

## R. Polosa – COI last 5 yrs

Full tenure Professor of Internal Medicine at the University of Catania (Italy)

LIAF (Italian Anti Smoking League) Scientific advisor – unpaid

CASAA (Consumer Advocates for Smoke-free Alternatives Association) Scientific advisor – unpaid

### Research grant

- **Pharma industry** (Pfizer, GSK, Novartis)
- **E-Cig industry** (Arbi Group Srl)

### Consultancy/Advocacy role

- **Governmental Authorities** (Cancer Research UK; Italian Ministry of Health's Technical Committee on e-cigarette; Food and Drug Administration, USA; French National Program of Clinical Research of the French Ministry of Health)
- **Pharma industry** (Global Health Alliance for treatment of tobacco dependence)
- **E-Cig industry** (Arbi Group Srl; ECITA - Electronic Cigarette Industry Trade Association; Innokin)

### Lectures fees

- **Governmental Authorities** (Cancer Research UK; UK All Party Parliamentary Group; Russian "National Research and Study Institute For Public Health")
- **Pharma industry** (Pfizer, Novartis)
- **E-Cig industry** (SFATA - Smoke-Free Alternatives Trade Association; FIVAPE; FIESEL; REAL FARMA)

# E-cigarettes and harm reversal: cardio-pulmonary health effects

**Prof. Riccardo Polosa**

*Professor of Internal Medicine*

*Università di Catania - ITALY*

*Scientific Advisor:*

*Lega Italiana AntiFumo (LIAF)*



## THE **E**-CIGARETTE SUMMIT

### Science, Regulation & Public Health

*The Royal Society ■ London ■ November 17th 2016*

# Health effects of vaping: Emerging Views

**Negative Aspects**

**The Past**



**Positive Aspects**

**The Future**

Janus head. Terracotta sculpture, from Vulci, II century BC (Rome, National Etruscan Museum of Villa Giulia).

# What is the long-term health impact of e-cigarettes? - 1

*The safety of long term EC use is a legitimate question and can be answered by:*

- large prospective studies of well-characterized EC users (impractical, costly)
- extrapolating responses to e-vapour in cell lines and/or in animal models (does not directly apply to real-life situation)

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# What is the long-term health impact of e-cigarettes? - 2

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- detecting early changes of subclinical injury with highly sensitive functional tests (“healthy” smokers)
- documenting changes with more robust and validated investigational tools (EC users with pre-existing disease)

# What is the long-term health impact of e-cigarettes? - 2

*The safety of long term EC use is a legitimate question and can be answered by:*

- detecting early changes of subclinical injury with highly sensitive functional tests (“healthy” smokers)
- documenting changes with more robust and validated investigational tools (EC users with pre-existing disease)

# Acute Studies: a note of caution

Transient effects on cardio-respiratory outcomes not informative\*:

- Suggest irritative effects
- Cannot establish causation of clinically relevant harm
- Do not have prognostic value

\*

*Vardavas C, et al. Chest. 2012;141:1400–6.*

*Flouris A, et al. Inhal Toxicol. 2013;25:91–101.*

*Ferrari M, et al. BMC Pulm Med. 2015 Oct 12;15:120.*

*Vansickel AR, et al. Cancer Epidemiol Biomarkers Prev 2010;19:1945–53.*

*Yan XS, and D'Ruiz C. Regul Toxicol Pharmacol 2014;71:24–34.*

*Vlachopoulos C, et al. J Am Coll Cardiol. 2016 Jun 14;67(23):2802-3.*



# Chronic Studies:

**Cardiovascular System**

**Respiratory System**

**Other**

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**Cardiovascular System**

Respiratory System

Other

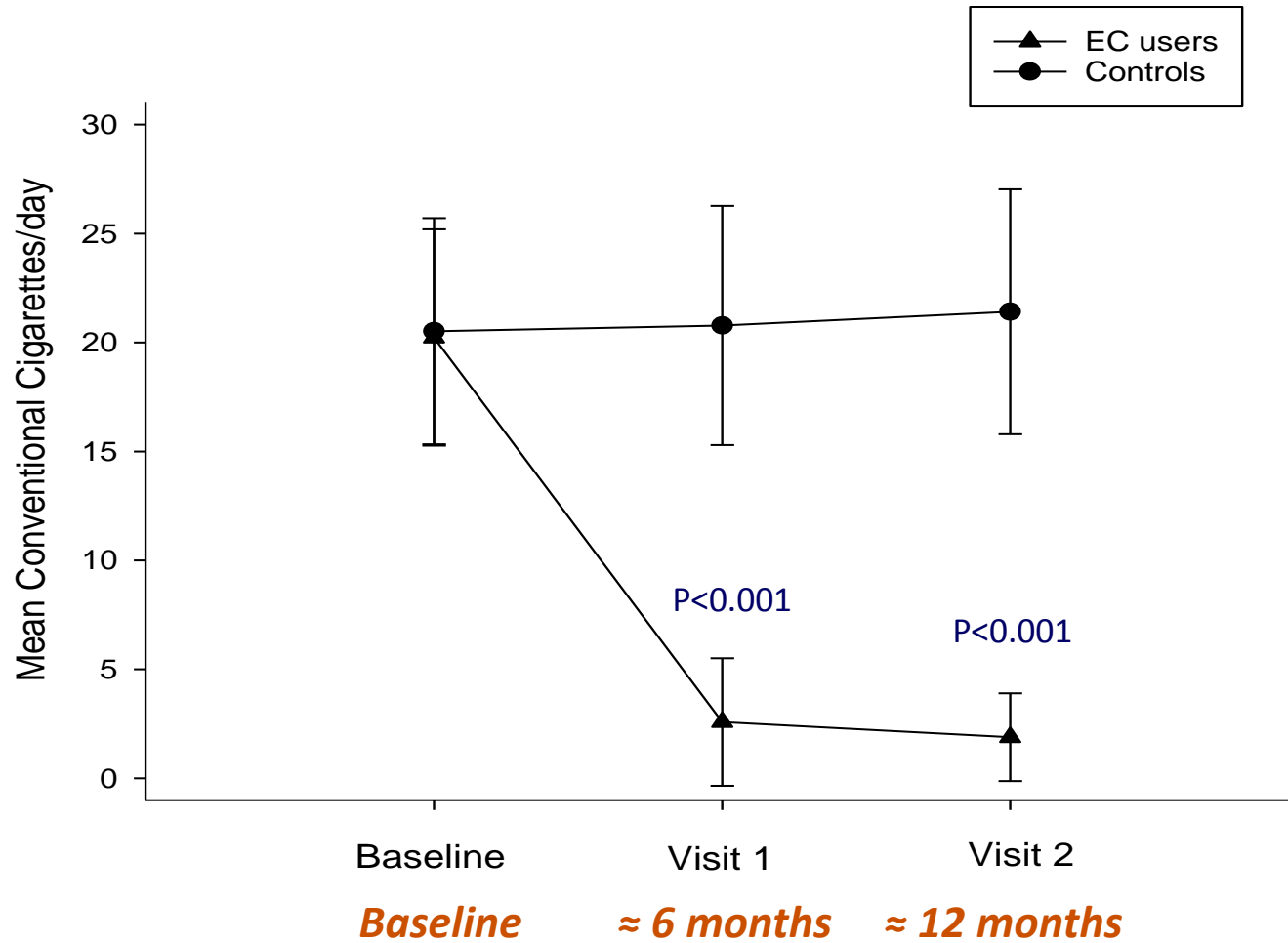
# BLOOD PRESSURE CONTROL IN SMOKERS WITH ARTERIAL HYPERTENSION WHO SWITCH TO ELECTRONIC CIGARETTES

Polosa et al. Int J Environ Res Public Health. 2016

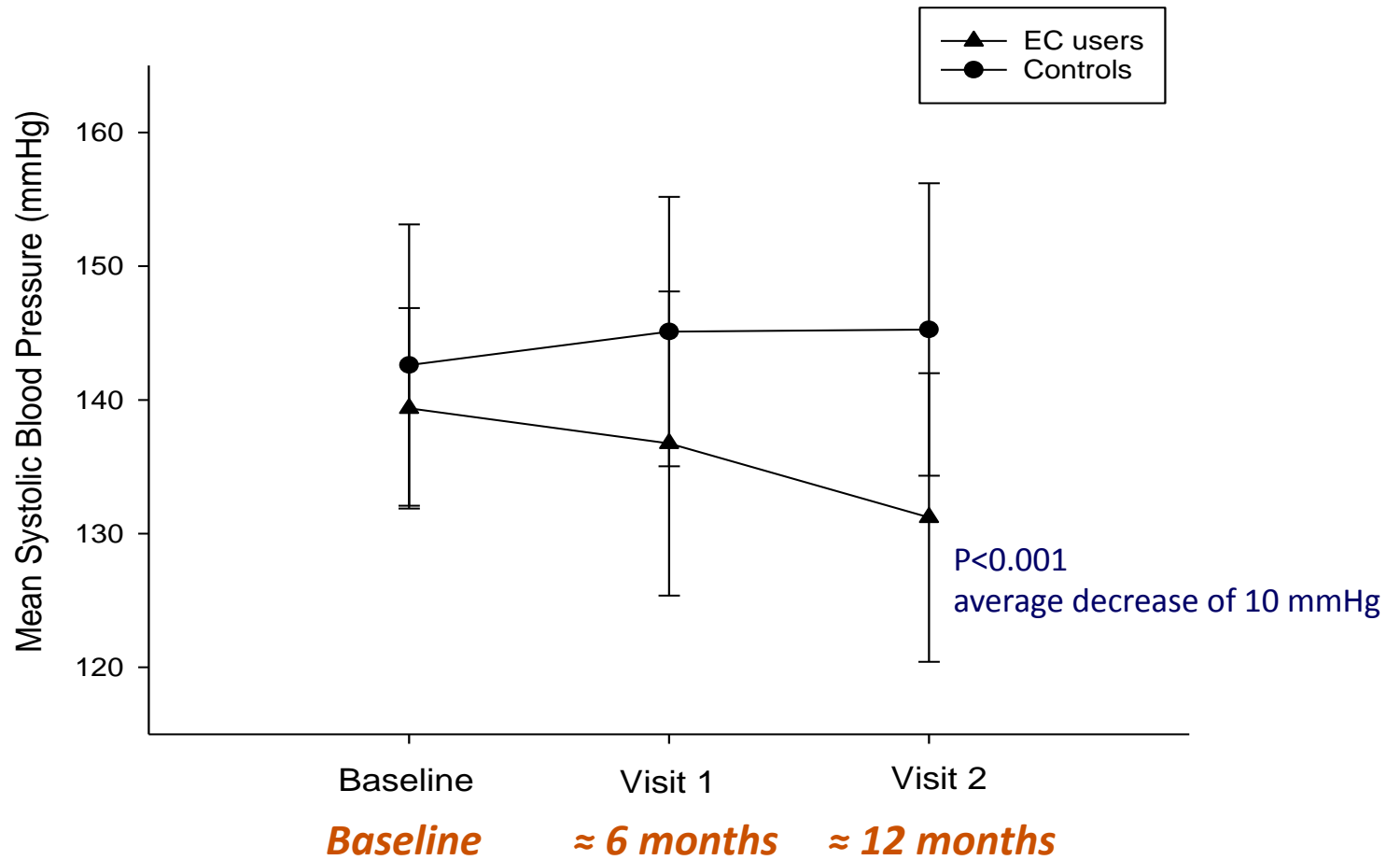


- ECs are effective and safe in RCTs of “healthy” smokers
- Smoking abstinence by using ECs may lower elevated systolic BP
- No data about EC use in smokers with pre-existing disease
- We investigated changes in BP and BP control in smoking hypertensive patients who switched to EC

# Changes in daily smoking from baseline



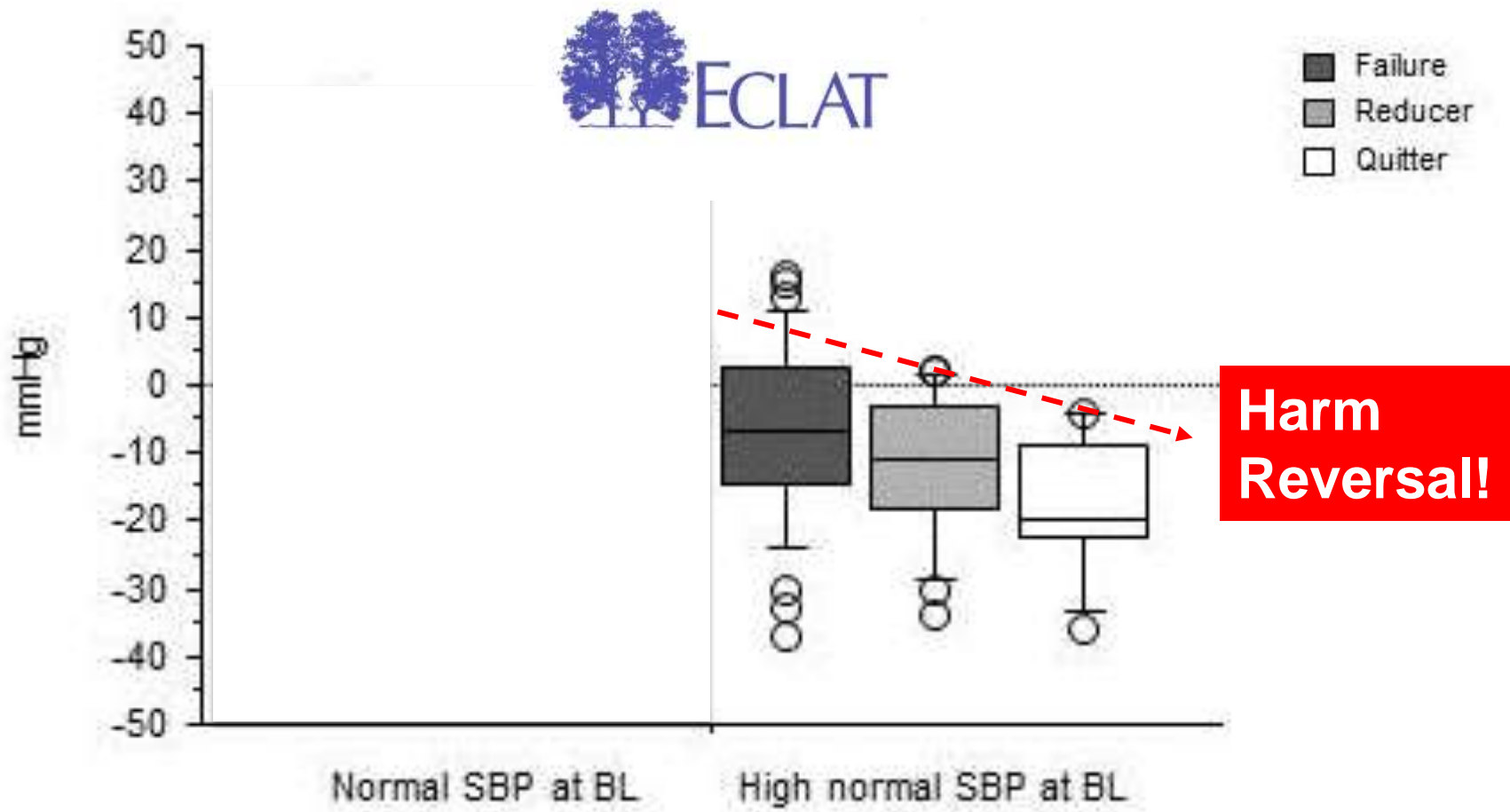
# Changes in SBP from baseline



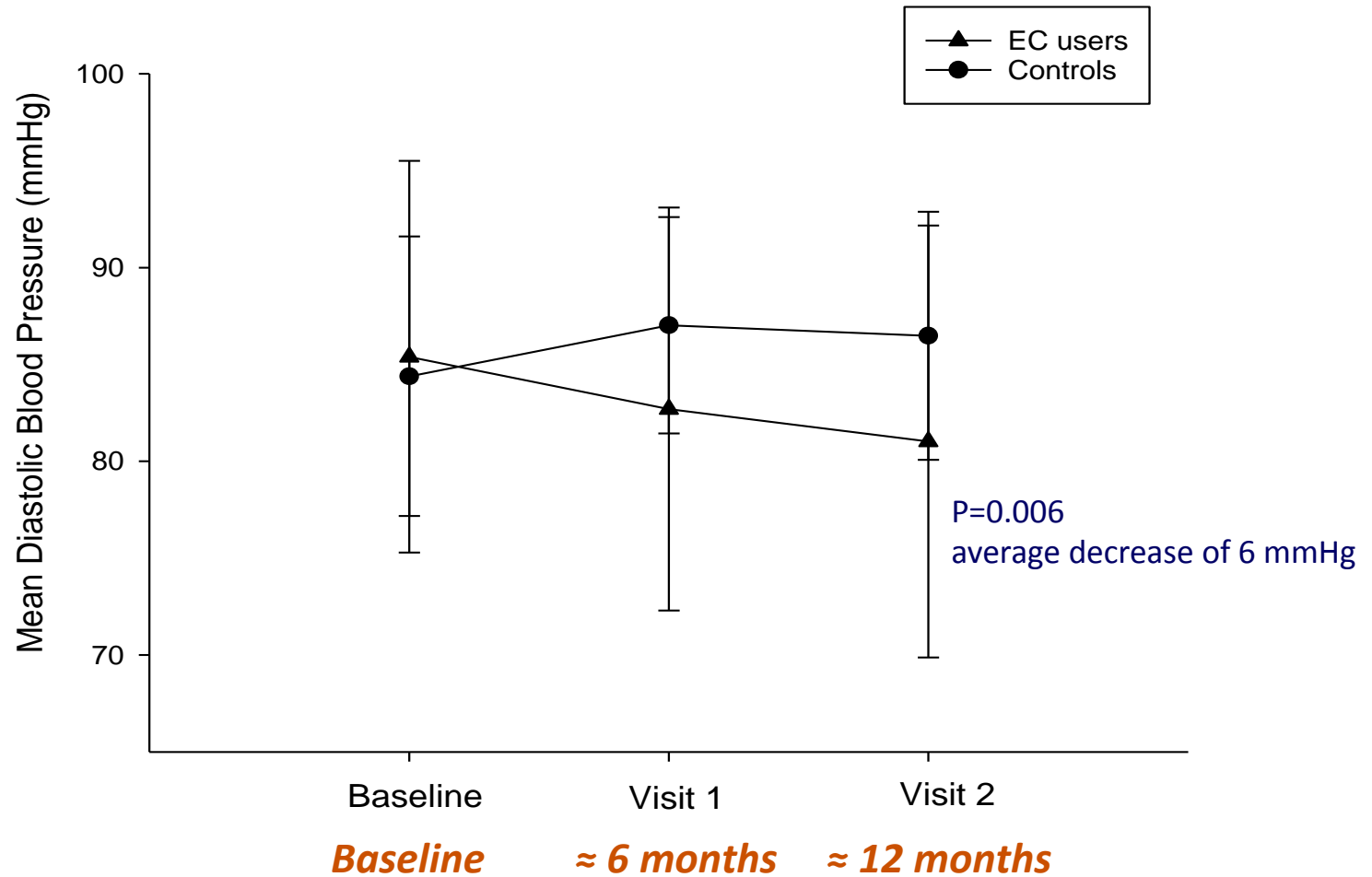


# Chronic Studies: effect on BP in smokers switching to ECs

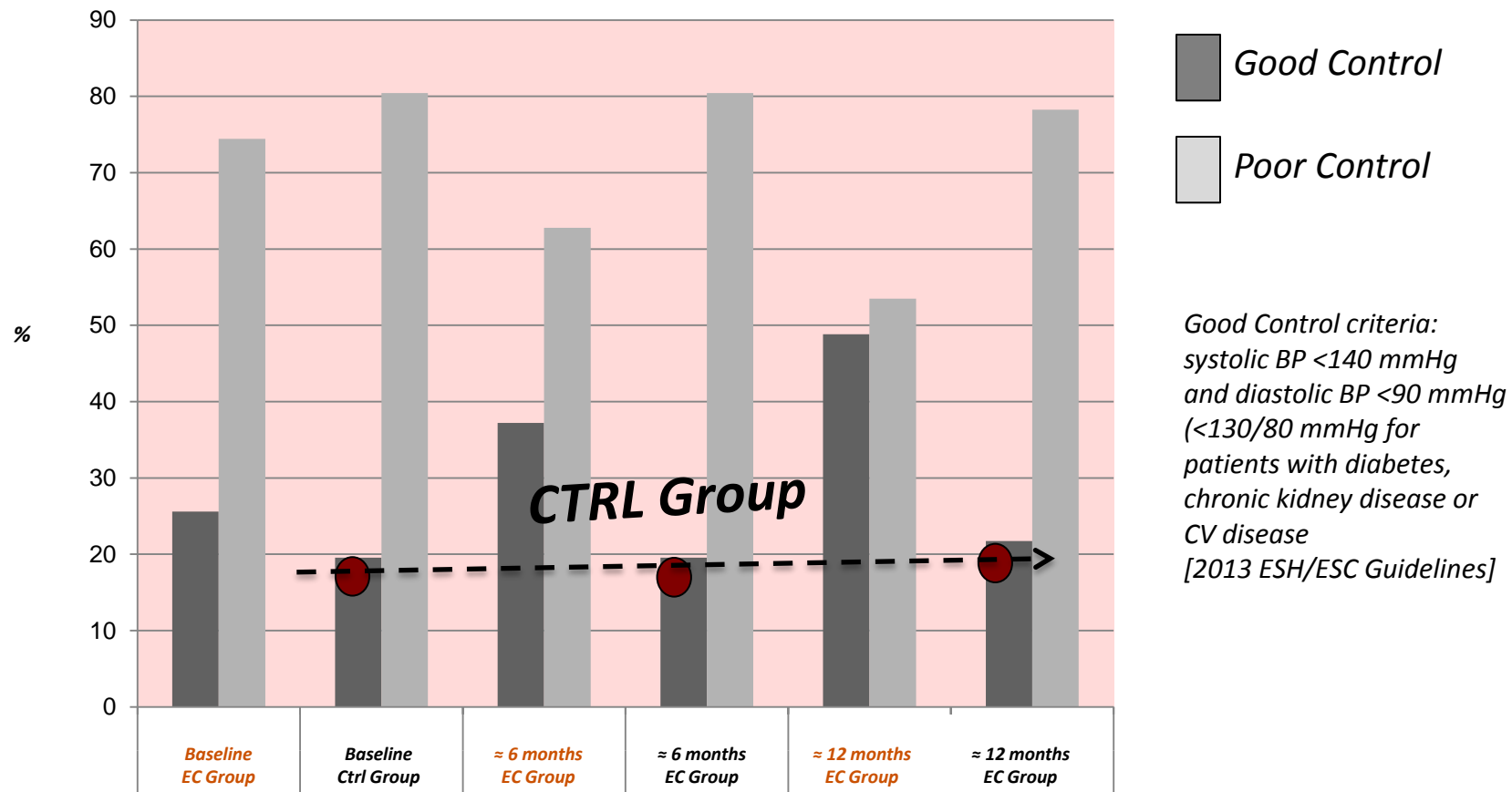
Systolic BP changes at Week 52 from baseline



## Changes in DBP from baseline

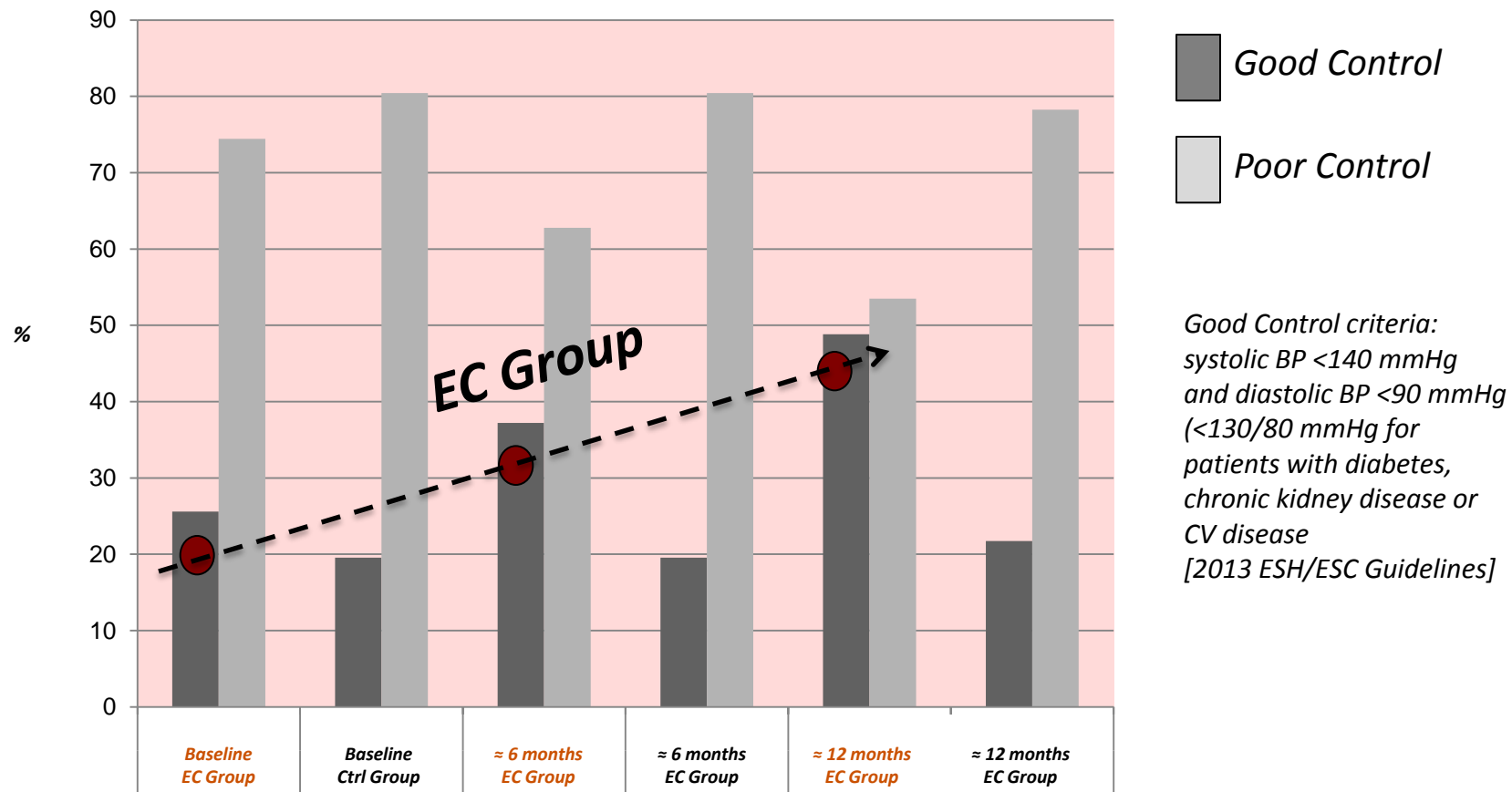


# Proportion of good and poor BP control throughout the study





# Proportion of good and poor BP control throughout the study



# Take Home Message

- Lowered BP and improved BP control in hypertensive patients;
- Improvements also reported in dual users;
- An helpful alternative to cigarettes, even in smokers with hypertension.

# Chronic Studies:

Cardiovascular System

**Respiratory System**

Other



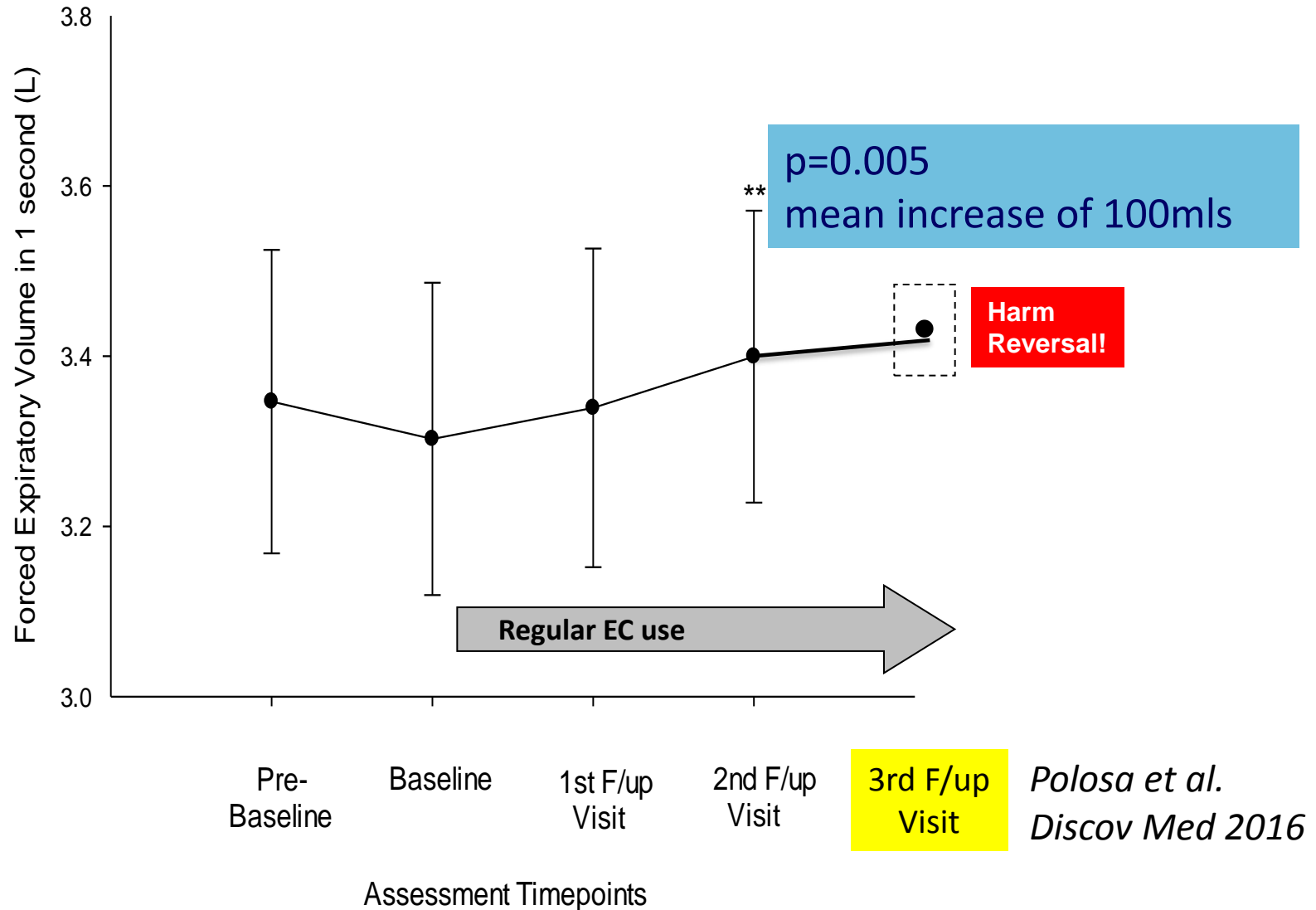
# **Persisting Long Term Benefits of Smoking Abstinence and Reduction in Asthmatic Smokers Who Have Switched to Electronic Cigarettes**

RICCARDO POLOSA, JAYMIN B. MORJARIA, PASQUALE CAPONNETTO, MASSIMO CARUSO, DAVIDE CAMPAGNA, MARIA DOMENICA AMARADIO, GIOVANNI CIAMPI, CRISTINA RUSSO, AND ALFREDO FISICHELLA

- ECs are effective and safe in RCTs of “healthy” smokers
- Smoking abstinence by using ECs may improve respiratory function and symptoms
- No data about EC use in smokers with pre-existing disease
- We investigated changes in subjective and objective asthma outcomes in smoking asthmatics who switched to EC

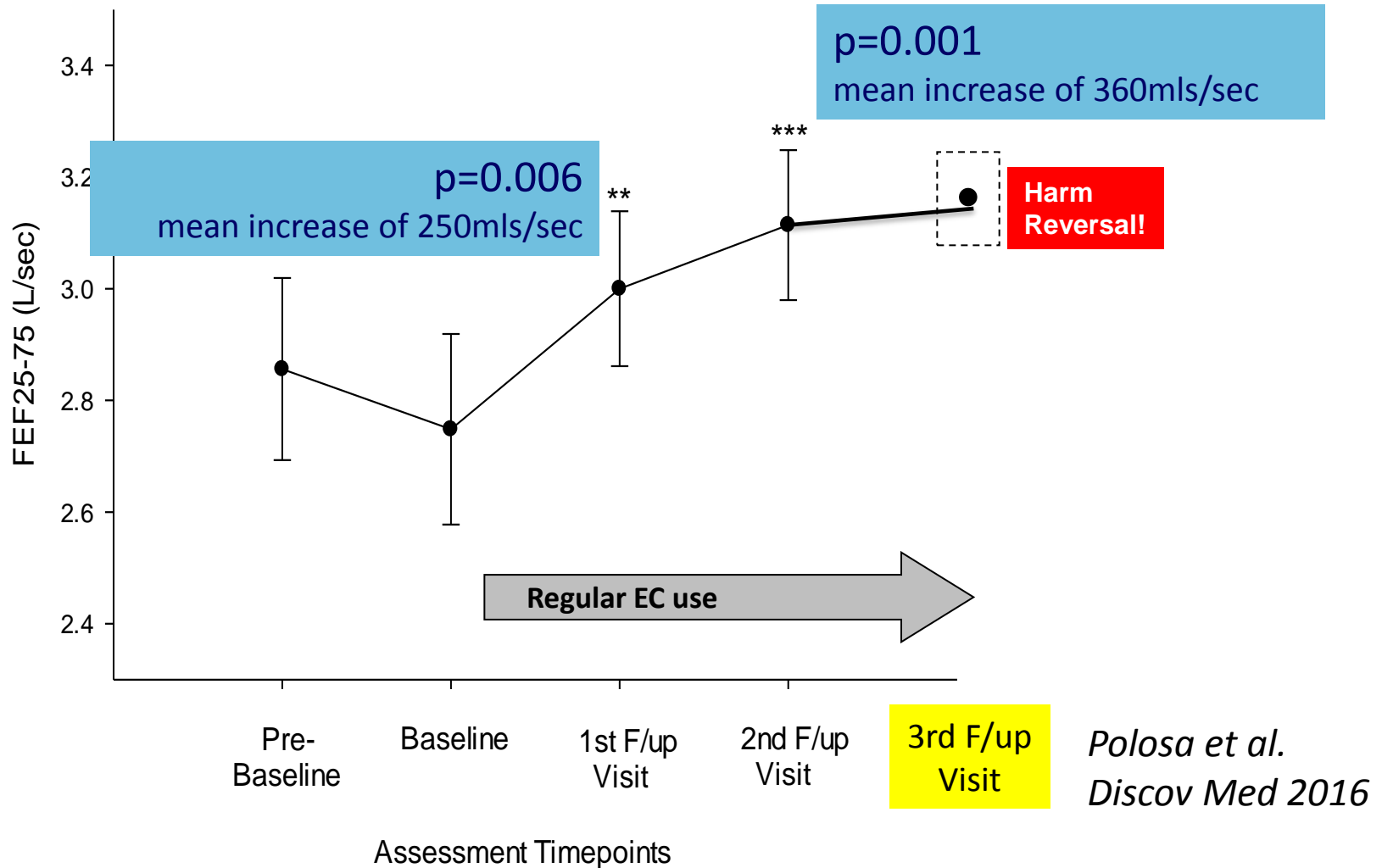
# FEV1

Improvement from baseline to 24 months

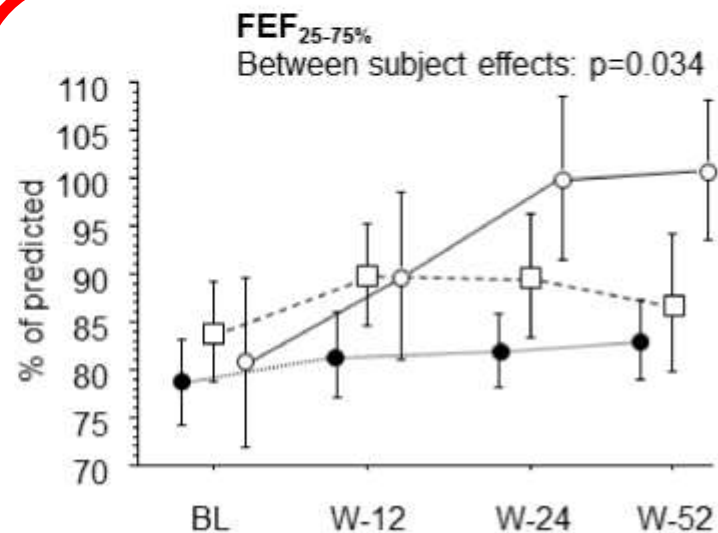
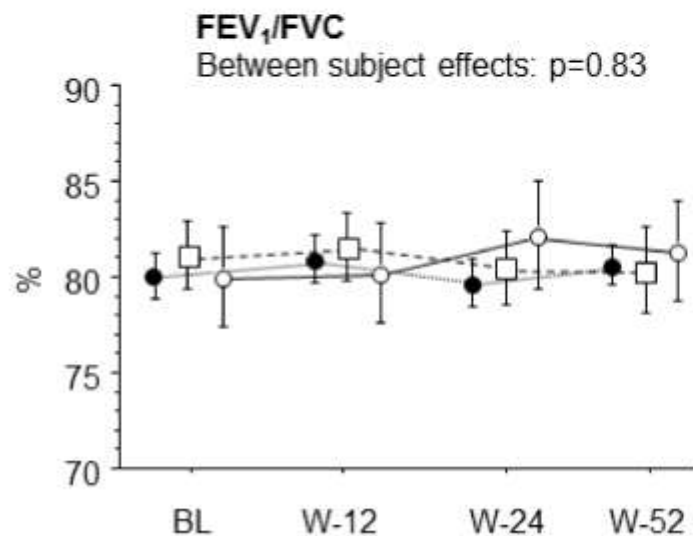
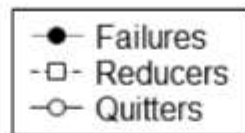
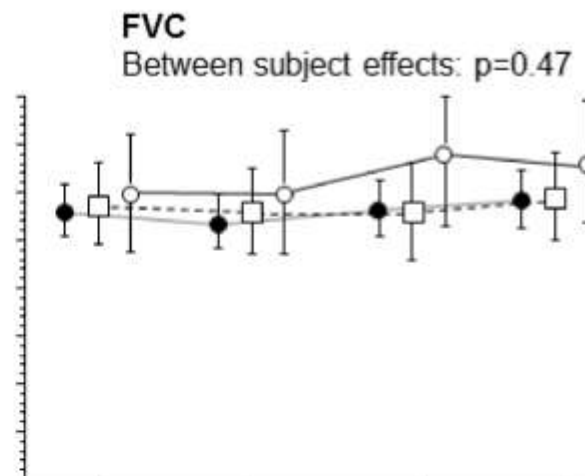
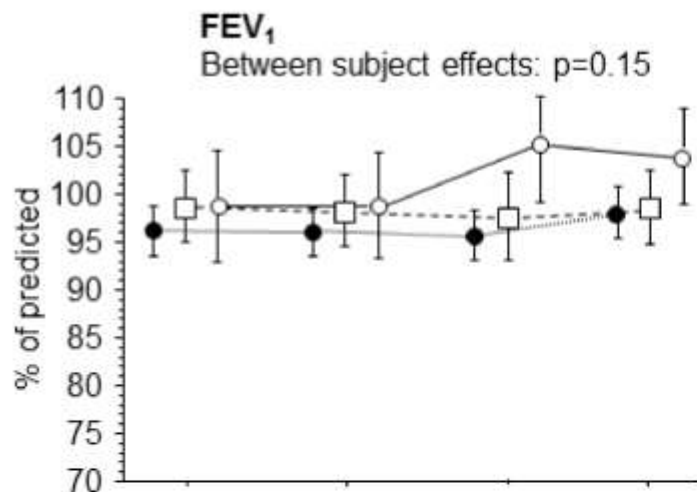


# FEF25-75

Improvement from baseline to 24 months

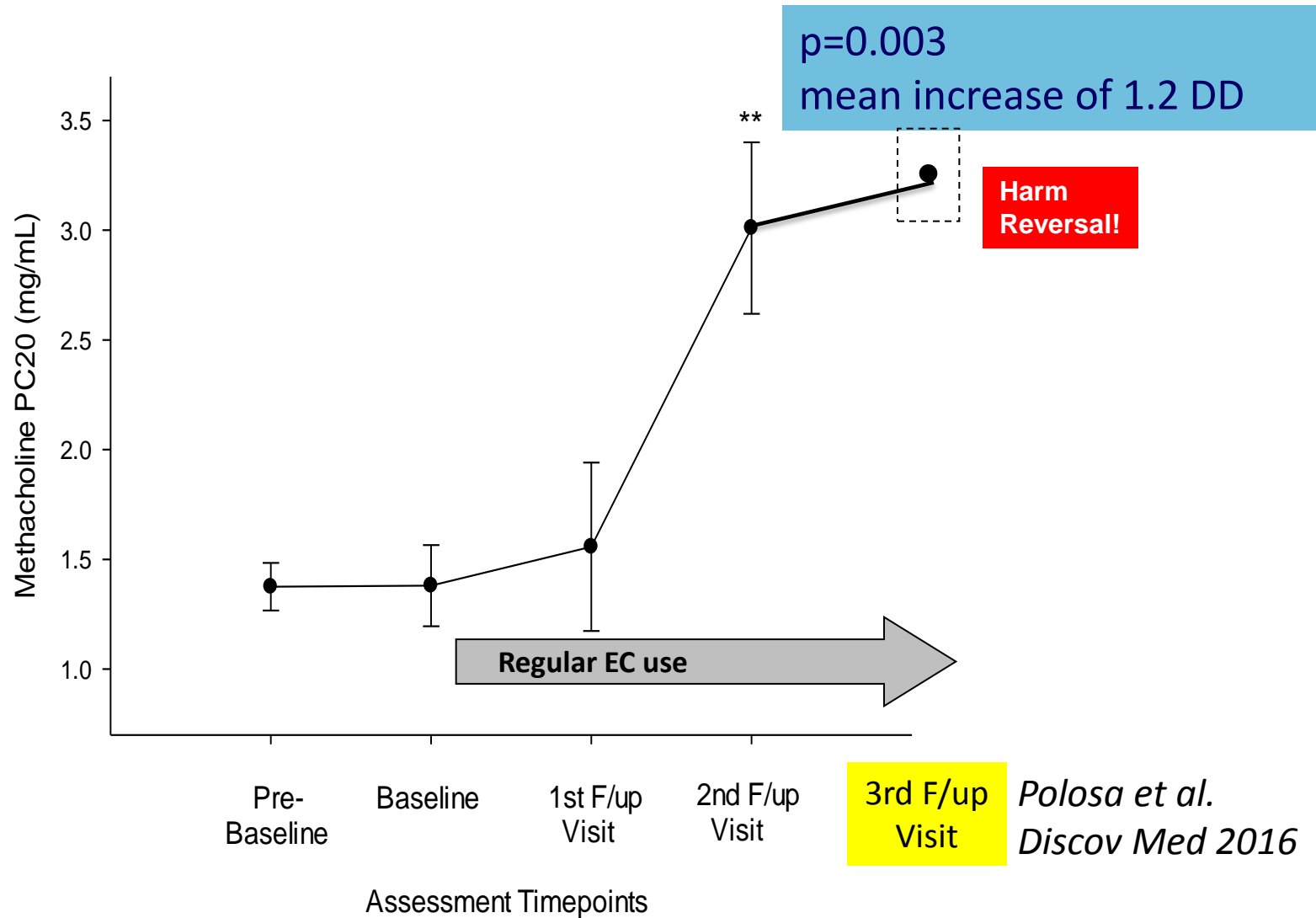


# Chronic Studies: effect on LFT in smokers switching to ECs



# Methacholine PC20

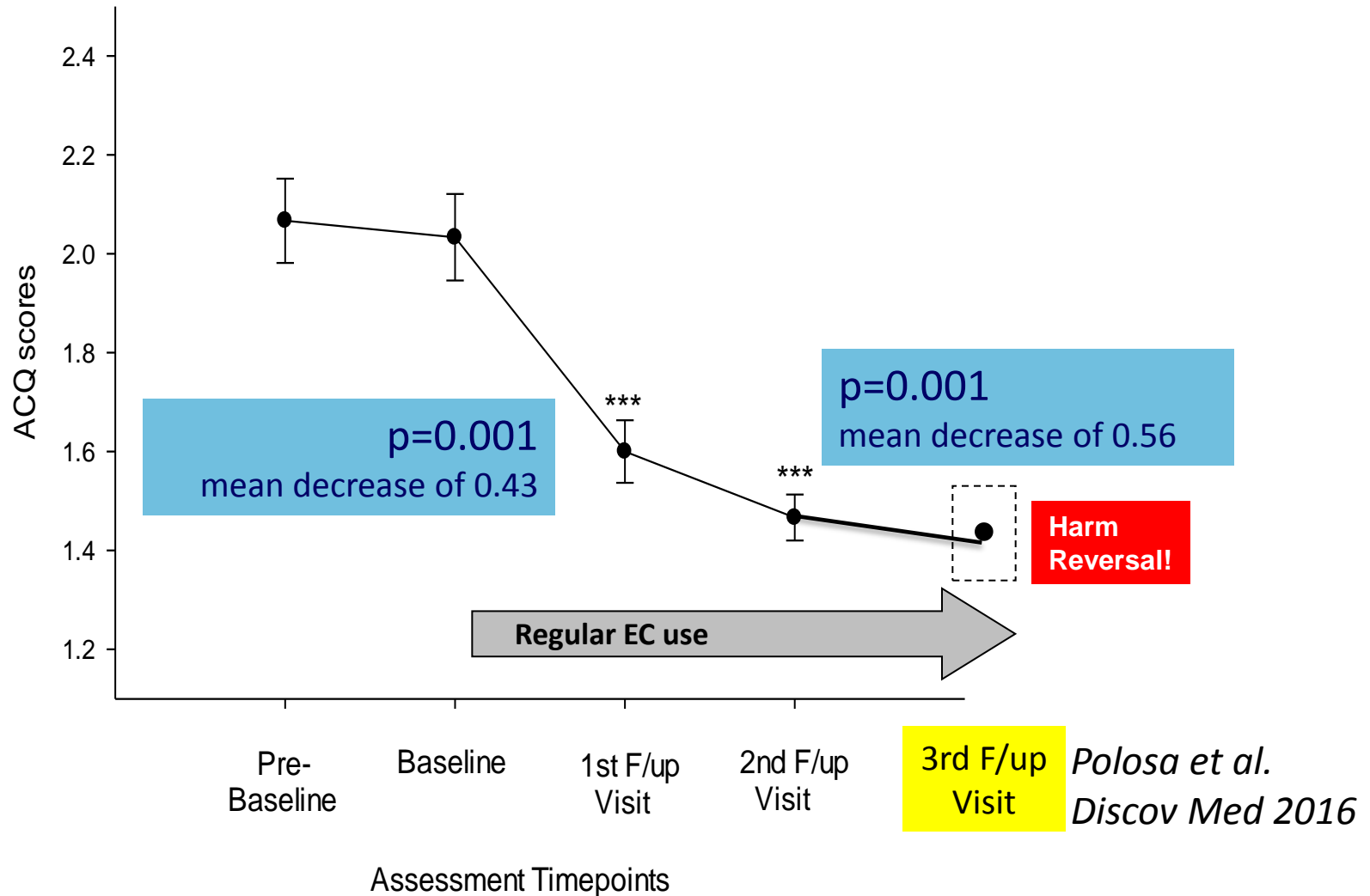
Improvement from baseline to 24 months





# Juniper's ACQ

Improvement from baseline to 24 months



# Vaping and asthma exacerbations

Parameter	Baseline	1 <sup>st</sup> follow-up visit		2 <sup>nd</sup> follow-up visit		3 <sup>rd</sup> follow-up visit w/o relapsers	
	N=18	(6 months) N=18	<i>p value to Baseline</i>	(12 months) N=18	<i>p value to Baseline</i>	(24 months) N=16	<i>p value to Baseline</i>
Cigarettes/day	21.9 (±4.5)	5.0 (±2.6)	<0.001	3.9 (±1.0)	<0.001	3.5 (±1.22)	<0.001
Exacerbations	1.17 (±0.9)	0.87 (±0.7)	0.296	0.78 (±0.7)	0.153	0.81 (±0.66)	0.190

Frequent exacerbators (≥ 2 exacerbations; n=6) halved their exacerbations at both follow-up visits

Exacerbation rate increased from 0 at 12 months to 2 at 24 months in the two patients relapsing to tobacco smoking

# Take Home Message

- Improved lung function, respiratory symptoms, subjective/objective asthma outcomes;
- Improvements also reported in dual users;
- EC use unlikely to warrant significant respiratory concerns;
- An helpful alternative to cigarettes, even in smokers with asthma/COPD.

# Health effects of vaping: Emerging Views

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**Negative Aspects**

**Minimize Risk**



**Positive Aspects**

**Maximize Benefit**

Janus head. Terracotta sculpture, from Vulci, II century BC (Rome, National Etruscan Museum of Villa Giulia).

## The Demise of the Traditional Cigarette is Long Past Due.

Traditional Cigarettes have been essentially the same since 1881 when James Bonsack invented the cigarette-making machine. Cigarettes may have changed over the years, but they have not progressed much.

# NOT ADAPTABLE



Source: An 1892 Duke of Durham box of machine-rolled cigarettes, [healthliteracy.worlded.org](http://healthliteracy.worlded.org)

*"Change Is Inevitable,  
but Progress Is Not"*

## Vaping is an Idea Whose Time Has Come.

Vaping is an idea whose time has come. I'm not surprised that the vaping phenomenon is here, but I am surprised that it took so long to get here. The adaptability of vaping technology will allow it not only to survive, but to thrive.

# EXTREMELY ADAPTABLE



3D Printed Mod

Source: [facebook.com/vapermod](https://www.facebook.com/vapermod)



Source: [super-smoke.com/bluetooth](http://super-smoke.com/bluetooth)

### Gamucci Launches New Scientific Products Division to Lead e-Cig Industry in Innovation and Quality

Gamucci Electronic Cigarettes are sold in 55 countries worldwide.