

# Η ορθή ανάγνωση μιας δημοσίευσης



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Ουρολογική Κλινική  
Πανεπιστημίου Θεσσαλίας

# Conflict of interest

*Speaker Honoraria and/or Company Consultant:*

GSK

Pierre Fabre Medicament

Lilly

Angelini Pharma Hellas

# Ανάγνωση δημοσίευσης: Επιλογή

Χρόνος, πρόσβαση και ικανότητες για την άσκηση EBM  
Ο μέσος ιατρός αφιερώνει 2 h την εβδομάδα ενώ όγκος  
ιατρικής πληροφορίας ↑↑↑

*Eisenberg JM. J Health Polit Policy Law 2001*

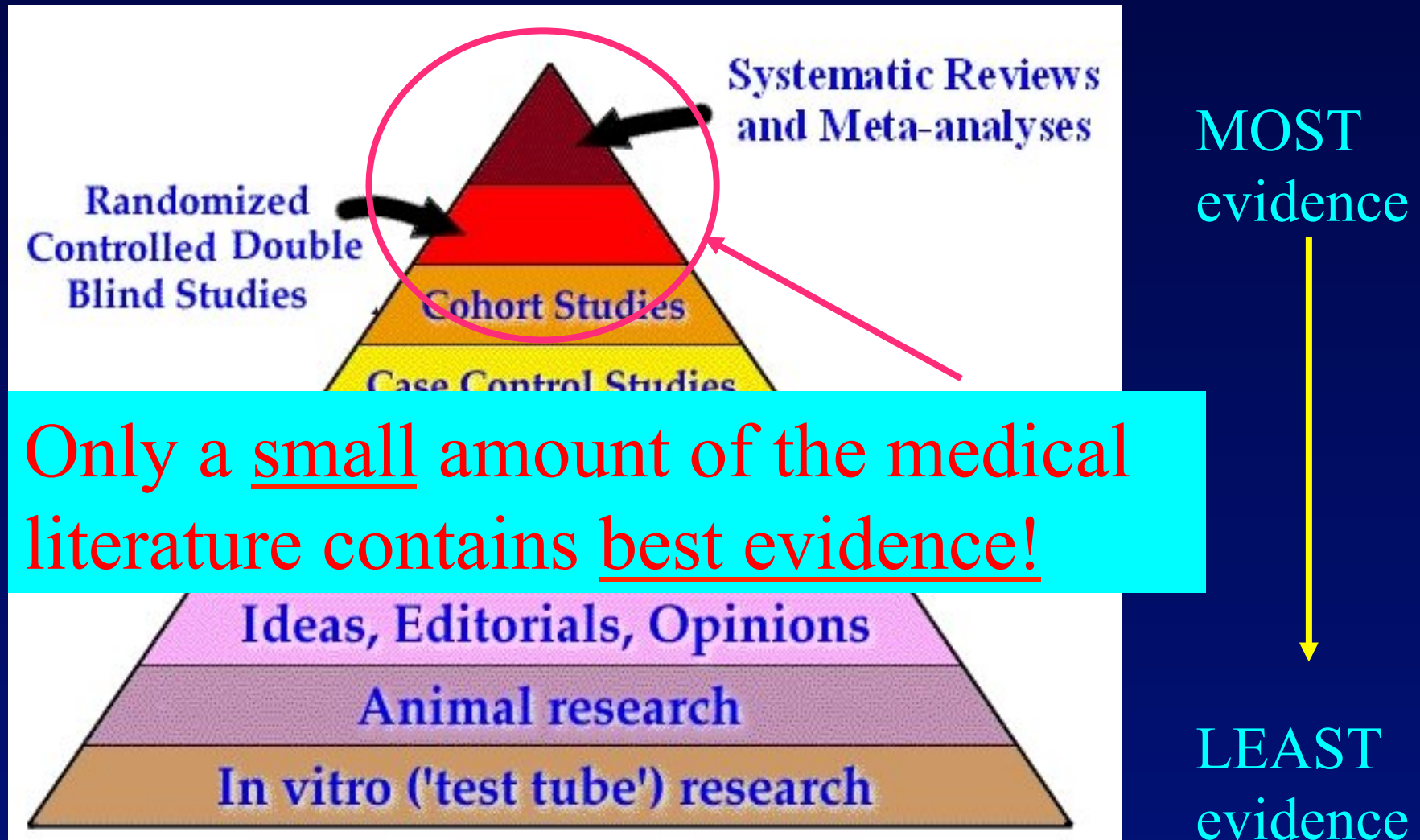
“Work; finish; publish”

*M. Faraday (1791-1867)*

“Publish or perish”

*WCE 2010 Chicago*

# Evidence Pyramid



*From SUNY Downstate Medical Research Library*

# Ανάγνωση δημοσίευσης: Βαθμός τεκμηρίωσης

Level	Type of Evidence
1a	Evidence obtained from meta-analysis of randomised trials
1b	Evidence obtained from at least one randomised trial
2a	Evidence obtained from one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental studies, such as comparative or correlation studies and case reports
4	Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

*Modified from Oxford Centre for Evidence-based Medicine – Levels of Evidence  
(March 2009)*

# Ανάγνωση: Consort Checklist for RCTs

**CONSORT 2010** checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item
<b>Title and abstract</b>		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts <sup>21 31</sup> )
<b>Introduction</b>		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
<b>Methods</b>		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
<b>Randomisation:</b>		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

# Ανάγνωση: Consort Checklist for RCTs

## Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms <sup>26</sup> )
<b>Discussion</b>		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
<b>Other information</b>		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

# Ανάγνωση: Υλικό και μέθοδος

- Ο πυρήνας του άρθρου
- Ίσως το λιγότερο διαβασμένο τμήμα του άρθρου
- Πως σχεδιάστηκε η μελέτη,  
πως πραγματοποιήθηκε,  
πως αναλύθηκαν τα στοιχεία
- Πρέπει να επιτρέπει την αναπαραγωγή



# Ανάγνωση: Υλικό και Μέθοδος

- Περίοδος εισαγωγής – παρακολούθησης ασθενών
- Τύπος μελέτης (αναδρομική, προοπτική, συγκριτική, τυχαιοποιημένη)
- Κριτήρια εισαγωγής / επιλογή ασθενών
- Κριτήρια αποκλεισμού / Γιατί;
- Συμμόρφωση με κανόνες ηθικής

## Preliminary Results of Prostate Vaporization in the Treatment of Benign Prostatic Hyperplasia by Using a 200-W High-intensity Diode Laser

Chien-Hsu Chen, Po-Hui Chiang, Yao-Chi Chuang, Wei-Ching Lee, Yen-Ta Chen, and Wei-Chia Lee

UROLOGY 75: 658–663, 2010.

## PATIENTS AND METHODS

### Study Population

This study included 55 patients diagnosed with LUTS secondary to BPH, treated between December 2007 and July 2008. All the patients responded poorly to medical treatment. A digital rectal examination was performed, and the serum prostate-specific antigen (PSA) levels were determined. Prostate biopsy was performed if prostate cancer was suspected. The subjective symptoms were evaluated using the following parameters: International Prostate Symptom Score (IPSS), maximum uroflow rate ( $Q_{max}$ ), prostate volume, postvoid residual (PVR) urine volume, quality of life score (QoLs), and PSA level. Complete blood cell count and serum chemistry profile were determined and urine analysis was performed before the surgery. The inclusion criterion for the patients was urinary symptoms of moderate to severe intensity, as indicated by  $Q_{max} \leq 15$  mL/s and  $IPSS \geq 10$ . Urodynamic studies, including pressure-flow studies, were performed only in cases in which neurogenic bladder was suspected. Informed consent was obtained from all the patients. Patients with neurogenic bladder, prostate cancer, prostate volume  $\leq 25$  mL, or those who had previously undergone urethral surgery were excluded from this study. Patients with ongoing treatment with anticoagulants, such as aspirin, clopidogrel and warfarin, were not excluded in this series. This study was approved by the institutional review board of our hospital.

# Ανάγνωση: Υλικό και Μέθοδος

- Τεχνικές ή μέθοδοι ή θεραπείες
  - λεπτομερής περιγραφή πρωτότυπων μεθόδων/τεχνικών
  - αναφορά (citation) γνωστών μεθόδων
  - θεραπείες που συγκρίνονται
  - Δόση, συχνότητα
- Follow up

## **Preliminary Results of Prostate Vaporization in the Treatment of Benign Prostatic Hyperplasia by Using a 200-W High-intensity Diode Laser**

Chien-Hsu Chen, Po-Hui Chiang, Yao-Chi Chuang, Wei-Ching Lee, Yen-Ta Chen, and Wei-Chia Lee

### **Procedure Performed With 200-W Diode Laser**

The physicians performing the procedure were highly experienced using potassium-titanyl-phosphate (KTP) laser and TURP. The surgery was performed using a diode laser with a power of 200 W (Urolaser 980; Limmer Laser, GmbH, Berlin, Germany). A side-firing laser fiber was introduced through a 24F Wolf continuous flow cystoscope into the prostate. Normal saline was used as an irrigant. The procedure was performed under general or spinal anesthesia. The power is usually set to 150 W with continuous wave mode at the start of the procedure. The lateral lobes were vaporized bilaterally at first. After the working space from bladder neck to verumontanum was created, the power setting was increased to 200 W to widen the cavity. The middle lobe, if present, was vaporized after completing the lateral lobe vaporization. The dedicated fiber emits the laser beam in a side-firing manner to permit vaporization, without direct tissue contact with the fiber surface. An output power of 150 W was used for vaporization of the apical and the anterior regions of the prostate. When bleeding was observed, the laser beam (at the same power setting) was directed to that region to achieve hemostasis. The end-point of the procedure is a deobstructed patent channel. Finally, a 20F 3-way Foley catheter was inserted and all the patients received prophylactic antibiotic therapy for 7 days after the operation.

### **Measurements**

The following parameters were assessed at baseline, 1 month after the surgery, and then at an interval of 6 months: IPSS,  $Q_{max}$ , PVR urine volume, and QoLs. The prostate volume and PSA level were assessed at baseline and 6 months after the operation. The prostate volume was calculated using transrectal ultrasound. The peri- and postoperative complications were recorded.

# Ανάγνωση: Υλικό και Μέθοδος

- Ποια test και που  
*students t-test*
- Εξαρτάται από το είδος  
των παραμέτρων
- Πολύπλοκες  
στατιστικές μέθοδοι
- Ανάγκη βασικής  
στατιστικής γνώσης

## Benign Prostatic Hyperplasia

### The Effects of Combination Therapy with Dutasteride and Tamsulosin on Clinical Outcomes in Men with Symptomatic Benign Prostatic Hyperplasia: 4-Year Results from the CombAT Study

Claus G. Roehrborn<sup>a,\*</sup>, Paul Siami<sup>b</sup>, Jack Barkin<sup>c</sup>, Ronaldo Damiao<sup>d</sup>, Kim Major-Walker<sup>e</sup>, Indrani Nandy<sup>e</sup>, Betsy B. Morrill<sup>e</sup>, R. Paul Gagnier<sup>e</sup>, Francesco Montorsi<sup>f</sup>  
on behalf of the CombAT Study Group

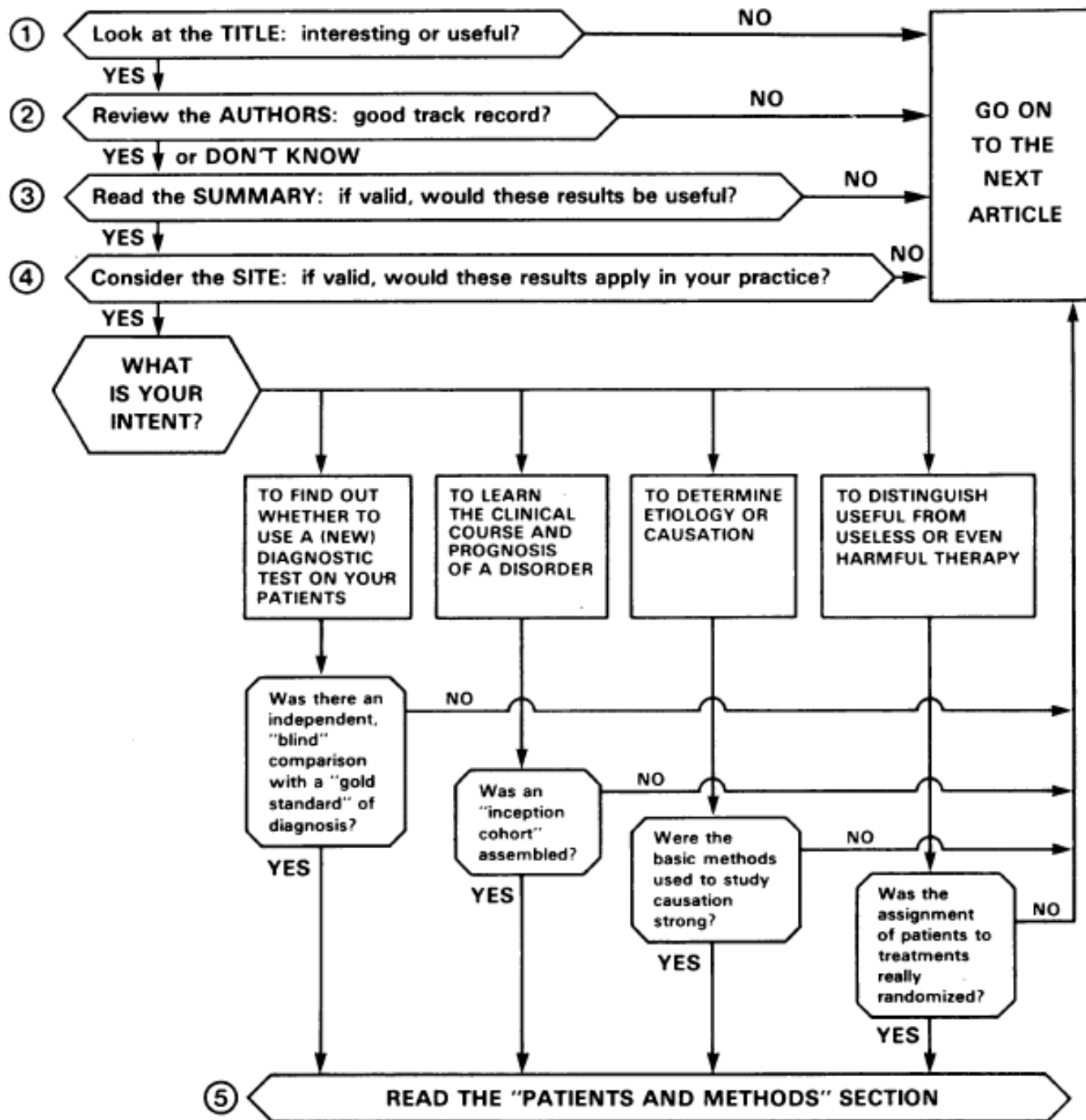
#### 2.3. Study end point and statistical analyses

The primary end point at 4 yr was time to first event of AUR or BPH-related prostatic surgery, defined as the number of days from the date of first dose of randomised study drug to the date of the initial event. The proportion of subjects experiencing AUR or BPH-related surgery was a supportive end point to the primary analysis. To address multiplicity, secondary end points were analysed in a predefined hierarchy (Table 1). Additionally, all primary and secondary end points defined and initially tested at 2 yr were included as secondary end points at 4 yr and analysed according to the hierarchy at year 2 [10]: We report IPSS,  $Q_{max}$ , and prostate volume outcomes in this paper.

The intent-to-treat population was the primary population analysed, consisting of all subjects randomised to double-blind study treatment. The primary comparison was combination versus tamsulosin, for which the study was powered at 94%; a comparison of combination versus dutasteride was also performed. The primary analysis used a log rank test stratified by investigative site cluster. Superiority for combination versus tamsulosin and dutasteride was based on a two-sided  $p$  value at  $\alpha = 0.01$ . The relative risk (hazard ratio) for the treatment effect and associated two-sided 95% confidence intervals were estimated using a Cox proportional hazards model with treatment as the only covariate and stratified by investigative site cluster.

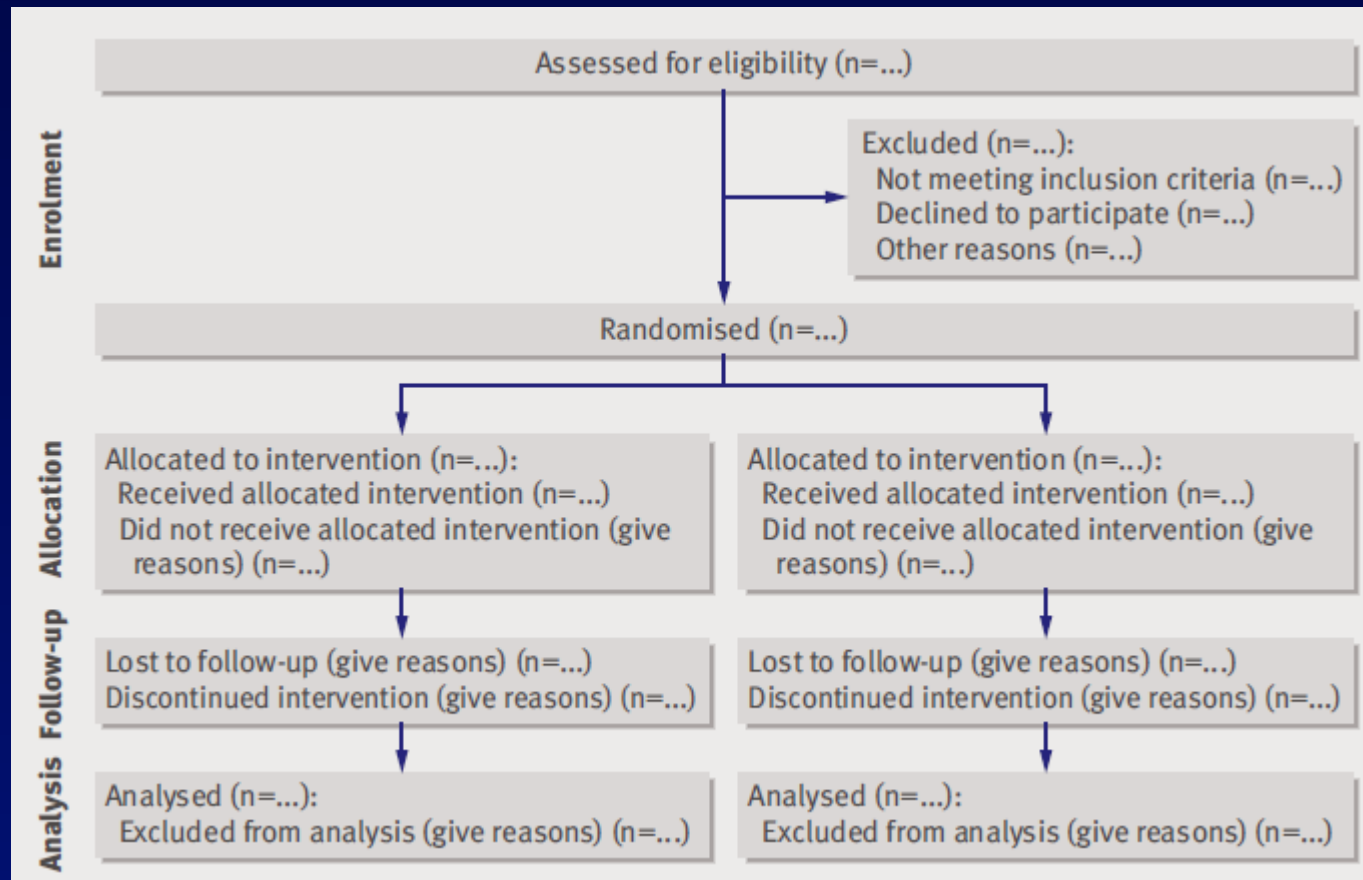
# Ανάγνωση δημοσίευσης: Επιλογή

*CMA Journal 1981*





# Ανάγνωση δημοσίευσης: Πίνακας ροής ασθενών



# Ανάγνωση: Αποτελέσματα

## Κύρια καταληκτικά σημεία

- Πριν (δείγμα σταθμισμένο)
- Μετά (λόγοι ευκολίας – θετικών αποτελεσμάτων)

## Αναπαραγωγή αποτελέσματα

- 0% επιπλοκές

"Never theorize before you have data.  
Invariably, you end up  
twisting facts to suit theories  
instead of theories to suit facts."

–Sherlock Holmes

# European Urology: Reporting

“We encourage authors to report outcomes and complications in a structured manner. We advise the use of peer reviewed documents to guide this such as: ”

EUROPEAN UROLOGY 61 (2012) 341–349

available at [www.sciencedirect.com](http://www.sciencedirect.com)  
journal homepage: [www.europeanurology.com](http://www.europeanurology.com)



## Guidelines

### Reporting and Grading of Complications After Urologic Surgical Procedures: An ad hoc EAU Guidelines Panel Assessment and Recommendations

*Dionysios Mitropoulos<sup>a,\*</sup>, Walter Artibani<sup>b</sup>, Markus Graefen<sup>c</sup>, Mesut Remzi<sup>d</sup>,  
Morgan Rouprêt<sup>e</sup>, Michael Truss<sup>f</sup>*

# Ανάγνωση: Αποτελέσματα

Στατιστική σημαντικότητα:

α) Δεν είναι στατιστικώς σημαντικό  
*Μικρό δείγμα??????*

β) Είναι στατιστικώς σημαντικό  
*Κλινικώς σημαντικό??????*

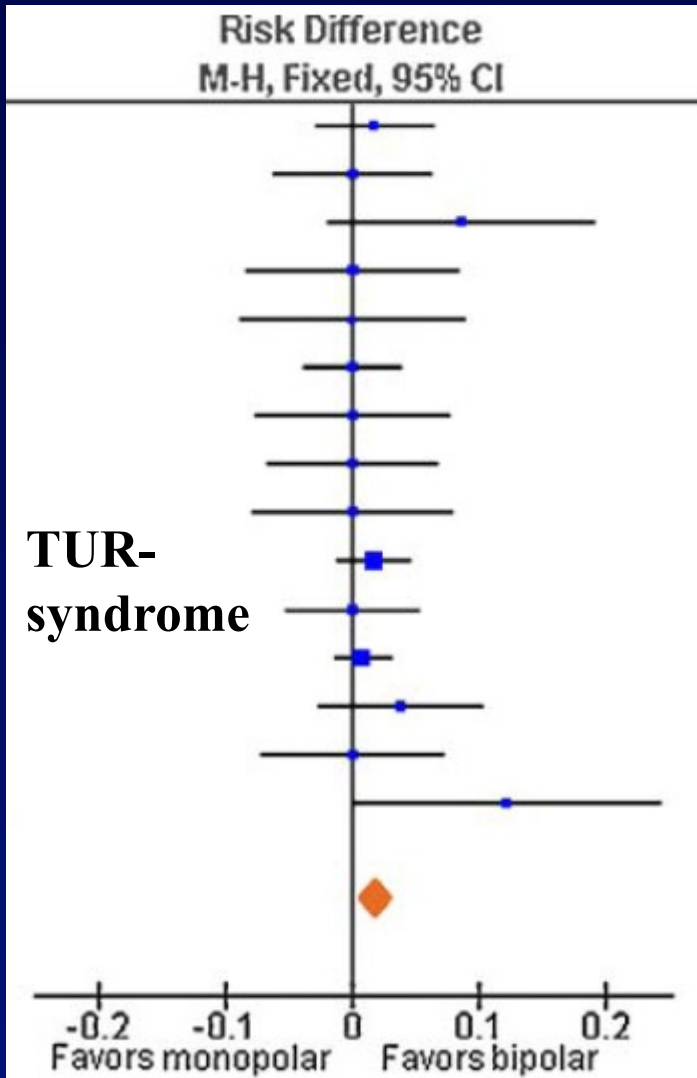
Table 1 Nocturnal voiding frequency (IPSS Q7)

Variable	Placebo	Tadalafil 5 mg
IPSS Q7 (all patients)		
<i>N</i>	735	742
Baseline (mean ± SD)	2.3 ± 1.2	2.3 ± 1.2
Endpoint (mean ± SD)	1.9 ± 1.2	1.7 ± 1.2
Change (mean ± SD)	-0.4 ± 1.1	-0.5 ± 1.2
Treatment difference LSM ± SE (95 % CI)	-0.2 ± 0.05 (-0.3, -0.1)	
<i>p</i> value	0.002	

*Oelke et al, World J Urol 2014*



# Ανάγνωση: Αποτελέσματα



NNT and NNH:  
Numbers Needed to Treat  
Numbers Needed to Harm

Serum Na<sup>+</sup> levels:

Significantly lower after M-TURP

TUR syndrome rates:

NNH = 50 (95% CI: 33-111)

*Mamoulakis et al Eur Urol 2009*

# Ανάγνωση δημοσίευσης: Αποτελέσματα

## Follow-up – απώλειες

### THREE-YEAR FOLLOW-UP OF FEEDBACK MICROWAVE THERMOTHERAPY VERSUS TURP FOR CLINICAL BPH: A PROSPECTIVE RANDOMIZED MULTICENTER STUDY

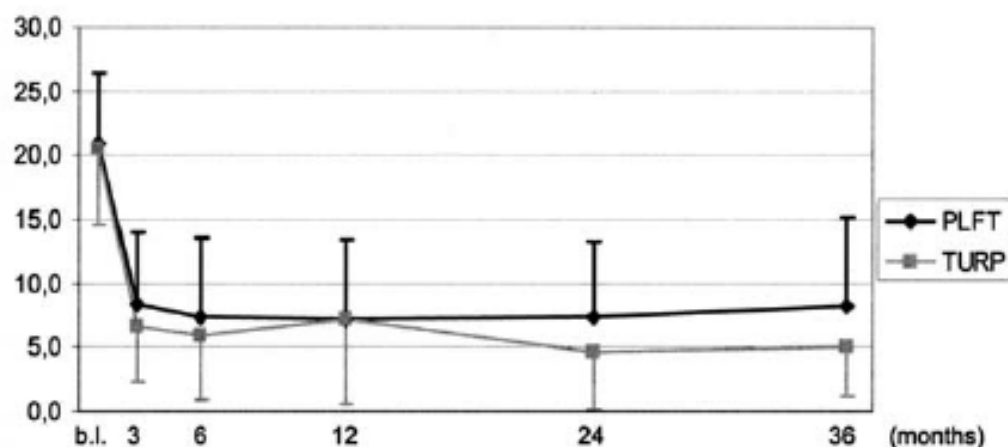


FIGURE 1. IPSS after PLFT and TURP during study period.

Ανάγκη Θεραπείας?  
ITT: Intention To Treat

Parameter	Baseline			12 mo			24 mo			36 mo		
	Mean (SD)	n	P Value	Mean (SD)	n	P Value*	Mean (SD)	n	P Value*	Mean (SD)	n	P Value*
IPSS												
PLFT	21.0 (5.4)	99	—	7.2 (6.2)	93	0.578	7.2 (5.9)	77	0.014	8.2 (6.9)	68	0.024
TURP	20.4 (5.9)	46	—	7.1 (6.6)	43		4.6 (4.4)	38		5.0 (3.9)	35	

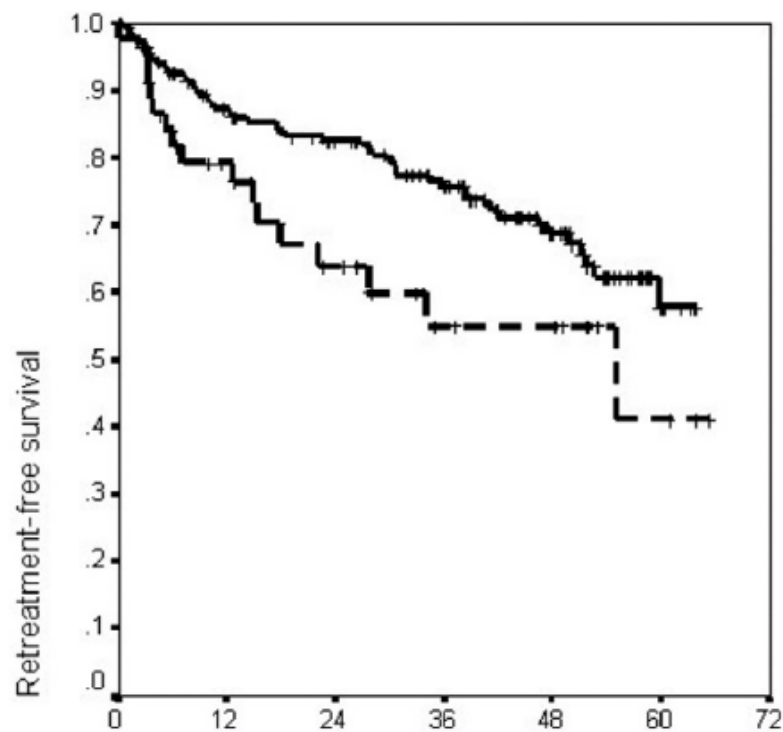
# Durability of 30-Minute High-Energy Transurethral Microwave Therapy for Treatment of Benign Prostatic Hyperplasia: A Study of 213 Patients With and Without Urinary Retention

**Table 2.** Clinical outcomes [mean (SD)] at baseline and to 60 months after treatment with TUMT 3.5

	Baseline	12 mo	24 mo	36 mo	48 mo	60 mo
No retention (n)	168	113	100	80	54	13
Qmax	8.5 (3.7)	14.8 (8.0)	13.1 (7.2)	12.1 (5.9)	13.2 (9.4)	9.9 (4.5)

## RESULTS

The overall mean follow-up period was 33.9 months, with a maximum of 65 months.



However, the objective and subjective responses of our study were determined from those patients who remained in the study and represent the responders.

*Gravas et al Urology 2007*

# Ανάγνωση δημοσίευσης: Συζήτηση

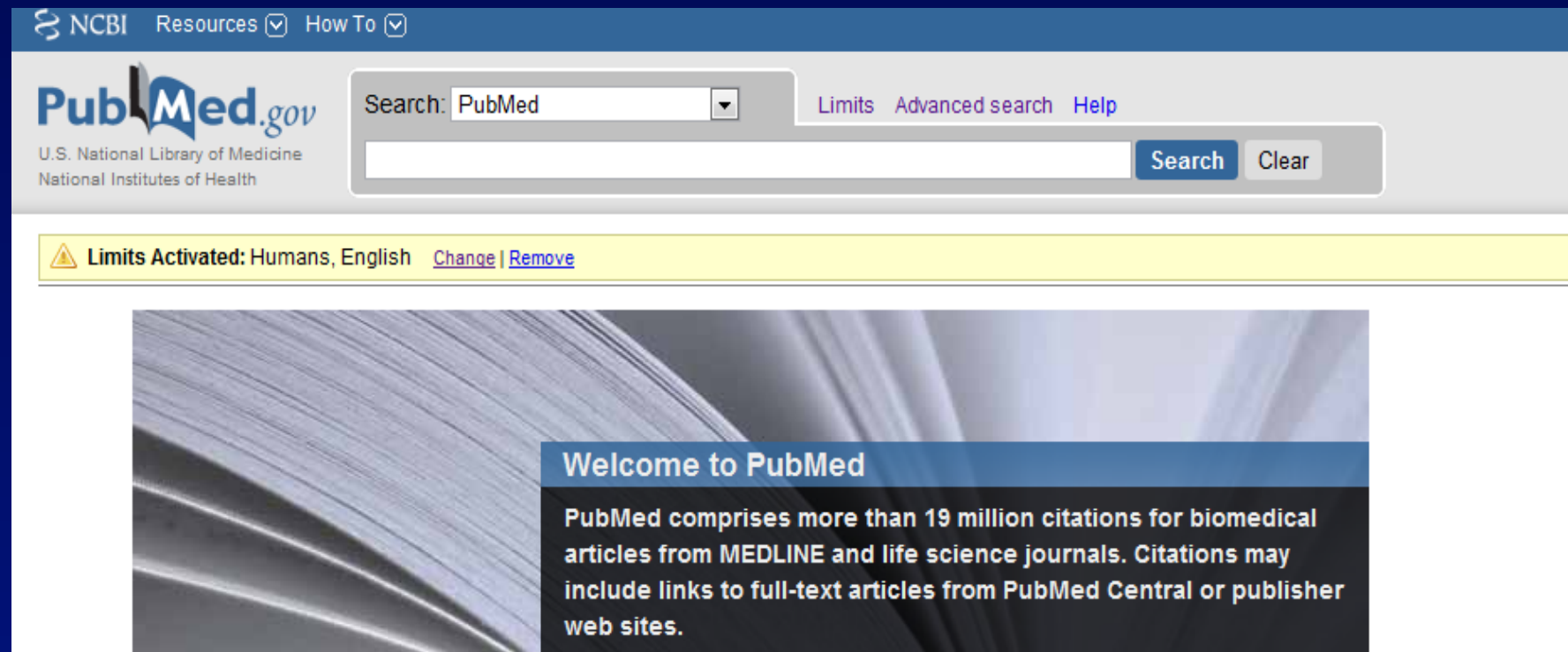
- Εφαρμογή αποτελεσμάτων στο γενικό πληθυσμό
- Μακρύ Follow-up

*Ογκολογικά αποτελέσματα*

*Το παράδειγμα της ΚΥΠ*

# Ανάγνωση δημοσίευσης: Συζήτηση

- Περιλαμβάνεται όλη η σημαντική βιβλιογραφία;
- Περιλαμβάνονται αντίθετες μελέτες;  
*Προϋπόθεση βαθιά γνώση βιβλιογραφίας  
(διάβασμα - πεδίο ενδιαφέροντος)*



The screenshot shows the PubMed.gov website interface. At the top, there is a navigation bar with "NCBI Resources" and "How To" dropdown menus. The main header features the "PubMed.gov" logo, the text "U.S. National Library of Medicine National Institutes of Health", and a search bar containing "PubMed". To the right of the search bar are links for "Limits", "Advanced search", and "Help". Below the search bar is a "Search" button and a "Clear" button. A yellow banner below the search bar indicates "Limits Activated: Humans, English" with "Change" and "Remove" links. The main content area features a "Welcome to PubMed" section with a background image of a book. The text in this section reads: "PubMed comprises more than 19 million citations for biomedical articles from MEDLINE and life science journals. Citations may include links to full-text articles from PubMed Central or publisher web sites."

## *How to read a paper*

# Papers that tell you what things cost (economic analyses)

Trisha Greenhalgh

*BMJ* 1997;315:596-9

### Examples of costs and benefits of health interventions

#### Costs

##### *Direct:*

“Board and lodging”  
Drugs, dressings, etc  
Investigations  
Staff salaries

##### *Indirect:*

Work days lost  
Value of “unpaid” work

##### *Intangible:*

Pain and suffering  
Social stigma

#### Benefits

##### *Economic:*

Prevention of illness that is expensive to treat  
Avoidance of admission to hospital  
Return to paid work

##### *Clinical:*

Postponement of death or disability  
Relief of pain, nausea, breathlessness, etc  
Improved vision, hearing, muscular strength, etc

##### *Quality of life:*

Increased mobility and independence  
Improved wellbeing  
Release from sick role

# Ανάγνωση: Υποστήριξη από τη βιομηχανία



Marketing  
Feasibility studies vs RCTs  
Περισσότερα θετικά  
αποτελέσματα  
MITs που έσβησαν  
Φάρμακα: ΑΕ  
Τουλάχιστον Disclosure CoI  
Αξιοπιστία?!



# Ανάγνωση: Υποστήριξη από τη βιομηχανία

**TABLE. Top 10 Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research**

1. Ensure clinical studies and publications address clinically important questions
2. Make public all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy
3. Improve understanding and disclosure of authors' potential conflicts of interest
4. Educate authors on how to develop quality manuscripts and meet journal expectations
5. Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghostwriting and guest authorship
6. Report adverse event data more transparently and in a more clinically meaningful manner
7. Provide access to more complete protocol information
8. Transparently report statistical methods used in analysis
9. Ensure authors can access complete study data, know how to do so, and can attest to this
10. Support the sharing of prior reviews from other journals



# Ανάγνωση δημοσίευσης: Συμπεράσματα

Διάβασμα - διάβασμα – διάβασμα  
Εκπαίδευση - Κριτική σκέψη  
Journal Club

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ON BEING A DOCTOR

**Annals of Internal Medicine**

**Don't Read This Article**

*Christopher A.K.Y. Chong, MD Ann Intern Med. 2013;158:566-567.*

But does anyone actually *read* all of the studies relevant to his or her practice? And perhaps more important, does the average clinician really *need* to?

..... So go ahead, just thumb through those papers, and impress your colleagues by talking about that article you haven't really read!

*Ευχαριστώ πολύ*