Quality of life in severe bronchial diseases

Pascal Chanez
Dept des Maladies Respiratoires
INSERM U454
CHU Montpellier France

HQOL and severe bronchial diseases

- Definitions
- Why HQOL in bronchial diseases ?
- New avenues ?
- Use in a routine setting ?

Asthma

GINA Guidelines 2001

«Is a chronic inflammatory disorder of the airways.Chronically inflamed airways lead to an increase in airway hyperresponsiveness with recurrent episodes of wheezing, coughing and shortness of breath, widespread, variable, and often reversible airflow limitation »

COPD

GOLD R.Pauwells et al AJRCM 2001

« Is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases »

Severe Asthma ?

Difficult Asthma
ERJ 1999

Refractory Asthma
AJRCCM 2000

GINA
National Guidelines
?????

ENFUMOSA BIOAIR /NHLBI Initiatives

Severe asthma

1- Real asthma responsive to bronchodilators or short course of oral corticosteroid (no other diagnosis, no compliance issue) life long non smokers or less than 5pq/yrs stopped more than 5 yrs before

2- Follow-up by a specialist for at least one year and compliance to treatment considered to be fair.

3- Asthma symptoms not controlled. At least one asthma exacerbation necessitating an hospitalization within the past year, daily symptoms requiring rescue medications

4- High doses of inhaled corticosteroids(2000µg of BDP eq) and LAß2(SMR or FMR), and SAß2 as required

5- On top of this treatment, a dose of Prednisone is sometimes required to avoid recurrence of severe exacerbations

6- Despite this treatment some patients remain uncontrolled.

Health outcomes in bronchial diseases

Physician view point

- **Clinical**: (daily symptoms, control, exacerbations,hospitalisations, ICU)
- **Functional**: (baseline airflow impairment,
- reversibility, BHR,Variability of PEFR)
- **Therapeutical**: (lowest quantity of drug to
- control, risk-benefit ratio, resistance)
- **Economical**: (productivity at work, at school !!,
- duration of sick leaves, lowest cost of disease)

Health outcomes in bronchial diseases

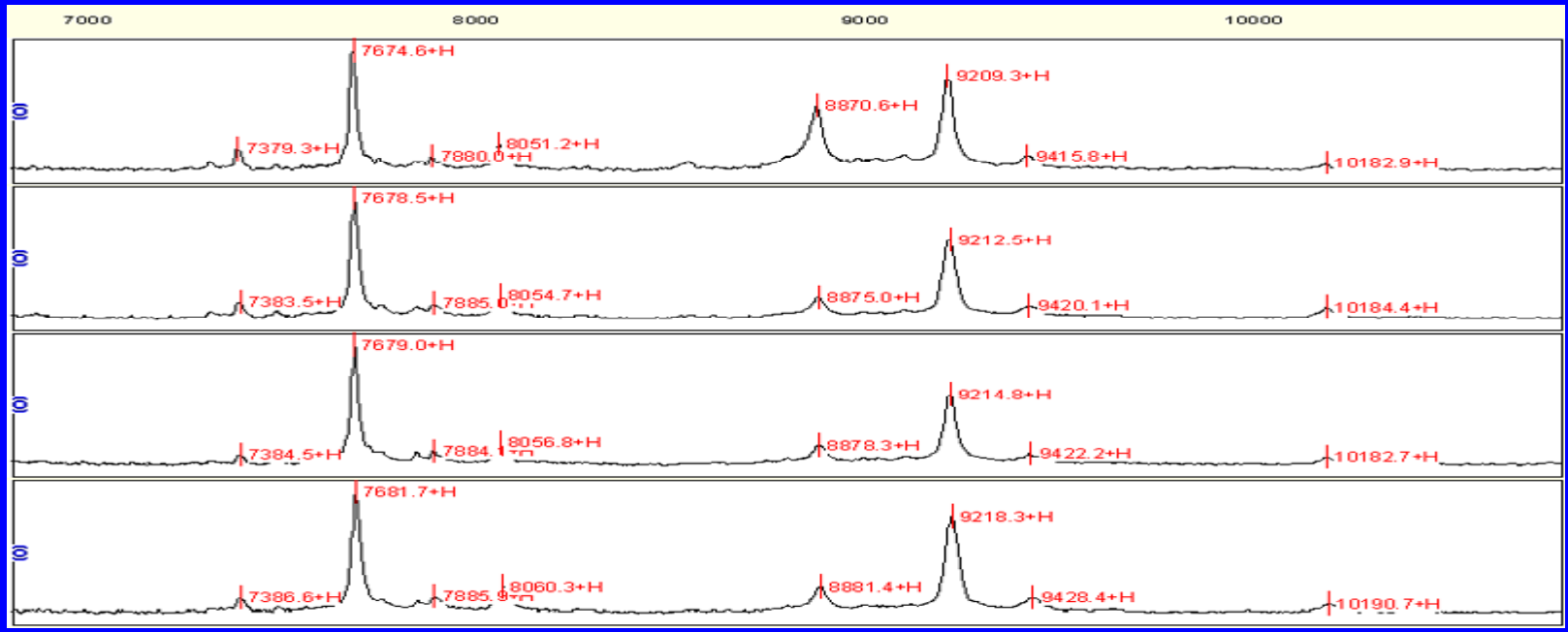
Physician view point : Future

- **Biomarkers :**
- Blood markers: ECP?
- Exhaled NO, Exhaled air condensates: mediators
- Temperature of the airways
- Sputum eosinophils and mediators
- Urine mediators
- **Morphological features:**
- Imaging CT-scan, MRI…..

Health outcomes in bronchial diseases

Physician view point:Future, future

Proteomic analysis of BAL fluid



Diagnosis, Follow-up, best therapeutic strategies…

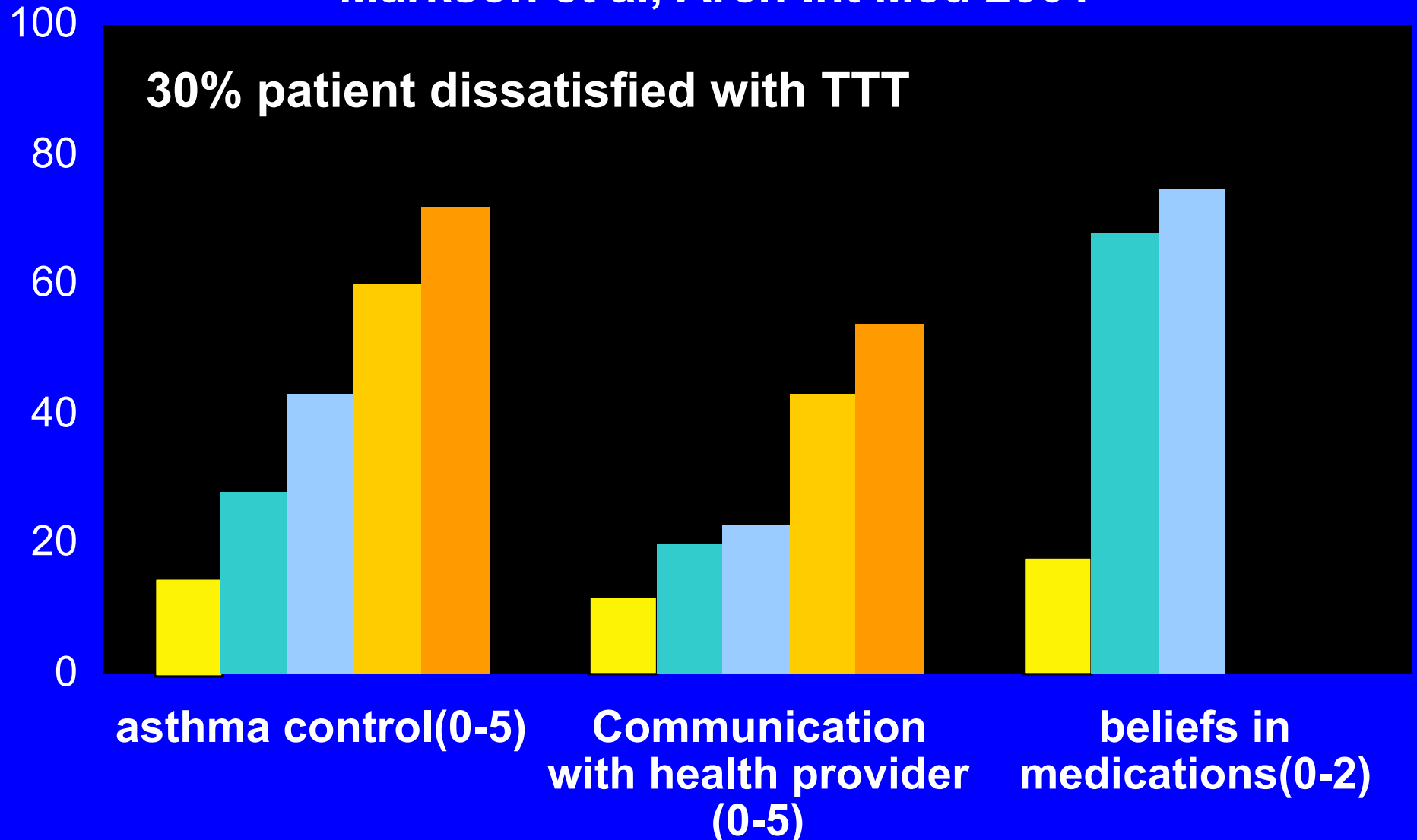
Health outcomes in chronic bronchial diseases

- Patient perspective :

- Overall satisfaction
- Symptom free days
- **Quality of life**

Modifiable factors associated with dissatisfaction with asthma treatment

Markson et al, Arch Int Med 2001



Patients Perspectives

Bronchial diseases are chronic diseases that can place considerable restrictions on the physical, emotional and social aspects of the lives of patients.. Many patients including the most severe, may not completely appreciate the impact of the disease on their social life and claim they lead "normal" lives because normality may be based on adjustements and restrictions they have already incorporated into their lifestyles or alternatively because they mask their restriction wanting to "live like others"

HQOL and severe bronchial diseases

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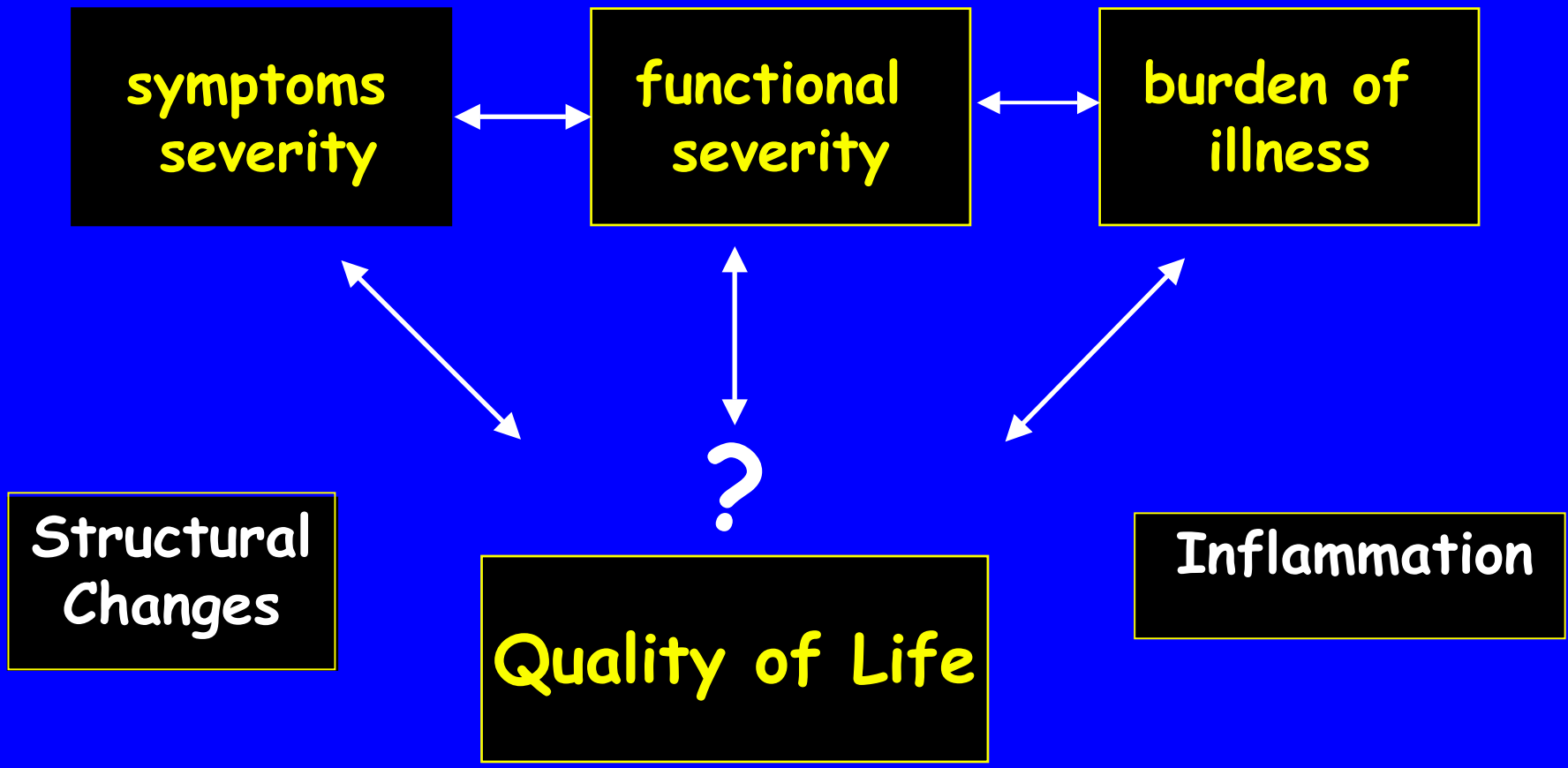
- New avenues ?
- Use in a routine setting ?

Severity of a chronic disease

adapted from Stein et al Lancet 1987



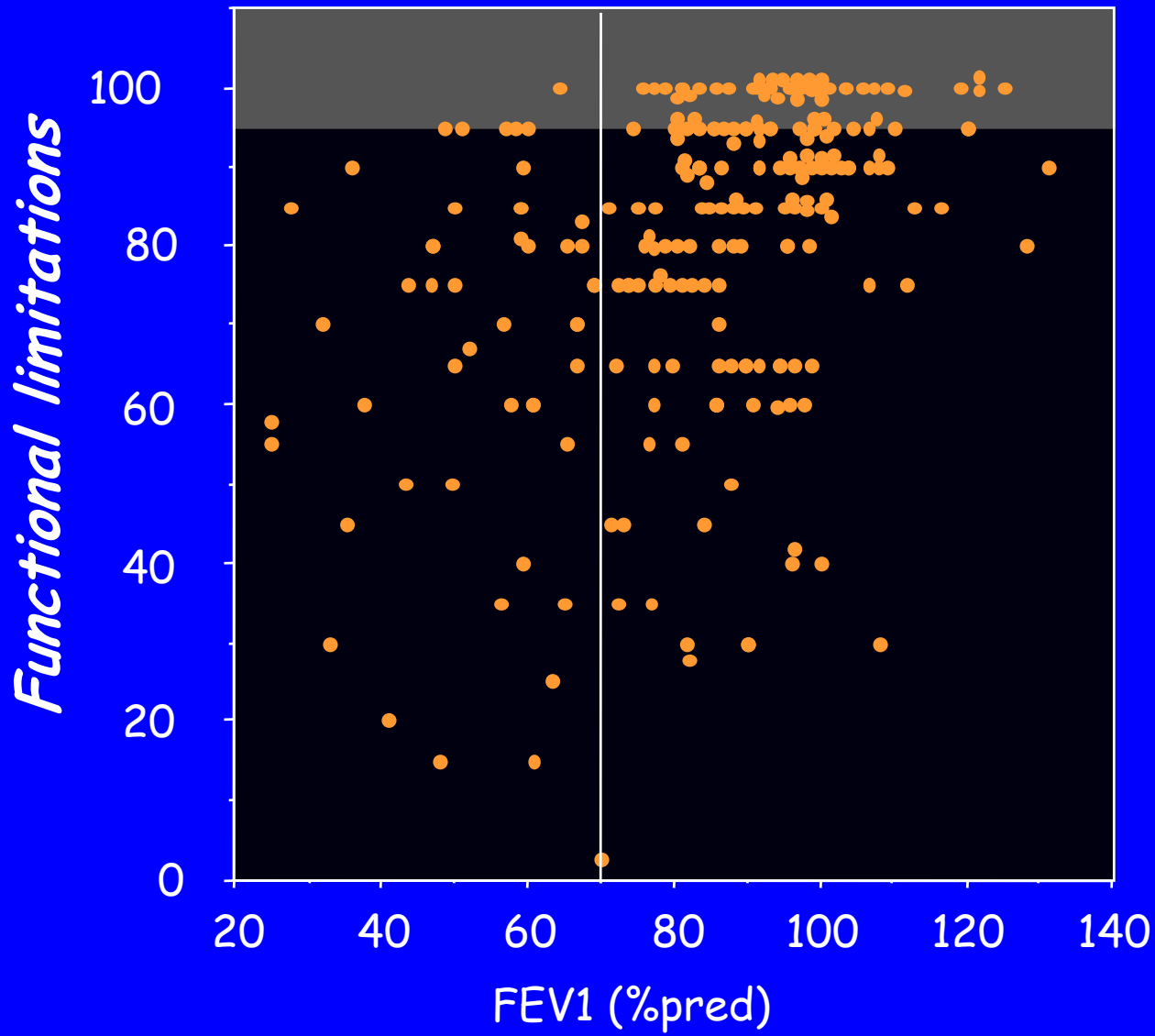
What is Quality of life ?

"Quality of life (QOL) is a concept including a large set of physical and psychological characteristics for assessing problems in the social context of life style "

Walker & Rosser 1987

Functional Limitation and FEV1(SF- 36)

Bousquet et al AJRCCM 1996

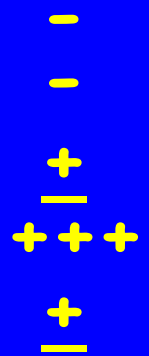


Predictors of overall HQOL by asthma severity

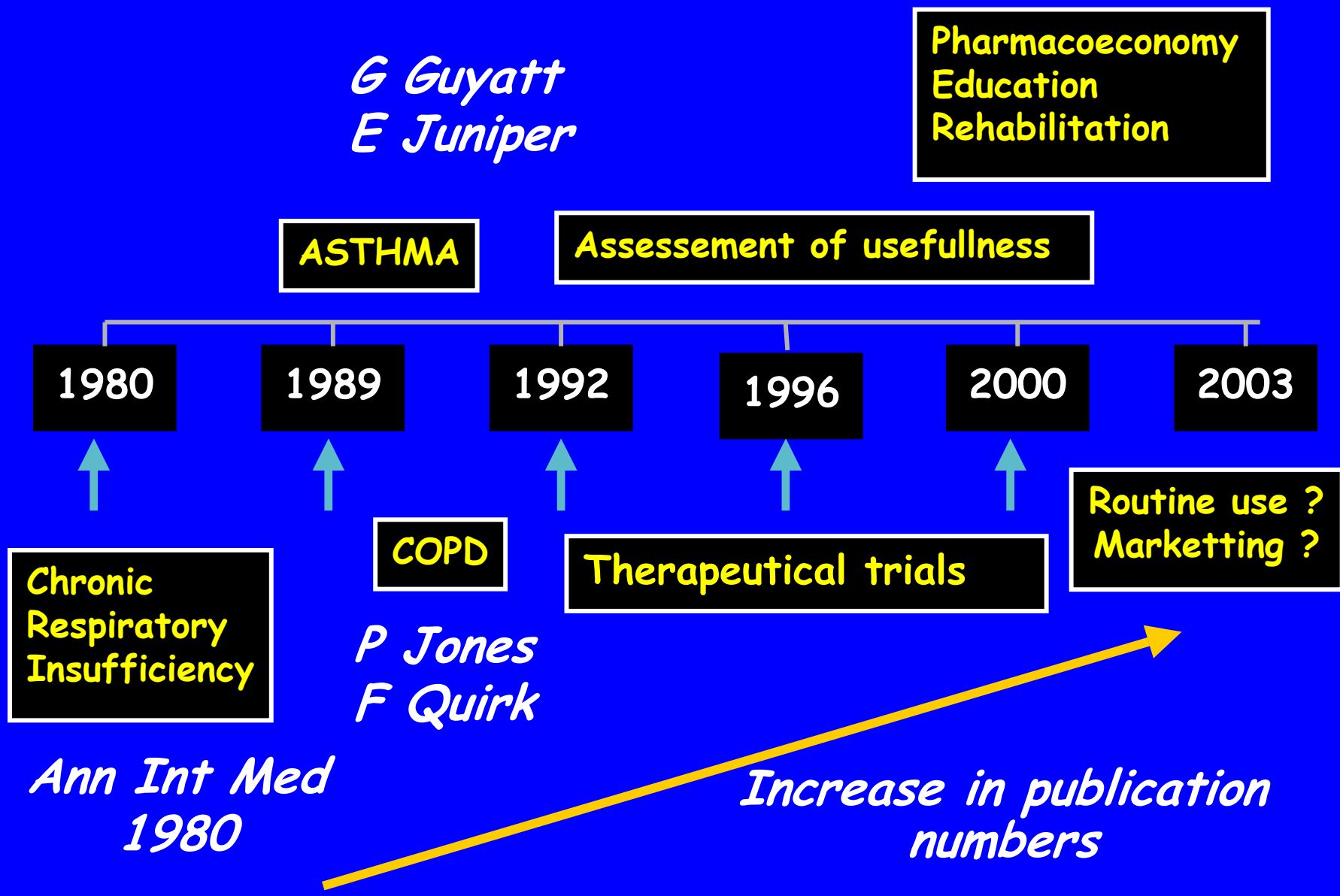
Moy et al AJRCCM 2001

253 and 359 asthmatic patients in 2 trials
AQLQ retrospective analysis
Lung function is not a predictor of HQOL

	Albuterc		ZiLeuto base		Zileutor final	
FEV1	0.08	NS	-0.09	NS	0.184	NS
AMPF	-0.0001	NS	0.0003	NS	-0.0003	NS
ß2 prn	-0.1393	0.02	-0.0057	NS	-0.06	0.01
SOB	-0.75	0.0001	-0.2	0.03	-0.858	0.001
Wheez	-0.376	0.03	-0.169	NS	-0.026	NS



Quality of life and Bronchial Diseases

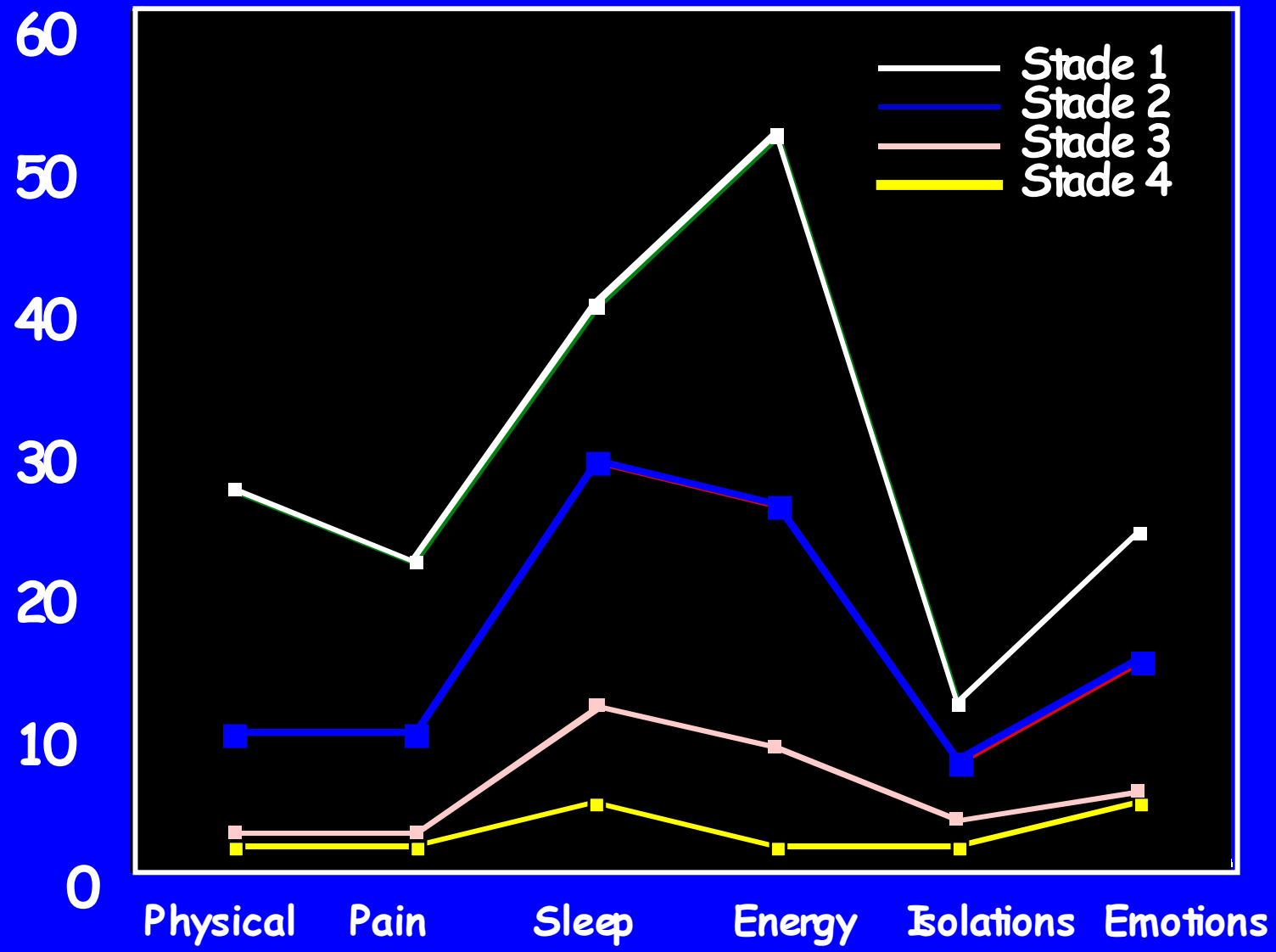


HQOL
Generic Questionnaires

- Population based
- Different chronic diseases
- Wide array of HRQL domains (side-effects)
- SIP, NHP, SF-36
- Not sensitive enough for a specific disease
- Lack of responsiveness for changes

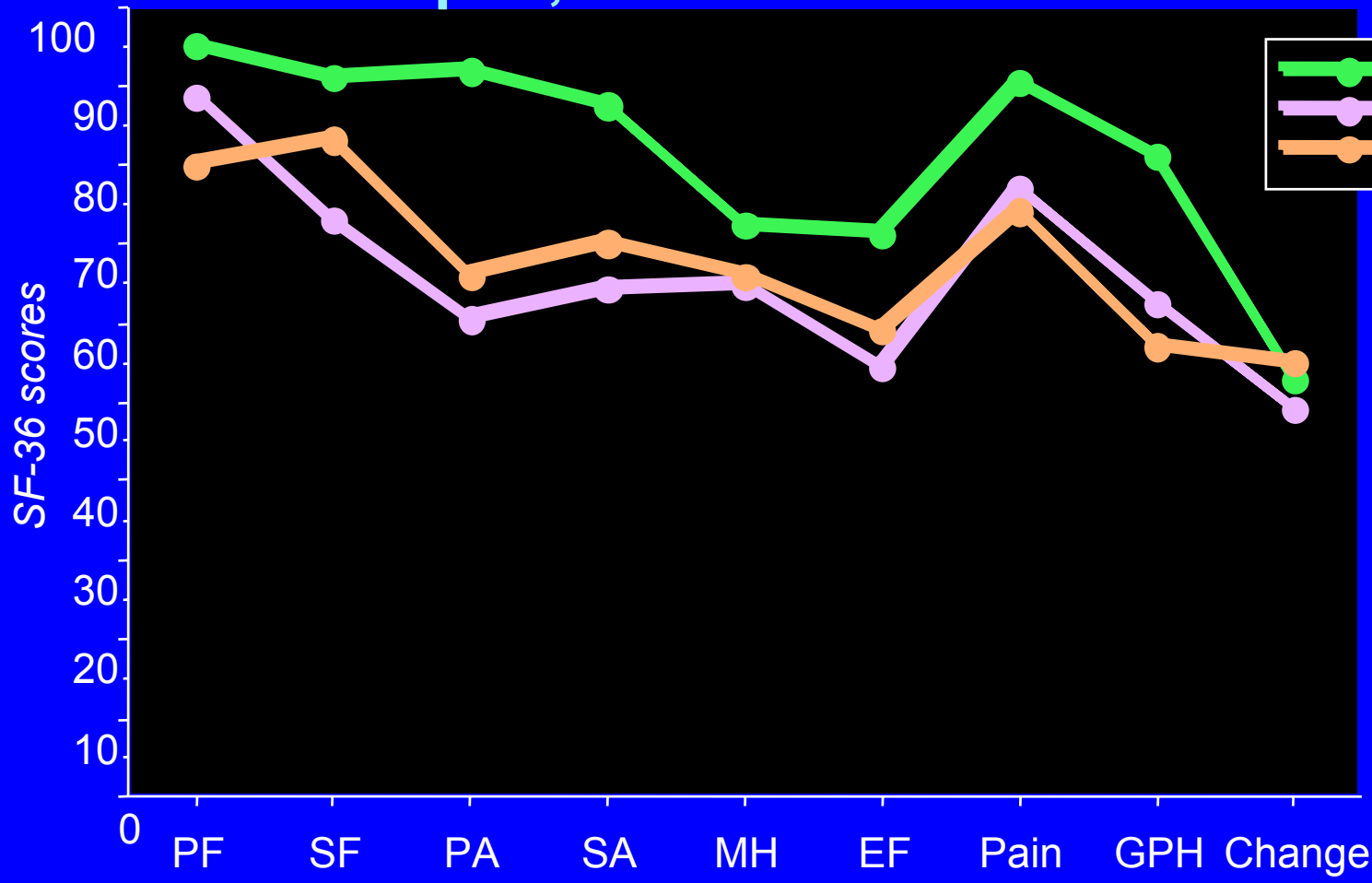
NHP and Asthma Severity

Godard et al ERJ 2002



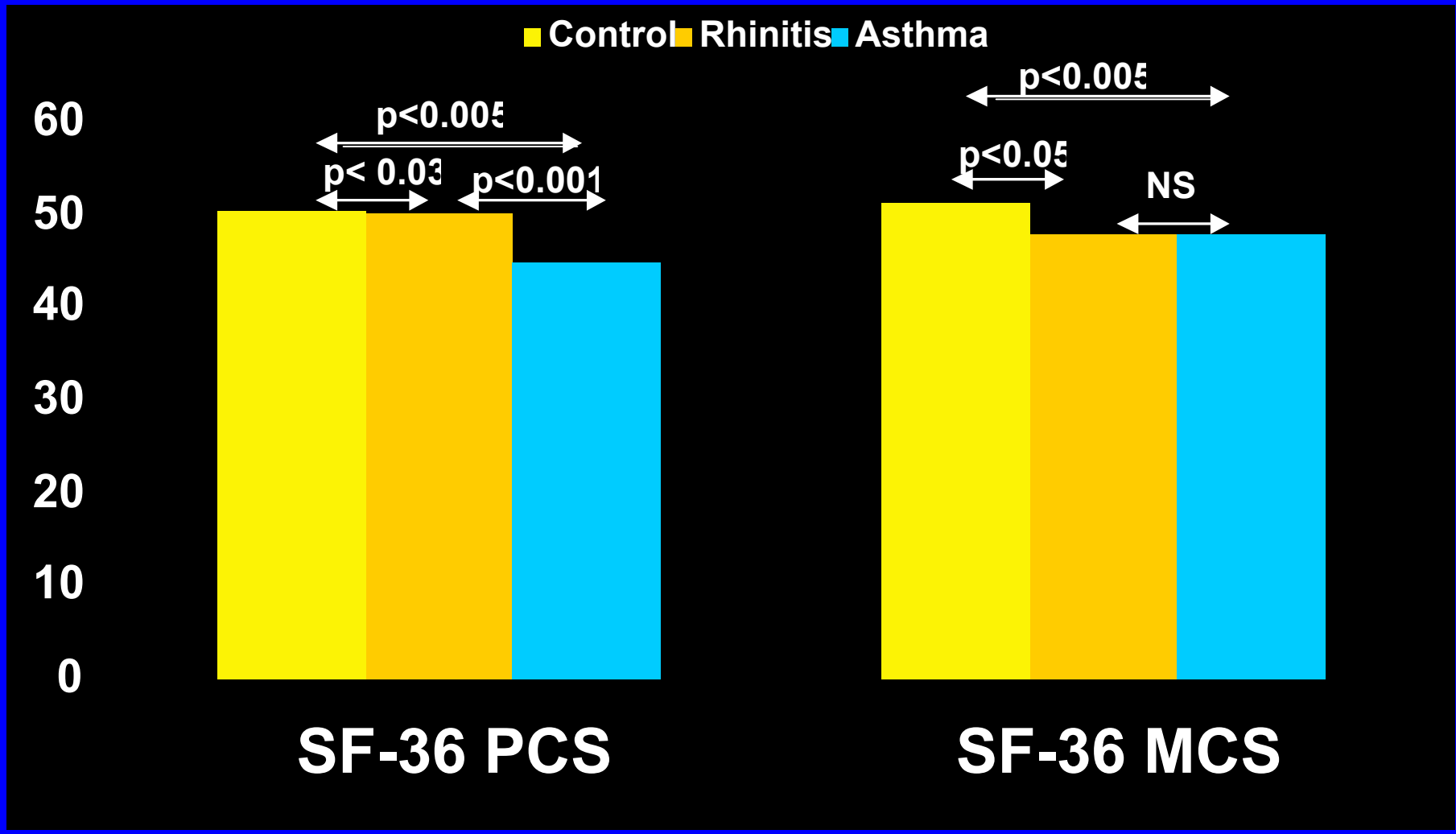
Comparison of non specific SF-36 QOL in asthma and rhinitis

J. Bousquet, JACI 1994 et AJRCCM 1994



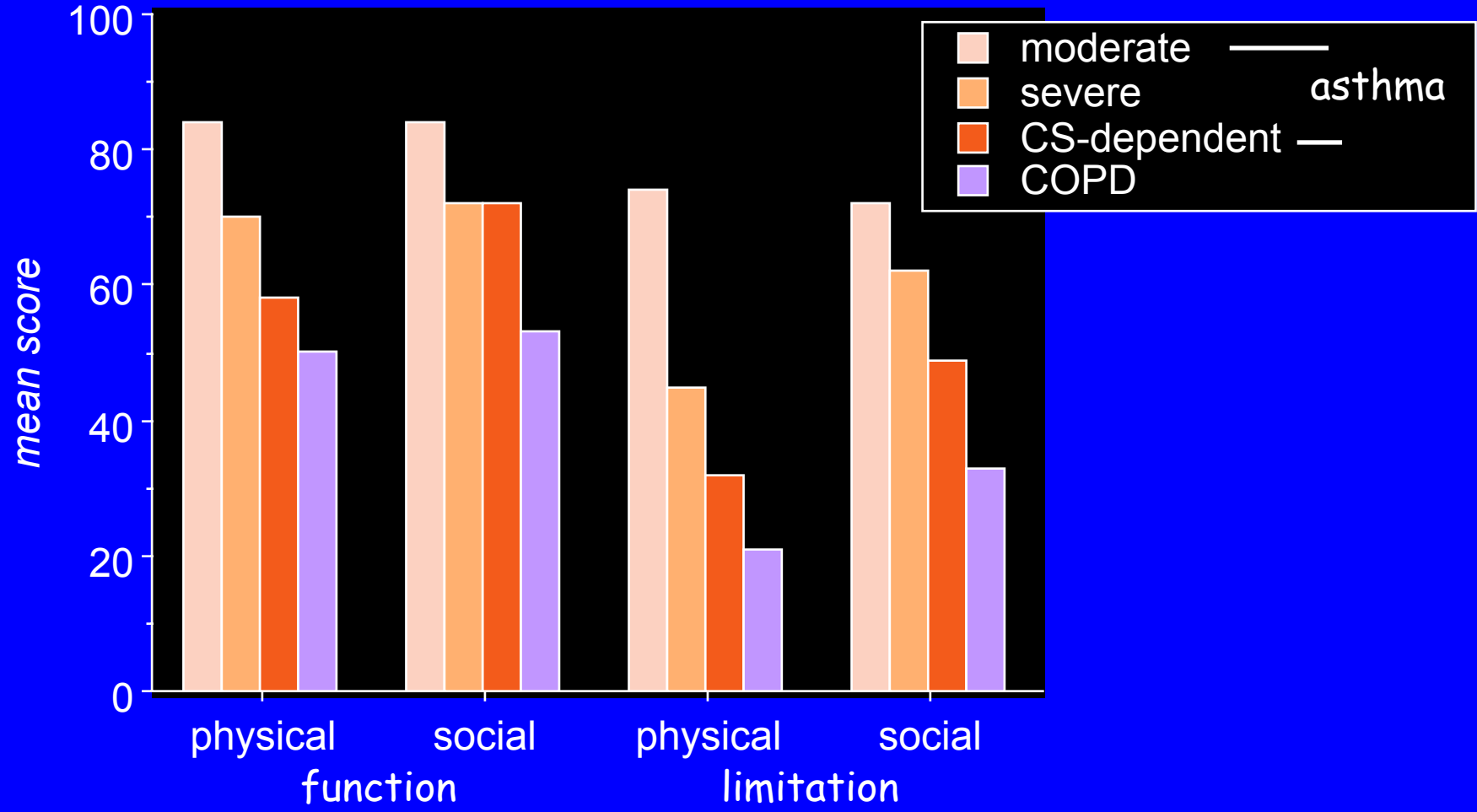
HQOL in asthma and rhinitis

Leynaert et al AJRCCM 2000



Quality-of-Life in asthma and COPD (SF-36)

Bousquet, Richard, Chicoye et al



HQOL
Disease-Specific Questionnaires

- Domain mostly relevant to the respiratory impairment
- Asthma, COPD, Lung failure…..
- Responsiveness to interventions (trials)
- AQLQ, SGRQ, MaugeriFoundation...
- No comparison with normal ?
- No comparison with other chronic conditions ?

Quality of life: Specific Questionnaires

derived from Mapi research InstituteWeb site

Name	Administration	Author	Disease	Nb items	Nb translation
AQLQ	Auto,Inter, Phone, enet ?	Juniper	Asthma adult	32	38
SGRQ	Auto	P.Jones	Asthma COPD	50	41
KASE-AQ	Auto	J.A.Winder	Asthma	60	0
miniAQLQ	Auto,	E.Juniper	Asthma	15	16
QLQ-asthma	Inter	DT. Brown	Asthma	20	0
BPQ	Auto	ME. Hyland et al	COPD	10/33	3

Properties of the questionnaires

- **Responsiveness:** ability to detect changes within patients even if they are small
- **Cross sectional and Longitudinal validities:** appropriate correlations and changes in established health status measures
- **Reliability:** High/ratio variance between patients vs variance within patients

Properties of the questionnaires

Clinical validity?

Threshold ?

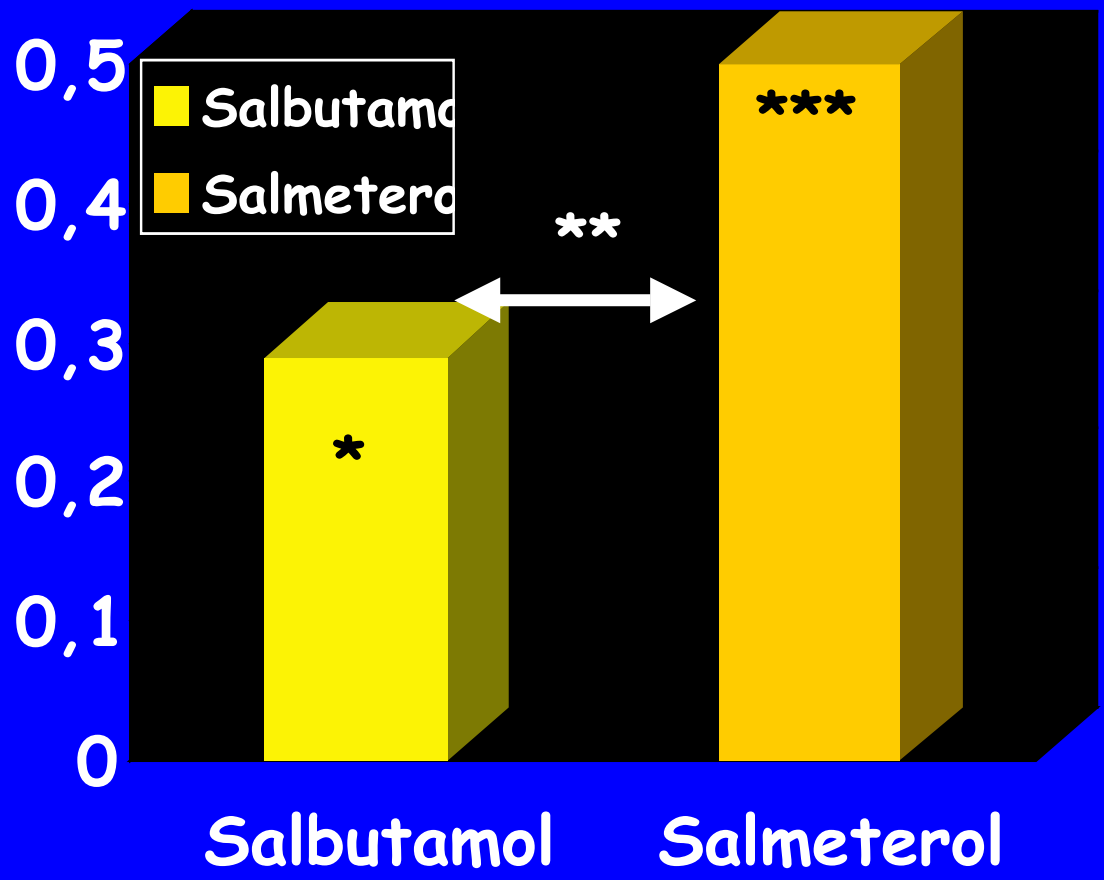
Doctors or Patients ?

AQLQ: 0.5

SGRQ: 4

AQLQ Changes

Rutten van Molken et al ERJ 1995

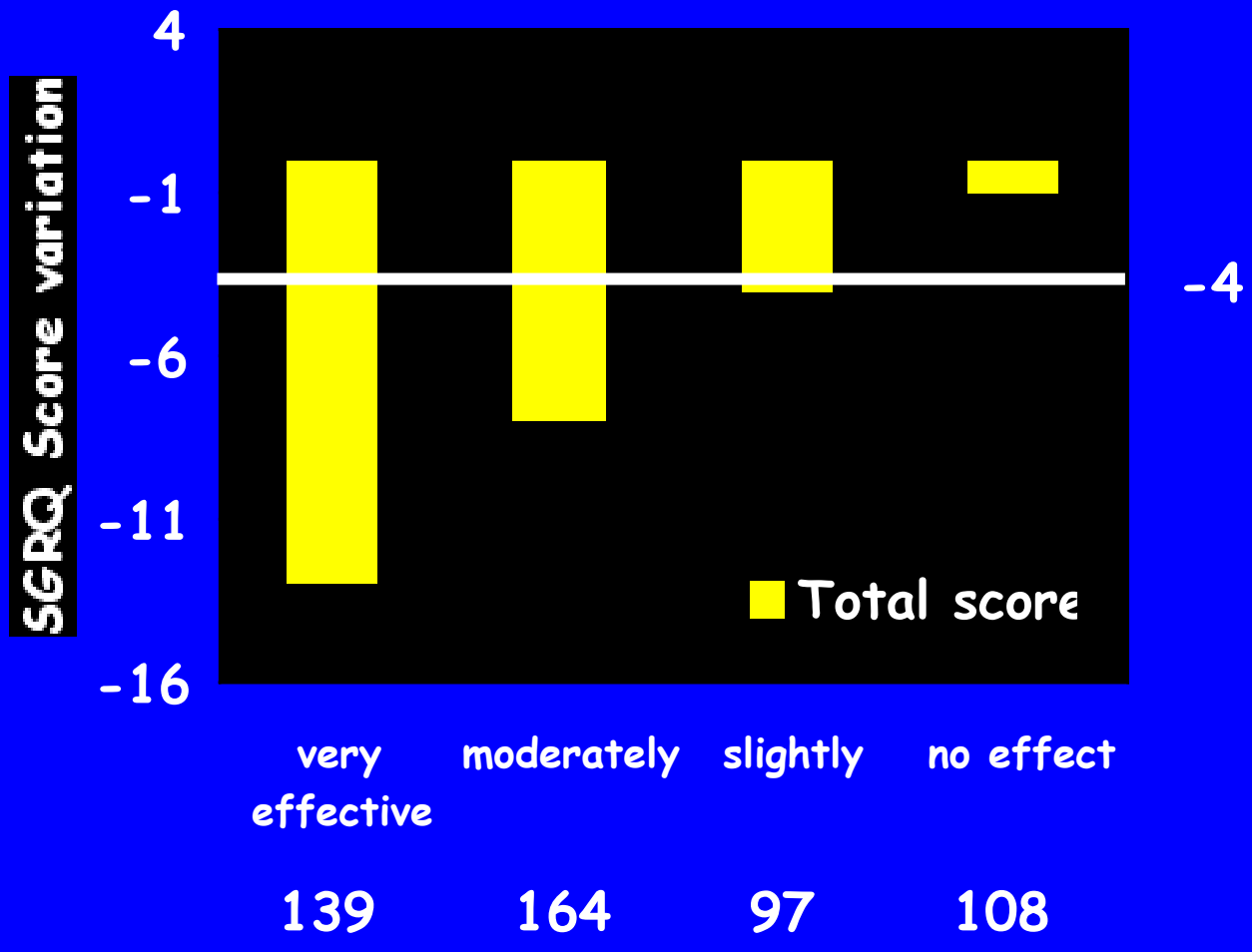


* p from <0.03 to
* * * < 0.001

0,49 when threshold is 0,50

SGRQ Changes

Jones et al ERJ ,Am J Respir Dis 1994

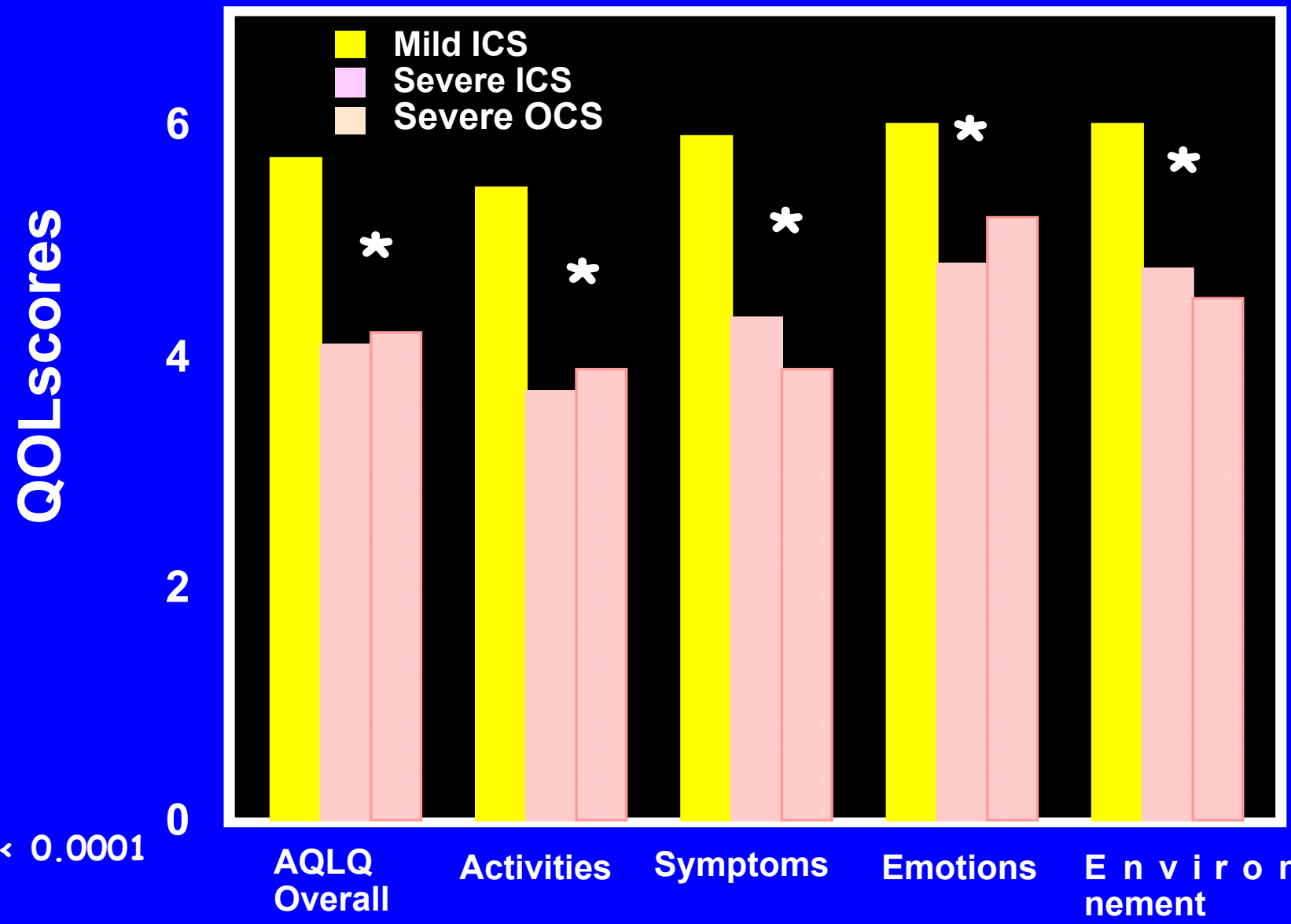


Quality of life
Specific Questionnaires

Instrument	Disease	Validity				
		Reliability		Respons	Longitudinal validity	Clinica interpretation
AQLQ	Asthma	Yes	Yes	Yes	Yes	Yes
Mini-AQLQ	Asthma	Yes	Yes	Yes	Yes	?
Living with asthma	Asthma	Yes	Yes	Yes?	?	?
St Georges	AS + COPD	Yes	Yes	Yes	Yes	Yes
Respiratory illness QOL	AS+COPD	?	Yes	?	?	?
Life activities Questionnaire for adult asthma	Asthma	?	?	?	?	?
Asthma bother profile	Asthma	?	?	?	?	?

AQLQ according to asthma severity

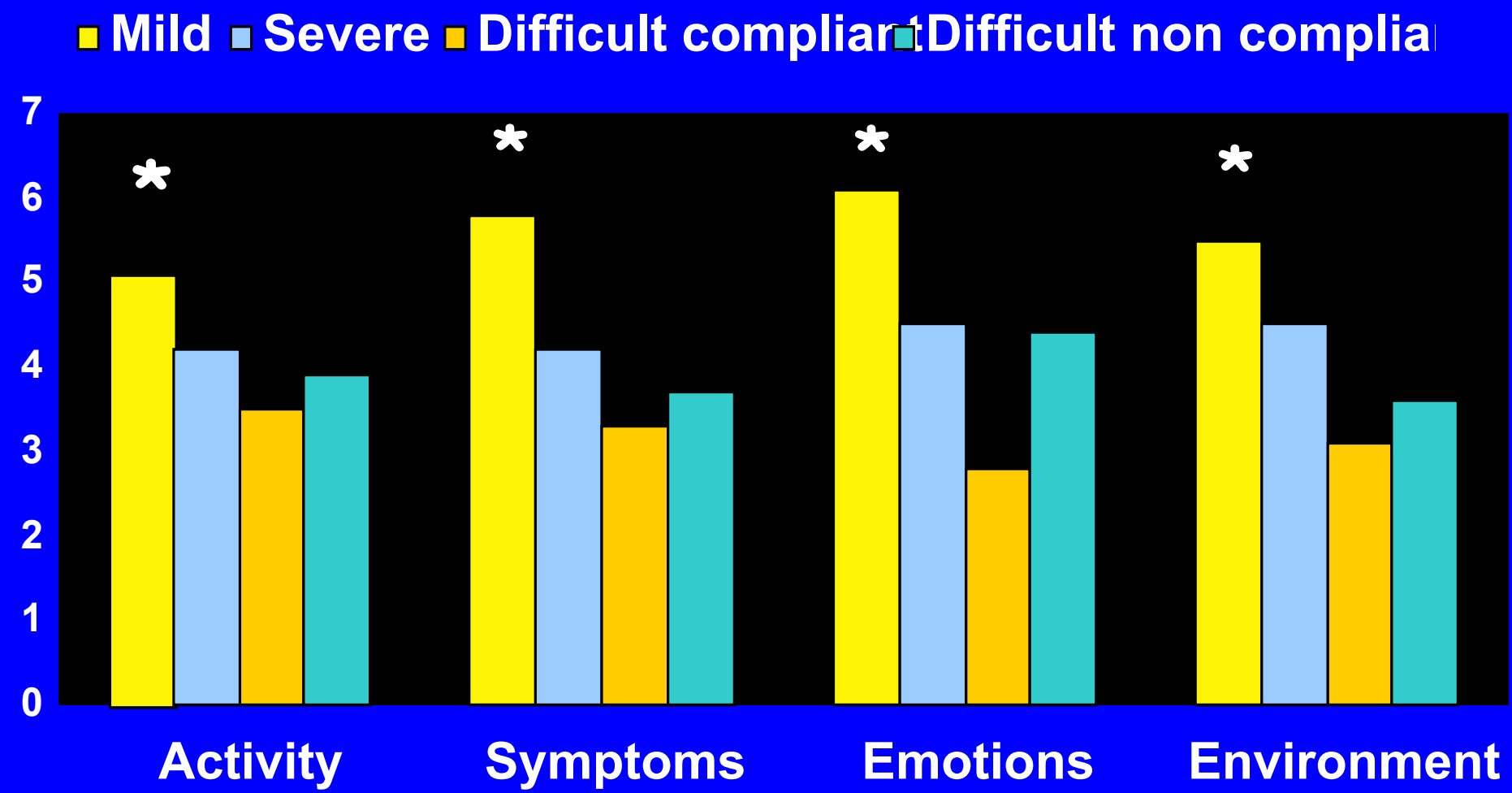
Enfumosa Study, AJRCCM 2000



* P < 0.0001

AQLQ according to asthma severity

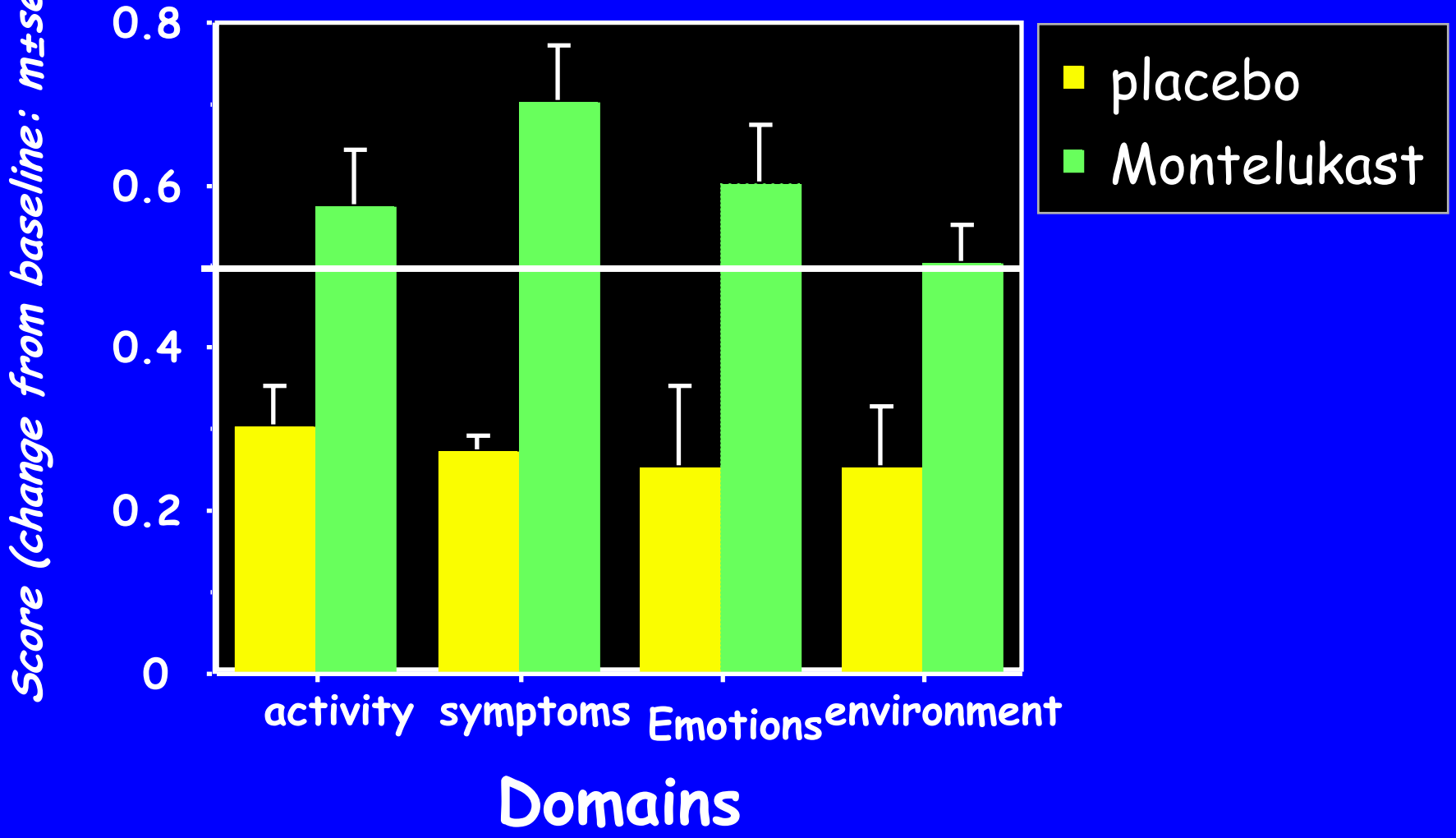
Difficult Asthma network in Montpellier, 2001



* P < 0.001

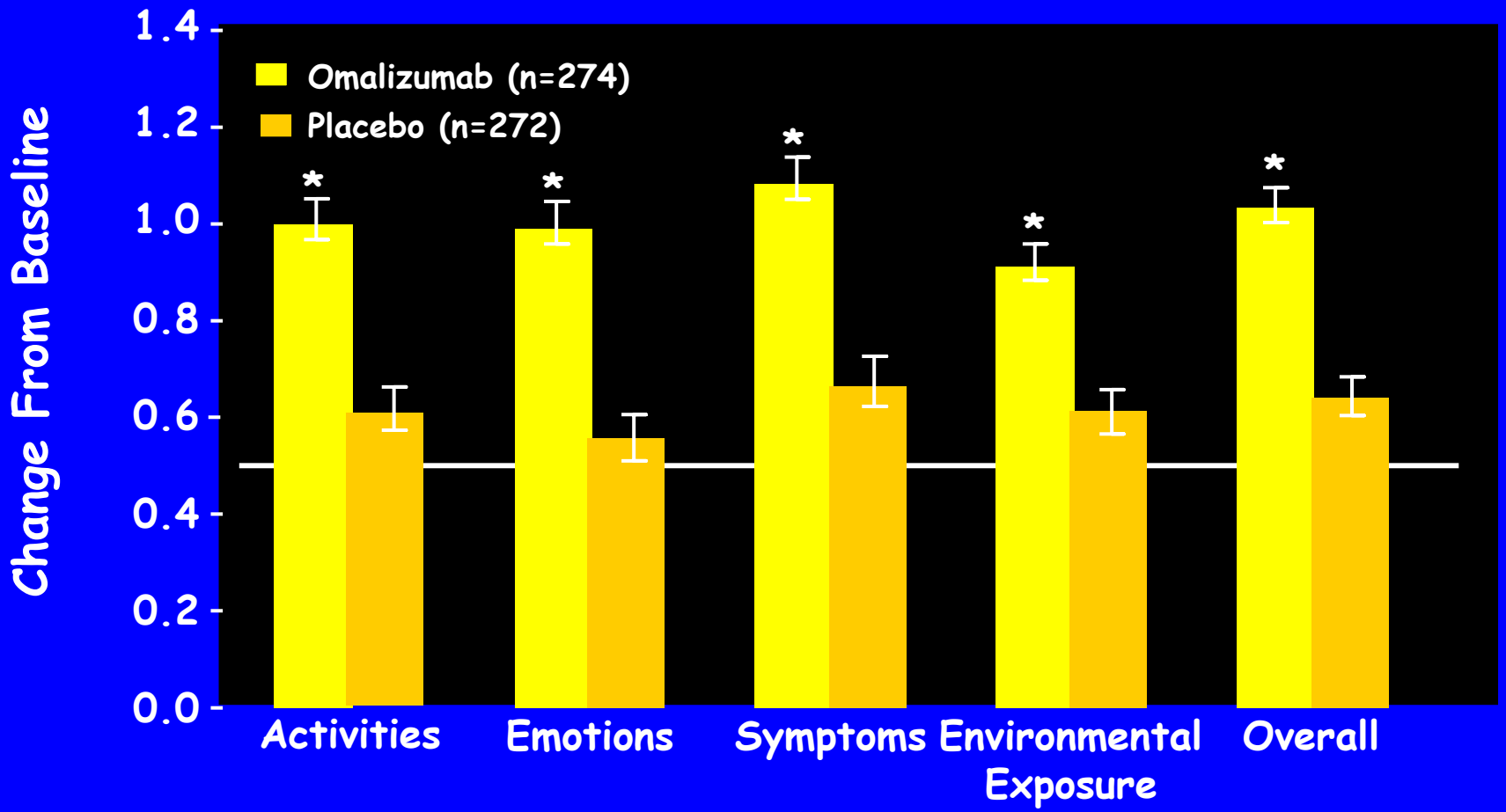
Adult chronic asthma study
AQLQ

T Reiss et al, Arch Intern Med 1998



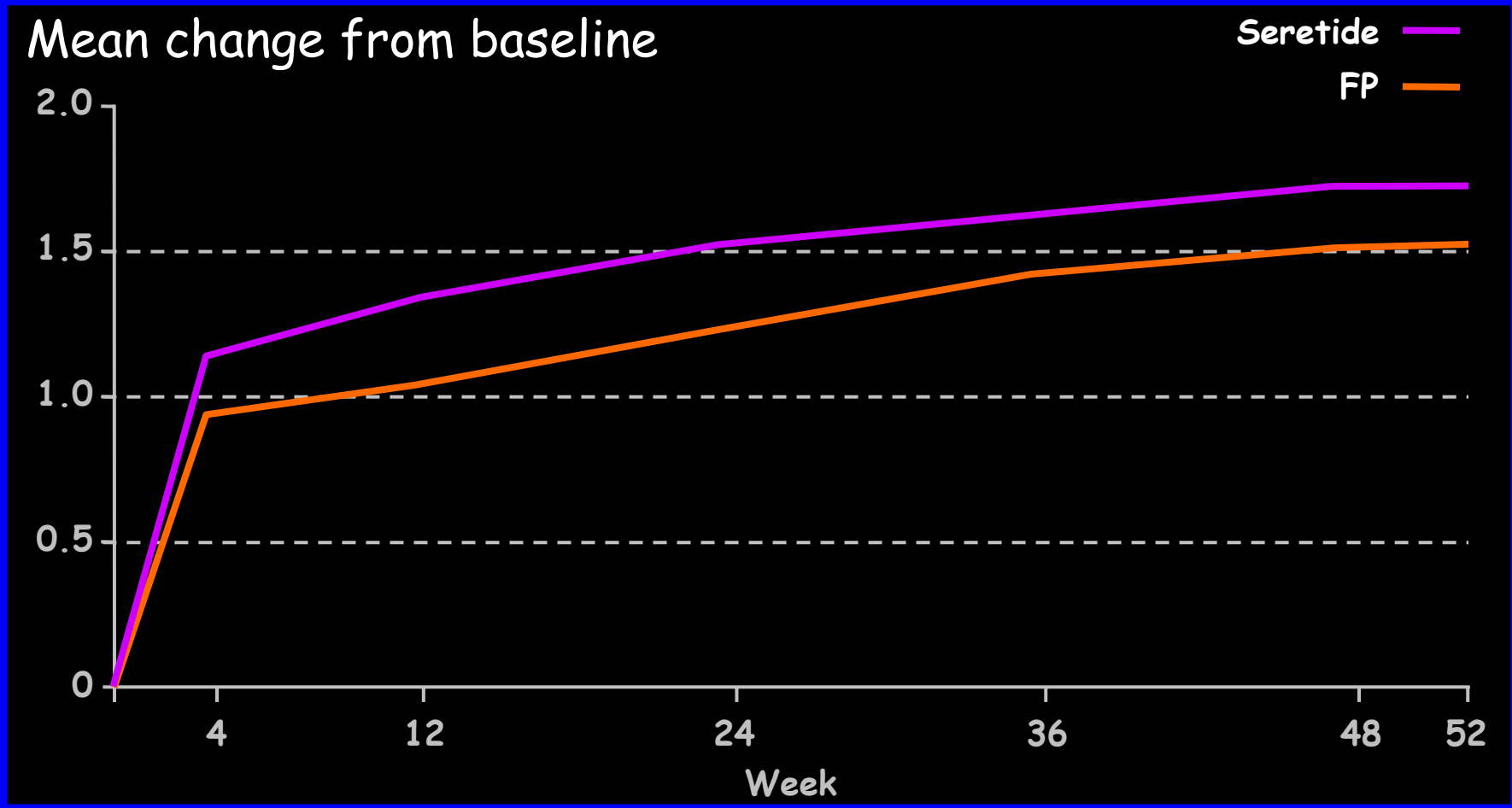
Omalizumab Improves Quality of Life

Bulh et al ERJ 2002



*$P \leq 0.003$

Significant improvement in AQLQ over 1 year: **Steroid naïve (S1)**



GOAL Study

HQOL and severe bronchial diseases

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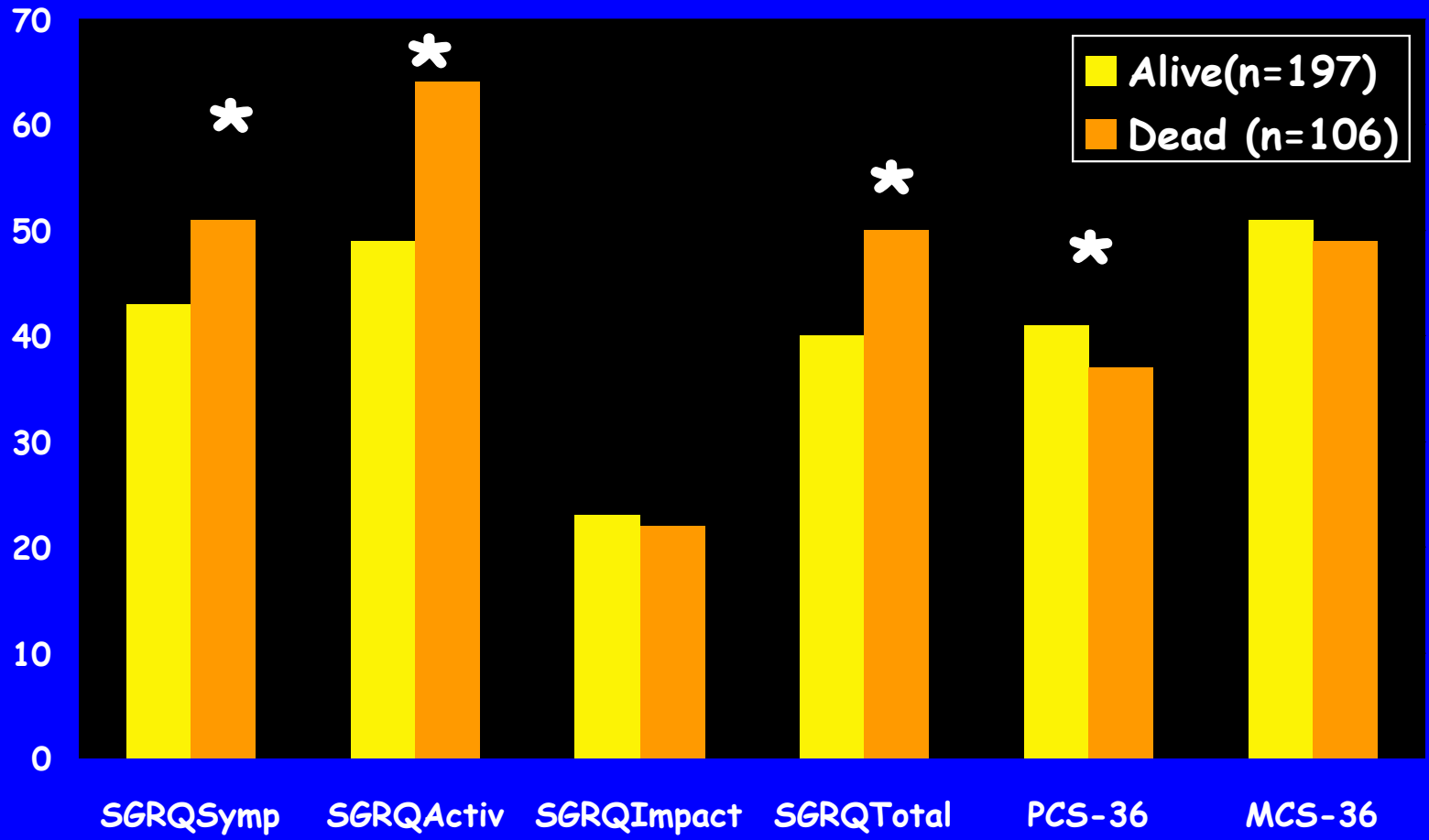
HRQOL is related to mortality in COPD

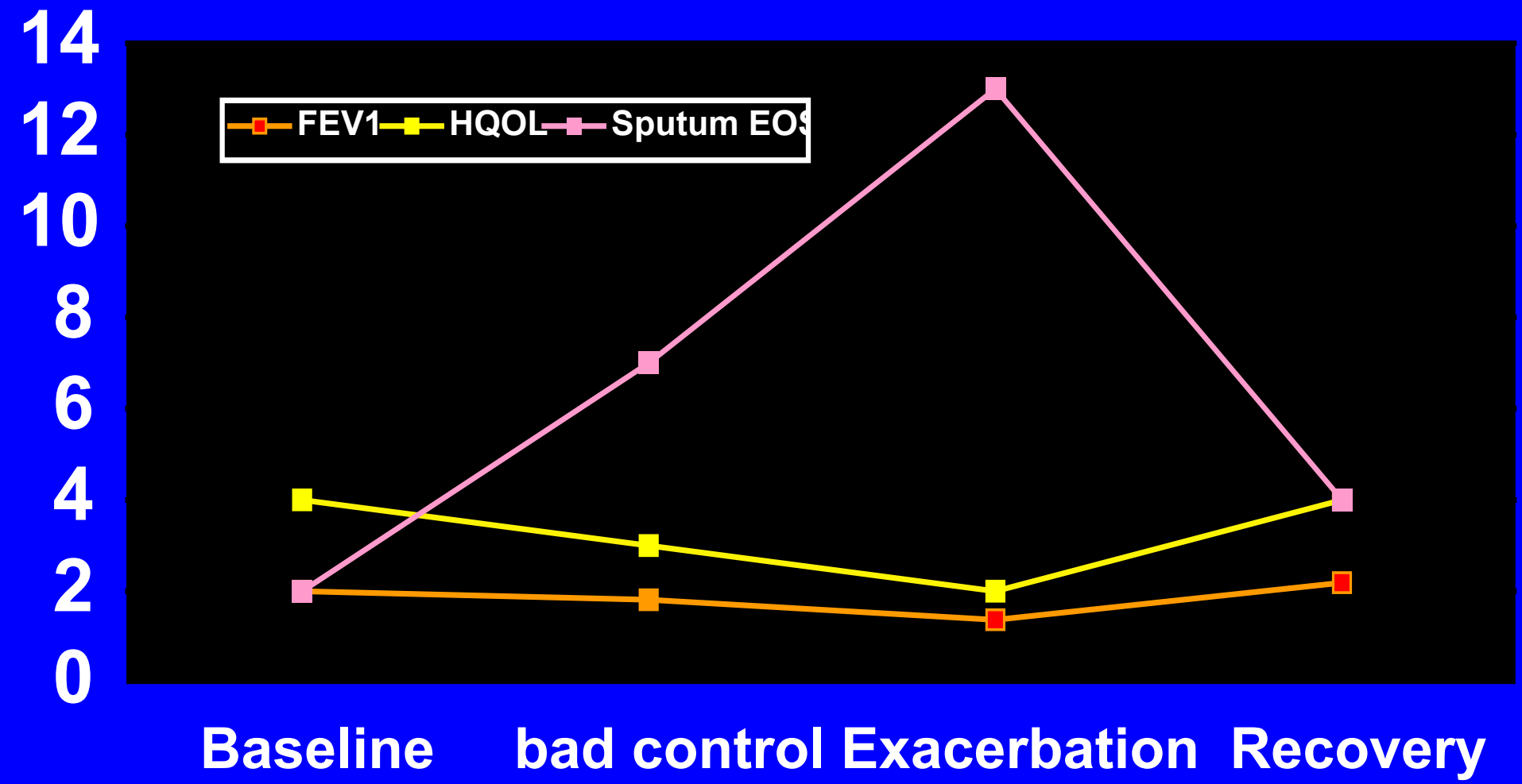
A. Domingo-Salvany et al AJRCCM 2002
follow-up to 4years



OR: FEV1: 2.04; SGRQ: 1.02; PCS-36:1.04 (cox model)

Changes induced by back titrating inhaled corticosteroids

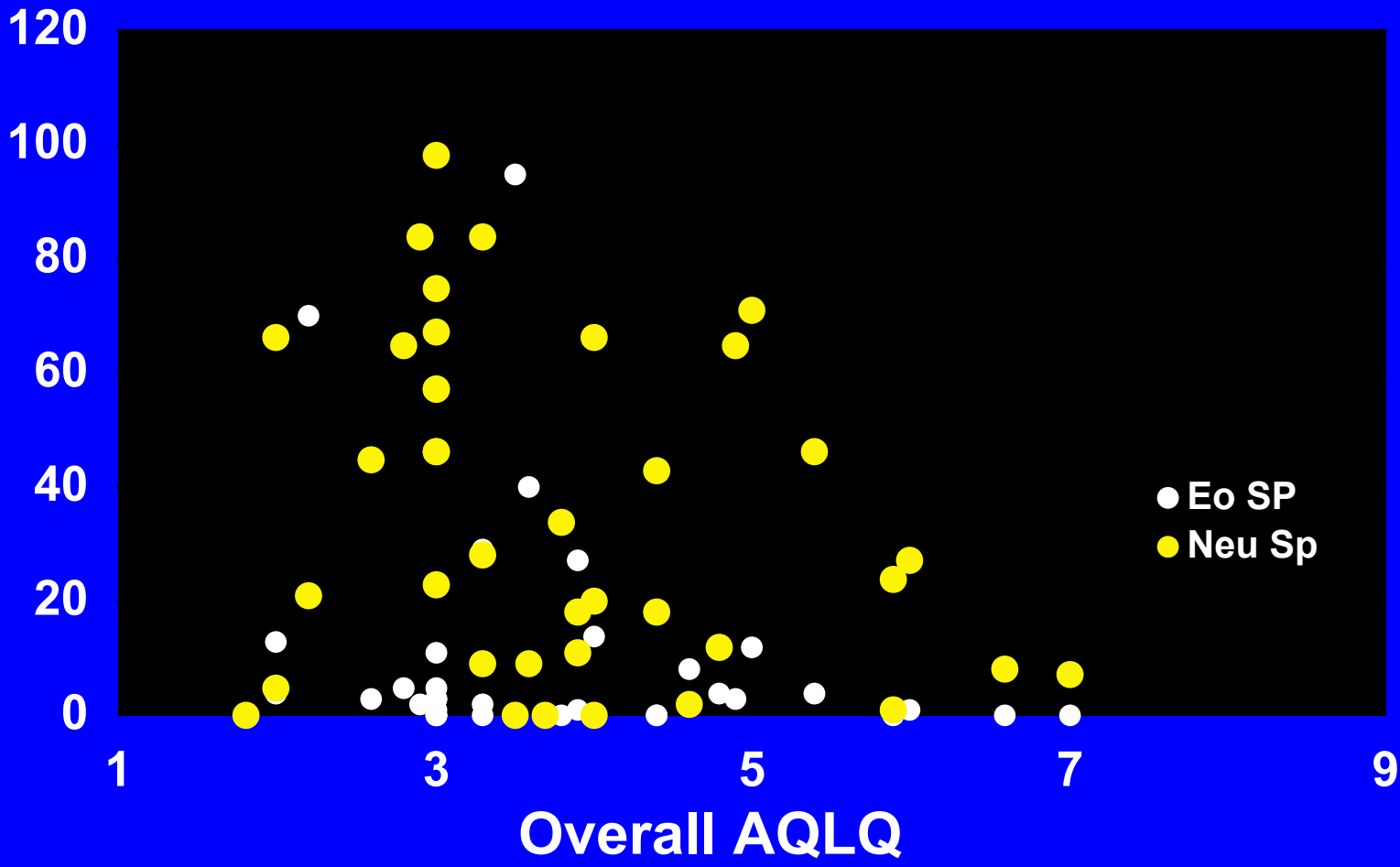
P. Gibson J All Clin Immunol 2000



HQOL and Sputum Eos and PMns

Difficult Asthma Network Montpellier 2001

n=69



Inhaled corticosteroids in COPD
Yes always ?
(3 major studies)

Major outcomes ?

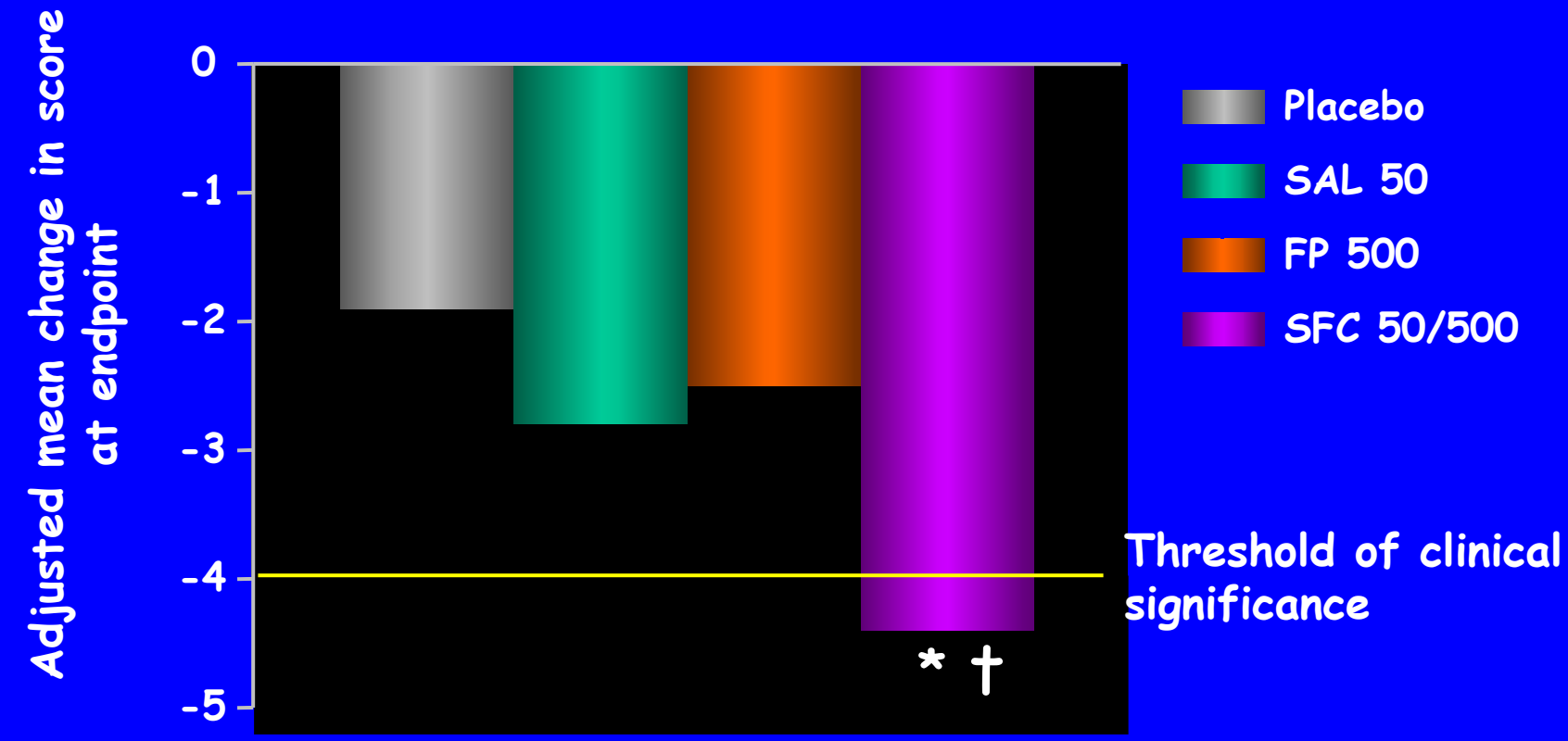
- 1 - Improvement of daily symptoms(dyspnea)
- 2 - Improvement of lung function
- 3 - Decrease number of exacerbations
- 4 - Improvement of QOL
- 5 - decrease rate of lung function decline

COPD QOL ISOLDE Study
BMJ 2000

SGRQ score	placebo	FP	p
Total	3.4	2.3	0.004
Symptoms	2.8	1.6	0.01
Activities	3.5	2.1	0.0003
Impact	3.7	2.6	0.03

- QOL degradation faster in the Placebo group: 3.2 U/yr vs 2 U/yr (p=0.004)

Health status – St George: total score



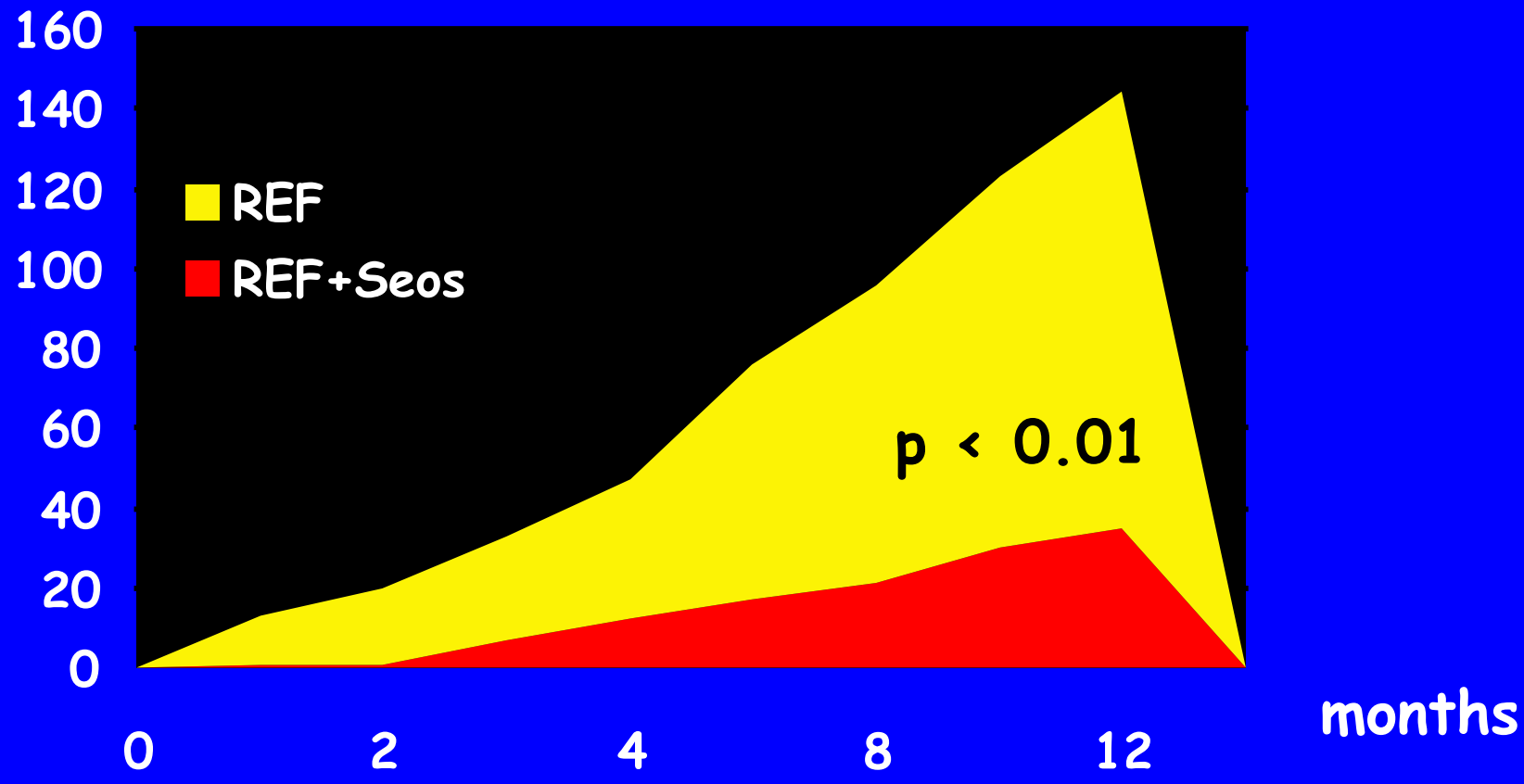
* p=0.008 vs Placebo
† p=0.039 vs FP

Calverley et al, Lancet 2003

Adjustement of therapy based on sputum eosinophilic content

RH Green et al; Lancet 2002

Exacerbations during one year



is there a potential model for using HR-QOL ?

HQOL and severe bronchial diseases

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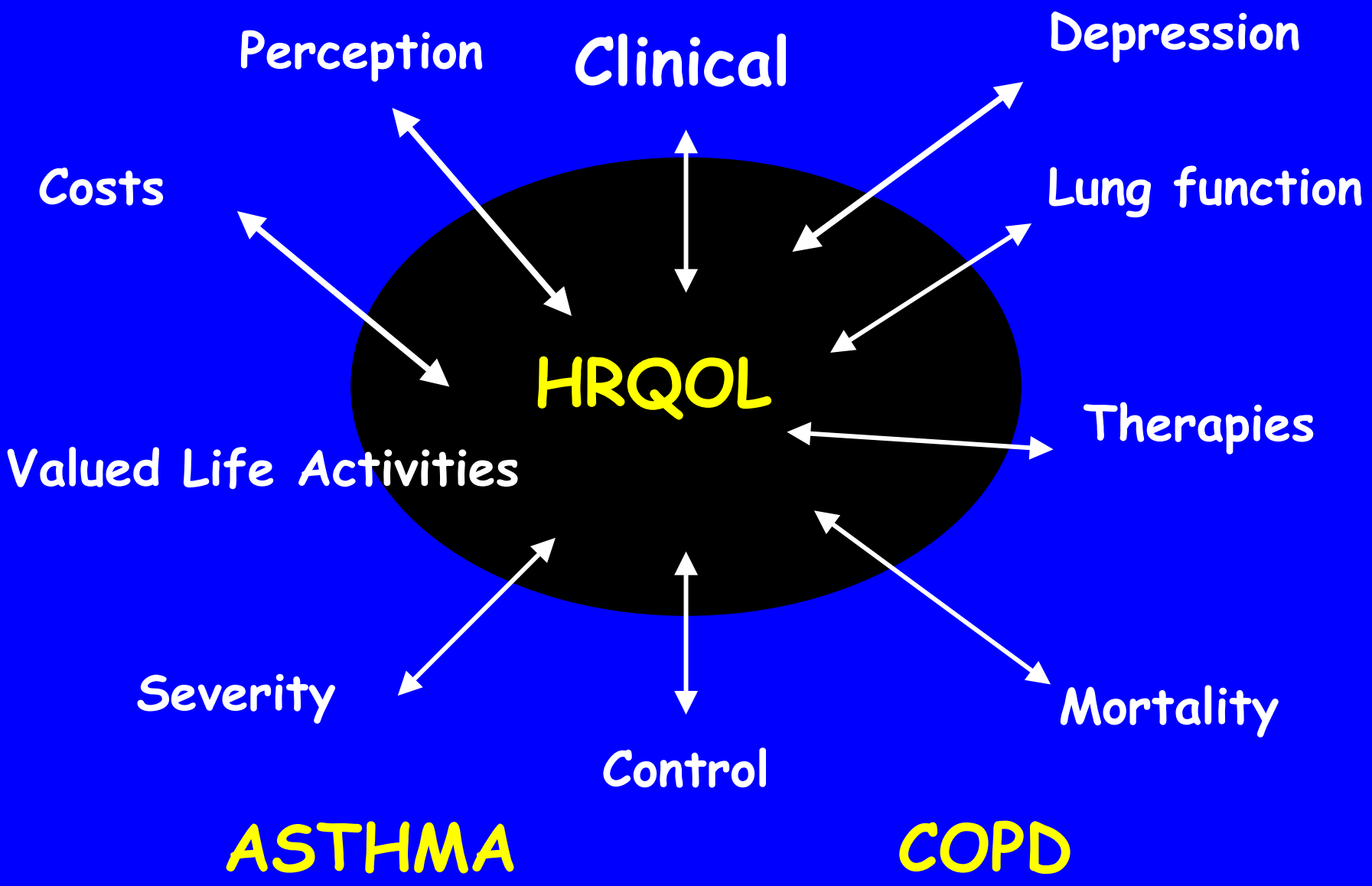
HRQOL measurement in asthma and COPD in the real life?

- Time is short, How do you feel ?
- « *The patients can not fill the form in the waiting room* by themselves»
- « *I do not know how to interpret the results* »
- Minimal clinically significant changes ?
- Doctor 's or patient 's perception ?
- No direct impact on disease management

Conclusions



Nathalie Carayol
Caroline Bonnans
Isabelle Vachier
Philippe Godard
Jean Bousquet
Claude Chavis
Megan Bresciani
Michaella Romagnoli
Giusi Chiappara
Rosi Gagliardo
Maurizio Vignola