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One-Year Outcomes of a UK Center Delivering Minimally Invasive Surgery for Bladder Outflow Obstruction Using Local Anesthetic Without Sedation in the Office Setting

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Abstract

Background: Minimally invasive surgical therapies (MISTs) for bladder outflow obstruction are now commonplace in many urological centers, often performed as day case procedures under general anesthetic or local anesthetic (LA) with sedation. Our center has adopted an outpatient clinic LA-only setting to deliver Rezum, Urolift, and iTind using prostatic block and LA gel. We present our 1-year outcomes to determine the feasibility of delivering MIST in this setting.

Methods: We retrospectively audited outcomes, collecting data on patient demographics, pre- and postoperative symptom questionnaires, flowmetry tests, and visual analogue scores (VASs) during the procedure. We compared pre- and postoperative changes using a paired *t* test, using a *p* value of <0.05 as significant.

Results: There were 81 procedures performed: 38 (46.9%) Rezum, 22 (27.2%) Urolift, and 21 (25.9%) iTind. The median age was 68 (interquartile range: 63–74). Preoperatively the mean International Prostate Symptom Score (IPSS) was 20.2 (±7), quality of life (QOL) score 4.6 (±1.4), Qmax 10.7 mL/s (±5.3), prostate serum antigen 2.5 (±3.1), and prostate size 48.8 mLs (±20.9). 70.4% of patients were on an α-blocker, and 44.4% on a 5-α-reductase inhibitors (ARI). The mean VAS was 4.3 (±2.8) out of 10. The total immediate postoperative complication rate was 11.1%, all less than Clavien–Dindo III. 91.4% attended the 3-month follow-up. Postoperatively the mean IPSS was 11.3 (±7.1) (44.1% reduction, $p < 0.01$), the QOL score 2.4 (±1.5) (47.8% reduction, $p < 0.01$), and the Qmax 13.1 mL/s (±5.5) (22.4% improvement, $p < 0.01$). Patients on an α-blocker had reduced to 34.6%, and 5ARIs to 13.6%.

Conclusion: We demonstrate the feasibility of delivering MIST under LA alone, without sedation, and report significant improvements in symptom scores and flowmetry outcomes. Patients tolerate the treatment well without sedation and have a short stay for their procedure, enabling the service to be delivered in an outpatient clinic setting, improving inpatient waiting lists and resource allocation to outpatient setting. Further research is required for long-term outcomes, but early results are promising in driving a change in the delivery of MIST.

Keywords: bladder outflow obstruction, minimally invasive surgical therapy, Rezum, Urolift, iTind, benign prostatic hyperplasia, benign prostatic enlargement

Introduction

Minimally invasive surgical therapies (MIST), such as Rezum (water vapor), Urolift (prostatic urethral lift), and iTind (nitinol device), have become integrated into the arsenal of treatments for bladder outflow obstruction (BOO) procedure. In the UK, they are included in the Getting It Right First Time document for the male BOO procedure[1] (recommended for prostates under 80 cc in size) and in the NHS England patient decision tool for an enlarged prostate.[2] These documents include information regarding their appropriate use and expected outcomes.

The main advantages of MIST over resection, vaporization, or enucleation techniques are their day-case nature and better sexual preservation, although at the cost of requiring reoperation sooner than more prostate-ablating treatments. Outcomes

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from clinical trials have shown significant improvement in symptom scores and flowmetry as well as a reduction in medical therapy for BOO.[3–5]

The majority of centers in the UK deliver these in an operating theater setting, either under general anesthesia (GA) or local anesthetic (LA) with sedation. We have previously described the feasibility of delivering Rezum as a day case LA-only (without sedation) procedure in an outpatient setting.[6] We have since incorporated Urolift and iTind in this setting and herein report our 1-year outcome of outpatient day case LA MIST. Our objective was to compare our outcomes with reported data under GA to assess the effectiveness of MIST delivered in this setting.

Patients and Methods

Study design

We retrospectively audited data from routinely collected electronic clinical notes on patients operated on from May 2023 (when the LA MIST service was started) to May 2024. This cutoff was decided to allow for the routine 3-month follow-up data to also be collected.

Setting

This was a UK single-center study. All patients received their treatment in an outpatient clinic, under LA only without sedation. The patient pathway, room setup, and postoperative care have been previously described in detail.[6] Patients receiving Urolift or iTind received LA gel only, while those receiving Rezum had a transperineal prostate block (20 mL 1% lidnocaine) also. The gel is typically held in for at least 5 minutes with a soft penile clamp. Patients are checked in on arrival, receive oral antibiotic prophylaxis, consented and then taken to the procedure room. The procedure from arrival to departure typically takes approximately 20 minutes. Following their treatment, they are taken to a day bed and observed before discharge. Patients receiving Rezum and iTind have their respective catheter or nitinol device removed in 1 week in clinic. All patients are booked in to a 3-month follow-up clinic where they receive symptoms questionnaires, perform flowmetry, and are reviewed by an advanced nurse practitioner.

Participants

Patients are identified from a benign enlarged prostate (BPE) one-stop clinic where they are reviewed by a urologist after extensive investigation with symptom questionnaires, blood tests including prosrate serum antigen (PSA), flowmetry, post void residual (PVR), and prostate sizing transurethral ultrasound. Cystometrography is performed at a separate appointment if required. They are informed about the types of treatment available and best suited for their symptoms and prostate size. Information leaflets are given to the patients to help them decide and begin the consenting process for their chosen procedure.

Variables

We reported patient demographics, mean PSA, mean prostate size, catheter use, relevant past medical history, the mean pre- and postoperative International Prostate Symptom Score (IPSS) and quality of life (QOL) score, International Index of Erectile Function (IIEF), maximum flow rate (Q-max), average flow rate, PVR, and prevalence of medical therapy, including α-blocker, α-reductase inhibitors (ARIs), anticholinergics, and β3 agonist. We will also report the median number of treatments given to each lobe for Rezum and Urolift, as well as the visual analogue scale (VAS) (Supplementary Fig. S1) out of 10 for each type of operation and their postoperative complications categorized by Clavien–Dindo classification (CD).

Statistical methods

We used the student *t* test to analyze the change in pre- and postop IPSS, QOL, IIEF, Q-max, average flow, and PVR. The McNemar chi-square test was used to compare paired proportions of BPE medications before and after treatment. A p-value of <0.05 was considered significant. Missing data were reported but not imputed because of the small cohort.

Ethics approval and consent to participate

No ethical approval was required, as this is not considered research within the UK.

As per the NHS Health Research Authority, this study comprises an audit and does not require ethical approval. As the data are anonymized and an audit, patient consent is not required as per the NHS Health Research Authority.

Results

We performed 81 procedures in total: 38 (46.9%) Rezum, 22 (27.2%) Urolift, and 21 (25.9%) iTind. Table 1 shows the overall patient demographics for each group. The overall median age was 68, and this was similar for all three treatments. The mean prostate size was greater for patients undergoing Rezum. The PSA density was similar for all groups at approximately 0.05. The Rezum group had a greater prevalence of a retention history and catheter use, as well as α-blockers and ARIs. The mean VAS was 4.3, and the average number of treatments for each lateral prostatic lobe was approximately 1.7 for Rezum and 1.5 Urolift.

There was a total follow-up rate of 91.4%. Table 2 shows the overall pre- and postoperative symptom score and flowmetry outcomes. There was a significant reduction (44.1%, $p < 0.01$) in IPSS from 20.2 to 11.3, QOL score from 4.6 to 2.5 (47.8%, $p < 0.01$), and PVR (43.5%, $p < 0.01$), and a significant improvement in Q-max from 10.7 mL/s to 13.1 mL/s (22.4%, $p < 0.01$) and average flow from 5.1 mL/s to 6.4 mL/s (15.6%, $p < 0.01$). There was no statistically significant improvement in the median IIEF from 11 (moderate) to 16 (mild to moderate) ($p = 0.3$), although this was poorly collected with a high rate of missing data. Figure 1 reports the symptom score and flowmetry outcomes for each type of operation. The greatest improvements in all parameters seemed to be in patients who received Rezum, where IPSS was reduced by 10.6 points (54.1%), QOL by 2.7 points (58.7%), and Q-max improved by 4 mL/s (40.4%). Respectively, Urolift and iTind reduced IPSS by 28.8% and 46.2%, QOL by 34% and 40.5%, and improved Q-max by 4.3% and 15.7%.

Table 1. Patient Demographics Stratified by Type of Operation

	All	*Rezum*	*Urolift*	*iTind*
Total number performed, *n* (%)	81	38 (46.9)	22 (27.2)	21 (25.9)
Median age (IQR)	68 (63–74)	69.5 (65–74)	67 (63–76)	67 (58–74)
PMH, *n* (%)				
Diabetes	13 (16.1)	5 (13.2)	7 (31.8)	1 (4.8)
Neurogenic disorder	5 (6.2)	0 (0)	3 (13.6)	2 (9.5)
Pre-op catheter use, *n* (%)	7 (8.6)	6 (15.8)	1 (4.5)	0 (0)
Long-term catheter, *n* (%)	*1 (1.2)*	*1 (2.6)*	*0 (0)*	*0 (0)*
Intermittent self-catheterization, *n* (%)	*6 (7.4)*	*5 (13.2)*	*1 (4.5)*	*0 (0)*
Previous history of retention, *n* (%)	10 (12.3)	9 (23.7)	0 (0)	1 (4.8)
Mean prostate size (SD)	48.8 (20.9)	59.1 (21.6)	38.9 (13.4)	37 (13.8)
Missing, *n* (%)	13 (16)	3 (7.9)	6 (27.3)	4 (19)
Mean PSA, (SD)	2.5 (3.1)	3.3 (4)	1.9 (2)	1.6 (1.3)
Missing, *n* (%)	8 (9.9)	4 (10.5)	0 (0)	4 (19.0)
PSA density	0.05	0.06	0.05	0.04
Mean number of treatments (SD)				
Left lobe		1.7 (0.6)	1.5 (0.7)	
Right lobe		1.7 (0.6)	1.4 (0.6)	
Median lobe		0.4 (0.7)	0.1 (0.3)	
Mean pain VAS (SD)	4.3 (2.8)	3.7 (3)	5.1 (2.4)	4.7 (2.7)
Missing, *n* (%)	17 (21)	8 (21.1)	4 (18.2)	5 (23.8)
Attended follow-up, *n* (%)	74 (91.4)	34 (89.5)	20 (90.9)	20 (95.2)

Percentages are given as column percentages except for the first row which are row percentages.
IQR = interquartile range; SD = standard deviation; VAS = visual analogue score. Neurogenic disorders, e.g., Parkinson's disease and multiple sclerosis.

Table 3 shows the pre- and postoperative proportions of BPE-related medications. There was a statistically significant reduction in the use of α-blockers and ARIs but not anticholinergics or β3 agonist. The overall immediate postoperative complication rate was 11.1% (9 patients), which was all less than CDIII (Table 4).

Discussion

Our 1-year data from our LA-only outpatient day case MIST service has shown appropriate patient demographic selection, with an average age of 68 and an average prostate size less than 50 cc and PSA density of 0.05. The majority (46.9%) of patients received Rezum treatment, but these patients had a larger mean prostate volume. Overall, there was a significant improvement in symptom questionnaire (IPSS 44.1%, QOL 47.8%) and flowmetry outcomes (Q-max 22.4%, PVR 43.5%) and a reduction in the requirement for BPE medication. The immediate postoperative complication rate was low and minor.

Since the overall results include a heterogenous group of three different procedures, we will compare separate MIST outcomes to the literature.

Our data for Rezum showed this was a tolerable procedure under LA only, using a combination of prostatic block and LA intraurethral gel. The mean VAS pain score was 3.7 out of 10, which is similar to the reported VAS pain score for transperineal biopsies for suspected prostate cancer.[7,8] At 3 months, the mean IPSS improved by 10.6 points, QOL by 2.7 points, and Qmax by 4 mL/s, which is similar to McVary et al.'s published

Table 2. Pre and Postoperative Symptoms Scores and Flowmetry Outcomes

	Preoperative	*Postoperative*	*% difference*	p *value*
Mean IPSS (SD)	20.2 (7)	11.3 (7.1)	44.1	<0.01
Missing, *n* (%)	42 (51.9)	13 (16)		
Mean QOL (SD)	4.6 (1.4)	2.4 (1.5)	47.8	<0.01
Missing, *n* (%)	45 (55.6)	17 (21)		
Median IIEF (IQR)	11 (1–14)	16 (5–28)	45.5	0.31
Missing, *n* (%)	64 (79)	39 (48.1)		
Mean Q-max	10.7 (5.3)	13.1 (5.5)	22.4	<0.01
Missing, *n* (%)	17 (21)	12 (14.8)		
Mean average flow	5.1 (2.3)	6.4 (2.6)	15.6	<0.01
Missing, *n* (%)	29 (35.9)	12 (14.8)		
Mean PVR	121.2 (146.9)	68.5 (88)	43.5	<0.01
Missing, *n* (%)	15 (18.5)	11 (13.6)		

IPSS = International Prostate Symptom Score; IIEF, International Index of Erectile Function Score; PVR, post void residual; QOL = quality of life score; Q-max = maximum flow rate.

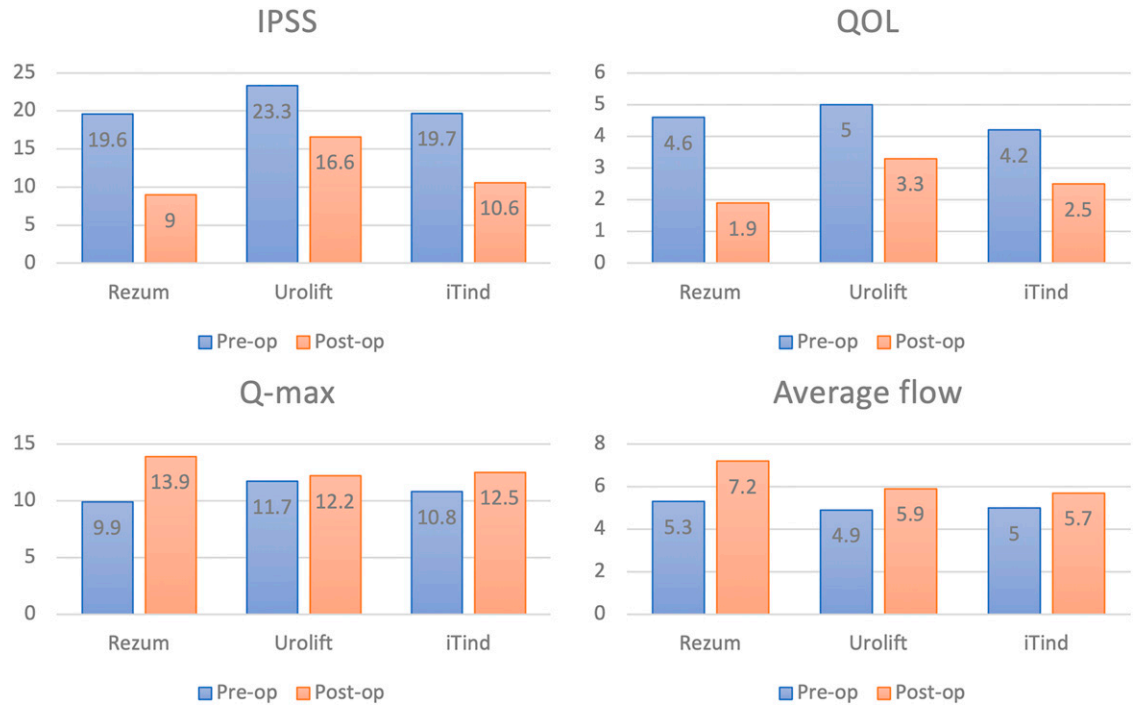

FIG. 1. Symptom score and flowmetry outcomes stratified by types of procedure. IPSS= International Prostate Symptom Score; PVR = post void residual; QOL = Quality of Life score; Q-max = peak flow rate.

randomized control trial that showed improvements of 11.5, 2.3, and 5.5 mL/s, respectively, at 12-month follow-up.[3] The significant reduction of BPH medication use was comparable to other reported rates, with α-blockers from around 70% to 40% and ARIs down to around 13%.[9]

Patients that underwent Urolift had a slightly higher mean pain score of 5.1 with LA intraurethral gel only. This may have impacted the outcome, especially if optimal treatment required more than one clip on each lateral lobe but the patient was intolerant of the procedure. The relatively small improvement in Qmax with Urolift may be explained by this, coupled with the relatively higher preop Qmax of these patients compared to Rezum and iTind. Since the completion of this audit, we have changed practice as a result and combine this with a prostatic block. Nonetheless, there was an improvement in IPSS (28.8%) and QOL (34%), but this is subpar compared to the LIFT study, which showed 36% and 50% improvement respectively.[4]

Patients who received the iTind device had a reduction in IPSS of 9.1 points and QOL of 1.7, which was similar to the 12-month follow-up findings in the randomized control trial by Chughtai et al. of 9.25 and 1.9 respectively.[5]

The majority of complications were infection related and under CD III. Prophylactic antibiotics are given in our practice (5–7 days with one dose before the procedure), and these are guided by local microbiology guidelines and previous sensitivities. An infection rate of 7% is in keeping with previously reported literature for these procedures.[10]

There was a statistically significant reduction in the number of patients requiring BPE medication following their procedure. Clinically, this is important to reduce side effects and cost. We did not expect a complete cessation in BPE medications. As with previous studies, there is a recognized continuation rate, especially following Urolift and iTind.[5,11]

These comparable results are promising and demonstrate the feasibility of delivering an effective LA-only MIST service in the outpatient setting. There are some limitations to this study, however. We present real-world retrospective data with short-term follow-up and cannot comment on re-treatment rate or long-term outcomes. Furthermore, missing data introduce bias, as they will reduce the statistical power and estimation of parameters, especially in a smaller cohort. However, the similarity of outcomes with previously published studies is reassuring

Table 3. Comparison of Prevalence of Pre- and Postoperative BPE Related Medications

Type of medication	*Preop,* n *(%)*	*Postop,* n *(%)*	*McNemar Chi²*	*Absolute difference*	*95% confidence interval*	p-*value*
α-blockers	57 (70.4)	30 (37)	25.1	0.3	0.2–0.5	<0.01
ARI	36 (44.4)	11 (13.6)	21.6	0.1	0.2–0.4	<0.01
PDE5i	7 (8.6)	6 (7.4)	0.2	0.01	–0.1–0.1	0.7
Anticholinergic	9 (11.1)	4 (4.9)	0.4	0.03	–0.1–0.1	0.5
β3 agonist	7 (8.6)	7 (8.6)	0	0	–0.1–0.1	1.0
None	15 (18.5	39 (48.1)	19.2	0.3	0.2–0.4	<0.01

ARI = α-reductase inhibitor; PDE5i = Phosphodiesterase 5 inhibitor.

Table 4. Immediate Postoperative Complications by Type of Procedure

	Rezum	*Urolift*	*iTind*
Total complications, *n* (%)	2 (5.3)	5 (22.7)	2 (9.5)*
UTI	1 (2.6)	2 (9.1)	0 (0)
Urosepsis	1 (2.6)	0 (0)	2 (9.5)
Other	0 (0)	3 (13.6) - misfired clip - misfired clip - postop hematuria	1 (4.8) - suprapubic pain

UTI = urinary tract infection (treated with oral antibiotics). Urosepsis required treatment with intravenous antibiotics.

*One patient had suprapubic pain following the procedure and also developed urosepsis.

to assess feasibility of our LA-only MIST procedures. We have a dedicated one-stop BPH clinic, and MIST procedures are now routinely offered under LA only if the patient chooses these over vaporization or enucleation procedures. GA will only be considered if a patient is too anxious and will not be able to lie still for the LA procedure, or there is an anatomical reason why LA cannot be delivered. As this service continues to develop, we hope to improve documentation of pre- and postoperative outcomes for further service development. Given the higher pain scores of Urolift and iTind which may have delivered suboptimal outcomes, further research will present a re-audit of outcomes following the change to add a prostate block to these patients, and longer-term outcomes to capture re-treatment rates.

Conclusions

We demonstrate the feasibility of delivering MIST under LA alone, without sedation, and report significant improvements in symptom scores and flowmetry outcomes. Patients tolerate the treatment well without sedation and have a short stay for their procedure, enabling the service to be delivered in an outpatient clinic setting, improving inpatient waiting lists and resource allocation to outpatient setting. These early results show promise in changing the delivery of MIST.

Authors' Contributions

S.K.: Methodology, software, formal analysis, resources, writing—original draft, and writing—review and editing. M.T.: Data curation. L.D.: Data curation. B.D.: Data curation, writing—review and editing. H.M.: Data curation. C.C.: Data curation and resources. S.G.: Writing—editing and review and supervision. F.A.J.: Writing—editing and review and supervision.

Ethics Approval and Consent to Participate

No ethical approval was required as this is not considered research within the UK.

As per NHS Health Research Authority decision tool (https://www.hra-decisiontools.org.uk/ethics/) this study comprises an audit and does not require ethical approval. As the data are anonymized and an audit, patient consent is not required as per NHS Health Research Authority. Local audit registration with NHS Fife Research and Development department.

The study adhered to the Declaration of Helsinki.

Consent for Publication

Not applicable.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Disclosure Statement

F.A.J.: Proctor for Rezum™ and received consultancy honoraria from Boston Scientific. No other conflicts of interest.

Funding Information

Not applicable

Supplementary Material

Supplementary Figure S1

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Abbreviations Used

ARIs = α-reductase inhibitors
BOO = bladder outflow obstruction
BPE = benign prostatic enlargement
CD = Clavien–Dindo classification
GA = general anaesthetic
IIEF = International Index of Erectile Function
IPSS = International Prostate Symptom Score
IQR = interquartile range
LA = local anaesthetic
MIST = minimally invasive surgical therapies
PDE5i = phosphodiesterase 5 inhibitor
PSA = prostate serum antigen
PVR = post void residual
Q-max = maximum flow rate
QOL = quality of life
SD = standard deviation
UTI = urinary tract infection
VAS = visual analogue scale