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REVIEW

Emerging Data on the Safety and Efficacy of Transurethral Water Vapour Therapy for Benign Prostatic Hyperplasia

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Abstract: Benign prostate disease is a disease of prevalence and over 25% of men affected by bothersome lower urinary tract symptoms (LUTS) as a result of it will require surgical intervention during their lifetime. While transurethral resection of the prostate (TURP) has served as the cornerstone treatment for many years, there now exist a multitude of minimally invasive alternatives including the Rezum system. The latter is a novel form of transurethral water vapour therapy, which is attracting increasing attention. It utilizes convective water vapour energy (WAVE) and thereby radiofrequency (RF) in order to generate heat energy. Early studies have demonstrated promising results. To date there have been 12 studies published on Rezum, however only one randomized trial. This review offers an overview and evaluation of this emerging evidence.

Keywords: Rezum, BPH, prostate, benign prostatic hyperplasia, minimally invasive surgery

Introduction

Benign prostatic hyperplasia (BPH) is a disease of prevalence and its natural history renders 25% of men to be affected by bothersome lower urinary tract symptoms (LUTS) caused by bladder outflow obstruction during their lifetime.[1,2] The sequelae are far reaching and can significantly affect their quality of life.[3] In cases refractory to conservative and medical treatments, surgery represents the next step in the management pathway. While transurethral resection of the prostate (TURP) has served as the cornerstone treatment for many years, there now exist a multitude of minimally invasive alternatives, which achieve effect through a range of mechanisms of action.[4] For example, prostatic urethral lift and iTIND rely principally on mechanical decompression whereas prostate artery embolization (PAE) induces glandular ischemia.[5,6,7] In order to achieve general uptake, new treatment modalities are required to demonstrate sufficient improvement across both objective and subjective outcome measures as well as maintaining a strong safety profile. Improvements should be durable and sustained at long term follow up while striving to adhere to a favorable financial model.

The Rezum system is a novel device, which utilizes convective water vapour energy (WAVE) and thereby radiofrequency (RF) in order to generate heat energy.[8] Large volumes of stored energy (540 cal/mL H_2O) are released when the water vapour (approx. 103°C) makes contact with the tissue and subsequent condensation occurs. Cell necrosis ensues as a result of temperature change. Through use of these

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steam injections, transurethral delivery of this energy can be targeted with precision and overlapping lesions are formed in the desired anatomical location. While still relatively new, early studies have demonstrated promising results and it obtained approval by the US Food and Drug Administration (FDA) in 2015 and the National Institute for Health and Care Excellence (NICE) guidelines in 2018.[9] While there has been an increasing amount of emerging data on Rezum, critical evaluation of its safety and efficacy remains under-reported. This review therefore aimed to deliver such an appraisal and provide an overview of its current status.

Methods

A comprehensive review of world literature was performed in order to find original studies on Rezum. Bibliographic databases searched included Medline, Google Scholar, Cochrane database and center for trials. All study types were considered eligible as long as full text articles were available in English language, and the search was completed in January 2021.

Rezum

To date there have been 12 studies published on Rezum, which have included 1391 patients (mean age 68.7 years, range: 46–90) (Tables 1 and 2).[9–20] Over half of these studies (n=7) have been published in the past 2 years, reflecting the increasing interest and uptake of this novel intervention. There has only been one randomized study and the remainder represent cohort studies (5x retrospective and 6 x prospective). Seven of these studies were performed in a multi-center setting.[10–12,14,17,18] The randomized study used a sham procedure as a comparator.-[14] This consisted of rigid cystoscopy with simulated active treatment sound effects. Across the studies, the mean prostate volume was 61.6 cc (range: 19.5–183). The mean number of steam injections administered was 6.5 (range: 4–10) in the seven studies, which reported this.[9,13,14,18,19] Duration of follow up ranged from 1 week (proof of concept study) to 5 years.[9,14] Selection criteria for studies are summarized in Table 3.

Efficacy

In 2020, a Cochrane review was published on this technology, however it only considered data from one study, the randomized trial.[14,21] The heterogeneity of parameters reported among published studies and wide range of follow up periods preclude formal meta-analysis in previous and current study. However, consistent improvements in clinical outcomes after Rezum can be observed across all the studies.

Eight of the studies reported on change in international prostate symptom score (IPSS) and each of these revealed improvements (Table 4).[11–16,19,20] In their prospective single center study of 210 patients, Johnston et al recorded mean improvement in IPSS of 78.5% after 12 months (20.4 vs 4.3, p<0.001) and mean improvement of 97.5% in maximum urinary flow rate (Qmax) of 97.5% (9.2 vs 18.2 mL/s, p<0.001) over the same time period.[16] These changes represent the most pronounced across all reported studies. Other studies have recorded at least 30% improvement in IPSS and McVary et al reported a mean change of −48% at the five year follow up assessment (<0.001).[14] This improvement had been stable since the 12 month follow up assessment when the mean improvement recorded was 52.2% (p<0.001). This was mirrored in the results for Qmax, where mean improvement was 49% (9.9 vs 14, p<0.001) after five years. Quality of life (QoL) data were reported by only four studies, however these all demonstrated improvement.[11,12,14,16] Mean change in QoL scores ranged from 37.8% to 72%. Again, in the five year follow up study of the randomized trial, the result had plateaued and remained largely similar since the initial 12-month assessment (45% improvement).[14] Dixon et al also reported a statistically significant mean improvement in QoL at two year follow up (4.4 vs 1.8, p<0.001).[11]

As well as the advantage of Rezum in treating patients with an obstructing median lobe, this intervention may offer the potential to become a standard treatment for patients with large prostate burden. While Rezum is acknowledged in the European Association of Urology (EAU) guidelines as a new intervention in the surgical management of BPH, it has yet to receive any formal recommendation.[2] However, NICE recommends its application only in the setting of prostate size between 30–80cc.[8] Two studies specifically analyzed the feasibility of Rezum in larger prostate size (>80cc).[15,19] Bole et al reported statistically significant improvements in IPSS (22 vs 13.4, p=0.04), post void residual (PVR) (305 vs 149 mL, p=0.05), and Qmax (7.7 vs 12.7mL/s, p=0.002) in a patient group (mean prostate volume 119cc).[15] Furthermore, 55.3% were catheter dependent preoperatively. The application of Rezum in catheter dependent patients with complete urinary retention would be a further advantage. In 2020, McVary et al reported findings from a registry of patients (n=38) with this clinical

Table 1 Baseline Demographics of the Included Studies

Author/ Country	Year	Study Type Level of Evidence	Sample Size		Mean Age – Years (SD, Range)		Mean Prostate Size Range – cc (SD, Range)		Mean No. Injections		Duration Follow Up – Months	Length of Stay – Days
Dixon/ USA[9]	2015	Single center prospective cohort	Grp 1	Grp 2	Grp 1	Grp 2	Grp 1	Grp 2	Grp 1	Grp 2	0.25	NR
			7	15	70.4 (4.2, 66–78)	69.9 (8.8, 58 −90)	51.2 (34.7, 19.5–125.5)	49.7 (19.6, 237–100)	10.3	7.2		
Mynderse/ Multi-national[10]	2015	Multi-center Prospective Cohort	44		NR		61.2 (20.4–133.2)		NR		6	NR
Dixon/ Multi-national[11]	2016	Multi-center center prospective cohort	65		66.6 (7.7, 50–90)		48.6 (20.5, 19.5–110.4)		NR		24	NR
Darson/ USA[12]	2017	Multi-center retrospective cohort	131		70.9 (9.4, 47.4–96.4)		45.1 (23.4, 12.9–183)		NR		12	NR
Mollengarden/ USA[13]	2018	Single center retrospective cohort	129		67.4 (8.0, 46–86)		52.6 (17.0, 20–85.9)		5.5		6**	NR
Bole/ USA[15]	2020	Retrospective Single center cohort	<80cc	≥ 80cc	<80cc	≥ 80 cc	<80cc	≥ 80cc	NR		3	NR
			135	47	69 (9, NR)	72 (10, NR)	49 (NR)	119 (NR)				
Johnston/ UK[16]	2020	Prospective single center cohort	210		66 (NR)		NR		NR		12	NR
Tutrone/ USA[17]	2020	Prospective multi-center cohort	23		69 (7.8, NR)		63 (39.3, NR)		NR		2	NR
Mcvary/ USA[18]	2020	Retrospective multi-center cohort	38*		76 (9.1, 59–90)		64.4 (35.4, NR)		5.4–5.7		2–48	NR
Siena/ Italy[20]	2021	Prospective multi-center cohort	135		69 (NR, 61–79)		60 (NR, 30–120)		7		6	<1
Mcvary/ USA[14]	2021	Multi-center RCT	188		63 ± 7.1		45.8 (13, NR)		4.7		60	NR
Garden/ USA[19]	2021	Retrospective single-center	< 80 cc	≥ 80 cc	<80 cc	≥80 cc	< 80 cc	≥ 80cc	4.76		2–12	NR
			168	36	65.41 (9.05, NR)	67.31 (7.17, NR)	45.33 (14.53, NR)	106.77 (37.57, NR)				

Notes: *All patients had indwelling catheter pre-operatively. **12 month reporting of complications.
Abbreviations: NR, not reported; Grp, group; USA, United States of America; UK, United Kingdom.

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Table 2 Additional Characteristics

Author	Catheter Pre op (%)		Mean IPSS		Mean Qmax (mL/s)		Mean QoL		Catheter Post op (%)/Time to Removal/ Duration (Days)	
Dixon[9]	NR		23.6		7.7		4.1		NR/NR	
Mynderse[10]	NR		NR		NR		NR		NR	
Dixon[11]	NR		21.66		7.9		4.3		55/4.1*	
Darson[12]	NR		19.5		8.6		4.3		NR	
Mollengarden[13]	NR		18.3		10.5		NR		65.1/4.4	
Bole[15]	<80cc	≥ 80cc	<80cc	≥ 80cc	<80cc	≥ 80cc	<80cc	≥ 80cc	<80cc	≥ 80cc
	25.2	55.3	22.1	22	9.2	7.7	NR	NR	12/Minimum 3 days	17/3 −41
Johnston[16]	11.9		20.4		9.2		4.3		100/3-5	
Tutrone[17]	NR		15.6		NR		2.5		87/4.5	
Mcvary[18]	100		NR		NR		NR		100/26.6	
Siena[20]	NR		21.5		8.1		NR		100/7*	
Mcvary[14]	NR		16.3		9.2		3.9		NR	
Garden[19]	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	100/3-7	
	5.95	22.2	16.6	15.2	9.5	7.4	NR	NR		

Note: *Median.
Abbreviations: IPSS, international prostate symptom score; Qmax, maximum urinary flow rate; NR, not reported.

profile.[18] 73% of these patients achieved a catheter free status and the median length of time to achieve this was 26 days (range: 4–65) after the procedure.

Safety

The most common low-grade complications (Clavien <2) associated with this intervention are urinary tract infection (UTI), urinary retention, hematuria and new onset bothersome lower urinary tract symptoms such as frequency and urgency. As demonstrated in Table 5, there is a range of these reported low-grade complications. Garden et al reported that hematuria, urgency, and frequency occurred in 39.29%, 30.36%, and 30.95% of patients respectively.[19] In the randomized trial performed by McVary et al, this same group of bothersome symptoms was also captured, albeit with lower rates.[14] In contrast, in other studies no such bothersome symptoms were reported. Given that many patients do experience such self-resolving bothersome symptoms of this nature, similar to the post PAE syndrome, these symptoms may not have been captured in some studies as patients presented to primary care or their symptoms resolved in time.[22] Most studies recorded rates of UTI between 10–20%. Similar to other adverse events such as dysuria and hematuria, a main reason for this is considered to be due to both the catheter being left in situ 5–7 days after the procedure and the necrotic tissue produced after the procedure. Increasingly therefore, a short course of antibiotics is recommended as part of the post intervention care plan. Rates of urinary retention varied from zero cases in some studies to as high as 33.8%.[11] Given the limited number of studies which have been performed using Rezum, this may be part of the evolution of patient selection for this procedure as the optimal candidate is being determined as well as the expected learning curve for centers newly adopting the technique. Inclusion criteria also varied across the studies, which also likely contributed to this. For example, Darson et al left patient selection to the discretion of the clinician whereas stricter measures were followed in other studies.[12]

Rates of serious adverse events were low across all the studies and these were all related to either sepsis or hematuria requiring return to theater to achieve endoscopic control. Late complications have been rare and include bladder neck contracture as reported in two studies.[13,14]

Table 3 Selection Criteria of Included Studies

Author	Inclusion	Exclusion
Dixon[9]	NR	• Bladder or sphincter abnormalities • Penile prosthesis, • Prior surgery for BPH • Confirmed or suspected prostate cancer • Prior radiation • Urethral strictures • Recent prostate biopsy (30 days)
Mynderse[10]	NR	NR
Dixon[11]	• ≥45 years • Prostate volume 20–120 cc, • IPSS ≥13, • Q_{max} ≤15 mL/s, • PVR <300 mL. • Median lobe included	• Prior surgery for BPH • Confirmed or suspected prostate or bladder cancer • Active UTI • Bacterial prostatitis within the last year
Darson[12]	No standardized protocol (median lobe included)	No standardized protocol
Mollengarden[13]	Clinical judgement of surgeon	NR
Bole[15]	NR	NR
Johnston[16]	NR	NR
Tutrone[17]	• Prostate volume 30–80cc.	No exclusion
Mcvary[18]	• Catheter dependent patients	NR
Siena[20]	• >18 years • No prior surgery for BPH, International Prostate Symptom Score (IPSS) ≥ 13, peak urinary flow rate (Qmax) ≤ 15 mL/sec with minimum voided volume of ≥ 125 mL, post-void residual ≤ 250 mL, prostate volume > 30 and ≤ 120 cc.	NR
Mcvary[14]	• ≥50 years • IPSS ≥13, • Prostate volume 30 80 cc, • Qmax of ≤15 mL/s • PVR urine <250mL	• PSA >2.5 ng/mL with a free PSA <25% unless prostate cancer was ruled out by biopsy • Active urinary tract infection
Garden[19]	NR	NR

Abbreviations: IPSS, international prostate symptom score; Qmax, maximum urinary flow rate; UTI, urinary tract infection; NR, not reported.

No study recorded late complication rate above 5%. No deaths were recorded across any of the studies.

Re-treatment rates also appear low although only a single study has achieved follow up to five years where the rate was 4.4%.[14] The range of re-treatment rates reported at 12 month follow up was 0.95% to 8.33%. In contrast, the re-treatment rate at five years reported in the LIFT study was 13.6%.[24] Tolerability and patient satisfaction appear favorable. Johnston et al reported that 91% of patients would be prepared to go through repeat Rezum procedure if ultimately required.[16]

Sexual Dysfunction

Six studies reported on incidence of de-novo sexual dysfunction occurring post treatment.[11–14,16,19] Three of these reported no new cases.[11,12,14] New onset erectile dysfunction (3.1%) was reported by Mollengarden et al and only in one other study.[13,19] Two studies revealed cases of retrograde ejaculation, however, rates were noticeably low (<6%).[13,16] Gupta et al compared outcomes of randomized trial 3 year follow up data with the Medical Therapy of Prostatic Symptoms (MTOPS) study (n=1209) in order to determine if either pharmacotherapy or a single

Table 4 Clinical Outcomes of the Included Studies

Author	Mean % Change in IPSS		Mean % Change in Qmax		Mean % Change in Prostate Volume	Mean Change in PSA	Mean % Change in QoL	Mean Change in IIEF 5 (%)	
Dixon[9]	NR		NR		NR	NR	NR	NR	
Mynderse[10]	NR		NR		−28.9	−0.2	NR	NR	
Dixon[11]	−58.5*		+44.6*		−30*	NR	+59*	+30.5	
Darson[12]	−45.2*		+51.4		−34.9	NR	−37.8*	NR	
Mollengarden[13]	−60.0*		+71.7*		−17.9*	−0.33	NR	NR	
Bole[15]	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	NR	NR	NR	NR	
	−45*	−39 0.04	+40.2 0.001	+65 0.002					
Johnston[16]	−78.9*		+97*		−33*	NR	+72*	+26*	
Tutrone[17]	NR		NR		−33.3	NR	NR	NR	
Mcvary[18]	NR		NR		NR	NR	NR	NR	
Siena[20]	−79.5%		NR		NR	NR	NR	+17	
Mcvary[14]	− 48*		+49*		NR	−2.5	45*	7.6	
Garden[19]	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	NR	NR	NR	< 80 cc	≥ 80 cc
	−32.4	−22.2	+15.%	+98*				NR	+8.6

Note: *Statistically significant (p<0.05).
Abbreviation: NR, not reported.

surgical intervention (Rezum) caused more deterioration in sexual symptoms among sexually active men.[25] Their findings concluded that both finasteride and combination therapy resulted in significant reduction in sexual desire as well as worsening of both erectile and ejaculatory function. In contrast, Rezum was not associated with negative impact on any of these domains. Four studies included a validated tool, International Index of Erectile Function (IIEF-5) as part of evaluation of treatment impact.[11,14,16,19] All of them reported improvements, which ranged from 7.6–30.5%.

Morphological Changes

In 2015, Dixon et al reported findings from an early, proof of concept study and performed gadolinium enhanced magnetic resonance imaging (MRI) at one week post surgery.[9] The mean volume of coalesced lesion was 9.6cm^3 and the largest recorded in the series was 35.1 cm^3. More recently, Mynderse et al enrolled 45 patients to also undergo regular imaging surveillance with MRI.[10] Early imaging at one week post procedure revealed similar results. The mean volume of the coalesced lesion created was 8.2 cm^3 (0.5–24.0 cm^3). At 6 months follow up, the mean reduction in volume of prostate was −28.9% and −38% in the transition zone. Three further studies have reported greater than 30% reduction in prostate volume.[12,16,17] The lack of specimen retrieval does represent a disadvantage of Rezum and as a consequence no histopathological analysis is possible. Little is known currently regarding interpretation of PSA values post Rezum treatment in regard to evaluation for possible prostate cancer. There is also a lack of data on impact of Rezum treatment on later surgery for both BPH and prostate cancer.

Cost

None of the included studies provided information regarding cost of Rezum. However, a recent cost effectiveness analysis by Ulchacker et al offers an early insight into the economic status of this device, which is favorable.[26] The cost for Rezum was given as $2489 (US), which includes cost for pre-operative assessment

Table 5 Complications (Early, Late) Reported in the Studies Including Sexual Dysfunction and Retreatment Rates

Author	Early Complications				Late Complications (n)	Retreatment Rate	Treatment Related Sexual Dysfunction
	Minor CD 1 to 2		Major 3 and Over				
Dixon[9]	NR		NR		NR	NR	NR
Mynderse[10]	NR		NR		NR	NR	NR
Dixon[11]	Urinary retention (33.8%) UTI (20%) Urgency (20%) Dysuria (21.5%) Pain 10.% Incontinence (1.5%) Nocturia (7.7%) Poor stream 13.8%) Fever (4.6%)		15.4% (no breakdown provided)		Nil	NR	Nil
Darson[12]	Urinary retention (10.7%) Frequency, urgency, frequency and urgency, hematuria and nocturia (<4%)		Nil		Nil	3%	Nil
Mollengarden[13]	UTI 22 (17.1%) Urinary retention 18 (14.0%) UTI Epididymo-orchitis 2 (1.6%)		Hematuria requiring return to theater (0.8%)		Urethral stricture (3.9%) Urinary incontinence (3.9%) Bladder stone (0.8) Bladder neck contracture 1 (0.8)	2.3%	Erectile dysfunction (3.1%) Retrograde ejaculation (3.1)
Bole[15]	<80cc	≥ 80 cc	<80cc	≥ 80 cc	NR	NR	NR
	UTI (15.6%)	Blood transfusion (4.3%)	Hematuria requiring return to theater x (2.15%) Sepsis (8.6%)	Hematuria requiring return to theater (4.3%) Sepsis (2.15%)			
Johnston[16]	UTI (5.7%) Persistent prostatitis (0.48%)		Hematuria requiring return to theater (0.95%)		Nil	0.95%	Retrograde ejaculation (2.9%)
Tutrone[17]	NR		NR		NR	NR	NR
Mcvary[18]	UTI (5.25%) Hematuria (10.5%) Dysuria (13%)		Nil		NR	NR	NR
Siena[20]	Urinary retention (11.8%)		Nil		Nil	2.2	NR
Mcvary[14]	Dysuria (16.9%), Hematuria (11.8%), frequency and urgency (5.9%), acute urinary retention (3.7%) urinary tract infection (3.7%)		Nil		Sepsis after follow up cystoscopy (0.5%) Bladder neck contracture + bladder calculi (0.5%)	4.4%	Nil

(*Continued*)

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Table 5 (Continued).

Author	Early Complications				Late Complications (n)		Retreatment Rate		Treatment Related Sexual Dysfunction	
	Minor CD 1 to 2		Major 3 and Over							
Garden [19]	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc	< 80 cc	≥ 80 cc
	Urgency (30.36%) Hematuria (39.29%) Frequency (30.95%) Bladder spasms (24.4%) Dysuria (23.21%) Urinary retention (21.43%) Fever (4.17%) Clot retention (1.79%) Hematospermia (2.38%) UTI (10.12%) COPD exacerbation (0.6%) COVID-19 infection (0.6%)	Urgency (50%) Hematuria (50%) Frequency (36.11%) Bladder spasms (30.56%) Dysuria (25%) Urinary retention (19.44%) Fever (8.33%) Clot retention (2.78%) Hematospermia UTI (19.44)	NR	Sepsis (5.56%)	Urine leakage (1.19%) Clot retention (1.19%) Testicular pain (0.6%) Retention (0.6%) Dysuria (1.79%)	Clot retention (2.78%)	8.33%	4.76%	Erectile dysfunction (1.79%)	Erectile dysfunction (5.56%)

Abbreviations: NR, not reported; UTI, urinary tract infection; COPD, chronic obstructive pulmonary disease.

with cystoscopy, transrectal ultrasound (TRUS) and urodynamic study (UDS) as well as post-operative assessment and one year follow up appointment. This was cheaper than for TURP ($4821), although their evaluation determined inferiority of clinical outcomes achieved with Rezum compared to TURP. However, when stratified according to outcomes based on cost, these two interventions were aligned and were the most cost-effective treatments compared to both branded and generic combination therapy (5α-reductase inhibitor + α-blocker), urolift and greenlight procedure. Cost modeling data reported by NICE, estimate that over a four-year period, Rezum is able to provide savings of £569 and £651 compared to TURP and holmium laser enucleation of the prostate (HoLEP) respectively.[8] It is difficult to know if these projected savings are realistic due to expert evaluations largely relying on the randomized trial data as it is the only study to achieve four year follow up to date. The key driver for this cost saving when compared with such other standard BPH treatments, relies on the provision of Rezum as a day case surgery procedure. Length of stay and therefore determination of success at performing Rezum as a day case procedure was poorly reported across the studies and therefore it is difficult to truly evaluate the feasibility of establishing a day case service. A fundamental component of why it can be done as an ambulatory procedure is the lack of general anesthetic and even intravenous sedation required. However, outside of the trial context, most units appeared to carry out Rezum under general anesthetic, at least in the early period. Therefore, there remains a lack of real-world data providing evidence of this nature.

Limitations and Further Limitations

While there has been a recent surge in studies on Rezum, which all deliver promising early results, there is a lack of randomized trial data. Future studies, which compare against other standard BPH surgeries are warranted as at present only one sham study exists in world literature. The Comparing uroLift Experience Against Rezum (CLEAR) study, a randomized trial, is currently ongoing. Caution should also be noted when interpreting these early results as in the setting of both pilot studies and clinical trials, inclusion/exclusion criteria can be very strict when in reality the demographics of patients who present in clinic and require surgical intervention for BPH are typically much broader. Standardized evaluation parameters will aid future evaluation of Rezum's efficacy. To date, no studies have formally assessed the learning curve for the procedure. However, expert opinion (Level V evidence) has highlighted that it is straight forward for those with sufficient endoscopic experience.

Conclusion

Current evidence regarding Rezum demonstrates that it holds a strong efficacy and safety profile. While low grade side effects such as self-resolving bothersome LUTS appear to be present in up to one third of patients, serious adverse events seldom appear. Lack of or minimal de-novo sexual dysfunction appears to be consistently maintained across all evidence available and represents a further advantage of this procedure. Future studies with intervention comparators and longer follow up will provide important data to help delineate its formal position in the treatment algorithm as well as establish the patient profile most suitable for this particular surgery.

Disclosure

The authors report no conflicts of interest in this work.

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