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**ORIGINAL ARTICLE**

# Safety and Efficacy of Holmium Laser Bladder Neck Incision for Small Prostate in Patients with and without Antithrombotic Therapy: A Prospective Study

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## ABSTRACT

**Background:** Benign prostatic hyperplasia (BPH) is a hyperplastic process of the glandular epithelial elements and fibromuscular stromal elements of the prostate. **Objectives**: evaluate the safety and efficacy of Holmium laser bladder neck incision for management of Bladder outlet obstruction (BOO) due to BPH less than 30 grams in patients with and without antithrombotic therapy. **Patients & Methods:** the current study included a total of 36 patients who admitted with symptomatic benign prostatic hyperplasia; 24 of them with antithrombotic and 10 patients without antithrombotic drugs to Department of Urology, Faculty of Medicine; Zagazig University Hospitals, during the period from January 2018 to November 2018. All patients were assessed as requiring surgical treatment for BOO due to BPH with: prostate size ≤ 30 cc, PVR ≤ 300 mL, IPS score ≥ 8, Qmax ≤ 15 mL/sec. **Results**: Our study confirmed the safety and efficacy of holmium laser bladder neck incision technique for management of small prostate (< 30g) patients without antithrombotic therapy. **Conclusions:** Ho BNI procedure is efficient and safe in relieving BOO with prostate size < 30 cc in patients with and without antithrombotic therapy. The risk of postoperative hematuria and bleeding is less with Ho BNI because of its better haemostatic properties.

**Keywords** Holmium Laser , Bladder Neck Incision,Small Prostate.

## INTRODUCTION

Transurethral resection of prostate (TURP) is so far the standard treatment for patients with bothersome lower urinary tract symptoms (LUTS) or urinary-retention due to BPH requiring surgical intervention, however this operation is not free of complications [1]. About 80% of patients underwent TURP complained from backward ejaculation, 15% become impotent, 5% may develop bladder neck contracture, and 13% of patients may require blood transfusion [2].

Bladder neck incision (BNI) is a relatively simple, cheap, and less invasive procedure than TURP [3]. Nearly 20-30% of the patients underwent TURP can be effectively managed with BNI and avoiding the drawbacks of TURP [4]. In many studies, BNI has definitely high acceptable results when compared to TURP in small size prostate [5], [6].

The updated European urology guidelines [7] recommended offering transurethral incision of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size < 30 mL, without a middle lobe (Level of evidence: la; Grade of recommendations [8] : A). BNI is traditionally done with Collins knife using monopolar electrocautery. Holmium laser has unique properties of incision and hemostasis for which it has been used in BNI also**.** With many elderly patients on chronic oral antithrombotic therapy for history of coronary stent, cardiac valve, arrhythmia, history of deep venous thrombosis or pulmonary embolism, peripheral vascular disease, and cerebrovascular disease, there is a significant concern for increased risk of bleeding and morbidity [9]**.** The use of monopolar current for endoscopic management of BPH is associated with high incidence of hemorrhagic complications in patients on antithrombotic therapy [10]**.** The aim of the work is to evaluate the safety and efficacy of Holmium laser bladder neck incision for management of BOO due to BPH less than 30 grams in patients on antithrombotic therapy.

The primary endpoints of the study: intra & post operative blood losses (hematuria and INR). The secondary endpoints: improvements (IPSS, Qmax, QoL, and PVR).

## AIM OF THE WORK

The aim of the work is to evaluate the safety and efficacy of Holmium laser bladder neck incision for management of BOO due to BPH less than 30 grams in patients with and without antithrombotic therapy

## PATIENTS AND METHODS

the current study included a total of 36 patients who admitted to Department of Urology, Faculty of Medicine; Zagazig University Hospitals, with symptomatic benign prostatic hyperplasia; 24 of them with antithrombotic and 10 patients without antithrombotic drugs during the period from January 2018 to November 2018

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Patients were sudivided into 2 groups:

Group (1): included 24 cases with antithrombotic drugs

Group (2) included 10 cases without antithrombotic drugs.

***Inclusion Criteria:***

All patients were assessed as requiring surgical treatment for BOO due to BPH with Prostate size ≤ 30 cc, Post-void residual urine (PVR) ≤ 300 mL, International Prostate Symptom Score **(**IPSS**)** score ≥ 8, Maximum flow rate (Qmax) ≤ 15 mL/sec, Patients on antithrombotic therapy (whatever the indication for antithrombotic therapy as long as the patient is fit for anesthesia according to ASA score) .

Patients will be categorized according to the type of antithrombotic therapy they receive as follows: Patients receiving acetylsalicylic acid, Patients receiving **thienopyridine adenosine diphosphate (ADP)-receptor antagonists,** Patients receiving warfarins

***Exclusion Criteria:***

Prostates with middle lobe, Patients who were diagnosed to have prostate cancer, Patients having urethral stricture, Patients with stone bladder and Patients with renal impairment.

**All patients were subjectd to**

Complete history taking including IPSS, clinical and physical examination, Routine laboratory investigation, Prostatic specific antigen (PSA) assay according to American Society of Anesthesiologists score (ASA score)

**ASA score [11]**

Anesthesia providers use this scale to indicate preoperative health to help decide if a patient should have an operation. For predicting operative risk, other factors to consider include, Age, Comorbidities, Extent and duration of the operative procedure, Planned anesthetic techniques, The skill set of the surgical team, Duration of surgery, Available equipment,

Blood products needed, based on five classes (I to V).

I. Patient is a completely healthy fit patient.
II. Patient has mild systemic disease.
III. Patient has severe systemic disease that is not incapacitating.
IV. Patient has incapacitating disease that is a constant threat to life.
V. A moribund patient who is not expected to live 24 hour with or without surgery.

**Radiological investigations include:** Transrectal ultrasound (TRUS) to assess prostate size, detect any abnormality and pelvic & abdominal ultrasound (US) to assess PVR, upper urinary tract. Outcomes of intra and post-operative measures including operative time, catheter durations, hospital stay, biochemical changes in Haemoglobin (HB) and Hematocrite (HTC), Qmax, PVR, International index of Erectile function (IIEF) and IPSS score. Perioperative complications such as need blood transfusion and bleeding. Patients in both groups were followed for 1,3 and 6 months.

**Technique:**

Resectoscop was introduced with the laser working element adapted with 2 metal fenestrated spatula. Isotonic saline was used during the procedure. We used the 100 w sphinx machine as source for Ho-YAG laser. Laser power was set as (power 1.5 – 2 joules, Frequency 17 – 20 pulse per minute, pulse duration 350 – 550 microsecond) on the 1000 micrometer laser fiber.

**Postoperative fellow up :**

- **1st postoperative day** for catheter removal and assessment of early postoperative complications. **1, 3 and 6 months** postoperative for assessment of improvement of study parameters (IPSS, Qmax, PVR), delayed complications. **The primary endpoints of the study :** intra &post operative blood losses. **The secondary endpoints:** improvements (IPSS, Qmax, quality of life (QoL) and PVR).

**Statistical Analysis**

All clinical and demographic data was recorded on investigative report form. These data analyzed using SPSS version 20. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD , the following tests were used to test differences for significance;. difference and association of qualitative variable by Chi square test ($X^2$) . Differences between quantitative independent groups by t test or Mann Whitney. P-value (level of significance): $p<0.05$= significant ; $P<0.001$= highly significant.

## RESULTS

**Table (1),** showed that the age distribution between groups was 63.91±4.72 and 63.7±4.49 respectively with no significant difference between groups, also there was no significance regard BMI as it was distributed as 25.31±4.25 and 26.41±3.98, No significant association or difference between groups regard clinical picture or US finding, there was no significant difference between groups regard TRUS, PSA, US, QMAX, Cr, Urea, IIEF and also for all coagulation profile items except PT as it was significantly longer in group (1). **Table (2),** showed that there was no significant difference between groups regard operation time, No significant difference regard amount of blood loss or association ps and blood loss between groups only 20% among control and only 25% among cases loss blood. Table 3), showed that there was no significant difference between studied groups regard HB or HTC pre and postoperatively**. Table (4),** showed that there was no significant difference or association between studied group regarding complications. **Table (5)**, showed that there was no statistical significant difference between studied patients regarding IPSS, post Void, regard QMAX and IIEF **Table (6),** showed that there was significant decrease of blood loss cases lower in HB, HTC, Partial thromboplastin time (PTT) and INR in group (1). **Table (7),** showed the only independent predictors for blood loss were hematuria and INR.

**Table 1: demographic and pre-operative data distributed between studied groups**

| | | | Group (1) (N=24) | Group (2) (N=10) | P |
|---|---|---|---|---|---|
| Age year (mean ± SD) | | | 63.91±4.72 | 63.7±4.49 | 0.903 |
| BMI (Kg/m2) | | | 25.31±4.25 | 26.41±3.98 | 0.489 |
| CP | Urine retention | N | 3 | 1 | 0.15 |
| | | % | 12.5% | 10.0% | |
| | Voiding symptoms | N | 11 | 8 | |
| | | % | 45.8% | 80.0% | |
| | hematuria | N | 10 | 1 | |
| | | % | 41.7% | 10.0% | |
| IPSS | | | 27.75±3.16 | 28.3±3.19 | 0.309 |
| TRUS.gm | | | 26.66±2.8 | 26.2±2.14 | 0.642 |
| PVR | | | 194.12±31.47 | 189.8±21.28 | 0.059 |
| US | Bilateral renal hydronephrosis | N | 10 | 2 | 0.22 |
| | | % | 41.7% | 20.0% | |
| | Free | N | 14 | 8 | |
| | | % | 58.3% | 80.0% | |
| PSA | | | 2.05±0.77 | 2.04±0.85 | 0.973 |
| QMAX (ml/sec) | | | 10.83±2.76 | 11.8±1.39 | 0.303 |
| SCr.mg/dl | | | 1.2±0.63 | 1.13±0.74 | 0.780 |
| Urea.mg/dl | | | 27.26±17.6 | 28.09±16.9 | 0.900 |
| Drug used | acetylsalicylic acid | | 10 33.3% | | |
| | Clopidogrel | | 6 25.0% | | |
| | Warfarin | | 8 41.7% | | |
| PT | | | 13.67±1.43 | 12.41±0.65 | 0.012* |
| PTT | | | 34.63±5.53 | 31.2±3.48 | 0.082 |
| INR | | | 1.16±0.41 | 1 | 0.127 |
| IIEF | | | 11.09±1.76 | 10.9±1.17 | 0.756 |

**Table 2: intra operative data Operation time and blood loss distribution between studied groups**

| | | | Group (1) (N=24) | Group (2) (N=10) | t | P |
|---|---|---|---|---|---|---|
| Operation time (min.) | | | 27.83±5.06 | 25.5±4.67 | 1.309 | 0.200 |
| | Yes | N | 6 | 2 | | |
| | | % | 25.0% | 20.0% | | |
| Blood loss amount /CC | | | 140.25±23.5 | 129.6±19.8 | 1.429 | 0.192 |

**Table 3 :HB & HTC pre and post distribution between groups**

| | Group (1) (N=24) | | Group (2) (N=10) | | P |
|---|---|---|---|---|---|
| | Preoperative (mean ±SD) | Postoperative (mean ±SD) | Preoperative (mean ±SD) | Postoperative (mean ±SD) | |
| HB | 12.84±1.84 | 12.45±1.95 | 12.72±1.69 | 12.53±1.87 | > 0.05 NS |
| HTC | 44.32±3.44 | 44.92±4.58 | 44.97±3.27 | | |
| | | | 44.69±3.42 | | |

**Table 4: Complication distribution between groups at early and late**

| | | | Group | | Total | $X^2$ | P |
|---|---|---|---|---|---|---|---|
| | | | Group (1) | Group (2) | | | |
| | Hematuria | N | 1 | 0 | 1 | | |
| | | % | 4.2% | 0.0% | 2.9% | | |
| | Urine retention | N | 0 | 1 | 1 | | |
| | | % | 0.0% | 10.0% | 2.9% | | |
| Complication Late | Urine retention | N | 1 | 0 | 1 | 0.88 | 0.64 |
| | | % | 4.2% | 0.0% | 2.9% | | |
| | Hematuria | N | 1 | 0 | 1 | | |
| | | % | 4.2% | 0.0% | 2.9% | | |
| Total | | N | 24 | 10 | 34 | | |
| | | % | 100.0% | 100.0% | 100.0% | | |

**Table 5: Results distribution between groups at different times**

| | Group (1) (N=24) | | | Group (2) (N=24) | | | P |
|---|---|---|---|---|---|---|---|
| | Post_1M | Post_3M | Post_6M | Post_1M | Post_3M | Post_6M | |
| IPSS | 25.75±12.04 | 18.82±2.96 | 12.05±2.86 | 23.3±3.46 | 19.2±3.67 | 11.5±2.87 | |
| Post void | 165.5±34.52 | 98.66±25.79 | 50.87±23.76 | 152.0±28.05 | 95.4±22.32 | 46.2±19.14 | |
| QMAX | 13.75±2.48 | 16.8±2.44 | 19.86±2.31 | 14.0±2.86 | 17.1±2.68 | 20.3±2.45 | P > 05 |
| IIEF | 13.87±1.8 | 16.98±1.97 | 19.9±2.22 | 14.1±1.91 | 17.2±2.0 | 20.02±2.21 | |

**Table 6: Univariate analysis for quantitative variable for blood loss**

| | Blood loss (N=8 ) | No (N=26) | t/ Mann Whitney | P |
|---|---|---|---|---|
| Age | 65.0±6.18 | 63.5±4.07 | 0.803 | 0.428 |
| HB_PRE | 12.43±1.04 | 12.92±0.69 | -1.536 | 0.134 |
| HTC_PRE | 44.37±4.13 | 44.55±3.17 | -0.132 | 0.895 |
| HB_POST | 11.5±0.86 | 12.77±0.7 | -4.241 | 0.00** |
| HTC_POST | 42.73±4.22 | 46.19±4.24 | -2.250 | 0.045* |
| PT | 13.96±1.59 | 12.48±1.27 | 0.318 | 0.752 |
| PTT | 39.06±4.39 | 32.46±4.91 | 3.399 | 0.002* |
| INR | 1.48±0.06 | 0.84±0.24 | 5.169 | 0.00** |
| PLT (platelet) | 235.62±68.1 | 231.0±48.5 | 0.214 | 0.832 |
| Operation time | 28.12±5.89 | 26.84±4.48 | 0.655 | 0.517 |

**Table 7: Multivariate Logistic Regression for independent predictors of blood loss (for only parameters were significantly in univariate)**

| | P | Adjusted OR | 95% C.I . | |
|---|---|---|---|---|
| | | | Lower | Upper |
| **Hematuria** | **0.028*** | **3.547** | **1.321** | **11.236** |
| **PTT** | **0.062** | **2.213** | **0.912** | **24.321** |
| **INR** | **0.00**** | **12.321** | **2.235** | **38.622** |

## DISCUSSION

Bladder neck incision (BNI) is a common, minimally invasive treatment option for bladder outflow obstruction (BOO) in men with a small prostate. Owing to its low-velocity ablation, holmium laser can be successfully used for BNI in small size prostate. Holmium laser energy is an excellent treatment for the prostate due its satisfactory cutting effect and superior visibility than electrocautery. Moreover, it has a minimal tissue penetration depth of 0.4 mm, with less scarring[12].

The current study showed that there no significant difference in the values of the tested pre-operative data including: age, body mass index, clinical picture, IPSS, TRUS, PSA QMAX, serum creatinine **(SCr)** , Urea, PTT, INR and IIEF between the studied groups. The values of PT showed a significant increase in group (1) compared to group (2) which are in agreement with a previous studies of **Ahyai et al.** [13] who reported that, the indications for pre-operative surgery were similar in both studied groups.

In comparison within our study, **Tyson et al.,** [14] who demonstrated that 39 patients on antithrombotics (13 on warfarin with a mean INR of 1.5 at the time of surgery, 24 on acetylsalicylic acid, and 1 on clopidogrel) in the perioperative HoLEP period compared to 37 controls. Five patients in the control arm and two patients in the antithrombotic arm had significant intraoperative hematuria (P = 0.34) that required early termination of the procedure and a second stage to complete Ho Laser technique.

Meanwhile, **Bishop et al.,** [15] who demonstrated that, the correlation between antithrombotic therapy use with age and comorbidity was borne out with the antithrombotic patients being older and having higher ASA physical status scores than the control cohort of non-antithrombotic patients.

In our study, the patients with small prostate group whom were treated with antithrombotic therapy including: warfarin, acetylsalicylic acid and clopidogrel in a percentage of (44%, 33% and 25%) respectively. who reported that, In the case of warfarin, returning to a normal coagulable state is unpredictable and defined to patients who need cover with heparin in the peri-operative period.

The obtained results from our study showed no significant difference in the values of the intra-operative data as operation time and blood loss between both groups. Also, there was no significant difference in catheter duration and hospital stay of post operative data between both groups. Our results are in agreement with **Aho et al.,** [16] who demonstrated that, HoBNI was significantly quicker to perform compared with HoLEP. Both groups showed significant improvement in Qmax, AUA and quality-of-life scores postoperatively compared with baseline results, with no significant difference between the two groups. Five patients in the HoBNI group with prostate volumes between 30 and 40 ml, remained urodynamically obstructed at 6 months.

However, **Bansal et al.,** [17] who reported that, HoBNI can be technically more difficult to perform than C-BNI, hence operative time in HoBNI group was significantly more than C-

BNI (16.4 ± 5.3 vs 12.8 ± 4.6 min, P = 0.0001).but in our results

Regarding the post-operative complications including: hematuria, clot and urine retention, the attained results of our study showed no significant increase between both groups of patients with and without antithrombotic therapy. Our results are in agreement with **Bansal et al., [17]** who conducted that, no patient in HoBNI technique developed hematuria or required blood transfusion. This can possibly be explained by the fact that better hemostasis and accuracy can be achieved by holmium laser, with depth of tissue coagulation upto 3-4 mm. This is one of the advantages of using holmium laser in BNI.

To our result PVR was Similarly to the study of **Marien et al, [18]** who reported that, there were no major intraoperative or postoperative complications. Voiding parameters and symptom scores had improved for all patients postoperatively, with an impressive improvement in PVR from 997 to 164 mL but in our results.

In contrast to our results, **Bishop et al., [15]** who reported, a higher rates of urinary retention and hematuria with the antithrombotic patients due to the included in their study larger prostate. The obtained outcomes of follow up data showed no significant changes in the values of estimated IPSS and PVR at 1, 3 and 6 months between both groups. Also, there was no significant difference between Qmax and IIEF between the small prostate patients with antithrombotic therapy group and small prostate patients group without antithrombotic therapy. Our results are harmony with various studies of **Sahito et al. (19)** which concluded that, the improvement at 3 months after BNI was considered significant if AUA scores decreased by approximately 5 times from baseline (eg.15 to 3) and Qmax increased by approximately 100% (eg.8.0 to 16.0 ml/sec)·

Similarly, **Elkoushy et al., [7]** who reported that, all subjective and objective voiding parameters, including IPSS, QoL, Qmax and PVR, significantly improved within groups. Also, **Bansal et al., [17]** who demonstrated that, surgical HoBNI is efficient in relieving BOO in prostate size less than 30 cc, and lead to significant improvement in AUA score, PVR and Qmax at 3 months follow-up, which was maintained till the last follow up (12 months).

The obtained results of biochemical analysis of Hb and HTC showed no singnificant difference in the pre and post operative values in both groups. Referring to changes assessments, our results showed that, there was a significant improvement in all post operative compared to preoperative parameters in both cases and control groups. Our results are mostly consistent with those of **Cornford et al., [20]** and **Elkoushy et al., [7]** 96.1 % (n=49/51) of HoBNI in prostate size < 30 cc prostate Bansal et al.,(2016) who revealed that, the success rate of HoBNI was higher than C-BNI (97.1% in men with a small size prostate.. However, in the latter study success rate dropped to 77.4 % (n=24/31) in cases where prostate size was > 30 cc. our results

In the univariate analysis for blood loss in our study showed a significant change in the levels of Hb, HTC, PTT and INR in cases of blood loss in patients with or without antithrombotic therapy. Simillary, **Shah, [21]** who concluded that, Holmium laser bladder neck incision is associated with favorable early postoperative outcome. Moreover

**Conclusion:** It could be concluded that, HoBNI procedure is efficient and safe in relieving BOO with prostate size < 30 cc in patients with or without antithrombotic therapy. The risk of postoperative hematuria and bleeding is less with HoBNI because of its better haemostatic properties.

No Conflict of Interest.
No Financial Disclosures.

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