



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, TUV 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 full-text 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 following tables;

Abbreviations

AUA	American Urological Association
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
UTI	Urinary Tract Infection

Study	Key efficacy findings			Key safety findings			Validity and generalisability
Hammadeh <i>et al.</i> 2000⁹, 1998⁸	Mean [SD] (at 3yrs)	TEVAP	TURP	Number of patients	TEVAP	TURP	<i>Potential for bias:</i>
Hammadeh, Madaan <i>et al.</i> 1998¹⁰	IPSS Symptom Score	4.1[3.3]	7.1[6.2] [†]	<i>Early</i>	N=52	N=52	• blinding of outcomes assessor at 2 and 3 year follow-up
UK	QoL	1.0[0.9]	1.6[1.4]*	Urinary retention	12	4*	• allocation concealment by sealed envelope – unclear if this is adequate
N=109	PVR Volume (mL)	30.0[38.0]	21.9[26.2] ^{pns}	Blood transfusion	0	1 ^{pns}	• small sample size may have limited power to detect differences
TEVAP: 55	Q _{max} (mL/sec)	22.2[8.5]	18.0[7.1]*	Clot retention	0	4*	• losses to follow-up
TURP: 54	<i>N of patients (%)</i>			2 nd haemorrhage	2	2	◦ 3 TEVAP and 2 TURP lost to early FU (after randomisation)
June 1995 – December, 1995	Reoperation rate yr 3	2/40	2/40	UTI	3	2 ^{pns}	◦ 12 in each arm at 3 years
	yr 2	2/47	2/47	TUR syndrome	0	0	◦ could not be traced: TEVAP-9, TURP – 9
<i>Follow-up: 3 years</i>	yr 1	2/51	2/51	<i>Long-term (after 3 years)</i>	N=40	N=40	◦ died of cardiopulmonary disease: TEVAP – 1, TURP – 2
<i>Selection Criteria:</i>	Incontinence	0	0	Irritative symptoms	13	18 ^{pns}	◦ could not attend due to declining mobility: TEVAP – 2, TURP – 1
• admitted from waiting list for TURP	Postop. impotence	5	3 ^{pns}	Urethral stricture	2	2	• conversions – 4 TEVAP to TURP
• IPSS Score > 13	Retrograde ejac.	21	25 ^{pns}	Bladder neck stenosis	1	2 ^{pns}	• did not measure effect size
• QOL > 3	Operative time (min)	25.9 (10-50)	21.6(10-50) [†]				• no power calculations
• Qmax < 15mL/sec	Catheterisation (hrs)	20.9 (9-24)	46.6(14-92) [‡]				
• with or without significant PVR volume	Hospital stay (days)	2.2 (1.7-3.8)	3.1(1.6-5.7) [§]				
Significant changes from pre to postoperative scores in all parameters (p<0.001) for both groups							<i>Outcome measures and their validity:</i>
							IPSS – International Prostate Symptom Score – validated patient symptom rating scale
							QOL – Quality of life – validation unknown
							<i>Other comments:</i>
							• 2 patients underwent repeat TUV
							• no detectable difference between senior and trainee surgeons

pns = not significant * = p < 0.05 † = p < 0.01 ‡ = p < 0.001 § = p < 0.0001

Study	Key efficacy findings			Key safety findings			Validity and generalisability
Erdagi et al. 1999¹¹ TURKEY	Mean (range) (at 6mths)	TEVAP	TURP	Number of patients	TEVAP	TURP	<i>Potential for bias:</i>
N=40	IPSS Symptom Score	0.9 (0-3)	3.9(1-9) ^{pns}	Haematuria	5	12*	• no information regarding randomisation, allocation concealment or blinding
TEVAP: 20	PVR Volume	3.6	6.0 ^{pns}	Clot retention (requiring recatheterisation)	0	5*	• small sample size may have limited power to detect differences
TURP: 20	Q _{max} (mL/sec)	21.4	17.7*	Blood transfusion	0	9*	• short follow-up period
August 1996 – January 1997	Operative time (mins)	61.5	67.7 ^{pns}	UTI	1	5*	• did not measure effect size
	Catheterisation (hrs)	25.8	81.6 [‡]	Urethral stricture	0	1 ^{pns}	• no power calculations
<i>Follow-up: 6 months</i>							
<i>Selection Criteria:</i>	<u>Sexually active patients</u>						<i>Outcome measures and their validity:</i>
• consecutive selection	Retrograde ejaculation	2/16	12/17 [‡]				IPSS – International Prostate Symptom Score – validated patient symptom rating scale
• excluded if known prostate cancer, neurogenic bladder, previous prostatic surgery	No change sexual function	16/16	17/17				
• included with chronic retention (10 in each arm) and indwelling catheter (5 in each arm)	Statistically significant changes from pre to postoperative scores in all parameters (p<0.001) for both groups						<i>Other comments:</i>
Küpelı et al. 1998¹² TURKEY	Mean [SD] (at 12mths)	TEVAP	TURP	Number of patients	TEVAP	TURP	<i>Potential for bias:</i>
N=66	AUA Symptom Score	6.1	7.0	Blood transfusion	0	2	• 76 eligible for TEVAP
TEVAP: 30	Q _{max} (mL/sec)	17.3	19.6	Urinary retention	1	0	• randomisation by toss of a coin – not clear if adequate
TURP: 36				Urethral stricture	0	0	• small sample size may have limited power to detect differences
July 1995 – October 1995	Operative time(mins)	38.6[7.3]	41.4[8.0] ^{pns}	UTI	4	3	• relatively short follow-up period and losses to follow-up (10 patients)
	Catheterisation (hrs)	38.4[19.2]	91.2[33.6] [§]	Irritative symptoms (longlasting)	10	3 [†]	• did not measure effect size
<i>Follow-up: 12 months</i>	Hospital Stay (days)	1.9[0.9]	4.2[1.5] [§]	Bladder perforation	1	0	• no power calculations
	Blood Loss (mL)	60	340 [‡]				
<i>Selection Criteria:</i>							<i>Outcome measures and their validity:</i>
• AUA Score > 7	<u>Number of patients</u>						Q _{max} – peak flow at maximum pressure
• Q _{max} < 15mL/sec	Reoperation	1	0				AUA – American Urological Association Symptom Score – validated patient symptom rating scale
• excluded prostate weight > 60g and prostate cancer	Incontinence	1	1				
	Note: statistical comparisons not reported for symptom score and peak flow.						<i>Other comments:</i>

pns = not significant * = p < 0.05 † = p < 0.01 ‡ = p < 0.001 § = p < 0.0001

Study	Key efficacy findings			Key safety findings			Validity and generalisability
Gallucci <i>et al.</i> 1998⁷ ITALY N=150 TEVAP: 70 TURP: 80 Dates not stated Follow-up: 12 months Selection Criteria: - symptomatic BPH and urodynamically assessed obstruction - excluded if complete urinary retention, bladder calculi, prostate weight > 70g, bladder or prostate cancer, mental or psychological illness	Mean (SE) (at 12m)	TEVAP	TURP	Number of patients	TEVAP	TURP	<i>Potential for bias:</i> - no information regarding randomisation, allocation concealment or blinding - power calculations not undertaken to calculate sample size (although states that sample has “sufficient numbers”) - relatively short follow-up period <i>Outcome measures and their validity:</i> IPSS – International Prostate Symptom Score – validated patient symptom rating scale <i>Other comments:</i> Although no patients were lost to follow-up at 12 months for most analyses there were significant missing data. The report does not state how many patients contributed to each analyses at each follow-up point.
	IPSS Symptom Score	4.0(0.5)	3.5(0.3) ^{pns}	Haematuria (no transfusion)	4	7	
	PVR Volume (mL)	5.2(2.4)	3.1(2.0) ^{pns}	Blood transfusion	0	0	
	Qmax (mL/sec)	20.3(0.7)	20.3(0.7) ^{pns}	Urethral stricture	3	3	
	Catheterisation (days)	48.0(2.4)	64.8(2.4) [§]	Cervical stricture	0	1	
	Hospital stay (days)	3.9(0.2)	4.7(0.2) [§]	Capsular perforation	1	0	
				Transient urinary retention	12	3	
				Epididymitis	1	4	
	<u>Number of patients</u>						
	Incontinence						
	Transient stress	13	0				
	12m stress	4	1				
	Urge	0	2				
	Postop. impotence	0	0				
	Incontinence significantly higher in TEVAP patients (p value not stated)			Significant changes from pre to postoperative scores in all parameters for both groups (p value not stated)			
Shokeir <i>et al.</i> 1998¹⁴ SAUDI ARABIA N=70 TEVAP: 35 TURP: 3 October 1995 – March 1996 Follow-up: 12 months Selection Criteria: - consecutive selection - AUA >15 - Qmax < 12mL/s - TRUS volume < 60g - excluded with neurogenic bladder, prostate cancer, bladder stone, prior prostate surgery, acute urinary retention, indwelling catheter	Mean [SD] (at 12m)	TEVAP	TURP	Number of patients	TEVAP	TURP	
	AUA Symptom Score	5.2[1.4]	4.7[1.5] ^{pns}	Persistent irritative symptoms	3	2	
	PVR Volume (mL)	23.4[10.1]	25.3[11.5] ^{pns}				
	Qmax (mL/sec)	20.1[3.2]	18.2[3.0] ^{pns}				
	Catheterisation (days)	26.4[9.6]	48.0[19.2] [‡]				
	Hospital stay (days)	1.5[0.7]	2.5[1.0] [‡]				
	<u>Sexually active patients</u>						
	Retrograde ejaculation	18/18	15/15				
	Postoperative impotence	2/18	0/15				
	Significant changes from pre to postoperative scores in all parameters (p<0.001) for both groups						

pns = not significant * = p < 0.05 † = p < 0.01 ‡ = p < 0.001 § = p < 0.0001

Study	Key efficacy findings				Key safety findings	Validity and generalisability
van Melick <i>et al.</i> 2002¹³ THE NETHERLANDS	Mean [SD] (at 6m)	TEVAP (n=33)	TURP (n=37)	Laser (n=33)	Not reported	<i>Potential for bias:</i>
N=141	IPSS	7.2[6.7]	5.3[5.1]	6.6[5.8]		• no information regarding randomisation, allocation concealment or blinding
TEVAP: 45	QoL	1.6[1.6]	0.9[1.2]	1.1[1.1]		• short follow-up period
TURP: 50	Bother Score	3.5[4.6]	2.1[4.2]	2.8[4.4]		• losses to follow-up (at 6 months 38 patients)
Contact laser: 46						
1996 - 2001	Qmax (mL/sec)	23.0[10.0]	24.0[7.0]	24.0[7.0]		<i>Outcome measures and their validity:</i>
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
<i>Selection Criteria:</i>						IPSS – International Prostate Symptom Score – validated patient symptom rating scale
• age > 45 years						QOL – Quality of life – AUA rating-validation unknown
• symptomatic BPH	No significant difference between the three groups postoperatively (p<0.05)					Bother score – Symptom Problem Index – validation unknown
• urodynamic obstruction (Schäfer Grade > 2)						<i>Other comments:</i>
• prostate volume 20 – 65mL	Statistically significant changes from preoperative scores for all measures in all groups (p<0.05)					• primarily study of urodynamic outcomes
• with or without significant PVR volume						• power calculations were done to determine required sample size
• excluded if met any exclusion criteria of International Consensus Committee on BPH						• 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

1. De La Rosette J, D'Ancona FCH, Debruyne FMJ. Current status of thermotherapy of the prostate. *Journal of Urology* 1997;**157**:430-438.
2. Bruskewitz RC. Management of symptomatic BPH in the US: who is treated and how? *European Urology* 1999;**36**(Suppl 3):7-13.
3. 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.
4. de Wildt M, De La Rosette J. Transurethral microwave thermotherapy: An evolving technology in the treatment of benign prostatic enlargement. *British Journal of Urology* 1995;**76**:531-538.
5. Jepsen J, Bruskewitz R. Recent developments in the surgical management of benign prostatic hyperplasia. *Urology* 1998;**51**(4A):23-31.
6. Portis A, Mador D. Treatment options for benign prostatic hyperplasia. *Canadian Family Physician* 1997;**43**:1395-1404.

Tabulated Studies

7. Gallucci M, Puppo P, Perachino M, Fortunato P, Muto G, Breda G, Mandressi A, Comeri G, Boccafroschi C, Francesca F, Guazzieri S, Pappagallo GL. Transurethral electrovaporization of the prostate vs. Transurethral resection - results of a multicentric, randomized clinical study on 150 patients. *European Urology* 1998;**33**(4):359-364.
8. Hammadeh MY, Fowles GA, Singh M, Philp T. Transurethral electrovaporization of the prostate - a possible alternative to transurethral resection - a one-year follow-up of a prospective randomized trial. *British Journal of Urology* 1998;**81**(5):721-725.
9. Hammadeh MY, Madaan S, Singh M, Philp T. A 3-year follow-up of a prospective randomized trial comparing transurethral electrovaporization of the prostate with standard transurethral prostatectomy. *BJU International* 2000;**86**(6):648-651.
10. Hammadeh MY, Madaan S, Singh M, Philp T. Two-year follow-up of a prospective randomised trial of electrovaporization versus resection of prostate. *European Urology* 1998;**34**(3):188-192.
11. Erdagi U, Akman RY, Sargin SY, Yazicioglu A. Transurethral electrovaporization of the prostate versus transurethral resection of the prostate: a prospective randomized study. *Archivio Italiano di Urologia, Andrologia* 1999;**71**(3):125-130.
12. Kupeli B, Yalcinkaya F, Topaloglu H, Karabacak O, Gunlusoy B, Unal S. Efficacy of transurethral electrovaporization of the prostate with respect to standard transurethral resection. *Journal of Endourology* 1998;**12**(6):591-594.
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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: 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. Reasons for exclusion: modified TEVAP procedure using thick loop instead of rollerball electrode

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