

The Importance of ED Management in Clinical Practice

Erectile Dysfunction (ED) Definition

“...the consistent or recurrent inability of a man to attain and/or maintain a penile erection sufficient for sexual performance”



If you have this, you DON'T have ED

The Importance of ED Management

ED is a common
problem

The Importance of ED Management

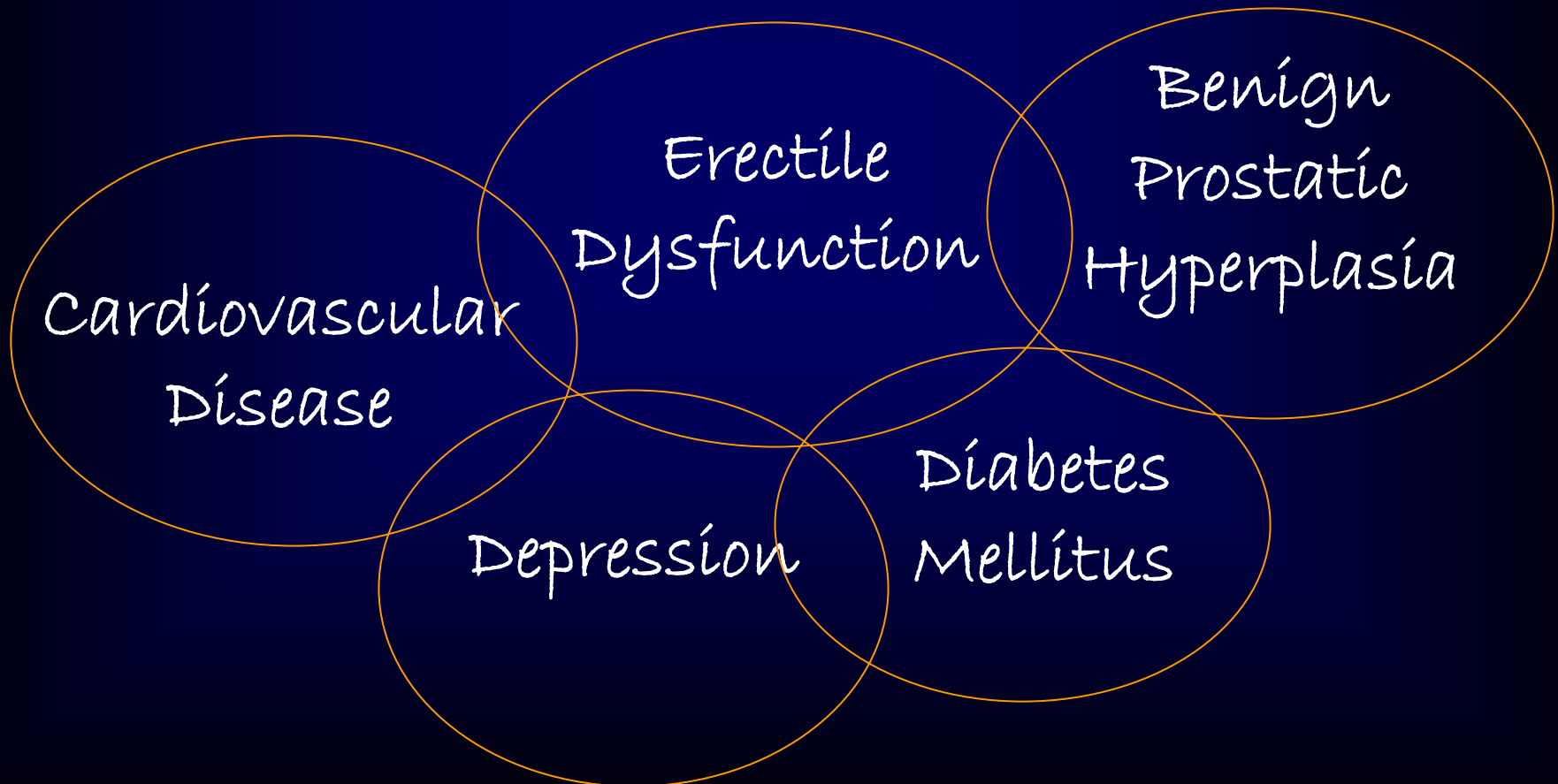


Women are complaining too!

**Diagnosing ED: What is the
clinical importance to the
Physician?**

Why Diagnosing ED Is Important

ED recognition may unmask undiagnosed underlying disease.....



Why Diagnosing ED Is Important

- ED screening may signal underlying disease
 - Diabetes
 - Hypertension
 - Dyslipidemia and coronary artery disease
 - Depression
- ED can result in
 - Anxiety
 - Decreased self-esteem
 - Reduced quality of life
 - Negative effect on relationships

ED and Comorbidities: A Reciprocal Diagnosis

- Screening for common disorders may reveal ED
- Screening for ED may reveal common disorders
 - Coronary artery disease / vasculopathies
 - Hyperlipidemia
 - Hypertension
 - Diabetes
 - Depression / Anxiety
 - Drug / Alcohol abuse
 - Sleep disruption
 - Hormonal abnormalities

Why Diagnosing ED Is Important

✓ Hypercholesterolemia:

- 70% of men with ED vs. 52% w/o ED
- HDL-C & TC/HDL-C significant predictors of ED
- 10-year CHD risk:
 - 56.5% in ED vs. 32% w/o ED

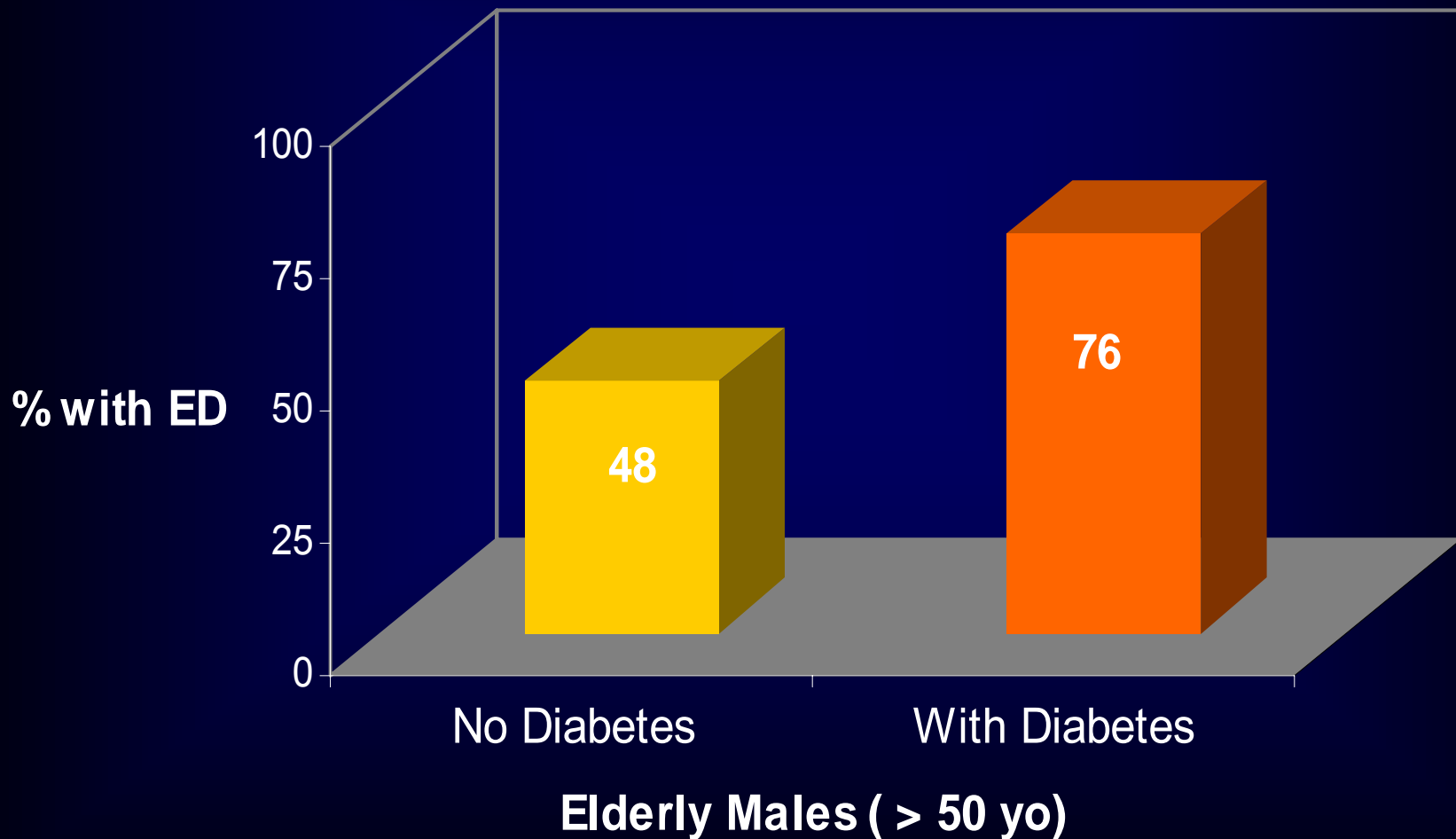
Why Diagnosing ED Is Important

✓ Diabetes Mellitus:

- ED is a common complication of DM (20% – 70%)
- ED occurs at an earlier age, regardless of insulin dependence, prevalence increases with age and duration of DM

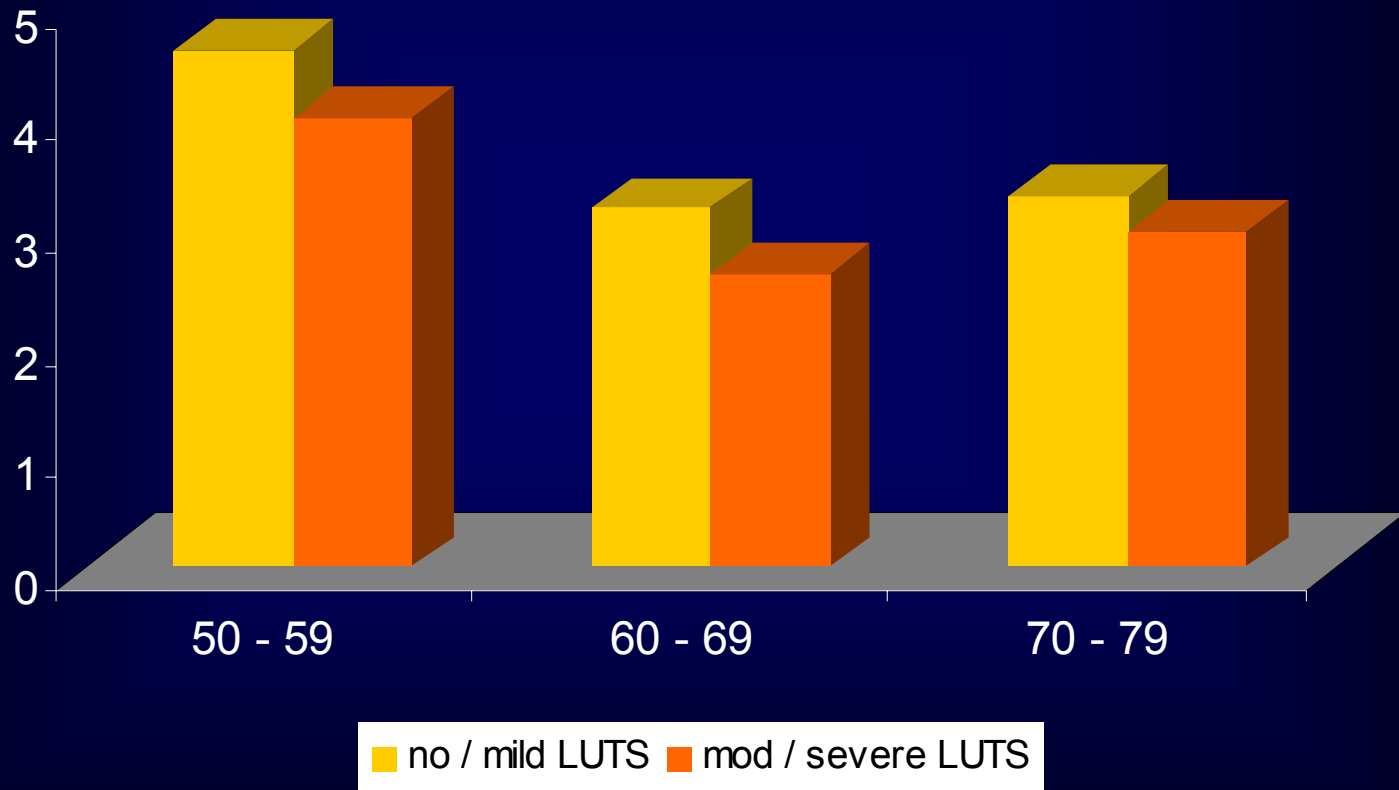
Experience with Tadalafil: The Asian Perspective

DAN – PSSex – ASAM Erectile Dysfunction



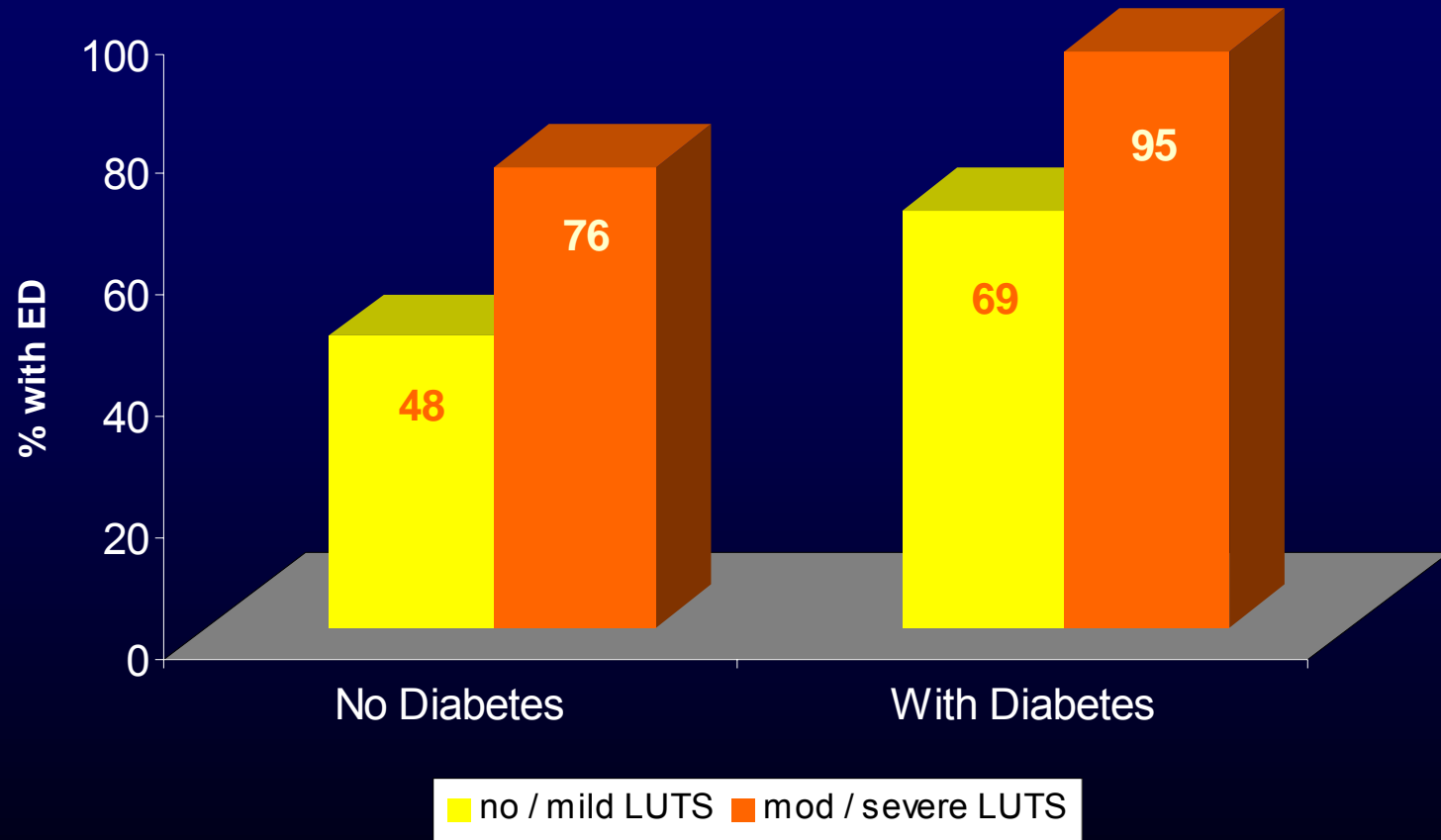
Experience with Tadalafil: The Asian Perspective

Average No. of sexual intercourse or activity per month in Asian Study



Experience with Tadalafil: The Asian Perspective

DAN – PSSex – ASAM Erectile Dysfunction



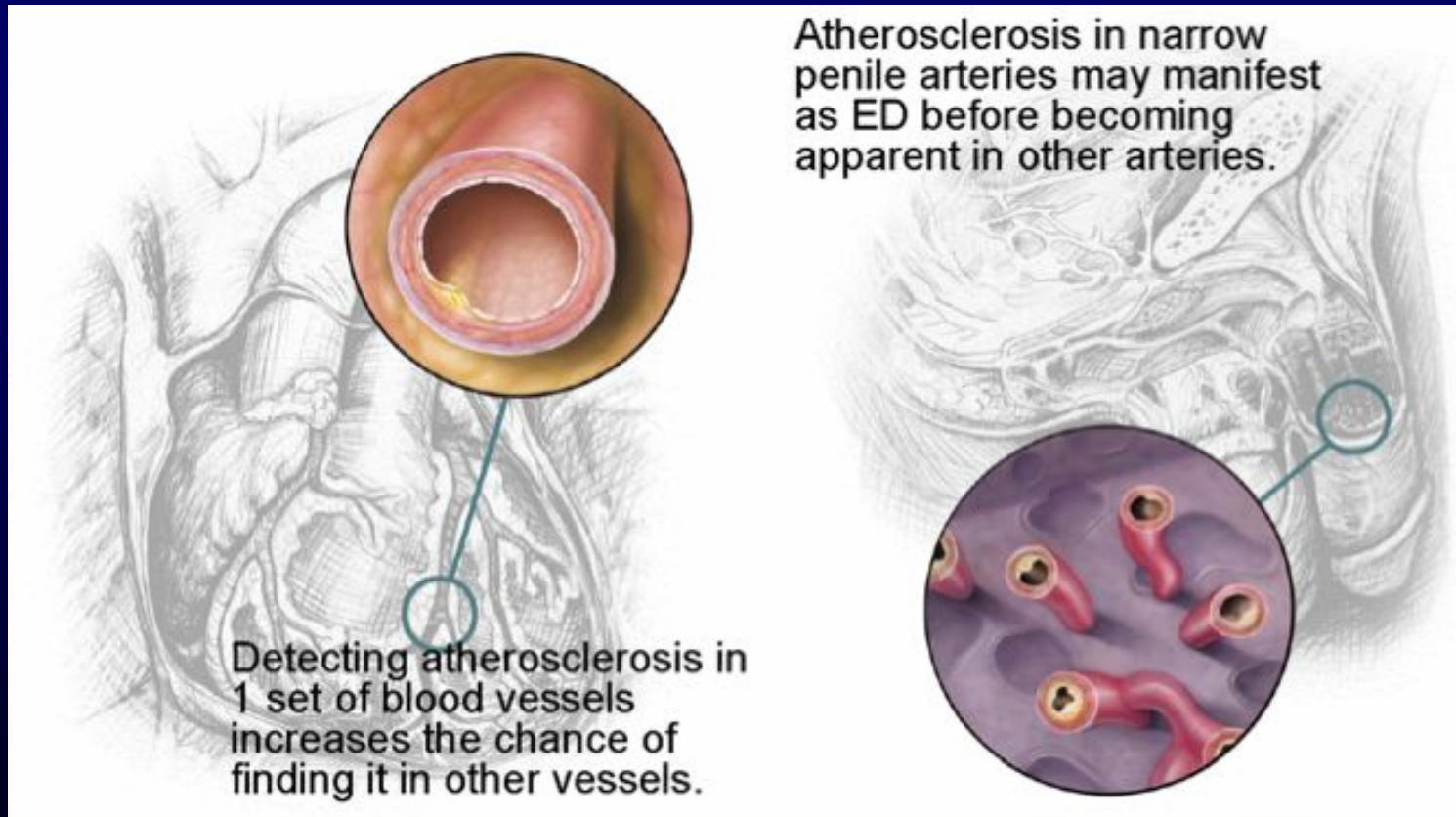
Why Diagnosing ED Is Important

✓ Heart Disease:

- 75% of cardiac patients have ED
- 56% of men with ED were found to have a positive stress test
- 40% of men with ED had significant coronary occlusions

**ED may serve as a
sentinel event for
coronary heart disease**

ED as a Predictor of Cardiovascular Disease



Association of ED and CV risk

CV evaluation conducted in 50 men with ED and asymptomatic for heart disease

- High prevalence of multiple CV risk factors, 80%
 - Smoking, 80%
 - Total-C > 220 mg/dL, 70%
 - HDL-C < 40 mg/dL, 36%
 - Hypertension, 48%
 - Diabetes, 20%
 - Family history of CVD, 64%
 - Sedentary lifestyle, 76%
- Abnormal exercise test, 46%
- High prevalence of angiographic CAD
 - Left main obstruction or 3-vessel disease, 12%
 - Moderate 2-vessel disease, 14%
 - Significant single-vessel disease, 14%

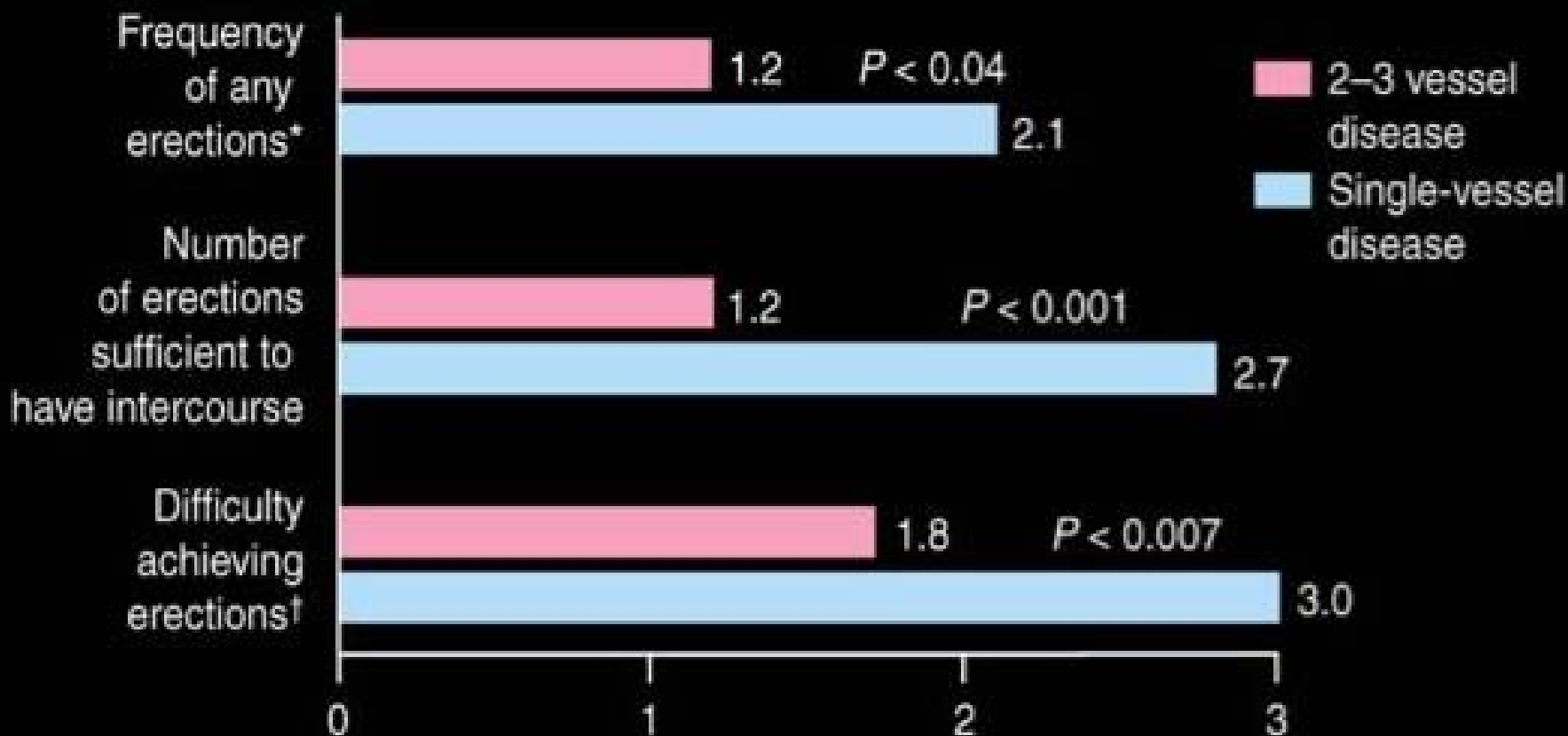
CVD = Cardiovascular Disease

ED = Erectile Dysfunction

Pritzker MR, Circulation, 1999; 100 (suppl) 1-711.

Degree of ED related to extent of CAD

Sexual activity in previous month (N = 40)



*0 = not at all, 4 = always

†0 = extreme difficulty (ie, no erections), 4 = no difficulty

ED = erectile dysfunction; CAD = coronary artery disease

Greenstein A, et al. *Int J Impot Res.* 1997;9:123-126.

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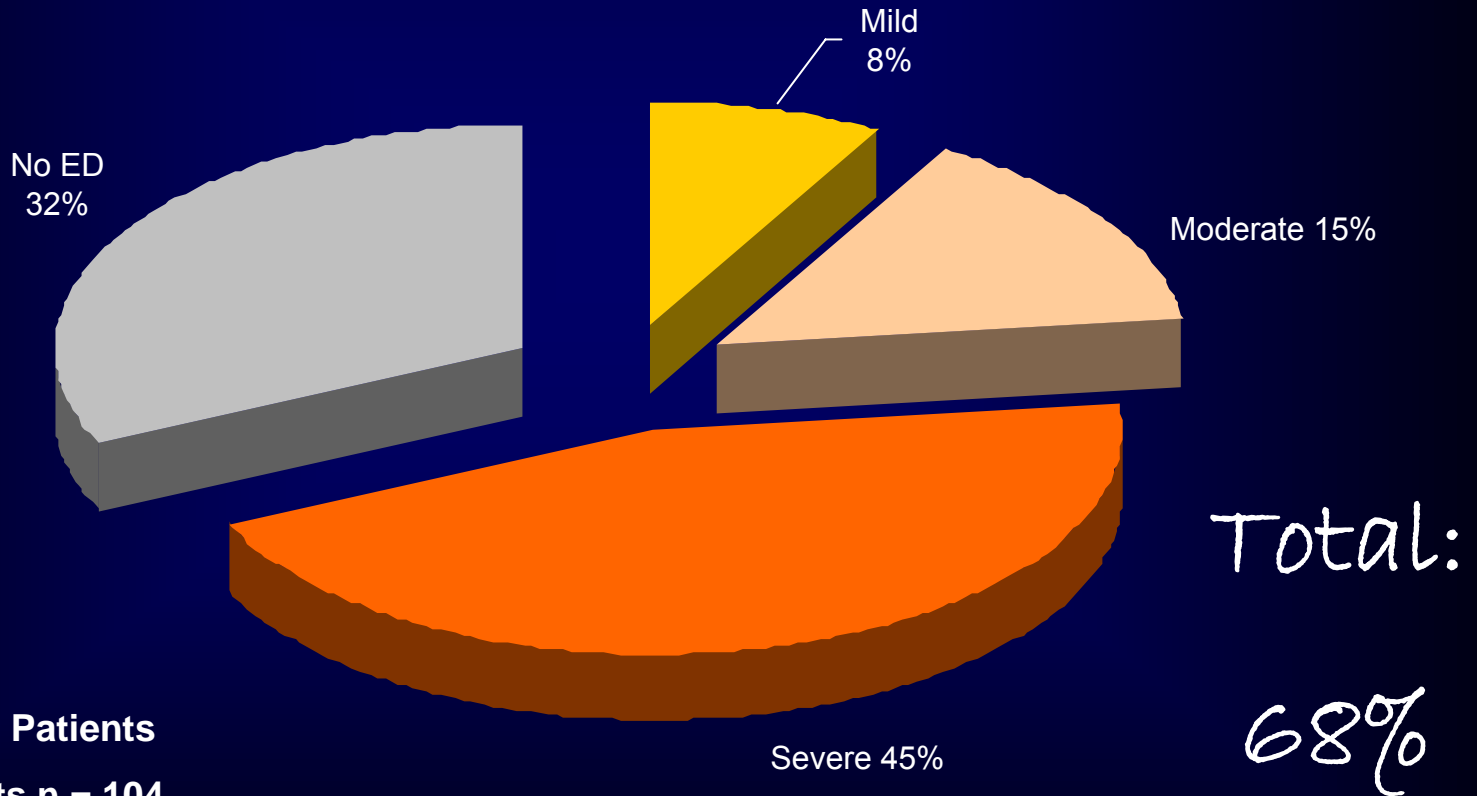
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Prevalence of ED in Men With Hypertension

Columbia – Presbyterian Medical Center Hypertension Center Survey



Hypertensive Patients
(Respondents n = 104
with mean age 62 years)

Lifestyle Factors and ED

GOOD

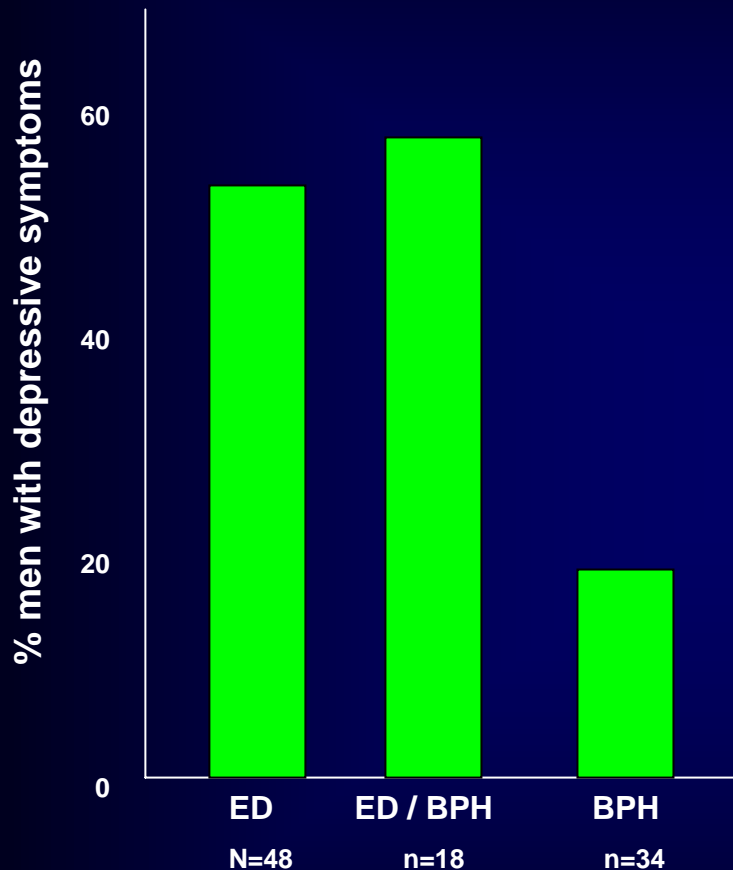
- ✓ Physical Activity – running 3 or more hours per week
- ✓ Staying lean

BAD

- x Watching TV > 20 hours
- x Smoking
- x Alcohol
- x Overweight

ED may unmask unhealthy lifestyle. Part of Mx includes promoting healthy lifestyle

Erectile Dysfunction:



Among 1,410 men aged 18-59 years, ED was significantly associated with:

- Low physical satisfaction*
- Low emotional satisfaction*
- Low general happiness*



Doctor: PLEASE pose the question

Why pose the question?!!!



Because your patients WANTS
YOU TO!

Patients Need You to 'Ask the Question'

- ✓ Many men with ED are not being asked about erectile problems¹
- ✓ 8 out of 10 men want their doctor to ask them about ED¹
- ✓ Worldwide estimates suggest that more than 70% of ED remains undiagnosed^{2,3}

1. Baldwin KC, et al. *J Urol*. 2000;163(suppl):243. Abstract 1080.

2. Mulcahy JJ. *J Urol*. 2000;163:471.

3. Chun J, Carson CC. *Urol Clin North Am*. 2001;28:249–258.

The Importance of ED Management

Sexual Activity Has the Same Exertion Effort as Normal Walking

| Estimated METs | Description | Physical Activities |
|----------------|----------------------------|---|
| 2 | Sitting | Reading, watching TV |
| 3 | Very light exertion | Moderate sexual activity with long-term partner, office work, strolling in park |
| 4-5 | Moderate exertion | Vigorous sexual activity, normal walking, golfing on foot, gardening |
| 5-6 | Vigorous to heavy exertion | Running, racquetball, fast biking, heavy snow-shoveling |

**METs = metabolic equivalents of oxygen consumption.
Sexual activity qualifies as moderate exertion.**

Adapted from DeBusk et al. *Am J Cardiol.* 2000;86:175-181.

ED Management

- Treat the underlying problem
- Treat ED



Penile Devices



Oral Therapy

ED Management

- Lifestyle Modification: Avoid Bad Habits

Smoking



*Excessive Alcohol
Intake*

Obesity

Lack of Exercise

**Cialis[®] (Tadalafil) for the
Treatment of Erectile
Dysfunction**

**Cialis[®] (Tadalafil) is
indicated for the treatment
of erectile dysfunction**

Efficacy of Tadalafil in Men With ED

- Studies in the general population
- Assessment of efficacy in subpopulations of men:
 - With diabetes
 - Post-prostatectomy
 - With benign prostatic hyperplasia
 - With other chronic diseases
 - Special subpopulations
- Duration of efficacy

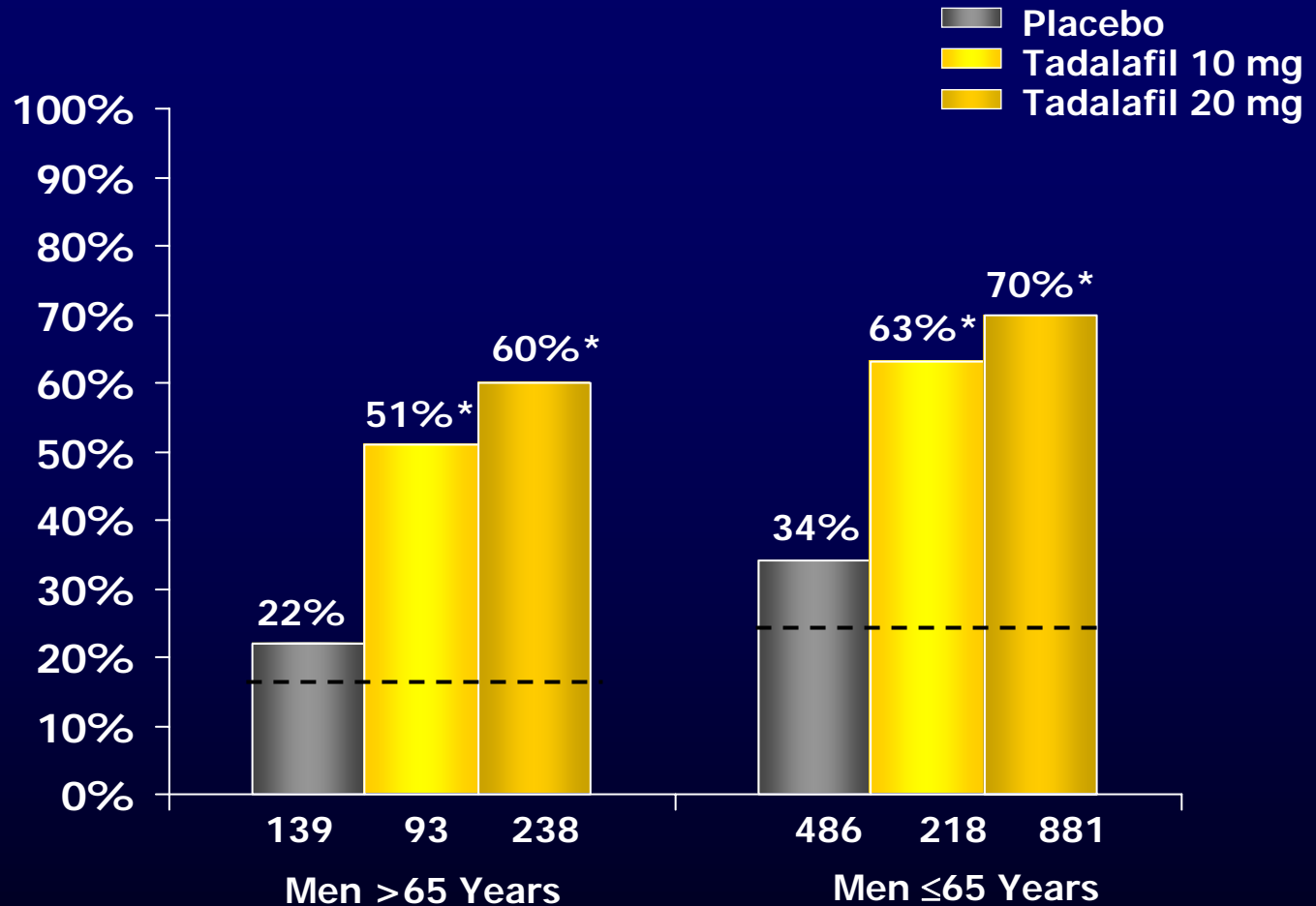
Efficacy Measures

- **Primary efficacy variables**
 - IIEF EF Domain Score
 - Sexual Encounter Profile diary Question 2 (SEP2): *“Were you able to insert your penis into your partner’s vagina?”*
 - Sexual Encounter Profile diary Question 3 (SEP3): *“Did your erection last long enough for you to have successful intercourse?”*
- **Secondary efficacy variables**
 - Global assessment question (GAQ): *“Has the treatment you have been taking improved your erections?”*
 - % of men with normal IIEF EF domain scores at end of treatment

**Efficacy of Cialis® (Tadalafil)
in Special Populations
of Men With ED**

Efficacy of Tadalafil in Men Older and Younger Than Age 65

Mean Per-Patient Percentage of "Yes" Responses to SEP Question 3[§]



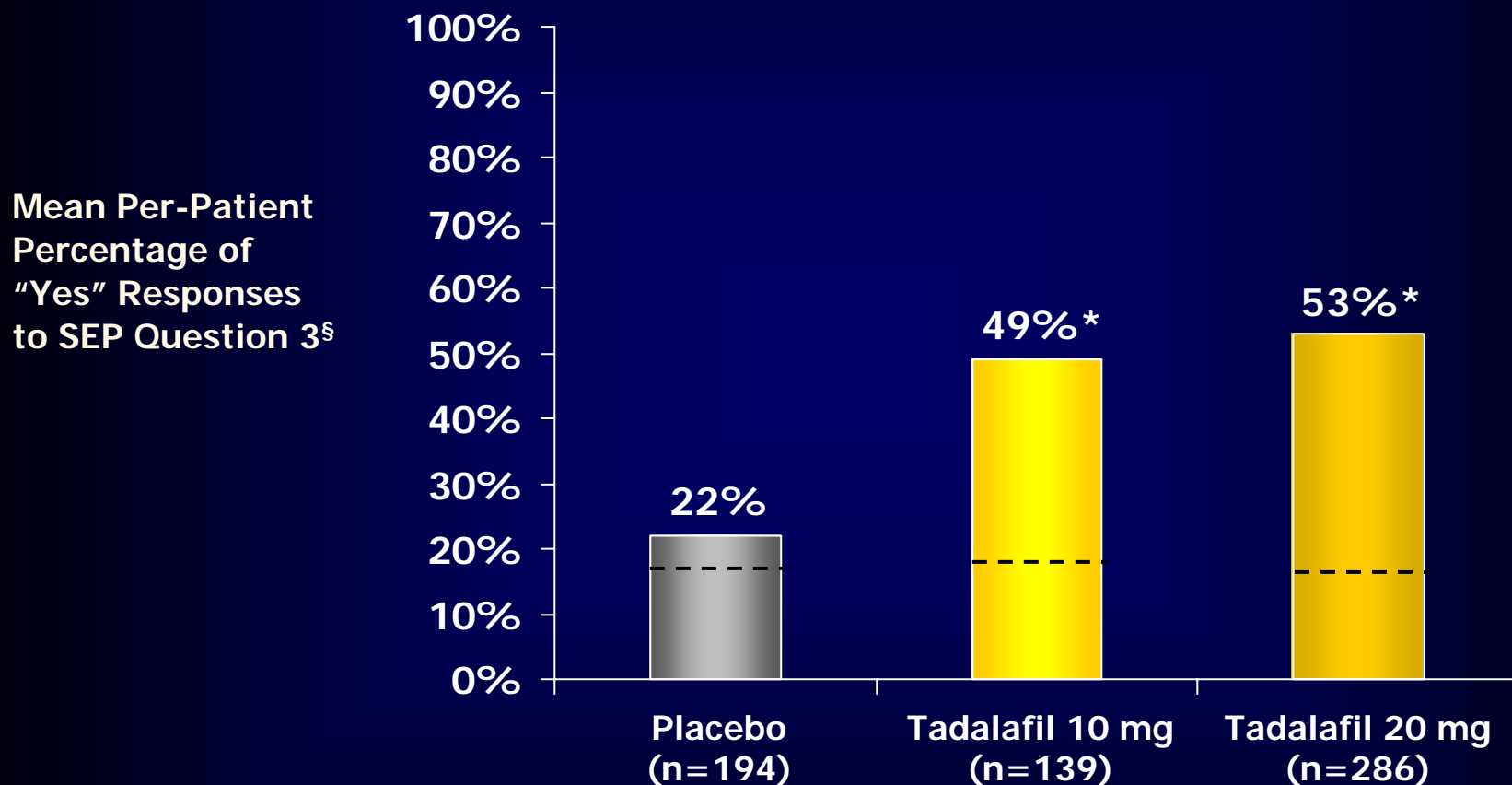
* $P < 0.001$ vs. placebo.

[§]SEP Question 3: Did your erection last long enough for you to have successful intercourse?

Number of subjects shown below each bar; dashed line within each bar represents baseline SEP3 score (% Yes).

Lewis R et al. Presentation during the 11th World Congress of the International Society for Sexual and Impotence Research. Buenos Aires, Argentina. October 17-31, 2004.

Efficacy: Mean Per-Patient Successful Intercourse (SEP3) in Men With Diabetes



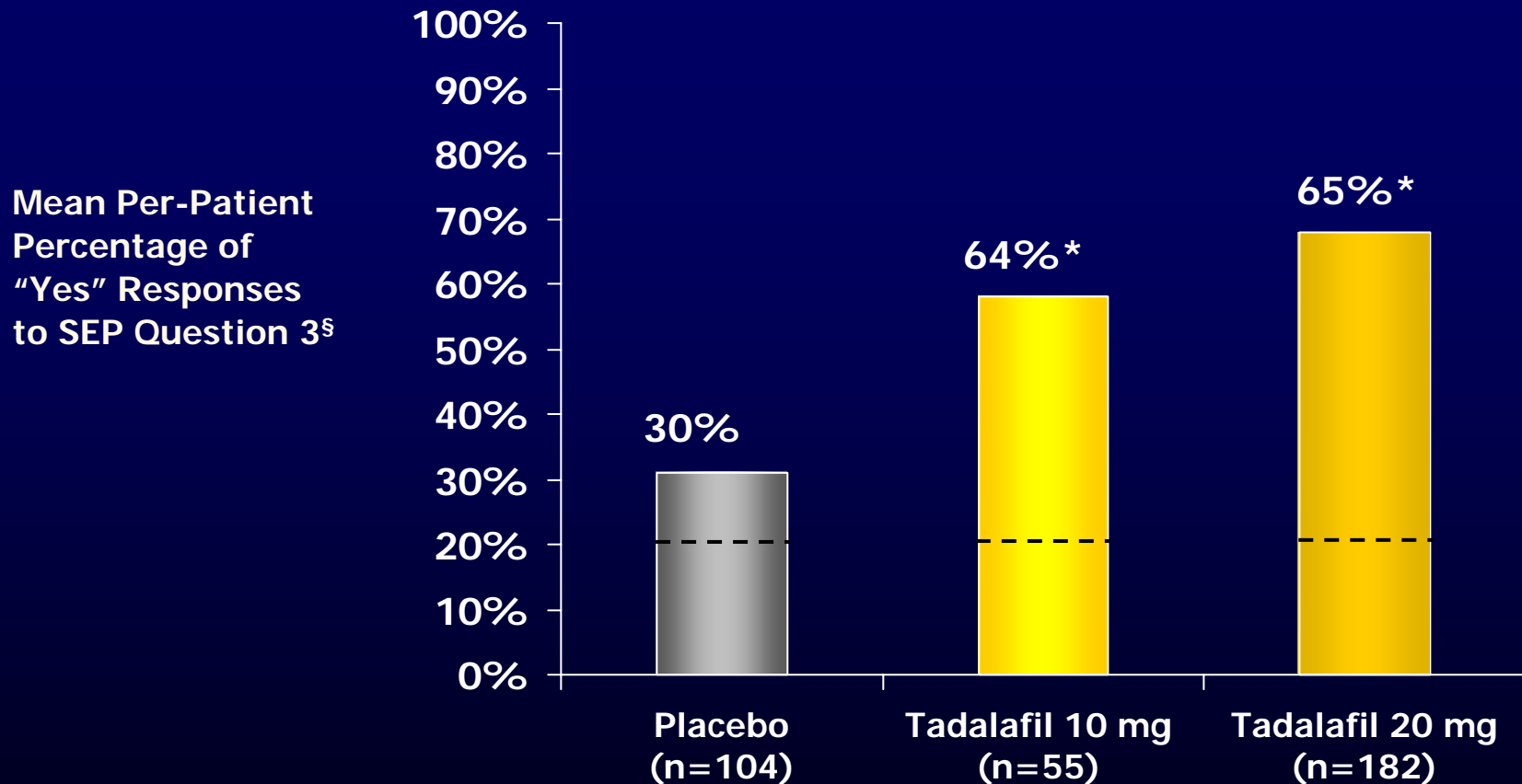
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[§]SEP Question 3: Did your erection last long enough for you to have successful intercourse?

Dashed line within each bar represents baseline SEP3 score (% Yes).

Fonseca V et al. *Diabetologia*. 2004. In press.

Efficacy: Mean Per-Patient Successful Intercourse (SEP3) in Men With BPH



* $P < 0.001$ vs. placebo.

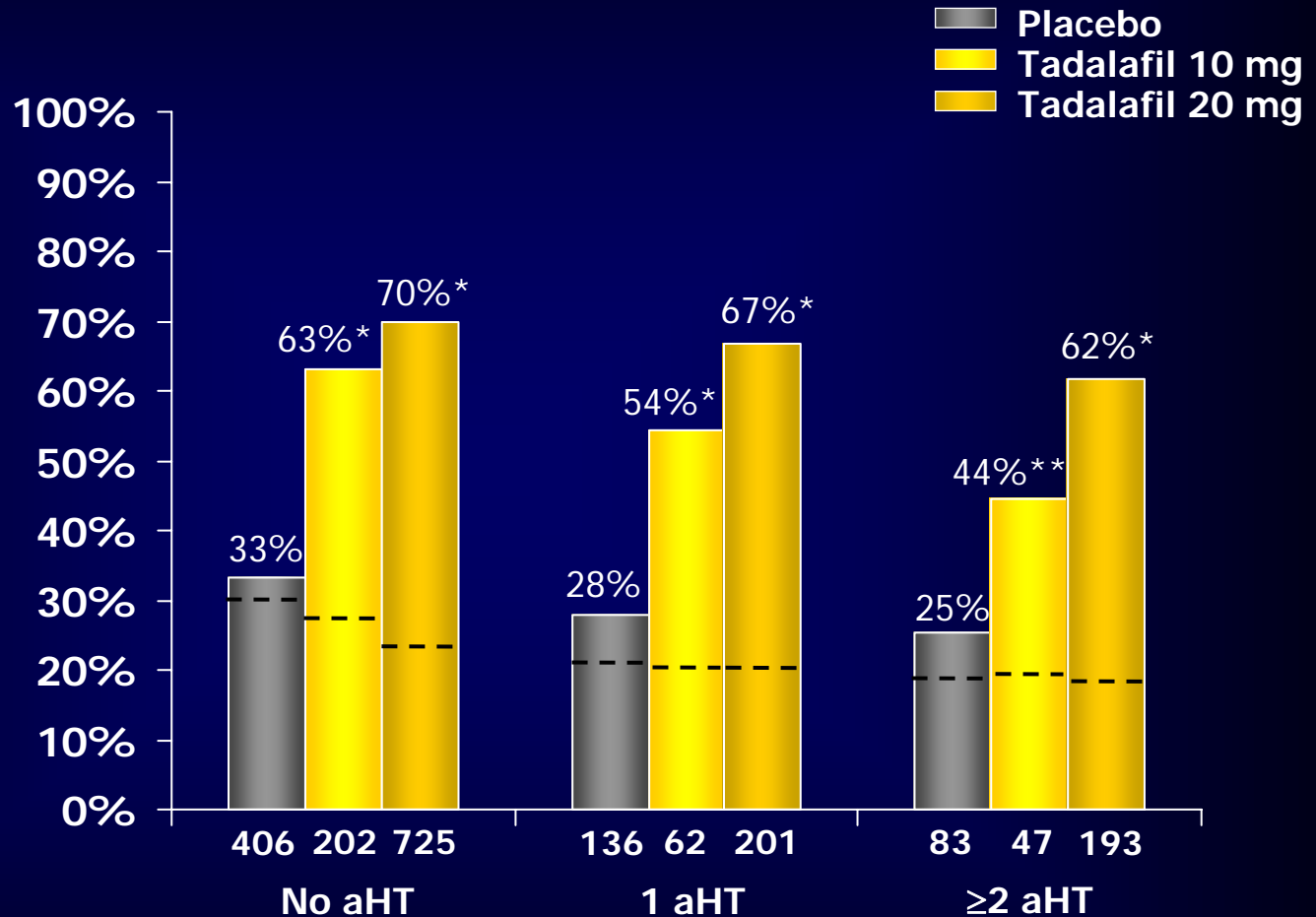
[§]SEP Question 3: Did your erection last long enough for you to have successful intercourse?

Dashed line within each bar represents baseline SEP3 score (% Yes).

Lewis RW et al. Presentation during the 83rd Annual Meeting of the South Central Section of the American Urological Association. Dublin, Ireland. September 8-12, 2004.

Efficacy: Mean Per-Patient Successful Intercourse (SEP3) in Men Taking Antihypertensives (aHT)

Mean Per-Patient Percentage of "Yes" Responses to SEP Question 3[§]



* $P < 0.001$ vs. placebo.

** $P = 0.002$ vs. placebo.

[§] SEP Question 3: "Did your erection last long enough for you to have successful intercourse?"

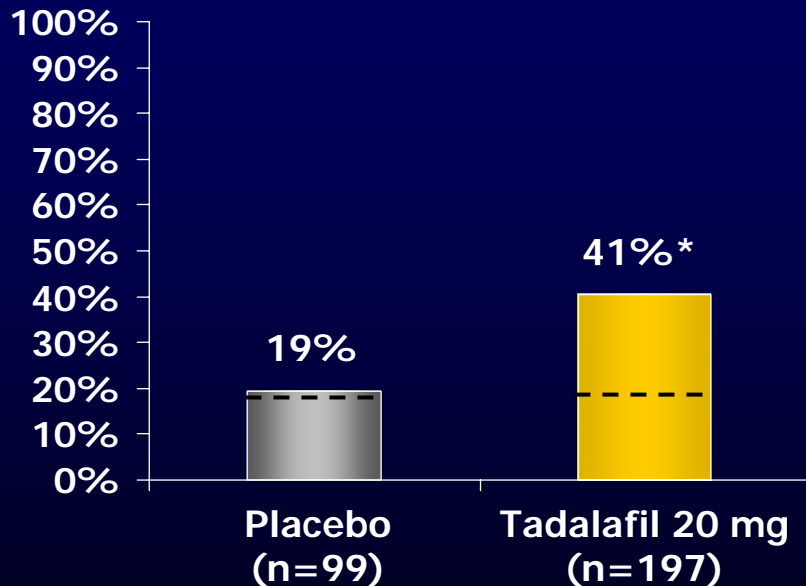
Number of subjects shown below each bar; dashed line within each bar represents baseline SEP3 score (% Yes).

Buvat J et al. Presentation during the 6th Congress of the European Society for Sexual Medicine. Istanbul, Turkey. November 16-19, 2003. Abstract P-028.

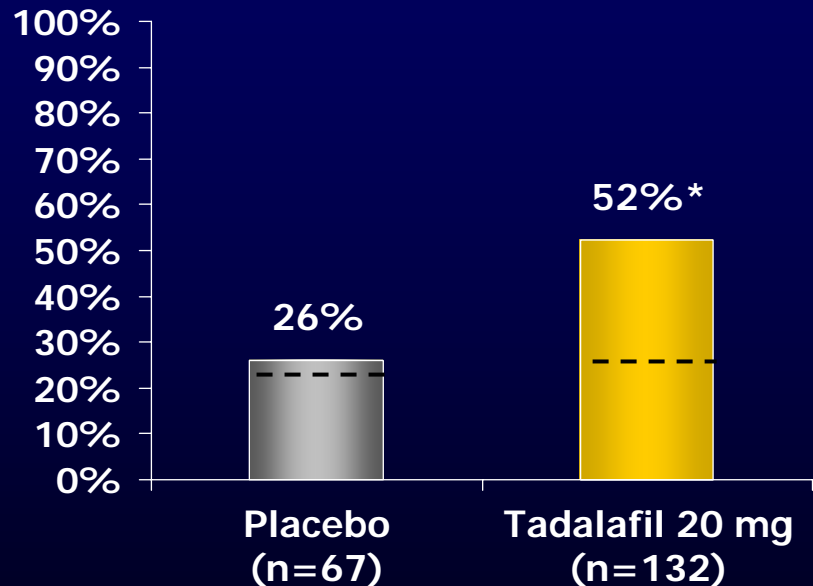
Efficacy: Mean Per-Patient Successful Intercourse (SEP3) Following Bilateral Nerve-Sparing RRP

Mean Per-Patient Percentage of "Yes" Responses to SEP Question 3[§]

All Randomized Patients



Randomized Patients With Post-Operative Tumescence



* $P < 0.001$ vs. placebo.

[§] SEP Question 3: "Did your erection last long enough for you to have successful intercourse?"

Dashed line within each bar represents baseline SEP3 score (% Yes).

Montorsi F et al. *J Urol*. 2004;172:1036-1041.

Duration of Effectiveness

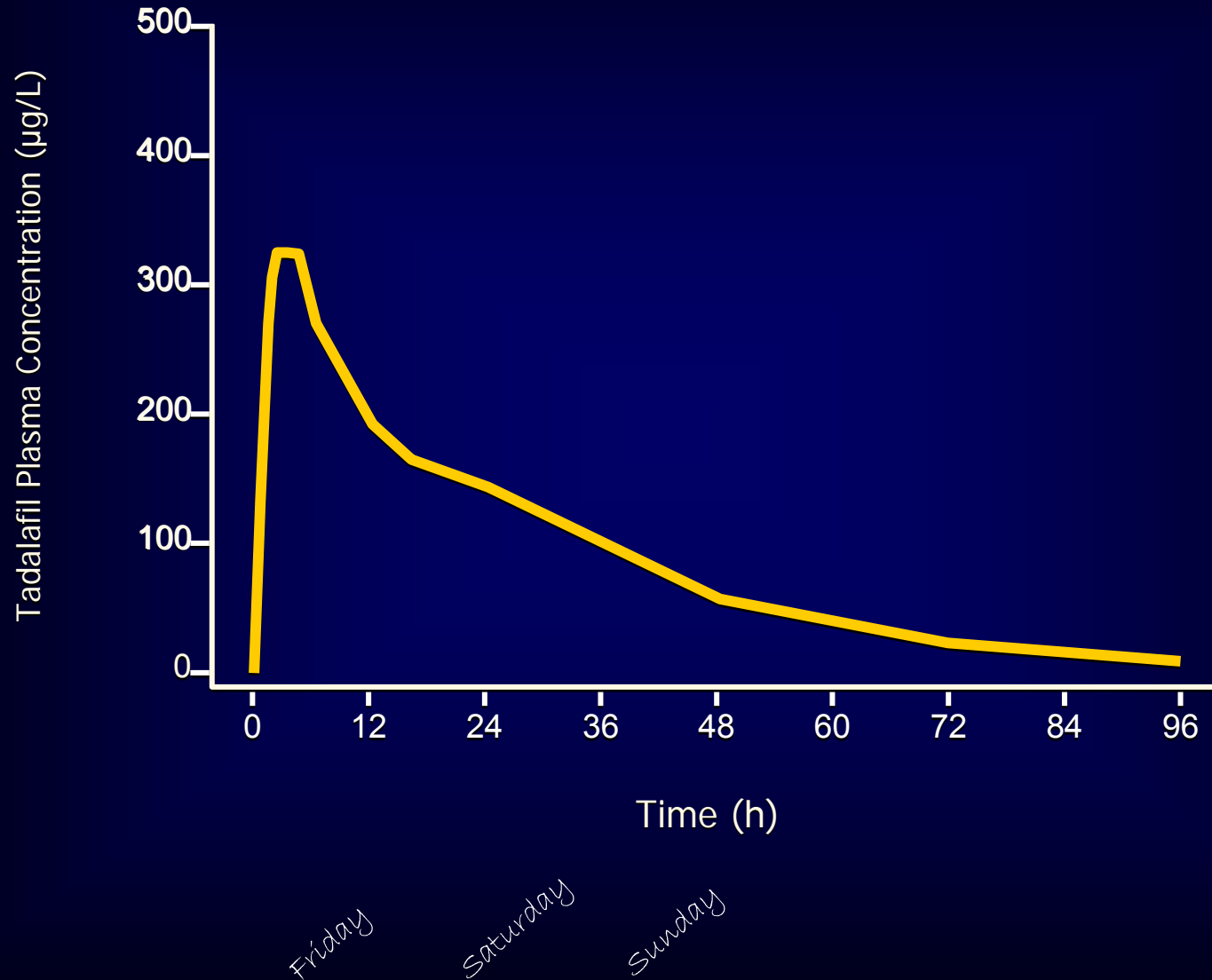


*1 Viagra Product Monograph

**2 Porst H AUA 2002

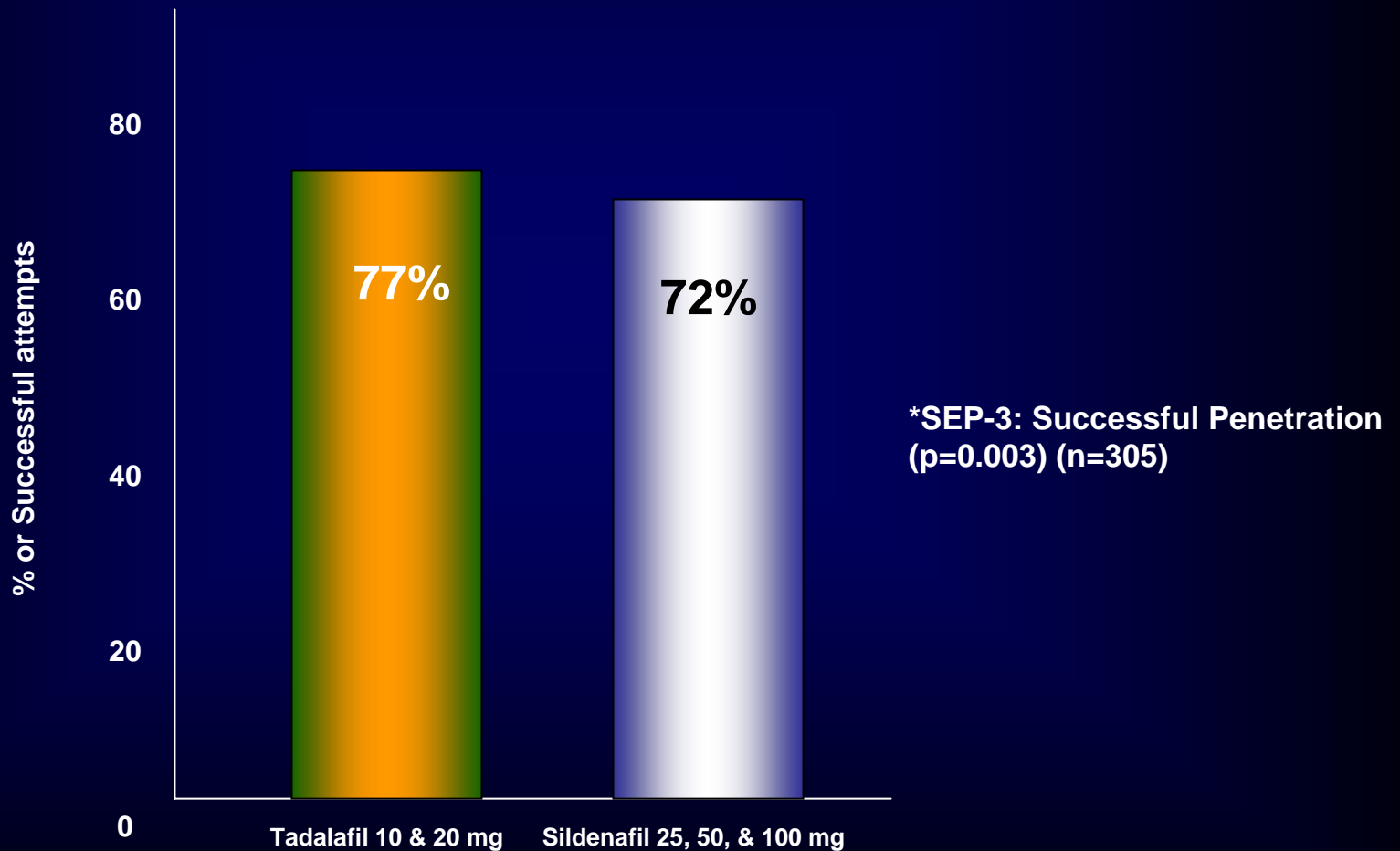
***3 Kietz, World J Uro, 2001

Duration of Effectiveness



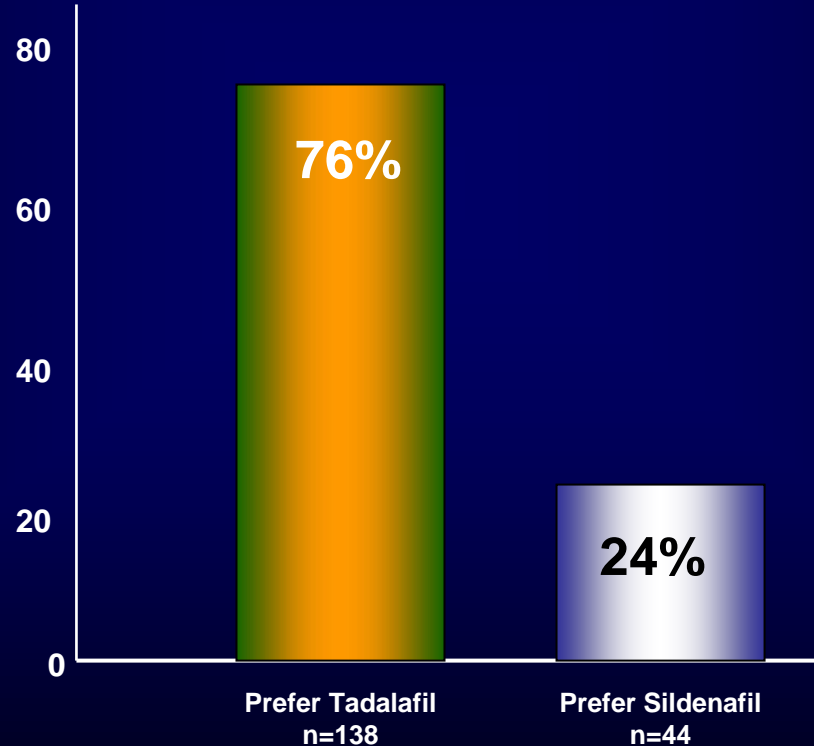
Duration of Effectiveness

Landmark Trial demonstrates Cialis Efficacy in 4 Hours



Preferred Treatment

76% of Filipino Men Preferred Cialis for the Treatment of ED in the Extension Phase



Cialis Dosing Instructions

- ✓ Avoid nitrates
- ✓ Best to take a 20mg tablet in the morning
- ✓ If sexual activity is expected at early morning, best to take dinnertime
- ✓ Non-responders – use 4 more doses before shifting to another PDE₅i

Cialis Contraindications

- Nitrates of any form
- Hypersensitivity to available or to any of the excipients

Cialis Precautions

- Not be used by men with cardiac disease for whom sexual activity is inadvisable
- Caution in prescribing to patients with severe renal and hepatic insufficiency
- Caution in prescribing to patients that might predispose them to priapism



Remember: Even with medicines, no erection if
the situation is not right



But when the time
is right



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Thank you!