

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Transurethral electrovaporisation of the prostate

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Transurethral electrovaporisation of the prostate (TEVAP). There are various other abbreviations including TVP, TUV/P, TUVP and TUEVAP.

SERNIP procedure number

112

Specialty society

British Association of Urological Surgeons

Executive Summary

Transurethral electrovaporisation of the prostate is a minimally invasive treatment for BPO. However, despite the number of randomised controlled trials which have been conducted, follow-up for this procedure has not been long (the longest follow-up being three years), and the quality of available evidence is average. Transurethral electrovaporisation of the prostate appears to be as efficacious as TURP in the short-term and differences could not be detected in rates of complication with the exception of short-term irritative symptoms and urinary retention. However, due to the relatively short follow-up periods, long-term treatment durability has yet to be established.

Indication(s)

Benign Prostatic Obstruction (BPO).

Benign prostatic obstruction (BPO), a non-malignant enlargement of the prostate, is a common cause of lower urinary tract symptoms in men older than 40 years of age and a widely accepted antecedent of bladder outlet obstruction.¹ Although the aetiology of BPO is still poorly understood, it is nonetheless prevalent in men over 50 years of age to the extent that two out of ten males will eventually require an operation to relieve the symptoms of BPO.^{2,3,4,5} Increasing resistance to urinary flow caused by the enlarged prostate gland results in bladder hypertrophy and progressively higher voiding pressure, which in turn produces obstructive symptoms such as a weak stream, hesitancy and incomplete voiding. The irritative symptoms such as frequency, nocturia and dysuria are generally attributed to the

increasing instability of the hypertrophied bladder. A syndrome of bladder decompensation can eventually develop if the bladder is unable to adapt.⁶ This can manifest as an accumulation of residual urine, which can lead to recurrent urinary tract infections and the formation of bladder calculi.⁵ In severe cases, acute urinary retention can occur and obstructive nephropathy can develop if high voiding pressures are transmitted back to the kidneys.⁶

BPO can be managed either medically or surgically. The gold-standard surgical treatment is Transurethral Resection of the Prostate (TURP). However, relatively high morbidity for this procedure has led to the development of a range of minimally invasive techniques, some of which utilise thermal energy. Transurethral electrovaporisation of the prostate is one such technique which utilises high voltage electrical current to vaporise prostatic tissue and create a cavity in the prostate, so that symptoms caused by obstruction are reduced.

Summary of procedure

Transurethral electrovaporisation of the prostate, an electroablative technique, is performed with a specially designed modified rollerball electrode. Under general or spinal anaesthesia, electrical energy is applied at 240-300W for cutting and 40-70W for coagulation. The electrode is rolled over the prostatic tissue to create an area of vaporisation of 3 to 4mm and an underlying coagulative necrosis of 0.1 to 0.5mm.⁷ Vaporisation continues until an appropriate cavity is created.⁸ A urethral catheter is left in-dwelling at the end of the procedure.

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on transurethral electrovaporisation of the prostate in the form of randomised controlled trials (RCT), other controlled or comparative studies, case series and case reports. Where there were 5 RCTs then no further studies were included.

Studies found: There were 15 RCTs retrieved from the literature. After considering the fulltext of the articles, four were excluded because they used a modified technique for electrovaporisation (three used a thick-loop resection technique, and one only used the rolling ball for cutting, and not coagulating). This left 11 RCTs which described the transurethral electrovaporisation of the prostate procedure. Selection of studies for inclusion in this overview was based on methodological quality and completeness of reporting on safety and efficacy outcomes. Results for six RCTs have been included, as one study, which compared transurethral electrovaporisation of the prostate both to TURP and to contact laser vaporisation, was included for completeness. (See Annex for list of excluded studies and reasons for exclusion.)

List of studies included: RCTs – 5 (comparator TURP) RCTs – 1 (comparators TURP and contact laser vaporisation)



Summary of key efficacy and safety findings

See followir	ng tables; ons
AUA	American Urological Assocation
BPH	Benign Prostatic Hyperplasia
BPO	Benign Prostatic Obstruction
LT	Long-term
PVR	Post Void Residual volume
Q _{max}	Peak Flow at Maximum Pressure
RCT	Randomised Controlled Trial
TEVAP	Transurethral Electrovaporisation of the Prostate
TRUS	Transrectal Ultrasonography
TUR	Transurethral
TURP	Transurethral Resection of the Prostate
1171	Lirinary Tract Infection

UTI Urinary Tract Infection



Study	Key efficacy finding	S		Key safety findings			Validity and generalisability
Hammadeh <i>et al</i> . 2000 ⁹ , 1998 ⁸	Mean [SD] (at 3yrs)	TEVAP	TURP	Number of patients	TEVAP	TURP	Potential for bias:
Hammadeh, Madaan <i>et al</i> .	IPSS Symptom Score	4.1[3.3]	7.1[6.2] [†]	Early	N=52	N=52	• blinding of outcomes assessor at 2
19981	QoL	1.0[0.9]	1.6[1.4]*	Urinary retention	12	4*	and 3 year follow-up
UK	PVR Volume (mL)	30.0[38.0]	21.9[26.2] ^{pns}	Blood transfusion	0	1 ^{pns}	• allocation concealment by sealed
N=109	O_{max} (mL/sec)	22.2[8.5]	18 0[7 1]*	Clot retention	0	4*	• small sample size may have limited
TEVAP: 55	Qmax (IIIL, See)	22.2[0.0]	10.0[7.1]	2 nd haemorrhage	2	2	power to detect differences
TURP: 54	N of patients (%)			UTI	3	2^{pns}	• losses to follow-up
June 1995 – December, 1995	Reoperation rate yr 3	2/40	2/40	TUR syndrome	0	0	 3 TEVAP and 2 TURP lost to
	yr 2	2/47	2/47	5			early FU (after randomisation)
Follow-up: 3 years	yr 1	2/51	2/51	Long-term (after 3 years)	N=40	N=40	\circ 12 in each arm at 3 years
	Incontinence	0	0	Irritative symptoms	13	18 ^{pns}	TURP – 9
Selection Criteria:	Postop, impotence	5	3 pns	Urethral stricture	2	2	• died of cardiopulmonary disease:
• admitted from waiting list	Retrograde eiac	21	25 ^{pns}	Bladder neck stenosis	1	2 ^{pns}	TEVAP -1 , TURP -2
for TURP $DSS Same > 12$	Rettograde ejae.	21	25				• could not attend due to declining
• IPSS Score > 15		25.0(10.50)	$21.((10.50)^{\dagger})$				mobility: $IEVAP - 2$, $IURP - 1$
• $Omax < 15mL/sec$	Operative time (min)	25.9 (10-50)	21.6(10-50)*				 did not measure affect size
 with or without significant PVR volume 	Catheterisation (hrs)	20.9 (9-24)	46.6(14-92)*				no power calculations
	Hospital stay (days)	2.2 (1.7-3.8)	$3.1(1.6-5.7)^{1}$				- no power carculations
							<i>Outcome measures and their validity:</i> IPSS – International Prostate Symptom

Significant changes from pre to postoperative scores in all parameters (p<0.001) for both groups

Other comments:

rating scale

unknown

• 2 patients underwent repeat TUVP

Score – validated patient symptom

QOL – Quality of life – validation

• no detectable difference between senior and trainee surgeons

pns = not significant * = p < 0.05 $\dagger = p < 0.01$ $\ddagger = p < 0.001$ \$ = p < 0.001

Prepared by ASERNIP-S

Study	Key efficacy findings	Key efficacy findings Key safety findings					
Erdagi <i>et al.</i> 1999 ¹¹	Mean (range) (at 6mths)	TEVAP	TURP	Number of patients	TEVAP	TURP	Potential for bias:
TURKEY	IPSS Symptom Score	0.9 (0-3)	3.9(1-9) ^{pns}	Haematuria	5	12*	• no information regarding
N=40	PVR Volume	3.6	6.0 ^{pns}	Clot retention (requiring	0	5*	randomisation, allocation
TEVAP: 20	Q _{max} (mL/sec)	21.4	17.7*	recatheterisation)			• small sample size may have limited
TURP: 20				Blood transfusion	0	9*	power to detect differences
	Operative time (mins)	61.5	67.7 ^{pns}	UTI	1	5*	• short follow-up period
August 1996 – January 1997	Catheterisation (hrs)	25.8	81.6 [‡]	Urethral stricture	0	1 ^{pns}	 did not measure effect size
<i>Follow-up:</i> 6 months							• no power calculations
	Sexually active patients						Outcome measures and their validity:
Selection Criteria:	Retrograde ejaculation	2/16	12/17 [‡]				IPSS – International Prostate Symptom
• consecutive selection	No change sexual function	16/16	17/17				Score – validated patient symptom
• excluded If known prostate cancer neurogenic bladder							rating scale
previous prostatic surgery							
• included with chronic	Statistically significant sha	Other comments:					
retention (10 in each arm)	nostoperative scores in all r						
and indwelling catheter (5	both groups						
in each arm)							
Küpeli et al. 1998 ¹²	Mean [SD] (at 12mths)	TEVAP	TURP	Number of patients	TEVAP	TURP	Potential for bias:
TURKEY	AUA Symptom Score	6.1	7.0	Blood transfusion	0	2	• 76 eligible for TEVAP
N-CC	Qmax (mL/sec)	17.3	19.6	Urinary retention	1	0	• randomisation by toss of a coin – not
N=00 TEVAP: 30				Urethral stricture	0	0	clear if adequate
TURP: 36		20 (17 2)	41 450 03PBS		0	0	• small sample size may have infined
	Operative time(mins)	38.6[7.3]	41.4[8.0] ^{ph3}	UII	4	3	• relatively short follow-up period and
July 1995 – October 1995	Catheterisation (hrs)	38.4[19.2]	91.2[33.6] [§]	Irritative symptoms	10	3*	losses to follow-up (10 patients)
Follow up: 12 months	Hospital Stay (days)	1.9[0.9]	4.2[1.5] [§]	(longlasting)			• did not measure effect size
<i>Follow-up:</i> 12 months	Blood Loss (mL)	60	340 [‡]	Bladder perforation	1	0	• no power calculations
Selection Criteria:		00	210	Diadadi periotation	-	Ũ	Outcome measures and their validity
• AUA Score > 7							O_{max} – peak flow at maximum pressure
• Qmax < 15mL/sec	Number of patients	1	0				AUA – American Urological
 excluded prostate weight > 60g and prostate concert 	Reoperation	1	0				Association Symptom Score –
oug and prostate cancer	Incontinence	1	1				validated patient symptom rating scale
	Note: statistical comparisons not reported for						
	symptom score and peak flo	OW.					complications of TEVAP may be a
							result of operator inexperience

pns = not significant * = p < 0.05 $\dagger = p < 0.01$ $\ddagger = p < 0.001$ \$ = p < 0.001

Study	Key efficacy findings Key safety findings						Validity and generalisability		
Gallucci <i>et al.</i> 1998 ⁷	Mean (SE) (at 12m)	TEVAP	TURP	Number of patients	TEVAP	TURP	Potential for bias:		
ITALY	IPSS Symptom Score	4.0(0.5)	$3.5(0.3)^{\text{pns}}$	Haematuria (no transfusion)	4 7		• no information regarding		
N-150	PVR Volume (mL)	5.2(2.4)	3.1(2.0) ^{pns}	Blood transfusion	0	0	randomisation, allocation		
TEVAP: 70	Qmax (mL/sec)	20.3(0.7)	20.3(0.7) ^{pns}	Urethral stricture	3	3	 power calculations not undertaken to 		
TURP: 80					0	1	calculate sample size (although		
-	Catheterisation (days)	48.0(2.4)	64.8(2.4) [§]	Cervical stricture	0	1	states that sample has "sufficient		
Dates not stated	Hospital stay (days)	3.9(0.2)	$4.7(0.2)^{\$}$	Capsular perforation	1	0	numbers"		
<i>Follow-up:</i> 12 months				Transient urinary retention	12	3	• relatively short follow-up period		
, , , , , , , , , , , , , , , , , , ,	Number of patients			Epididymitis	1	4	Outcome measures and their validity:		
Selection Criteria:	Transient stress	13	0				IPSS – International Prostate		
• symptomatic BPH and	12m stress	4	1				Symptom Score – validated patient		
urodynamically assessed	Urge	0	2				symptom rating scale		
• excluded if complete urinary							Other comments: Although no patients		
retention, bladder calculi,	Postop. impotence	0	0				were lost to follow-up at 12 months		
prostate weight $> 70g$,	Incontinonac significantly		for most analyses there were						
bladder or prostate cancer,	Incontinence significantly higher in TEVAP patients (p value not stated) significant missing data. The re-								
mental of psychological	Significant changes from	does not state how many patients							
illness							contributed to each analyses at each		
Shokeir <i>et al.</i> 1998 ¹⁴	Mean [SD] (at 12m)	TEVAP	TURP	Number of natients	TEVAP	TURP	lonow-up point.		
SAUDI ARABIA	AUA Symptom Score	5.2[1.4]	$4.7[1.5]^{pns}$	Persistent irritative	3	2	-		
	PVR Volume (mL)	23.4[10.1]	25.3[11.5] ^{pns}	symptoms	-	_			
N=70	Omax (mL/sec)	20 1[3 2]	$18.2[3.0]^{pns}$						
TEVAP: 35	Qinax (IIIL/ See)	20.1[5.2]	10.2[5.0]						
1014.5	Catheterisation (days)	26.4[9.6]	48.0[19.2] [‡]						
October 1995 – March 1996	Hospital stay (days)	1.5[0.7]	2.5[1.0] [‡]						
<i>Follow-up:</i> 12 months									
Selection Criteria	Sexually active patients								
consective selection	Retrograde ejaculation	18/18	15/15						
• AUA >15	Postoperative impotence	2/18	0/15						
• $Qmax < 12mL/s$									
• TRUS volume < 60g									
excluded with neurogenic									
bladder, prostate cancer,	Significant changes from	pre to postope	erative scores						
bladder stone, prior prostate	in all parameters (p<0.001) for both groups								
		,	-rp-						

pns = not significant * = p < 0.05 † = p < 0.01 ‡ = p < 0.001 § = p < 0.001

Study	Key efficacy finding	S			Key safety findings	Validity and generalisability
van Melick <i>et al.</i> 2002 ¹³ THE NETHERLANDS	Mean [SD] (at 6m)	TEVAP (n=33)	TURP (n=37)	Laser (n=33)	Not reported	<i>Potential for bias</i>:no information regarding
	IPSS	7.2[6.7]	5.3[5.1]	6.6[5.8]	-	randomisation, allocation
N=141 TEVAP: 45	QoL	1.6[1.6]	0.9[1.2]	1.1[1.1]		concealment or blinding
TURP: 50 Contact laser: 46	Bother Score	3.5[4.6]	2.1[4.2]	2.8[4.4]		 losses to follow-up period losses to follow-up (at 6 months 38 patients)
1996 - 2001	Qmax (mL/sec)	23.0[10.0]	24.0[7.0]	24.0[7.0]		Outcome measures and their validity:
Follow-up: 6 months	Schäfer Grade	1.0[0.7]	0.8[0.6]	1.0[1.0]		Schäfer Grade – urodynamic obstruction rating 0-4
 Selection Criteria: age > 45 years symptomatic BPH urodynamic obstruction (Schäfer Grade > 2) prostate volume 20 - 65mL 	No significant difference (p<0.05)	the between the th	ree groups post	operatively	IPSS – International Prosta Score – validated patient sy rating scale QOL – Quality of life – AU validation unknown Bother score –Symptom Pr Index – validation unknow	Score – validated patient symptom rating scale QOL – Quality of life – AUA rating- validation unknown Bother score –Symptom Problem Index – validation unknown
 with or without significant PVR volume excluded if met any exclusion criteria of International Consensus Committee on BPH 	measures in all groups ((p<0.05)	eoperative score	es for all		 Other comments: primarily study of urodynamic outcomes power calculations were done to determine required sample size urodynamic outcomes reported for 6 month follow-up point, as losses to follow-up significant at 12 month follow-up point (90 patients)

Specialist Advisors' opinions

Specialist advice was sought from the British Association of Urological Surgeons.

Specialist Advisors rated transurethral electrovaporisation of the prostate as a variation of the TURP procedure, however one rated it as definitely novel. They suggested that TEVAP is being used by no more than 25% of urologists and only in a minority of hospitals. The impact on the NHS was expected to be moderate. One Specialist Advisor stated that there were no adverse effects or safety concerns regarding transurethral electrovaporisation of the prostate, however the other advisors stated that serious post-operative haemorrhage (for several hours) and the possibility of metabolic disorders were potential complications, although no citations were supplied for these. There was some evidence of an increased risk of incontinence compared with TURP but otherwise adverse events were about the same with less blood loss in transurethral electrovaporisation of the prostate. With regard to efficacy, the Specialist Advisors raised concerns about the long-term durability of transurethral electrovaporisation of the prostate, and suggested that efficacy is probably limited to smaller prostates (<40g). One Advisor suggested that training for transurethral electrovaporisation of the prostate should be easily encompassed within standard endoscopic urological training. Another Advisor stated that transurethral electrovaporisation of the prostate was "thought to be too widely used considering the paucity of outcome data".

Issues for consideration by IPAC

The technique of transurethral electrovaporisation of the prostate has now evolved to utilise a large resection loop for vaporisation instead of the rolling ball electrode. Three RCTs were identified which utilised this new technique.

A randomised controlled trial comparing TURP with transurethral diathermy vaporisation of the prostate was identified from the National Research Register. It is not clear from the available information whether this uses the same technique as transurethral electrovaporisation of the prostate. The trial is being conducted by Mr Christopher Fowler at the Royal London Hospital.



References

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- Roehrborn CG, Issa MM, Bruskewitz RC, Naslund MJ, Oesterling JE, Perez MR, Shumaker BP, Narayan P. Transurethral needle ablation for benign prostatic hyperplasia: 12-month results of a prospective, multicenter U.S. study. *Urology* 1998;**51**(3):415-421.
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Tabulated Studies

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 possible alternative to transurethral resection a one-year follow-up of a prospective randomized trial. *British Journal of Urology* 1998;81(5):721-725.
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- 13. Shokeir AA, Alsisi H, Farage YM, Elmaaboud MA, Saeed M, Mutabagani H. Transurethral prostatectomy a prospective randomized study of conventional resection and electrovaporization in benign prostatic hyperplasia. *British Journal of Urology* 1997;**80**(4):570-574.
- 14. van Melick H, van Venrooij G, Eckhardt M, Boon T. A randomised controlled trial comparing transurethral resection of the prostate, contact laser prostatectomy and electrovaporisation in men with benign prostatic hyperplasia: urodynamic effects. *Journal of Urology* 2002;**168**:1058-1062.

Annex – Excluded Studies

Nathan MS, Wickham JEA. TVP: A cheaper and effective alternative to TURP. *Minimally Invasive Therapy & Allied Technologies* 1996;**5**(3):292-296. <u>Reasons for exclusion</u>: a cost analysis therefore limited data available, on safety in particular

Kupeli S, Baltaci S, Soygur T, Aytac S, Yilmaz E, Budak M. A prospective randomized study of transurethral resection of the prostate and transurethral vaporization of the prostate as a therapeutic alternative in the management of men with bph. *European Urology* 1998;**34**(1):15-18. <u>Reasons for exclusion</u>: short follow-up (3 months) and no or very limited information regarding randomisation, allocation concealment, and blinding, and no power calculations to determine sample size

Cetinkaya M, Ulusoy E, Adsan O, Saglam H, Ozturk B, Basay S. Comparative early results of transurethral electroresection and transurethral electrovaporization in benign prostatic hyperplasia. *British Journal of Urology* 1996;**78**(6):901-903. <u>Reasons for exclusion</u>: short follow-up (3 months) and no or very limited information regarding randomisation, allocation concealment, and blinding, and no power calculations to determine sample size

Cetinkaya M, Ozturk B, Akdemir O, Ozden C, Aki FT. A comparison of fluid absorption during transurethral resection and transurethral vaporization for benign prostatic hyperplasia. *BJU International* 2000;**86**(7):820-823. <u>Reasons for exclusion:</u> intra-operative results only therefore limited data on safety and efficacy

Patel A, Fuchs GJ, Gutierrez-Aceves J, Andrade-Perez F. Completeness and efficiency of prostate tissue removal: loop resection compared with a new operative technique of transurethral electrovaporization. *BJU International* 1999;**84**(1):43-49. <u>Reasons for exclusion:</u> prostate volume study therefore limited data on safety and efficacy

Netto NR, De Lima ML, Lucena R, Lavoura HS, Cortada PD, Netto MR. Is transurethral vaporization a remake of transurethral resection of the prostate? *Journal of Endourology* 1999; **13**(8):591-594. <u>Reasons for exclusion:</u> not describing TEVAP procedure

Holmes M, Cox J, Stewart J, King D, Bary P, Wright W. Thick vs thin loop transurethral resection of the prostate: a double-blind prospective trial of early morbidity. *BJU International* 2002;**89**(3):197-201. <u>Reasons for exclusion:</u> modified TEVAP procedure using thick loop instead of rollerball electrode

Talic RF, El Tiraifi AM, El Faqih SR, Hassan SH, Attassi RA, Abdel-Halim RE. Prospective randomized study of transurethral vaporization resection of the prostate using the thick loop and standard transurethral prostatectomy. *Urology* 2000;**55**(6):886-890. <u>Reasons for exclusion:</u> modified TEVAP procedure using thick loop instead of rollerball electrode

Helke C, Manseck A, Hakenberg OW, Wirth MP. Is transurethral vaporesection of the prostate better than standard transurethral resection? *European Urology* 2001;**39**(5):551-557. <u>Reasons for exclusion</u>: modified TEVAP procedure using thick loop instead of rollerball electrode