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TITLE PAGE

“Prostatic urethral lift versus prostate arterial embolisation: Novel non-ablative strategies in the management of LUTS secondary to BPH”

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Abstract (unstructured)

Prostate urethral lift and Prostate arterial embolisation represent two evolving techniques with contrasting mechanisms of action (mechanical decompression versus angiographic embolisation). **Both yield relief of LUTS over a period of several weeks.** They display similar safety profiles with self-limiting pelvic discomfort characterising the commonest minor adverse event. Both procedures have the potential to be carried out under local anaesthesia

and in the outpatient setting with suitability for patients with cardiovascular co-morbidities. Neither has been found to cause degradation of sexual function. Further randomised studies are needed to delineate the formal position of these techniques in the surgical management of BPH.

INTRODUCTION

The advent of newly available, minimally invasive surgical therapies has confirmed that the therapeutic landscape for lower urinary tract symptoms (LUTS) secondary to benign prostate hyperplasia (BPH) is changing. The prostatic urethral lift (PUL) system known as the UroLift device (NeoTract Inc., Pleasanton, CA, USA) and Prostate Artery Embolisation (PAE) represent the latest newcomers to the global stage [1,2]. While TURP continues to represent the gold standard surgical intervention, the paradigm shift towards minimally invasive surgery coupled with advances in uro-technology, have prompted the urology community to re-evaluate the position of this resective technique. In order to be formally accepted as part the urologist's armamentarium, an emerging technique such as PUL or PAE must elucidate itself to be a safe, effective and durable alternative, which is able to improve both subjective and objective disease status measures.

To this effect, it must withstand rigorous validation through multi-centre randomised studies. While there are an increasing number of data series being reported from studies on PUL and PAE alike, critical appraisal on these two surgical methods is lacking. Therefore, we aim to evaluate these evolving techniques.

MATERIALS AND METHODS

A search strategy was conducted to include EMBASE, Pubmed, Web of Science and Scopus, databases. Search terms included “benign prostate hyperplasia”, “lower urinary tract symptoms”, “urolift”, “urethral lift”, and “prostate artery embolisation”. Relevant abstracts and proceedings from conferences were also hand searched. We included studies that had 10 or more patients with a minimum follow-up of 12 months to allow for short and mid term follow up of efficacy and safety.

CURRENT TREATMENTS FOR BPH

BPH is a progressive disease and histopathological examination of affected tissue reveals hyperplasia of the epithelial and stromal architecture in the transition zone of the gland [3]. The prevalence of this pathology exceeds 50% in men over 60 years and is exponential thereafter [4]. Alpha 1-adrenoreceptor (AR) antagonist monotherapy has been the traditional first line in the medical management of LUTS secondary to BPH. Although this pharmacological treatment demonstrates significant efficacy over placebo, α -AR antagonists are associated with adverse effects such as postural hypotension and retrograde ejaculation [5]. Furthermore, they do not yield any effect on disease progression nor do they prevent acute urinary retention [6]. 5 α -reductase inhibitors (5 α -RIs) such as Dutasteride and Finasteride serve to mediate the conversion of testosterone to dihydrotestosterone (DHT) as well trigger prostatic epithelial cell apoptosis [7]. Unlike alpha-blockers, 5 α -RIs can significantly alter BPH progression [8]. While this translates into a reduction in prostate size by up to 28%, their onset of action is slow and the side effect profile includes diminished libido, erectile dysfunction and potential

depression [9]. The unwanted sequelae of these two drug treatments can therefore lead to poor tolerability and subsequent withdrawal.

For over 30 years, Transurethral resection of the prostate (TURP) has remained the mainstay surgical intervention for BPH with moderate to severe symptoms and refractory to medical therapy. However, the numbers of this endoscopic procedure performed each year has steadily declined [10]. Although major morbidity associated with TURP is less than 1% and mortality is virtually 0%, retrograde ejaculation continues to be recorded in up to 75% of cases [11]. The case for TURP is weakened further, by the requirement for a general anaesthetic and inpatient stay. The median hospital stay after TURP in the United Kingdom (UK) is 48 hours [12]. The era of transurethral laser prostatectomies has carved a new chapter in the evolution of BPH practice patterns. The recently published, 12 month results of the European GOLIATH study have upheld the non-inferiority of GreenLight Vaporisation versus TURP in regards to various efficacy outcomes including International Prostate Symptom Score (IPSS) and maximum urinary flow rate (Qmax) [13]. Equally, Holmium laser enucleation of the prostate (HoLEP) has received increasing attention for its potential role as a “size independent” procedure [14]. However, the rate of retrograde ejaculation has been reported at 22% and 78% after these two laser procedures respectively [15]. Management of LUTS secondary to BPH is multi- dimensional and the rationale for the patient’s treatment pathway is stratified according to a number of patient characteristics including personal expectations, medical co-morbidities, pre-existing sexual function and prostate burden. Surgeon experience as well as the accessibility

and diffusion of the technique will also shape the treatment a patient is able to receive. HoLEP, for example, is associated with a steep learning curve and is unlikely to be offered to patients attending smaller centres. A void in the therapeutic armamentarium for this condition has therefore developed. The search continues for a surgical treatment, which has an attainable learning curve and efficacy outcomes rivalling TURP, which can also preserve sexual function.

UROLIFT:

Technique

This endoscopic and non-ablative procedure serves to establish an uninterrupted channel in the prostatic fossa extending from the bladder neck down to the verumontanum [16]. It achieves this via mechanical compression with adjustable, trans-prostatic implants. The 3 core components of these biocompatible implants are a capsular nitinol tab, stainless steel urethral end piece and an adjustable polymeric monofilament [17].

The procedure can be performed under local anaesthesia and sedation. Following cystoscopy the bladder is emptied. The trans-prostatic implants are typically deployed at the 2 and 10 o'clock positions in the anterolateral direction under cystoscopic guidance. This is done using a 19-gauge needle, which houses the components of the implant and is passed through the prostate lobe. Full retraction of the needle causes the prostate capsule to be engaged by the tab and the monofilament to be placed under tension, which secures the device. Once the urethral end piece is attached to the monofilament, the latter is then cut. Owing to the tissue-sparing nature of the procedure, which allows for preservation of bladder neck integrity (implants

should therefore be deployed atleast 1.5cm distal to this site and angulated carefully), antegrade ejaculation is protected [18]. The result is retraction of the encroaching lateral lobes and therefore expansion of the urethral lumen without causing compromise to vital anatomical structures such as the primary neurovascular bundles and the dorsal venous complex. Avoiding the use of a thermal energy source is thought to keep the risk of erectile dysfunction to a minimum. The number of implants installed per case is adenoma dependent and ranges between 2 to 10 according to Garcia et al [18]. Larger prostates require more implants. Computed Tomography (CT) can confirm positioning of these invaginated devices at follow up.

Evolution of the technique:

An Australian group led by Henry Woo, at the University of Sydney, has largely pioneered this novel device [17,18,19]. They carried out their debut PUL procedure in 2005 and in 2011 published results from a prospective, cohort study in 19 men [17]. Their results showed the mean IPSS to be reduced by 37% at 2 weeks. The following year, the same author group released findings from a single arm registry of 64 men [20]. At the 24-month end point the IPSS and Qmax had improved by 42% and 30% respectively. No adverse events related to retrograde ejaculation or erectile dysfunction was reported, which led the authors to conclude that this non-cavitating approach allows for preservation of sexual function. The next year, Roerhborn et al reported from the first randomised blinded trial of PUL across 19 international centres [21]. Two hundred and six men were randomly assigned to either a PUL or sham procedure (involving rigid cystoscopy with simulated sounds of implants being deployed). The mean American Urological

Association Symptom Index (AUA-SI) value was reduced from 22.1 at baseline to 11.1 after 12 months ($p<0.001$) in the PUL group. No de novo cases of ejaculatory or erectile dysfunction were reported. The author group later published the 24 month results, which found that PUL reduced AUA-SI 88% more than the sham therapy (-11.1 vs -5.9 , $p=0.003$) [22].

In 2013, PUL gained US Food and Drug Administration (FDA) approval. In 2014, Cantwell et al published results from a crossover study involving patients enrolled in the sham arm of the aforementioned study [23]. Each patient therefore acted as his own control. The therapeutic feasibility of PUL was announced by the authors as their study showed statistical improvements in IPSS (-37% , $p<0.001$), Health Related Quality of Life (HRQL) (-41% , $p<0.001$), BPH Impact Index (BPHII) (-44 , $p<0.001$) and Qmax (35% , $p<0.005$). Most recently, in 2015, Sonksen et al released the 12 month results from the BPH6 study, the first randomised trial to compare PUL versus TURP [24]. This demonstrated that the quality of recovery was greater after PUL than TURP ($p=0.0008$) and so too was the preservation of ejaculatory function ($p<0.0001$).

See Table 1 for summary of study characteristics, Table 2 for 12 month objective outcomes and Table 3 for 12 month subjective outcomes.

Patient Selection and work-up

Exclusion criteria for PUL include renal insufficiency, previous prostate surgery and large median lobes (see See Supplementary Table 1 for summary of selection criteria). It is considered best suited for patients with obstruction secondary to lateral lobe enlargement. Pre-operative assessment should include urodynamic studies, radiological imaging and evaluation of

patient expectations. The technique is not suitable in candidates with a size of prostate exceeding 100ml.

Complications

Minor adverse events related to PUL include dysuria, haematuria and urgency, all of which should resolve spontaneously. Extrusion of the implants into the bladder lumen can lead to encrustation. If significant, these can be later removed with endoscopic forceps. However, according to published series', the most cases are asymptomatic and require conservative management only. Should the patient require TURP at a later date, the resectoscope is able to melt the implants without difficulty. See Supplementary Table 2 for summary of complications.

PROSTATIC ARTERY EMBOLISATION

Procedure

This is a radiological technique which aims to occlude the arterial supply to the prostate and thereby infarct the gland. This debulks the prostate and therefore relieves outlet obstruction leading to symptom resolution [2].

The hypogastric artery is accessed under local anaesthesia using a femoral approach and once in the anterior division, Digital Subtraction Angiography (DSA) is used to verify arterial anatomy before advancing further. Super-selective embolisation of the feeding prostatic vessels is carried out using hydrophilic micro-catheters and non-spherical poly-vinyl alcohol (PVA) particles. Repeat angiography takes place before embolisation is repeated on the contra lateral side using the same method [31].

Evolution of the technique:

The role of angiographic embolisation in the control of intractable haemorrhage from pelvic organs is well established [32]. In 2000, De Merritt et al were the first to publish its potentially, therapeutic role in the case of a patient with acute urinary retention (AUR) whose medical co-morbidities precluded standard surgical management [33]. This was followed by experimental studies on both canine and porcine models, which determined targeted transcatheter embolisation to result in significant reduction in prostate volume. The largest dataset has been published by Pisco et al in 2013 [27]. They selected 255 patients with LUTS secondary to BPH and refractory to pharmacotherapy to undergo PAE. At 12 months, the mean IPSS had improved from 24 to 10.4 ($p < 0.0001$) and the mean PVR had fallen from 102.9ml to 51.7ml ($p < 0.0001$). For those subjects followed up to 36 months, the overall improvement in IPSS was 62.5% and Qmax had increased by 51%. The mean pain score was 1.7 (scale 0 -10) and 76.4% of subjects reported no pain at all during the procedure. Sexual function was enhanced in 48.2% of the group with no cases of de novo dysfunction. Most recently, Wang et al released findings from their study comparing PAE for large (mean 129ml) and medium (mean 64ml) sized prostates in 115 men [30]. Subjects in the former group demonstrated a significantly greater decrease in mean IPSS compared to in the latter group (large sized prostate group vs. medium sized prostate group mean: -14 vs -10.5; $p = 0.02$); and a significantly greater rise in mean Qmax (6.0 vs 4.5ml; $p = 0.04$). Short term results from the first prospective study in the UK have found PAE to reduce prostate volumes by 45% and improve QoL by 3 points [34]. PSA levels rise sharply within the first 24 hours after PAE and can exceed levels exceeding 20 times the baseline

value. However, return to baseline level is observed after 1 month and at 12 months follow up, PSA levels have been reported to have decreased by up to 27% [27].

At present, the procedure is sanctioned by NICE for research purposes only. The Society of Interventional Radiology (SIR) has marked PAE as a research priority [35] and The United Kingdom – Registry of Prostate Embolisation (UK-ROPE) trial is underway to further delineate the formal role of this technique. See Table 1 for summary of study characteristics, Table 2 for 12 month objective outcomes and Table 3 for 12 month subjective outcomes.

Patient Selection and work-up

High rates of technical and clinical success are achieved through detailed patient selection measures and intensive pre-operative work up, which are of the utmost importance. Urethral strictures, coagulation disorders and renal insufficiency form part of the standard list of contra-indications (see See Supplementary Table 1 for summary of selection criteria). This planning should incorporate CT imaging in order to provide accurate visualisation of the vascular anatomy as well as formal urodynamic studies. Physical examination and assessment of functional burden using validated instruments compliment this algorithm. Patient selection for PAE is usually done as a multidisciplinary team approach between the urologists and interventional radiologist. While the urologist should be responsible for the patient selection taking into account the inclusion and exclusion factors, the interventional radiologist does the technical intervention. The imaging follow-up and the clinical follow-up is done by a team approach between the radiologist and urologist.

Complications

The procedure is documented to cause symptoms of nausea and a burning sensation in the urethra and it has been coined, the so-called “Post-PAE syndrome” [36]. This occurrence can be minimised by patients commencing an anti-inflammatory medication and prophylactic antibiotics for 2 days prior to the procedure. A rare, but serious adverse event associated with PAE is ischaemic injury of closely related structures due to non-targeted embolisation. There have been 2 separate injuries of this kind reported in the literature, which resulted in desquamation of the bladder wall and ischaemic proctitis respectively [27,38].

See Supplementary Table 2 for summary of complications.

DISCUSSION

PUL and PAE represent two evolving non-ablative techniques with contrasting mechanisms of action. While Urologists do the former interventional radiologists usually do the later. They are able yield relief of LUTS over several weeks without significant morbidity. Studies with 12 months follow up suggest these clinically meaningful gains are durable. They display similar safety profiles, with self-limiting pelvic discomfort and dysuria characterising the commonest minor adverse events affiliated with both procedures.

Limitations and restrictions

Poorly-targeted embolisation is the noteworthy major adverse event associated with PAE and confirms the close attention to pre-operative assessment and vascular mapping, which is mandated. In contrast, candidates for PUL do not have to be triaged for suitable vascular anatomy. While PAE may be suitable for patients with an obstructing median lobe, it is not effective for other causes of LUTS such as detrusor failure and

neurogenic bladder. The average procedure time for PAE and PUL in the included studies was 110 minutes and 58 minutes respectively. A recent prospective randomized trial by Yang et al, which compared thulium laser transurethral enucleation of the prostate (ThuLEP) and plasmakinetic bipolar resection of the prostate (PKRP) recorded mean procedure times of 65.4 minutes and 47.4 minutes respectively []. Procedure times for PUL are therefore comparable to other minimally invasive techniques and of shorter than for PAE. The procedure duration of PAE is extended through the requirement for fluoroscopy, which can last upwards of 30 minutes. PAE has the potential to produce significant radiation dosage, however this seems to have been reduced with newer technology, low dose protocol and pulsed frame rate DSA. Aside from radiation injury, contrast induced toxicity is another potential, adverse effect associated with the use of angiography. The majority of PUL subjects in these included studies did not require a catheter after void trial and in the remainder of subjects, catheter time was typically less than one day. Post-operative catheter time in PAE is prolonged in comparison. Inconsistent reporting among included studies has prevented calculation of mean catheter times.

None of the included studies on PUL, achieved a final Qmax value greater than 15ml/s. This is in accordance with the results of a recent systematic review and meta-analysis by Perera et al, which reported a sustained improvement in Qmax of only 3.8-4.0ml/s over 12 months [39]. However, the authors add that given the heterogeneity among Qmax outcomes observed during the analysis as well as the small number of data sources of varying quality, that these results should be interpreted cautiously. PUL may

therefore prove to have only a moderate benefit on this functional outcome. The efficacy of PUL appears to be limited by large sized prostates whereas PAE potentially has no size cut off. Given PUL does not halt disease progression, continued growth may require further surgical intervention at a later date. Re-vascularisation and subsequent de novo growth can occur with PAE and warrant repeat embolisation. Moreover, cases of advanced atherosclerosis and excess iliac vessel tortuosity may prevent technical achievement of PAE on one or both sides.

Sexual function:

A significant proportion of patient with bothersome LUTS secondary to BPH will be sexually active. Compromise in sexual function has been a chief limitation of existing surgical interventions for BPH. With the development of any BPH related procedure, improvement of voiding parameters is a critical outcome. Secondary to this, outcome measures in sexual (dys)function are important, concomitant factors to consider when evaluating a new technique and navigating a patient's treatment. To this end, PUL and PAE are a promising development in the surgical management of BPH.

Learning curve:

The learning curve associated with both techniques remains under reported. Chin et al hypothesised that for a practicing urologist, 2 procedures should provide suitable proficiency for carrying out PUL and that after 5 cases, optimal implant placement technique can be achieved [20]. It is the authors' opinion that the learning trajectory for PAE will in any case be steeper, in part owing to the strong elements of interventional radiology involved.

Financial costs and implications for practice:

In the current climate of increasing financial burden and bed crisis faced by medical institutions, the potential these techniques hold for being day case procedures is very attractive. Comparative studies incorporating cost benefit analyses are required in order to determine the long term financial benefit of these technologies. Additionally, they are also suitable for patients with multiple co-morbidities, which contra-indicate general anaesthesia. Shore et al has successfully carried out LA in PUL in 100% of cases and discharged all patients within 24 hours [40]. In regards to PAE, Pisco et al achieved use of solely LA in all patients and 88% of patients were discharged between 3 and 8 hours after the procedure [27]. Drug therapy can be discontinued after both procedures.

Future research:

Given the heterogeneity of inclusion parameters across the studies and lack of standardised end points combined with only a few studies exceeding 12 months follow up, the long term therapeutic feasibility of PUL and PAE requires further research. This is accompanied by a lack of systematic reporting on complications according to formal grading criteria such as the Clavien system [41]. The majority of research on PAE has been carried out at single centres only. As such, modalities such as TURP and arguably HoLEP (for large prostate burdens) are likely to remain the reference treatments for the time being. Future research needs to focus on comparing these all these techniques in a randomised setting with standardised outcome and complication reporting [42]. At present, we are not aware of a multicentre study of PAE versus sham procedure similar to the aforementioned study

involving PUL. See Supplementary Table 3 for summary of advantages and disadvantages of each technique.

Conclusion

Global advances in the surgical management of BPH are indefatigable with the minimally invasive paradigm growing each year. Determining the long-term clinical durability of such advances in the midst of the hype they receive is difficult. PUL and PAE are two inaugural techniques, which can both improve efficacy outcomes including IPSS, QoL and Qmax, which evidence suggests are durable at 12 months follow up. As technical steps of both procedures are mastered further, greater margins in improvement are likely to be achieved. Further refinement of technique is needed in order to consistently deliver these procedures under local anaesthesia and in the outpatient setting. We anticipate that in the younger patient demographic, for candidates with suitable prostate anatomy, PUL will be perceived as an attractive treatment choice owing largely to its strengths in preserving the sexually active status of candidates. For those patients with an obstructing median lobe, whose symptoms are refractory to pharmacotherapy, PAE may represent a suitable alternative to standard interventions.

In the clinician's role as a patient advocate, the urologist must strive to carefully navigate the patient's treatment through counselling and close adherence to the latest evidence available.

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Key for Abbreviations

PAE Prostate Artery Embolisation
PUL Prostatic Urethral Lift
BPH Benign Prostatic Hyperplasia
TURP Trans-urethral Resection of Prostate
IEFF International Index of Erectile Function
AUR Acute Urinary Retention
HoLEP holmium laser enucleation of the prostate
PVR Post Void Residual
QoL Quality of Life
IPSS International Prostate Symptom
PV Prostate Volume
QMAX Maximum Urinary Flow Rate
PSA Prostate Specific Antigen
DSA Digital Subtraction Angiography

Author	Woo [17]	Chin [20] Woo [19]	McNicholas [16]	Roehrborn [21,22] McVary [25]	Cantwell [23]	Sonksen [24]	Antunes [26]	Pisco [27]	Kurbatov [28]	Gao [29]	Wang [30]	
Technique	Prostatic Urethral Lift						Prostate Artery Embolisation					
Publication year	2011	2012, 2012	2013	2013, 2015, 2014	2014	2015	2013	2013	2014	2014	2015	
Sample size	19	64	102	140	53	45	11	255	88	114	115	
Mean age (Years)	66	67	68	67	64	63	68.5	65.5	66.38	67.7	71.5	
Mean procedure time (mins)	NR	NR	57.8	66	53	55	197.5	73	84	89.7	Medium sized prostate group	Large sized prostate group
											105	110
Mean hospital time (days)	NR	NR	NR	NR	NR	1	NR	NR	NR	2.9	2.5	3.5
Local Anaesthetic (%)	0	41	16	82	88	NR	0	100	NR	100	100	100

Table 1. Summary of study characteristics

Author	Mean Prostate Volume (cm ³)		Mean PVR (ml)		Mean Qmax (ml/s)		Mean PSA (ng/ml)	
	Pre-procedure	12 months	Pre-procedure	12 months	Pre-procedure	12 months	Pre-procedure	12 months
Prostate Artery Embolisation								
Antunes [27]	69.7	NR	NR	NR	NR	11.9	10.1	4.3
Pisco [27]	83.5	69.9	102.9	51.7	9.19	12.8	5.68	5.08
Kurbatov [28]	129.31	71.2	75.25	18.38	7.28	16.89	3.67	2.12
Gao [29]	64.7	35.6	126.9	27.3	7.8	22.1	3.7	2.1
Wang [30]	Medium sized prostate subgroup							
	64	45.5	120	60	8.5	13	3.9	3.1
	Large sized prostate subgroup							
	129	74.5	145	65	7.5	13.5	4.2	3.4
Prostatic Urethral Lift								
Woo [17]	49	NR	170	130	7.4	9.9	5.3	4.4
Chin [20]	51	NR	89	98	8.2	10.8	4	4.3
Woo [19]								
McNicholas[16]	48	NR	NR	NR	7.8	11.9	NR	NR
Roerhborn[21,22]	44.5	NR	82	72	8.1	12.1	2.4	NR
McVary [25],								
Cantwell [23]	40.3	NR	68.02	56.8	9.9	12.5	2.26	NR
Sonksen[24]	38	NR	86.3	93.7	9.6	13.6	2.4	NR

Table 2. 12 month objective outcomes

NR Not Reported

Author	Mean IPSS		Mean QoL		IIEF-5 (SHIM)	
	Pre-procedure	12 months	Pre-procedure	12 months	Pre-procedure	12 months
Prostate Artery Embolisation						
Antunes [26]	NR	2.8	NR	NR	NR	NR
Pisco [27]	24.1	10.4	4.39	1.96	20.6	20.1
Kurbatov [28]	23.98	10.4	5.1	7.28	NR	15.3
Gao [29]	22.8	12.8	4.8	7.8	NR	NR
Wang [30]	Medium sized prostate group					
	23.5	12	4.5	2.5	18	NR
	Large sized prostate group					
	26	12	5.5	2	10	NR
Prostatic Urethral Lift						
Woo [17]	22.1	12.5	4.6	2.5	NR	NR
Chin [20]	22.5	12.1	4.8	2.5	17.9	19.7
Woo [19]						
McNicholas [16]	23.9	11.6	4.8	2.3	NR	NR
Roerhborn [21,22]	21.8	11.1	4.8	2.5	18.2	18.6
McVary [25]						
Cantwell [23]	23.3	14.6	12.8	16.5	15.9	16.8
Sonksen [24]	22	10.7	4.7	1.9	20.8	20.7

Table 3. 12 month subjective objectives

NR Not Reported