72° Congresso Nazionale
FIMG Metis
Medicina di Famiglia: cambiare per mantenere i propri valori

Dismetabolismi, dall'obesità alla gotta: i veri nemici della salute sessuale

Maggi, Scotto di Fasano, Jannini

3-8 ottobre 2016
Domus de Maria (CA)

Mario Maggi
m.maggi@dfc.unifi.it
L'abbacchio

Vi racconto un altro giallo,
Di un signor che vien da Lucca,
Un omon, gran maresciallo
Tutto il giorno lui pilucca

Carne arrosto, abbacchio lesso
Saltinbocca coi piselli
Mangia tanto, niente sesso
E ripensa ai tempi belli…

BD00340_.mid


Mario Soldati
I racconti del Maresciallo
Sellerio editore Palermo

Chi è lui?

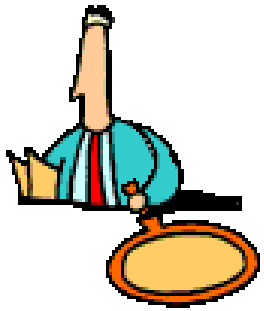
Antonio 58 anni (25 Settebre 2006)

- **Titolo di studio: Maturità**
- **Maresciallo dei Carabinieri della provincia di Lucca**
- **Molto contento del lavoro, molte preoccupazioni**
- **Non fuma. Ha fumato dai 12 anni ai 50 anni < 20 sig./die**
- **Non stupefacenti, non beve alcolici**
- **Sviluppo puberale nella norma**
- **Abile alla leva**
- **Padre deceduto a 37 anni per patologia renale (?)**
- **Madre 81 anni DM tipo II in ADO**
- **5 fratellastri da madre risposata con altro marito**
- **Operato di adenoidi, tonsille, varici, cisti sebacee**
- **Prende Valpression 80 mg/die, Samyr 200 mg/die,**
- **Viagra 50 mg al bisogno**

Chi è lei?

- **Annamaria 48 anni, stanno insieme da 30 anni**
- **rapporto coniugale ottimo, non litigi**
- **sta bene di salute**
- **desiderio sessuale normale**
- **riesce sempre a raggiungere l'orgasmo**
- **fa uso di spirale con progestinico**
- **oligomenorrea**
- **due figlie femmine 24 e 28 anni che stanno bene**
- **buona privacy**
- **ambiente familiare sereno**

Qual è il problema?



- **impossibilità totale ad ottenere una qualsiasi erezione nel 50%,**
- **erezione incompleta e insuff. per coito nel 45%, sufficiente nel 5%**
- **spesso perde erezione durante il rapporto**
- **il problema è iniziato da 9 mesi in modo graduale**
- **erezioni spontanee mattutine o notturne molto diminuite**
- **autoerotismo 1-2 mese, vissuto bene, erez. peggio che nel rapporto coitale,**
- **desiderio sessuale normale**
- **raggiunge l'orgasmo**
- **volume dell'eiaculato molto ridotto da 9 mesi**
- **hanno circa 2 rapporti la settimana**
- **non altri disturbi ejaculatori**
- **non IPP**
- **mediocre risposta a Viagra 50 mg + cefalea**

International Journal of Impotence Research (2003) 15, 210–220

0955-9930/03 $25.00
www.nature.com/ijir

Structured interview on erectile dysfunction (SIEDY©): a new, multidimensional instrument for quantification of pathogenetic issues on erectile dysfunction

L Petrone[1], E Mannucci[2], G Corona[1], M Bartolini[3], G Forti[1], R Giommi[4] and M Maggi[1]*

[1]*Andrology Unit,* [2]*Endocrinology Unit,* [3]*Radiology Units; and* [4]*Department of Clinical Physiopathology, University of Florence and International Institute of Sexuology, Florence, Italy*

S.I.E.DY©

Multidomain SIEDY scores

		Punteggio Antonio
➢ Scala 1	= dominio organico	= 7/12 (>4)
➢ Scala 2	= dominio relazionale	= 0/12 (>2)
➢ Scala 3	= dominio intrapsichico	= 3/18 (>3)

ORIGINAL RESEARCH—ENDOCRINOLOGY

ANDROTEST©: A Structured Interview for the Screening of Hypogonadism in Patients with Sexual Dysfunction

Giovanni Corona, MD,*† Edoardo Mannucci, MD,‡ Luisa Petrone, MD,* Giancarlo Balercia, MD,§ Alessandra D. Fisher, MD,* Valerio Chiarini, MD,† Gianni Forti, MD,* and Mario Maggi, MD*

*Andrology Unit, Department of Clinical Physiopathology, University of Florence, Florence, Italy; †Endocrinology Unit, Maggiore-Bellaria Hospital, Bologna, Italy; ‡Diabetes Section Geriatric Unit, Department of Critical Care, University of Florence, Florence, Italy; §Endocrinology Unit, Department of Internal Medicine, Polytechnic University of Marche, Ancona, Italy

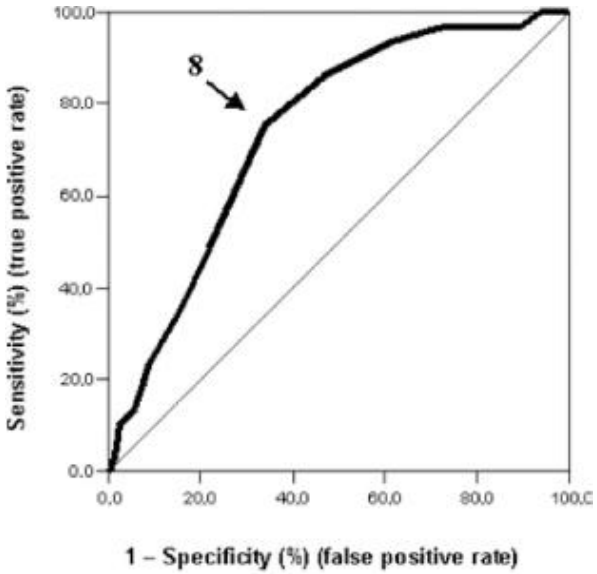
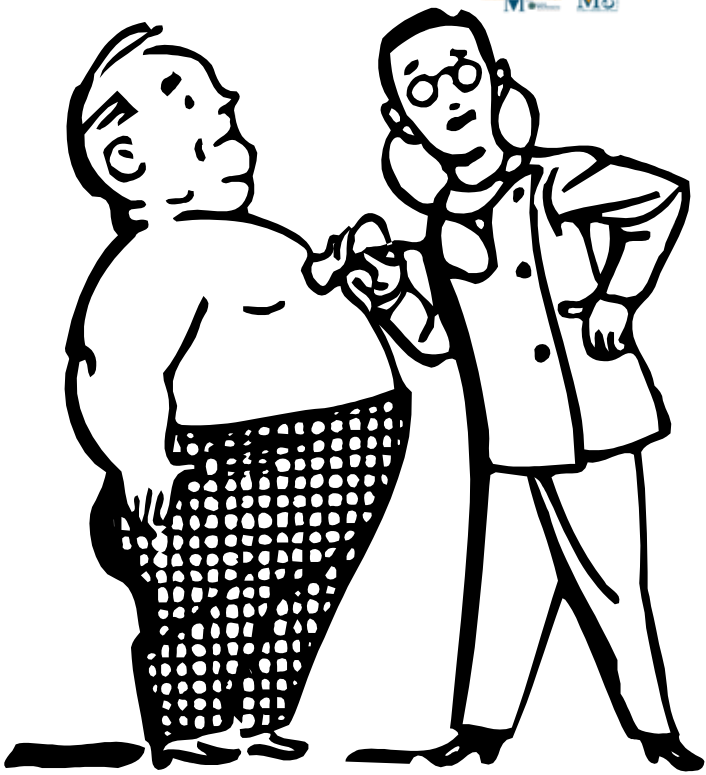


Figure 1 ROC curve for ANDROTEST© scores in the identification of patients with hypogonadism in Sample A.

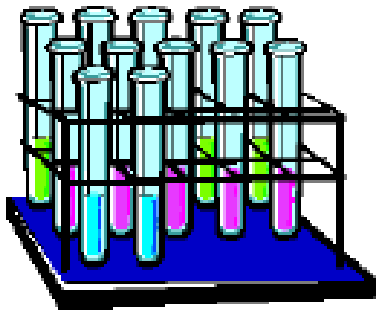
Antonio's score = 14 (VN<8)

Esame obiettivo



- peso = 106 kg
- altezza; 174 cm
- BMI = 35.01
- waist: 118 cm
- testicolo destro = 22 mL
- testicolo sinistro = 15 mL
- prostata normale per età, non noduli
- Tiroide non palpabile
- PA = 140/95
- battito cardiaco = 64/min

Testosterone totale=7.5 nmol/L (10-30)
SHBG=23.4 nmol/L (12.9-61.7)
Calcolato freeT=173 pmol/L (>225)
TSH= 1.18 mU/L
LH=2.74 mU/L
FSH=4.11 mU/L
PRL=117 mU/L
Glicemia= 112 mg/dL
Colesterolo tot = 210 mg/dL
Colesterolo HDL=48 mg/dL
Trigliceridi= 153 mg/dL
PSA=2.51 mg/ml
Hb= 14.1 g%
Hct = 41.4%



MIDDLESEX HOSPITAL QUESTIONNAIRE (MHQ)

(modificato)

NOME...

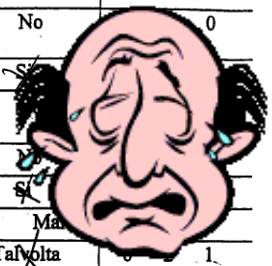
SPORT.....ETA'.

Istruzioni

Le domande sotto elencate riguardano il
il tipo di risposta corrispondente al suo

1 Si sente spesso irritato senza una ragi particolare?	Spesso	Talvolta	Mai
2 Ha paura di trovarsi in luoghi chiusi (ascensori, negozi, ecc..)?	Si	Talvolta	No
3 La gente dice che lei è troppo scrupol	Spesso	Talvolta	Mai
4 E' disturbato da capogiri o difficoltà d	Di rado	Spesso	Mai
5 Riesce a pensare rapidamente?	Si		No
6 Le sue opinioni sono facilmente influe	Si		No
7 Ha avuto mai la sensazione di svenire	No		Si
8 Si preoccupa di poter prendere qualch incurabile?	Si	Un po'	No
9 Tiene eccessivamente alla pulizia?			
10 Avverte spesso un senso di nausea o indigestioni?			
11 Pensa che la vita richieda troppo fatic			
12 Le piace vivere molto attivamente?			
13 Si sente a disagio ed irrequieto?			
14 Si sente più rilassato a casa?			
15 Trova che nella sua mente ricorrano pensieri sciocchi ed irragionevoli?			
16 Avverte talvolta sensazioni di ronzio o formicolio nel corpo, nelle braccia o nelle gambe?			
17 E' abituato a rimpiangere spesso il suo comportamento passato?			
18 E' una persona eccessivamente emotiva?			
19 Si sente, talvolta, in preda al panico?			
20 Si sente a disagio quando viaggia in pullman o in treno?			

21 Si sente più felice quando lavora o studia?	Si	No	2 0 0
22 Il suo appetito è diminuito recentemente?	No	Si	0 0 2
23 Le capita spesso di svegliarsi troppo presto la mattina o durante la notte?	Si	No	0
24 Le piace essere al centro dell'attenzione?	No		
25 Ritiene di essere una persona facilmente preoccupabile?	Si	Poco	
	Si		
	No		
	pesso	Talvolta	Mai
	Mai	Spesso	Talvolta
	Mai	Talvolta	Spesso
	Si	No	2 0 0
	No	Si	0 0 2
	Si	No	2 0 0
	No	Si	2 0 0
		Talvolta	No 2 1 0
	Si	No	2 0 0
	Si	No	2 0 0
	lolto	Un po'	No 2 1 0
	lolto	Un po'	No 2 1 0
41 Le viene da piangere?	No	Si	0 0 2
42 Le piacciono le situazioni drammatiche?	Spesso	Talvolta	Mai 2 1 0
43 Fa brutti sogni che la disturbano al risveglio?	Si		No 2 0 0
44 Si lascia prendere dal panico quando è tra la folla?	Mai	Talvolta	Spesso 0 1 2
45 Le succede di preoccuparsi in modo irragionevole per cose che non hanno eccessiva importanza?	Sempre	Talvolta	Mai 2 1 0
46 I suoi interessi sessuali sono recentemente cambiati?	Mai	Spesso	Talvolta 0 2 1
47 Le piace molto stare in compagnia'	Meno	Uguali	Più 2 0 0
48 Si accorge mai che sta posando o tentando di apparire diverso da quello che è?	Si		No 0 0 2
	Si		No 2 0 0



Free floating axiety: 8 (nv < 5)
Phobic anxiety: 11 (nv<5)
Obsessive symptoms: 12 (nv < 7)
Somatization: 5 (nv < 5)
Depression: 5 (nv < 4)
Hysterical symptoms: 8 (nv < 4)

A=8 F=11 O=12 S=5 D=5 I=

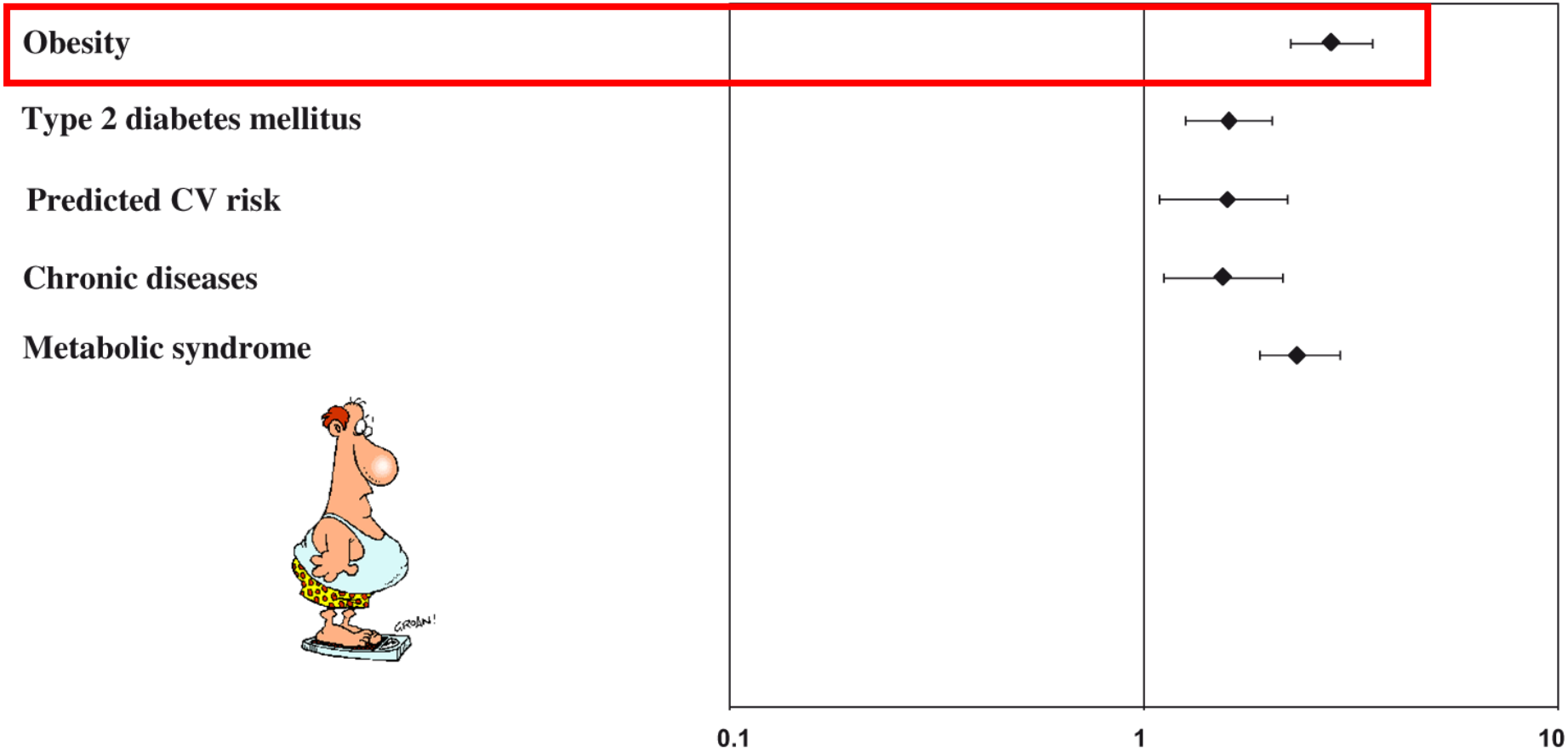
E' un vero ipogonadismo, va trattato?

1. Sì, va trattato.
2. Sì andrebbe trattato, ma non ci sono i sintomi.
3. No, perché è solo un ipogonadismo subclinico.
4. Sì, va trattato, ma solo dopo aver valutato la prostata.
5. No, e non va trattato.

Perché Antonio è ipogonadico?

1. Per l'andropausa
2. Orchite parotitica contratta in caserma
3. Perché è un grave obeso
4. Perché ha la sindrome metabolica
5. Perché è iperteso

Age-adjusted risk for late-onset hypogonadism (LOH) according to EMAS criteria (<11 nmol/L+ sexual symptoms) for different conditions, as evaluated in a consecutive series (n = 3293) of outpatients seeking medical care for male sexual dysfunction between 2000 and 2011 at UNIFI



Corona et al., Best Pract Res Clin Endocrinol Metab. 2013 Aug;27(4):557-79

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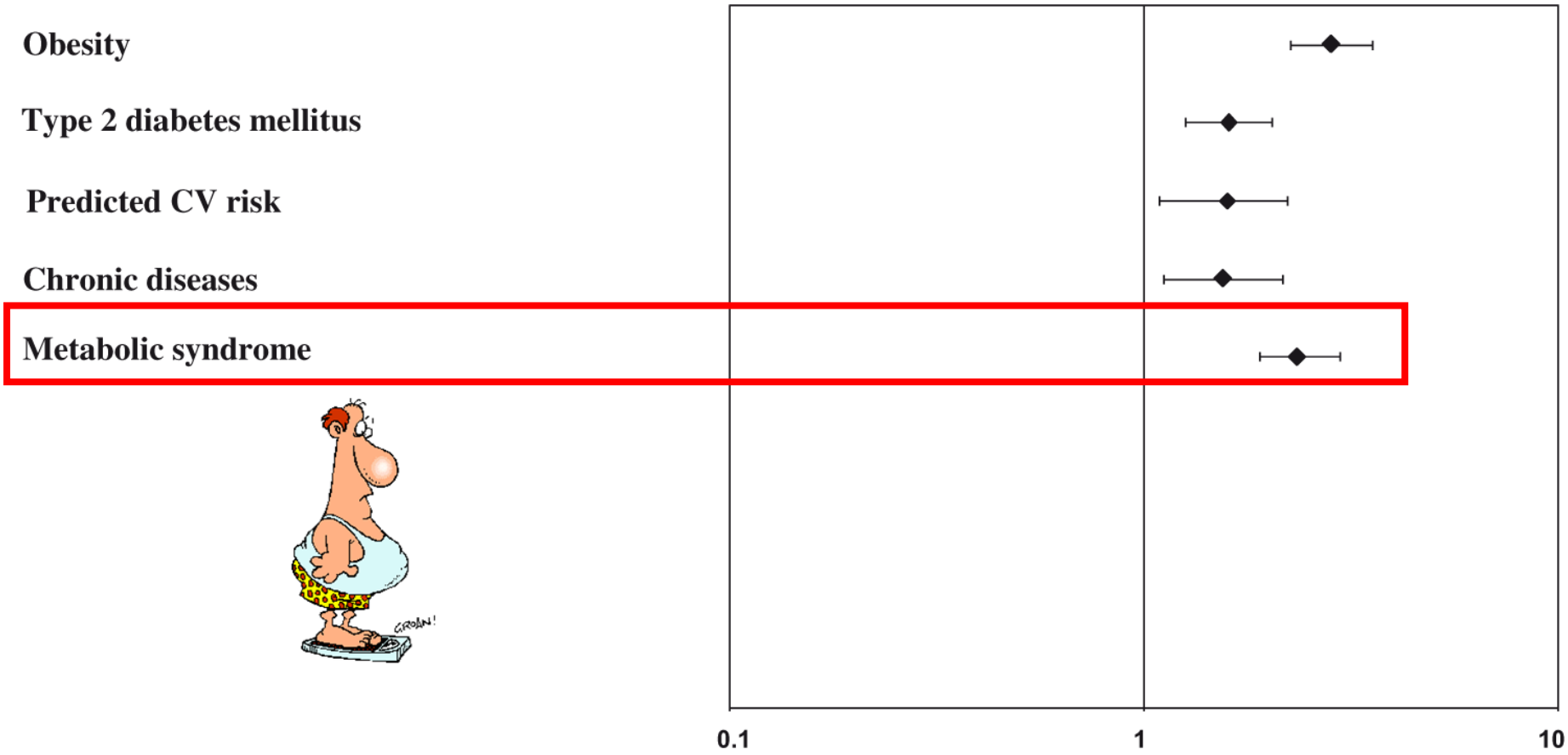

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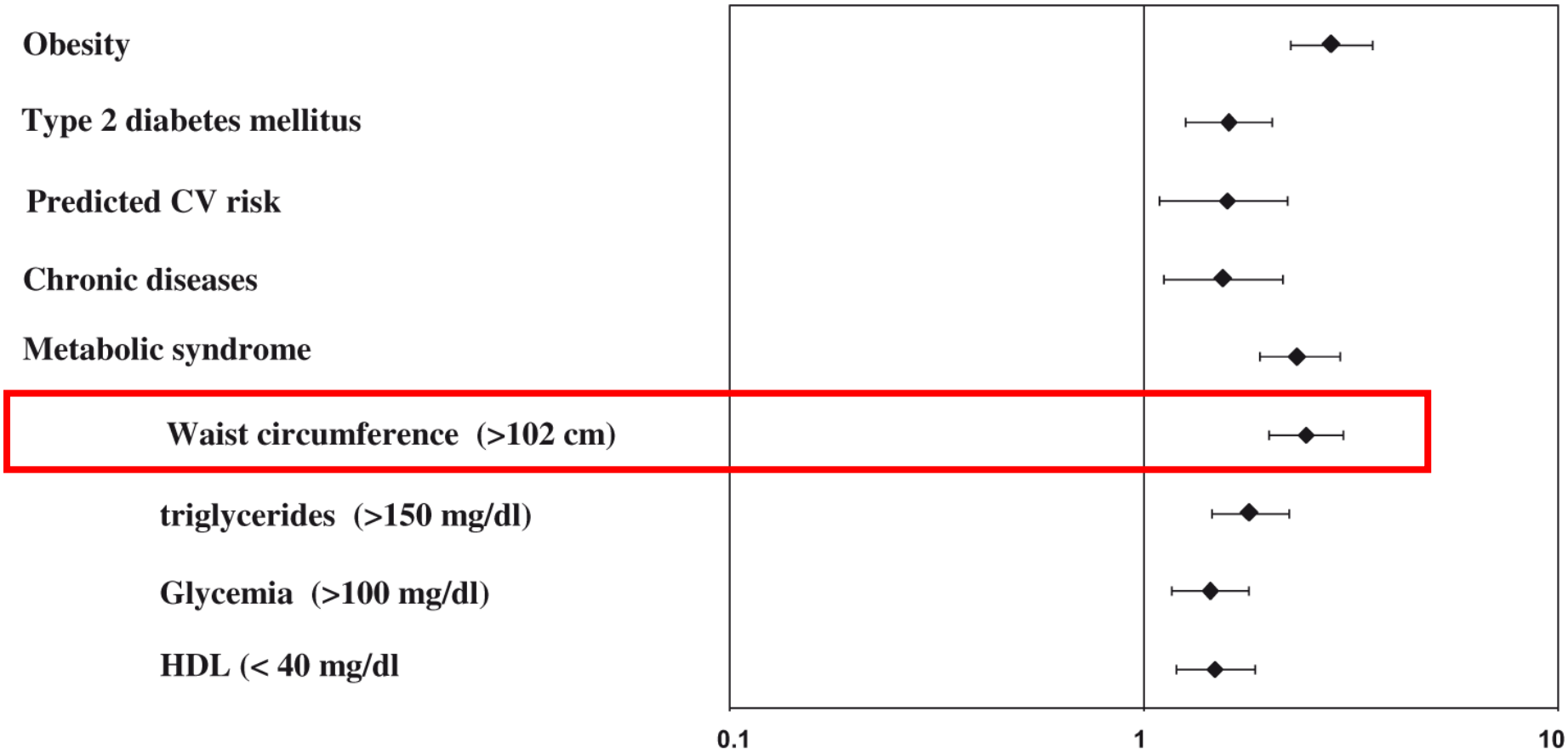
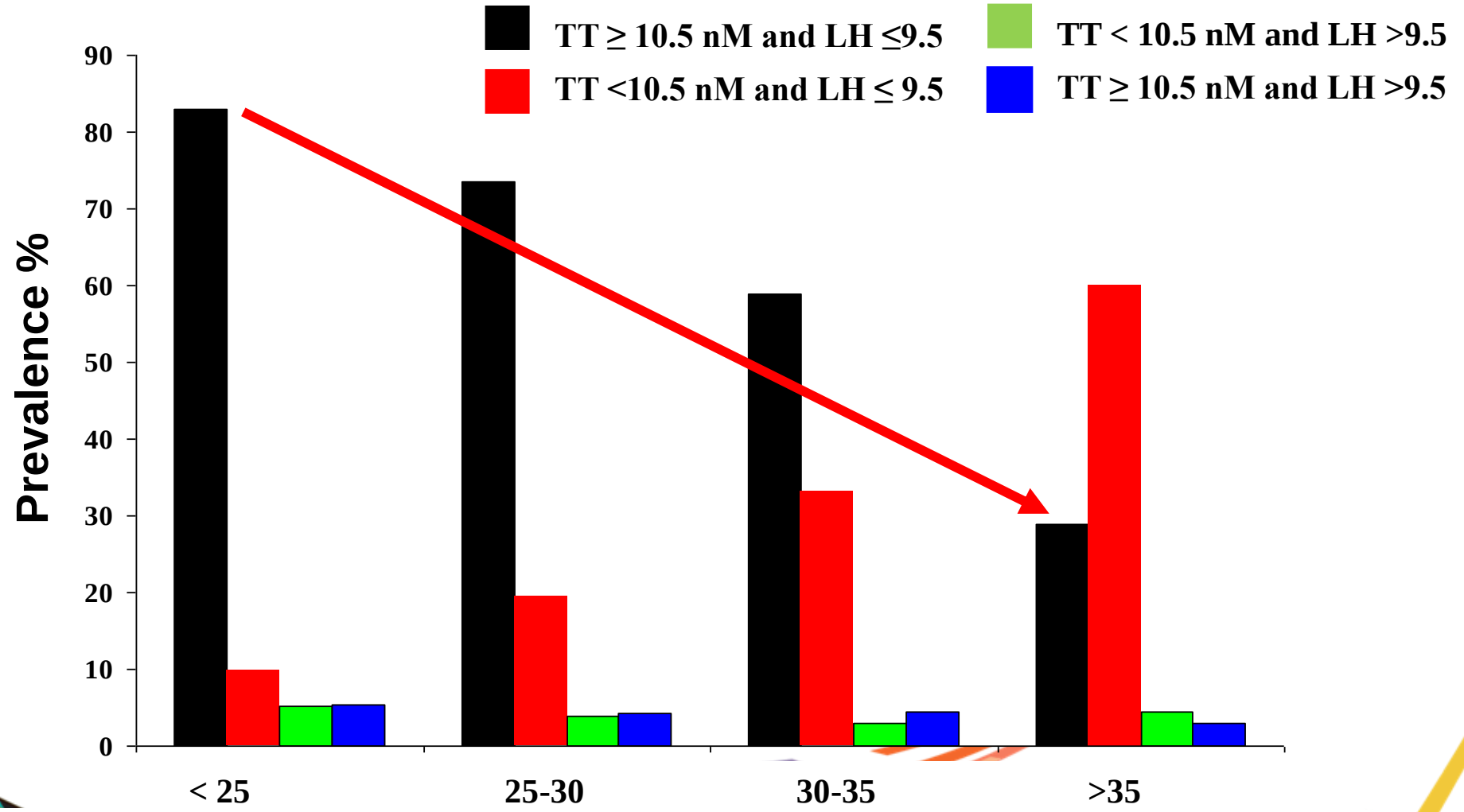


Corona et al., Best Pract Res Clin Endocrinol Metab. 2013 Aug;27(4):557-79

Che tipo di ipogonadismo si associa a obesità e sindrome metabolica?

1. Ipogonadismo primitivo
2. Ipogonadismo secondario
3. Ipogonadismo da resistenza agli androgeni
4. Ipogonadismo misto
5. Ipogonadismo subclinico

Prevalence of different types of hypogonadism in a non-selected series of 4173 men (mean a51.3 ± 13.3 years) attending our Andrology Clinic for sexual dysfunction at UNIFI, according to BMI classes.



Corona et al., Mol Cell Endocrinol. 2015 Dec 15;418 Pt 2:120-33

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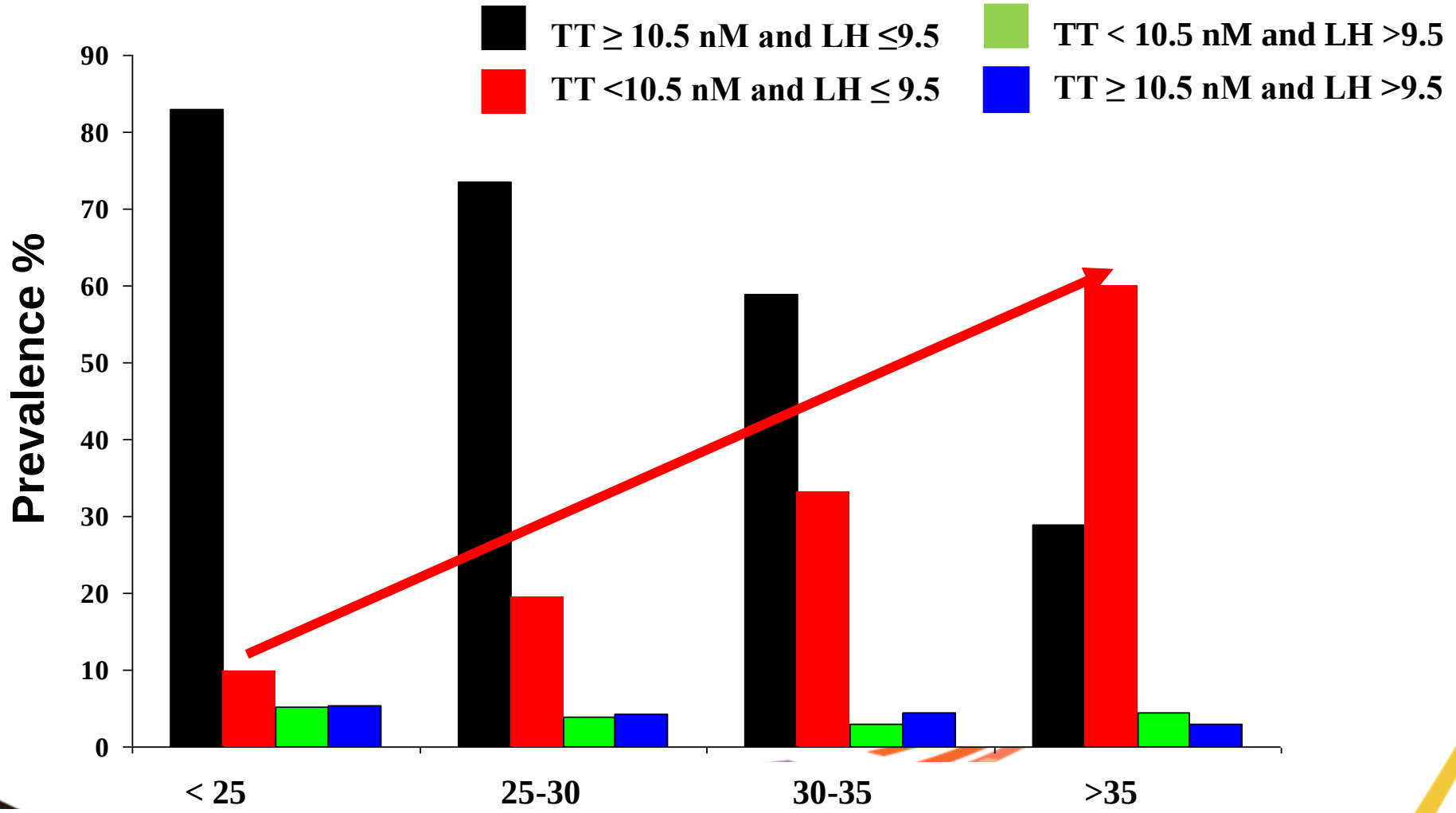

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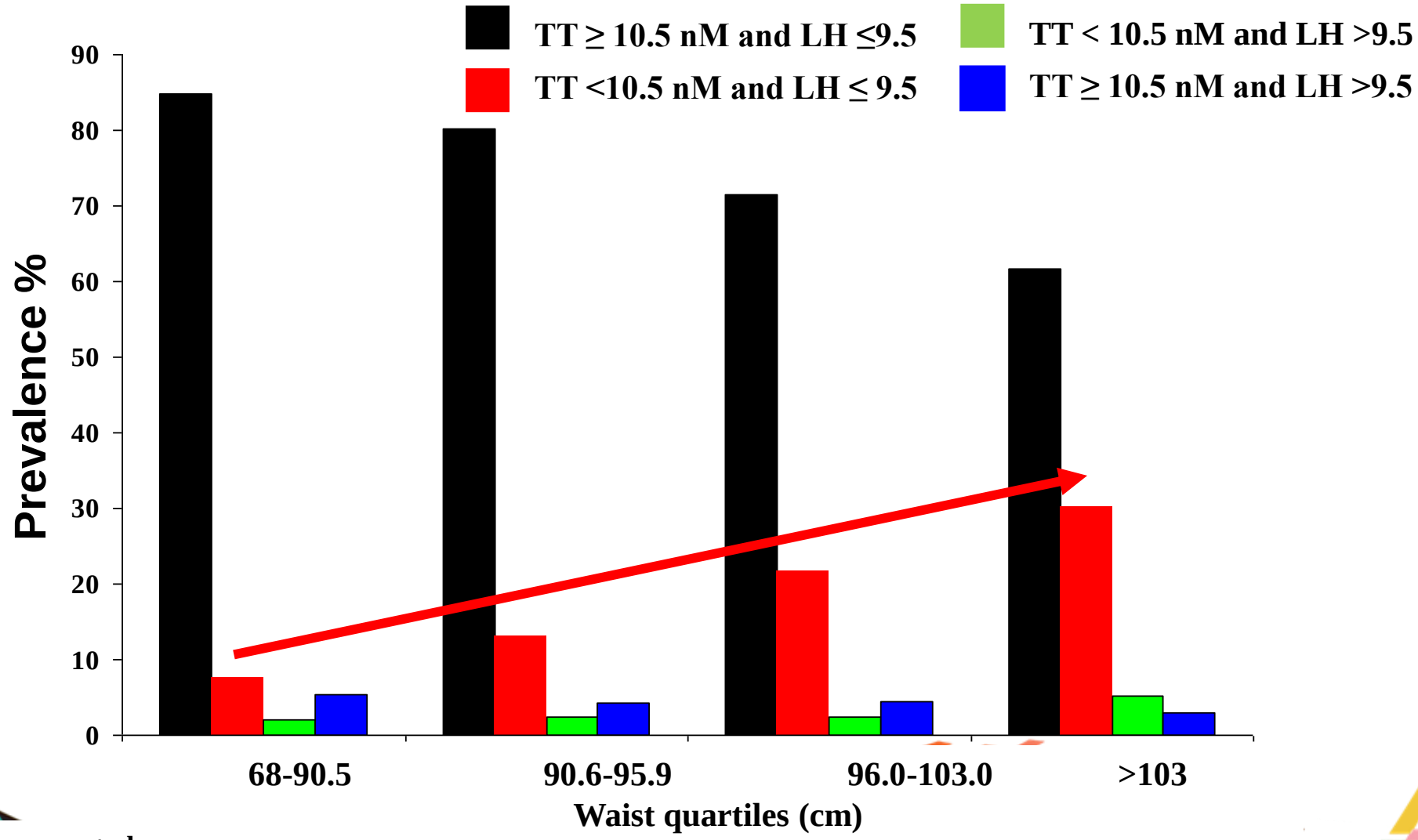
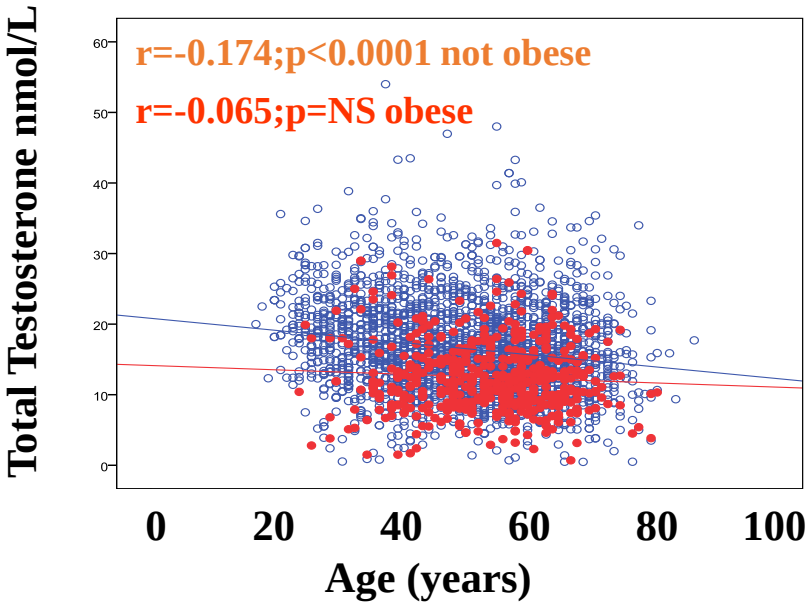


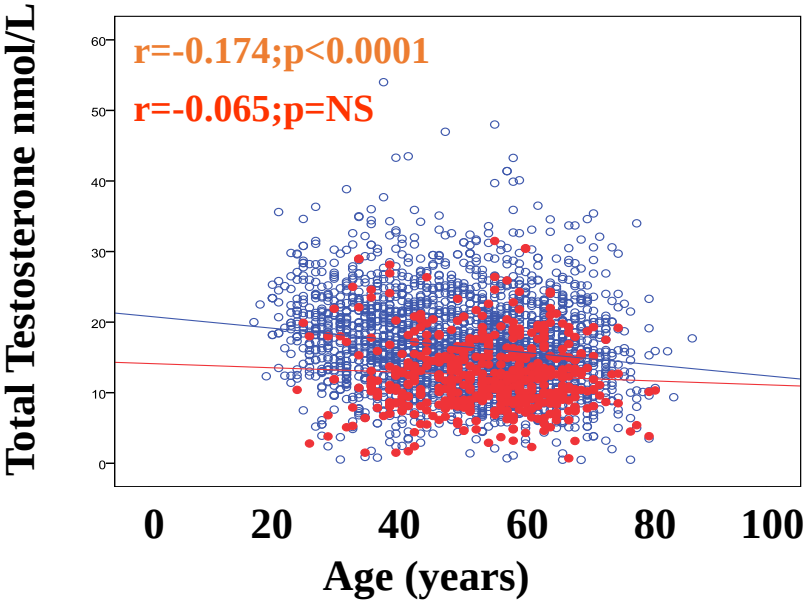
Corona et al., Mol Cell Endocrinol. 2015 Dec 15;418 Pt 2:120-33

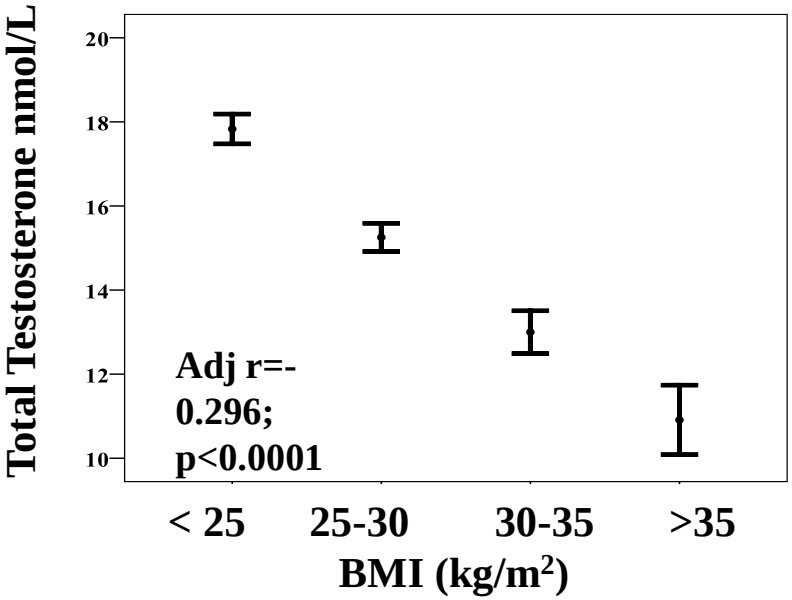
Metabolic syndrome

visceral obesity



Corona et al., Horm Mol Biol Clin Invest. 2010;1:509





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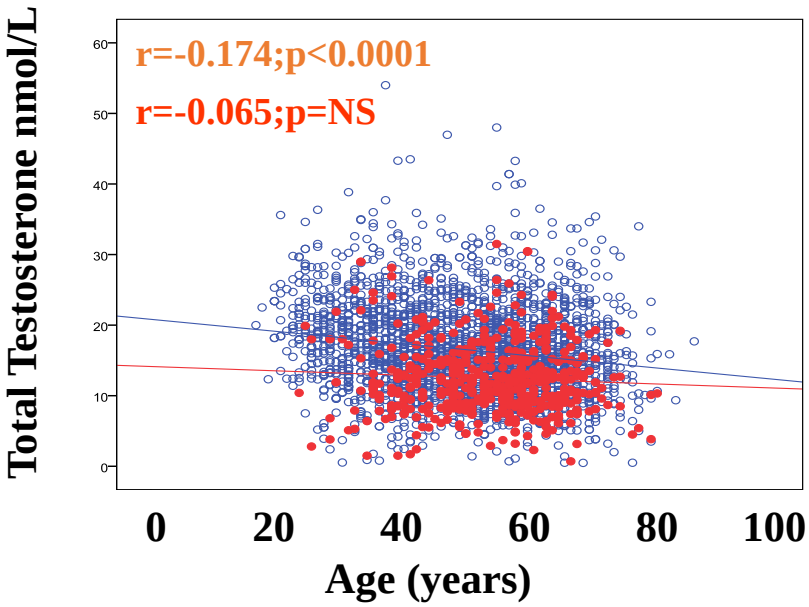

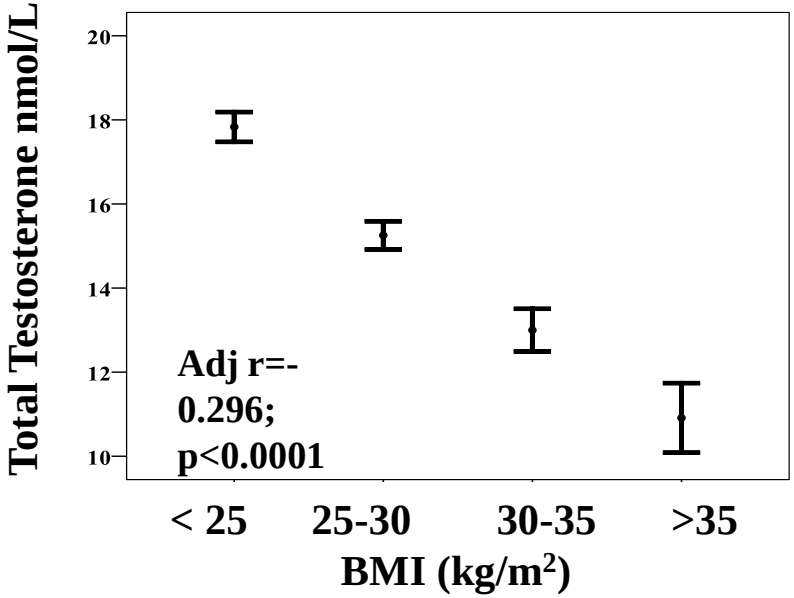

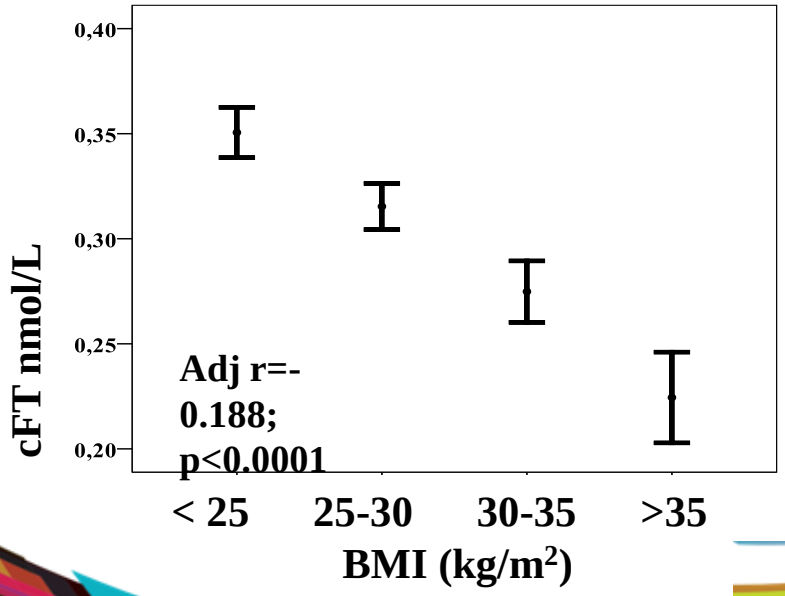

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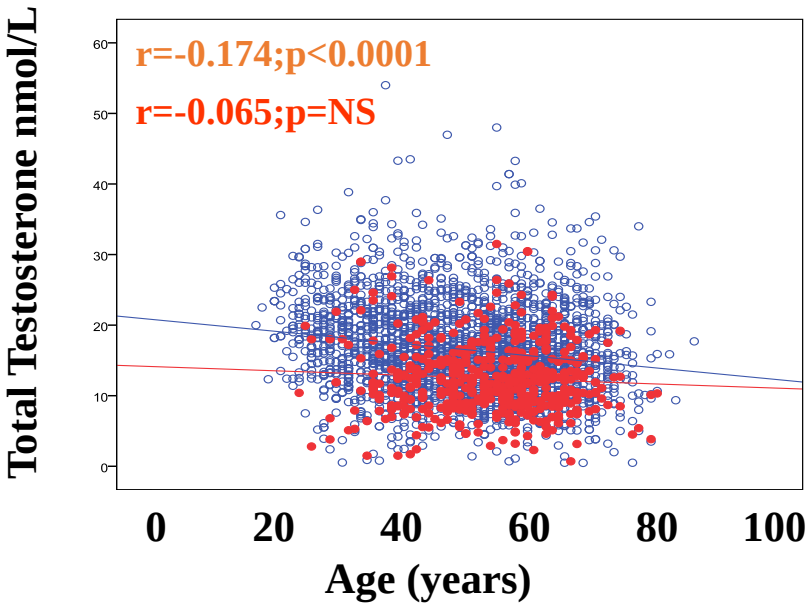
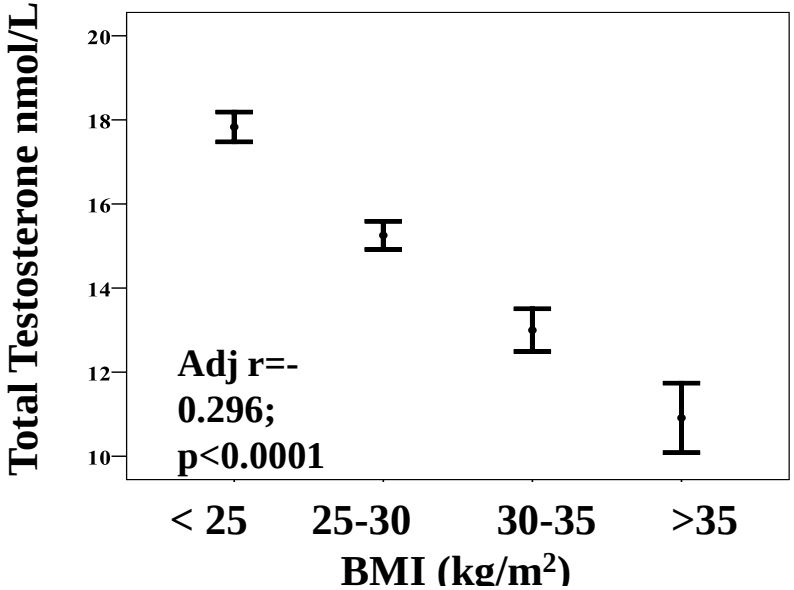
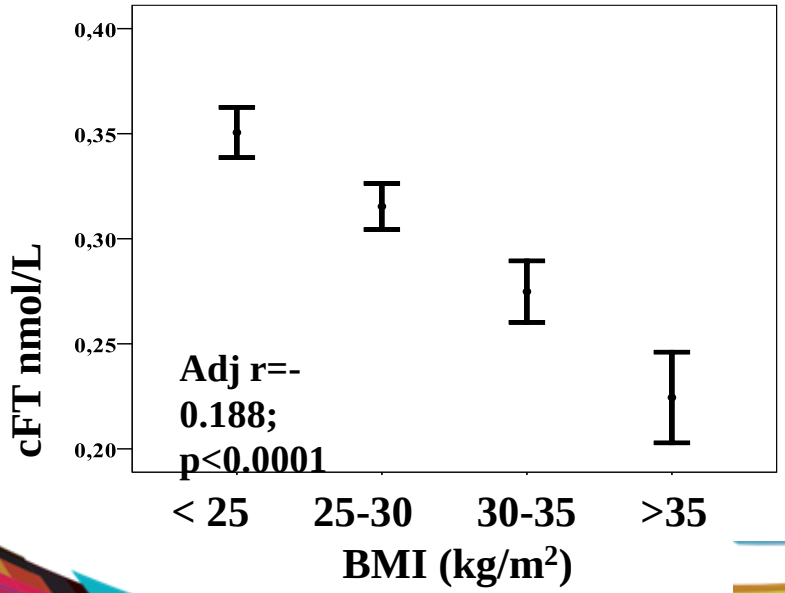
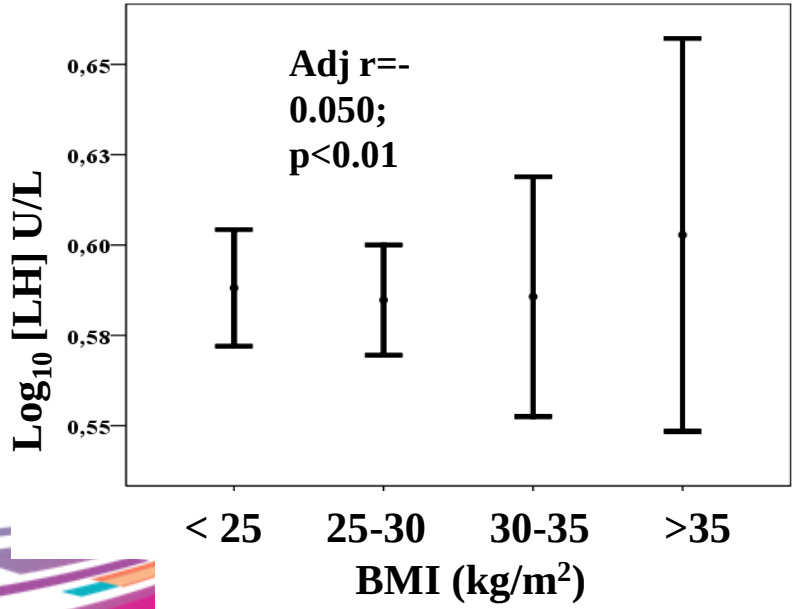

r=-0.174;p<0.0001
r=-0.065;p=NS
Total Testosterone nmol/L
Age (years)


Adj r=-0.296; p<0.0001
Total Testosterone nmol/L
< 25
25-30
30-35
>35
BMI (kg/m²)


Adj r=-0.188; p<0.0001
cFT nmol/L
< 25
25-30
30-35
>35
BMI (kg/m²)

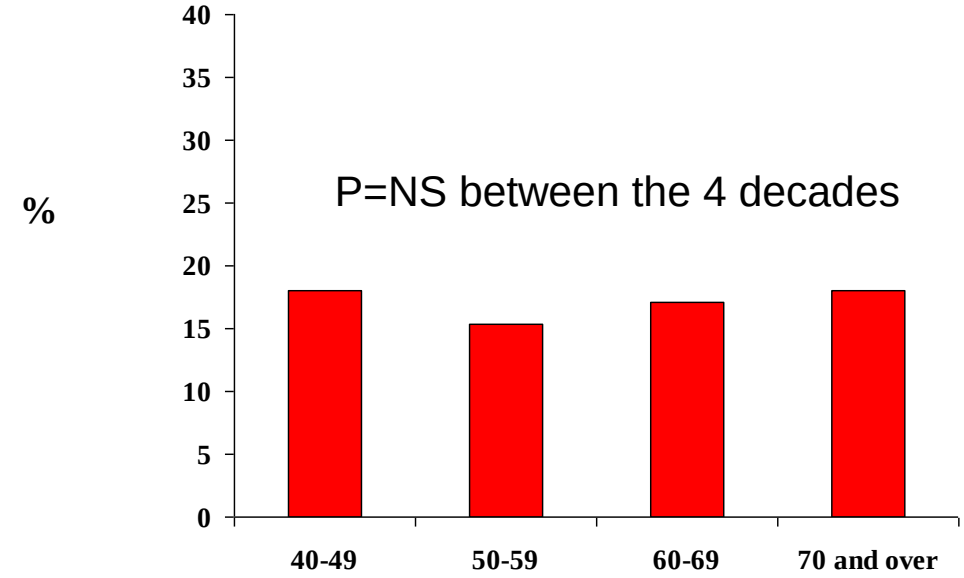

Adj r=-0.050; p<0.01
Log10 [LH] U/L
< 25
25-30
30-35
>35
BMI (kg/m²)

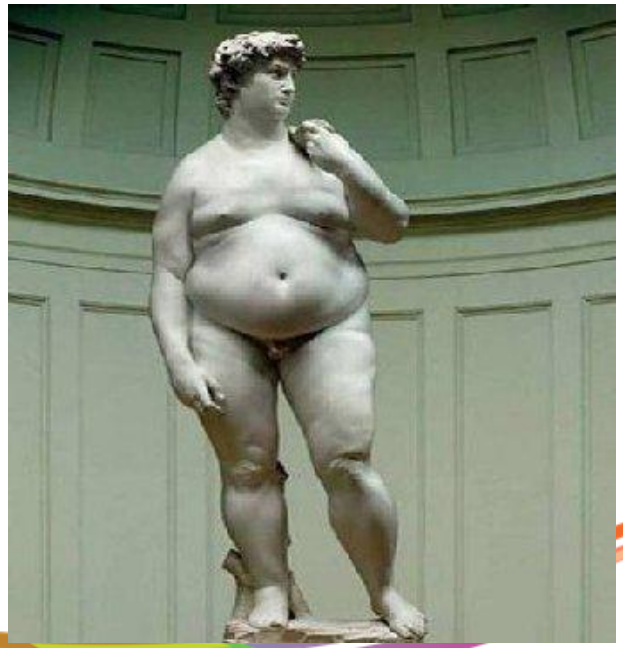
Quanta obesità c'è nei maschi adulti di Firenze?

1. 10%
2. 15%
3. 25%
4. 50%
5. 20%

OBESITY IN FLORENCE (BMI ≥30 kg/m²)

random series of 431 community-dwelling men (EMAS) studied at the University of Florence, Florence, Italy



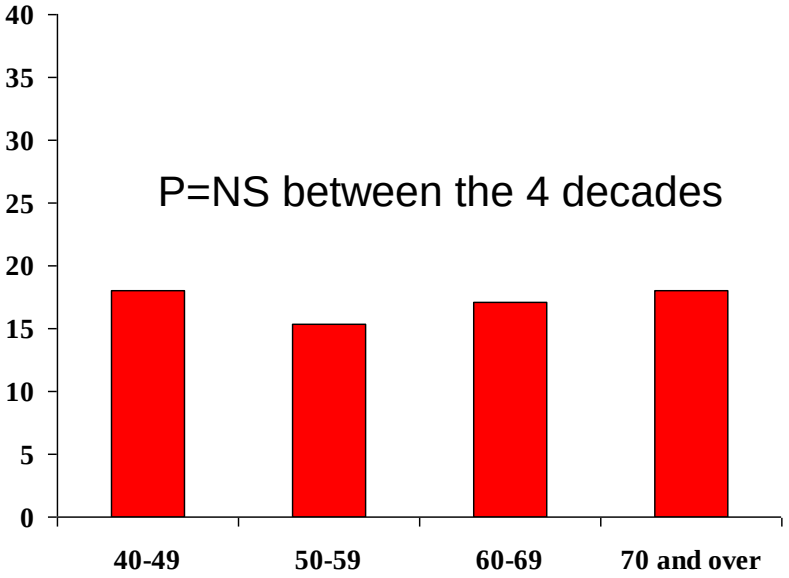


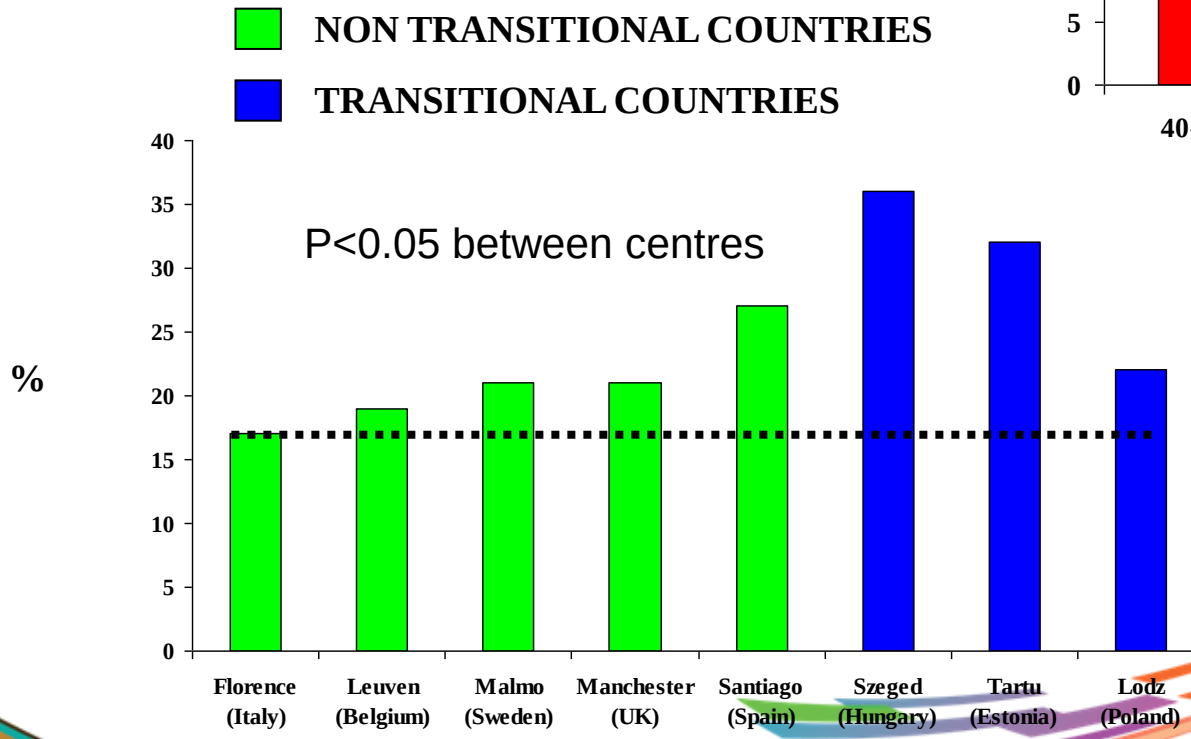
Obesity in Florence

Corona et al., 2010
J Sex Med 7:1362-80

OBESITY IN FLORENCE (BMI ≥30 kg/m²)

random series of 431 community-dwelling men (EMAS) studied at the University of Florence, Florence, Italy





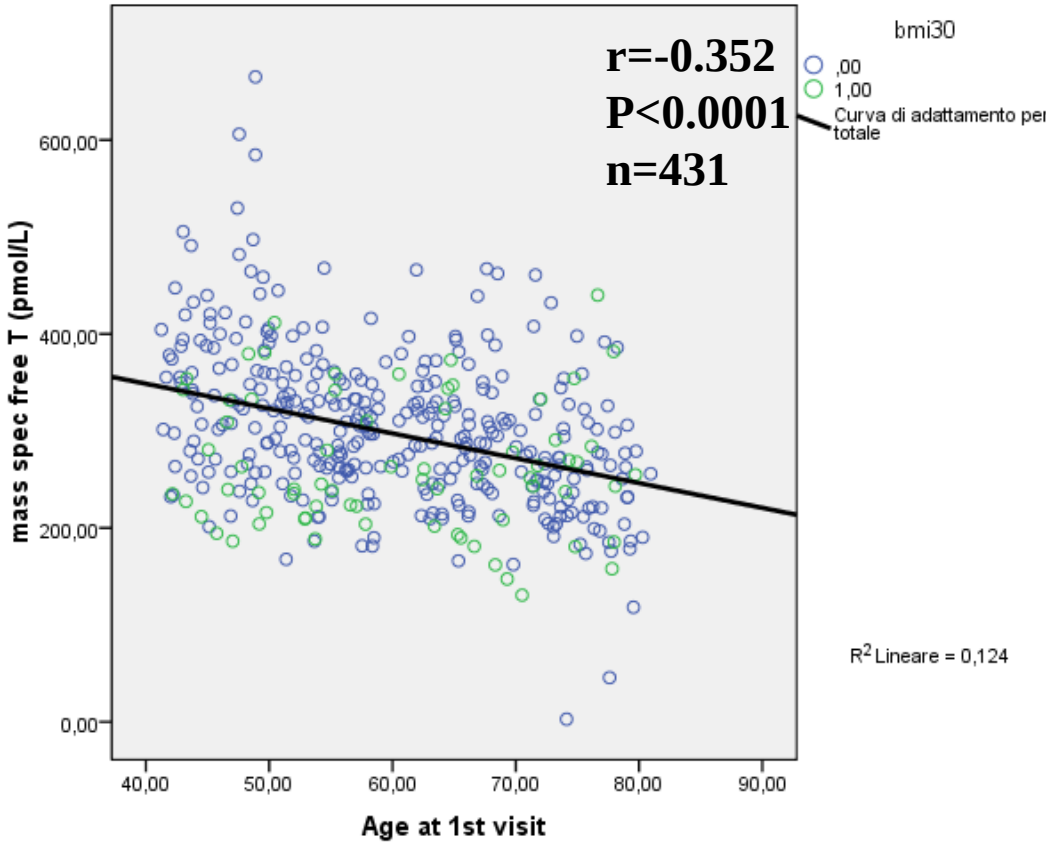
OBESITY IN EUROPE (BMI ≥30 kg/m²)

random series of 3369 community-dwelling men (EMAS)

Corona et al., 2010
J Sex Med 7:1362-80

Age-dependent testosterone decline in a random series of 431 community-dwelling men (EMAS) studied at the University of Florence, Florence, Italy

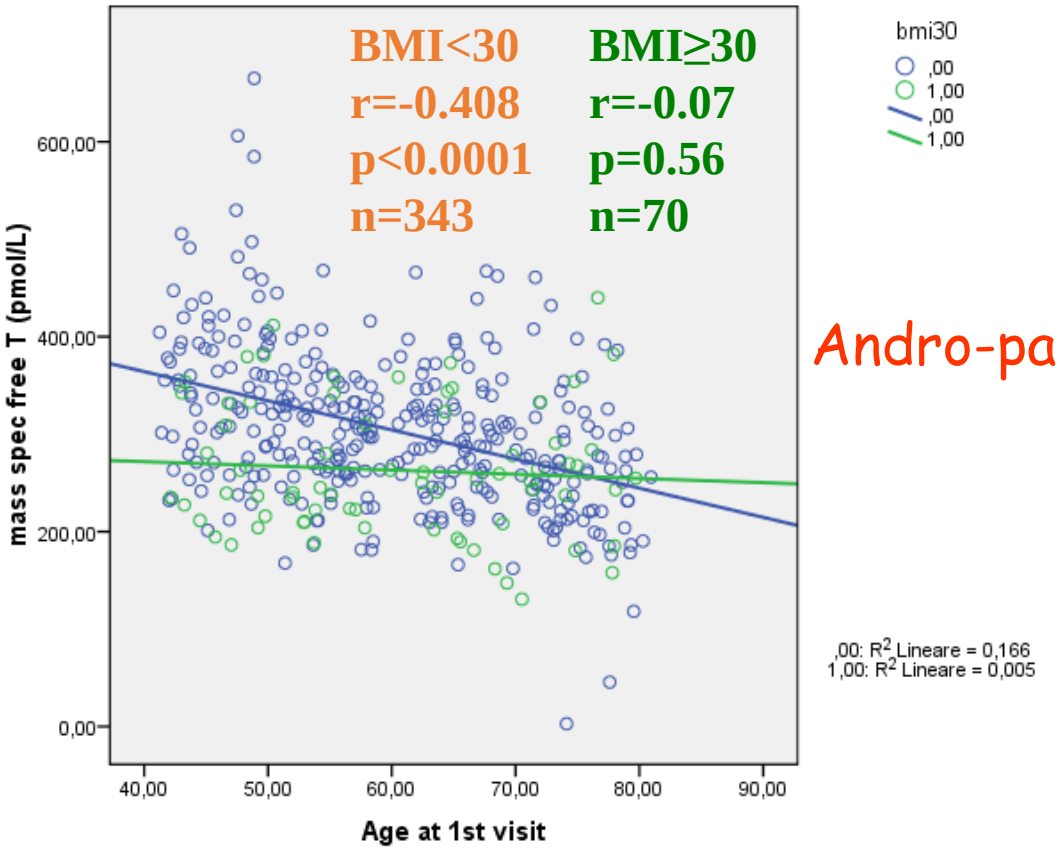
Free-T (mass spec)



EMAS European Male Ageing Study

Age-dependent testosterone decline in a random series of 431 community-dwelling men (EMAS) studied at the University of Florence, Florence, Italy

Free-T (mass spec)

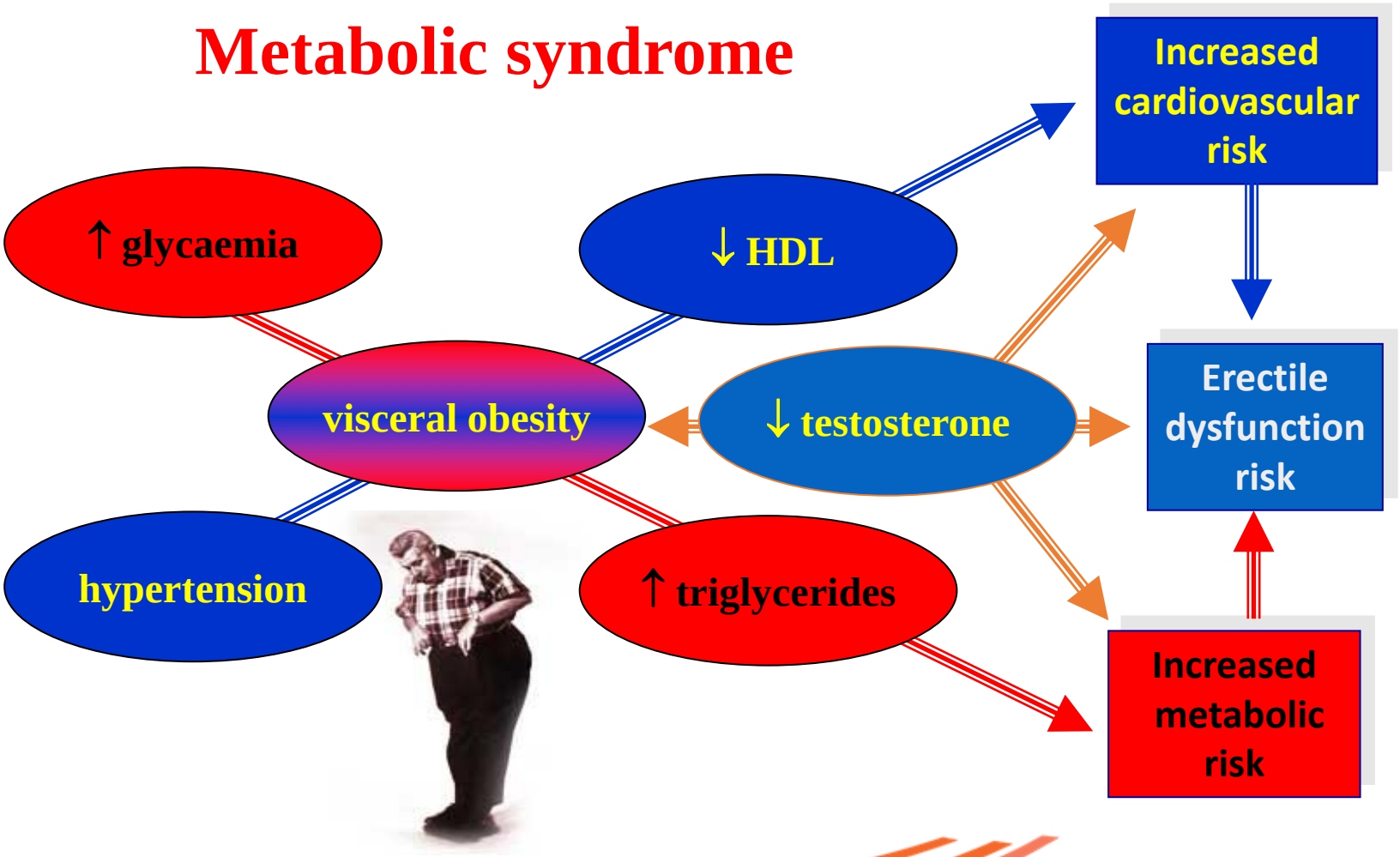


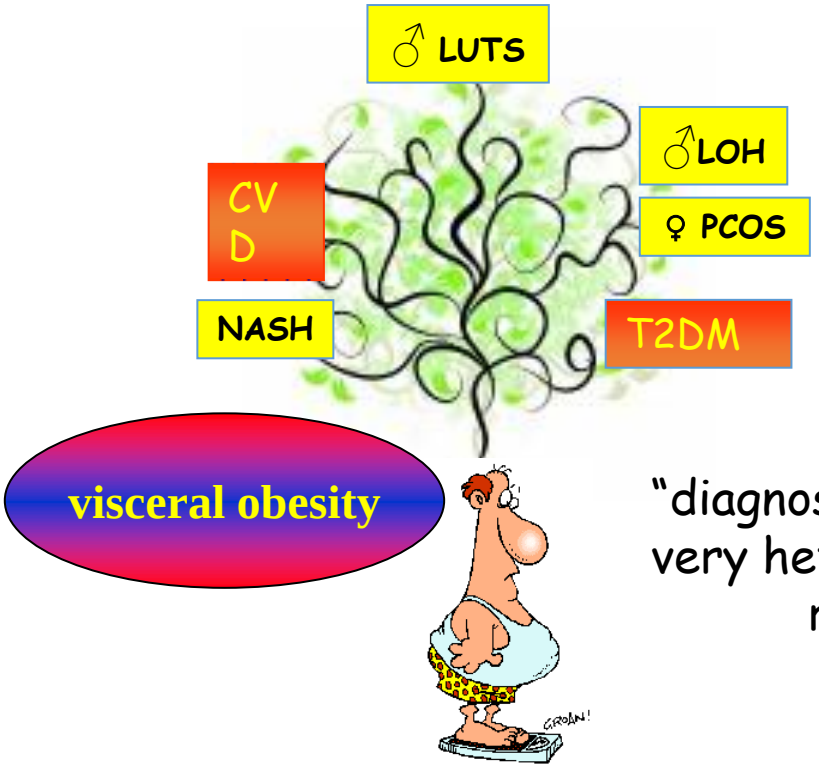
EMAS European Male Ageing Study

Andro-pause=lean-pause!

When divided according to BMI, testosterone decline is evident only in lean subjects, obese ones are already T deficient in the youngest age!

Metabolic syndrome





MetS

"diagnostic category with a very heterogeneous clinical ramification"

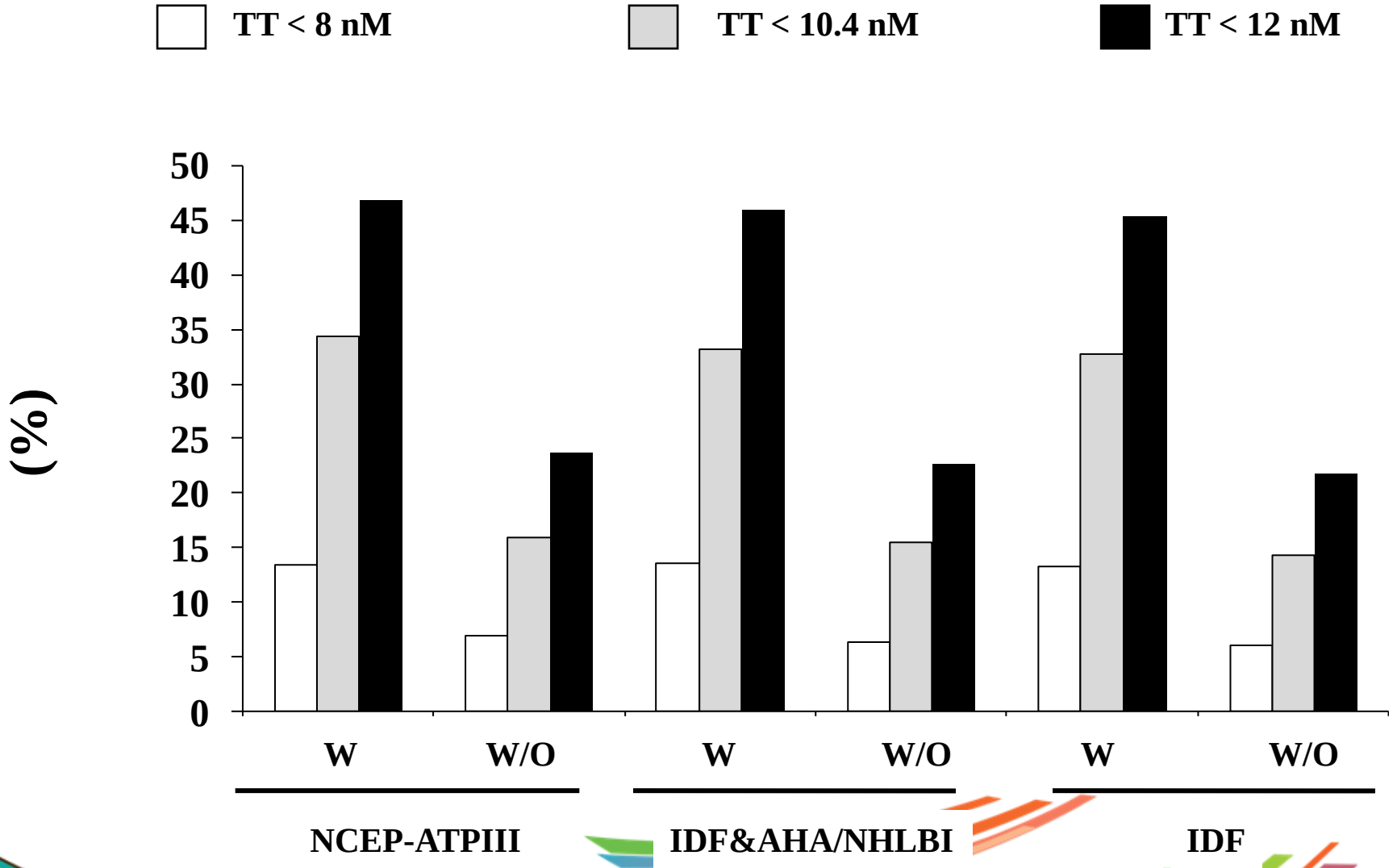
Different definitions of metabolic syndrome

Table 2
Comparisons of definitions of metabolic syndrome: National Cholesterol Education Program-Third Adult Treatment Panel (NCEP-ATPIII), International Diabetes Federation (IDF), American Heart Association/National Heart, Lung and Blood Institute (AHA/NHLBI) and common definition by IDF and AHA/NHLBI. In blue are shared factors among different definitions.

NCEP-ATPIII	IDF	AHA/NHLBI	IDF&AHA/NHLBI
3 or more of the following • Central obesity (waist circumference >102 cm) • Hypertriglyceridaemia: triglycerides ≥150 mg/dl (1.7 mmol/L) or treatment • Low HDL-cholesterol: <40 mg/dl (1.03 mmol/L) or treatment • Hypertension: blood pressure ≥130/85 mmHg or treatment • Fasting plasma glucose: ≥110 mg/dl (6.1 mmol/L) or diabetes	Central obesity (waist circumference ≥94 cm) and 2 or more of the following • Hypertriglyceridaemia: triglycerides ≥150 mg/dl (1.7 mmol/L) or treatment • Low HDL-cholesterol: <40 mg/dl (1.03 mmol/L) or treatment • Hypertension: blood pressure ≥130/85 mmHg or treatment • Fasting plasma glucose: ≥100 mg/dl (5.6 mmol/L) or diabetes	3 or more of the following • Central obesity (waist circumference >102 cm) • Hypertriglyceridaemia: triglycerides ≥150 mg/dl (1.7 mmol/L) or treatment • Low HDL-cholesterol: <40 mg/dl (1.03 mmol/L) or treatment • Hypertension: blood pressure ≥130/85 or treatment • Fasting plasma glucose: ≥100 mg/dl (5.6 mmol/L) or treatment	3 or more of the following • Central obesity (population- and country-specific definitions) • Hypertriglyceridaemia: triglycerides ≥150 mg/dl (1.7 mmol/L) or treatment • Low HDL-cholesterol: <40 mg/dl (1.03 mmol/L) or treatment • Hypertension: blood pressure ≥130/85 mmHg or treatment • Fasting plasma glucose: ≥100 mg/dl (5.6 mmol/L) or treatment

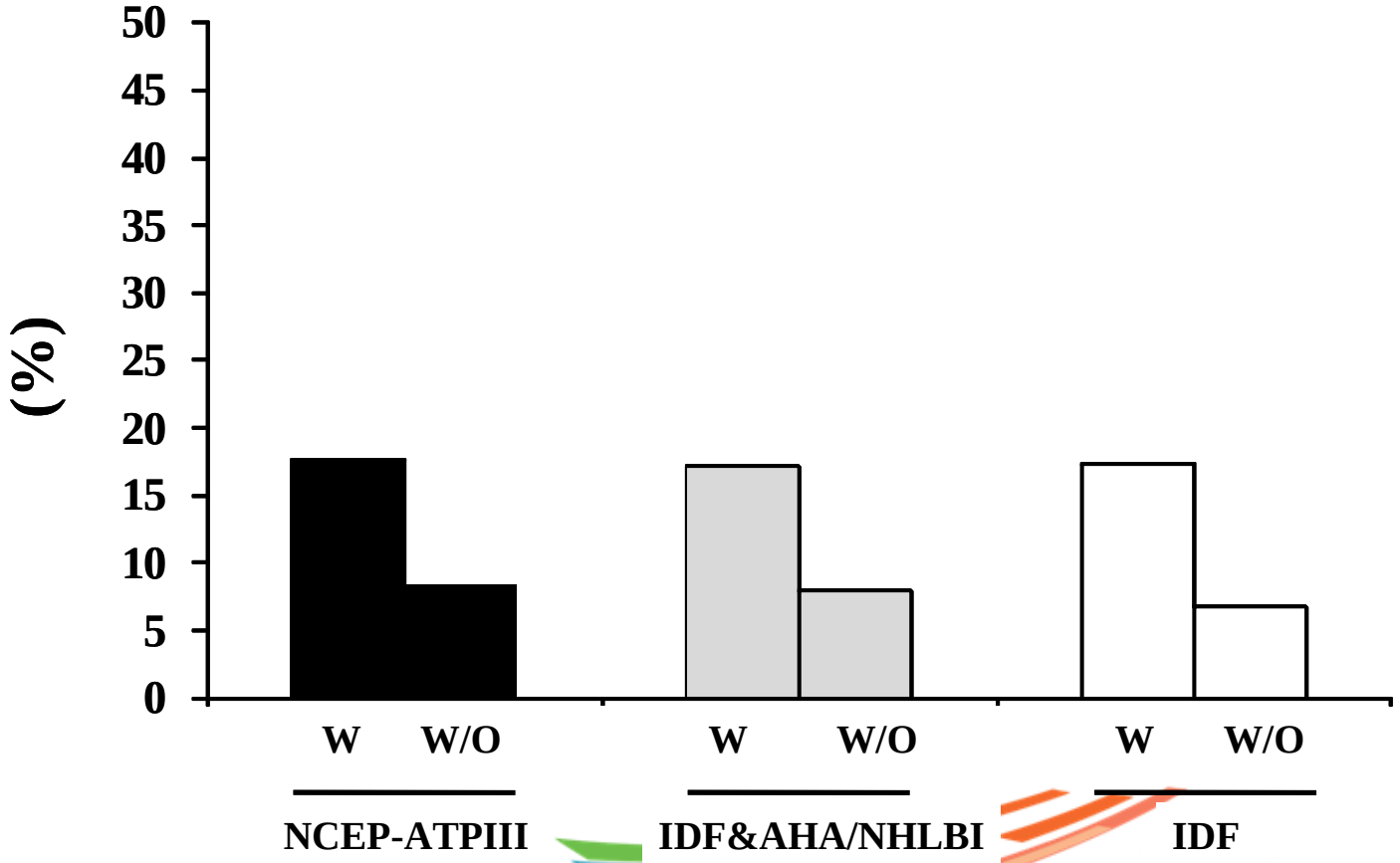
Corona et al., Best Pract Res Clin Endocrinol Metab. 2011 25:337-53

MetS is associated with a double prevalence of biochemical hypogonadism

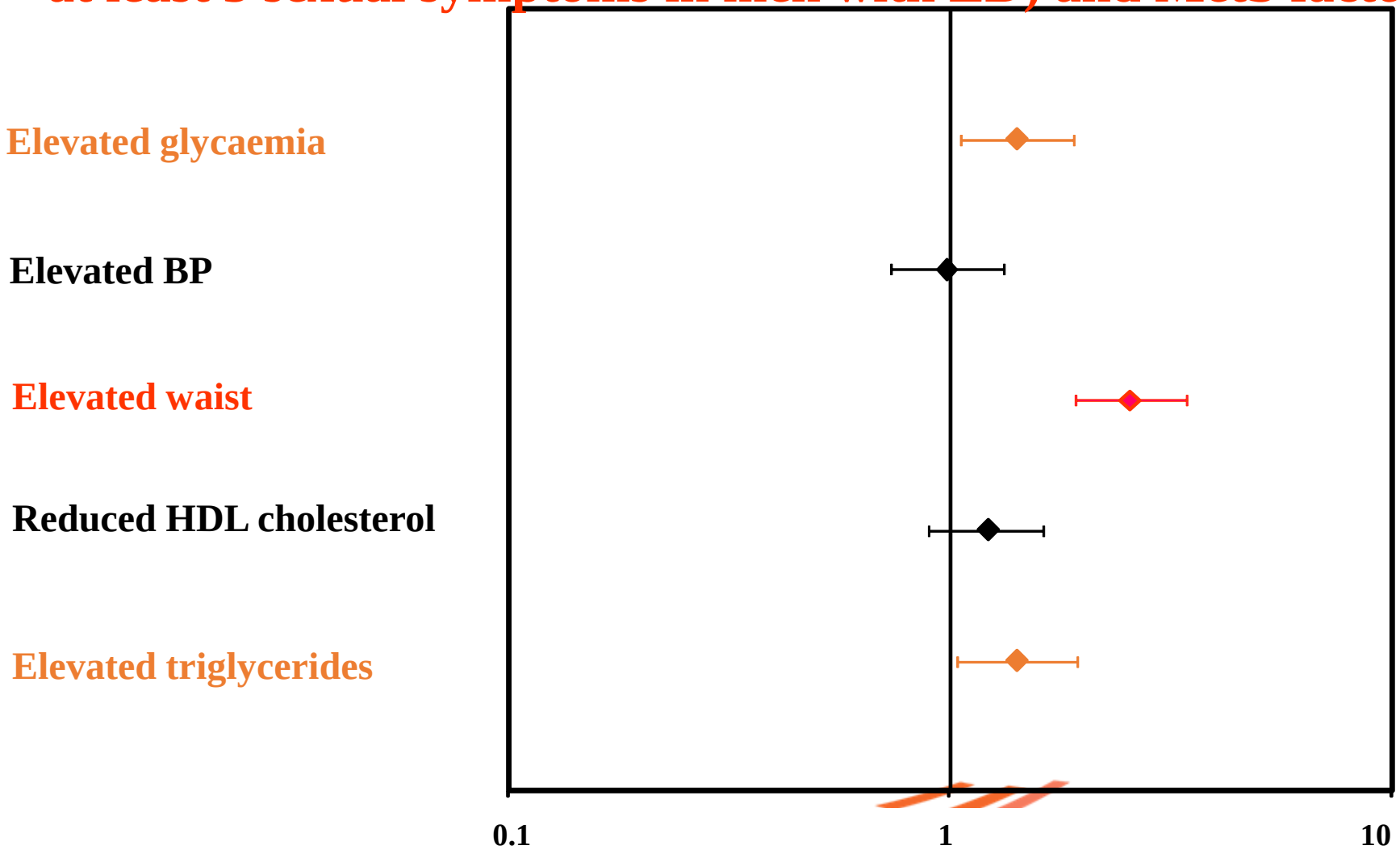


Corona et al., J Endocrinol Invest 2011 Jul-Aug;34(7):557-67

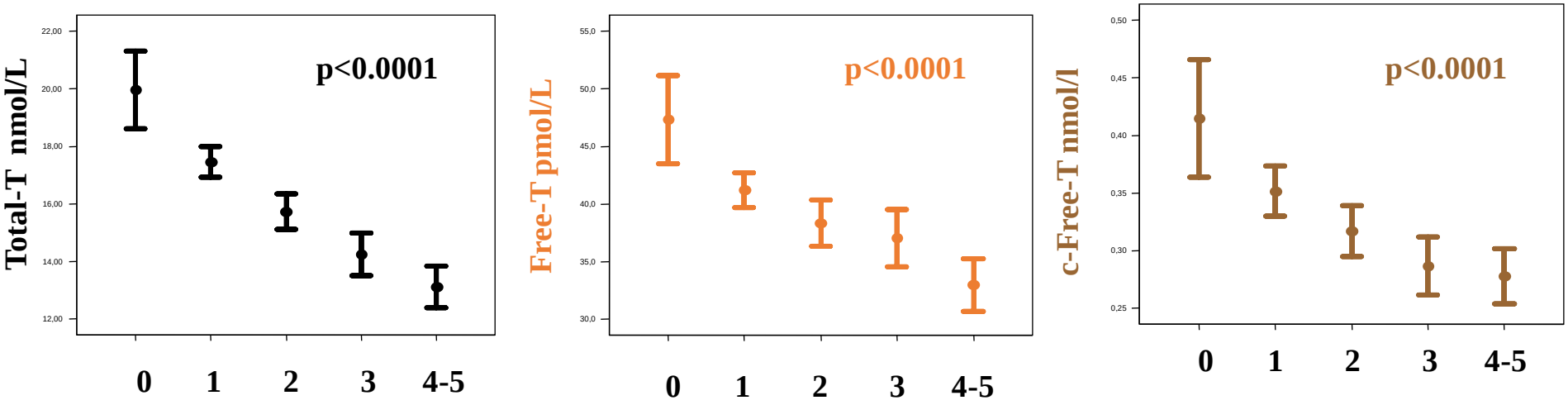
MetS is associated with higher prevalence of hypogonadism (decreased testosterone <11 nM and at least 3 sexual symptoms in men with ED)



HR of hypogonadism(decreased testosterone <11 nM and at least 3 sexual symptoms in men with ED) and MetS factors



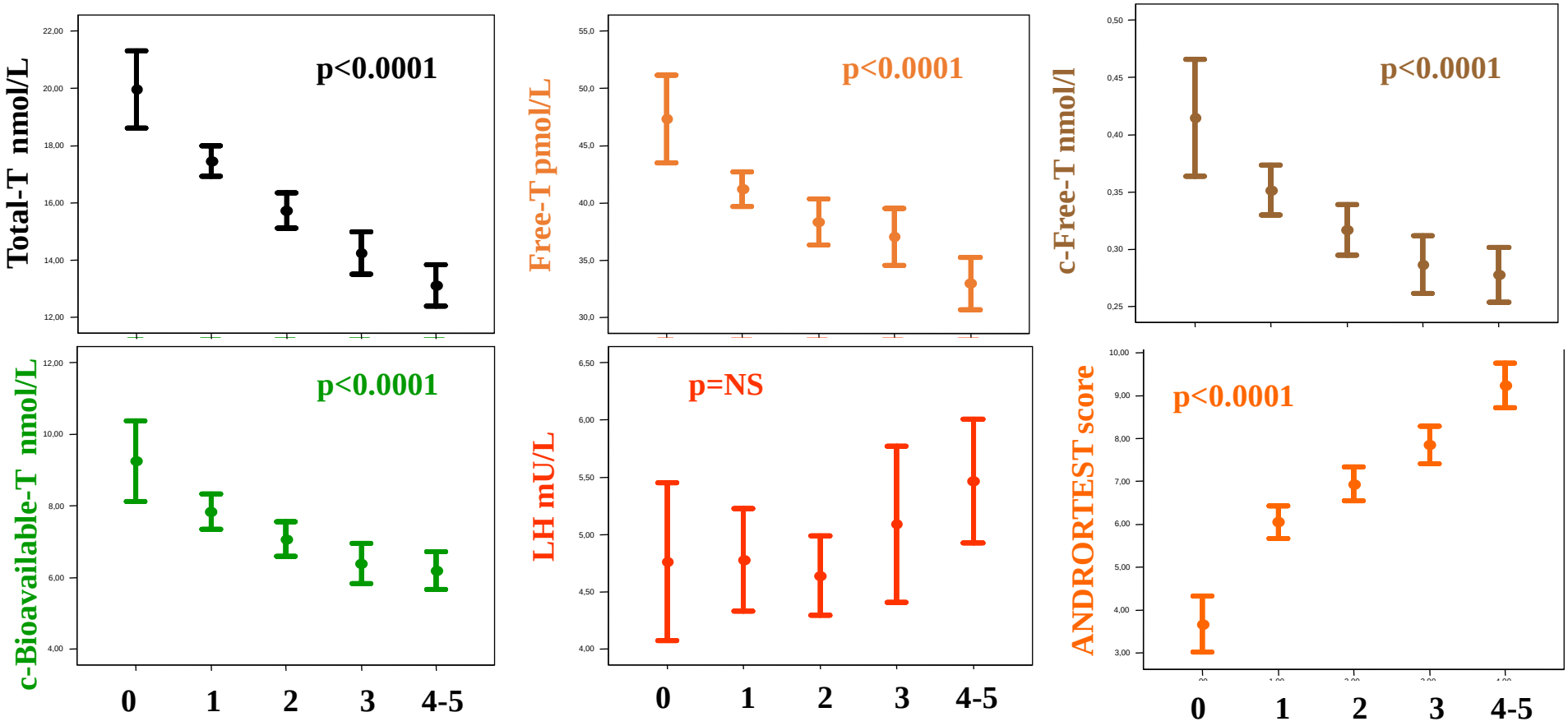
Androgen levels according to the number of metabolic sindrome factors



Metabolic sindrome factors (#)

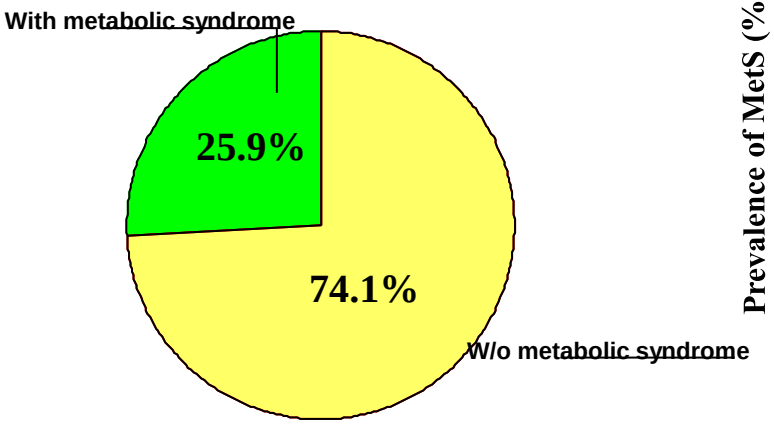
Corona et al., Int J Androl. 2009;32:587-98

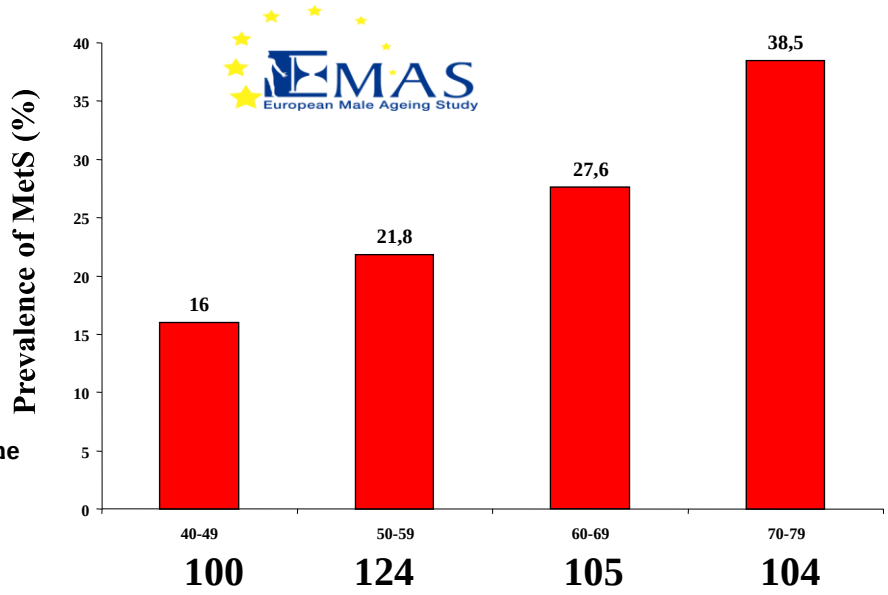
Androgen levels according to the number of metabolic sindrome factors



Corona et al., Int J Androl. 2009;32:587-98

Prevalence of metabolic syndrome (NCEP-ATPIII) in Florence general population, random series of 431 community-dwelling men (EMAS), studied at the University of Florence, Florence, Italy





Corona et al., 2010 J Sex Med 7:1362-80

Quanto aumenta avere la sindrome Metabolica il rischio di eventi Cardiovascolari maggiori (MACE)?

1. Il rischio non aumenta
2. Aumenta 10 volte
3. Aumenta 3 volte
4. Aumenta 2 volte
5. Diminuisce

Università degli Studi di Firenze

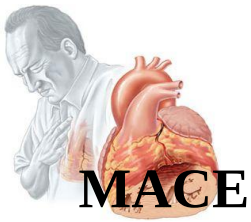
Observational prospective study (2000-2007) of ED subjects at the University of Florence - SIEDY©

1687 Male subjects with sexual dysfunction = a cohort at high CV risk!

Università degli Studi di Firenze

Observational prospective study (2000-2007) of ED subjects at the University of Florence

- **SIEDY©**
- **ANDROTEST©**
- **Physical examination, hormonal parameters, psychiatric symptoms (MHQ)**
- **Basal and dynamic penile color Doppler ultrasound**



MACE

Mean follow up 4.3±2.6 years

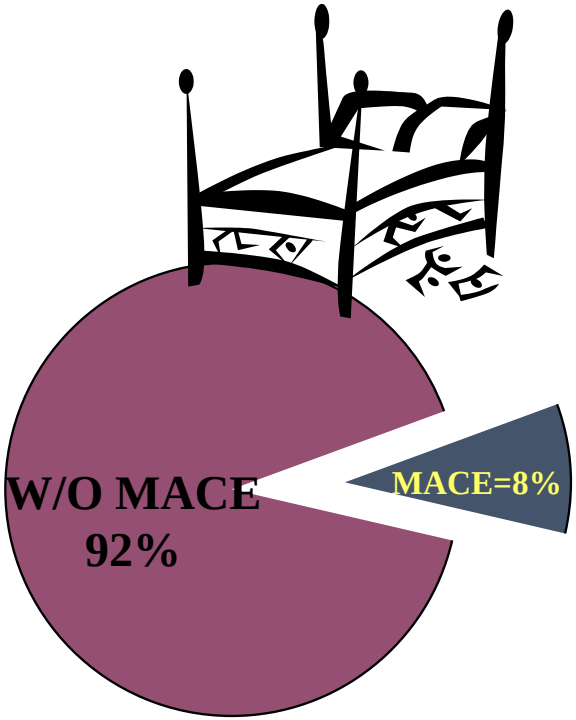
City of Florence Registry Office:
major adverse cardiac events (MACE)

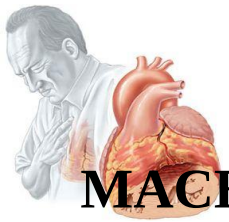
- ischemic heart disease (ICD 410-4)
- other heart diseases (ICD 420-9)
- sudden death for cardiac d. (ICD 798-799)
- cerebrovascular diseases (ICD 430-4, 436-8)
- peripheral arterial diseseas (ICD 440)

Università degli Studi di Firenze

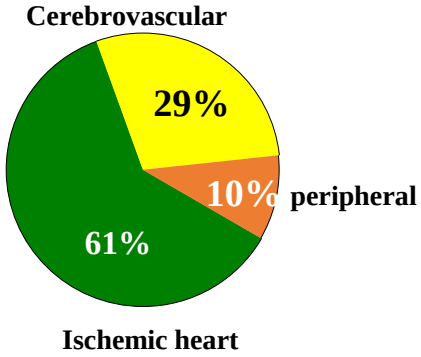
Observational prospective study (2000-2007) of ED subejcts at the University of Florence

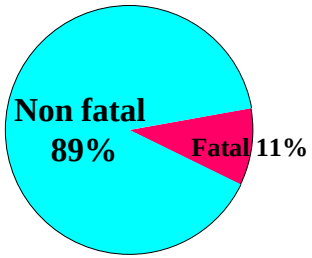
- **SIEDY©**
- **ANDROTEST©**
- **Physical examination, hormonal parameters, psychiatric symptoms (MHQ)**
- **Basal and dynamic penile color Doppler ultrasound**



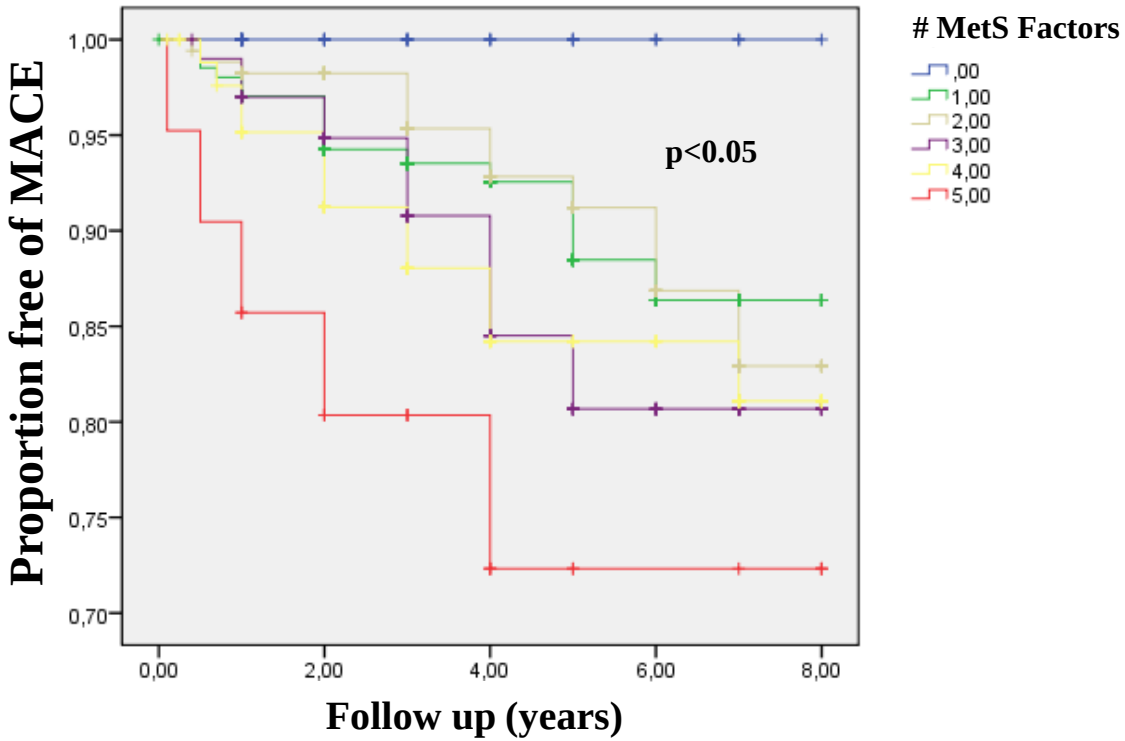


MACE



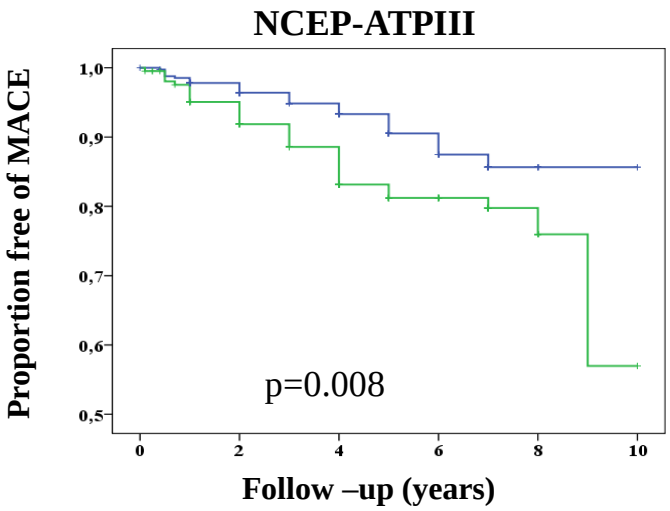


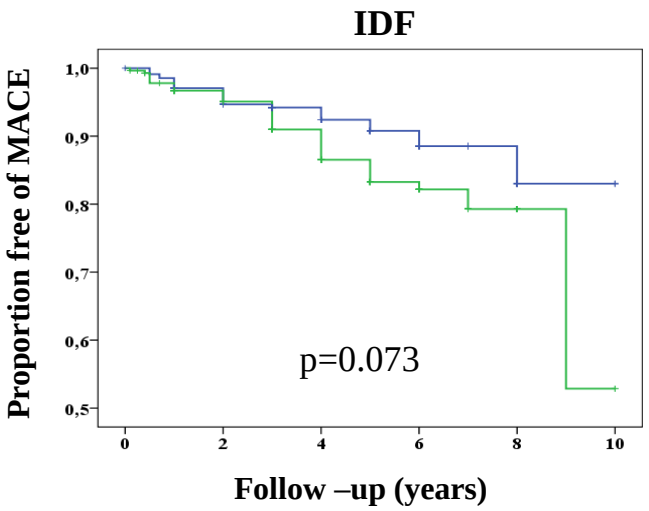
Proportion free of MACE (Kalplan-Meier curves) as a function of the presence of Metabolic syndrome (ATPIII) in a consecutive series of 1687 ED subjects at the University of Florence, Florence, Italy

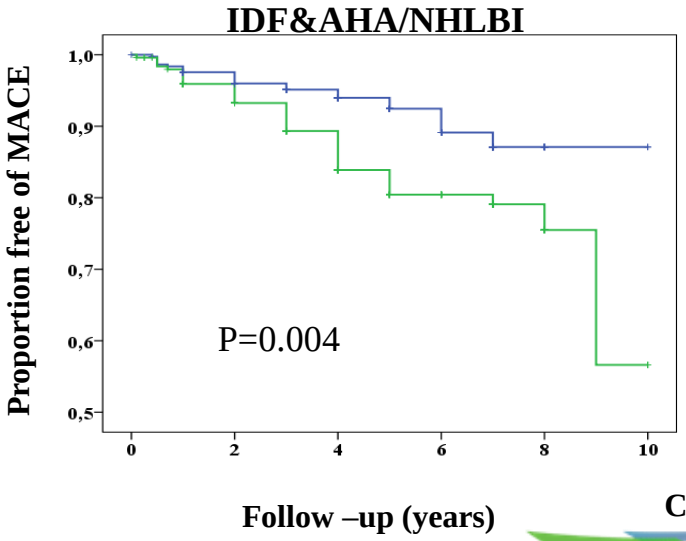


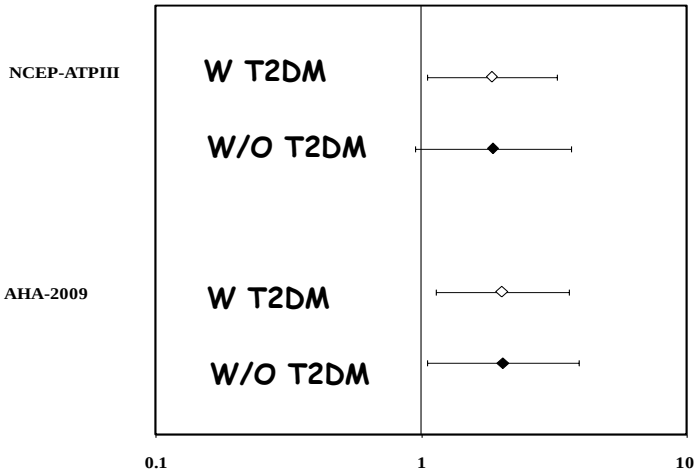
Corona et al.,
J. Sex. Med., 2011
Feb;8(2):504-11

MetS is associated with an increase risk of MACE
after adjusting for confounders (Cox regression HR= 1.8 [1.07-2.9])









Corona et al., J Endocrinol Invest 2011 Jul-Aug;34(7):557-67

AZIENDA OSPEDALIERA CAREGGI
S.O.D. di Andrologia
Centro di Riferimento Regionale per la DE
Direttore ff. Prof Mario Maggi

Servizio di Ecografia Andrologica

Firenze 25 settembre 2006

Ecografia peniena con ecocolor-doppler

Esame eseguito in condizioni basali e dopo stimolazione farmacologia intracavernosa con 10 mcg di PGE1

Arteria cavernosa destra
Velocità di picco sistolico basale…… ..15,7 cm/s
Accelerazione basale…….. 3,13 m/s^2
Velocità di picco sistolico massimo……..... 39,8 cm/s
Velocità diastolica minima…… 7,1 cm/s

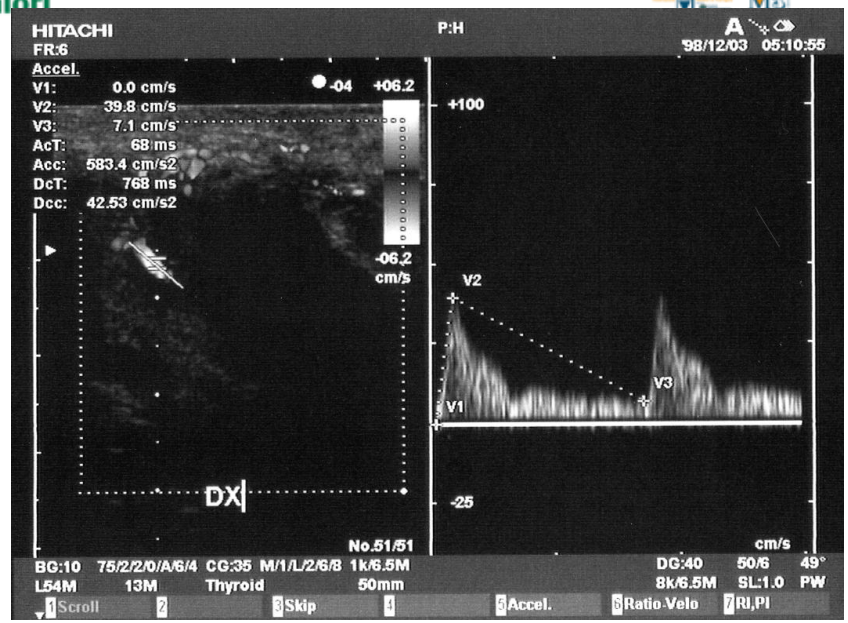
Arteria cavernosa sinistra
Velocità di picco sistolico basale…….... 27,0 cm/s
Accelerazione basale…….... 5,40 m/s^2
Velocità di picco sistolico massimo…….. 32,7 cm/s
Velocità diastolica minima…….. 7,7 cm/s

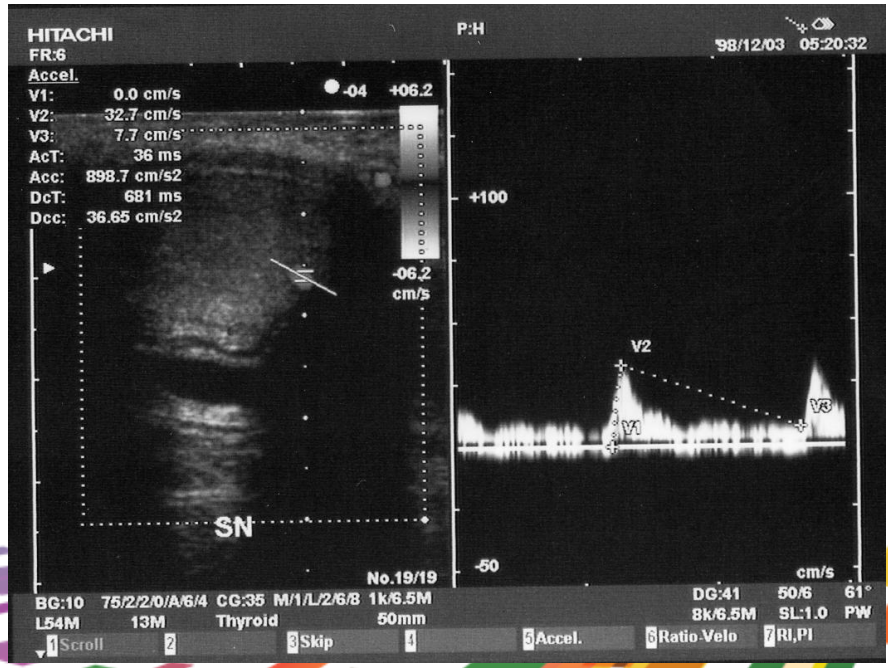
A carico dell'arteria cavernosa destra si rilevano valori velocimetrici normali sia in condizioni basali sia dopo stimolo farmacologico, anche se poco al di sopra dei limiti inferiori di normalità.
A carico dell'arteria cavernosa sinistra si rilevano valori velocimetrici normali in condizioni basali e al di sotto della norma dopo stimolo farmacologico.
Persistenza bilaterale di elevati valori di velocità diastolica.
Tali dati si accompagnano ad una progressione emodinamica dell'erezione che raggiunge una risposta obiettiva di grado 1-2.
Normale lo spessore della tunica albuginea e del setto intercavernoso lungo tutto il decorso dell'asta.

CONCLUSIONI: i dati velocimetrici orientano per la presenza di iniziali lesioni arteriopatiche nei distretti vascolari esaminati.

Dott. [illegible]

Prof. Mario Maggi



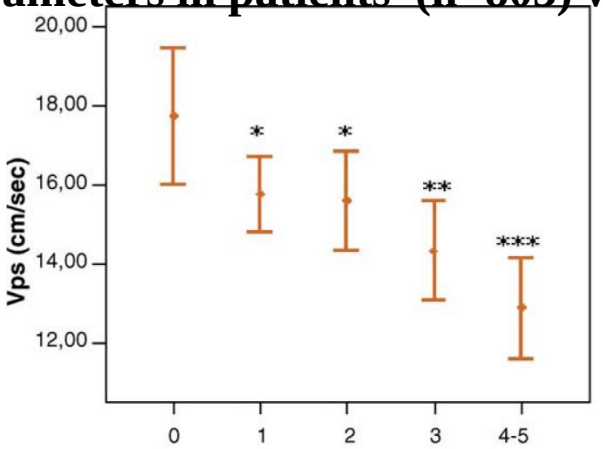


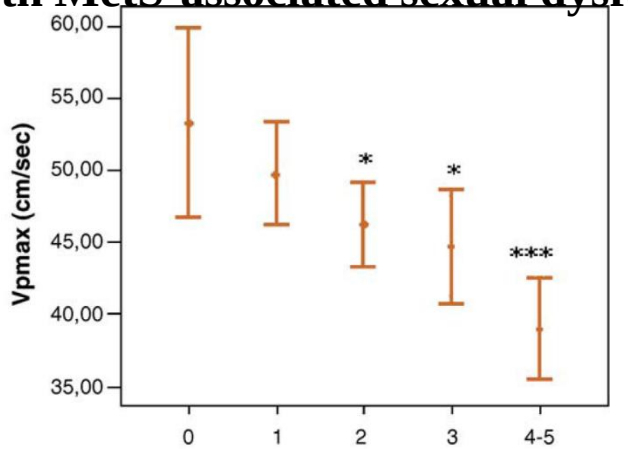
Antonio ha dei flussi vascolari penieni patologici

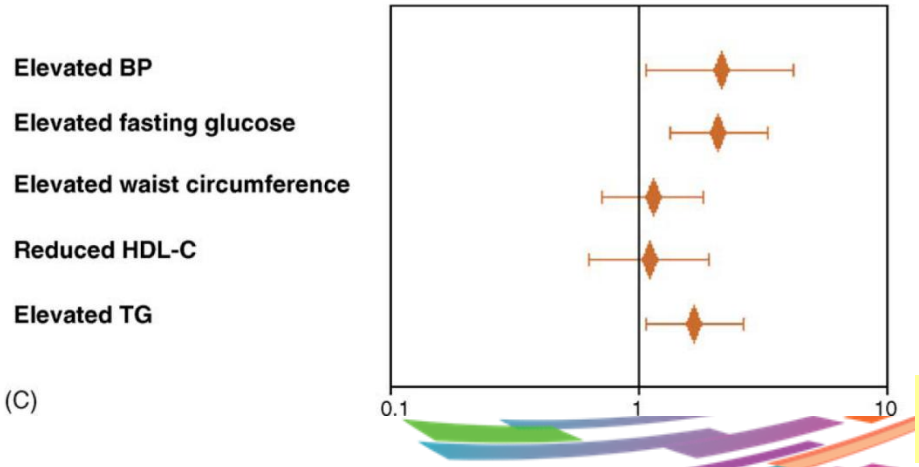
Perchè Antonio ha un flusso vascolare penieno ridotto?

1. Sindrome metabolica
2. Ipertensione
3. Dislipidemia e iperglicemia
4. Ipogonadismo
5. Tutte le precedenti

Effect of MetS (NCEP-ATP III) components on penile Doppler ultrasound parameters in patients (n=803) with MetS-associated sexual dysfunction.



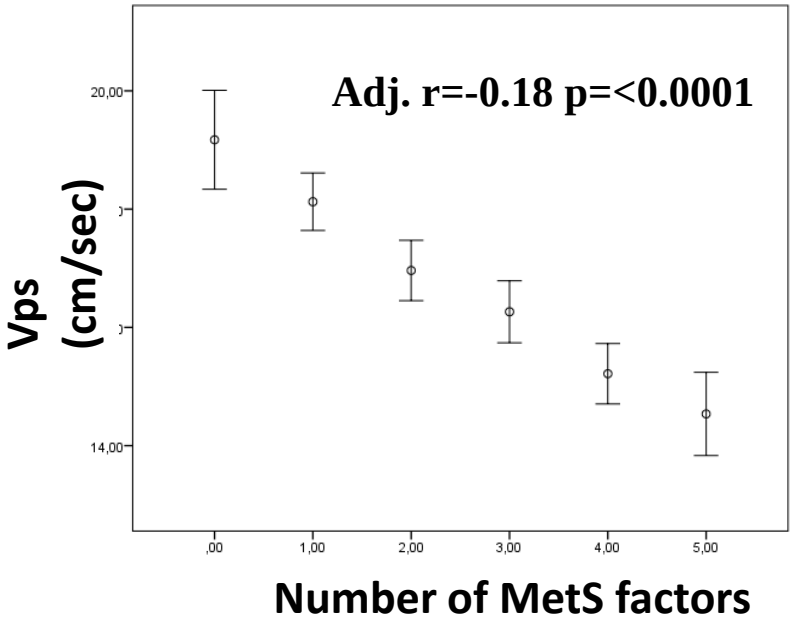


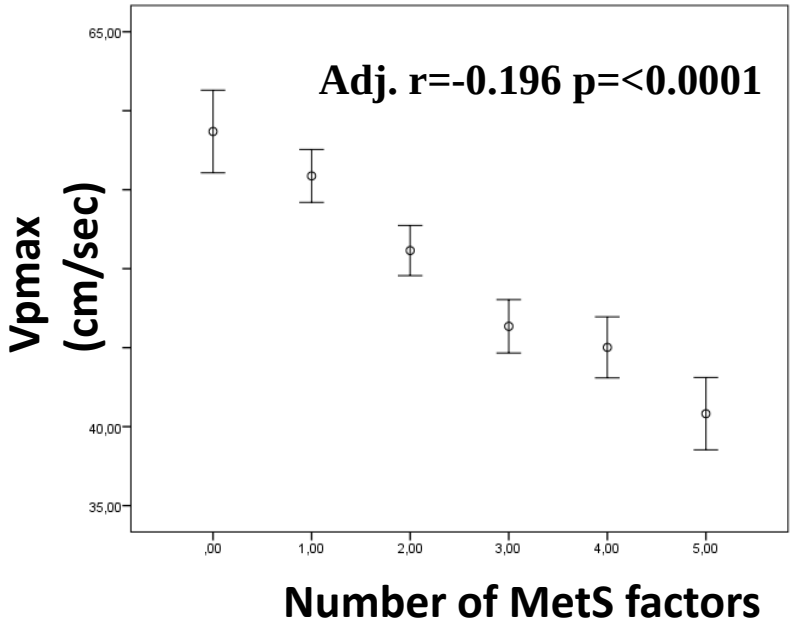


Odds ratio (95% CI) for pathologic Vpmax (<30 cm/s)

Corona et al., Eur Urol. 2006;50:595-604

Effect of MetS (NCEP-ATP III) components on penile Doppler ultrasound parameters in patients (n=2049) with MetS-associated sexual dysfunction.



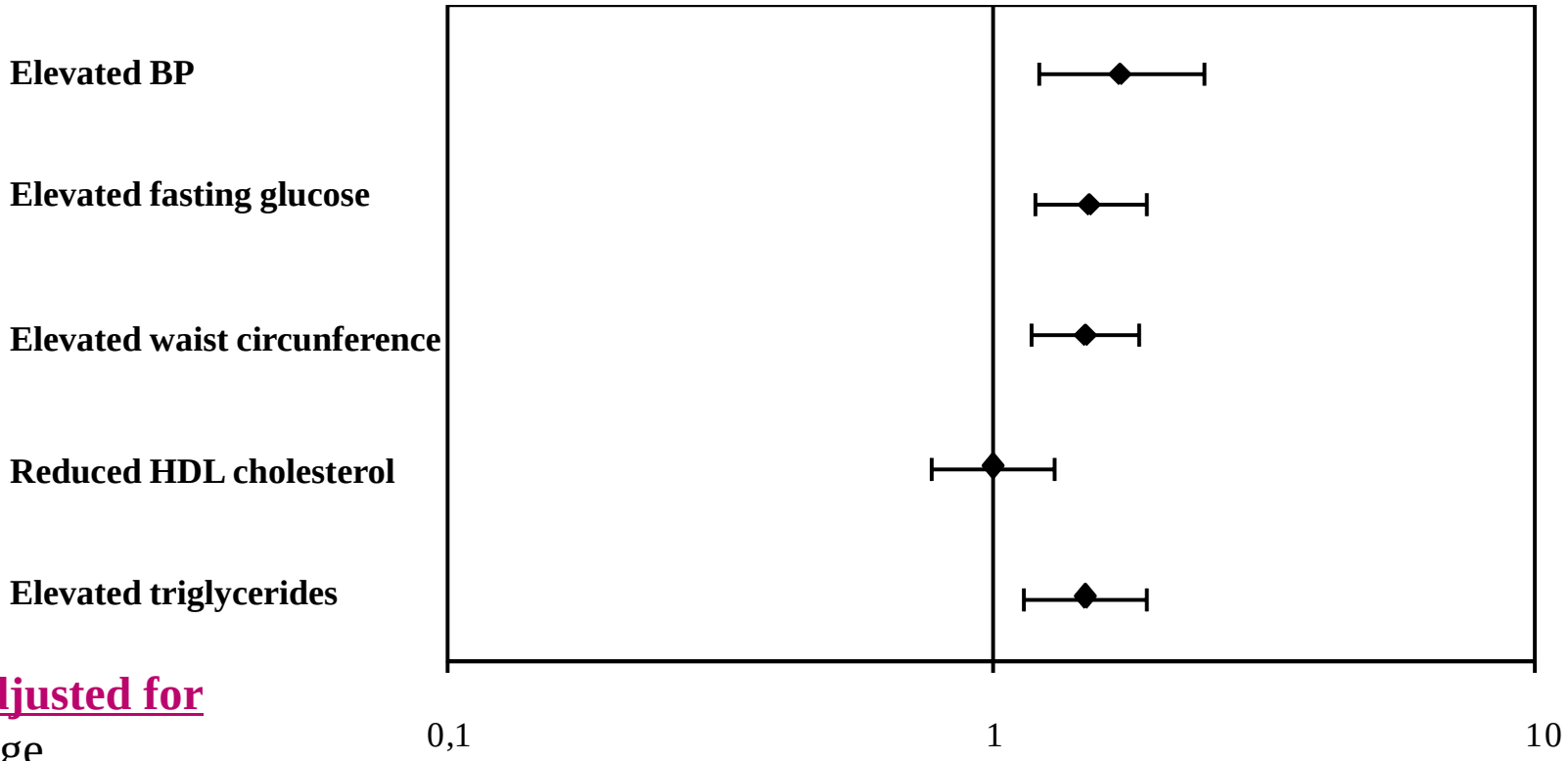


Adjusted for

- Age

Corona et al., unpublished 2016

Age-adjusted odds ratio for impaired flaccid PSV (< 13 cm/sec) according to MetS in patients (n=2049) with MetS-associated sexual dysfunction

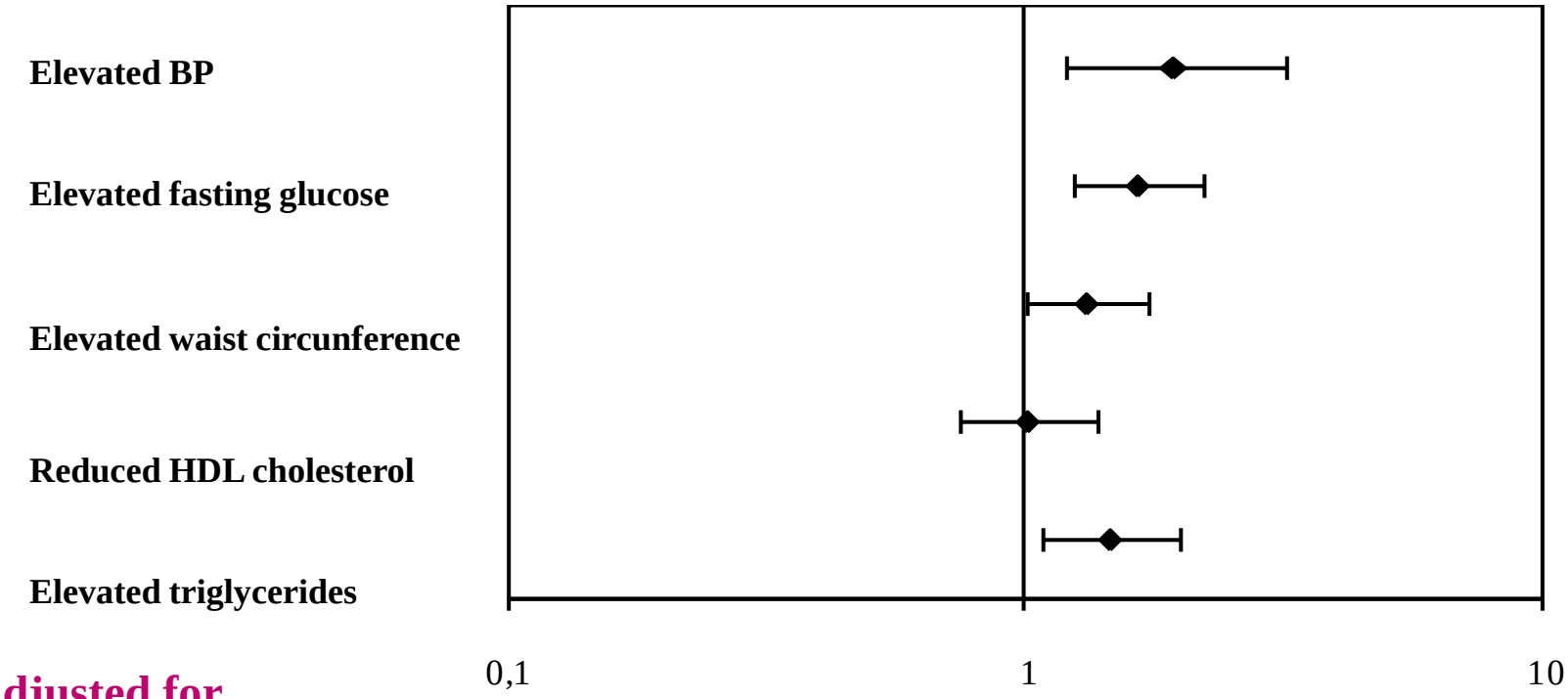


Adjusted for

- Age

Corona et al., unpublished 2016

Age-adjusted odds ratio for impaired dynamic PSV (< 30 cm/sec) according to MetS in patients (n=2049) with MetS-associated sexual dysfunction

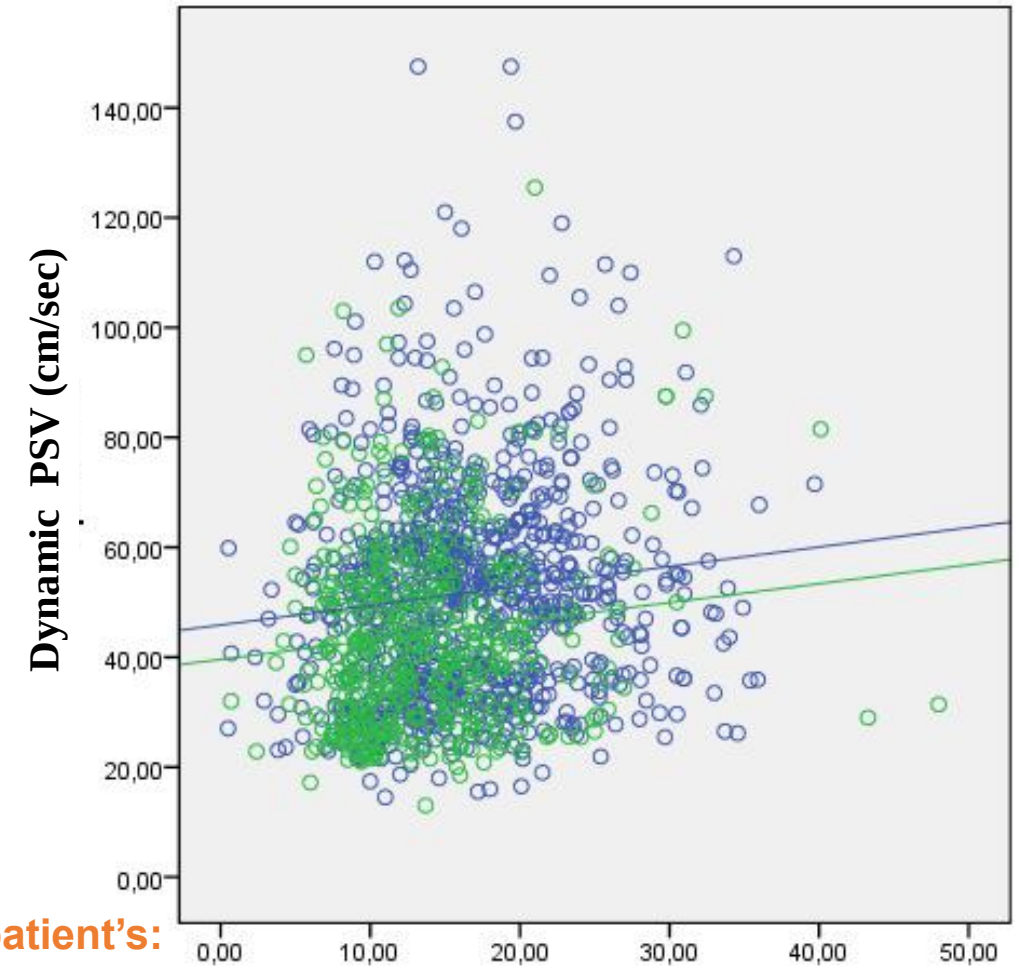


Adjusted for

- Age

Corona et al., unpublished 2016

Relationship between penile blood flow (PCDU)and testosterone in patients with and without metabolic sindrome (n=1994)



w/o MetS adj r.=0.064, p<0.05

with MetS adj r.=0.128, p<0.005

Adjusted for patient's:
- age
- smoking habit

Quale terapia per l'ipogonadismo di Antonio?

1. GnRH
2. Antiestrogeni
3. Gonadotropine
4. Testosterone
5. Testosterone e stile di vita

Review

Emerging medication for the treatment of male hypogonadism

Expert Opin. Emerging Drugs (2012) 17(2):239-259

Giovanni Corona, Giulia Rastrelli, Linda Vignozzi & Mario Maggi†
†Sexual Medicine and Andrology Unit, Department of Clinical Physiopathology, Florence, Italy

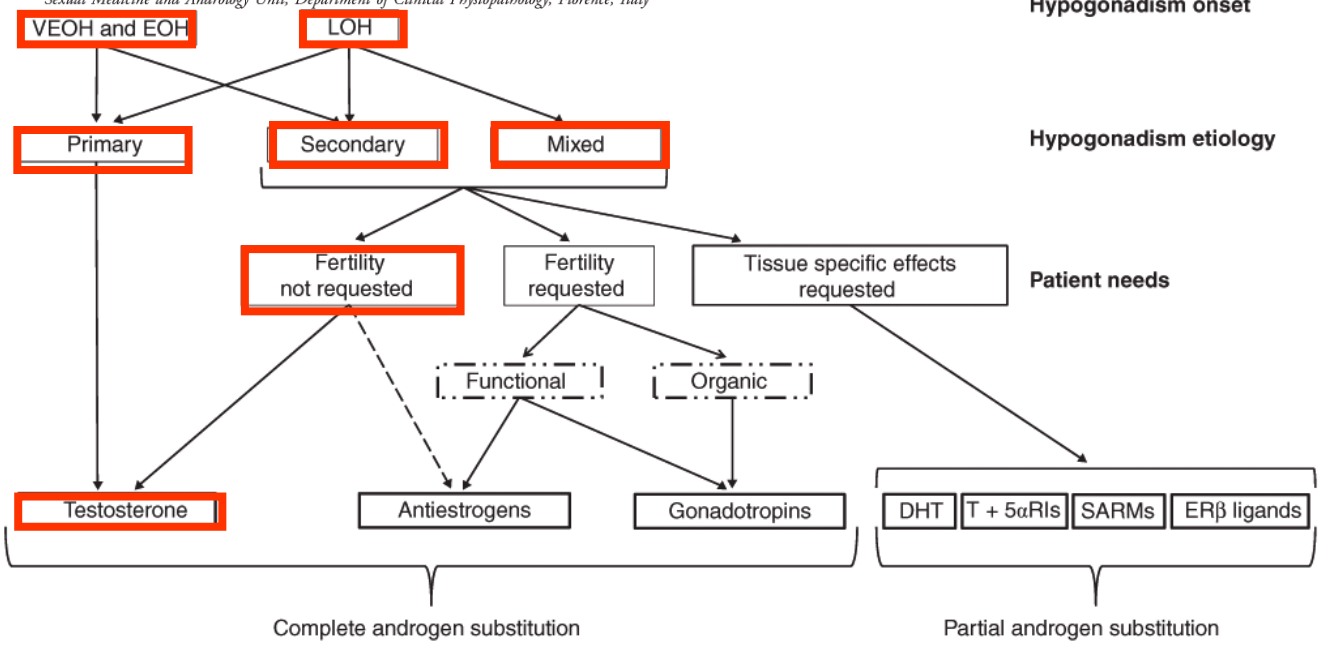


Figure 3. Suggested approach to male hypogonadism according to the age onset and etiology of the problem and patient needs.

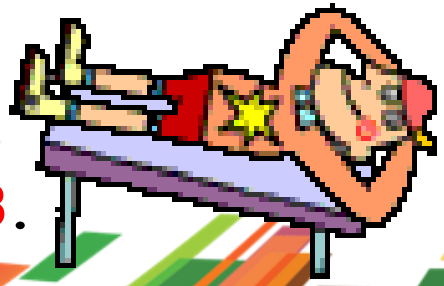
Corona et al., Expert Opin Emerg Drugs. 2012 Jun;17(2):239-59

Terapia proposta:

- Gel di testosterone 50 mg 1+1/2
- Dieta ipocalorica
- Attività fisica (palestra)
- Valsartan 160 mg
- PDE5inibitore

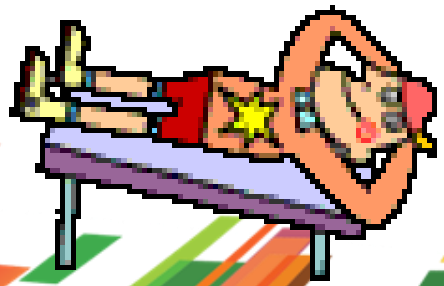
Tornano dopo 2 mesi (17/2/07)…

- ha fatto palestra e dieta: –2.5 Kg e –3cm waist
- sta prendendo Valpression 160 mg + gel di T 1 + ½ bustina
- OGTT basale 121 mg/dL e 120' 185 mg/dL
- HbA1c=6.5%
- cFT=274 pM (>225)
- PSA= 0.62, Hct=44.8
- ha fatto terapia con meno difficoltà a penetrare, (anche senza PDE5i)
- sereni rapporti con la moglie
- PA= 140/80
- consiglio stessa terapia + metformina 500 x 3.



Tornano dopo 4 mesi (21/4/07)…

- ha fatto palestra e dieta: –5 Kg e –5cm waist
- sta prendendo Valpression 160 mg + gel di T 1 + ½ bustina + metformina 500 x 3.
- glicemia= 105 mg/dL, col T= 179 mg/dL, HDL=41, TG=102 mg/dL
- TT= 3 ng/mL (2-10)
- PSA= 0.65, Hct=43.2
- HbA1c=6.1%
- riesce ad avere rapporti anche senza PDE5i
- PA= 120/80
- consiglio stessa terapia
- riferisce aumento del numero dei rapporti

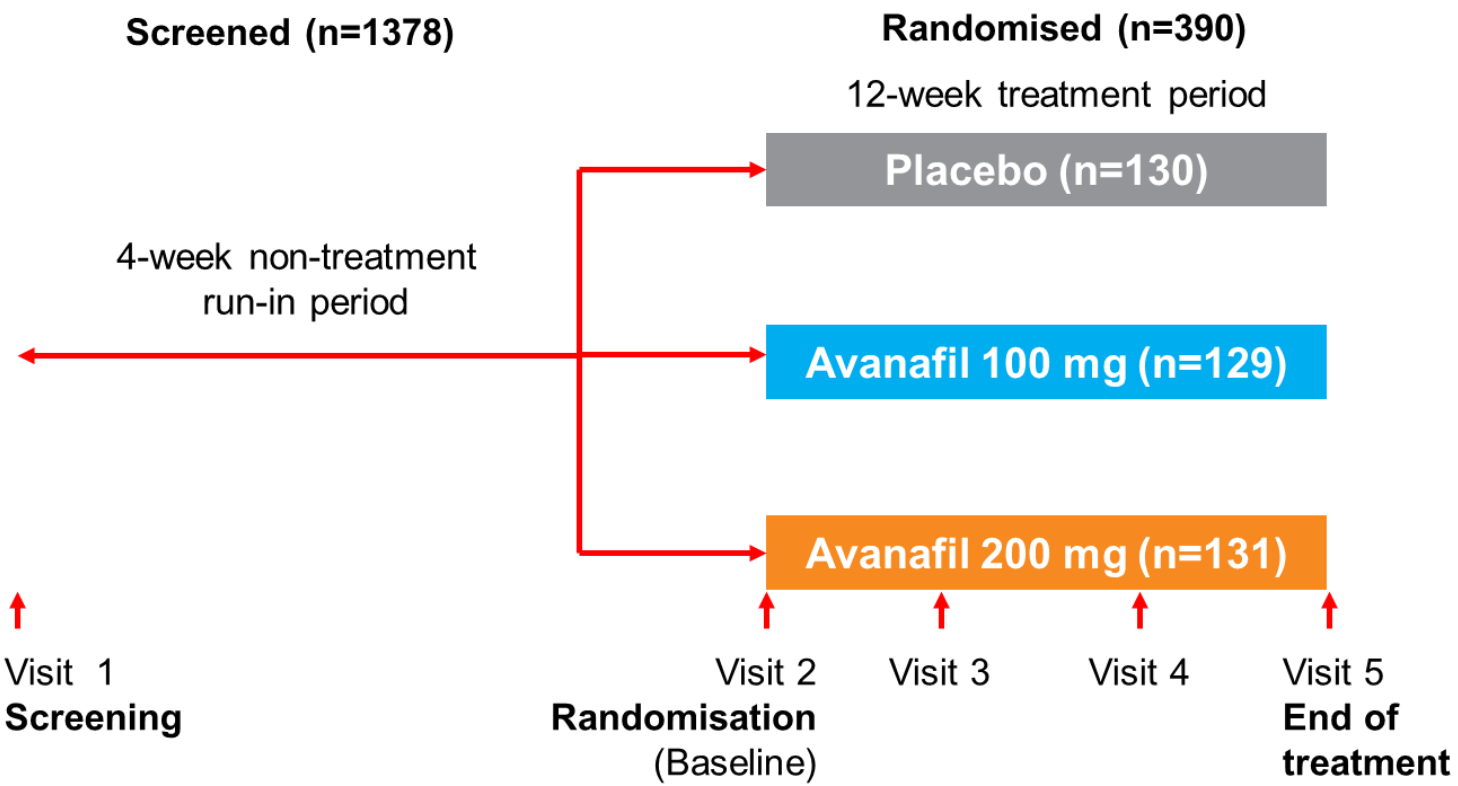


Passano gli anni ma otto son lunghi
E il maresciallo ne ha fatta di strada
(07/11/15)…

E' in pensione dal 2011, fa volontariato e coltiva orto

- sta prendendo Valsartan 160 mg + idroclorotiazide 25 mg
- testosterone undecanoato 1000 mg ogni tre mesi + metformina 850 x 3.
- glicemia= 125 mg/dL, col T= 181 mg/dL, HDL=46, TG=112 mg/dL
- TT= 14.87 nmol/L (10-30), HbA1c=45 mmol/mole
- PSA= 0.76, Hct=45.2, creatinina=
- 0.83 mg/dL
- rapporti anche senza PDE5i ma spesso usa avanafil 200 mg
- PA= 135/90
- continua così…

REVIVE-Diabetes/TA-302: Study design



Randomisation criteria:

- ≥50% failure rate in maintaining erections of sufficient duration to allow for successful intercourse
- IIEF-EF domain score of 5–25
- Documentation of ≥4 attempts at sexual intercourse during run-in

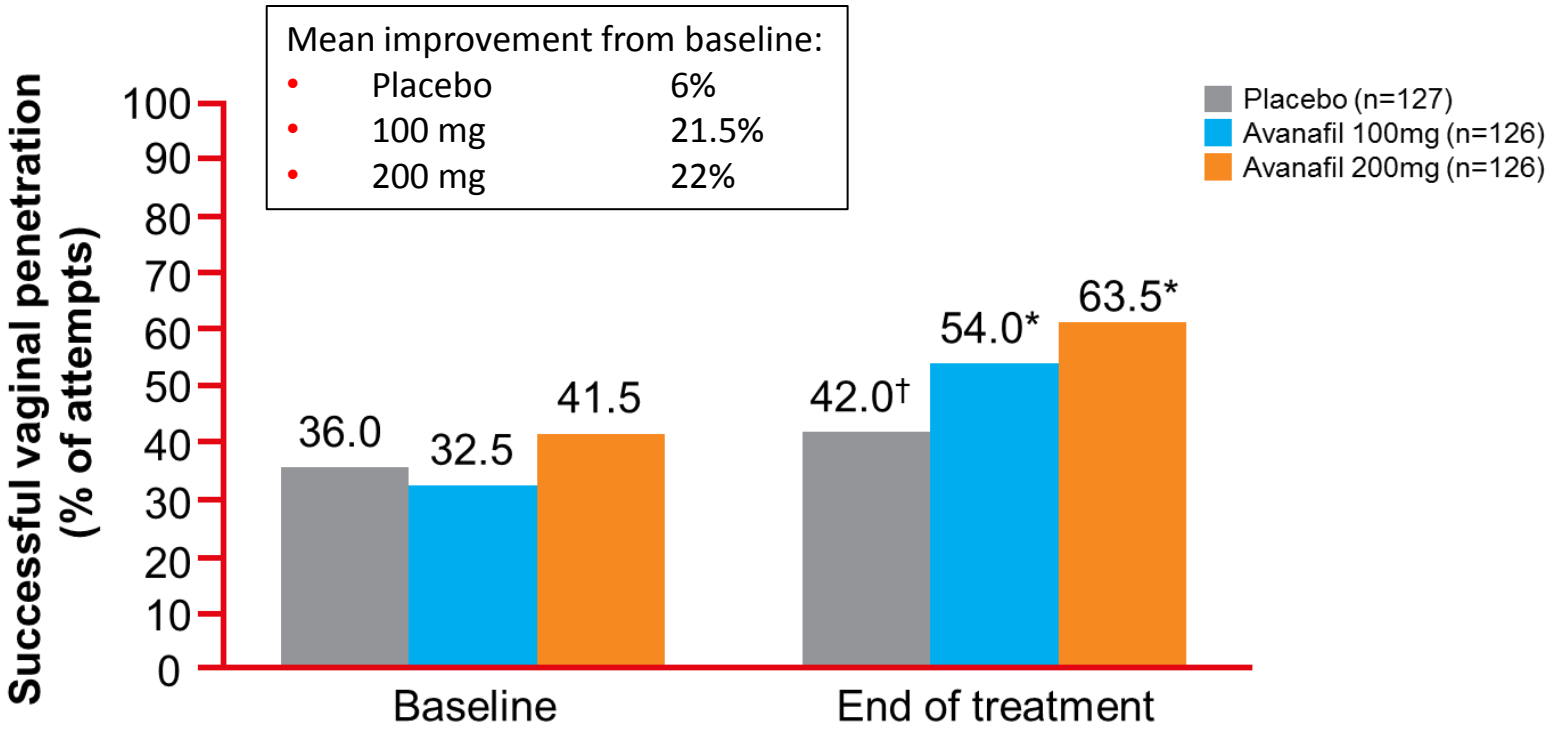
Goldstein et al. Mayo Clin Proc. 2012;87:843-5

REVIVE-Diabetes/TA-302: Baseline demographics and disease characteristics

Characteristic	Placebo (n=130)	Avanafil 100 mg (n=129)	Avanafil 200 mg (n=131)
Mean age (years)	58.2	58.2	57.5
Race, n (%) Black White	 24(18.5) 103 (79.2)	 16 (12.4) 111 (86.0)	 27 (20.6) 100 (76.3)
Mean weight, kg	100.0	98.6	99.6
ED severity, n (%) Mild Moderate Severe	 29 (22.3) 40 (30.8) 61 (46.9)	 28 (21.7) 40 (31.0) 61 (47.3)	 28 (21.4) 42 (32.1) 61 (46.6)
Mean duration of ED, months	78.7	73.8	64.6
Type of diabetes, n (%) Type 1 Type 2	 14 (10.8) 116 (89.2)	 15 (11.6) 114 (88.4)	 12 (9.2) 119 (90.8)
Mean duration of diabetes, years	11.1	11.2	11.6

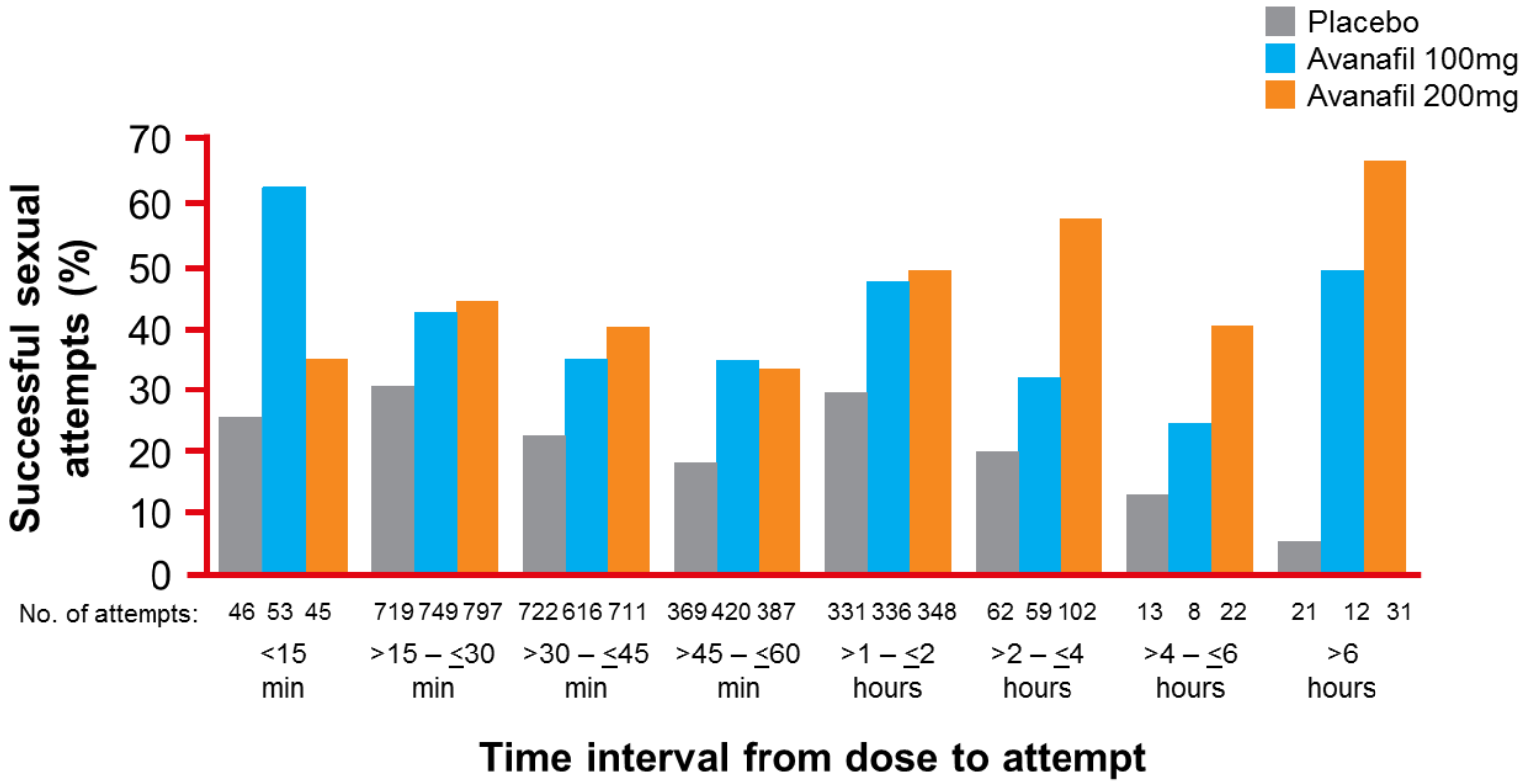
Goldstein et al. Mayo Clin Proc. 2012;87:843-5

REVIVE-Diabetes/TA-302: SEP 2 (co-primary endpoint)



*p<0.001 vs baseline; †p=0.009 vs baseline

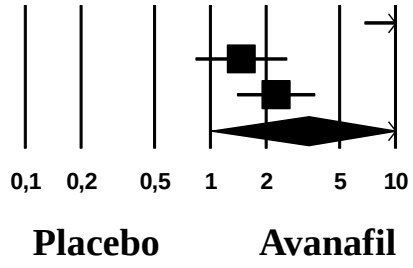
REVIVE-Diabetes/TA-302: Successful intercourse (SEP 3) by 15-minute time interval post-dose to attempt



Goldstein et al. Mayo Clin Proc. 2012;87:843-5

Successful intercourse < 15 min (SEP 3; 200 mg vs placebo)

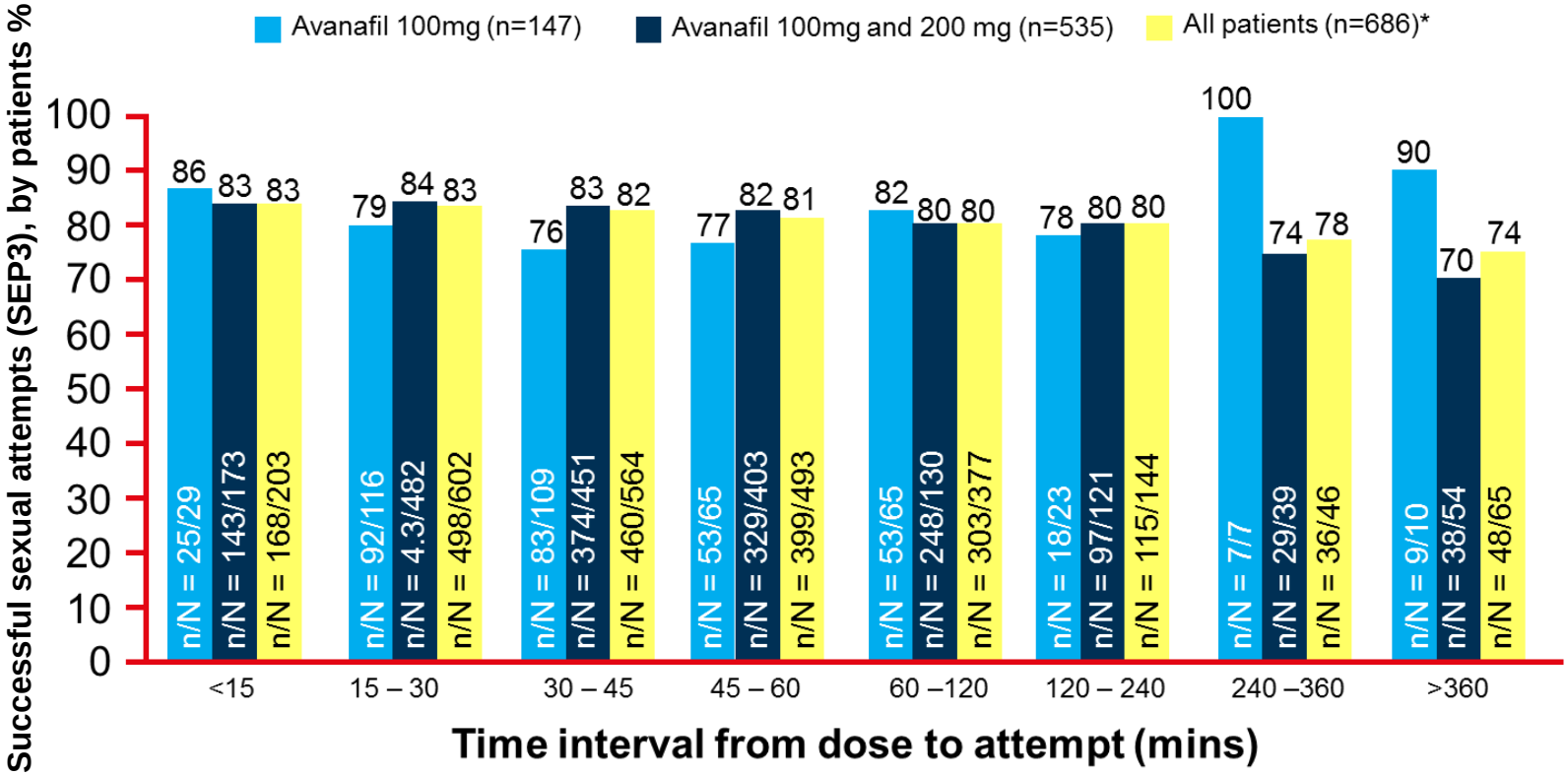
Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Goldstein et al., 2012JSM	11,69	6,81	20,08	8,92	0,00
Goldstein et al., Mayo	1,47	0,83	2,59	1,33	0,18
Hellstrom et al., 2015	2,26	1,40	3,67	3,31	0,00
Overall	3,39	1,01	11,33	1,98	0,05



Meta Analysis

Corona et al., Expert Opin Drug Saf. 2016;15:237

Long-term, open-label extension study (TA-314): Successful intercourse by time interval from dose to attempt (SEP 3)



*Includes three patients who took both 100 mg and 50 mg and one patient who took all three doses
N=patients making sexual attempts; n=patients with ≥1 successful sexual attempt

Belkoff et al. Int J Clin Pract 2013;67:333