank test. Normal distribution assumption for continuous variables was analysed with the Shapiro-Wilk test. A value of $p<0.05$ was considered statistically significant.

RESULTS

Among the 337 patients included in the study, 24.6% (n = 83) received the AP, while 15.1% (n = 51) received the AC therapy. The pre-operative characteristics of the study patients were not statistically different between groups except age (p=0.015) and the ASA score. Patients with the AP and the AC showed more comorbidities (higher ASA status, p<0.001) (Table 1). In the AP group, history showed coronary heart disease in 56 patients (67.5%); cerebrovascular accident in 8 (9.6%); peripheral arterial occlusive disease in 9 (10.8%); and other reasons (primary prevention for coronary artery disease) in 10 (12.1%). Among the patients who received AC, 21 (41.2%) of them had chronic atrial fibrillation; 12 (23.5%) had a cerebrovascular event; 8 (15.7%) had a prosthetic heart valve; 5 (9.8%) had a pulmonary embolism; 3 (5.9%) had a vascular prosthesis; 2 (3.9%) had deep veined thrombosis.

Peri-operative outcomes did not differ significantly among the three groups. The median time of enucleation and morcellation was 46 min (IQR:15-120, p=0.548) and 15 min (IQR:4-60, p=0.168). Enucleation and morcellation efficiency were 1.58 (IQR:0.87-3.13, p=0.115) and 5 (IQR:1-8.08, p=0.204), respectively. There was no difference between the three groups as to haemoglobin decrease within 12 hours (peri-operatively) and 1-week postoperatively (p=0.225 and p=0.545, respectively) (Table 2). In the present study, all patients underwent the HoLEP safely with no adverse TE within 3 months postoperatively.

In three groups, International Prostate Symptom Scores (IPSS), post-voiding residual volume (PVR), and QoL score significantly decreased and maximum flow rates (Qmax) significantly increased postoperatively compared with the pre-operative values (p<0.001) (Fig. 1A-D). Three months after surgery, these functional results had improved significantly in all groups, with no differences between the groups.

The post-operative complications were grouped based on the Clavien-Dindo classification of surgical complications. No significant difference was observed in the complications, except prolonged catheterisation (Table 3). The prolonged catheterisation associated with the need for prolonged irrigation occurred in 36 (10.7%)

patients. Three groups were different significantly from each other for prolonged catheterisation (p=0.028). Also, the AP and AC groups were compared with the NT group in terms of prolonged catheterisation (AP vs. NT; OR: 2.77, 95% CI: 1.28-5.96, p=0.007 and AC vs. NT; OR: 1.67, 95% CI:0.61-4.55, p=0.391). In general, one (1.2%) patient in the AP group required blood transfusion on 4 days postoperatively due to clot retention and significant haemoglobin decrease (p = 0.216). The patient was catheterized, and the clot was evacuated with no need for an operation. The AP and NT groups were compared for blood transfusion and clot retention, no statistically significant difference was observed (AP vs. NT; OR: 1.012, 95% CI: 0.988–1.037, p=0.29). Also, there was no significant difference between the groups according to urinary tract infection (UTI) and urethral stricture/bladder neck contracture (Table 3). Consequently, there was no adverse TE in any patient within 3-month postoperatively.

DISCUSSION

The published data demonstrated explicitly that the percentage of elderly cases with co-morbid diseases (i.e., coronary artery disease, cardiac valve disease, peripheric arterial disease, deep vein thrombosis, and pulmonary emboli) is flourishing. The majority pose the risk of TE requiring AT with certain agents such as acetylsalicylic acid, P2Y12 inhibitors, NOAC, coumadin. Taking this along with the increasing prevalence of elderly male patients with BPH under the above-mentioned treatment into account, endoscopic surgical interventions to remove the outlet obstruction in these cases carry the increased risk of complications.[9] Given the procedure-related peri-operative bleeding risk and post-operative TE, the AC treatment regimen needs to be well-balanced to limit the chance of the above and occasionally life-threatening problems.

Several organisations have provided various recommendations on the peri-operative management of AT agents in the urological field. For patients undergoing elective HoLEP concerning the peri-operative management of AP therapy, the EAU recommends stopping AP agents before surgery and restarting when bleeding poses no longer a serious risk – typically four days post-surgery–.[8] On the other hand, ESC suggests that AP agents can be discontinued before surgery and continue taking aspirin after surgery should be based on an individual decision that depends on the perioperative bleeding risk, weighed against the risk of thrombotic complications.[4] In a study by Lotrionte et al., it was stated that the discontinuation of aspirin in patients at risk of coronary artery disease increased the risk of cardiovascular events threefold and that aspirin should be maintained to provide surgery and the post-operative period.[10] Regarding the peri-operative management of AC therapy, both EAU and ESC recommend the protocol applied in this study. Similar to the management of AP agents, EAU recommends restarting when bleeding is no longer a serious risk– typically four days post-surgery. In our study, unlike the recommendations of these guidelines, we had a shorter initiation time of postoperative AC therapy and we practised the operations under AP monotherapy. A study published as clinical practice recommendations on this topic suggested that laser prostate surgery can be safely accomplished for the patient with a therapeutic INR who is at significant risk for thrombosis without the discontinuation of oral AC/AP [11]. However, in the light of current guidelines [4, 8], we used bridging with vitamin K antagonist and DMWH in high-risk patients.

In our opinion, the rational application of this protocol in cases with large-volume prostates will limit the risk of bleeding and associated complications. In parallel, the very early initiation of the AC agents could be possible in this risk group of cases in which the complete removal of enlarged adenomas. While the surgical procedure (HoLEP) could be performed under AT in patients with small-sized prostates [12-14], performing the procedure in large-sized prostates made increase the risk of serious bleeding and related problems think. Still, the results of our study suggest that this concern is unfounded.

There were three groups in the study and no patient showed TE. In a similar study, but with a smaller series, on Thulium Laser Vapoenucleation of the Prostate (ThuVEP), Castellani et al.[15] pointed out two early admissions in the intensive care unit and one late myocardial infarction. In our study and the study of Castellani et al., the rate of patients with ASA[?]3 was 33.8% and 71.6%. The absence of TE in our study may be connected to the slightly lower rate of this. Deuker et al.[16] noted that one patient died in their

study in which they analysed the data of 268 HoLEP-treated patients. In this study, noteworthy that the treatment of patients receiving coumadin was stopped 10 days before.

Bleeding in terms of Hb drop was evaluated with the post-operative Hb values obtained at two different time intervals (post-operative 12 hours and 1 week) after the procedure. Previously, Zheng et al. conducted a meta-analysis and claimed that the hg change after HoLEP was comparable in the AT and Non-AT groups.[17] In this study, even though the AP and AC groups had a higher risk of bleeding, remarkably, the Hb drop after HoLEP was similar between the three groups. Our results supported the results of studies conducted with similar methodology.[13, 14] Examination of our cases revealed that although cases undergoing AP and AC treatment were older with associated co-morbid diseases, the efficiency of enucleation and morcellation procedures were similar in both groups. Our data were compared with the results of previous studies.[18, 19] Recommendations for anatomical endoscopic enucleation of the prostate (AEEP) in patients with BPH receiving AT therapy were observed by Netsch et al.[20] In the study in which all enucleation procedures were discussed, it was noticed that patients under AP treatment showed fewer bleeding-related complications compared to those under AC treatment. Although patients receiving both AP and AC therapy are associated with increased bleeding complications, most studies show that AEEP is feasible in patients treated with AT and functional outcomes are not different from patients receiving AT therapy. In addition, Netsch et al noted that these findings were only for prostate glands between 50 and 110 ml. In our study, HoLEP was an effective and safe surgical procedure in AT-treated patients with a large prostate (>100ml).

Regarding prolonged catheterisation issues in the three groups, the results were found different ($p = 0.028$, 3x2 chi-square test). Also, in case of patients undergoing AP treatment when compared with those with no treatment, the AP and AC groups were compared with the NT group as to prolonged catheterisation and our findings showed that catheterisation time was significantly longer (AP vs NT; OR: 2.77, 95% CI: 1.28-5.96, p=0.007 and AC vs NT; OR: 1.67, 95% CI:0.61-4.55, p=0.391, 2x2 chi-square test). It has been shown that antithrombotic therapies have a significant effect on hospitalisation and catheterisation time.[21, 22] Likewise, Boeri et al. reported a comparatively longer hospital stay and catheter maintenance, while they did not see any difference concerning operation time.[23] HoLEP applied to 116 patients who received continuous and intermittent AT treatment by EI Tayeb et al.[12] The transfusion rates were 3.5% for AC patients and 1.6% for the non-AC group, which showed no significant difference. Compared with the non-AC group, the length of hospitalisation and duration of continuous bladder irrigation were longer in the AC group (27.8 h vs. 24 h, 15 h vs. 13.5 h; $p < 0.001$, respectively). Furthermore, there were no differences in enucleation time, catheterization time, and transfusion rate between receiving AT patients and the intermittent AT group. In addition, although not statistically significant in our study, one case in the AP group required blood transfusion with clot retention after the procedure (AP vs NT; OR: 1.012, 95% CI: 0.988–1.037, p=0.29).

Finally, assessment of the efficiency in the removal of obstruction during a three-month evaluation period in all groups in terms of pre-operative and post-operative Qmax, PVR, IPSS, and QoL parameters revealed no significant difference between the three groups. These findings again indicated the successful removal of the obstruction with the HoLEP procedure in all group cases. In other words, our findings revealed the efficiency and performance of a successful HoLEP in cases with large-sized prostates with or without AP medication.

Our study has some potential limitations. First of all, the retrospective nature of our study method may be a major limitation. Second, performing all procedures by an experienced surgeon may have had a positive effect on the outcomes. Besides, the use of the ASA score instead of the Charlson co-morbidity index may make up another limitation. Last but not least, the limited duration of irrigation time could be the final possible limitation. Still, despite these possible limitations, we believe that considering the highly limited data published in the literature focusing on the possibility of early initiation of AC management, particularly following the surgical intervention for large prostates; Our findings could contribute to the existing information with reliable clinical implications.

WHAT IS NEW AND CONCLUSION

Our results reveal that the HoLEP procedure could be applied without leaving AP in a safe and highly

efficient manner in cases with large-sized prostates carrying a high risk of bleeding besides thromboembolic events. Additionally, this procedure could be conducted following the cessation of AC treatment with the chance of very early initiation of these agents to limit well the potential risk of thromboembolic events. However, we noted that this approach may prolong the duration of catheterization after the procedure, which may cause necessary precautions.

CONFLICT OF INTEREST

None declared.

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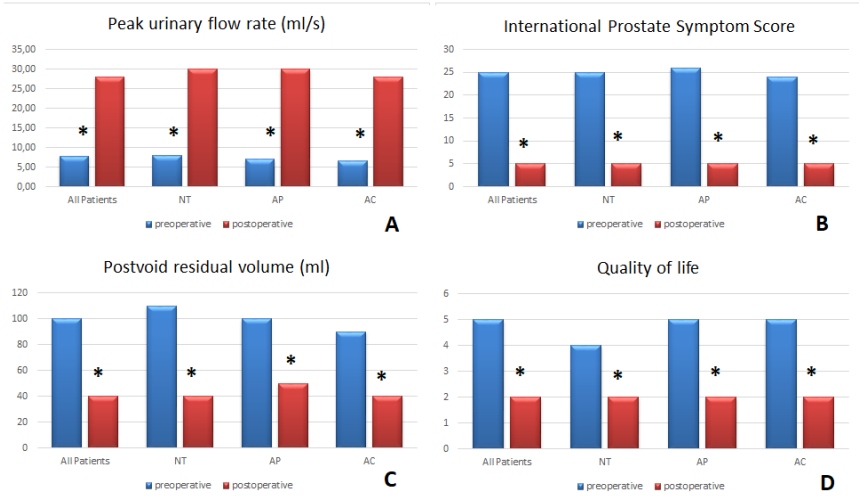
FIGURE LEGENDS

Figure 1. Comparison of functional results preoperative and postoperative 3rd month. (A) Qmax (Maximum flow rate), (B) IPSS (International prostate symptoms score), (C) PVR (Postvoiding residual volume), and (D) QoL (Quality of life). *p < 0.001. NT: Non-Treatment, AP: Antiplatelet therapy, AC: Anticoagulation therapy.



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