



6. AF Zirvesi *Bahar Toplantısı*
7 - 8 Nisan 2017 / Cornelia Hotel, Antalya

AF ABLASYONUNDA «SHAM» ÇALIŞMALARININ ZAMANINI GELDI..

Dr Özcan Özeke
Türkiye Yüksek İhtisas Hastanesi

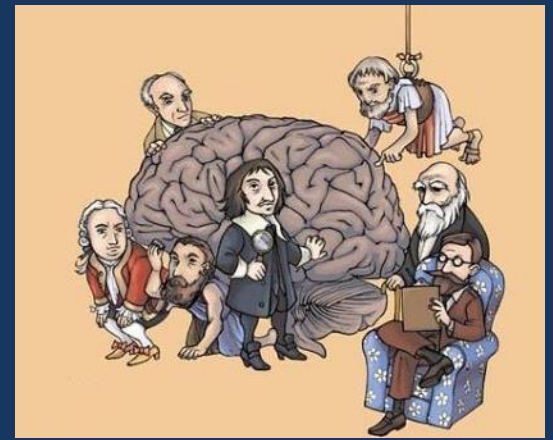
65 YAŞINDA ERKEK HASTA

ILACA DİRENÇLİ SEMPTOMATİK PAF ATAKLARI

ABLASYON SONRASI KONTROLDE

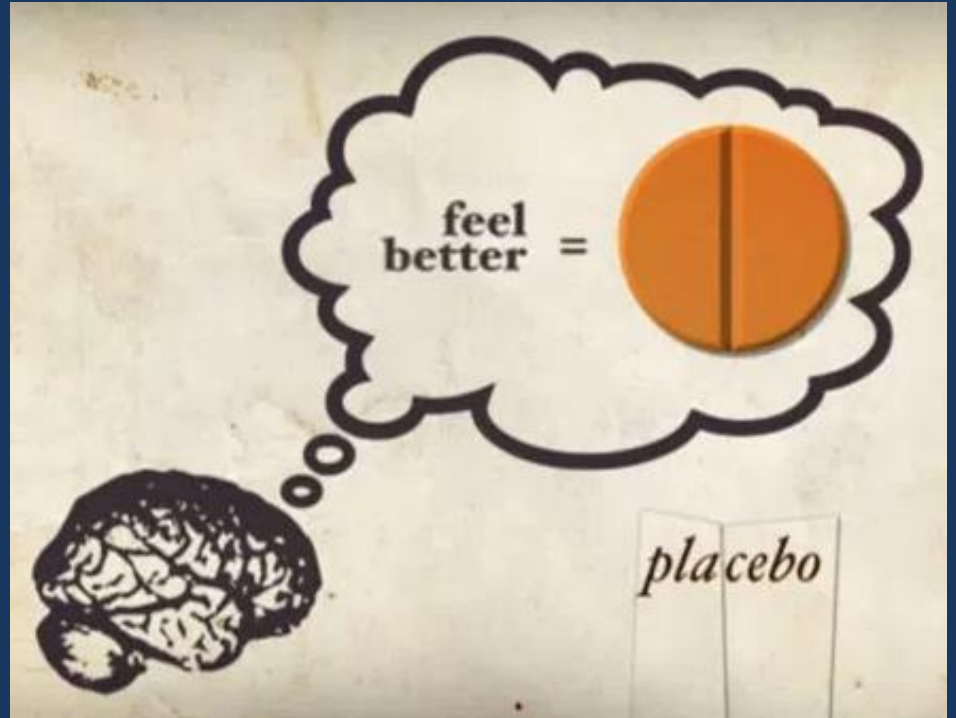


BİLİM FELSEFESİ



- **Modern bilim** iki bileşenin bileşiminden ortaya çıkmış bir etkinliktir
- bir yanıyla **empirik/eylemsel** (gözlem, deney..)
- Diğer yanıyla **zihinsel** (kavram, hipotez, akılyürütme) etkinlik

**AF ABLASYONUNDA «SHAM»
ÇALIŞMALARININ ZAMANI GELDI..**





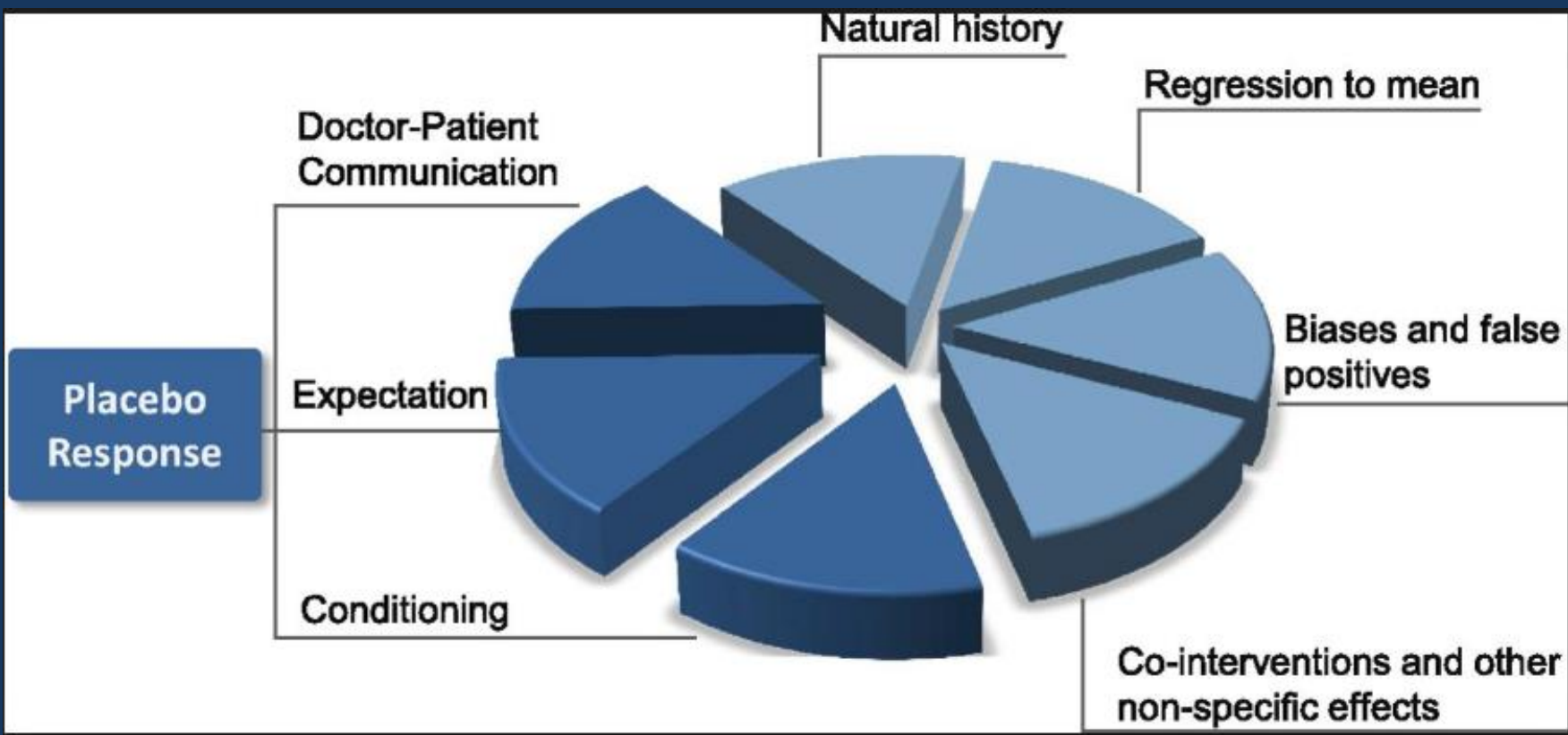
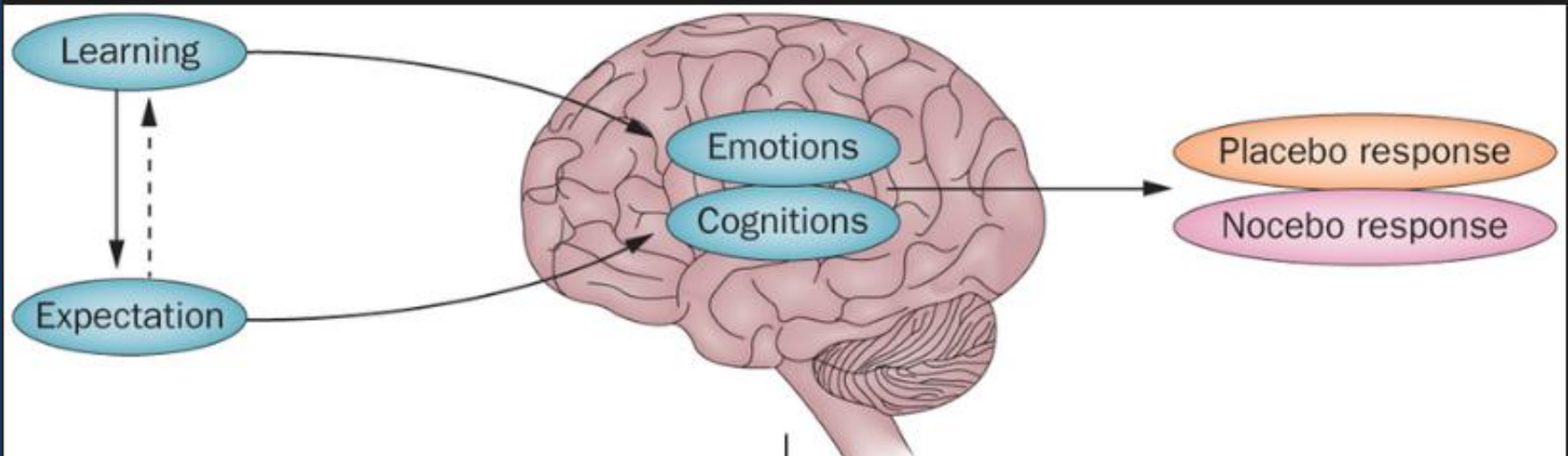
Nocebo:

**A harmless thing
that causes harm
because you believe it's harmful.**

"You have one month to live," or "There is no cure for cancer." E

Sham vs placebo ?





Expectation

„You may experience a temporary **increase** in symptoms“

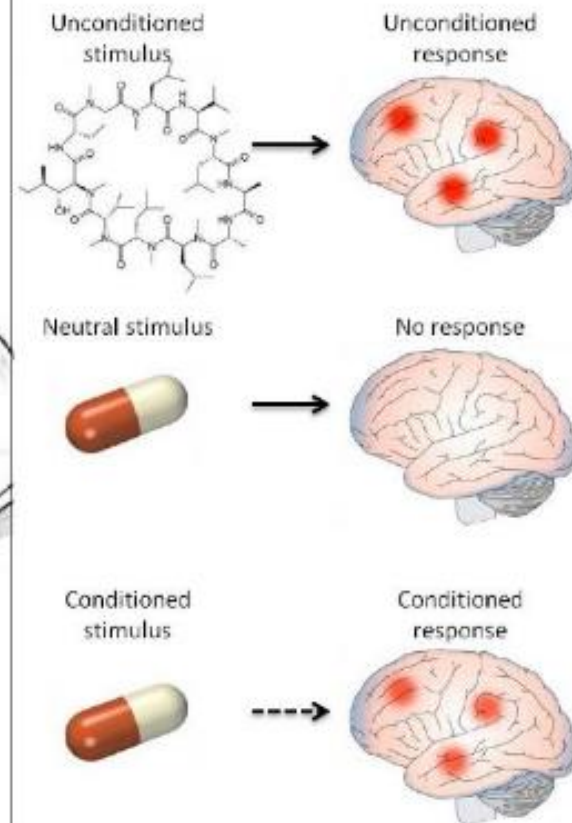
„ You may experience a temporary **decrease** in symptoms“



Doctor-Patient Communication



Conditioning



**AF ABLASYONUNDA «SHAM»
ÇALIŞMALARININ ZAMANI GELDI..**

The Age of Paternalism

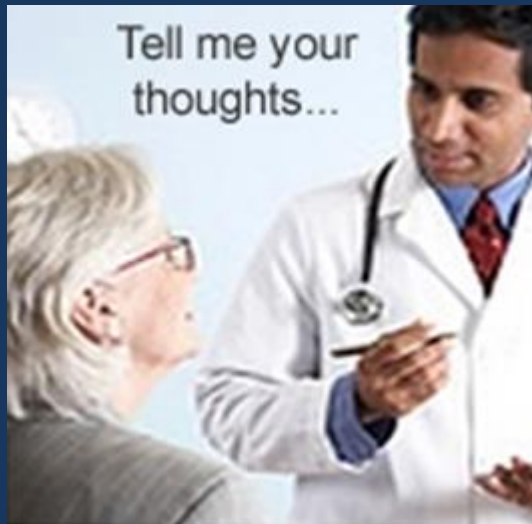


"If I've told you once I
told you 1,000 times,
stop smoking!!"

I'm a
DOCTOR
what's your
SUPERPOWER?

I'm a
SURGEON
What's your
SUPERPOWER?

The Age of Autonomy

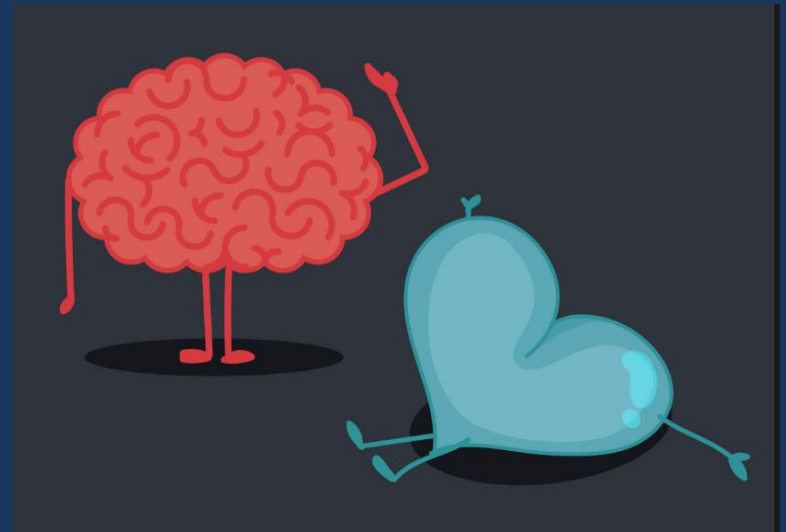


**Patients'
Rights**





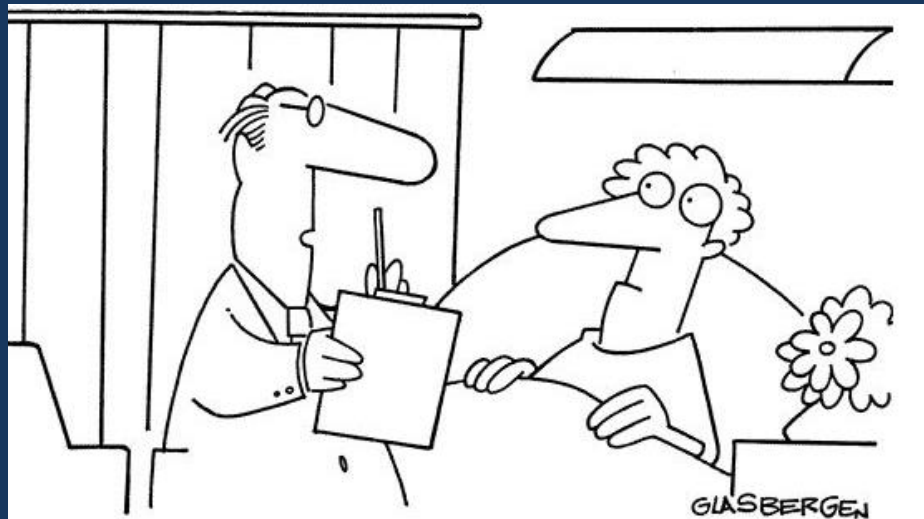
**DON'T WORRY
I'M A DOCTOR**



Dear Doctor,
YOUR WORDS
ARE POWERFUL

**AF ABLASYONUNDA «SHAM»
ÇALIŞMALARININ NIYE ZAMANı GELDI..**

The Age of Bureaucracy



**"Your insurance only pays 80% of my fee,
so I only took out 80% of your appendix."**





Why Doctors Are Losing the Public's Trust





Why Doctors Are Losing the Public's Trust

“Just as in a patient-doctor relationship, trust is the most important element of meaningful interactions.”

Therese Lockemy



Edited by
DAVID A. SHORE

Founding Director, Trust Initiative
Harvard School of Public Health

THE
TRUST
CRISIS
IN HEALTHCARE

Causes, Consequences, and Cures

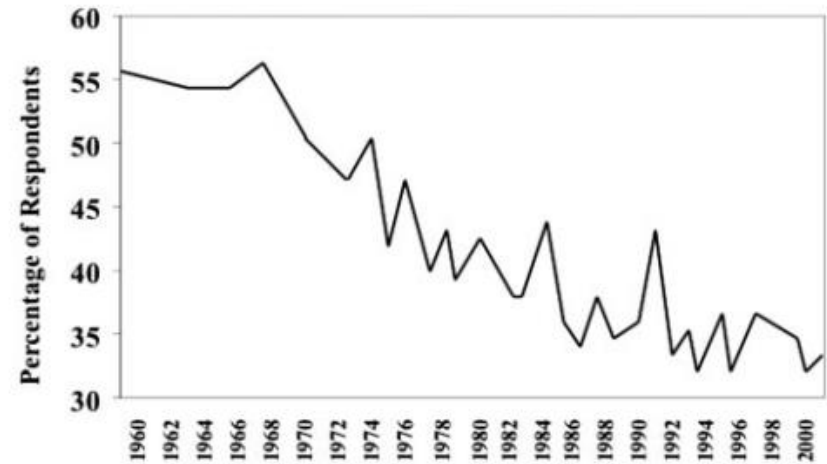
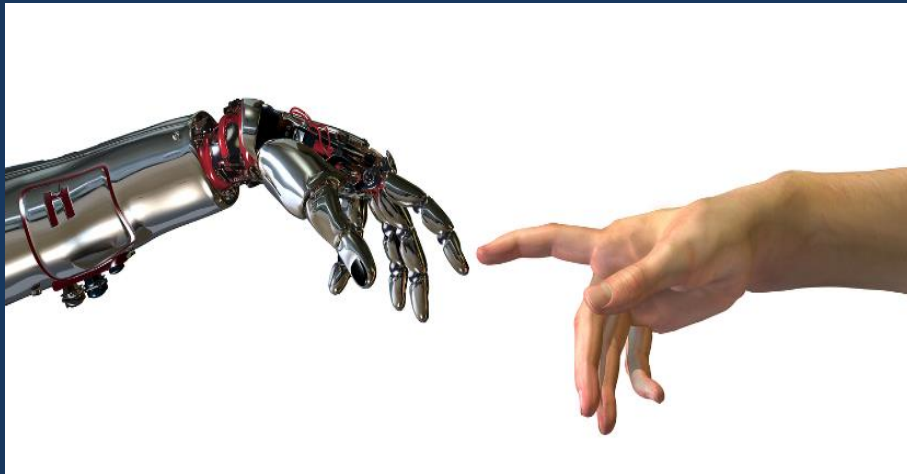
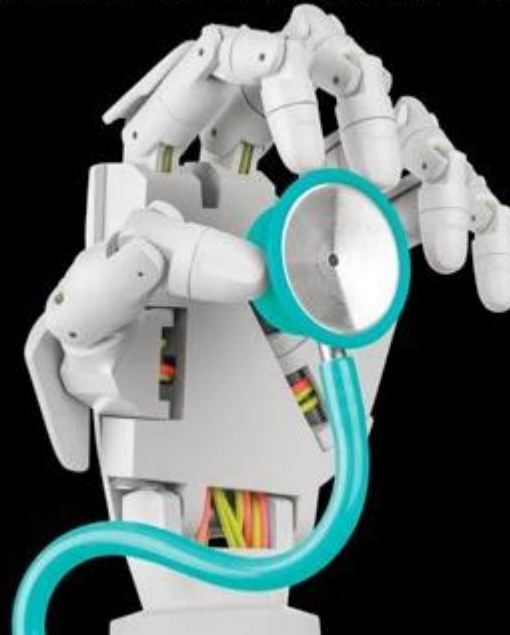


Figure 1. Decline in interpersonal trust. Percentage of respondents agreeing "most people can be trusted." Adapted with permission from Purdy.¹²

[Circulation](#), 2005 Jun 28;111(25):3494-8.

The Robot Will See You Now



Michel de Lorgeril, M.D.

CHOLESTEROL AND STATINS

SHAM SCIENCE AND BAD MEDICINE



- How pharma-funded research was deliberately biased
- Why statins save no lives but can make you ill



DR. OZ ON THE OFFENSE
SAYS HE WON'T BE SILENCED, NOT GOING ANYWHERE



Adding a Lawyer to the Health Care Team:

Guide to Winning Your Malpractice Lawsuit



"The cost of malpractice claims is considerable, both monetarily and in terms of impact on the healthcare system," says Brian K. Atchinson, President of the Physician Insurers Association of America (PIAA). "Wary of possible lawsuits, many physicians have closed their practices, stopped performing high-risk procedures, or reduced their care of high-risk patients, leading to a situation in which some areas of the country have limited – or even no – access to medical specialists."



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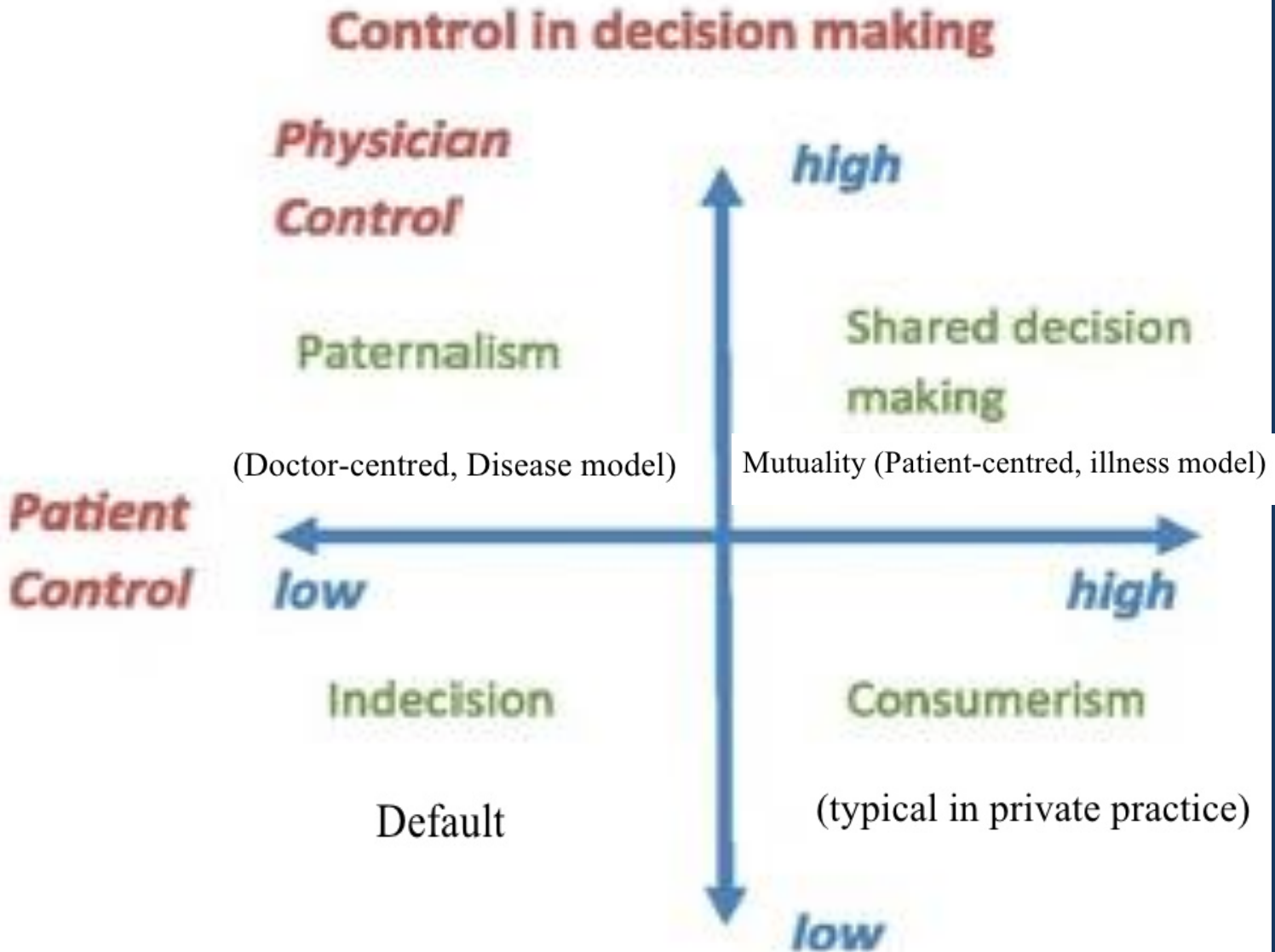


MAKE MONEY AS A CONSULTANT AND SPEAKER IN HEALTHCARE

**A Step by Step System to Build, Market and Grow
a Profitable Consulting and Speaking Business**

DENNIS C. MAHONEY, MPH, CSP

Types of doctor-patient relationships



Hospitals Test Paying Doctors for Performance, But Get Mixed Results

It seems like a good idea to pay physicians better when their patients do better, but that may not be the case.

By [Lacie Glover](#), Contributor | Aug. 13, 2015, at 11:29 a.m.



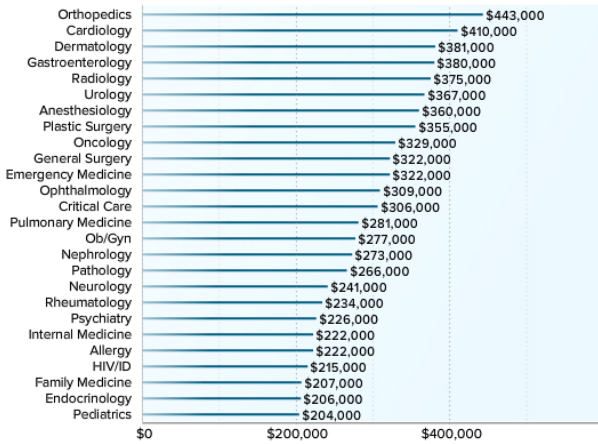
Medscape Physician Compensation Report 2016

Carol Peckham | April 1, 2016

[Contributor Information](#) | [References](#)

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< 2 of 35 >

How Much Do Physicians Earn Overall?



Performansa Dayalı Ödeme: Sağlık Bakanlığı Uygulaması

Tablo 8: Bazı Unvanlara Yapılan Aylık Ödeme Ortalaması

Serbest Çalışmayan Uzman Tabip	Aylık Ödeme Ortalaması
Ortopedist	4.657 TL
KBB Uzmanı	4.614 TL
Göz Hastalıkları Uzmanı	4.554 TL
Radyoloji Uzmanı	4.548 TL
Kardiyoloji Uzmanı	4.411 TL
Çocuk Cerrahisi	4.036 TL
Üroloji Uzmanı	3.944 TL
Kadın Doğum Uzmanı	3.806 TL
Enfeksiyon Hastalıkları Uzmanı	3.666 TL
Tüm Tabiplerin Ortalaması	4.080 TL

JAMA. 2000 Jul 26;284(4):483-5.

Is US health really the best in the world?

Starfield B¹.

suggests there are 12 000 deaths per year from unnecessary surgery, 7000 deaths per year from medication errors in hospitals, 106 000 deaths per year from nonerror adverse effects of medication. Numbers like these reinforce the perception that medical care is suboptimal.¹¹

AMELİYAT SAYISI ARTTI

2007 yılında başlanan performansa dayalı ek ödeme sistemi ile birlikte doktor başına düşen ayakta tedavi sayısında yüzde 71,51; yatan hasta sayısında da yüzde 38,63 artış oldu. Cerrahi hekimbaşına düşen ameliyat sayısı yüzde 8,85 arttı. Hasta başına ortalama 0,13 olan damar yolu açılışı, yeni sistemde 2,14'e tırmandı.



The Physician - Pharma Relationship

The unethical gift-giving of drug companies

Md Shamsul Arefin

Profit and ethics are both important for the sustainability of a business. But if we take the case of pharmaceutical companies as our point of debate, which we consider a noble business, it has been observed in some cases that a few of these companies take undue advantage of doctors prescribing and promoting drugs which have no brand and time tested reputation. Here, we see profits being prioritised over ethics.

The basic role of a medical representative is to apprise the doctor about his or her company's new drugs. There is nothing wrong in that as long as the ultimate beneficiary of this information is the patient. Unfortunately, there is often a conflict of interest between the patient and the doctor as far as the drug promotion of a less reputed company is concerned.



23
Shares

TOP NEWS

- First 2 s
- Rajon K
April 11
- Govt to
- SC upho
- Police c
terroris
- Hindu c

Physicians Receive Payments From Industry



84%

of U.S. physicians
report receiving
**payments, gifts,
meals, drug samples,
or travel** from industry

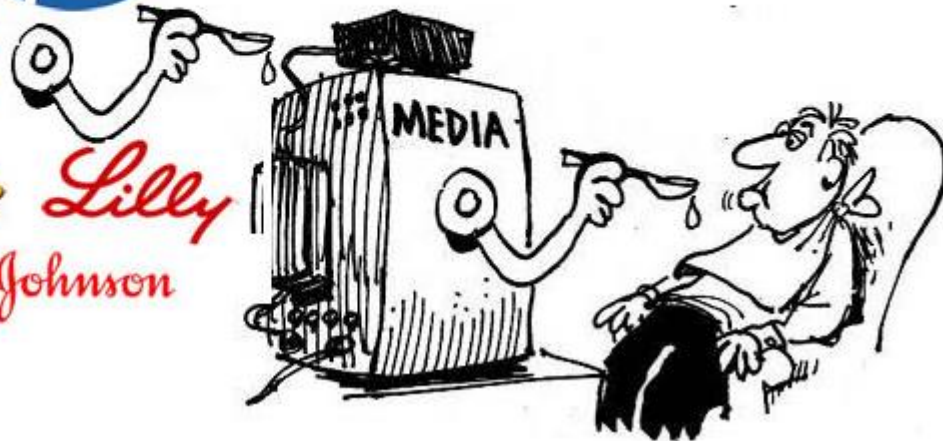


More than \$27 billion
was spent on marketing to
physicians by the pharmaceutical
industry in 2012

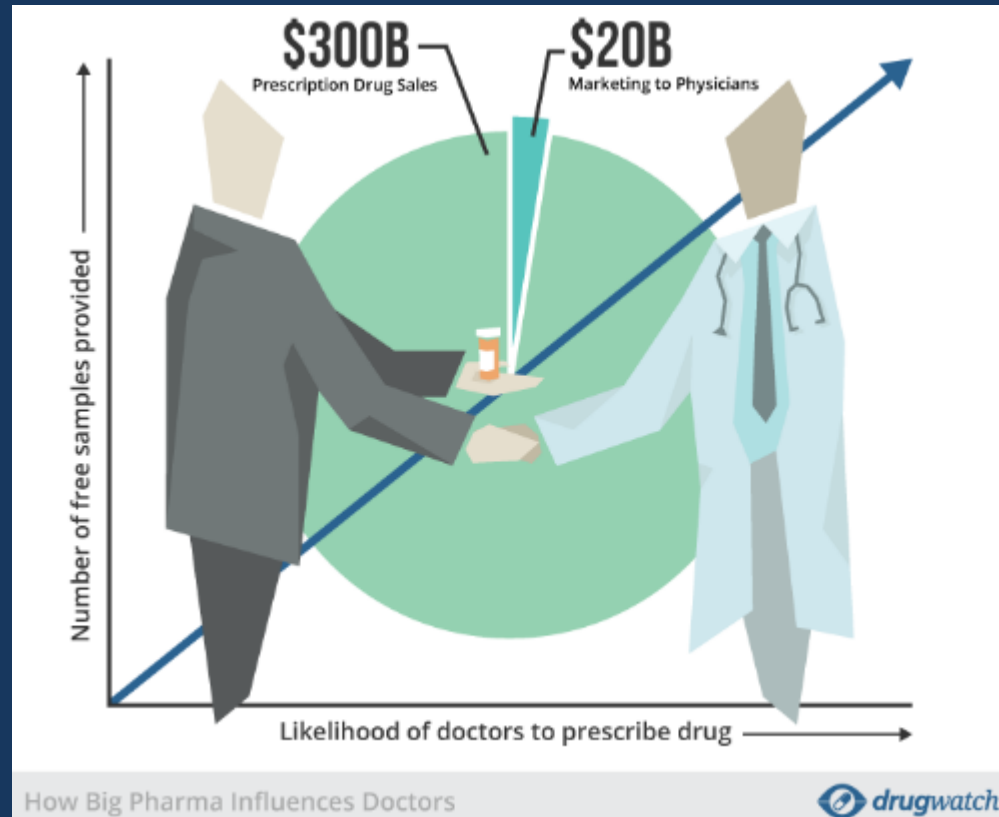
UNETHICAL RELATIONSHIP BETWEEN DOCTORS AND DRUGS COMPANIES

PhARMA

Media as Middleman



CONCLUSION : It is being realized more now than ever before that the interaction between doctors and drug companies should be contained within acceptable boundaries. It would be impracticable to ask the medical professionals to distance themselves from drug companies. The real challenge for the medical profession, drug companies and the Govt. is to formulate mutually acceptable guidelines to avoid certain egregiously unethical medical practice. The ultimate arbiter of this malpractice is of course the medical profession itself. It is for them to decide whether or not to accept the proffered



The Physician - Pharma Relationship

*"İnsan mı paraya baęlı ?
Para mı insana baęlı ?
Bu insana baęlı..."*

Özdemir Asaf



How to Learn if Your Doctor Takes Big Pharma Money

The U.S. Government requires all doctors to report all payments from pharmaceutical companies over \$10. These payments are then stored in a national database that anyone can search. To search the database, visit [OpenPaymentsData.cms.gov](https://openpaymentsdata.cms.gov). Users of the website can look for all payments to every doctor by state. They can also search for doctor payments by first and last name, city, zip code and specialty.



Q: IS IT TIME TO END THE WAR ON DRUGS?

NO.



NO.



NO.



**Medical journals are an
extension of the
marketing arm of drug
companies**

Richard Smith
Chief executive, United Health Europe
Formerly editor BMJ

INFURIATING REPORT SHOWS HOW GOVT & BIG PHARMA INTENTIONALLY BREAK LAWS TO REAP MASSIVE PROFIT

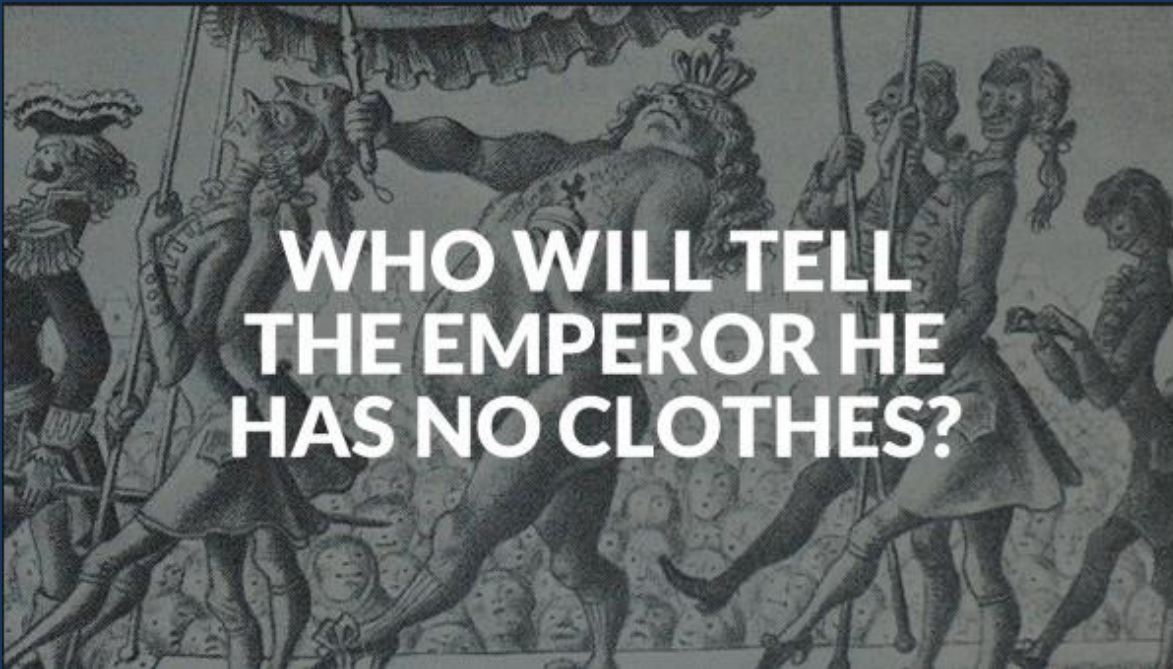


No arrests or prosecution of Big Pharma executives

One of the most astonishing realizations in all this is that given all the **criminal fraud**, bribery, misrepresentation, lying to the FDA, price fixing and other crimes that are going on in the pharmaceutical industry, you'd think somebody somewhere might be arrested and charged with a crime, right?

Nope.

To date, not a single pharmaceutical CEO, marketing employee or drug rep has been charged with anything related to all this fraud. In America, **drug company employees are "above the law"** just like top mafia bosses of a bygone era.



Int J Health Serv. 2002;32(2):379-416.

The end of the golden age of doctoring.

McKinlay JB¹, Marceau LD.

Physician mistrust and the end of the doctor-patient relationship



"Doctor, I'm not sure I can trust you."

Adı Soyadı	Özcan Özeke
Görev	Konuşmacı
Durumu	Kabul ediyorum.
Taahhüt	TÜRK KARDİYOLOJİ DERNEĞİ (TKD) tarafından düzenlenen Ulusal Aritmi Toplantısı 2017 Türk Kardiyoloji Kongresi'nde önerilen görevi kabul ediyorum.
Direkt kişisel finansal ilişki	Sağlık, medya, eğitim şirketleriyle direkt finansal ilişkim bulunmamaktadır.
Kurumsal finansal ilişki	Sağlık, medya, eğitim şirketleriyle kurumsal finansal ilişkim bulunmamaktadır.
Konumsal Bildirim	Kardiyoloji alanında konumumdan kaynaklanan olası bir yanlılık bulunmamaktadır.

Circulation

MY

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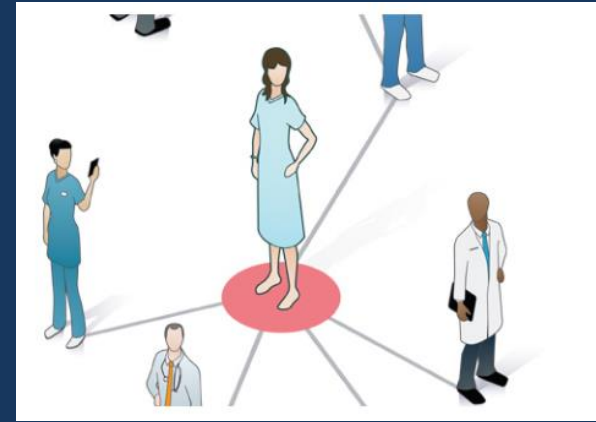
SPECIAL REPORTS

Rebuilding an Enduring Trust in Medicine

[Lancet](#). 2016 Aug 20;388(10046):755. doi: 10.1016/S0140-6736(16)31362-9.

Rebuilding patient-physician trust in China.

[Tucker JD](#)¹, [Wong B](#)², [Nie JB](#)³, [Kleinman A](#)⁴; [Patient-Physician Trust Team](#).



AF ABLASYONUNDA «SHAM» ÇALIŞMA GIBI SAÇMA BİR ŞEYE GEREK YOKTUR ?





Stuff They Don't Want You to Know - The Placebo Effect





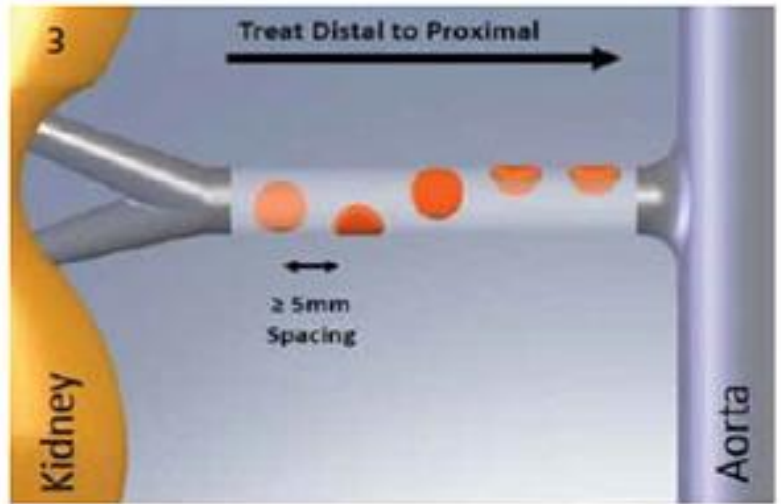
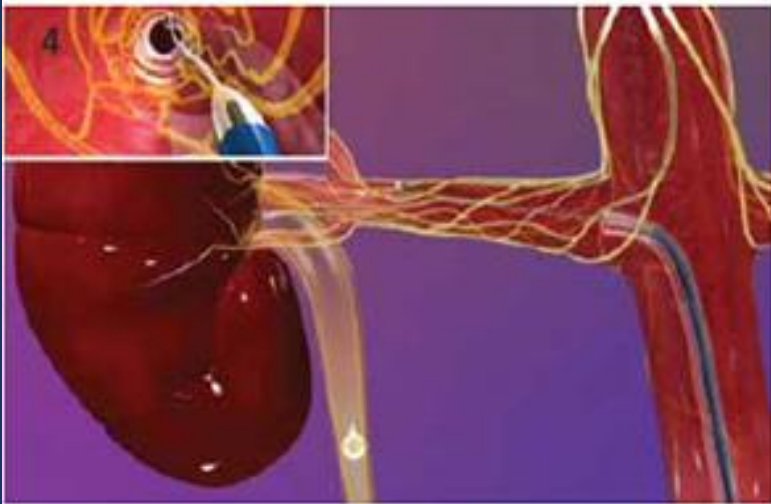
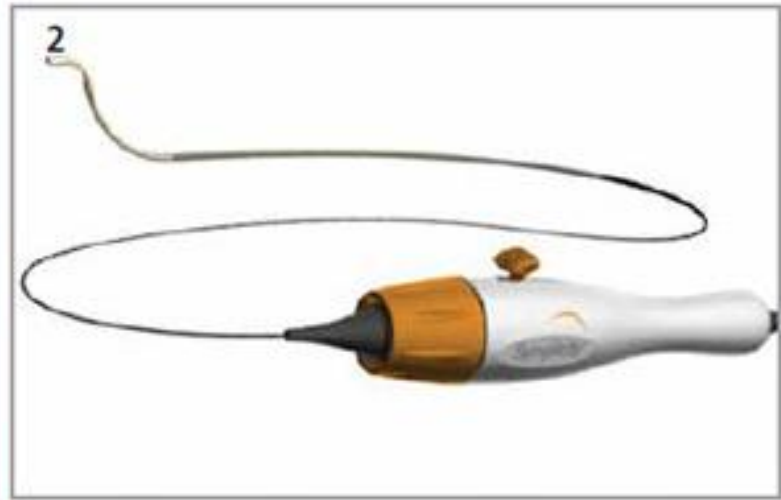
Antidepressants: A Triumph of Marketing Over Science?

David O. Antonuccio

Veterans Affairs Sierra Nevada Health Care System and University of Nevada School of Medicine

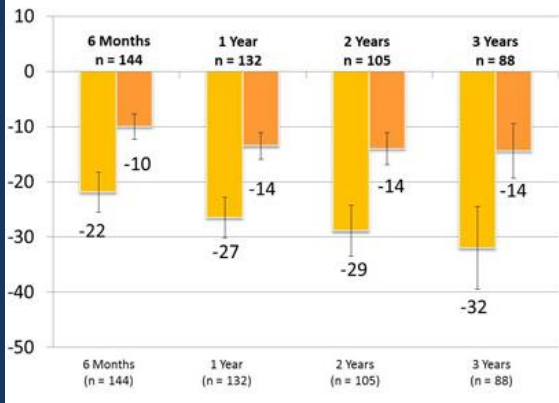
David D. Burns
Stanford University

William G. Danton
Veterans Affairs Sierra Nevada Health Care System and University of Nevada School of Medicine



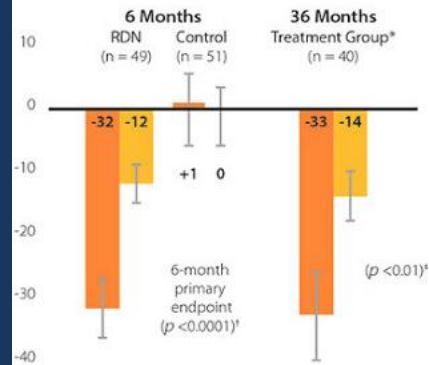


SYMPPLICITY HTN-1



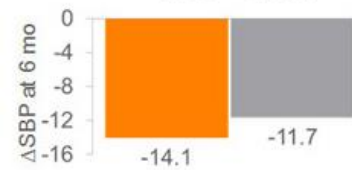
Symplicity HTN-2

Proven superior to medical management at 6 months



Results from the SYMPPLICITY HTN-3 Clinical Trial

■ RDN ■ Control



	RDN	Control	P value
Baseline SBP	179.7	180.2	0.765
6 mo SBP	165.6	168.4	0.260
Change	-14.1 $P < 0.001$	-11.7 $P < 0.001$	0.255

-2.39 (-6.89, 2.12), $P = 0.255$ (Primary analysis with 5 mm Hg superiority margin)

- Did not meet primary efficacy endpoint



Randomized open-label controlled studies



	VPS	VASIS	SYDIT	
Pts no.	54	42	93	
Mean age	43	60	58	
Median no. of syncopes	14-35	5.5	7-8	<i>Risk ↓</i>
Tilt test	+	+	+	
Control arm	no pm	no pm	atenol	83%
Recurrence (Pm arm)	22%	5%	4%	92%
Recurrence (control arm)	70%	61%	25%	
p value	0.000	0.000	0.004	
Pacemaker	RDR	DDI 45-80	RDR	
Mean FU: few mo — 3.7 yrs				

VPS. J Am Coll Cardiol 1999; 33: 16-20

VASIS. Circulation 2000; 102: 294-299 SYDIT. Circulation 2001;104:52-57

Randomized double-blind placebo-controlled trials

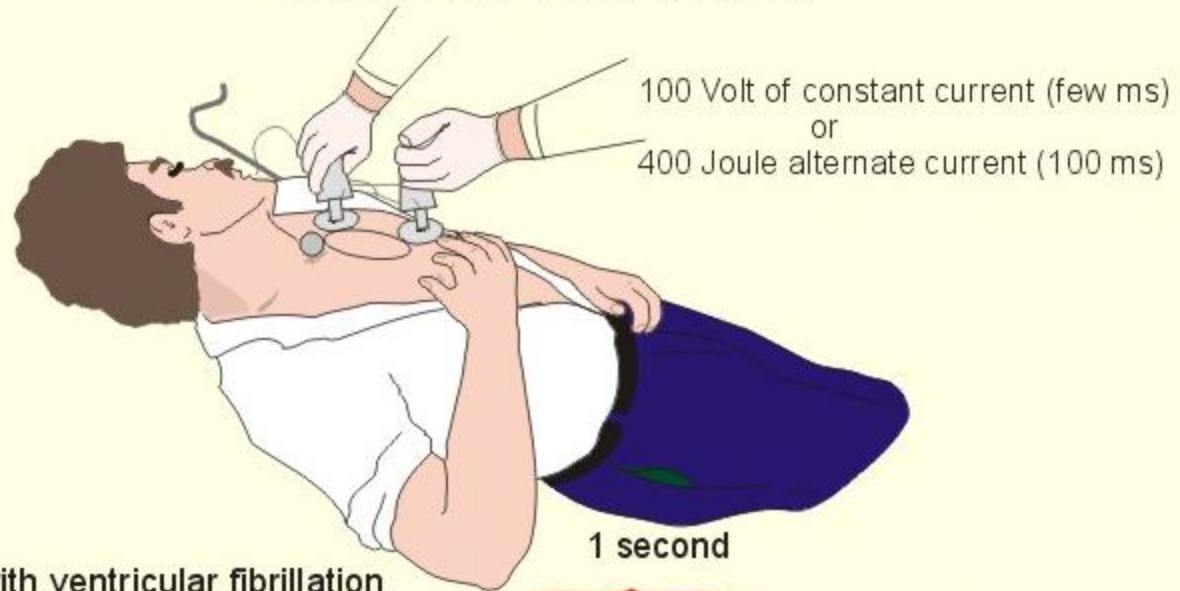
	VPS II	SYNPACE	
Pts no.	100	29	
Mean age	49	53	
Median no. of syncopes	16	14-10	Risk ↓
Tilt test	+ / -	+	-21%
Control arm	pm off	pm off	
Recurrence (Pm arm)	33%	50%	+32%
Recurrence (control arm)	42%	38%	
p value	ns	ns	
Pacemaker	RDR	RDR	

VPS II. JAMA 2003; 289: 2224-2229

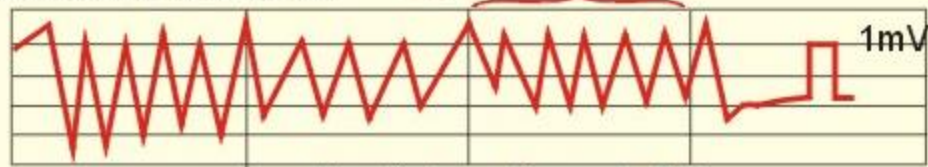
SYNPACE. Eur Heart J 2004; 25: 1741-8

**NEDEN KAVRAMSAL OLARAK
«SHAM» İHTİYACI VAR YA DA YOK ?**

Ventricular Defibrillation

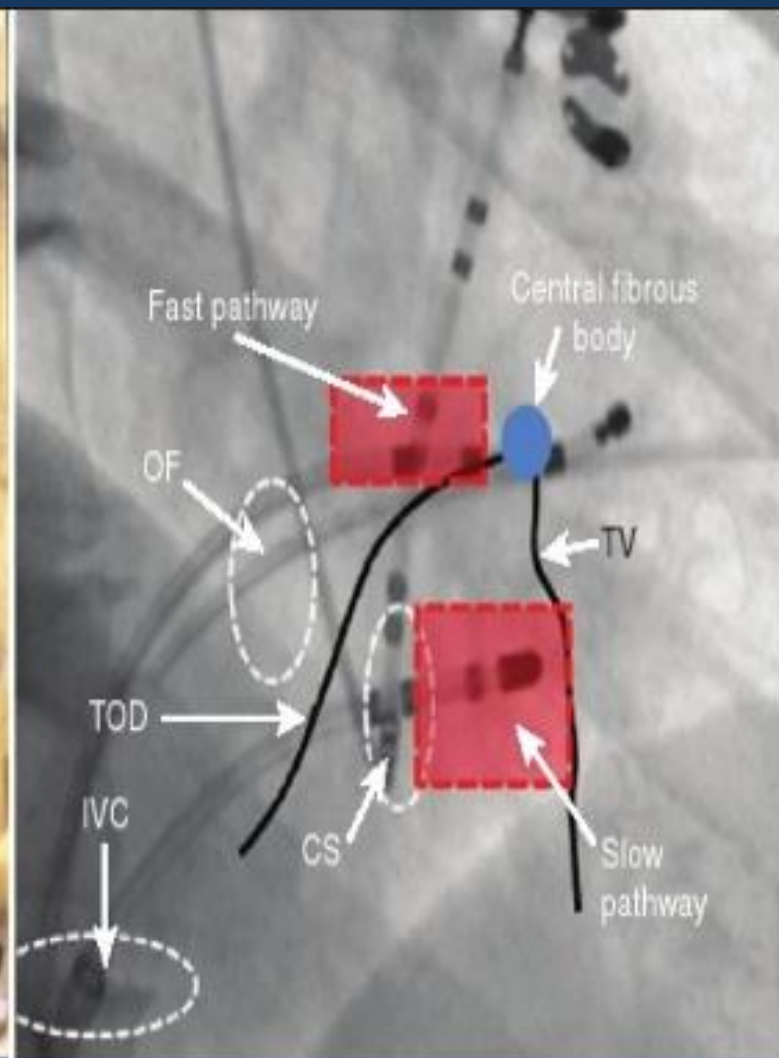
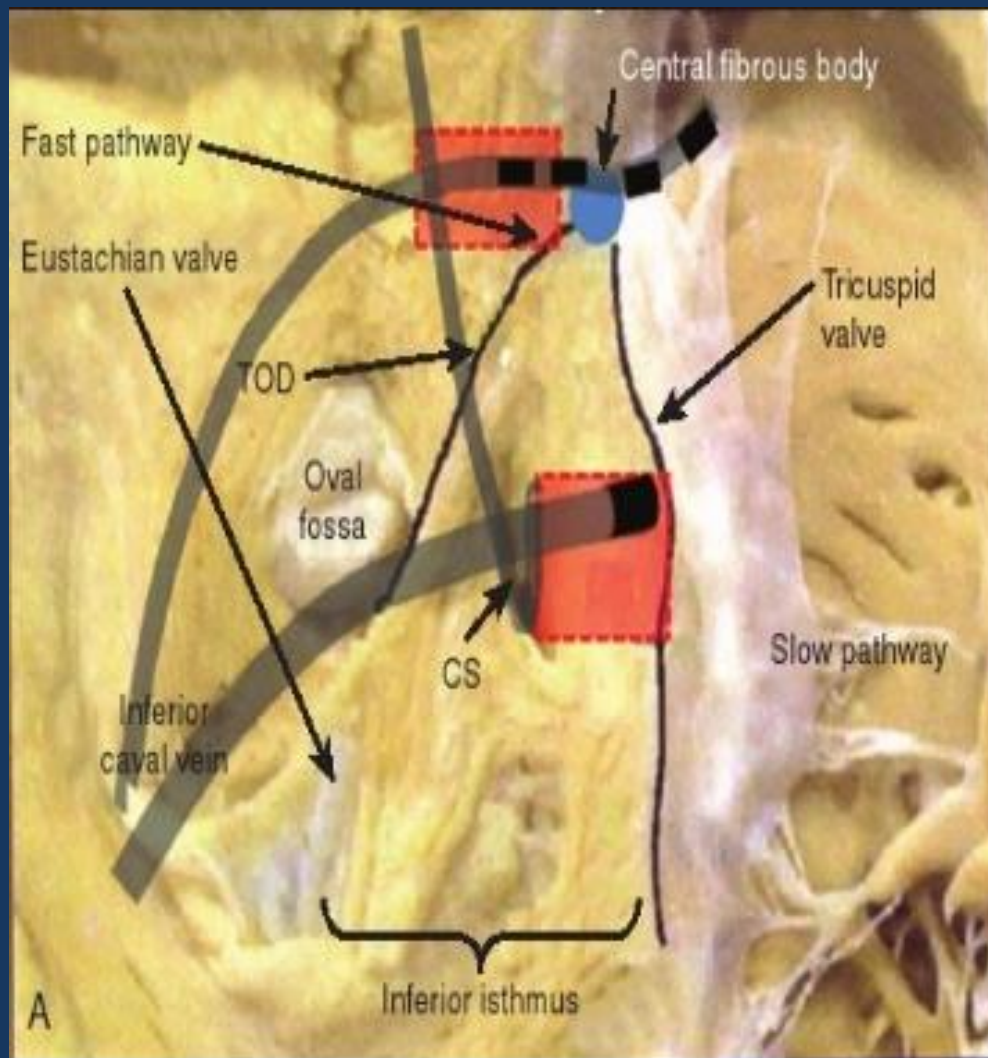


ECG with ventricular fibrillation



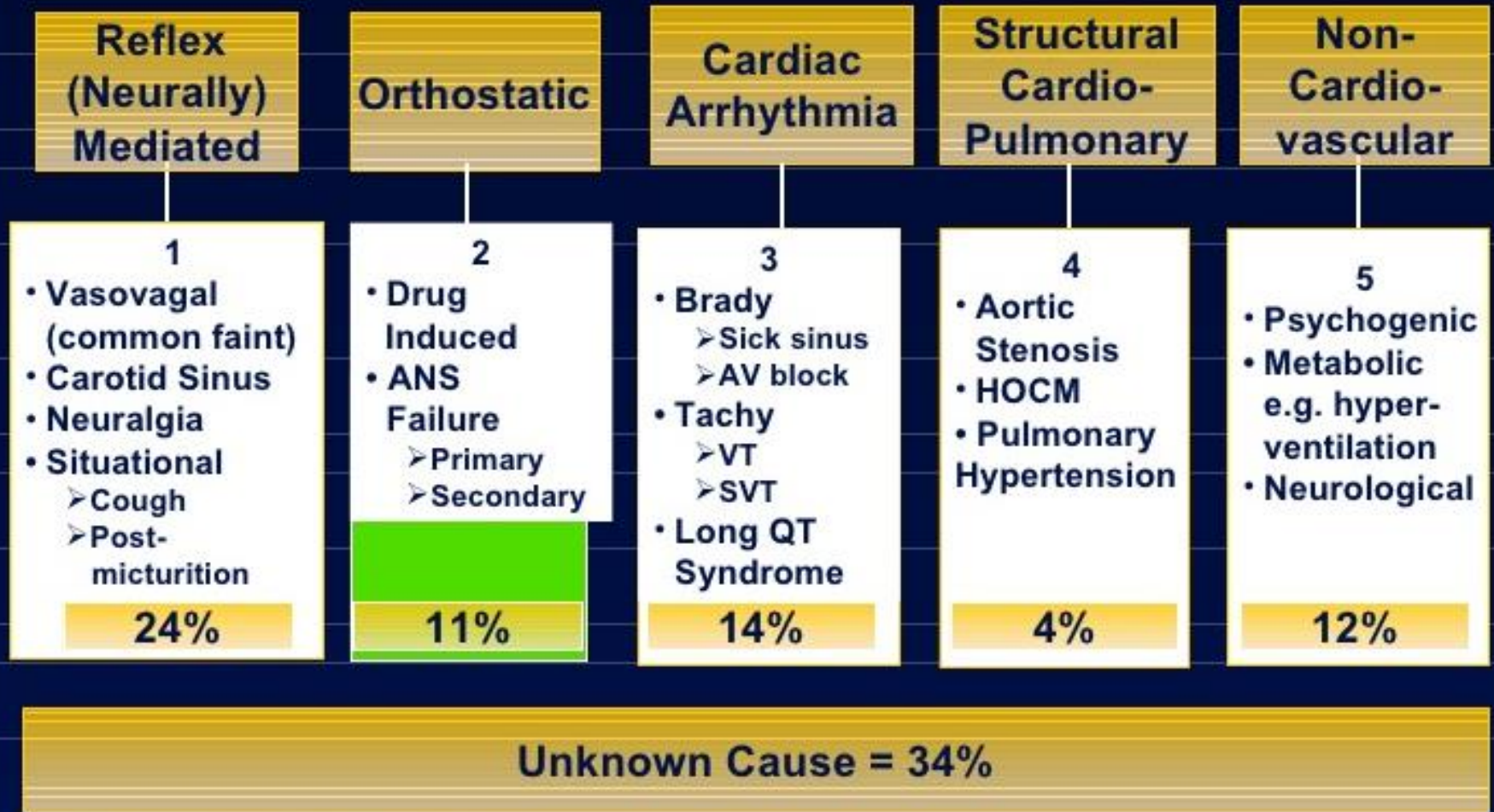
Ventricular action potential



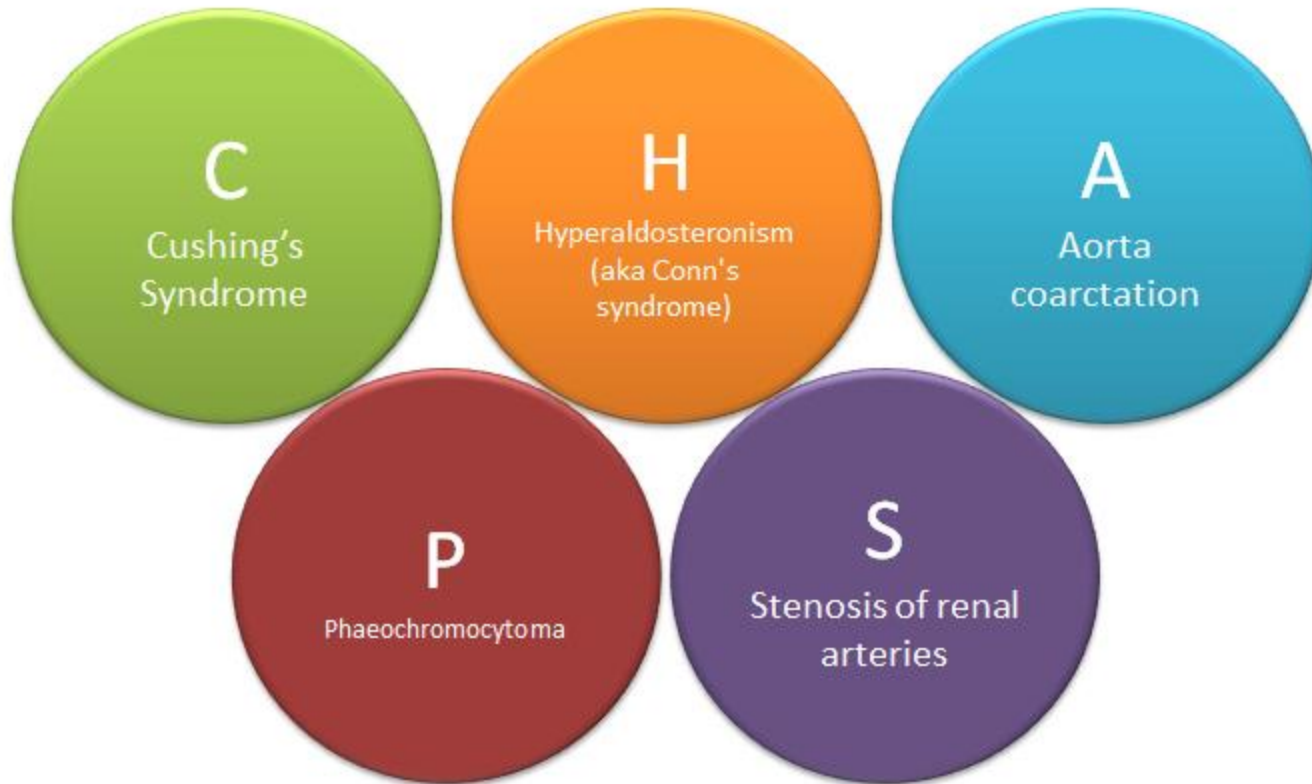


- Amerikalı psikolog Maslow

"Elinde çekiç olan her şeyi çivi olarak görür"

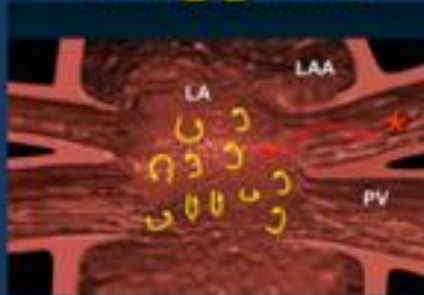


Mnemonic: "CHAPS"



PEKI ATRİYAL FİBRİLASYON ?

Triggers



PV sleeve, 1988, Haissaguerre M
IVC/SVC/LAA

Modulating Factors



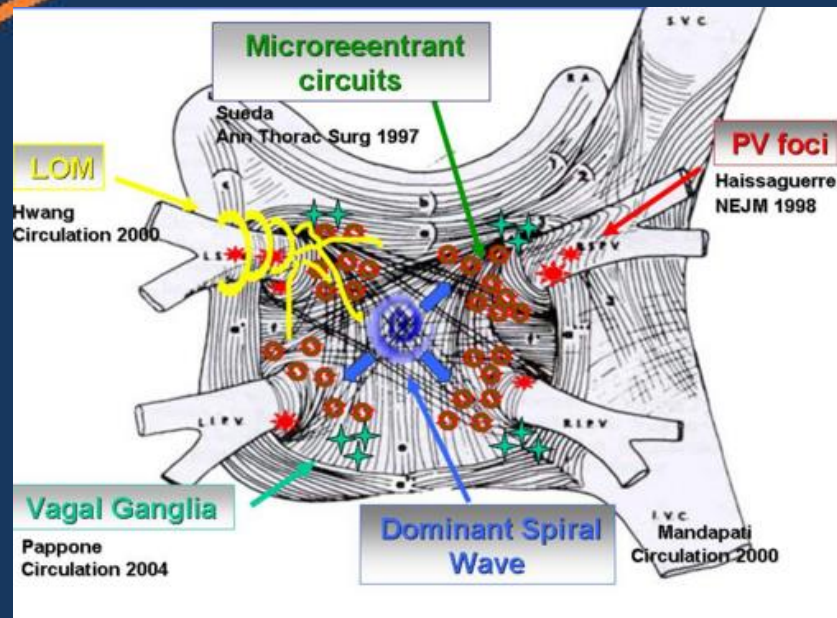
Substrate

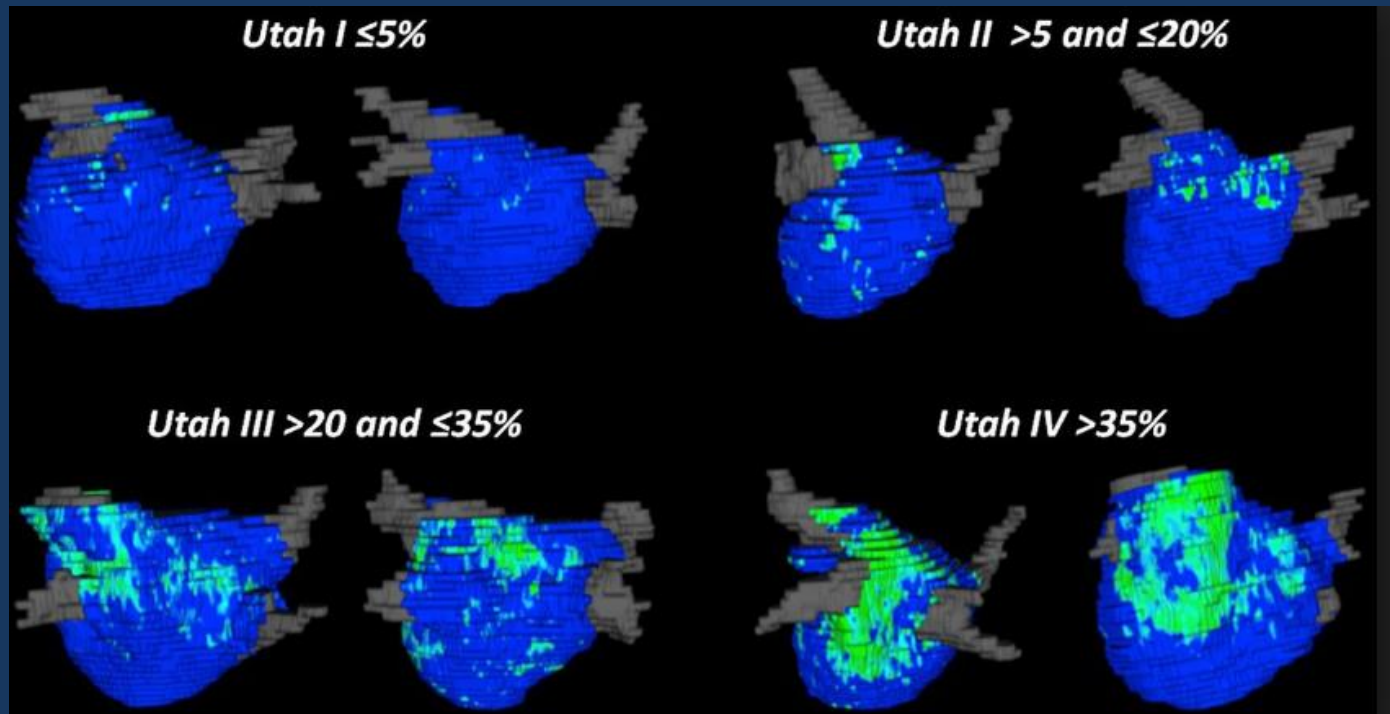
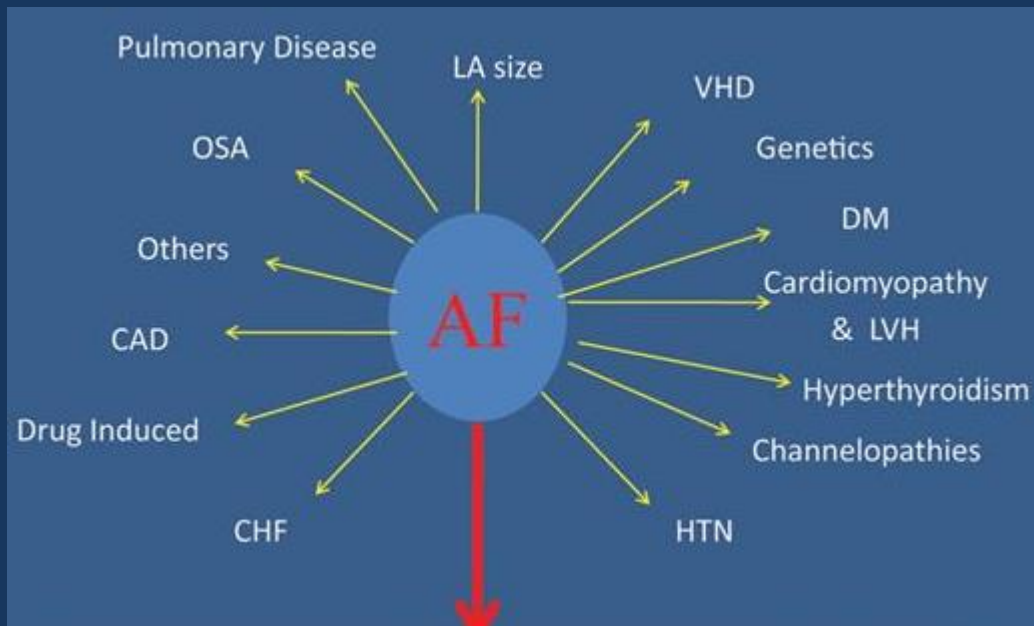
Drivers-substrate

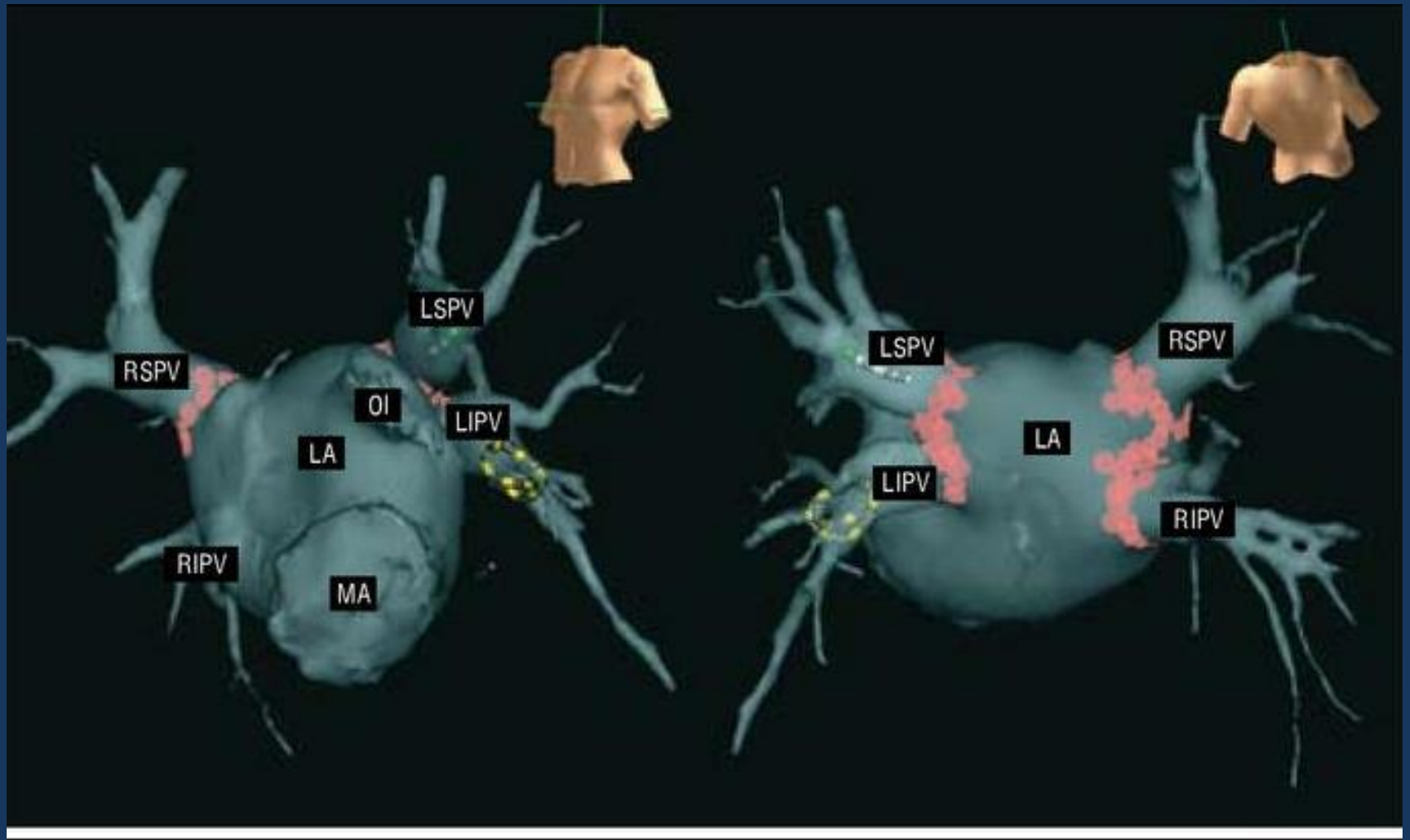
Çoklu reentri

CAFE

rotors



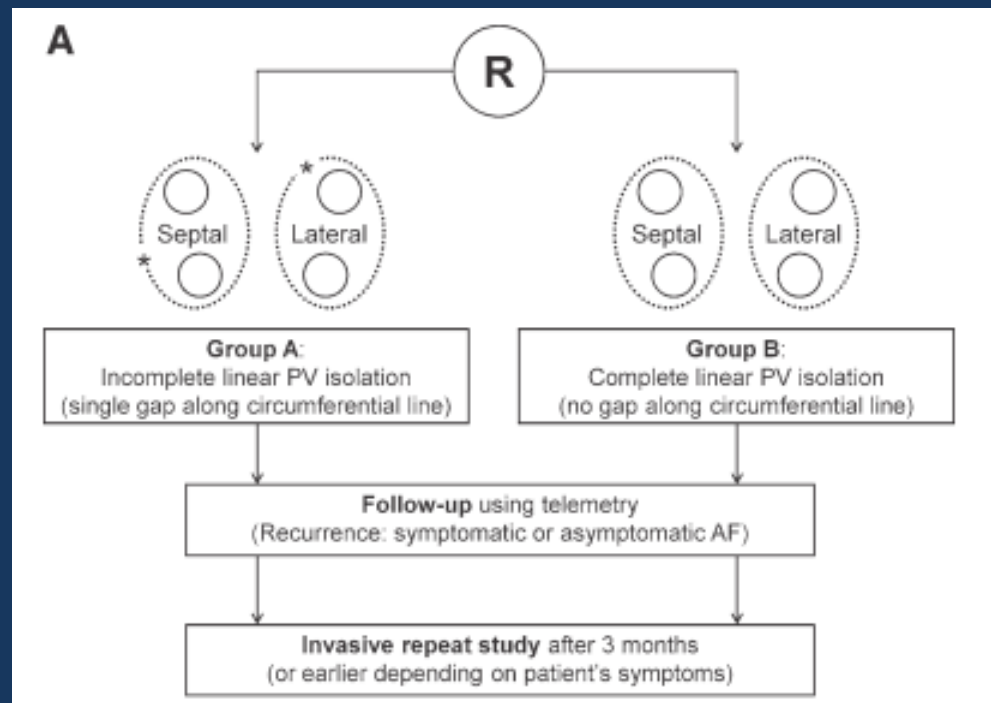




GAP-AF

(Circ Arrhythm Electrophysiol. 2016;9:e003337)

Karl-Heinz Kuck, MD; Boris A. Hoffmann, MD; Sabine Ernst, MD; Karl Wegscheider, PhD; Andras Treszl, MD; Andreas Metzner, MD; Lars Eckardt, MD; Thorsten Lewalter, MD; Günter Breithardt, MD; Stephan Willems, MD; for the Gap-AF–AFNET 1 Investigators*



In this group, complete PVI was attempted. After deployment of a circular lesion inducing block of the PVs (elimination of all PV potentials or dissociated activity), a waiting period of 30 minutes was held. Subsequent radiofrequency current applications were deployed in cases of spontaneous or adenosine-induced reconduction. After achievement of the intended procedure end points in groups A and B, a repeat angiography of all PVs was performed to exclude acute PV stenosis (Figure 1A).

Methods and Results—Patients with drug-refractory, symptomatic paroxysmal AF were randomly assigned to either incomplete (group A) or complete PVI (group B). In group A, a persistent gap was intentionally left within the circumferential ablation line, whereas in group B, complete PVI without any gaps was intended. At 3 months, all patients underwent invasive reevaluation to assess the rate of persistent PVI. Clinical follow-up was based on daily 30-s transtelephonic ECG transmissions. Primary study end point was the time to first recurrence of (symptomatic or asymptomatic) AF. A total of 233 patients were enrolled (116 in group A and 117 in group B). AF recurrence within 3 months was observed in a total of 161 patients (136 [84.5%] with symptomatic and 25 [15.5%] with asymptomatic AF); AF recurred in 62.2% of group B patients and 79.2% of group A patients ($P<0.001$), for a difference in favor of complete PVI of 17.1% (95% confidence interval, 5.3%–28.9%). Invasive restudy in 103 group A patients and 93 group B patients revealed conduction gaps in 92 (89.3%) and 65 (69.9%) patients, respectively.

Conclusions—This study proves the superiority of complete PVI over incomplete PVI with respect to AF recurrence within 3 months. However, the rate of electric reconnection 3 months after PVI is high in patients with initially isolated PVs.

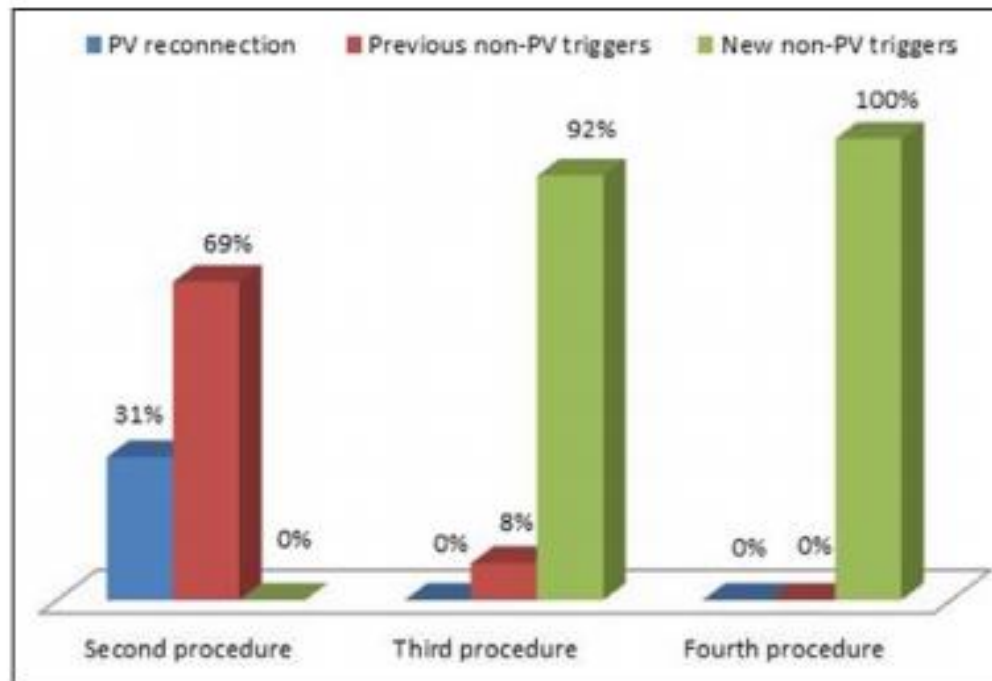
Although the first and the second main findings may not be surprising, they do add scientific evidence from a multicenter randomized trial to current expert opinion.^{8,9} The third finding is surprising. A 70% PV reconnection rate after 3 months in patients with acute complete PVI is extremely high. But

ORIGINAL ARTICLE

Pulmonary Vein Antrum Isolation in Patients With Paroxysmal Atrial Fibrillation

More Than a Decade of Follow-Up

Yalçın Gökoğlan, Sanghamitra Mohanty, Mahmut F. Güneş, Chintan Trivedi, Pasquale Santangeli, Carola Gianni, Issa K. Asfour, Rong Bai, J. David Burkhardt, Rodney Horton, Javier Sanchez, Steven Hao, Richard Hongo, Salwa Beheiry, Luigi Di Biase, Andrea Natale





Volume 35, Issue 22
7 June 2014

EDITOR'S CHOICE

The Atrial Fibrillation Ablation Pilot Study: an European Survey on Methodology and results of catheter ablation for atrial fibrillation conducted by the European Heart Rhythm Association FREE

Arbelo E¹, Brugada J², Hindricks G³, Maggioni AP⁴, Tavazzi L⁵, Vardas P⁶, Laroche C⁴, Anselme F⁷, Inama G⁸, Jais P⁹, Kalarus Z¹⁰, Kautzner J¹¹, Lewalter T¹², Mairesse GH¹³, Perez-Villacastin J¹⁴, Riahi S¹⁵, Taborsky M¹⁶, Theodorakis G¹⁷, Trines SA¹⁸; Atrial Fibrillation Ablation Pilot Study Investigators.

Collaborators (272)

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Seventy-two centres in 10 European countries

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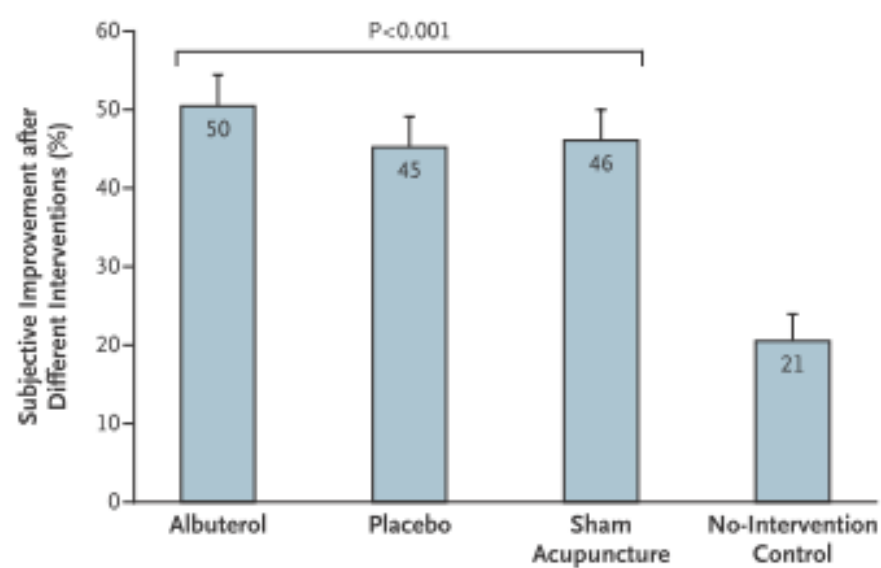
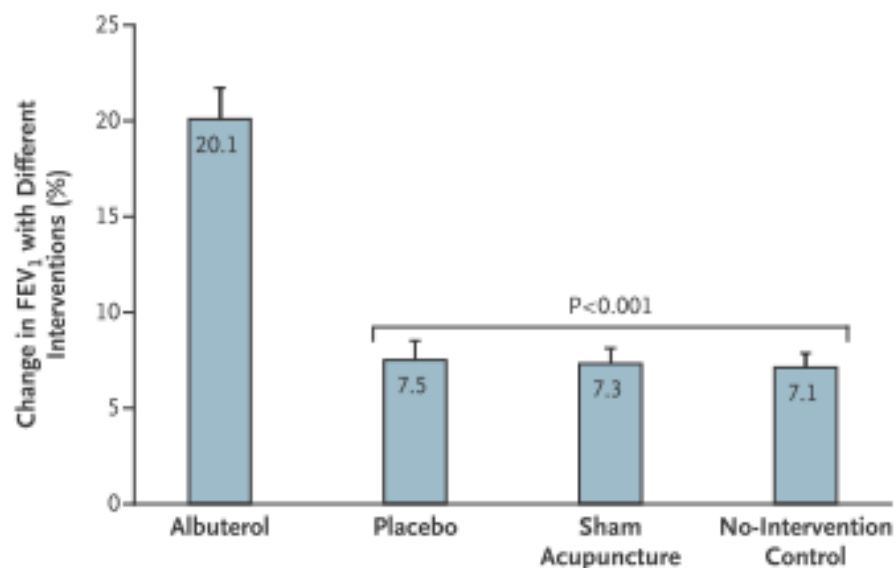
METHODS AND RESULTS: Seventy-two centres in 10 European countries were asked to enrol 20 consecutive patients undergoing a first AFib ablation procedure. A web-based case report form captured information on pre-procedural, procedural, and 1-year follow-up data. Between October 2010 and May 2011, 1410 patients were included and 1391 underwent an AFib ablation (98.7%). A total of 1300 patients (93.5%) completed a follow-up control 367 ± 42 days after the procedure. Arrhythmia documentation was done by an electrocardiogram in 76%, Holter-monitoring in 52%, transtelephonic monitoring in 8%, and/or implanted systems in 4.5%. Over 50% became asymptomatic. Twenty-one per cent were re-admitted due to post-ablation arrhythmias. Success without antiarrhythmic drugs was achieved in 40.7% of patients (43.7% in paroxysmal AF; 30.2% in persistent AF; 36.7% in long-lasting persistent AF). A second ablation was required in 18% of the cases and 43.4% were under antiarrhythmic treatment. Thirty-three patients (2.5%) suffered an adverse event, 272 (21%) experienced a left atrial tachycardia, and 4 patients died (1 haemorrhagic stroke, 1 ventricular fibrillation in a patient with ischaemic heart disease, 1 cancer, and 1 of unknown cause).

CONCLUSION: The AFib Ablation Pilot Study provided crucial information on the epidemiology, management, and outcomes of catheter ablation of AFib in a real-world setting. The methods used to assess the success of the procedure appeared at least suboptimal. Even in this context, the 12-month success rate appears to be somewhat lower to the one reported clinical trials.

ORIGINAL ARTICLE

Active Albuterol or Placebo, Sham Acupuncture, or No Intervention in Asthma

Michael E. Wechsler, M.D., John M. Kelley, Ph.D., Ingrid O.E. Boyd, M.P.H.,





AF & Symptoms



Atrial Fibrillation

Symptomatic

palpitations, dyspnea, fatigue,
angina, dizziness, syncope

Asymptomatic or Silent

not perceived at all by the
patient

CABANA

Trial Milestones

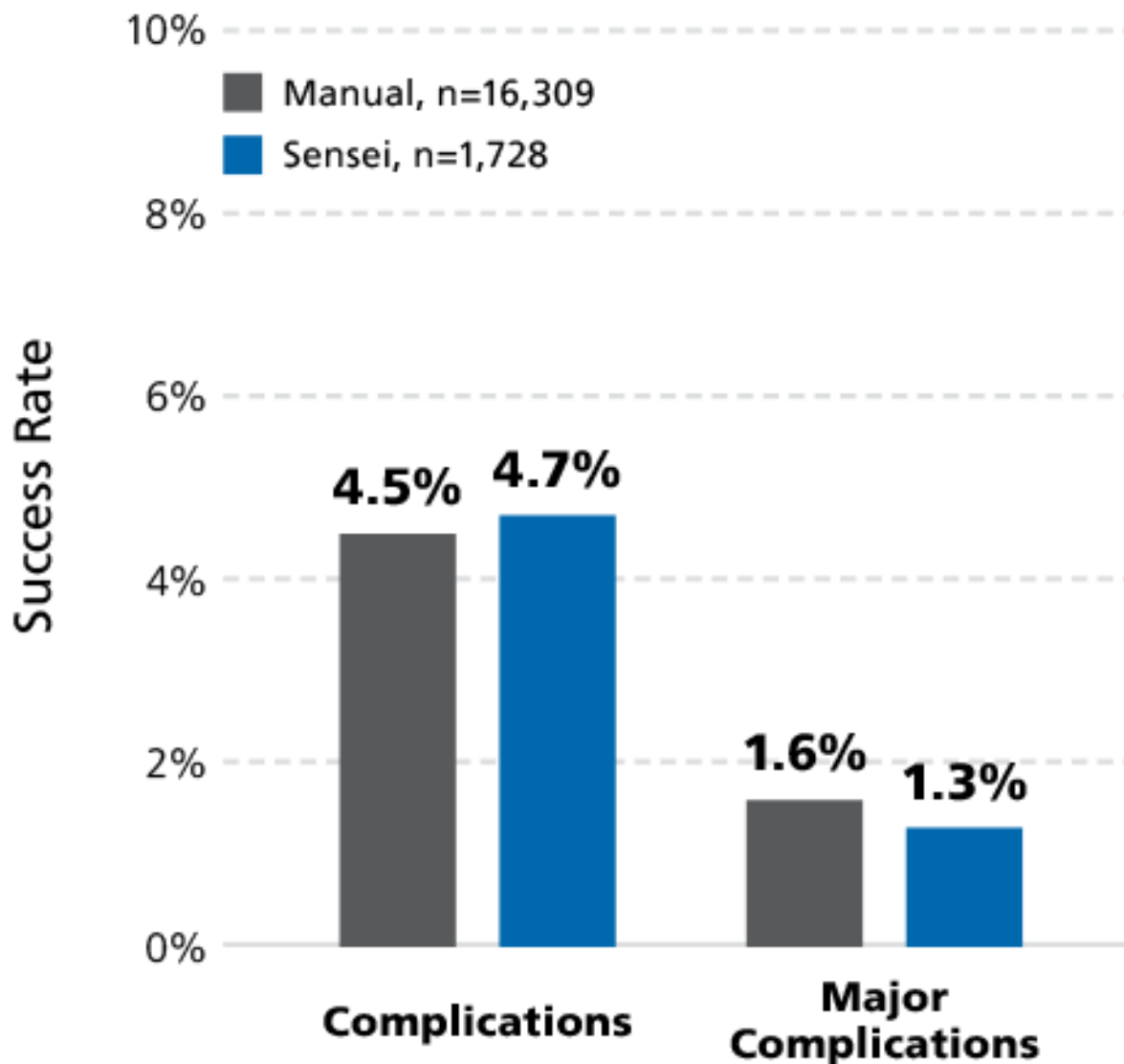
The following dates are available for this trial. Trial information last updated on 14 September 2015.

1 AUG 2009	28 MAY 2009	1 DEC 2017	1 JUN 2018	1 SEP 2015	UNAVAILABLE
Start Date	First Received	1st Completion	Completion	Verification	Results

EAST

1 FEB 2011	1 FEB 2011	1 JUN 2019	1 NOV 2019	1 JUL 2015	UNAVAILABLE
Start Date	First Received	1st Completion	Completion	Verification	Results

AF Ablation Complications





Volume 35, Issue 22
7 June 2014

EDITOR'S CHOICE

The Atrial Fibrillation Ablation Pilot Study: an European Survey on Methodology and results of catheter ablation for atrial fibrillation conducted by the European Heart Rhythm Association ^{FREE}

Arbelo E¹, Brugada J², Hindricks G³, Maggioni AP⁴, Tavazzi L⁵, Vardas P⁶, Laroche C⁴, Anselme F⁷, Inama G⁸, Jais P⁹, Kalarus Z¹⁰, Kautzner J¹¹, Lewalter T¹², Mairesse GH¹³, Perez-Villacastin J¹⁴, Riahi S¹⁵, Taborsky M¹⁶, Theodorakis G¹⁷, Trines SA¹⁸; Atrial Fibrillation Ablation Pilot Study Investigators.

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AF Ablation is Overused in the US

March 11, 2017 By [Dr John](#)

Filed Under: [AF ablation](#), [Doctoring](#), [General Ablation](#), [General Cardiology](#)

A colleague recently asked me if atrial fibrillation (AF) ablation was overused.

Yes it is. [AF ablation](#) has become the wild west of electrophysiology. There is essentially no scrutiny of this invasive, expensive and risky procedure. I also include here the add-on “[maze-like](#)” [procedures](#) done during heart surgery for other conditions. I believe they too are overused.

JOHN MANDROLA, MD

Welcome, Enjoy, Interact.



I – No scrutiny *before* AF ablation:

Getting an AF ablation approved is easy. All a doctor has to say is that the patient is “symptomatic” and/or failed a drug. You don’t have to say what sort of drug; you don’t have to say what dose of the drug (low doses often fail), and you don’t have to say anything about the nature of the symptoms. I’ve seen people undergo ablation for brief (less than an hour) episodes occurring once every three months. That is wrong.

Doctors don’t have to try treating obesity or sleep apnea before AF ablation. I’ve seen massively obese people undergo futile AF ablation. Doctors don’t have to recommend reducing alcohol intake. I’ve seen people have AF ablation so they could keep drinking 3+ cocktails per night. In athletes, you don’t have to discuss the possibility that exercise addiction may be causing AF, and that if they go back to the same pattern, the AF will likely come back.



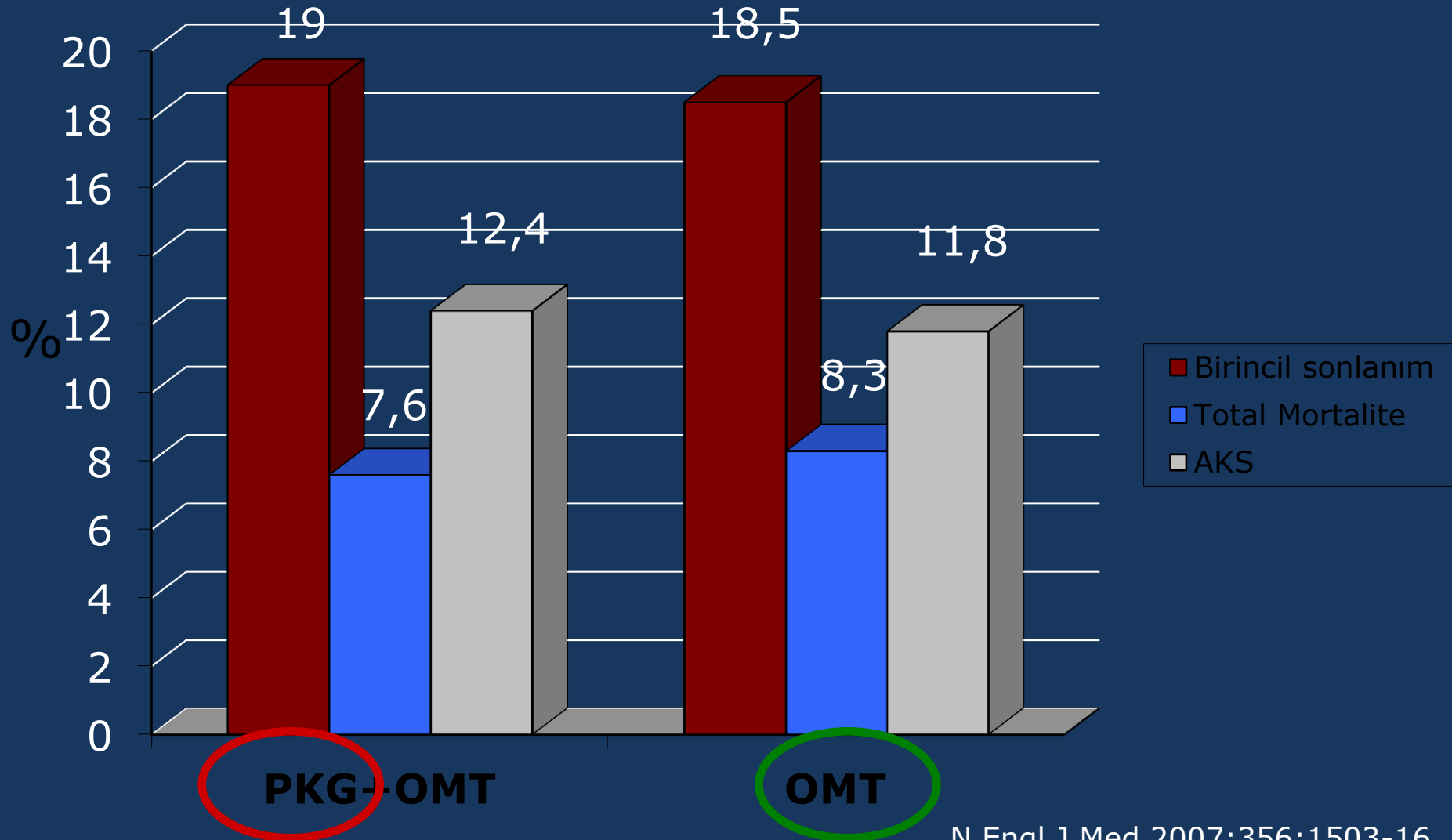
V – Reasons for Overuse of AF Ablation in the US:

One reason for overuse is misaligned incentives. AF ablation makes doctors and hospitals a lot of money. We are paid per procedure. The more procedures we do, the more we make. Here I reference [Upton](#)

[Sinclair](#).

ILGINÇ ...

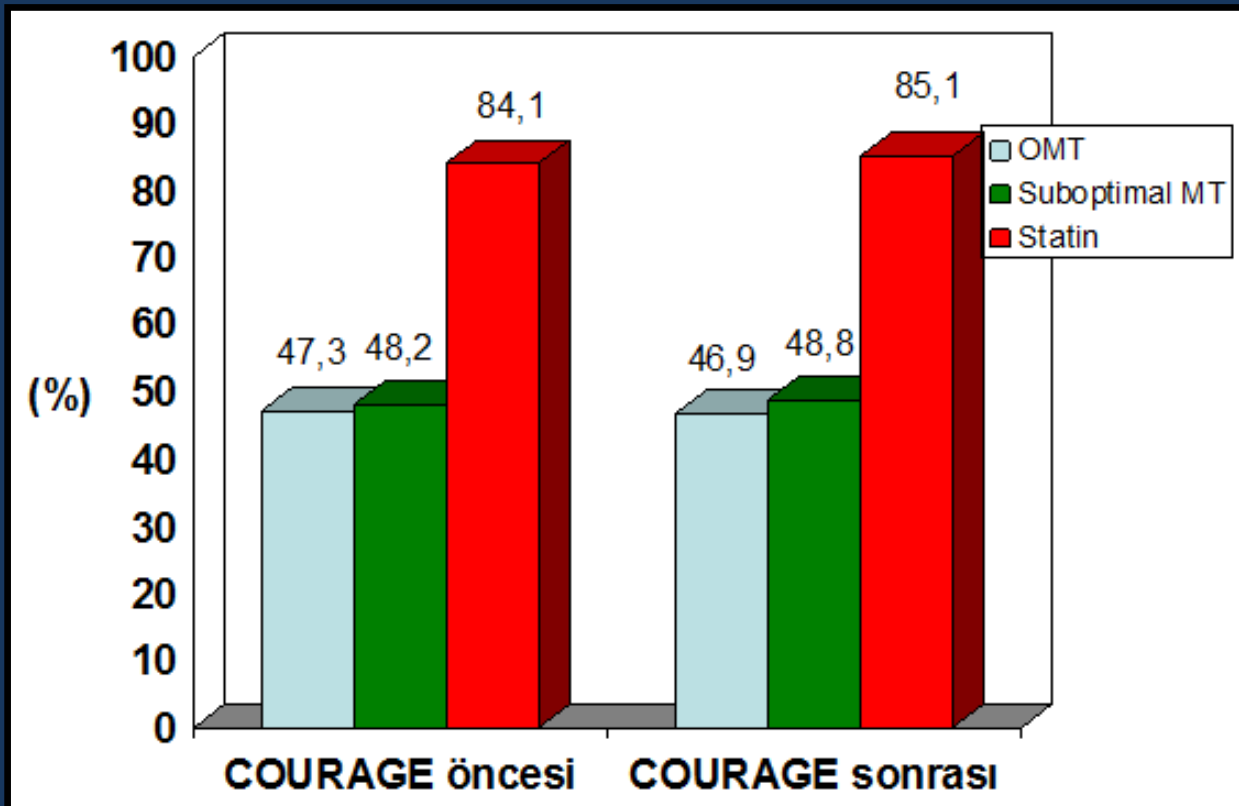
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ORIGINAL RESEARCH

Practice Patterns and Trends in the Use of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention in Ontario

Pallav Garg, Harindra C. Wijeyesundera, Lingsong Yun, Warren J. Cantor, Dennis T. Ko



Stent

ClinicalTrials.gov

Objective Randomised Blinded Investigation With Optimal Medical Therapy of Angioplasty in Stable Angina (ORBITA)

This study is currently recruiting participants. (see [Contacts and Locations](#))

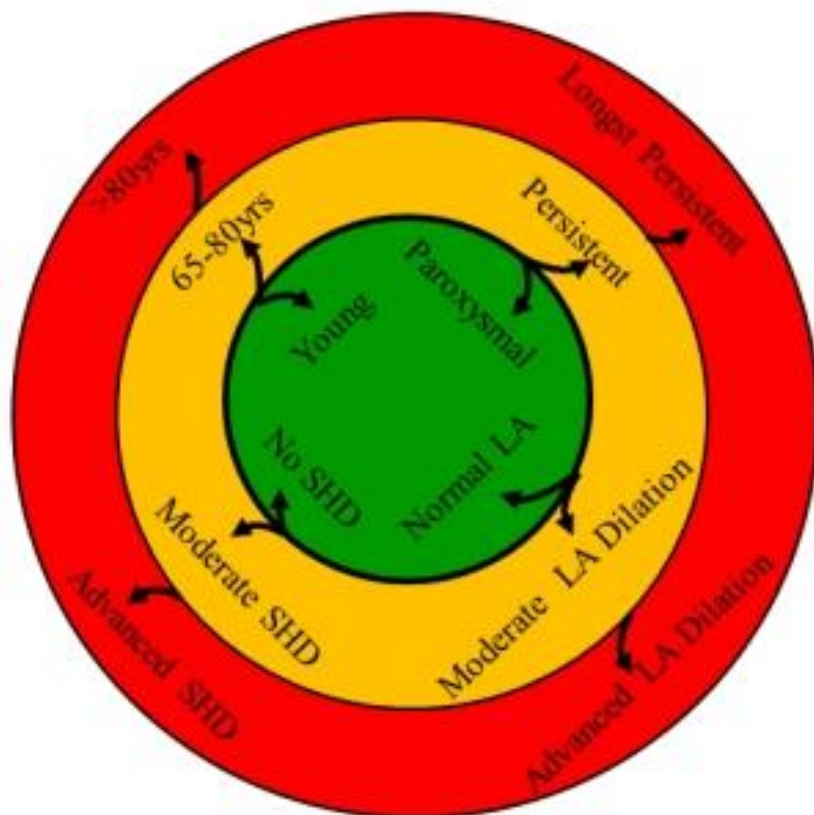
Verified February 2017 by Imperial College London

ClinicalTrials.gov Identifier:

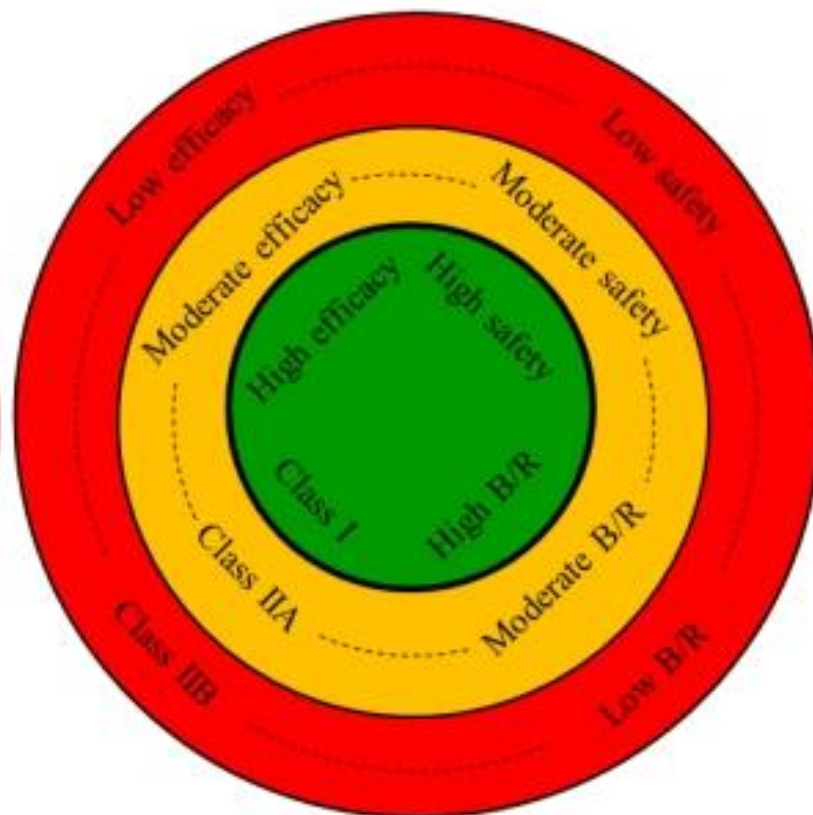
NCT02062593



Patient profile



Benefit/risk ratio



YOU ARE THE
PLACEBO

Making Your Mind Matter



Ethics







First do no harm

The Hippocratic Oath



The good physician treats the disease; the
great physician treats the patient who has the
disease.

William Osler