

ΚΥΠ:

Νεότερα δεδομένα στη χειρουργική αντιμετώπιση

Χαράλαμπος Κ. Μαμουλάκης

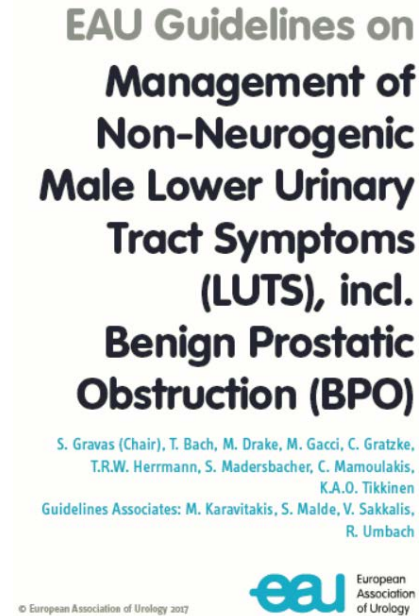
Αναπληρωτής Καθηγητής Ουρολογίας Παν. Κρήτης

Διευθυντής Ουρολογικής Κλινικής

Πανεπιστημιακό Γενικό Νοσοκομείο Ηρακλείου



Συστηματική ανασκόπηση διεθνούς βιβλιογραφίας



Literature Search Update for
EAU guidelines on Management of non-neurogenic male LUTS, 2017

- ◆ Πλήρη άρθρα σύγκρισης των χειρουργικών τεχνικών:
 - Τυχαιοποιημένες Κλινικές Δοκιμές (RCTs)
 - Συστηματικές ανασκοπήσεις/Μετα-αναλύσεις RCTs



Ποιότητα των RCTs

- ◆ High-quality surgical - urologic RCTs with adequate follow-up: scarce in several fields including BPO-related LUTS management
- ◆ Consequent limitations of RCT-based meta-analyses
- ◆ **Rely on “best available” evidence**

Bachmann et al. Eur Urol. 2013;63:677-9

Mamoulakis et al. Eur Urol. 2013;63:679-80



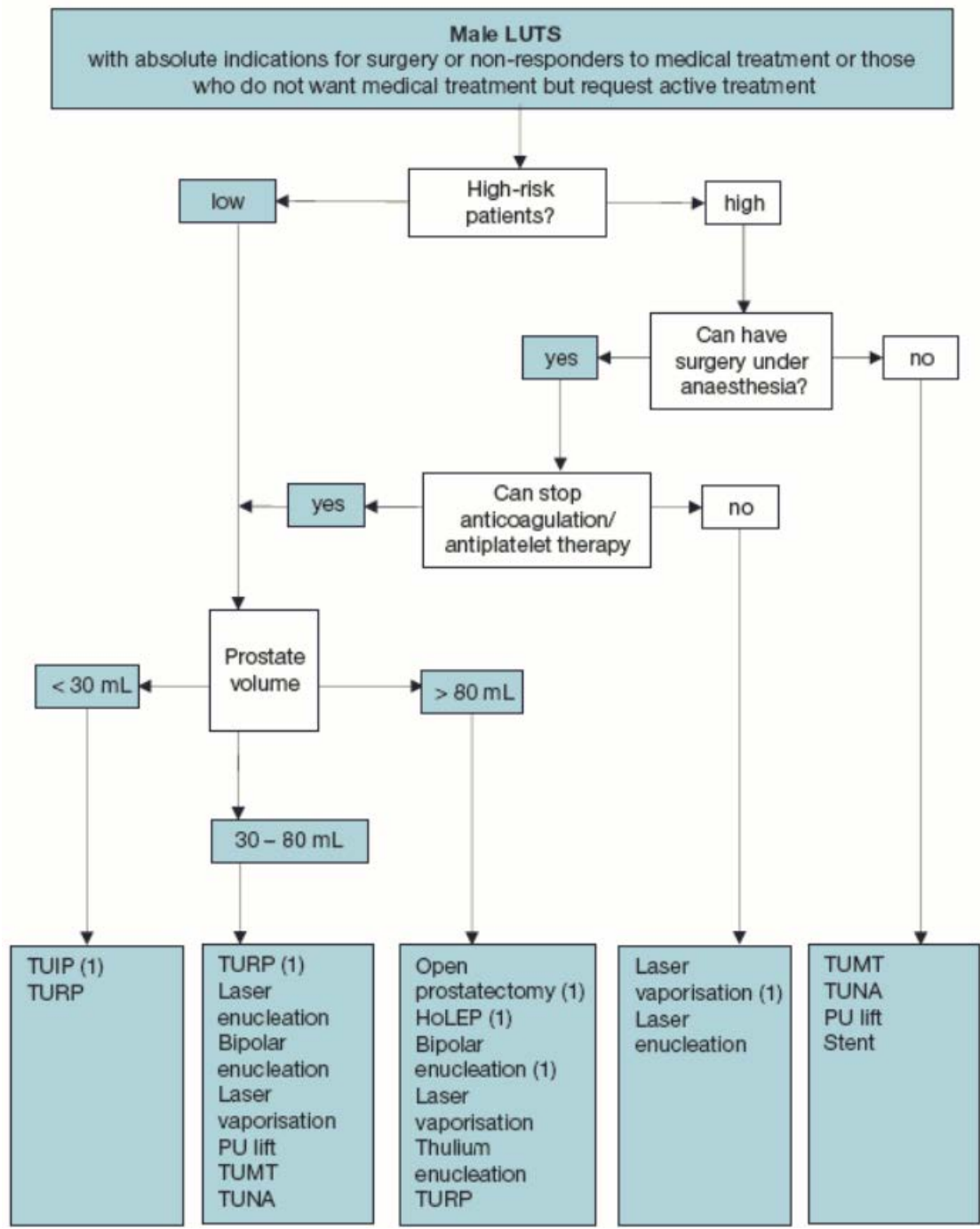
Agenda

- ◆ EAU guidelines surgical treatment algorithm of LUTS/BPO
- ◆ M-TURP (main comparator) / B-TURP
- ◆ Open prostatectomy (OP)
- ◆ Transurethral (Endoscopic) Enucleation of the Prostate (EEP)
- ◆ Laser vaporization of the prostate (532 nm - Greenlight)
- ◆ Prostatic urethral lift



EAU guidelines surgical treatment algorithm of LUTS/BPO (overview)





EAU Guidelines on Management of Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO)

S. Gravas (Chair), T. Bach, M. Drake, M. Gacci, C. Gratzke, T.R.W. Herrmann, S. Madersbacher, C. Mamoulakis, K.A.O. Tikkinen
 Guidelines Associates: M. Karavitakis, S. Malde, V. Sakkalis, R. Umbach

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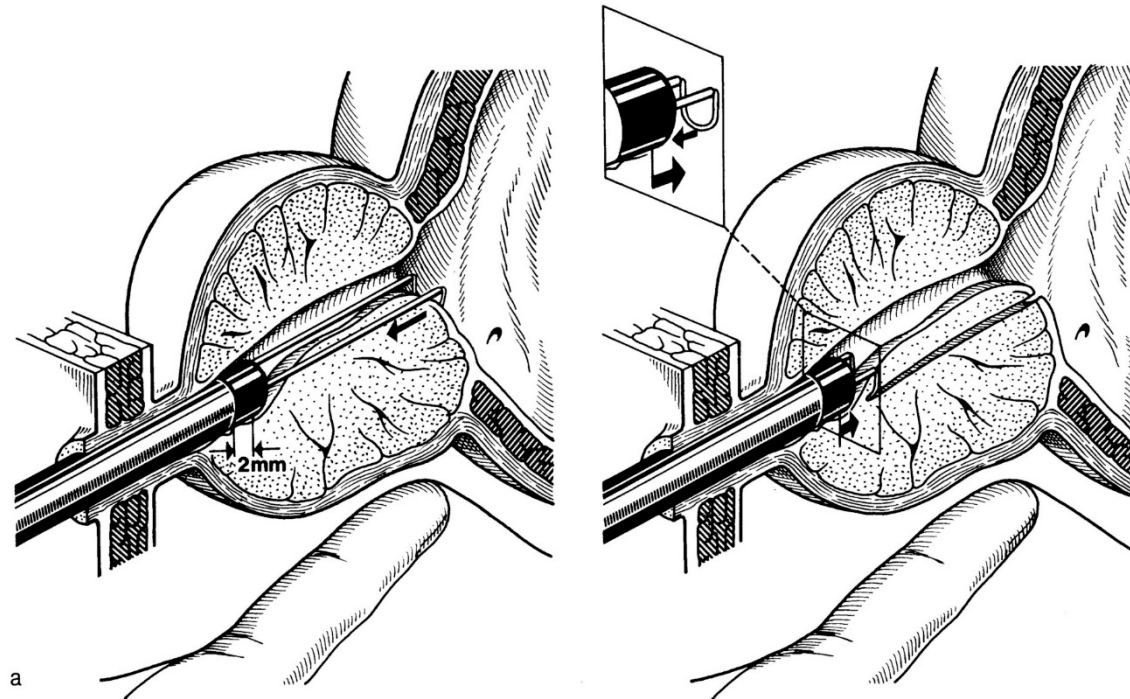
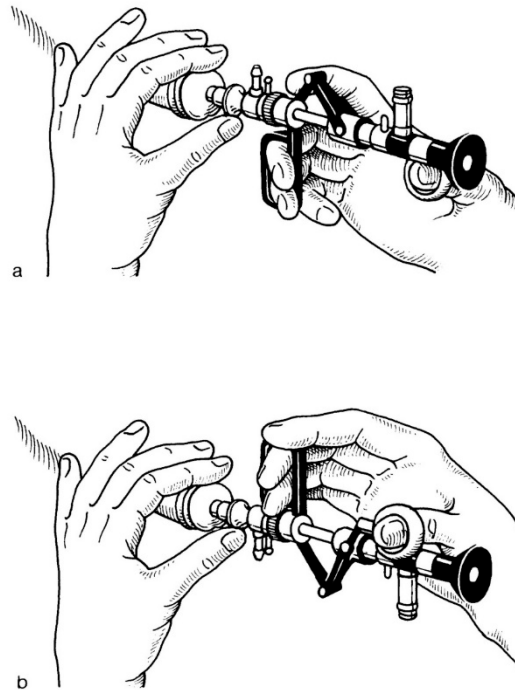


M-TURP (main comparator) / B-TURP



M-TURP – «χρυσός κανόνας» αντιμετώπισης LUTS/BPO

Maximillian Stern of New York: Resectoscope was born



Stern M. JAMA 1926; 87: 1726-30



M-TURP – «χρυσός κανόνας» αντιμετώπισης LUTS/BPO: υψηλό επίπεδο τεκμηρίωσης

- ◆ Συστηματικές ανασκοπήσεις
- ◆ Μετα-αναλύσεις τυχαιοποιημένων κλινικών μελετών
- ◆ Μελέτες οικονομικής αξιολόγησης

Reich et al. Eur Urol 2006; 49: 970-8

Lourenco et al. Health Technol Assess 2008; 12: 1-515

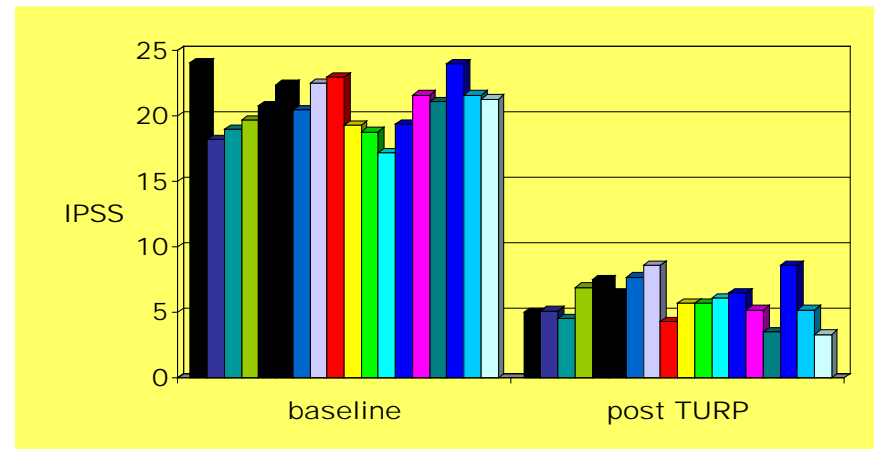
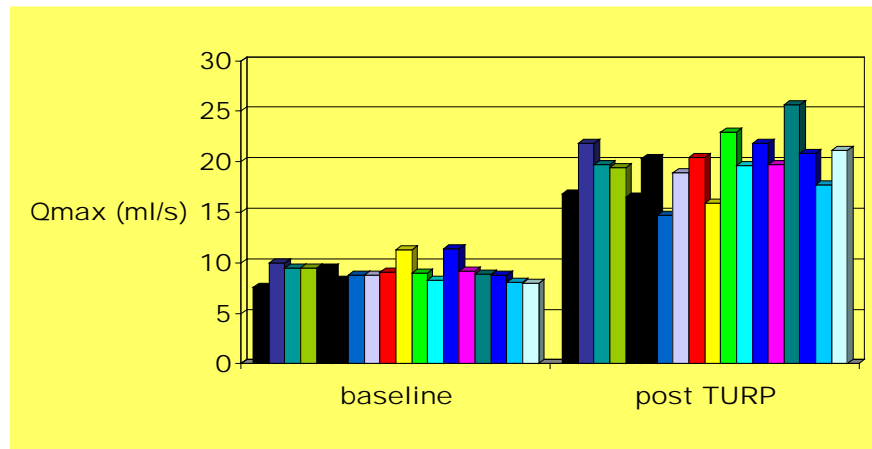
Lourenco et al. BMJ 2008; 337: a1662

Lourenco et al. BMJ 2008; 337: a449



M-TURP – «χρυσός κανόνας» αντιμετώπισης LUTS/BPO

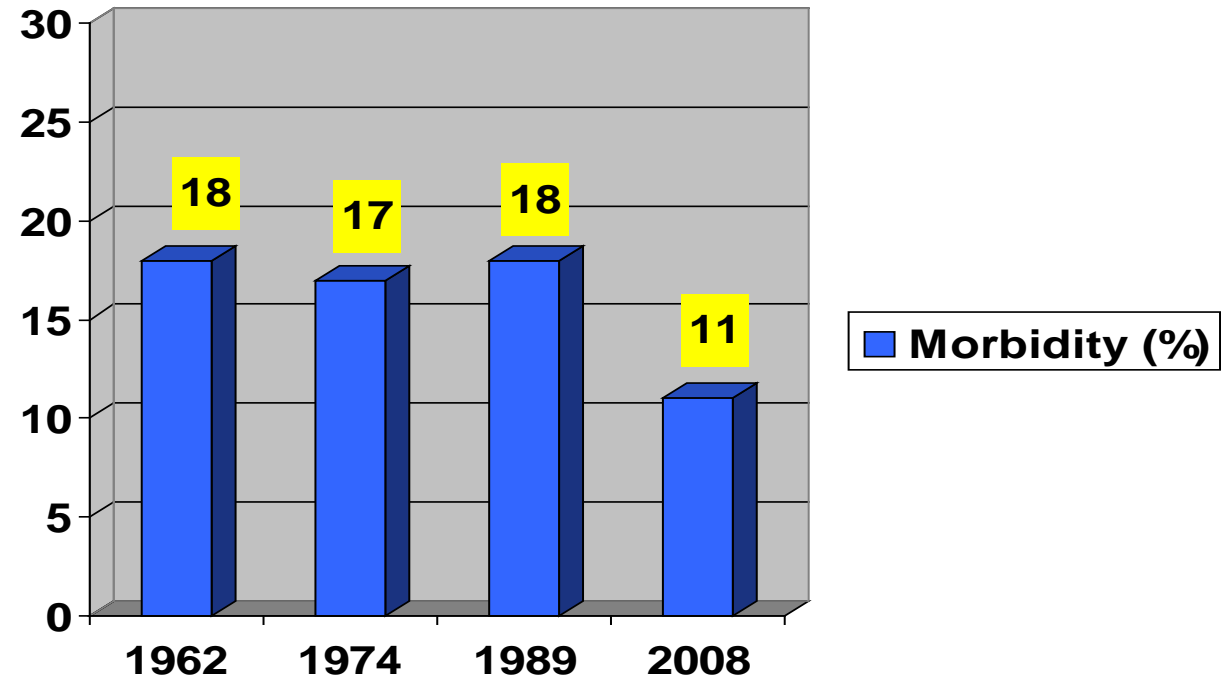
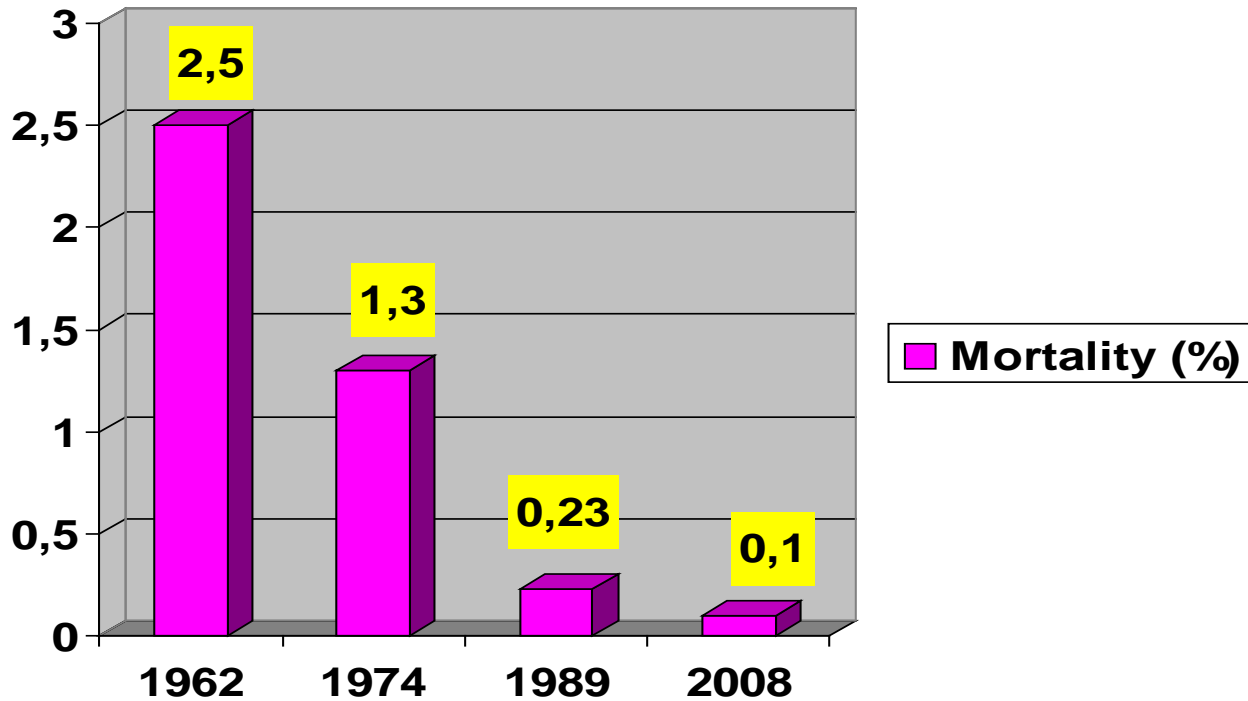
- ◆ Υψηλή αποτελεσματικότητα
- ◆ Διατήρηση αποτελεσματικότητας σε βάθος χρόνου
- ◆ Ικανοποιητική σχέση κόστους-αποτελεσματικότητας



Αποδεκτή νοσηρότητα ?



M-TURP: Θνητότητα & Νοσηρότητα



Holtgreve & Valk. J Urol 1962; 87: 450 **(2.015 ασθενείς)**

Melchior et al. J Urol 1974; 112: 634 **(2.223 ασθενείς)**

Mebust et al. J Urol 1989; 141: 243 **(3.885 ασθενείς)**

Reich et al. J Urol 2008; 180: 246 **(10.654 ασθενείς)**



Δυνητικές επιπλοκές της M-TURP

- ◆ Σύνδρομο διουρηθρικής - TUR syndrome (1,1-2,1%)
- ◆ Κλινικά σημαντική αιμορραγία
 - ◆ - Μεταγγίσεις (2,0-5,1%)
 - ◆ - Επίσχεση από πήγματα αίματος (1,3-5,0%)
- ◆ Στένωμα ουρήθρας (2,2-9,8%) ή αυχένα κύστης (0,3-9,2%)
- ◆ Λοιμώξεις
- ◆ Οξεία επίσχεση μετά την αφαίρεση του καθετήρα (AUR)
- ◆ Κακώσεις (ουρητηρικά στόμια, έξω σφιγκτήρας)
- ◆ Στυτική δυσλειτουργία

Rassweiler et al. Eur Urol 2006;50:969-80

Reich et al. J Urol 2008;180:246-249



M-TURP – «χρυσός κανόνας» αντιμετώπισης LUTS/BPO

EAU Guidelines on
Management of
Non-Neurogenic
Male Lower Urinary
Tract Symptoms
(LUTS), incl.
Benign Prostatic
Obstruction (BPO)

S. Gravas (Chair), T. Bach, A. Bachmann, M. Drake, M. Gacci,
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EAU
European
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of Urology

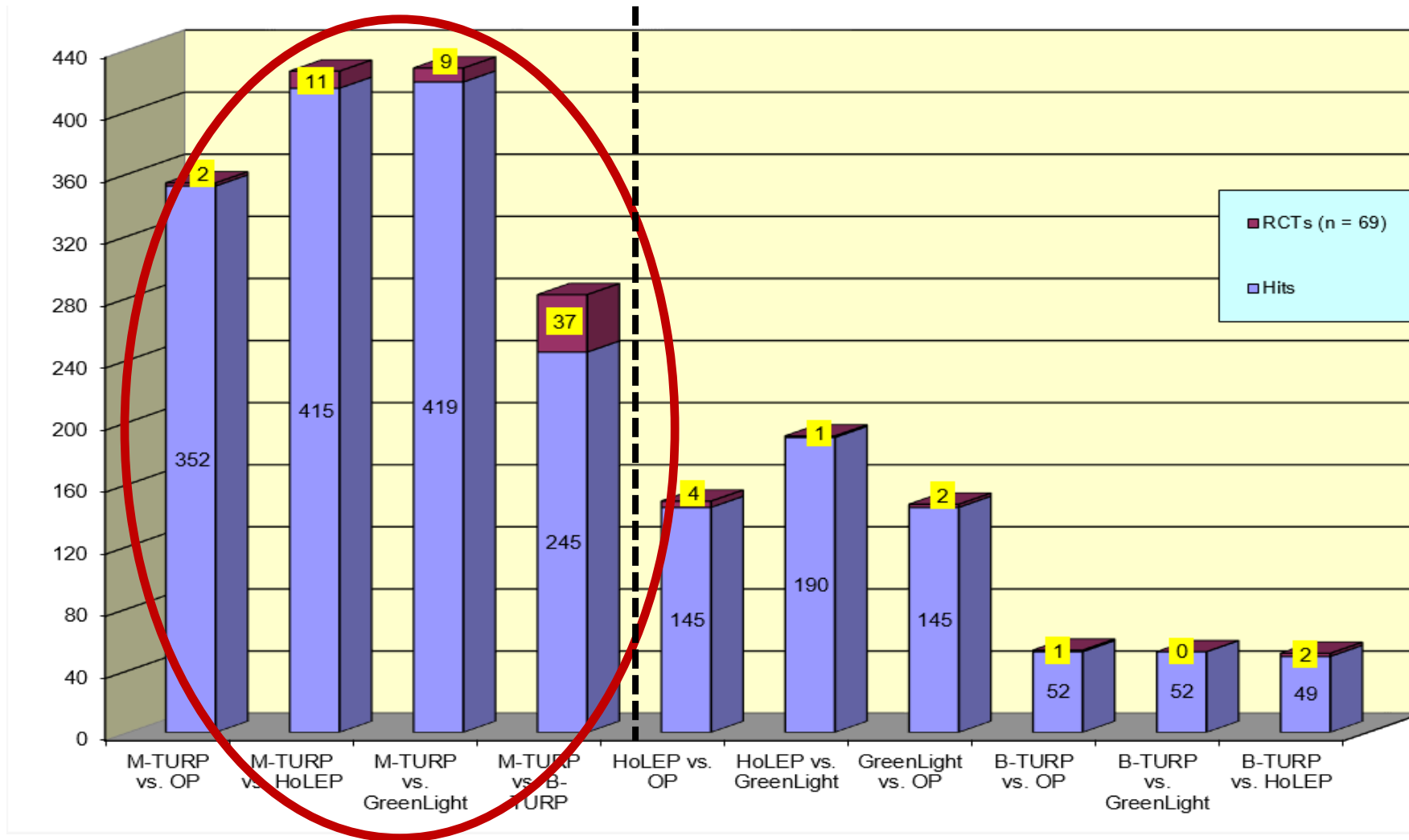
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Recommendations	LE	GR
M-TURP is the current surgical standard procedure for men with prostate sizes of 30-80 mL and bothersome moderate-to-severe LUTS secondary of BPO. M-TURP provides subjective and objective improvement rates superior to medical or minimally invasive treatments.	1a	A
The morbidity of M-TURP is higher than for drugs or other minimally invasive procedures.	1a	A

EAU guidelines on Management of non-neurogenic male LUTS, 2016

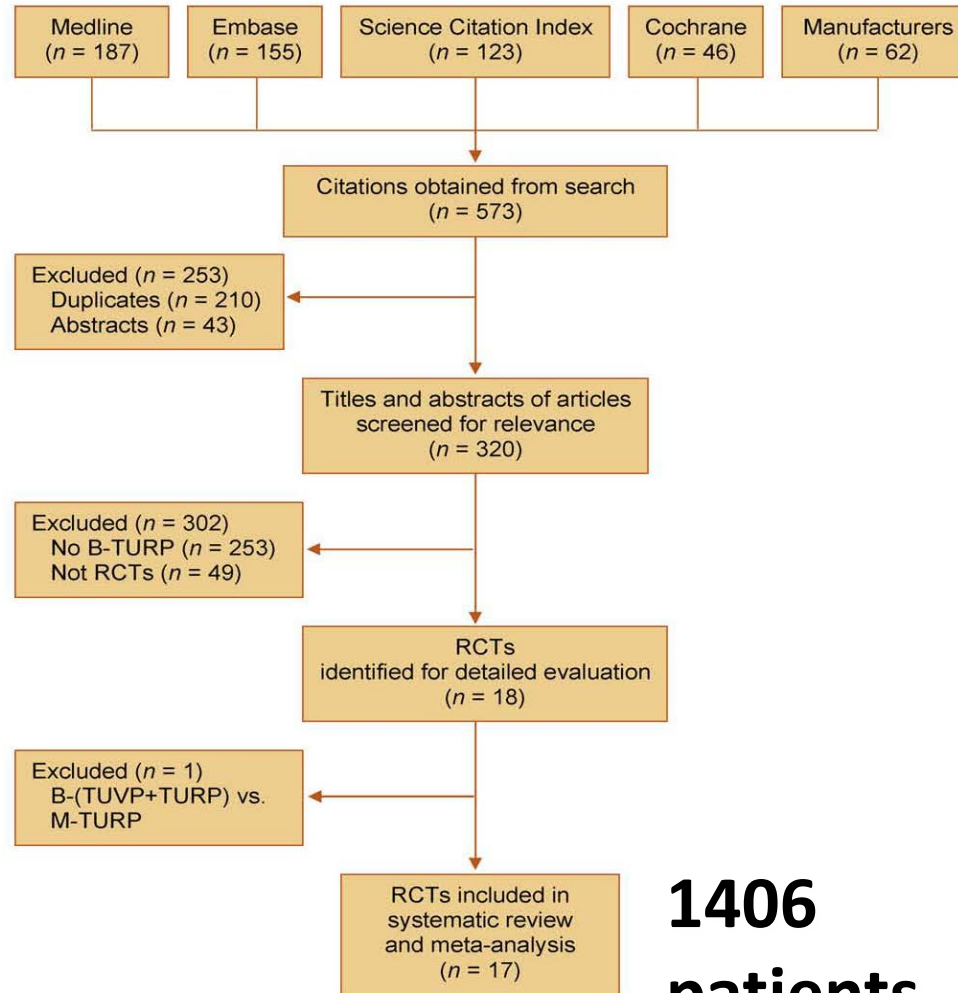


Συγκρίσεις με τον “χρυσό κανόνα”

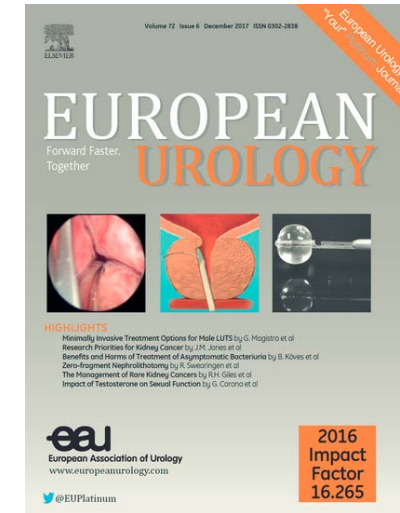


Bipolar versus Monopolar Transurethral Resection of the Prostate: A Systematic Review and Meta-analysis of Randomized Controlled Trials

Charalampos Mamoulakis ^{1,2}, Dirk T. Ubbink ³, Jean J.M.C.H. de la Rosette ⁴



1406 patients



M-TUPP vs. B-TURP: Current Level of Evidence (1a)

- ◆ No difference in efficacy (12 mo FU)
- ◆ No difference in OR time, AUR and stricture rates
- ◆ **B-TURP is “preferable” (more favorable safety profile):**
 - Postop. serum Na⁺ levels significantly higher
 - TUR syndrome elimination
 - Less bleeding (fewer clot retentions/transfusions)
 - Shorter irrigation & catheterization/hospitalization time



2 Μετα-αναλύσεις (24/17 RCTs):

Omar et al. BJU Int. 2014;113:24-35

Cornu et al. Eur Urol 2015;67:1066-96

Καμία επιπλέον
πληροφορία



B-TURP vs. M-TURP: Cochrane Meta-analysis (Υπό δημοσίευση)

Bipolar versus monopolar transurethral resection of the prostate for lower urinary tract symptoms secondary to benign prostatic obstruction (Protocol)

56 RCTs; >6000 patients

Mamoulakis C, Sofras F, de la Rosette J, Omar MI, Lam TBL, N'Dow JMO, Ubbink DT



**THE COCHRANE
COLLABORATION®**

Bipolar versus monopolar transurethral resection of the prostate for lower urinary tract symptoms secondary to benign prostatic obstruction

Review information

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⁴Urology Department, NHS Grampian, Aberdeen Royal Infirmary, Aberdeen, UK

Mamoulakis et al. Cochr. Database Syst Rev 2014 (1): CD009629



Summary of RCTs NOT meta-analyzed to date

RCT	Country	Trial Size	Bipolar Technology	Follow-up (months)	Main Conclusions	Favors	
1. Acuña-López, 2010	Mexico	30	Gyrus	-	Similar Na and Hb drop, clot retention and AUR rates	NONE	
2. Xie, 2012	China	220	Gyrus	60	<p>Similar long term efficacy and safety</p> <p>Shorter operation time, irrigation time, lower Na/Hb drop shorter catheterization/hospitalization time, less clot retentions</p>	<p>NONE</p> <p>B-TURP</p>	
3. Akman, 2012	Turkey	286	TURis	12	<p>Similar efficacy, similar safety (bleeding, ED rates)</p> <p>Shorter operation time, lower Na drop</p>	B-TURP	
4. Huang, 2012	China	136	Gyrus	-	Less intraoperative Hb drop and Less postoperative bleeding	B-TURP	
5.	Mamoulakis, 2013	Multinational	218	Autocon	12	Similar effect on overall sexual function (IIEF-15)	NONE
	Mamoulakis, 2013	Multinational	279	Autocon	36	Similar US/BNC/reintervention rates	NONE
6. Giulianeli, 2013	Italy	160	Gyrus	36	<p>Shorter catheterization/hospitalization time, surgical re-treatment-free rate</p>	B-TURP	
7. Kumar, 2013	India	186	Gyrus	12	Similar efficacy, similar safety	NONE	
8. El Saied Hafez, 2014	Egypt	50	Gyrus	-	Less drop in serum Na, Hb level and fluid overload	B-TURP	
9. Ghozzi, 2014	Tunis	60	TURis	12	Shorter irrigation/catheterization/hospitalization time	B-TURP	



- ◆ Μεσοπρόθεσμα δεδομένα παρακολούθησης (>12–60 μήνες)
- ◆ Δεδομένα επίδρασης στη σεξουαλική λειτουργία
- ◆ Δεδομένα κόστους
- ◆ Δεδομένα σε ειδικούς υπο-πληθυσμούς ασθενών
- ◆ Υπο-αναλύσεις Συστημάτων (Μετα-ανάλυση για το TURis)



Trials	Inter-vention	Patients (n)	Follow-up months	IPSS Decrease		Qmax (mL/s)		US/BNC (%)	LE
				Absolute	(%)	Absolute	(%)		
Autorino et al. 2009	M-TURP	31	48	-17.9 ^a	-74 ^a	+15.0 ^a	+242 ^a	6.5/3.2	1b
	B-TURP (Gyrus)	32		-17.3 ^a	-72 ^a	+12.7 ^a	+179 ^a	3.1/3.2	
Chen et al. 2010	M-TURP	50	24	-18.0 ^a	-83 ^a	+16.9 ^{a, b}	+214 ^a	6.0/4.0	1b
	B-TURP (TURiS)	50		-19.1 ^a	-84 ^a	+18.4 ^a	+259 ^a	4.0/2.0	
Geavlette et al. 2011	M-TURP	170	18	-15.9 ^a	-66 ^a	+14.2	+222	5.1/4.1	1b
	B-TURP (TURiS)	170		-16.1 ^a	-67 ^a	+14.5 ^a	+238 ^a	6.3/3.4	
Xie et al. 2012	M-TURP	79	60	-16.2 ^a	-71 ^a	+15.2 ^a	+157 ^a	5.1/10.1	1b
	B-TURP (Gyrus)	78		-16.6 ^a	-70 ^a	+16.5 ^a	+167 ^a	5.1/5.1	
Mamoulakis et al. 2012	M-TURP	108	36	-16.0 ^a	-69 ^a	+10.8 ^a	+126 ^a	9.3/1.9	1b
	B-TURP Autocon	122		-15.4 ^a	-66 ^a	+10.7 ^a	+122 ^a	8.2/6.6	
Giulianelli et al. 2013	M-TURP	80	36	-19.4 ^a	-83 ^a	+13.5 ^a	+208 ^a	NA/13.3	1b
	B-TURP (Gyrus)	80		-20.3 ^a	-91 ^a	+14.1 ^a	+158 ^a	NA/2.5	



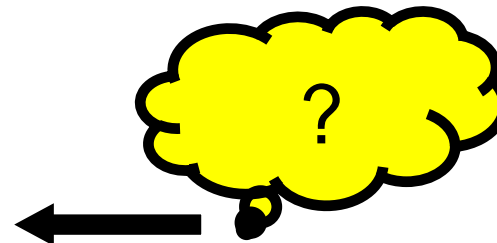
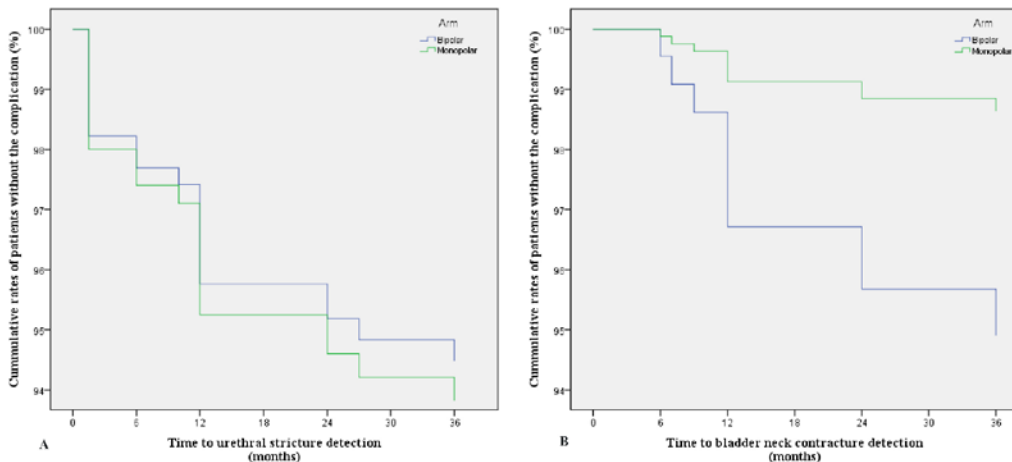
Platinum Priority – Benign Prostatic Obstruction

Midterm Results from an International Multicentre Randomised Controlled Trial Comparing Bipolar with Monopolar Transurethral Resection of the Prostate



Charalampos Mamoulakis^{a,b,*}, Michael Schulze^c, Andreas Skolarikos^d, Gerasimos Alivizatos^d, Roberto M. Scarpa^e, Jens J. Rassweiler^c, Jean J.M.C.H. de la Rosette^a, Cesare M. Scoffone^e

- ◆ Μεσοπρόθεσμη (36 μήνες) ασφάλεια (US, BNC rates)
- ◆ Αποτελεσματικότητα, ποσοστά επανεπέμβασης
- ◆ Μή στατιστικά σημαντικές διαφορές



Mamoulakis et al. Eur Urol. 2013;63:667-76





Incidence of urethral stricture after bipolar transurethral resection of the prostate using TURis: results from a randomised trial

Komura et al. BJU Int. 2015;115:644-52

- ◆ 136 ασθ. (τυχαιοποίηση 1:1) B-TURP (TURis)/M-TURP
- ◆ Παρακολούθηση 36 μήνες
- ◆ Πρωτεύον καταληκτικό σημείο: ασφάλεια (στενώματα)
- ◆ Στατιστικά σημαντική διαφορά υπέρ M-TURP (6.6 vs. 19%)
- ◆ Υποανάλυση με βάση όγκο προστάτη
- ◆ $\leq 70\text{mL}$: TURis 3/40 [7.5%] vs. M-TURP: 3/39 [7.7%]; $P=1.00$)
- ◆ **$>70\text{ mL}$: TURis (9/23 [39.1] vs 1/22 [4.6%]; $P=0.01$)**



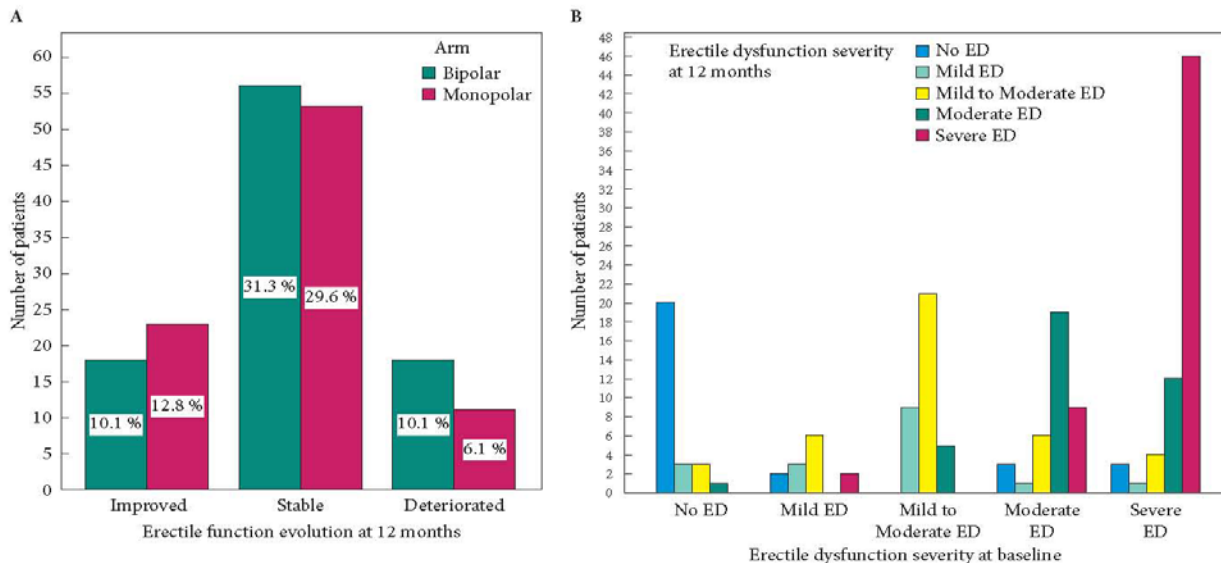
Δεδομένα επίδρασης στη σεξουαλική λειτουργία

Bipolar vs monopolar transurethral resection of the prostate: evaluation of the impact on overall sexual function in an international randomized controlled trial setting



Charalampos Mamoulakis^{1,2}, Andreas Skolarikos³, Michael Schulze⁴, Cesare M. Scoffone⁵, Jens J. Rassweiler⁴, Gerasimos Alivizatos³, Roberto M. Scarpa⁵ and Jean J.M.C.H. de la Rosette¹

◆ Καμία διαφορά μεταξύ M-TURP & B-TURP στη συνολική σεξουαλική λειτουργία (IIEF-15) στους 12 μήνες



Mamoulakis et al. BJU Int. 2013;112:109-20



Δεδομένα Κόστους

Nationwide administrative data base in Japan (6686 patients)

In-Hospital Outcomes and Cost Assessment Between Bipolar Versus Monopolar Transurethral Resection of the Prostate

Purpose: We compared the in-hospital outcomes between bipolar and monopolar transurethral resection of the prostate (B-TURP and M-TURP, respectively) on a real-world practice using a large database.

Patients and Methods: Patients who underwent TURP were extracted from the Diagnosis Procedure Combination database, which is a case-mix administrative claims database in Japan. TURP procedures were classified into M-TURP and B-TURP groups according to intraoperative use or nonuse of D-sorbitol solution, respectively, which is the only nonelectrolyte bladder irrigation fluid for M-TURP available in Japan. To exclude causality among autologous and homologous transfusion events, we confined eligible hospitals to those in which no autologous blood preparation was undertaken for TURP and whose annual surgical caseloads were 15 cases or more. Multivariate analyses were conducted for homologous transfusion, postoperative complications, operative time, postoperative length of stay, and total costs.

Results: There were 5155 M-TURP and 1531 B-TURP patients identified. The results for M-TURP vs B-TURP (effect sizes were evaluated with reference to M-TURP) were 2.3% vs 1.3% for transfusion (odds ratio [OR]=0.54; $P=0.013$), 3.3% vs 1.7% for postoperative complications (OR=0.46; $P<0.01$), 98 vs 116 minutes for operative time (20.5% increase; $P<0.001$), 8.65 vs 8.45 days for postoperative stay (3.6% reduction; $P=0.003$), and \$6103 vs \$6062 for cost (1.7% reduction; $P=0.018$).

Conclusion: B-TURP had significantly lower rates of transfusion and postoperative complications, but a longer operative time. The impacts of B-TURP on shortening the hospital stay and lowering the costs were of little clinical significance.

◆ Στατιστικά σημαντικό (αλλά μικρό) όφελος υπέρ B-TURP:
\$6103 vs. \$6062 (1.7% μείωση κόστους)

Sugihara et al. J Endourol. 2012;26:1053-8



Bipolar Transurethral Resection of the Prostate: Darwinian Evolution of an Instrumental Technique

Charalampos Mamoulakis and Jean J. M. C. H. de la Rosette

Bipolar transurethral resection of the prostate (B-TURP) represents a Darwinian evolution of an instrumental technique that has been justified by reinforcing the leading position of monopolar transurethral resection of the prostate. Notwithstanding limitations, the best available evidence recommends B-TURP as an attractive alternative. It may serve as a reliable training platform for modern residents. High-quality evidence is lacking to definitely define its position in treating special subpopulations (anticoagulation dependence, comorbidities, and large adenomas). Regarding economic issues, preliminary evidence supports B-TURP, warranting further investigation. Future perspectives include attempts toward improvements of the existing technology, combining advantages with those of other new techniques, and evolution to novel, potentially safer, or more efficient techniques to address remaining challenges. UROLOGY 85: 1143–1150, 2015. © 2015 Elsevier Inc.



Mamoulakis & de la Rosette. Urology. 2015 May;85:1143-50



Safety and Efficacy of Bipolar Versus Monopolar Transurethral Resection of the Prostate in Patients with Large Prostates or Severe Lower Urinary Tract Symptoms: Post Hoc Analysis of a European Multicenter Randomized Controlled Trial.

Abstract

PURPOSE: We compare bipolar vs monopolar transurethral prostate resection safety/secondary outcomes including efficacy in patients with large prostate volume or severe lower urinary tract symptoms.

MATERIALS AND METHODS: From July 2006 to June 2009 candidates for transurethral prostate resection were recruited at 4 centers, randomized 1:1 into monopolar/bipolar transurethral prostate resection arms and followed up to 36 months. Post hoc data analysis from patients with large prostate volume or severe lower urinary tract symptoms is presented. Patients with large prostate volume or severe lower urinary tract symptoms were defined as those with transrectal ultrasound based prostate volume greater than 80 ml or International Prostate Symptom Score greater than 19. Safety was estimated using sodium/hemoglobin changes immediately after surgery, complications during the early postoperative period (up to 6 weeks), and short-term (up to 12 months) and midterm (up to 36 months) followup. Secondary outcomes included, among others, efficacy quantified by changes in maximum urine flow rate, post-void residual urine volume and International Prostate Symptom Score compared with baseline.

RESULTS: A total of 279 patients were randomized. Post hoc analysis of data from patients with a large prostate volume or severe lower urinary tract symptoms was based on analysis A-in 62 of 279 participants (22.3%) (monopolar transurethral prostate resection 32, bipolar transurethral prostate resection 30) or analysis B-in 126 of 279 participants (45.2%) (monopolar transurethral prostate resection 57, bipolar transurethral prostate resection 69). Mean (SD) prostate volume was 108.0 (25.9) ml for monopolar transurethral prostate resection and 108.9 (23.4) ml for bipolar transurethral prostate resection ($p=0.756$). Mean International Prostate Symptom Score was 25.0 (4.2) for monopolar transurethral prostate resection and 25.3 (3.7) for bipolar transurethral prostate resection ($p=0.402$). Neither safety nor any secondary outcome differed significantly between the arms throughout followup. The only exception was the decrease in sodium (analysis A), which was significantly greater after monopolar transurethral prostate resection (-4.2 vs -0.7 mmol/l, $p=0.023$) and did not translate into a significant difference in transurethral resection syndrome rates (monopolar transurethral prostate resection 1 of 32 vs bipolar transurethral prostate resection 0 of 30, $p=1.000$).

CONCLUSIONS: Bipolar and monopolar transurethral prostate resection show similar safety/efficacy in these patient subpopulations.

Mamoulakis et al. J Urol. 2016;195:677-84



Υποαναλύσεις Συστημάτων (Μετα-ανάλυση για TURis)

NICE National Institute for
Health and Care Excellence

The TURis system for transurethral
resection of the prostate

Issued: February 2015

NICE medical technology guidance 23

“TURis reduces the risk of TUR-syndrome and the need for blood transfusion compared to M-TURP. It is plausible that TURis reduces length of hospital stay and readmissions after surgery, although the evidence on these outcomes is limited.”



Practical considerations: B-TURP offers an attractive alternative to M-TURP in patients with moderate-to-severe LUTS secondary to BPO, with similar efficacy but lower peri-operative morbidity [268]. The duration of improvements with B-TURP were documented in a number of RCTs with a follow-up of greater than twelve months. Mid-term results (up to five years) for B-TURP showed that safety and efficacy are comparable to M-TURP. The choice of B-TURP should be based on equipment availability, surgeon's experience, and patient's preference.

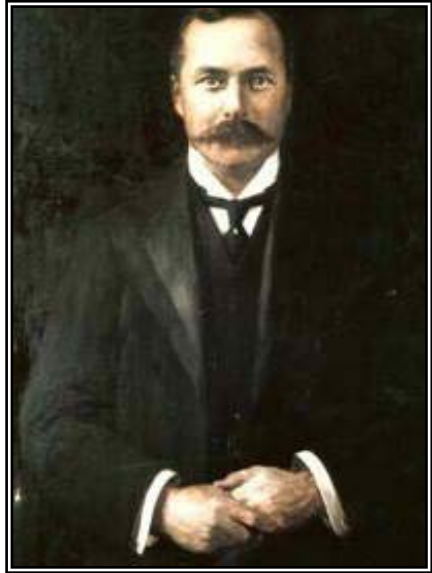
Recommendations	LE	GR
Offer bipolar- or monopolar- transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size of 30-80 mL.	1a	A

EAU guidelines on Management of non-neurogenic male LUTS, 2017

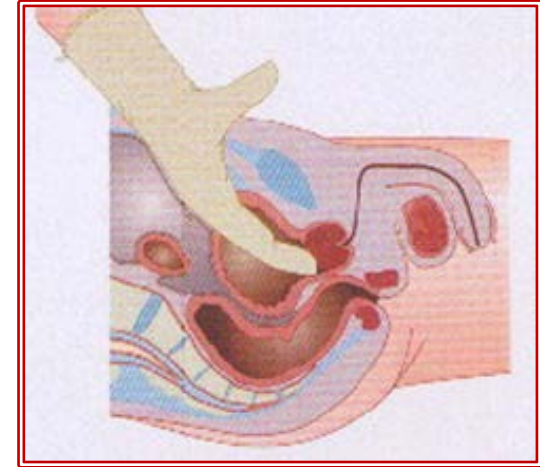


Open prostatectomy (OP)

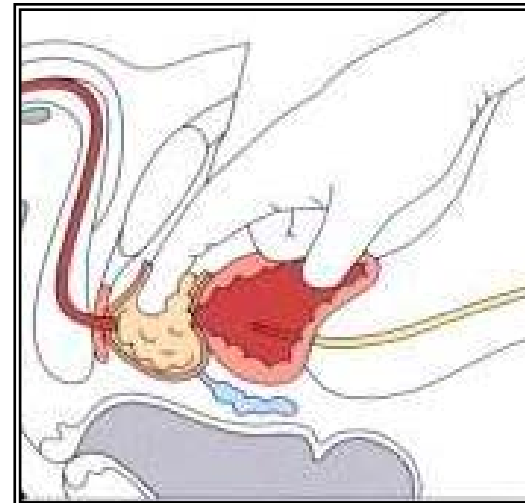




Sir Peter Johnson Freyer
BMJ 1901;11:125



Terence Millin
Lancet 1945; ii: 693



◆ Efficacy:

- IPSS ↓: 63-86% (12.5-23.3 points)
- QoL score ↓: 60-87%
- Qmax ↑: 375% (16.5-20.2 mL/s)
- PVR ↓: 86-98%
- Efficacy maintained for up to 6 years

◆ Safety:

- Mortality: < 0.25%
- Transfusions: 7-14%
- UI (transient): ≤ 10%
- BNC/US: 6%

Practical considerations: Open prostatectomy is the most invasive surgical method but it is an effective and durable procedure for the treatment of LUTS/BPO. Endoscopic enucleation techniques require experience and relevant endoscopic skills. In the absence of an endourological armamentarium including a holmium laser or a bipolar system, OP is the surgical treatment of choice for men with prostates > 80 mL.

*EAU guidelines on Management of non-neurogenic male LUTS,
2017*

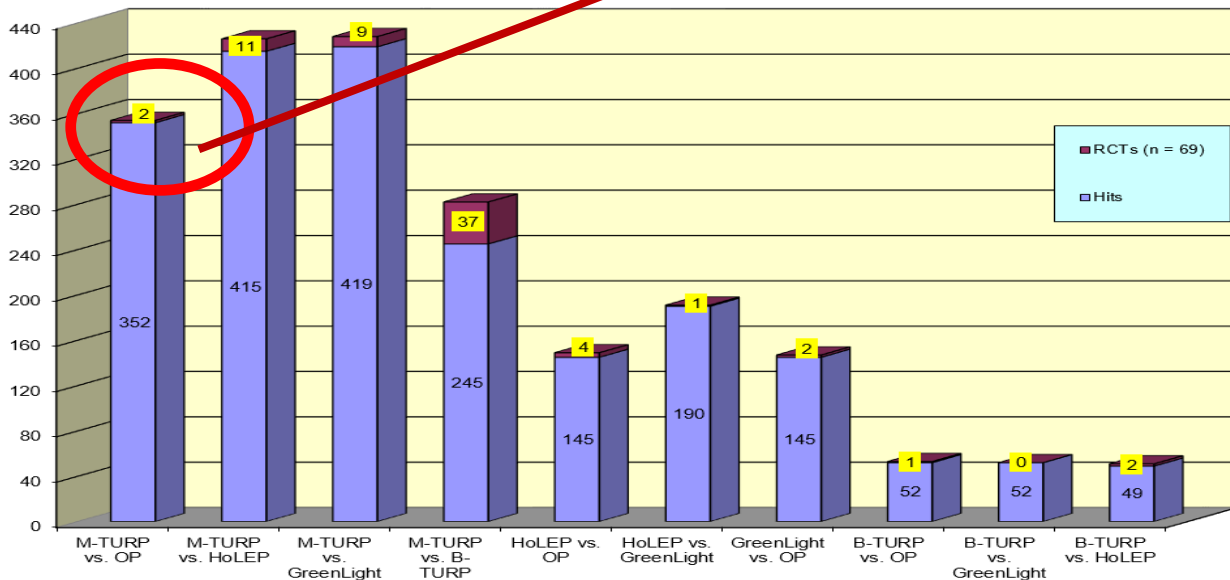


Recommendation	LE	GR
Offer endoscopic enucleation of the prostate or open prostatectomy to treat moderate-to-severe LUTS in men with prostate size > 80 mL.	1a	A

EAU guidelines on Management of non-neurogenic male LUTS, 2017

But...

“TURP comparison with OP has been based on retrospective, open, and single center series”



Campbell's Urology



Transurethral (Endoscopic) Enucleation of the Prostate (EEP)



Birth of EEP (Hiraoka, 1983)

Monopolar current-based enucleation–resection
(blueprint for all subsequent EEP techniques)
but remained a local phenomenon in Japan

— 122 — (896)

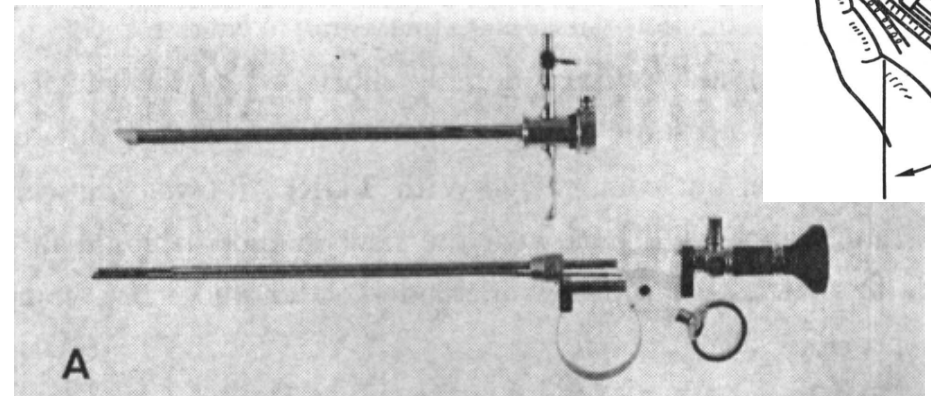
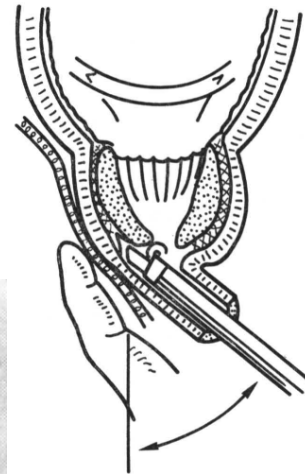
J. Nippon Med. Sch., Vol. 50, No. 6 (1983)

—Preliminary Note—

A new method of prostatectomy, transurethral detachment
and resection of benign prostatic hyperplasia

Yasunori Hiraoka

Department of Urology (Director : Prof. Masao Akimoto), Nippon Medical School



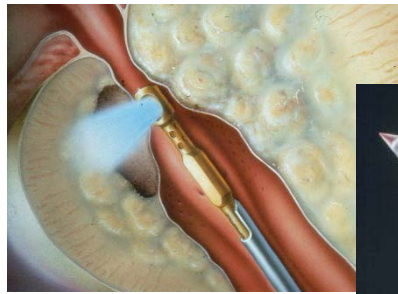
27050 CE



27050 CE Electrode, for cold enucleation, 24/26 F color code: black



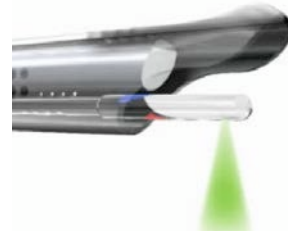
EPP teamed up with laser technology



Costello

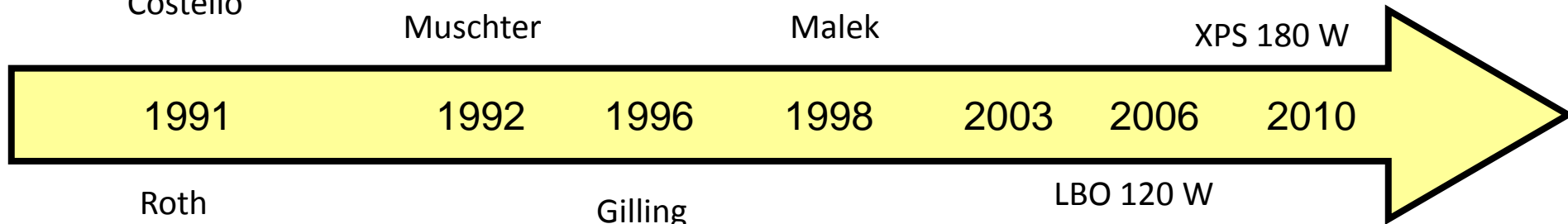
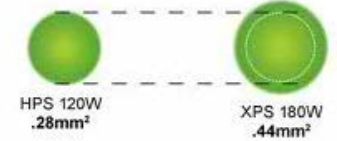


Muschter



Malek

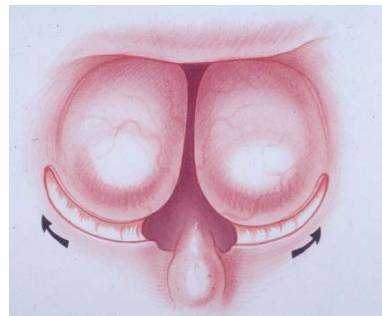
$$\text{Power Density} = \frac{\text{Power}}{\text{Beam Area}}$$



Roth



Gilling



LBO 120 W

KTP 80 W



TABLE 1 Main characteristics of different lasers

Type of laser	Wavelength, nm	Chromophore	Penetration depth, mm	Mode	Application
Nd : YAG	1064	Water and haemoglobin	10	Pulsed or continuous	Coagulation
Ho : YAG	2140	Water	0.4	Pulsed	Vaporization, resection, enucleation
KTP (LBO)	532	Haemoglobin	0.8	Quasi-continuous	Vaporization
Tm	2000	Water	0.25	Continuous	Vaporization, resection, enucleation
Diode	940	Water and haemoglobin	Various	Pulsed or continuous	Vaporization
	980				
	1470				

Gravas et al. BJU Int. 2011;107:1030-43



EFP teamed up with mechanical tissue morcellator



Evolution of EEP

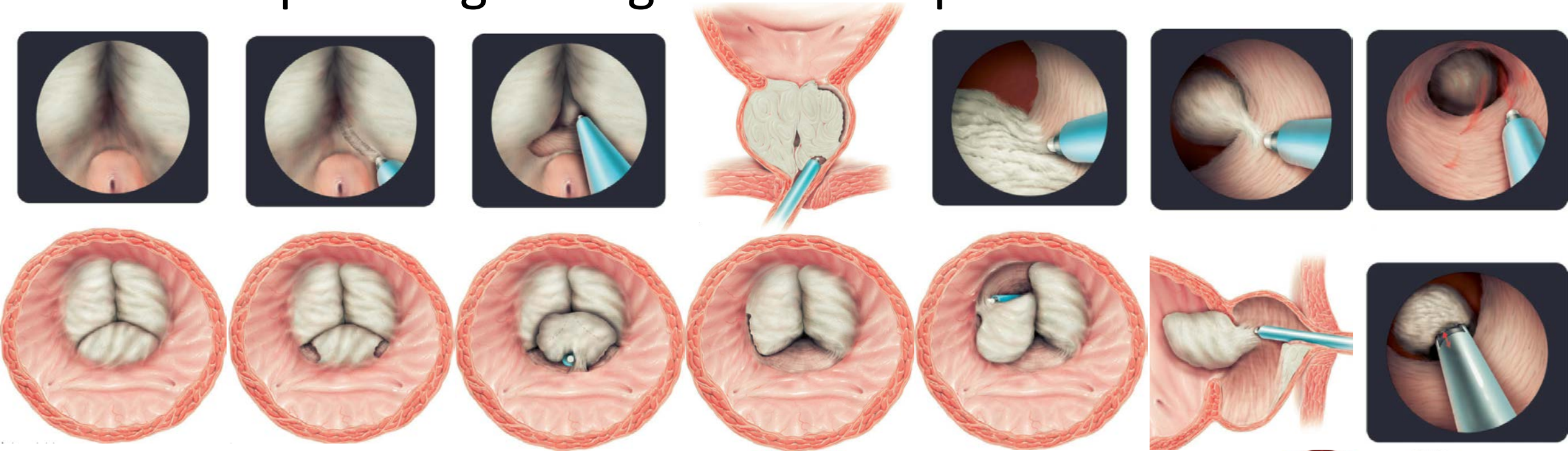
- ◆ Ho:YAG Laser Enucleation of the Prostate (HoLEP) [1998]
- ◆ Plasmakinetic Enucleation of the Prostate (PkEP) [2006]
- ◆ Tm:YAG Vapoenucleation (ThuVEP) [2009]
- ◆ Tm:YAG Laser Enucleation of the Prostate (ThuLEP)[2010]
- ◆ Bipolar Plasma Enucleation of the Prostate (BPEP) [2013]
- ◆ Diode Laser Enucleation of the Prostate (DiLEP) [2014]
- ◆ Lithium-Borate “Greenlight” enucleation of the prostate (GreenLEP) [2015]

Herrmann. World J Urol. 2016;34:1353-5



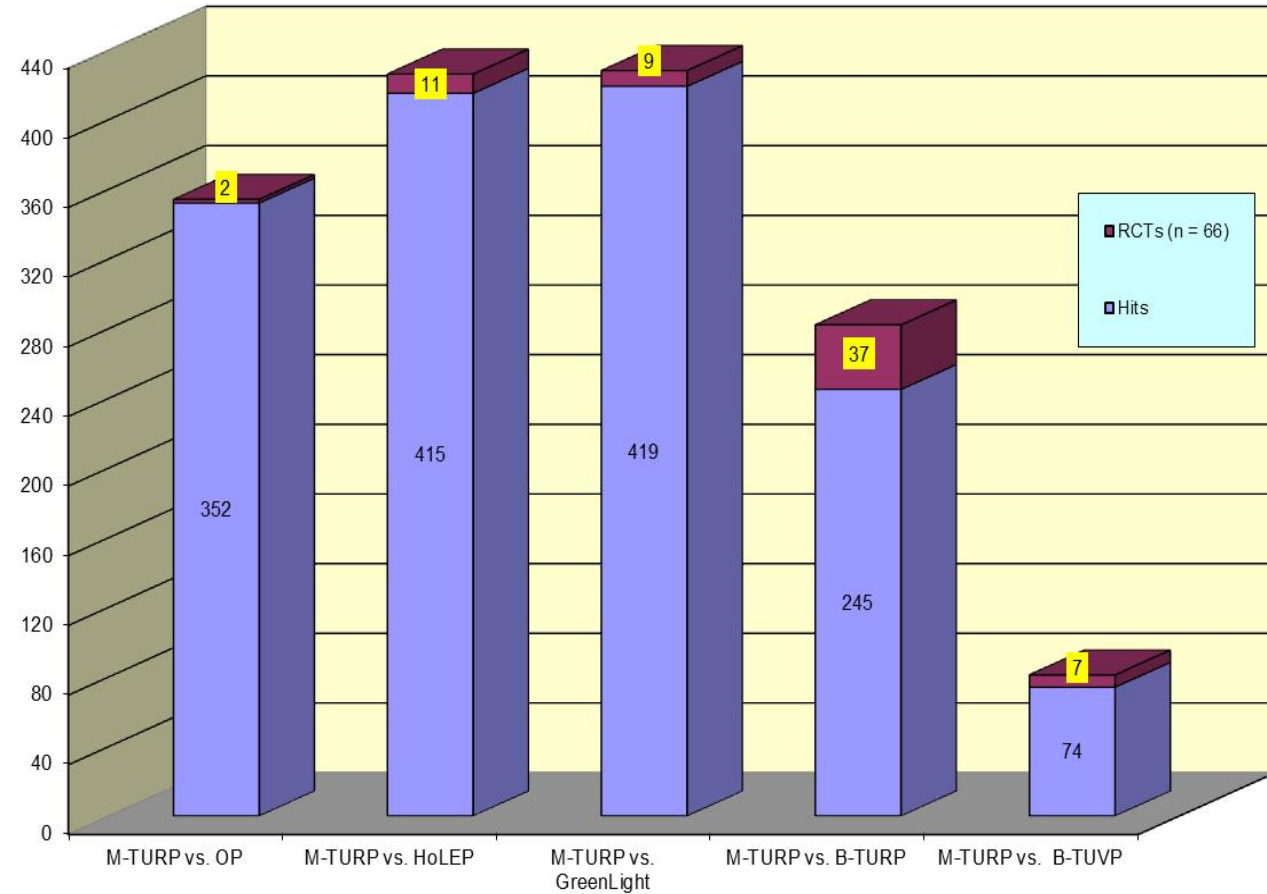
HoLEP (Technique)

High-powered holmium laser (>60 W); 6 F ureteric catheter;
550 μ m laser fiber; Laser resectoscope continuous-flow (26 F)
30° telescope - large bridge - endoscopic camera - morcellator



Gilling P. BJU Int. 2008;101:131-42

HoLEP vs. TURP



3 Meta-analyses:

similar results

Tan et al. Br J Surg. 2007;94:1201-8

(4 RCTs; n=460)

Yin et al. J Endourol. 2013;27:604-11

(6 RCTs; n=541)

Cornu et al. Eur Urol. 2015;67:1066-96

(6 RCTs; n=570)



Current Level of Evidence (1a): Summary

- ◆ Similar or better efficacy (Yin et al; Cornu et al) for HoLEP
- ◆ Similar safety (Tan et al & Yin et al; Cornu et al)
- ◆ HoLEP: Better perioperative profile:
 - Less hemorrhage - transfusions (Yin et al)
 - Shorter catheter-hospital duration (Yin et al; Cornu et al)
- ◆ TURP: Shorter OR duration (Tan et al; Yin et al; Cornu et al)
 - Less dysuria (Tan et al & Yin et al)



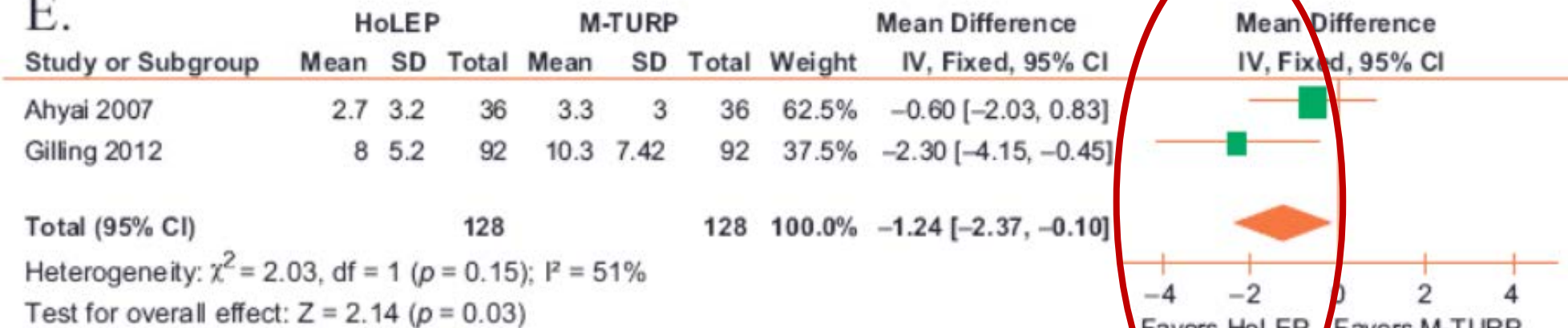
Potential limitations of the meta-analyses

- ◆ Relative low number of RCTs
- ◆ Relatively low quality of RCTs
- ◆ Relative heterogeneity among RCTs
- ◆ Relatively short follow-up (12 mo)

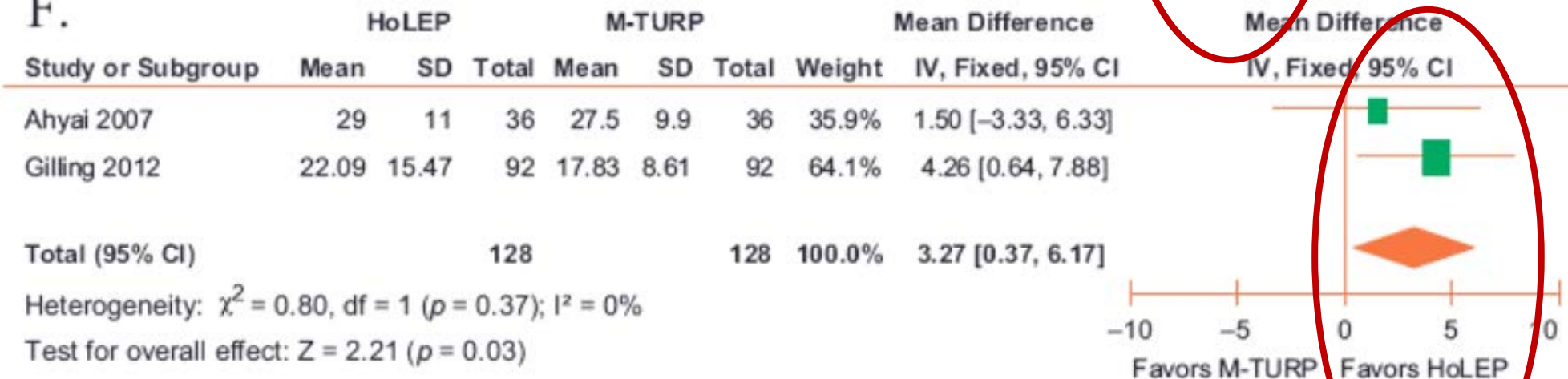


Long term results (3-7 y): Meta-analysis (IPSS-Qmax)

E.



F.



Cornu et al. Eur Urol. 2015;67:1066-96



HoLEP vs. OP

3 meta-analyses (4 RCTs-Pvol>100 ml; n= 323; FU: 12 (1-60) mo

Large heterogeneity - Relatively low quality of RCTs

- ◆ Significantly shorter OR time for OP
- ◆ Significantly shorter catheter/hospital duration for HoLEP
- ◆ Significantly lower transfusion rate for HoLEP
- ◆ No difference in efficacy or any other outcome

Cornu et al. Eur Urol. 2015;67:1066-96

Li et al. PLoS One. 2015;10:e0121265

Lin et al. World J Urol. 2016;34:1207-19



HoLEP vs. TURP or OP

EAU Guidelines on Management of Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO)

S. Gravas (Chair), T. Bach, M. Drake, M. Gacci, C. Gratzke, T.R.W. Herrmann, S. Madersbacher, C. Mamoulakis, K.A.O. Tikkinen
Guidelines Associates: M. Karavitikis, S. Malde, V. Sakkalis, R. Umbach

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Recommendations	LE	GR
HoLEP and 532-nm laser vaporisation of the prostate are alternatives to TURP in men with moderate-to-severe LUTS leading to immediate, objective, and subjective improvements comparable with TURP.	1a	A
The long-term functional results of HoLEP are comparable with TURP or open prostatectomy.	1b	A

EAU guidelines on Management of non-neurogenic male LUTS, 2017



HoLEP vs. Other techniques

Scarce RCTs; no firm statement can be made at present:

HoLEP vs.	n	PV (ml)	FU (mo)	IPSS/ Qmax	OR Time	Catheter Time	Hospital Time
B-TURP (TURis) ¹	120	70	12	HoLEP	B-TURP	HoLEP	HoLEP
B-TURP (PK; Gyrus) ²	280	50	24	NS	B-TURP	HoLEP	HoLEP
PVP ³	80	90	12	NS/HoLEP	NS	NS	NS

1. *Fayad et al. Urology. 2015;86:1037-41;*
2. *Chen et al. J Urol. 2013;189:217-22;*
3. *Elmansy et al. J Urol. 2012;188:216-21*



PkEP (Neill, 2006)

HoLEP vs.	n	PV (ml)	FU (mo)	IPSS/Qmax	OR Time	Catheter Time	Hospital Time
PKEP	40	55	12	NS	HoLEP	NS	NS

ABSTRACT

Objectives. To compare the alternative energy sources of the holmium:yttrium-aluminum-garnet laser and bipolar plasmakinetic energy for endoscopic enucleation.

Methods. A prospective, randomized controlled trial was undertaken, with 20 patients assigned to each group. The preoperative and postoperative measures included transrectal ultrasound-assessed prostate volume, postvoid residual urine volume, and urodynamic evaluation findings. The intraoperative measures included procedure length, energy use, and specimen weight. All adverse events were recorded at each postoperative visit in a 1, 3, 6, and 12-month protocol.

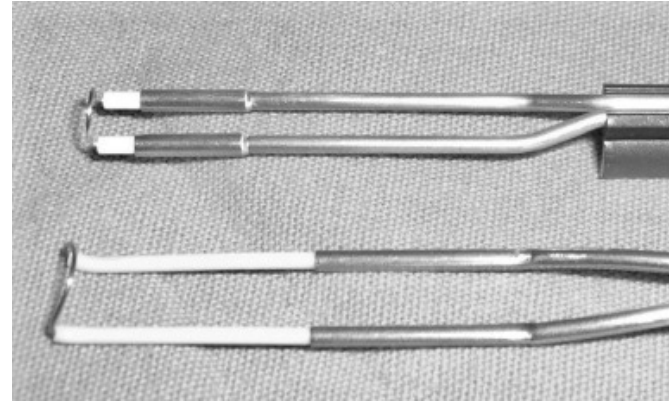
Results. No differences were found in the preoperative characteristics between the two groups. The significant differences favoring holmium laser enucleation of the prostate compared with plasmakinetic enucleation of the prostate were seen in the operative time (43.6 versus 60.5 minutes), recovery room time (47.1 versus 65.6 minutes), and bladder irrigation requirement (5% versus 35%). The outcomes after holmium laser enucleation of the prostate and plasmakinetic enucleation of the prostate were in all other respects similar by the postoperative outcome measures assessed.

Conclusions. Plasmakinetic enucleation of the prostate is a safe and technically feasible procedure for the enucleation of prostatic adenomata. Plasmakinetic enucleation of the prostate is limited by the longer operative and recovery room times, as well as a more pronounced postoperative irrigation requirement because of reduced visibility and a greater propensity for bleeding. The transfusion rates and catheterization and hospitalization times were similar. The optimal energy source for enucleation should still be considered the holmium laser, but bipolar energy can be considered by users already experienced with holmium laser enucleation of the prostate. UROLOGY 68: 1020–1024, 2006. © 2006 Elsevier Inc.

*Neill et al. Urology. 2006;
68:1020-4*



PkEP (Technique)



Gyrus Plasmakinetic SuperPulse System (Gyrus Medical, Cardiff, UK),
PlasmaSect electrode; power (cut):130-160W;(coagulation):60-80 W
26F continuous-flow resectoscope (K Storz, Tuttlingen, Germany)



Neill et al. Urology. 2006; 68:1020-4

Chen et al. Eur Urol. 2014; 66: 284–291

Hiraoka. Nihon Ika Daigaku Zasshi. 1983;50:896-8



PkEP vs. OP

2 meta-analyses (3 RCTs-Pvol>110 ml; n= 335; FU: 12 (12-72) mo

Large heterogeneity - Relatively low quality of RCTs

- ◆ Significantly shorter OR time for OP
- ◆ Significantly shorter catheter/hospital duration for PkEP
- ◆ Significantly lower transfusion rate for PkEP
- ◆ No difference in efficacy or any other outcome

Cornu et al. Eur Urol. 2015;67:1066-96

Li et al. PLoS One. 2015;10:e0121265

Lin et al. World J Urol. 2016;34:1207-19



BPEP (Geavlete, 2013)

BPEP vs.	n	PV (ml)	FU (mo)	IPSS/ Qmax	OR Time	Catheter Time	Hospital Time
OP	140	130	12	NS	NS	BPEP	BPEP

BJU Int. 2013 May;111(5):793-803. doi: 10.1111/j.1464-410X.2012.11730.x. Epub 2013 Mar 7.

Bipolar plasma enucleation of the prostate vs open prostatectomy in large benign prostatic hyperplasia cases - a medium term, prospective, randomized comparison.

Geavlete B¹, Stanescu F, Iacobosie C, Geavlete P.

Author information

¹Department of Urology, 'Saint John' Emergency Clinical Hospital, Bucharest, Romania. bogdan_geavlete@yahoo.com

Geavlete et al. BJU Int. 2013; 111:793-803

Abstract

OBJECTIVES: To evaluate the viability of bipolar plasma enucleation of the prostate (BPEP) by comparison with open transvesical prostatectomy (OP) in cases of large prostates with regard to surgical efficacy and peri-operative morbidity. To compare the medium-term follow-up parameters specific for the two methods.

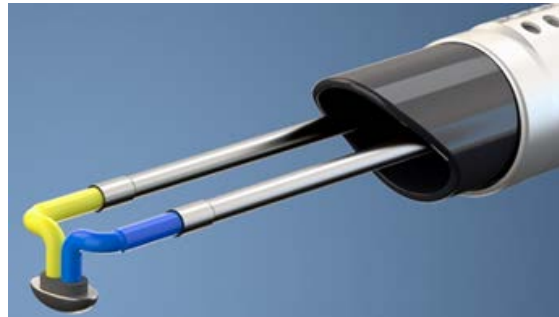
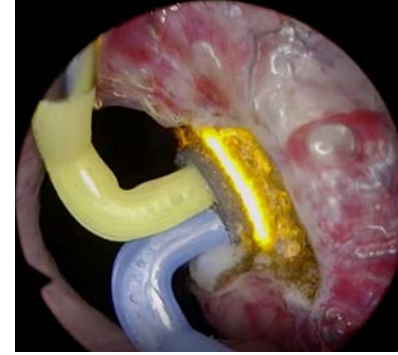
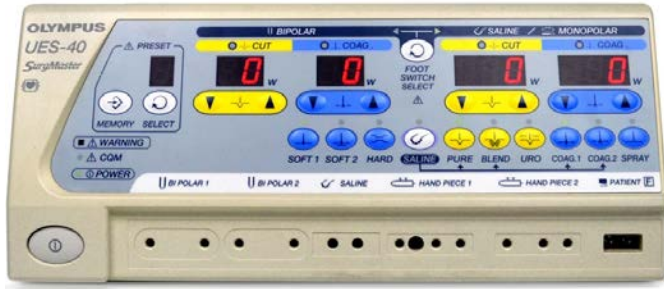
PATIENTS AND METHODS: A total of 140 benign prostatic hyperplasia (BPH) patients with prostate volume >80 mL, maximum flow rate (Qmax) <10 mL/s and International Prostate Symptom Score (IPSS) >19 were randomized in the two study arms. All cases were assessed preoperatively and at 1, 3, 6 and 12 months after surgery by IPSS, Qmax, quality of life score (QoL) and post-voiding residual urinary volume (PVR). The prostate volume and prostate specific antigen (PSA) level were measured at 6 and 12 months.

RESULTS: The BPEP and OP techniques emphasized similar mean operating durations (91.4 vs 87.5 min) and resected tissue weights (108.3 vs 115.4 g). The postoperative haematuria rate (2.9% vs 12.9%) as well as the mean haemoglobin drop (1.7 vs 3.1 g/dL), catheterization period (1.5 vs 5.8 days) and hospital stay (2.1 vs 6.9 days) were significantly improved for BPEP. Recatheterization for acute urinary retention was more frequent in the OP group (8.6% vs 1.4%), while the rates of early irritative symptoms were similar for BPEP and OP (11.4% vs 7.1%). During the follow-up period, no statistically significant difference was determined in terms of IPSS, Qmax, QoL, PVR, PSA level and postoperative prostate volume between the two series.

CONCLUSIONS: BPEP represents a promising endoscopic approach in large BPH cases, characterized by good surgical efficiency and similar BPH tissue removal capabilities compared with standard transvesical prostatectomy. BPEP patients benefited from significantly reduced complications, shorter convalescence and satisfactory follow-up symptom scores and voiding parameters.



BPEP (Technique)

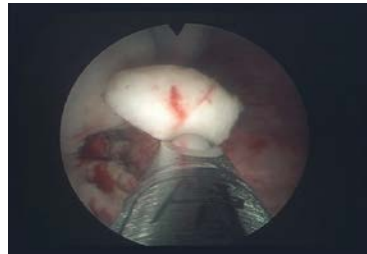
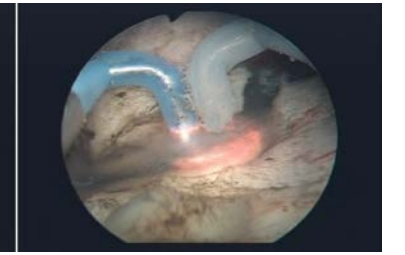
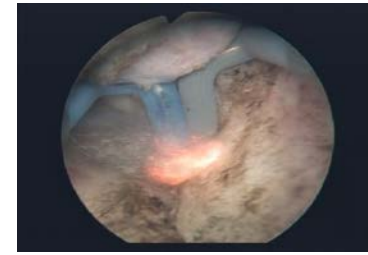
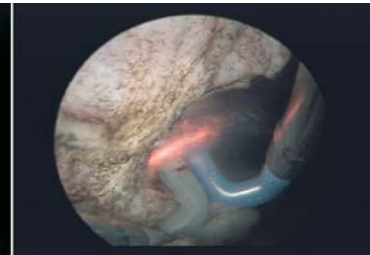
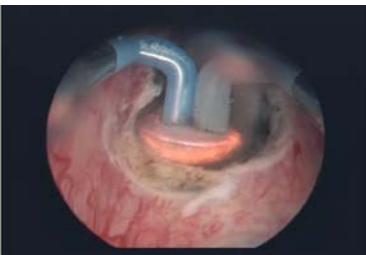
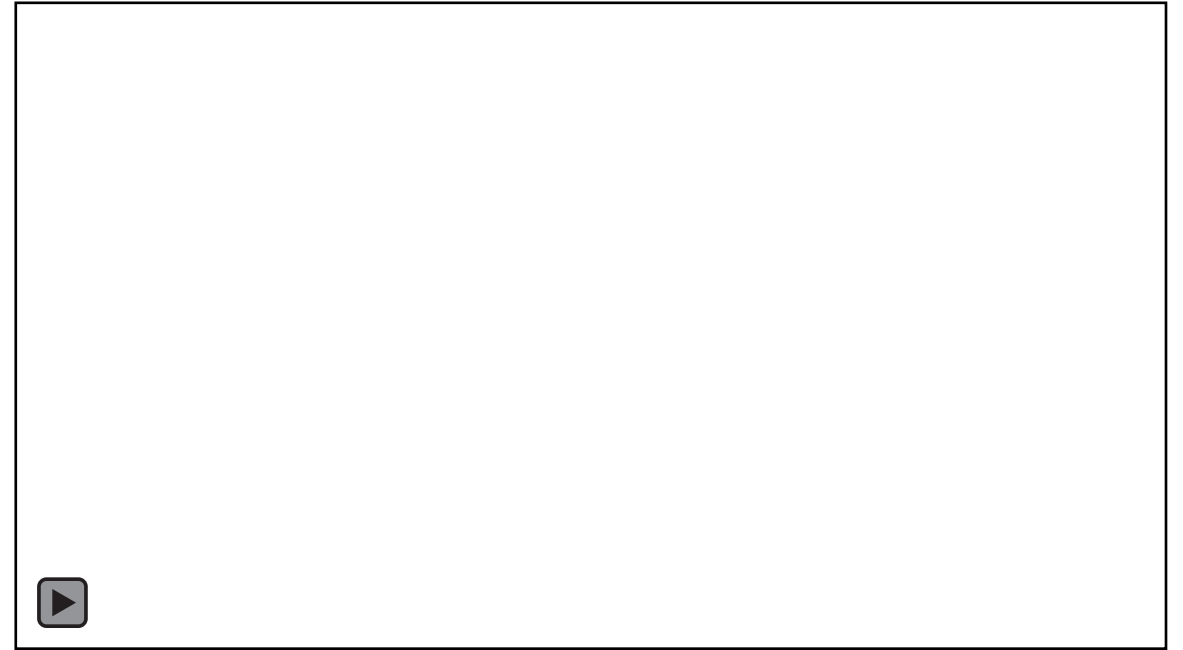
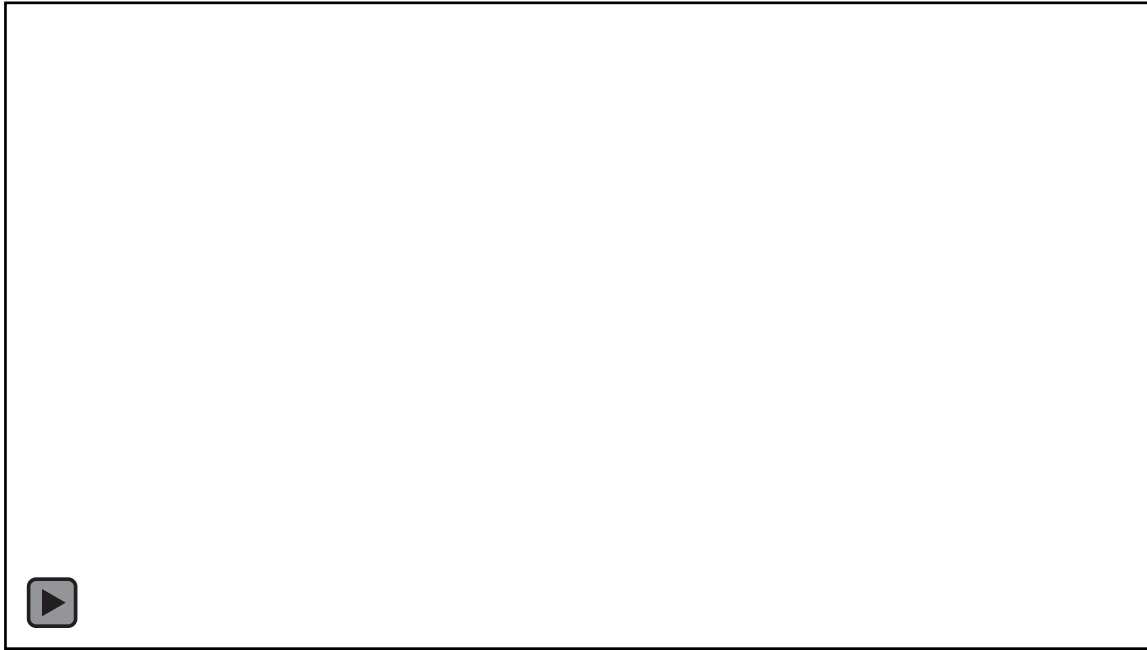


SurgMasterUES-40/ESG 400 (Olympus Europe, Hamburg, Germany),
PlasmaButton/OvalButton electrode, OES-Pro bipolar resectoscope,
Piranha morcellator (R.Wolf GmbH, Knittlingen, Germany)

Geavlete et al. Eur Urol Today. 2011;23:37



BPEP (Technique)

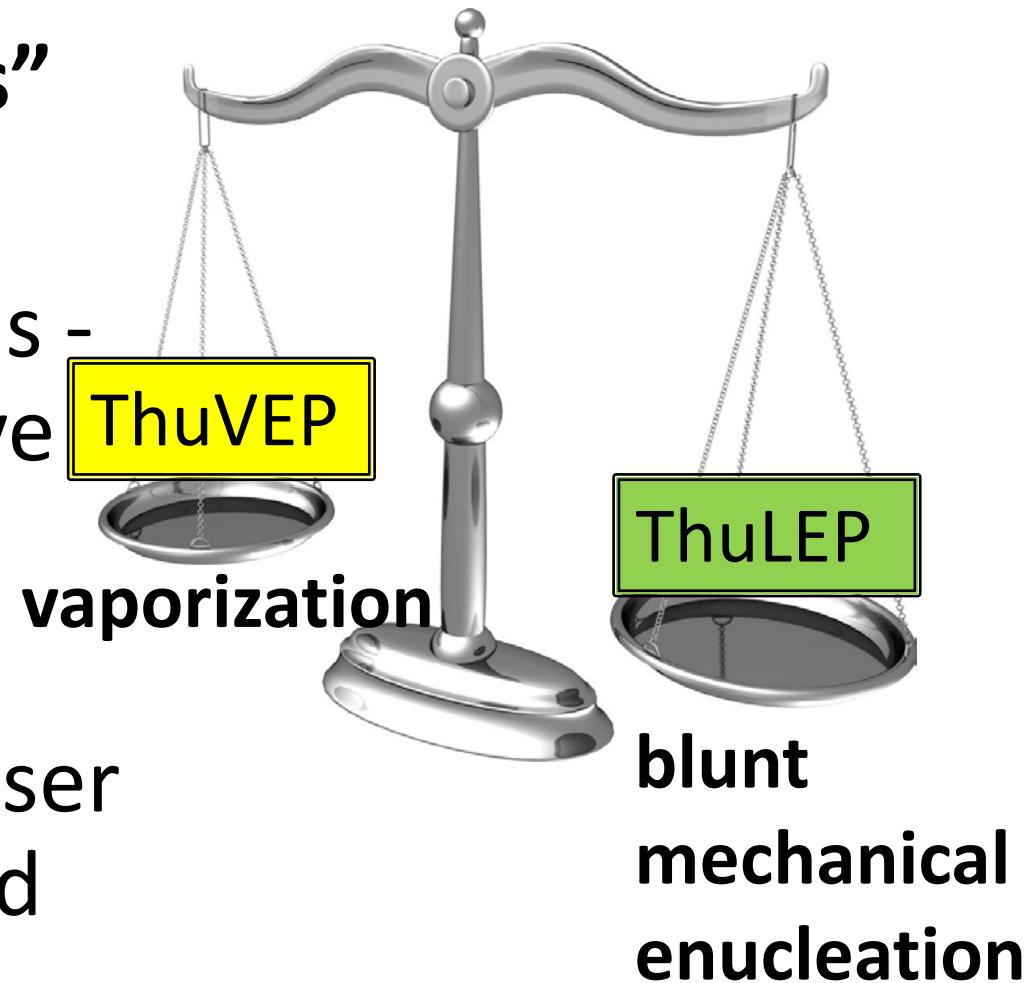


Geavlete et al. *BJU Int.* 2013;111:793-803



ThuVEP & ThuLEP

- ◆ ThuVEP and ThuLEP: “**surgical twins**”
- ◆ ThuVEP focuses on the favorable **vaporization effect** of the continuous - wave laser to perform a fast, effective and safe enucleation
- ◆ ThuLEP focuses on almost **blunt mechanical enucleation** using the laser only for dissection of adhesences and mucosa



ThuVEP (Thechnique)

70 W Tm:YAG laser; 550 μ laser fiber

(Revo-Lix[®], LISA Laser products, Katlenburg, Germany)

26 Fr. continuous-flow laser resectoscope & morcellator

(R. Wolf, Knittlingen, Germany)

Technique similar to the three lobe technique in HoLEP (5-7-12h incisions)



ThuVEP & ThuLEP: RCTs

Comparison	n	PV (ml)	FU (mo)	IPSS/ Qmax	OR Time	Catheter Time	Hospital Time
ThuVEP vs. (TURP) ¹	59	60	12	NS	ThuVEP	ThuVEP	ThuVEP
ThuLEP vs. PKRP ²	158	70	60	NS	PKRP	ThuLEP	ThuLEP
ThuLEP vs. TURis ³	208		3	NS	NS	ThuLEP	ThuLEP
ThuLEP vs. HoLEP ⁴	133	45	18	NS	HoLEP	NS	-
ThuLEP vs. PKEP ⁵	127	90	12	NS	NS	ThuLEP	NS

ThuVEP & ThuLEP: References and Conclusions

1. *Hong et al. Chin Med J (Engl). 2015;128:884-9*
2. *Yang et al. Lasers Med Sci. 2016;31:1797-802*
3. *Bozzini et al. Actas Urol Esp. 2017;41:309-315*
4. *Zhang et al. Urology. 2012;79:869-74*
5. *Feng et al. J Endourol. 2016;30:665-70*

**EAU Guidelines on
Management of
Non-Neurogenic
Male Lower Urinary
Tract Symptoms
(LUTS), incl.
Benign Prostatic
Obstruction (BPO)**

S. Gravas (Chair), T. Bach, M. Drake, M. Gacci, C. Gratzke,
T.R.W. Herrmann, S. Madersbacher, C. Mamoulakis,
K.A.O. Tikkinen
Guidelines Associates: M. Karavatakis, S. Malde, V. Sakkalis,
R. Umbach

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Thulium enucleation may be an alternative to TURP and HoLEP in men with moderate-to-severe LUTS leading to immediate and mid-term objective and subjective improvements.	1b	A
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EAU guidelines on Management of non-neurogenic male LUTS, 2017



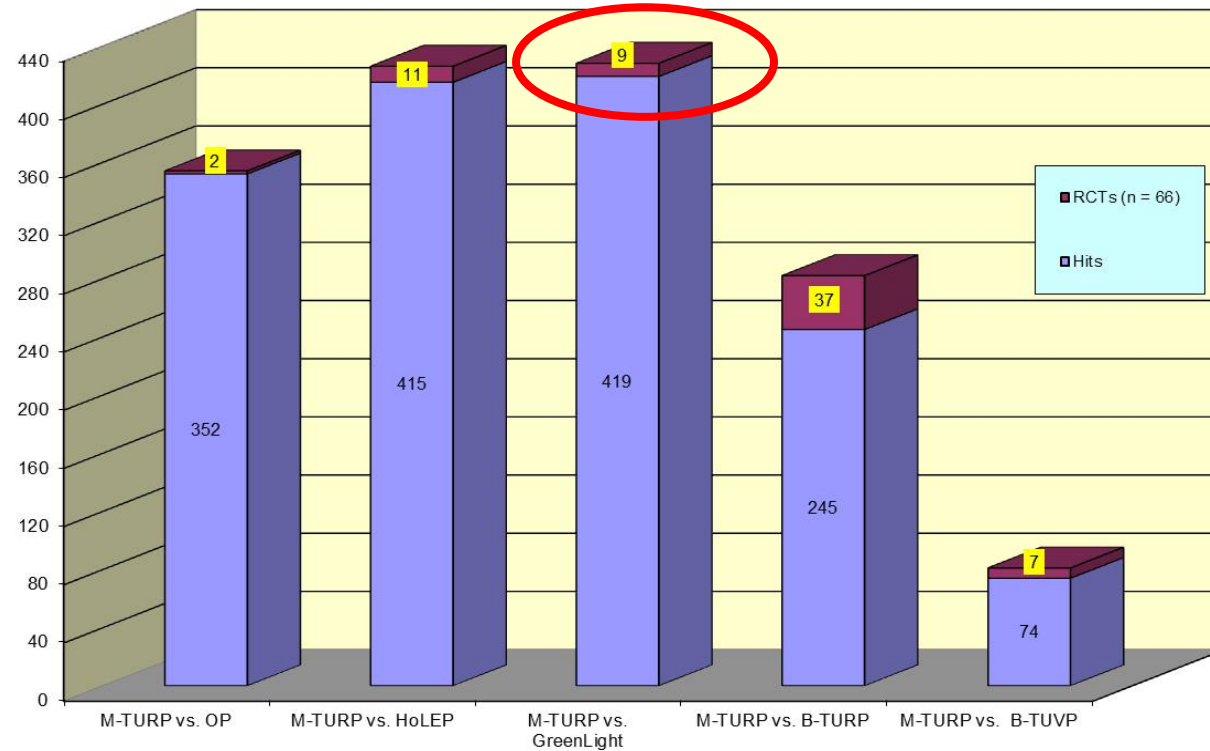
Laser vaporization of the prostate (532 nm - Greenlight)



The Kalium-Titanyl-Phosphate (KTP) and the lithium triborate (LBO; HPS) lasers work at a wavelength of 532 nm. Energy is absorbed by Hgb - not by water. PVP leads to immediate BPO/ LUTS relief. Currently, the standard system is the 180-W-XPS but the majority of evidence comes from the former systems (that differ in max power output, fiber design/energy tissue interaction)



Greenlight laser vs. TURP



2 Meta-analyses: similar results

Thangasamy et al. Eur Urol. 2012;62:315-23 (9 RCTs [KTP/LBO]; n=889)

Cornu et al. Eur Urol. 2015;67:1066-96

(6 RCTs [LBO]; n=697)



Limitations of the meta-analyses

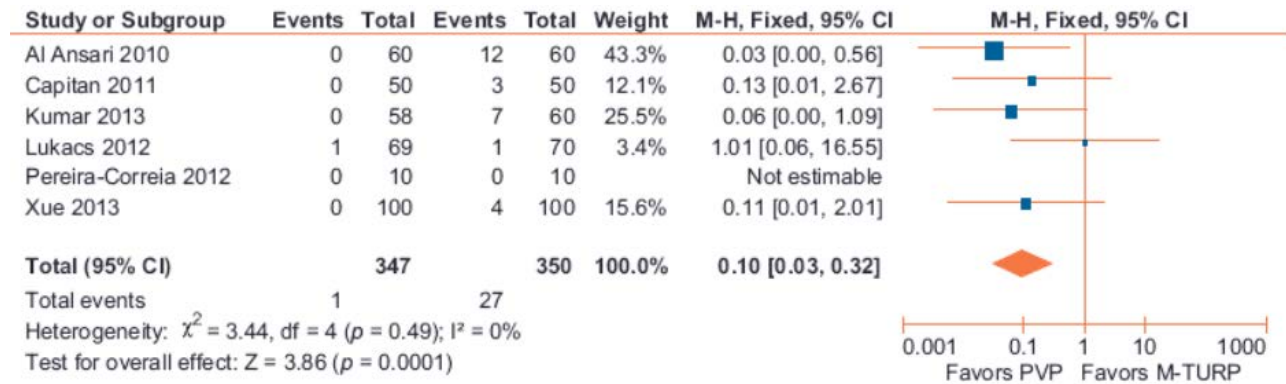
- ◆ Relative low number of RCTs
- ◆ Relatively low quality of RCTs
- ◆ Relative heterogeneity among RCTs
- ◆ Relatively short follow-up (12 mo)
- ◆ No data for the 180-W-XPS
- ◆ Lack of subgroup analysis (KTP, LBO; Thangasamy)



Greenlight (LBO) laser vs. TURP

- ◆ Similar efficacy (12 mo)
- ◆ Similar safety (AUR, UTI, BNC, stricture rates)
- ◆ Greenlight: Better perioperative profile:

- Lower risk of transfusion



- Shorter catheterization-hospitalization duration

- ◆ TURP: Shorter OR duration, lower reoperation rate

Cornu et al. Eur Urol. 2015;67:1066-96



Greenlight (XPS) laser vs. TURP

- ◆ Goliath Study: Multicentre (29 centers/9 European countries) Non-inferiority RCT
- Largest RCT (N=281; 1:1) to compare GL with TURP
- The only RCT to compare 180W-XPS with TURP
- 3 publications to date: results at 6 mo 12 mo and 24 mo



Platinum Priority – Benign Prostatic Obstruction
Editorial by Jean-Nicolas Cornu and Stephan Madysbacher on pp. 103–104 of this issue

A Multicenter Randomized Noninferiority Trial Comparing GreenLight-XPS Laser Vaporization of the Prostate and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: Two-yr Outcomes of the GOLIATH Study



Platinum Priority – Benign Prostatic Obstruction
Editorial by Charalambos Mamoulakis on pp. 943–945 of this issue

180-W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-Month Safety and Efficacy Results of a European Multicentre Randomised Trial—The GOLIATH Study

A European Multicenter Randomized Noninferiority Trial Comparing 180 W GreenLight XPS Laser Vaporization and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 12-Month Results of the GOLIATH Study

570 | www.jurology.com
0022-5347/15/1932-0570/0
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<http://dx.doi.org/10.1016/j.juro.2014.09.001>
Vol. 193, 570-578, February 2015
Printed in U.S.A.



The Goliath Study: Conclusions

Conclusions: XPS was shown to be noninferior (comparable) to TURP in terms of IPSS, Q_{\max} , and proportion of patients free of complications. XPS results in a lower rate of early reinterventions but has a similar rate after 6 mo.

Trial registration: ClinicalTrials.gov, identifier NCT01218672.

Conclusions: Followup at 1 year demonstrated that photoselective vaporization of the prostate produced efficacy outcomes similar to those of transurethral resection of the prostate. The complication-free rates and overall reintervention rates were comparable between the treatment groups.

Conclusions: Twenty-four-mo follow-up data demonstrated that GL-XPS provides a durable surgical option for the treatment of BPO that exhibits efficacy and safety outcomes similar to TURP.

Bachmann et al. Eur Urol. 2014;65:931-42

Bachmann et al. J Urol. 2015;193:570-8

Thomas et al. Eur Urol. 2016;69:94-102



Greenlight laser vaporization of prostate

Recommendations	LE	GR
Holmium laser enucleation and 532-nm laser vaporisation of the prostate are alternatives to transurethral resection of the prostate (TURP) in men with moderate-to-severe LUTS leading to immediate, objective, and subjective improvements comparable with TURP.	1a	A
The short-term and mid-term functional results of 532-nm laser vaporisation of the prostate are comparable with TURP.	1b	A
With regard to intra-operative safety, 532-nm laser vaporisation is superior to TURP.	1b	A
532-nm laser vaporisation should be considered in patients receiving anticoagulant medication or with a high cardiovascular risk.	3	B

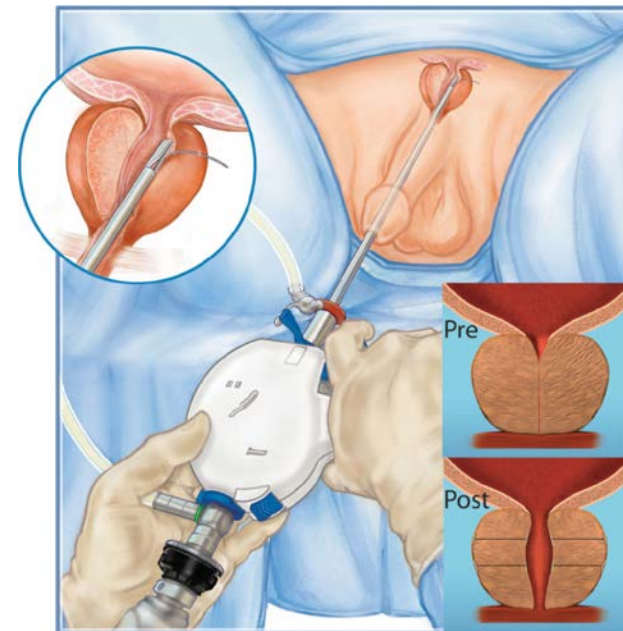
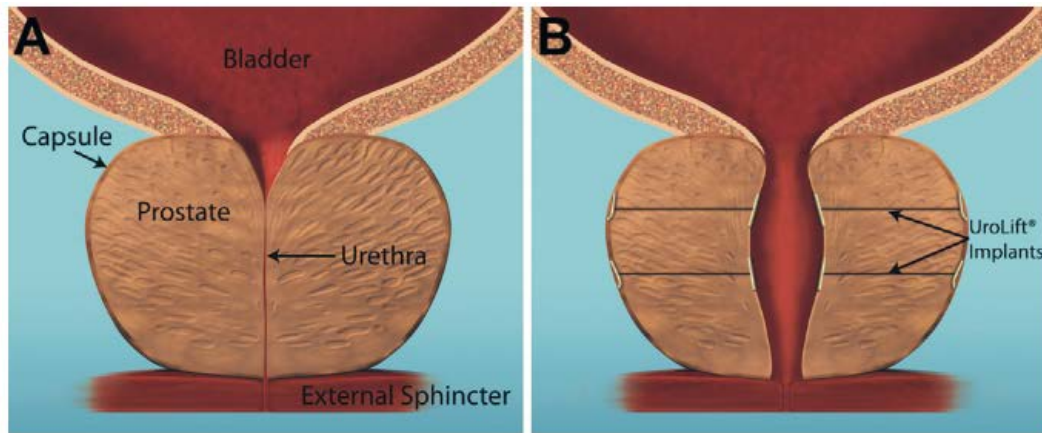
EAU Guidelines on Management of Non-Neurogenic Male LUTS, 2017



Prostatic urethral lift (PUL)



Under local or general anesthesia, lateral lobes are compressed by small permanent suture-based implants delivered under cystoscopic guidance (Urolift[®]), resulting in a prostatic urethra opening that leaves a continuous anterior channel through the prostatic fossa from the bladder neck to the verumontanum



The Prostatic Urethral Lift for the Treatment of Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The L.I.F.T. Study

Roehrborn et al. J Urol. 2013;190:2161-7

- ◆ Multicenter blind study (19 sites: USA – Canada – Australia)
- ◆ PUL vs sham randomization: 2-1 N=206 (PUL: 140/sham: 66)
- ◆ Incl. criteria: Age ≥ 50 , IPSS ≥ 13 , $Q_{\max} \leq 12$ ml/s, PV:30-80 ml
- ◆ Sham: Rigid cystoscopy with sounds mimicking the PUL
- ◆ Primary endpoint: Reduction of IPSS at 3 mo
- ◆ Follow up 12 mo



Results: A total of 206 men were randomized (prostatic urethral lift 140 vs sham 66). The prostatic urethral lift and sham AUASI was reduced by 11.1 ± 7.67 and 5.9 ± 7.66 , respectively ($p = 0.003$), thus meeting the primary end point. Prostatic urethral lift subjects experienced AUASI reduction from 22.1 baseline to 18.0, 11.0 and 11.1 at 2 weeks, 3 months and 12 months, respectively, $p < 0.001$. Peak urinary flow rate increased 4.4 ml per second at 3 months and was sustained at 4.0 ml per second at 12 months, $p < 0.001$.

Adverse events were typically mild and transient. There was no occurrence of de novo ejaculatory or erectile dysfunction.

Conclusions: The prostatic urethral lift, reliably performed with the patient under local anesthesia, provides rapid and sustained improvement in symptoms and flow, while preserving sexual function.



Three year results of the prostatic urethral L.I.F.T. study.

Roehrborn et al. Can J Urol. 2015;22:7772-82

RESULTS: The therapeutic effect of PUL regarding IPSS was 88% greater than sham at 3 months. Average improvements from baseline through 3 years were significant for total IPSS (41.1%), quality of life (48.8%), Qmax (53.1%), and individual IPSS symptoms. Symptomatic improvement was independent of prostate size. There were no de novo, sustained ejaculatory or erectile dysfunction events and all sexual function assessments showed average stability or improvement after PUL. Fifteen of the 140 patients originally randomized to PUL required surgical reintervention for treatment failure within the first 3 years.

CONCLUSIONS: PUL offers rapid improvement in voiding and storage symptoms, quality of life and flow rate that is durable to 3 years. Patients demonstrated a level of symptom relief that is associated with significant patient satisfaction. PUL, a minimally invasive procedure, is very effective in treating bothersome LUTS secondary to benign prostatic obstruction (BPO) and is unique in its ability to preserve total sexual function while offering a rapid return to normal physical activities.



available at www.sciencedirect.com
journal homepage: www.europeanurology.com



Sønksen et al. Eur Urol.
2015;68:643-52

Platinum Priority – Benign Prostatic Hyperplasia

Editorial by Bilal Chughtai, Alexis E. Te, Steven A. Kaplan and Richard K. Lee on pp. 653–654 of this issue

Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month Results from the BPH6 Study



Trials

Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study

Gratzke et al. BJU Int.
2017;119:767-75



Tolerability and safety: The most common complications reported post-operatively included haematuria (16-63%), dysuria (25-58%), pelvic pain (5-17.9%), urgency (7.1-10%), transient incontinence (3.6-16%), and UTI (2.9-11%). Most symptoms were mild-to-moderate in severity and resolved within two to four weeks after the procedure.

Practical considerations: An obstructed/protruding median lobe cannot be effectively treated, and the effectiveness in large prostate glands has not been shown yet. Long-term studies are needed to evaluate the duration of the effect in comparison to other techniques.

Recommendation	LE	GR
Offer Prostatic urethral lift (Urolift®) to men with LUTS interested in preserving ejaculatory function, with prostates < 70 mL and no middle lobe. Inform patients that long-term effects have not been evaluated.	1a	B

EAU Guidelines on Management of Non-Neurogenic Male LUTS, 2017



Ευχαριστώ

