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ORIGINAL PAPER

Initial safety and efficacy of holmium laser enucleation of the prostate: Real world evidence from a tertiary centre

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Summary ***Objective: This study aims to evaluate the initial safety and efficacy of Holmium enucleation of the prostate (HoLEP) in managing benign prostatic hypertrophy (BPH) in a single tertiary centre.***
Materials & methods :A retrospective cohort study was conducted focusing on a single tertiary hospital in which data was collected from electronic medical records which includes demographic information, preoperative characteristics, surgical details, and post-operative outcomes; complications were classified using the Clavien-Dindo classification.
Results: 104 patients with BPH and lower urinary tract symptoms (LUTS) were analysed in this study, with a mean prostate volume of 109.3 ± 47.2 ml. The mean change in post void residual volume (PVR) was (-)75%, whilst the mean change in maximum flow rate (QMax) was (+)109%. 21/104 (19%) patients presented with post-operative complications, the majority of these (13) were Grade I complications with three patients being Grade III. Increasing age (p = 0.014) was shown to have contributed to complications. Pre-operative anticoagulation was shown to yield no significance (p = 0.066).
Conclusion: HoLEP remains a viable treatment modality for BPH especially in larger prostates (> 100 ml). However, considerations regarding post-operative outcomes should be taken when offering this treatment to more elderly patients. Additionally, HoLEP provides a good treatment option for patients on anticoagulation.

KEY WORDS: *HoLEP; Benign Prostatic Hyperplasia (BPH); Low Urinary Tract Symptoms (LUTS).*

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INTRODUCTION

Bladder outlet obstruction caused by *benign prostatic hypertrophy* (BPH) is a common urological condition that causes *lower urinary tract symptoms* (LUTS) in men and significantly affects their quality of life (1). According to the established guidelines on management of non-neurogenic male LUTS, management of symptoms due to BPH are divided into conservative, pharmacological, and surgical management (1).
Surgical management of *bladder outlet obstruction* (BOO) and LUTS is historically managed with *Transurethral resection of the Prostate* (TURP), particularly in patients with severe or resistant symptoms (1). However, in recent years new techniques were developed to rival the safety and efficacy of TURP.
Holmium LASER Enucleation of the Prostate (HoLEP) is one surgical technique developed for the management of BPH which has been described in literature to rival TURP (3); it utilizes a holmium LASER to enucleate prostatic tissue. Current literature suggests this approach to be effective, particularly in patients with large prostates (> 80 ml). HoLEP is associated with reduced perioperative morbidity, including lower rates of bleeding, shorter catheterization times, and quicker recovery (4, 5).
This study evaluates the initial safety and efficacy of HoLEP in patients with BPH in a single training tertiary centre hospital, focusing on early functional outcomes, complication rates, and the impact of specific patient factors, including age and anticoagulant use. By providing a comprehensive analysis of perioperative and postoperative outcomes, this study seeks to contribute to the growing body of evidence supporting HoLEP as a valid first line surgical treatment for patients with BPH.
This study aimed to evaluate the initial safety and efficacy of HOLEP in managing BPH in a single tertiary centre.

MATERIALS AND METHODS

Study design and setting

This is a retrospective cohort study conducted at a single tertiary hospital between May 2022 and May 2024. This study aimed to evaluate the safety of HoLEP in patients with enlarged prostate and LUTS, focusing on complications as defined by the Clavien-Dindo classification within 30 days post-operatively (6). The study also aimed to evaluate the functional outcomes of HoLEP. An initial review was conducted 1 week post-operatively at the time of catheter removal. Caldicott approval for the study was obtained in line of local trust information governance guidance.

Patient selection

The study included all patients who underwent HoLEP during the specified period. Inclusion criteria were male

patients who were experiencing LUTS and diagnosed with BPH and underwent HoLEP.
Exclusion criteria included patients who had incomplete medical records, and those who underwent other surgical interventions for BPH.

Data collection

Patient data was collected from electronic medical records and included: demographic information, preoperative clinical characteristics, surgical details, and postoperative outcomes.
The data collected included:

- Demographics: Age and BMI
- Clinical Information: Indication for surgery, prostate size (by trans-abdominal ultrasound or MRI), pre-op catheterisation status, and uroflowmetry
- IPSS - eight-item questionnaire which includes questions on seven symptoms and one Quality of Life question. The scores are then categorised into Mild (1-7points), Moderate (8-19 points), and Severe (20-35) (*Barry, al.* 1992)
- Surgical Details: Date of operation, size of enucleation, type of morcellator used, and whether a trainee was scrubbed in.
- Postoperative Outcomes: Duration of catheterization, hospital stay, post-operative uroflowmetry, and post-operative complication.
- Post-operative outcomes were recorded for up to 30 days.

Data analysis

Statistical analyses were performed using SPSSv 25 for Mac (*IBM Corp., Armonk, NY, USA*). Categorical variables were compared using the Chi-square test, while continuous variables were analysed using the independent t-test. Pearson's correlation coefficient was calculated to assess potential correlations between variables. A p-value of < 0.05 was considered statistically significant.

Results

A total of 108 patients with an enlarged prostate and lower urinary tract symptoms had undergone HoLEP successfully between May 2022 and May 2024. Four patients were excluded due to incomplete or missing documents. Patient's characteristics and perioperative data are summarized in Table 1.
The data from the Table 2 demonstrates significant improvements in urinary function following *Holmium LASER Enucleation of the Prostate* (HoLEP). Most notably, the mean Q_{max} improved by 109%, rising from 11.34 ml/sec to 23.7 ml/sec postoperatively. There is also an improvement in patient's mean post void residual volume with a difference of 75.8%, improving from 187.9 ml to 45.6 ml.
Using the Clavien-Dindo classification system, our patient cohort showed that, 13 patients experienced haematuria, of which 6 were admitted for a 3-way catheter for clot retention (CD1) and 1 required a blood transfusion had developed complications (CD 2). Three patients were categorised with CD3 complications (refractory haematuria) requiring clot evacuation under anaesthetic. Seven patients experienced a post operative infection and were treated with antibiotics (CD 2) (6). No patients had a CD4 or CD5 complication. Comparisons between baseline characteristics and complications can be seen in Table 3.
The study identified advanced age as a significant predictor of complications, this was evident in the age group ≤ 80yrs old, where the incidence of complications was 13 (14.8%) compared to the 8 patients (40%), > 80 yrs that had post operative complications.

Table 1.
Baseline patients characteristics and perioperative data.

Patients (n = 104)	
Parameter	**Mean ± SD**
Age (years)	73.4 ± 8.6
Preoperative PSA (µg/l)	6.2 ± 6.1
Preoperative QMax (ml/sec)	11.3 ± 15.7
BMI	28.4 ± 4.4
Prostate volume (cm^3)	109.3 ± 47.2
Catheter duration (days)	11.4 ± 10.5
Hospital Stay Duration (days)	2.19 ± 1.7
IPSS	21.9 ± 8.5
Enucleation time (min)	46.7 ± 24.1
Morcellation Time (min)	21.9 ± 30.3
Size of enucleation (ml)	66.7 ± 46.6

PSA: prostate-specific antigen; Q_{max}: maximum flow rate; BMI: Body mass index; IPSS: international prostate symptom score.

Table 2.
Functional parameter pre- and postoperative.

Parameter	**Preoperative**	**Postoperative**	**Percentage change (%)**
PVR volume (ml)	187.9 ± 198.2	45.4 ± 43.0	-75.8
Void Volume (ml)	122.6 ± 70.6	187.5 ± 88.6	+52.9
Q_{max} (ml/sec)	11.34 ± 15.7	23.7 ± 17.6	+109.0

Q_{max}: maximum flow rate; PVR, post void residual.

Table 3.
Correlation of baseline characteristics and complications.

Parameter	**Complication**	**No complication**	**p value**
Patients n (%)	21 (19.2)	83 (80.8)	-
Age ≤ 80 n (%)	13 (14.8)	71 (85.2)	0.0141
Age > 80 n (%)	8 (40.0)	12 (60.0)	
Anticoagulated n (%)	7 (38.9)	11 (61.1)	0.0666
Not Anticoagulated n (%)	14 (14.6)	72 (85.4)	
BMI ≥ 25 n (%)	18 (19.8)	69 (80.2)	0.775
BMI < 25 n (%)	3 (17.6)	14 (82.4)	
Mean Enucleation Time (min)	42.8	47.7	0.4112
Mean Morcellation Time (min)	15.9	23.4	0.3261
Prostate volume (ml)	120.7	105.76	0.2697

BMI: Body mass index.

Table 4.
Correlation of preoperative prostate volume and incidence of complications.

Pre-op prostate volume (ml)	Number (n)	Complications (%)	p value
< 100 ml	44	5 (11%)	1.41×10^{-7}
100-150 ml	21	6 (29%)	0.078
> 150 ml	15	4 (27%)	0.118

We also recorded the incidence of complications in patients who were on anticoagulation. Clopidogrel was withheld for 5 days whilst *direct oral anticoagulants* (DOACs) were withheld for 2 days prior to surgery. 7/18 (38.9%) experienced complications whilst, 13/89 (14.6%) of patients not on prior anticoagulation presented with complications; p value = 0.0666.
Prostates > 100 ml had a relatively consistent complication rate: Prostates measuring 100-150 ml had a complication rate of 6/21 (29%) whilst prostates > 150 ml had a complication rate of 4/15 (27%).
For this specific parameter, 24 patients were excluded from the comparison due to incomplete data regarding pre-operative prostate volume (ml).
Postoperative follow-up highlighted 32 patients (30.1%) that reported experiencing *transient urinary incontinence* (TUI); however, all patients were successfully managed conservatively with pelvic floor exercise referrals and incontinence resolved. The follow-ups also highlighted 2 (1.9%) patients that were experiencing erectile dysfunction.

Discussion

This audit provides an insight into the initial safety and efficacy of HoLEP in the immediate post operative period. By evaluating patient outcomes, the study supports the growing evidence of HoLEP' s viability as a first-line surgical intervention for BPH, particularly in patients with larger prostates. The pre and post operative functional parameters reflect substantial improvements in urinary function. However, the study also highlights an elevated risk of postoperative complications among patients above the age of 80, raising important considerations for patient selection, counselling and perioperative management.
The postoperative improvements in uroflowmetry parameters demonstrated HoLEP's early efficacy. The mean increase in Q_{max} by 109%, from 11.34 ml/sec to 23.7 ml/sec, shows significant improvement in urine flow on catheter removal a week following the procedure. Similar outcomes have been reported in a systematic review by *Ahyai et al* (7). Further improvements would be expected at 3 months and beyond postoperatively (7) which unfortunately was beyond the scope of this audit.
This study's demonstration of significant improvements in both Q_{max} and PVR are consistent with those of *Cornu et al* (8) which also demonstrated significant improvements in both domains post-HoLEP. This contributed to their recommendation that enucleation should be offered to patients, especially those with prostates over 100 ml, (8) aligning with our mean prostate volume of 109.3 ± 47.2 ml.
A notable finding from *Elmansy et al* (4) is the reduction in mean PVR volume, which dropped by 75.8%, results which align with our own. The study also demonstrated a long-term decrease in PVR following HoLEP; further supporting its ability to relieve bladder outlet obstruction effectively.
The most frequent complication reported was postoperative haematuria, affecting 12.0% of patients. Previous studies corroborate this finding, with haematuria reported in up to 15% of cases, though the majority resolve with conservative management (9, 10).
Our study has shown no statistical difference in postoperative outcome in patients who are on anticoagulated versus patients who are not. This conclusion is supported by *El Taye* (11) who found that postoperative outcomes between anticoagulated vs non-anticoagulated patients were not statistically significant. This is due to the use of LASER for enucleation which has been shown to reduce the incidence of bleeding complications (12). This reaffirms HoLEP as a safe option for higher risk cases, though individual risk assessment remains crucial.
This study identifies advanced age as a significant predictor of complications, a finding supported by *Elsaqa M et al* (13). Patients over 80 years of age had a complication rate of 40%, significantly higher than the 14.8% seen in patients < 80 yrs (p = 0.0101).
Previous studies have reported similar trends, with older patients exhibiting higher rates of postoperative complications due to comorbidities and diminished physiological reserve (14, 15). Though this stance on HoLEP has been refuted by *Mmeje, C.O., et al.* who in 2013 stated that age had no significant effect on post operative outcomes and that patients > 80 yrs had similar complications to younger age groups (16). Despite the increased risk we report, the outcomes of HoLEP in elderly patients remain favourable (17).
Initial, *transient urinary incontinence* (TUI) was reported by 29.6% of patients in the initial one month post operative review. Incontinence incidence decreases significantly over time as sphincter function recovers with continence returning in all patients (3). Early recognition and onward referral to specialized pelvic floor therapy was crucial in achieving this outcome.
Nam Jk et al (18) in 2015 stated that patient age above 65 yrs and total operative time > 65 mins were associated with an increased occurrence of post-operative transient urinary incontinence. This paradigm aligns with our study that highlights the average age of patients as 73 years old and our average operative time being 68 minutes (46.7 mins for enucleation + 21.9 mins for morcellation). Possible assumptions would be a combination of chronic pelvic floor weakness and larger prostates enucleated with longer operative times. Long-term studies suggest that the incidence of persistent incontinence following HoLEP is low, between 1% and 5% after 12 months (4).
Erectile dysfunction (ED) is a rare but known side effect for patients undergoing prostate surgery. In this study, only 1.85% of patients reported new-onset ED, a result consistent with the literature (19). HoLEP has been shown to

have minimal impact on erectile function compared to other surgical treatments, largely because it spares the neurovascular bundles responsible for erectile function (5).
The result from this study is further supported in a meta-analysis by *Tan et al* (3) which found that sexual function is preserved in the vast majority of HoLEP patients making it an appealing option for sexually active men who want better long-term functional outcomes. Despite the high rate of premature ejaculation expected, HOLEP remained a desirable and durable therapy for BPH in that cohort.

Limitations

While this study provides valuable data on the early outcomes of HoLEP, we acknowledge that the retrospective design of this study exposes us to risk of selection bias due to incomplete data. Second, the follow-up period was limited to one month post HOLEP, and longer-term functional outcomes were not assessed in this cohort. This study design was to demonstrate HoLEP's favourable early safety and efficacy. Future prospective studies with longer follow-up periods are necessary to provide more comprehensive data on the durability of functional outcomes and complication rates.
Morcellation weight was not included due to significant tissue loss leading to a lack of consistent and reliable specimen weight obtained (20). Therefore, pre-op imaging was utilised.

Conclusions

This study affirms the short-term safety and efficacy of HoLEP in treating patients with benign prostatic hypertrophy, particularly those with larger prostates. The procedure offers significant improvements in urinary function, as evidenced by our early postoperative uroflowmetry data, while maintaining minimal risk of significant complications. However, risk factors, more especially age > 80 yrs, are associated with a higher likelihood of postoperative complications, necessitating careful patient selection, patient counselling, and peri/postoperative management.

Declarations

Ethical approval and consent for participate: *This study was conducted as a retrospective audit to evaluate clinical outcomes following Holmium Laser Enucleation of the Prostate (HoLEP) at a single local centre. In accordance with institutional policy and UK Health Research Authority (HRA) guidelines, this work did not require formal ethics committee approval as it falls within the definition of a clinical audit. Caldicott approval was obtained through the local NHS trust in line with local information governance protocols. All patient data were anonymized and handled in accordance with the Data Protection Act and GDPR regulations. Consent for use of anonymized clinical data for audit and quality improvement purposes is routinely obtained at the time of surgical consent, and no identifiable information was used in the analysis or reporting of this study.*

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