

**Σάββατο, Μάρτιος 7, 2015 - 10:00 to 10:30**

**UroSwords**

## **Uro-Swords II: Η στύση επανέρχεται μετά ριζική προστατεκτομή**

**Διαιτητής:**  
**Πέτρος Περιμένης**



**Κωνσταντίνος  
Χατζημουρατίδης**

**Υπερ**



**Δημήτρης Χατζηχρήστου**

**Κατά**

# Δήλωση συμφερόντων

## Δ. Χατζηχρήστου

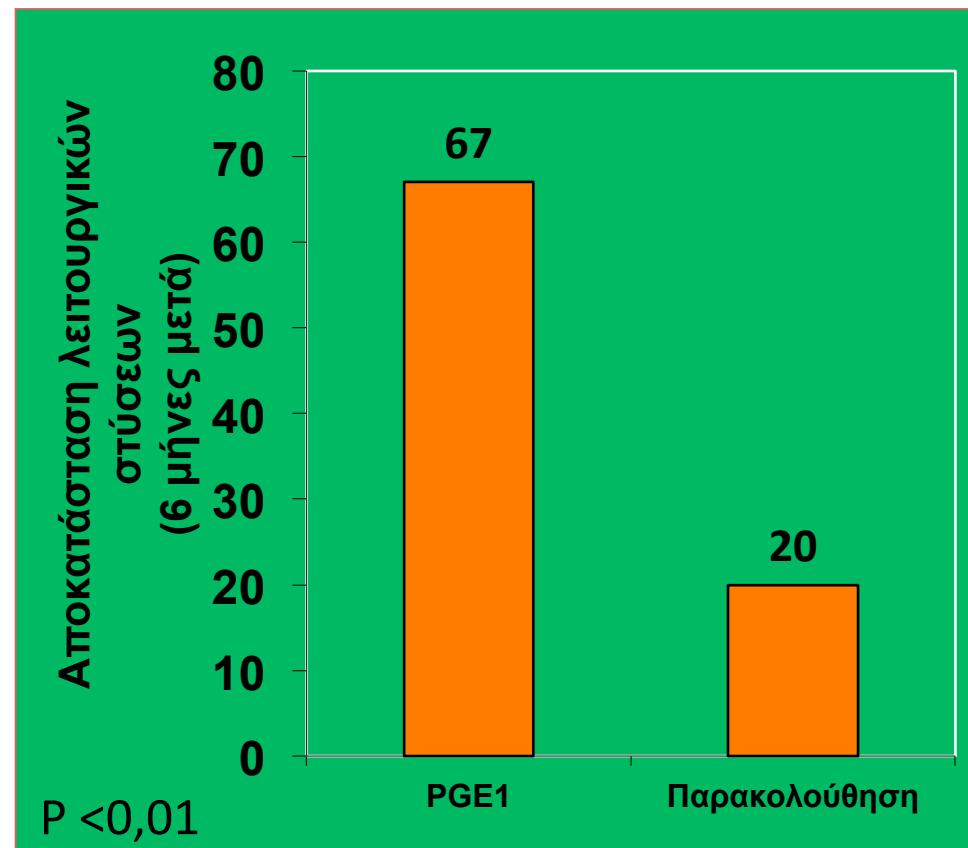
- Lilly
- Menarini
- GSK
- BAYER

# Δήλωση συμφερόντων Κ. Χατζημουρατίδης

- Lilly
- Janssen
- GSK
- Merck

# Πρώιμη χορήγηση αλπροσταδίλης

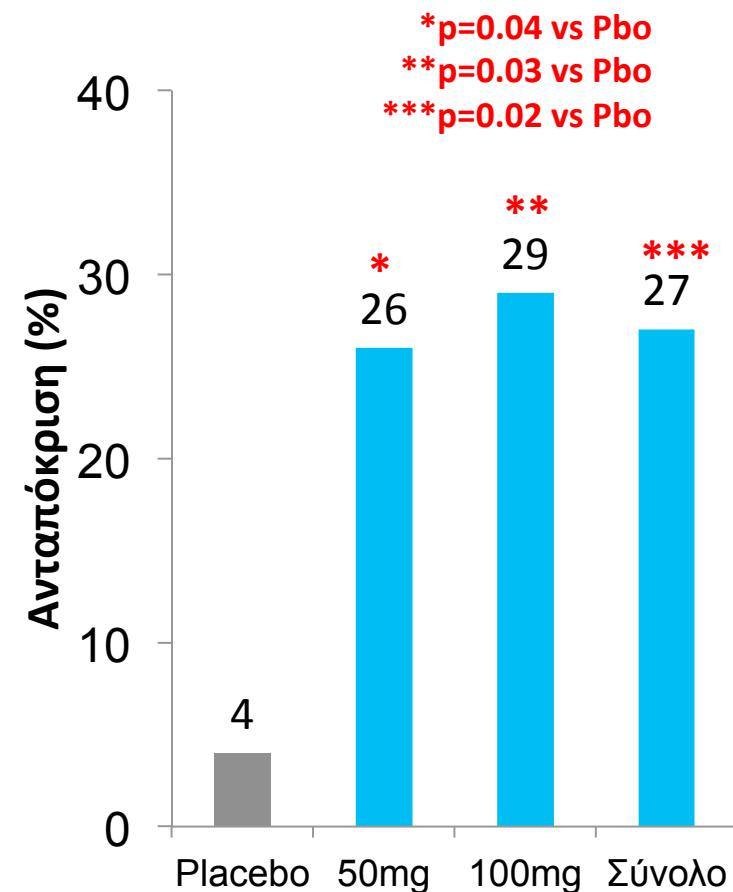
- 3 ενδοσηραγγώδεις ενέσεις αλπροσταδίλης ( $2,5 - 14\mu\text{g}$ ) ανά εβδομάδα για 12 εβδομάδες
- Έναρξη 1 μήνα μετά τη ΡΠ
- Σκοπός ήταν η επίτευξη κάποιου βαθμού διόγκωσης του πέους και όχι απαραίτητα στύσεις ικανές για κολπική διείσδυση
- Σε όλους τους ασθενείς έγινε διατήρηση των σηραγγωδών νεύρων



Montorsi F et al. J Urol 1997, 158:1408-1410

# Πρώιμη χορήγηση σιλδεναφίλης

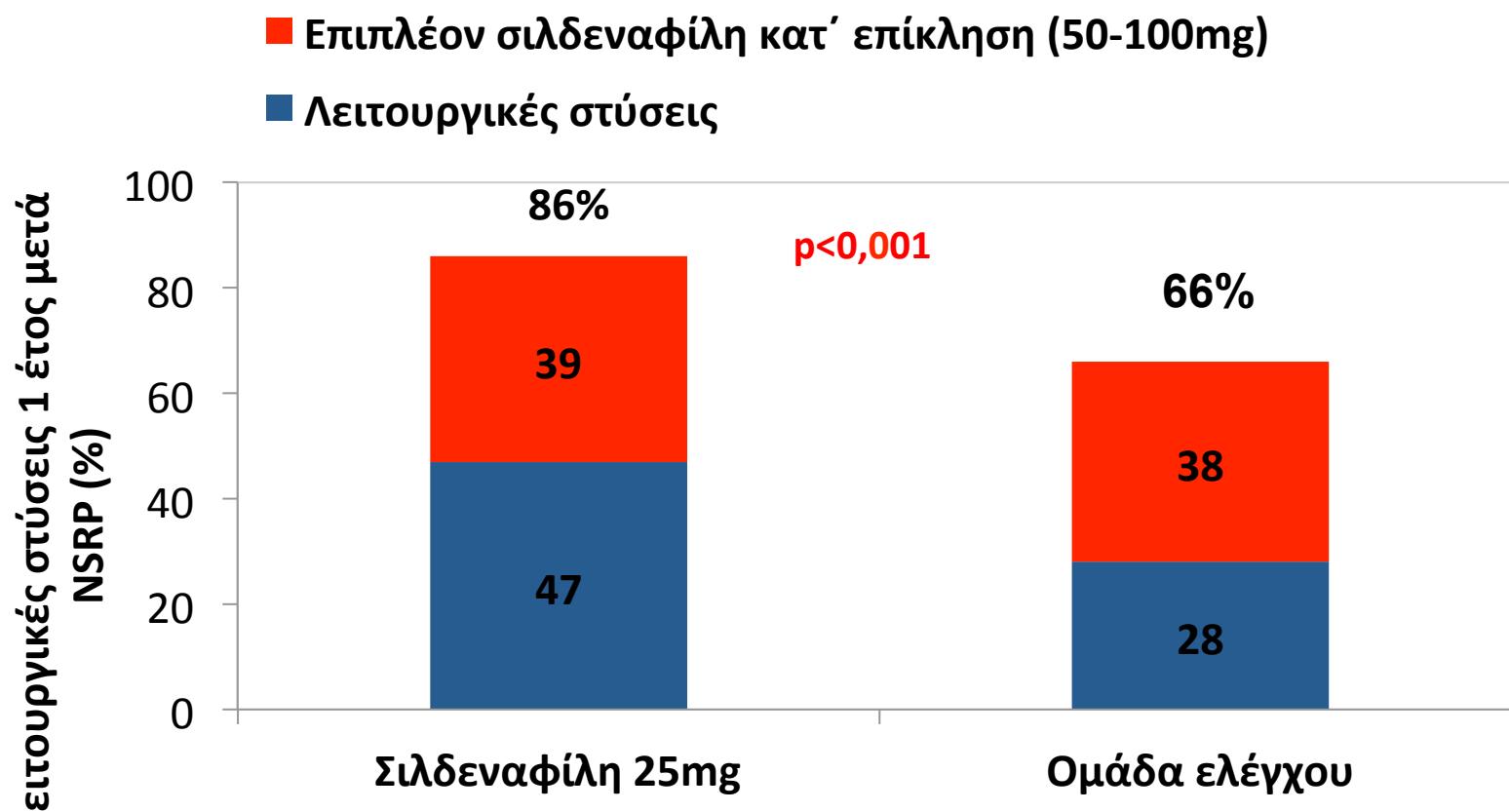
- 76 ασθενείς, έναρξη σιλδεναφίλης 50 ή 100mg, 1 μήνα μετά BNSRP
- Ανταπόκριση μετά από 36 εβδομάδες υπό αγωγή και 8 επιπλέον εβδομάδες χωρίς αγωγή
- Η ανταπόκριση ορίστηκε ως βαθμολογία  $\geq 8$  στις ερωτήσεις 3 και 4 του IIEF και απάντηση 'ναι' στην ερώτηση: 'Κατά τη διάρκεια των τελευταίων 4 εβδομάδων, είχες ικανοποιητικές στύσεις για σεξουαλική δραστηριότητα;'



Padma-Nathan H et al. Int J Impot Res 2008, 20:479-486

Η πρώιμη καθημερινή χορήγηση χαμηλής δόσης σιλδεναφίλης μπορεί να είναι αρκετή για την αποκατάσταση λειτουργικών στύσεων

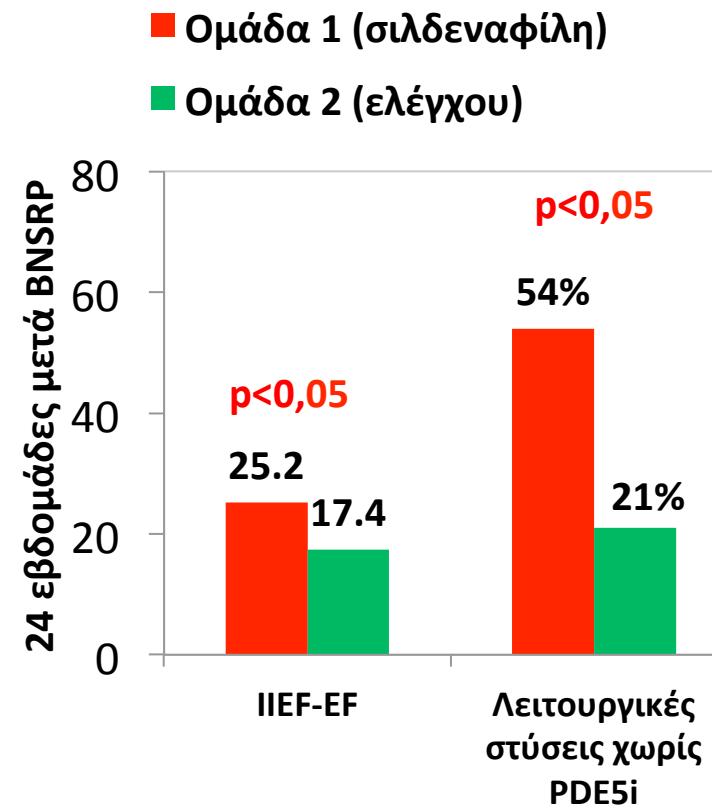
N=43, BNSRP: 32, UNSRP: 11 – Έναρξη την ημέρα μετά την αφαίρεση του καθετήρα  
23 ασθενείς έλαβαν σιλδεναφίλη 25mg κάθε βράδυ, 18 ασθενείς έλαβαν placebo



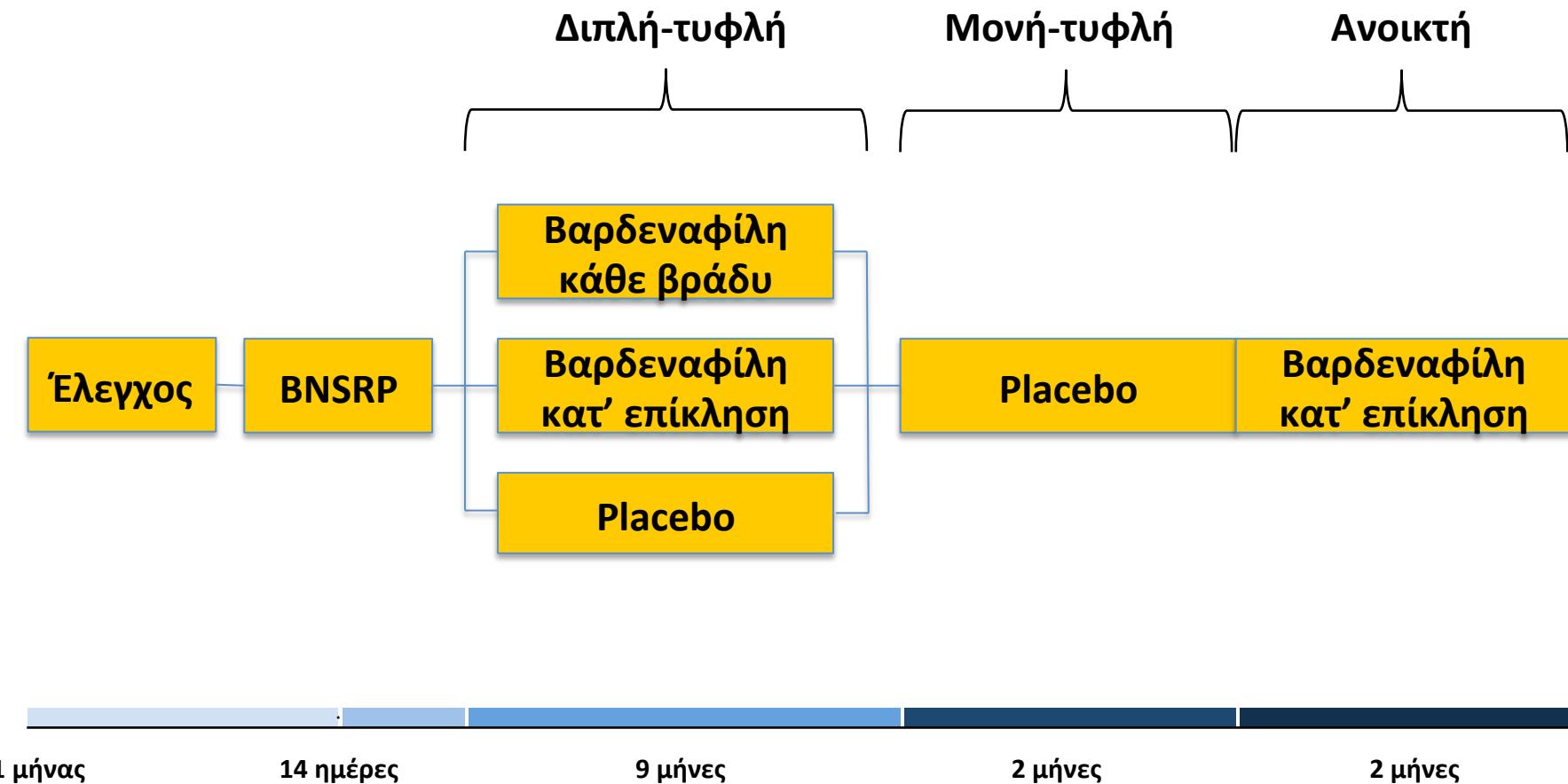
Bannowsky A et al. BJU Int 2008, 101:1279-1283

## Η πρώιμη καθημερινή χορήγηση σιλδεναφίλης βοηθά στην αποκατάσταση λειτουργικών στύσεων

- 40 ασθενείς, BNSRP
- Μέση ηλικία: 58,5
- Προεγχειρητικό IIEF-EF  $\geq 26$
- Έναρξη: 14 ημέρες μετά
- Ομάδα 1: σιλδεναφίλη 50-100mg κάθε βράδυ για 8 εβδομάδες (20 ασθενείς)
- Ομάδα 2: ομάδα ελέγχου (20 ασθενείς)
- Παρακολούθηση για 24 εβδομάδες



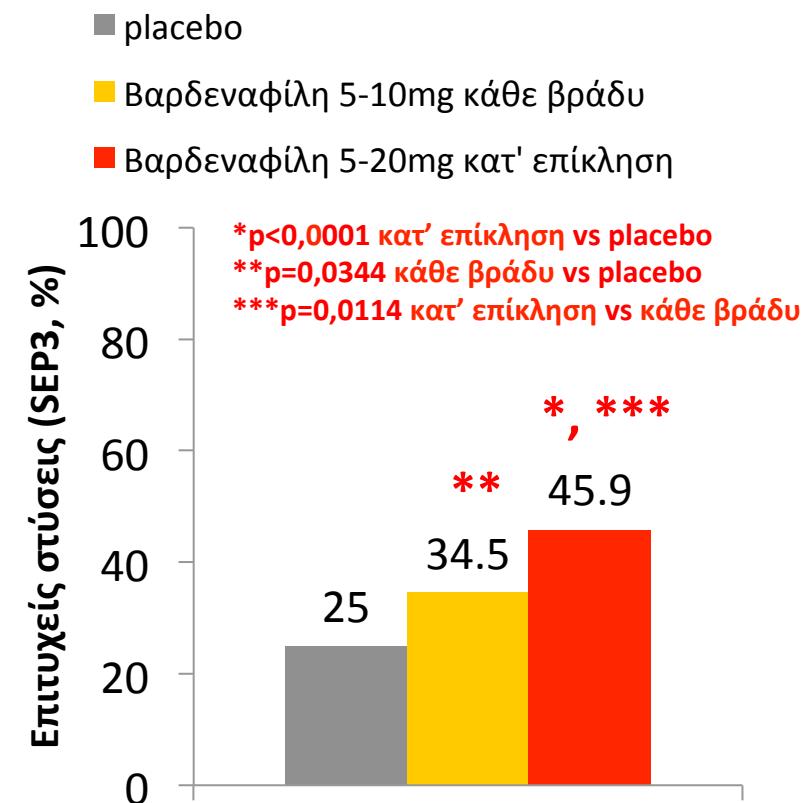
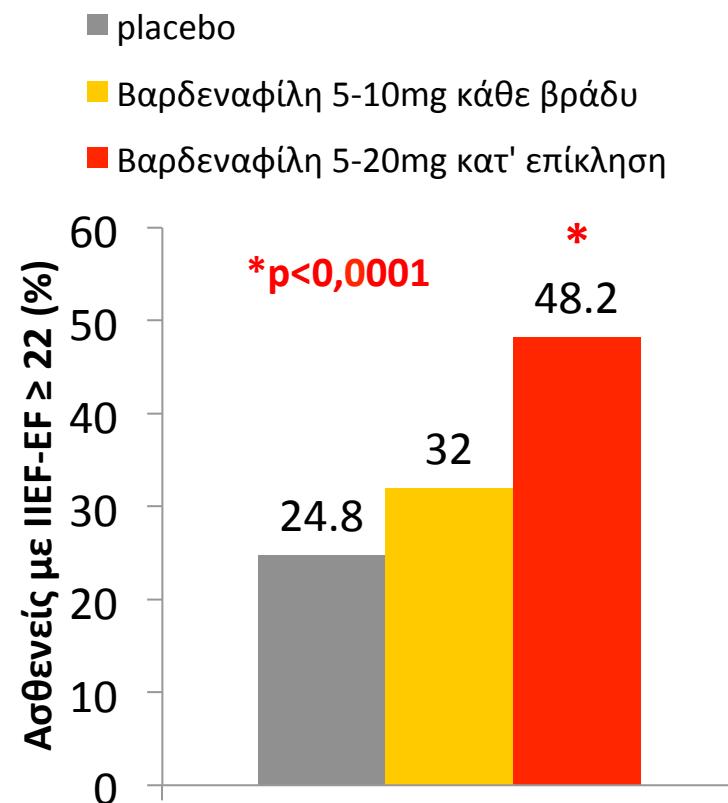
# Κατ' επίκληση ή καθημερινή χορήγηση;



Montorsi F, et al. Eur Urol 2008;54:924-931

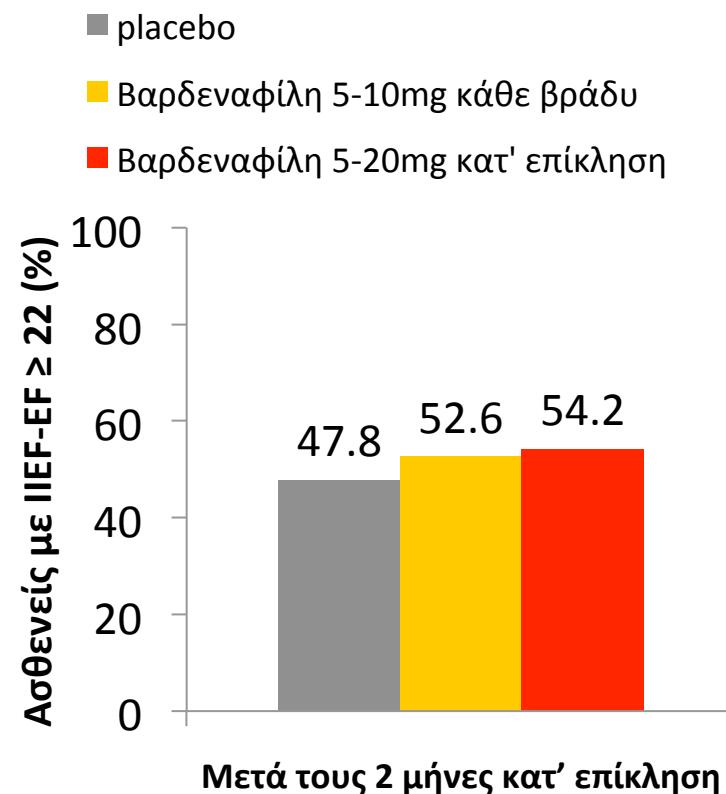
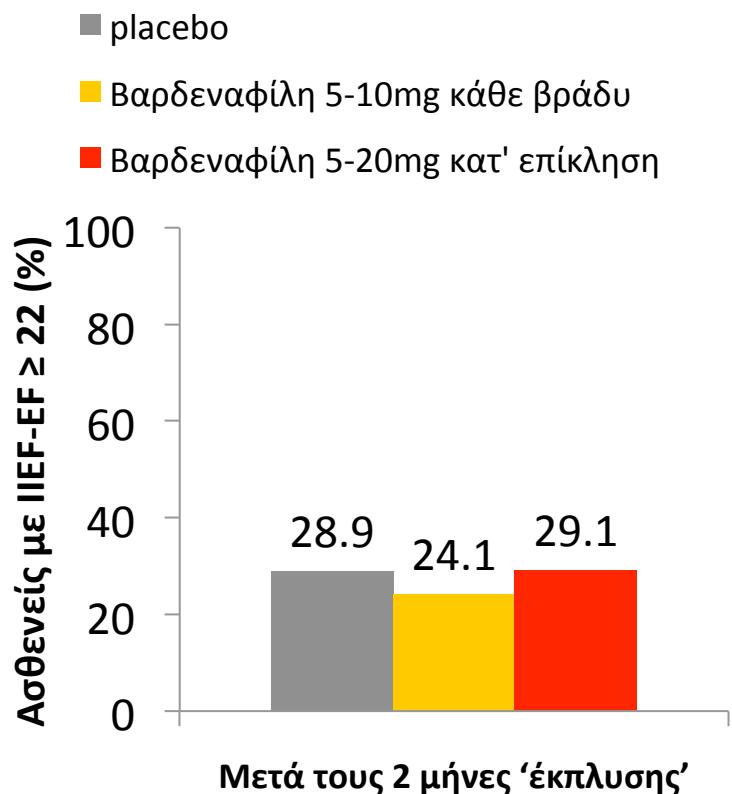
# Η βαρδεναφίλη κατ' επίκληση έχει καλύτερα αποτελέσματα από την καθημερινή χορήγηση

N=628, BNSRP, IIEF-EF $\geq$ 26 πριν τη τυχαιοποίηση



Montorsi F, et al. Eur Urol 2008;54:924-931

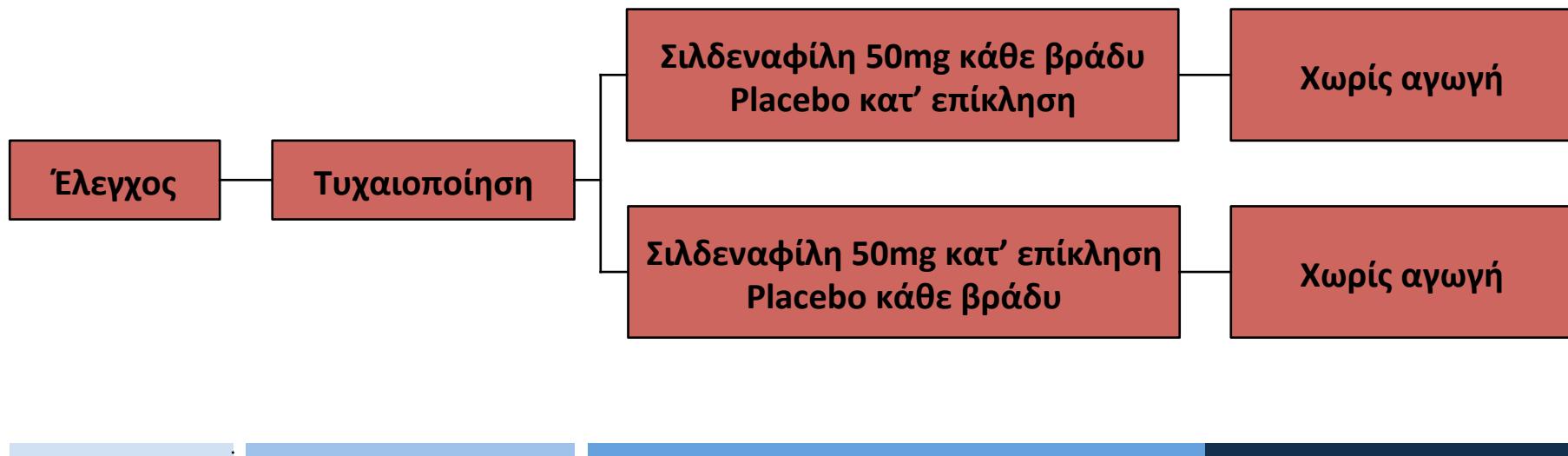
Η βαρδεναφίλη κατ' επίκληση έχει καλύτερα αποτελέσματα από την καθημερινή χορήγηση



Montorsi F, et al. Eur Urol 2008;54:924-931

# Σιλδεναφίλη καθημερινά ή κατ' επίκληση;

- Εκτίμηση της ποιότητας διατήρησης των NVB με τη χρήση βαθμολογίας (0-4)
- Η ποιότητα αυτή ήταν ο καλύτερος προγνωστικός παράγοντας



IIEF-EF ≥25

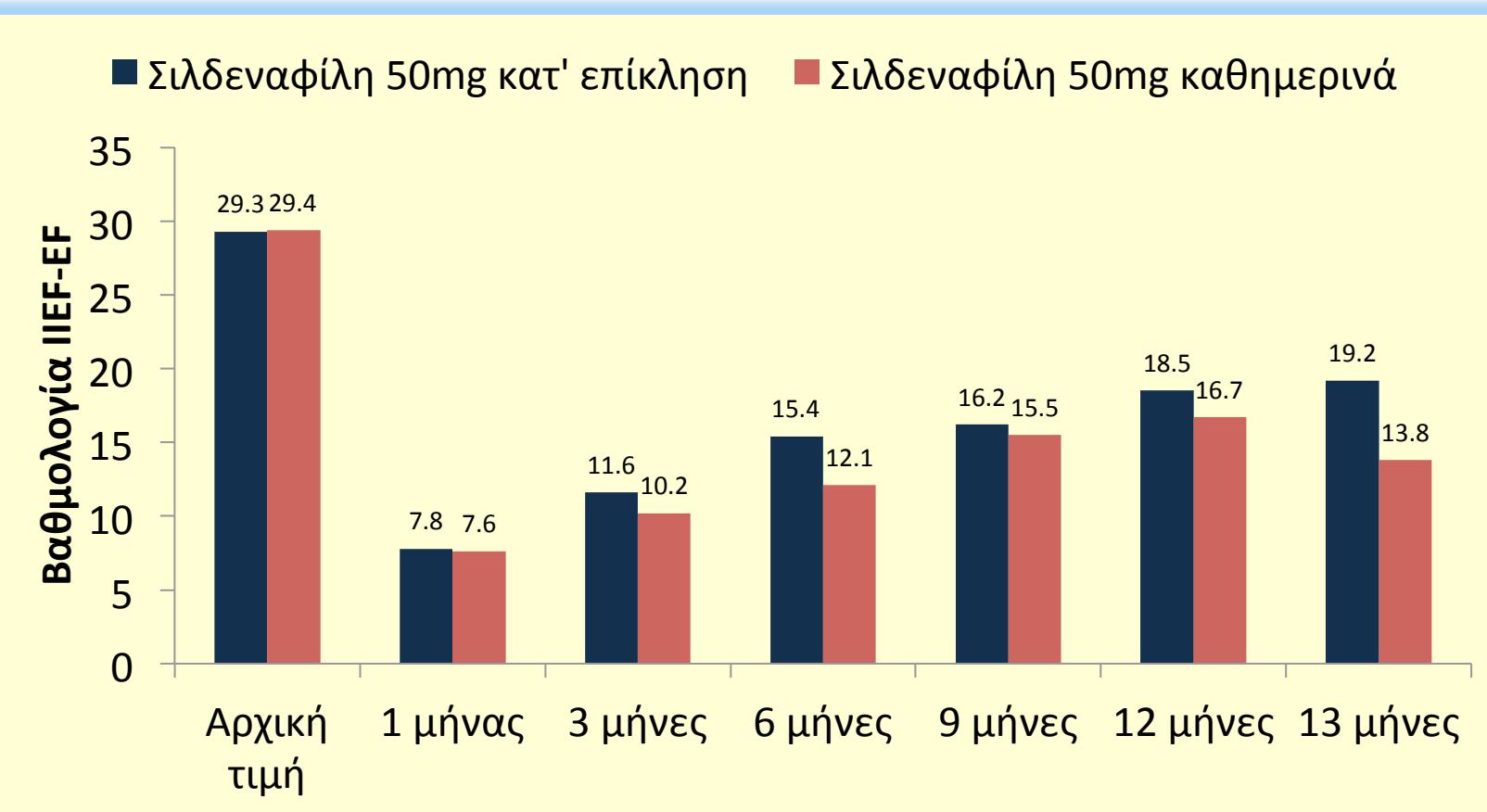
BNSRP: 100 ασθενείς  
Λαπαροσκοπική: 77  
Ρομποτική: 23

9 μήνες  
Έναρξη την επομένη της ΡΠ  
Κατ' επίκληση: max 6/μήνα

1 μήνας

# Η καθημερινή χορήγηση σιλδεναφίλης δεν ήταν καλύτερη από την κατ' επίκληση

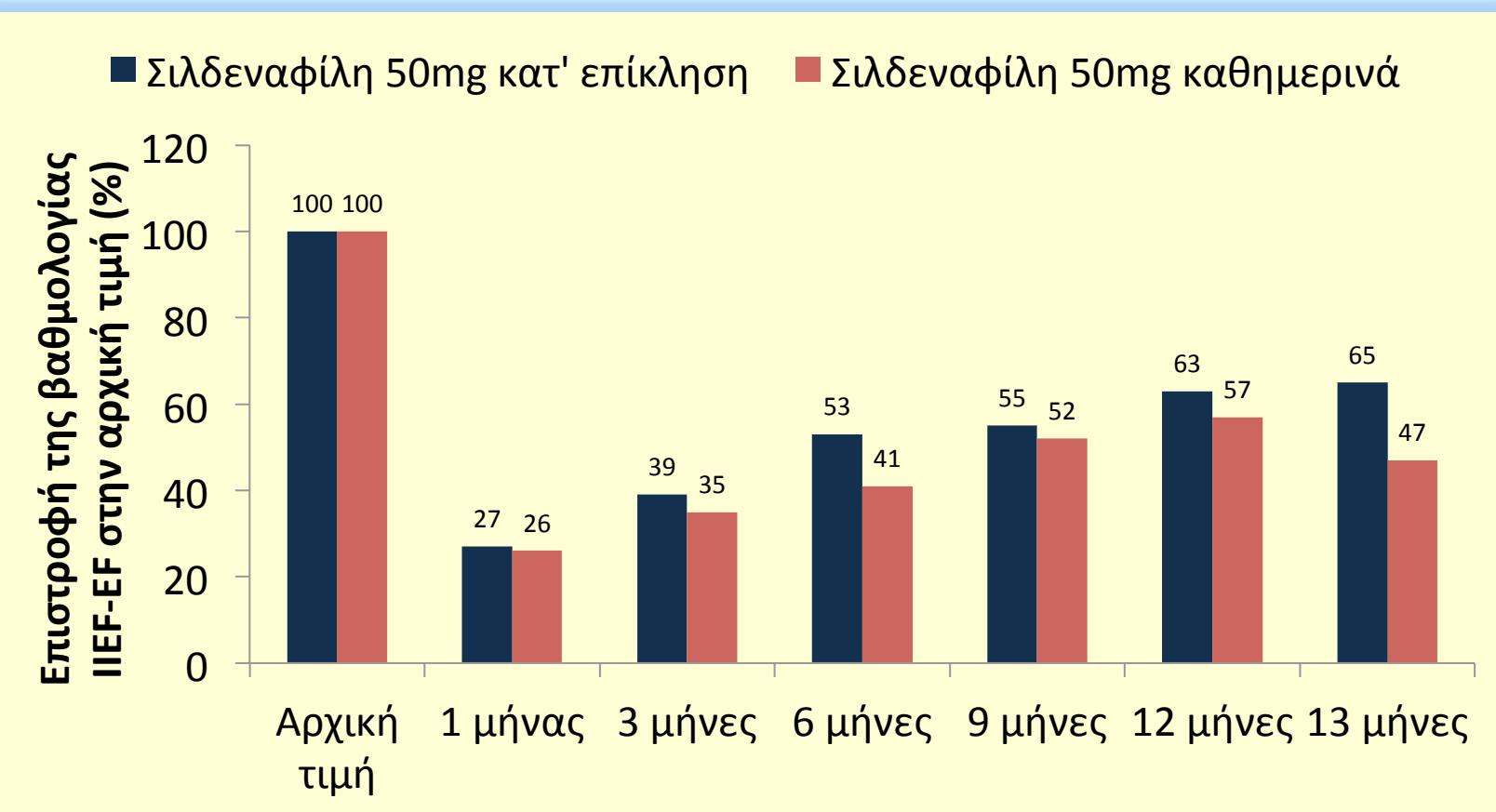
- Η μόνη στατιστικά σημαντική διαφορά ήταν τον 13<sup>ο</sup> μήνα ( $p=0,022$ )



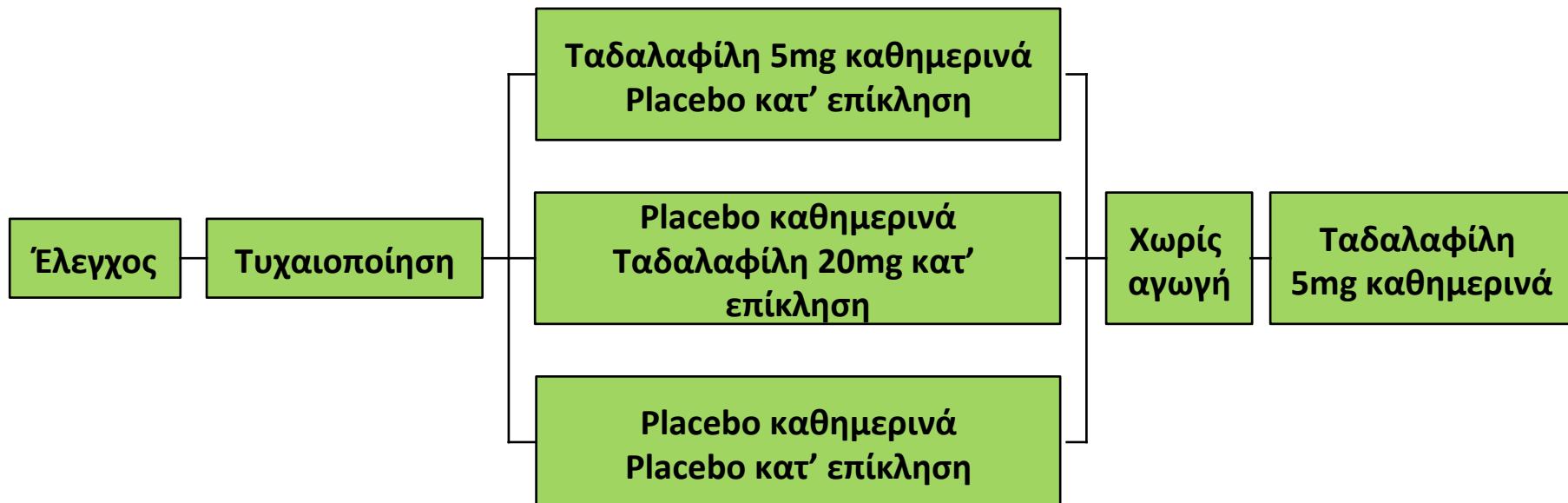
Pavlovich CP, et al. BJU Int 2013;112:844-851

# Η καθημερινή χορήγηση σιλδεναφίλης δεν ήταν καλύτερη από την κατ' επίκληση

- Η μόνη στατιστικά σημαντική διαφορά ήταν τον 13<sup>ο</sup> μήνα ( $p=0,018$ )



# Ταδαλαφίλη καθημερινά ή κατ' επίκληση;



IIEF-EF ≥22

Εντός 6 εβδομάδων  
BNSRP: 100 ασθενείς

Ανοικτή: 189

Λαπαροσκοπική: 88

Ρομποτική: 116

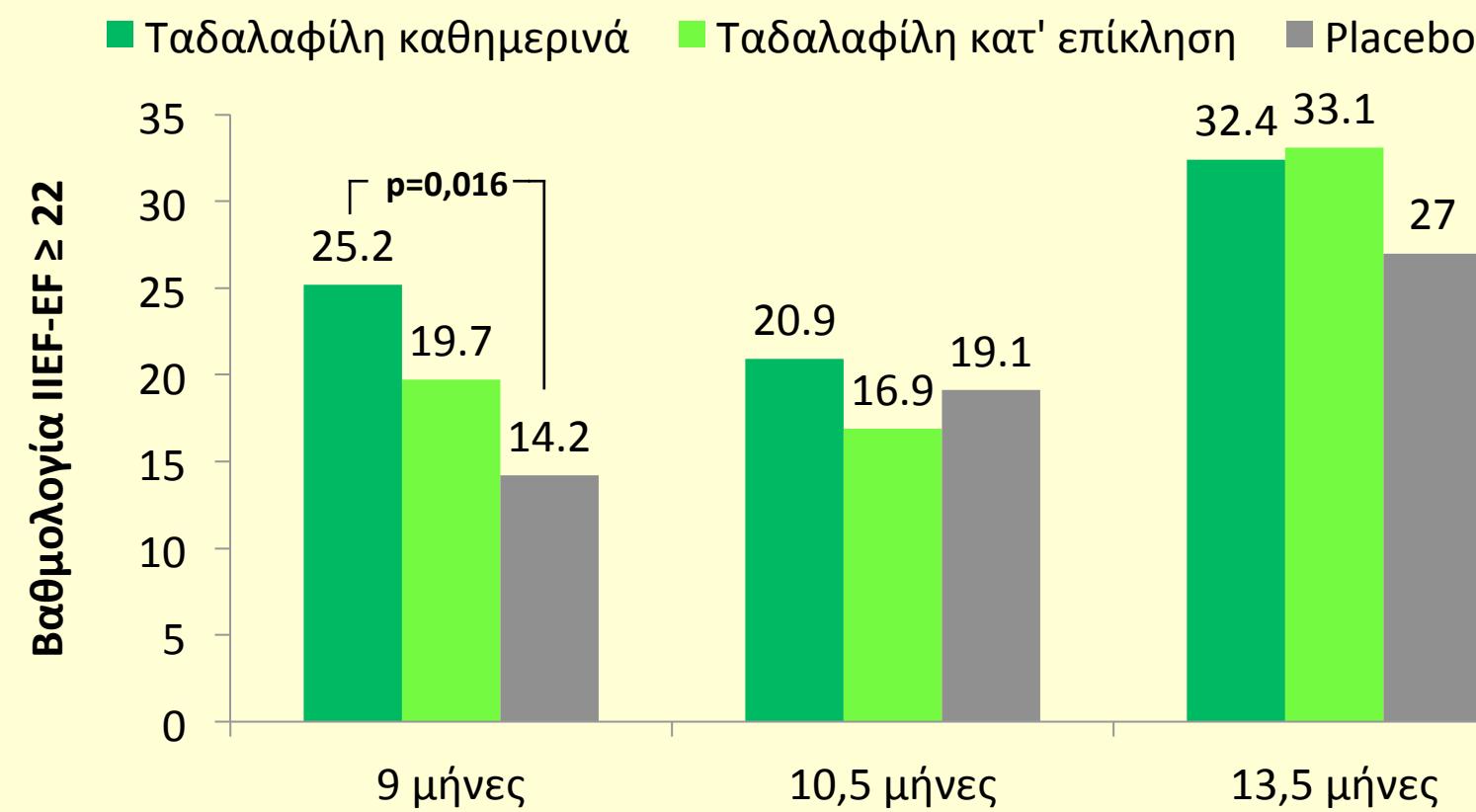
9 μήνες  
Κατ' επίκληση: max 3/εβδομάδα

6  
εβδομάδες

3 μήνες

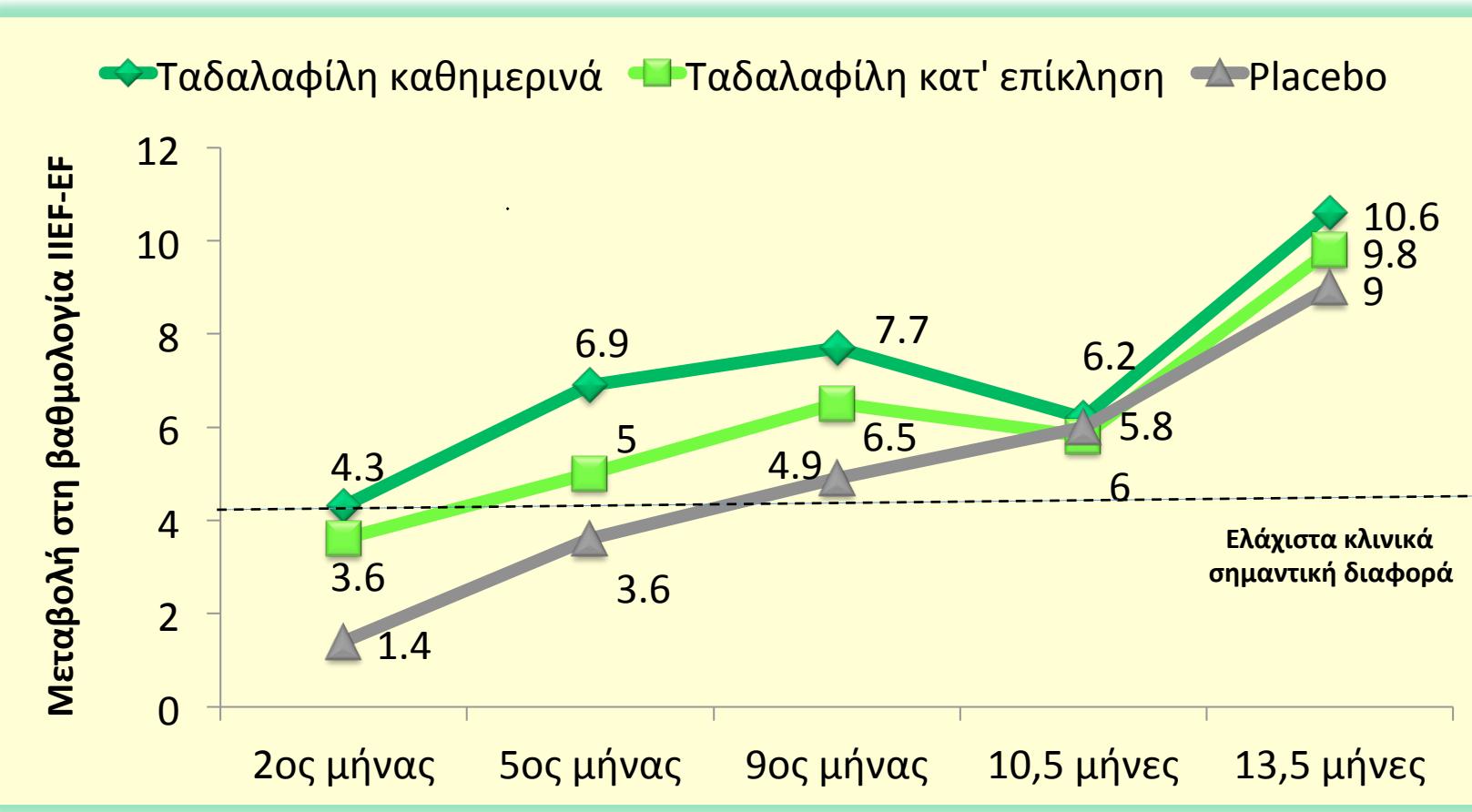
Montorsi F, et al. Eur Urol

# Η καθημερινή χορήγηση ταδαλαφίλης ήταν καλύτερη από την κατ' επίκληση



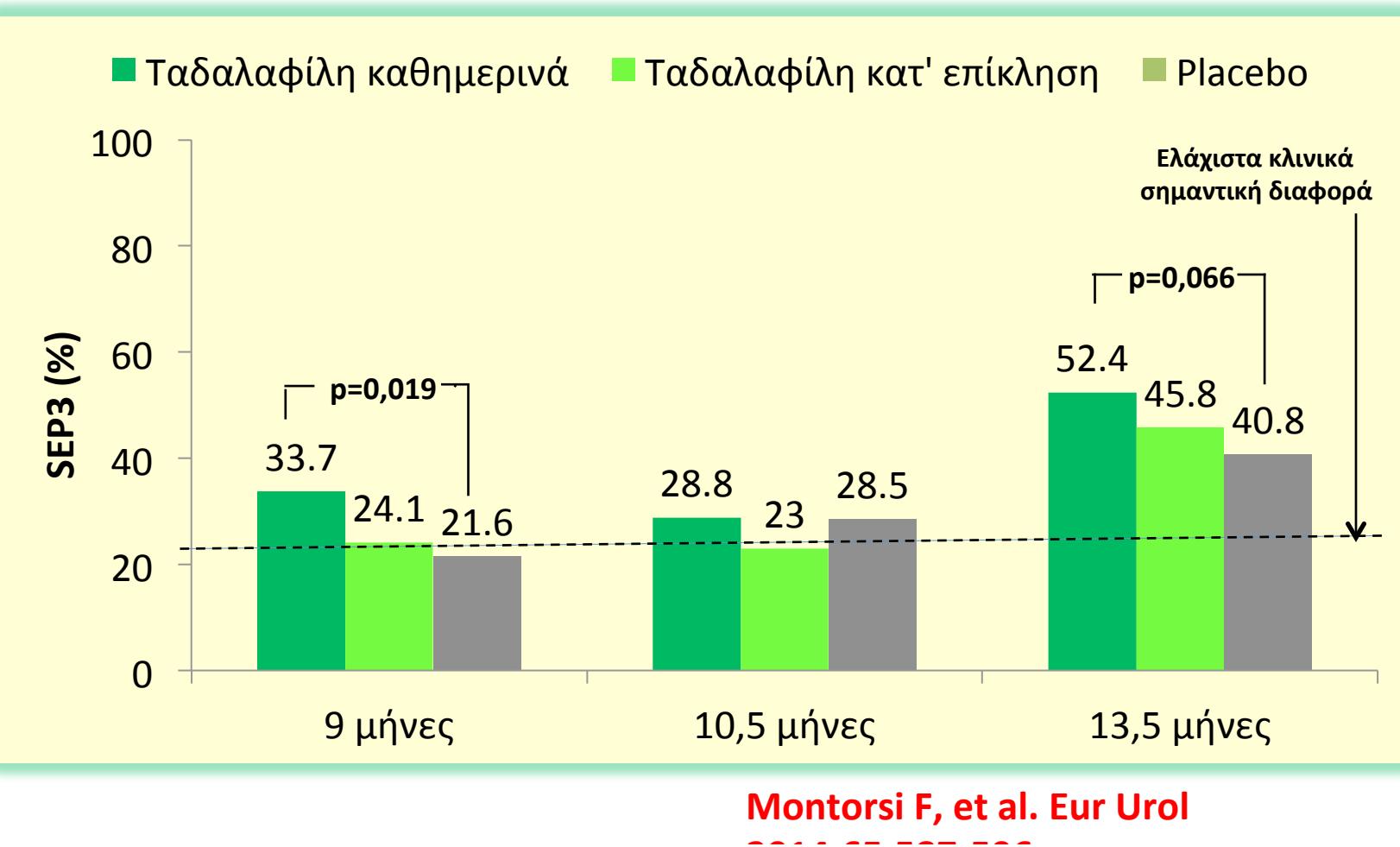
Montorsi F, et al. Eur Urol

# Η καθημερινή χορήγηση ταδαλαφίλης ήταν καλύτερη από την κατ' επίκληση

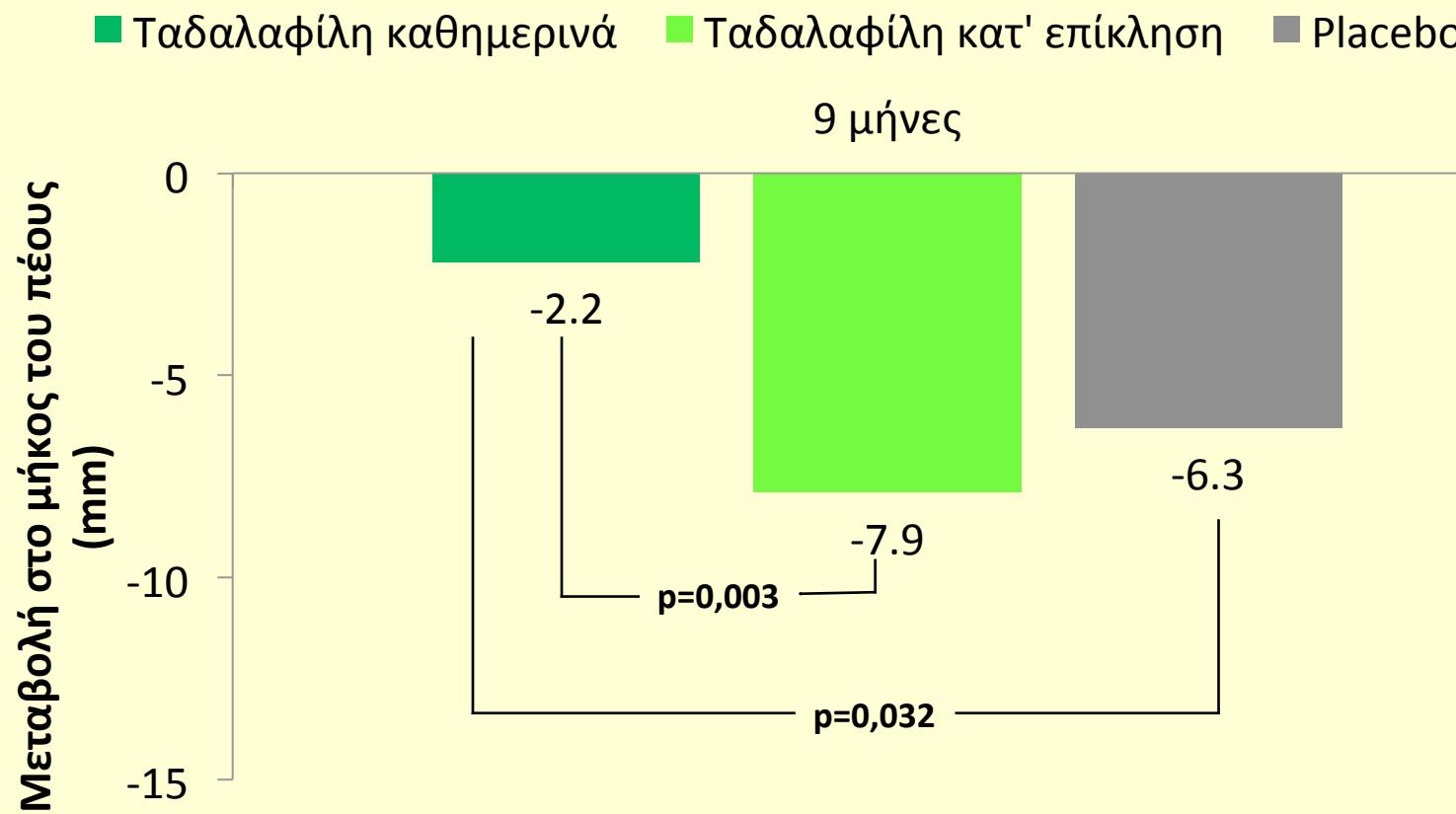


Montorsi F, et al. Eur Urol

# Η καθημερινή χορήγηση ταδαλαφίλης ήταν καλύτερη από την κατ' επίκληση



Η απώλεια μήκους του πέους ήταν μικρότερη στους ασθενείς με καθημερινή χορήγηση ταδαλαφίλης



Montorsi F, et al. Eur Urol

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



### Platinum Priority – Editorial

Referring to the articles published on pp. 261–272 and on pp. 273–286 of this issue

## Post–Radical Prostatectomy Erectile Function: The Five Ws and the H

Dimitris Hatzichristou \*

2nd Department of Urology and Institute for the Study of Urological Diseases, Aristotle University of Thessaloniki, 33 Nikis Avenue, 54622 Thessaloniki, Greece

I keep six honest serving-men

(They taught me all I knew);

Their names are What and Why and When

And How and Where and Who.

—Rudyard Kipling, *Just So Stories*

# The Five Ws and the H

**Who** is considered for nerve-sparing radical prostatectomy?

**Why** is there such a discrepancy in post-prostatectomy erectile dysfunction rates?

**How** do we define erectile function?

**Where** should we use rehabilitation protocols?

**What** rehabilitation protocol should we consider?

**When** should we stop rehabilitation?

“The patient has the inalienable right to be given realistic expectations regarding his postoperative erectile and sexual function. This will help anyone (ie, physicians and patients) understand how to start with the prevention of damage and his subsequent recovery, reducing possible false expectations and subsequent frustrations”  
Salonia A, et al: Eur Urol 2012;62: 261–72.



# **Who** is considered for nerve-sparing radical prostatectomy?

- Candidates for this procedure are patients with oncologic indications and a desire for normal postoperative sexual function.
- Almost a third of patients report that preservation of erectile function (EF) is not important to them;
- Very often these patients desire sexual activity a few months after successful recovery from surgery.
- If the patient has moderate or severe erectile dysfunction (ED), the man should be informed that he is more likely to lose his limited erectile capacity postoperatively. Because the prevalence of both prostate cancer and ED and ED-associated comorbidities (cardiovascular disease, diabetes mellitus) increase with age, a small proportion of relatively younger patients are the best candidates for NSRP.

# **Why** is there such a discrepancy in post-prostatectomy erectile dysfunction rates?

Choices about the exact type of procedure are individual to the surgeon and to each patient, and every surgeon makes individual choices about the exact steps of each operation (extent of neurovascular band preservation), depending mostly on his personal experience (volume is important), the technology resources of the institution (type of procedure), and the cost (insurance). NSRP should still be considered innovative surgery because it remains a challenge for urologists.

**Innovative surgery always raises multiple challenges:**

- (1) potential harm to patients (eg, the oncologic criteria for selecting the appropriate patients for the appropriate technique);
- (2) compromised informed consent (urologists should deliver honest information to their patients prior to surgery based on their own series and technical skills rather than on data coming from centers of excellence);
- (3) unfair allocation of health care services (physicians need to refer the patient to appropriate services when they cannot offer the selected treatment); and
- (4) conflicts of interest (information offered to patients regarding available treatment options should come exclusively from the best articles of the most respected journals rather than industry-supported Internet sources or biased-selected scientific articles with low levels of evidence).

# **How** do we define erectile function?

- 22 different definitions of favorable EF outcome.
- It is not surprising that the best results come from papers that either did not report how they define adequate erectile capacity (more than a third of the studies) or did not consider potent all responders to phosphodies- terase type 5 inhibitors.
- For both problems, the responsibility belongs equally to the researchers, as well as to the journals that accepted the papers for publication.
- I strongly endorse the statement by Salonia et al. that **clinicians may “bypass the errors of the scientific literature, eventually providing patients with more realistic expectations”**.
- Discussion is also ongoing about the best method to report erectile function; however, the International Index of Erectile Function (IIEF) is clearly the main tool to assess and compare results because it is the most extensively studied end-point measure in the literature.

# **Where** should we use rehabilitation protocols?

- It seems that current best practice supports the use of vasoactive agents right after the removal of the catheter.
- Such a strategy may only be reserved for patients who had uncomplicated NSRP, however, whose erectile function preoperatively was adequate for sexual intercourse (with or without PDE5-I use).
- Attention should be paid to the observation that rehabilitation protocols are beneficial even in men with spontaneous erections postoperatively because further improvement in such patients was reported.
- Patients with certain postoperative erectile capacity may even benefit more from such protocols.

## **What** rehabilitation protocol should we consider?

- Data show no definitive conclusion on the superiority of daily use of PDE5-Is compared with on-demand use.
- However, in clinical trials, patients intended to use PDE5-I quite often (two to three times per week); such PDE5-I use is not common in everyday clinical practice, especially the initial postoperative period.
- Therefore, it is clear that a man who uses on-demand treatment once or twice per month should not be considered a follower of a rehabilitation protocol.
- A difficult question to answer is the treatment protocol of choice for those nonresponders to PDE5-Is. In such cases, intracavernosal injection (ICI) therapy two to three times per week seems to be the best protocol.
- The best compound for ICI is again the one with minimal side effects (especially pain) and good results.
- A very important issue in every rehabilitation protocol is its efficacy.
- Because cost is a significant obstacle to the rehabilitation program, patients who respond poorly to the protocol, unable to have successful intercourse, are candidates for early dropout.
- We should not ignore, especially in such patients, the important role of psychosexual counseling because everyday clinical practice has shown that some of them will respond to treatment after only a few sessions with a certified sex therapist.

# **When** should we stop rehabilitation?

- It remains uncertain how long such a protocol has to be followed
- Data have shown that recovery of spontaneous or assisted functional erection via PDE5-Is during the initial 3-mo postoperative period is an excellent prognostic indicator.
- For the nonresponders, the question is raised at every visit to the doctor's office whether or not erections will come back.
- Do we expect that patients without any erectile capacity at 12 mo—not even tumescence—will be able to restore their erectile function in 2 or 4 yr? Most of us will respond negatively, despite the lack of comprehensive data from the literature.
- To answer this question, a well-designed study with IIEF data every 3 mo and long follow-up is needed because improvement has been noticed even 4 yr after surgery.
- At the present time, informing the patients about the current evidence, as well as the gaps in our knowledge, is the best clinical practice.
- At the end of the day, patients' choice will play the most important role in the decision to move to the next step, the implantation of a penile prosthesis.

# Πόσοι ασθενείς δέχονται το πρωτόκολλο αποκατάστασης της στύσης;

- 49% patients freely decided not to start any ED therapy
- Of the remaining patients, 36% opted for an as-needed PDE5-I, whereas 15% decided to use a daily PDE5-I
- At the 18-mo follow-up, the overall discontinuation rate from both treatment modalities was 72.6%
- Treatment effect below expectations was the main reason for treatment discontinuation, followed by loss of interest in sex due to partner's causes.

Salonia A, et al: Eur Urol, 53 (2008), pp. 564–570

# Τυχαιοποιημένες μελέτες με ομάδα ελέγχου

Μελέτη (φάρμακο)	Ασθενείς/ Ηλικία/ Πολυκεντρική	Έτος ΡΠ/ Μέθοδος	Ομάδα ελέγχου	ΣΛ πριν τη ΡΠ	Τυχαιοποίηση (μήνες μετά ΡΠ)	Διάρκεια αγωγής (μήνες)
Montorsi 1997 (αλπροσταδίλη)	15/63/όχι	1995/Ανοικτή, NS	Παρακολούθηση	Φυσιολο- γική	1	3
Raina 2006 (VCD)	35/58.2/όχι	1999-2001/ Ανοικτή/NS (29), NNS (6)	Παρακολούθηση	IIEF-5≥16	1	9
Kohler 2007 (VCD)	11/60.5/ναι	-/Ανοικτή, NS	Παρακολούθηση	IIEF-5≥12	1	6
Padma-Nathan 2008 (σιλδεναφίλη)	25/56/ναι	1999-2001/ Ανοικτή/BNS	placebo	IIEF≥26	1	9
Montorsi 2008 (βαρδεναφίλη)	145/57.1/ναι	2004-2007/ Ανοικτή/BNS	placebo	IIEF≥26	0.5	9 (11)
Pace 2010 (σιλδεναφίλη)	20/58.5/όχι	2005-2009/ Ανοικτή/BNS	Παρακολούθηση	IIEF≥26	0.5	5.5
Aydogdu 2011 (ταδαλαφίλη)	33/58.1/όχι	2006-2008/ Ανοικτή/BNS	Παρακολούθηση	IIEF≥26	0.75	12
Bannowskyi 2012 (βαδεναφίλη)	12/61.4/όχι	2009-2011/ ανοικτή/UNS	Παρακολούθηση	IIEF-5≥19	0.5	12
Montorsi 2014 (ταδαλαφίλη)	115/57.6/ναι	2009-2011/ ανοικτή, LRP, RARP/BNS	placebo	IIEF≥22	1.5	9 (10.5)

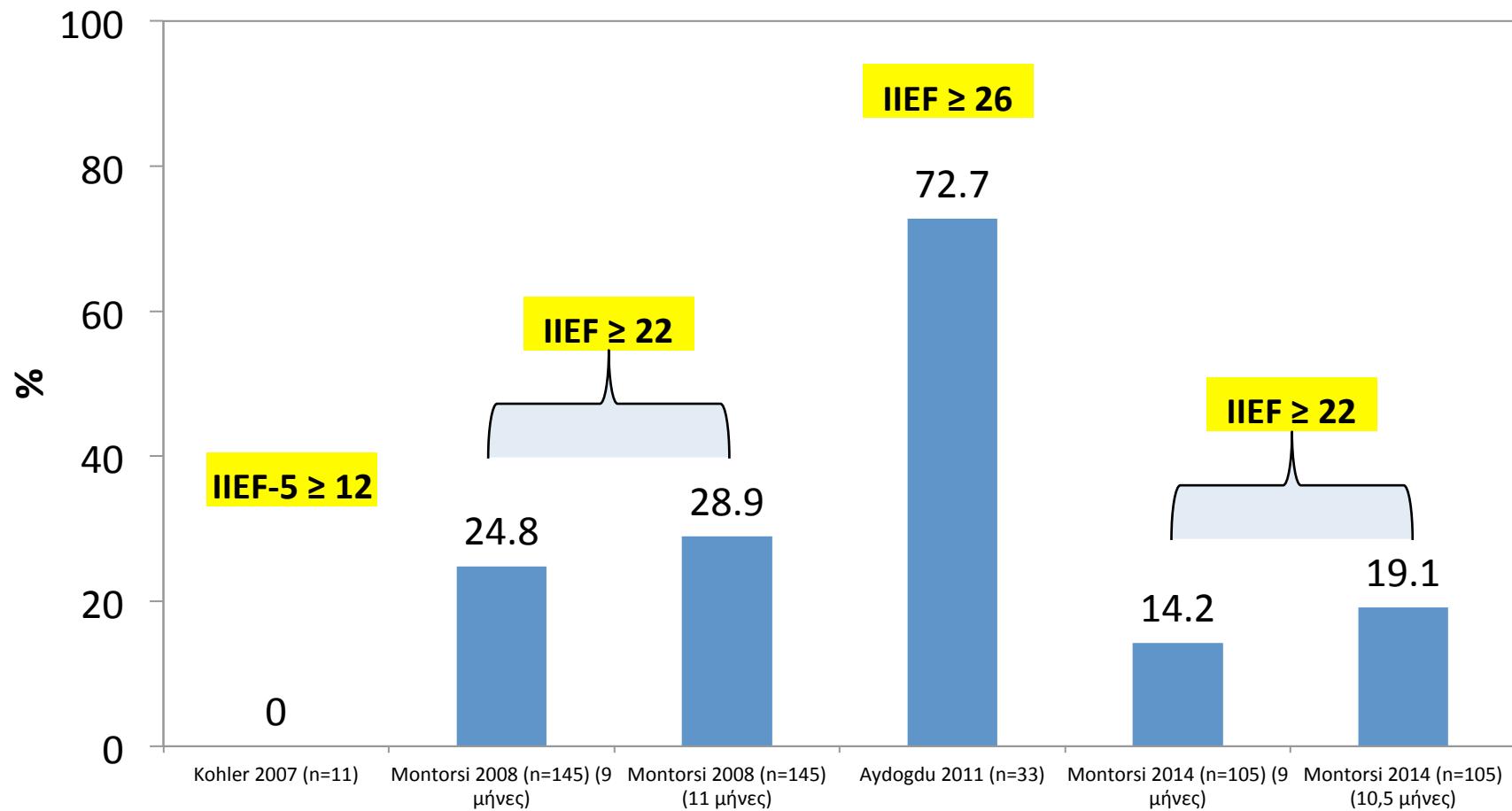
# Ομάδες ελέγχου – IIEF



# Ομάδες ελέγχου – IIEF-5



# Ομάδες ελέγχου – ‘Αποκατάσταση’ στύσεων



# Ομάδες ελέγχου – SEP3

