



# Riacutizzazione e qualità di vita nell'asma grave

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## Comportamento delle vie aeree in corso di stimolo allergenico

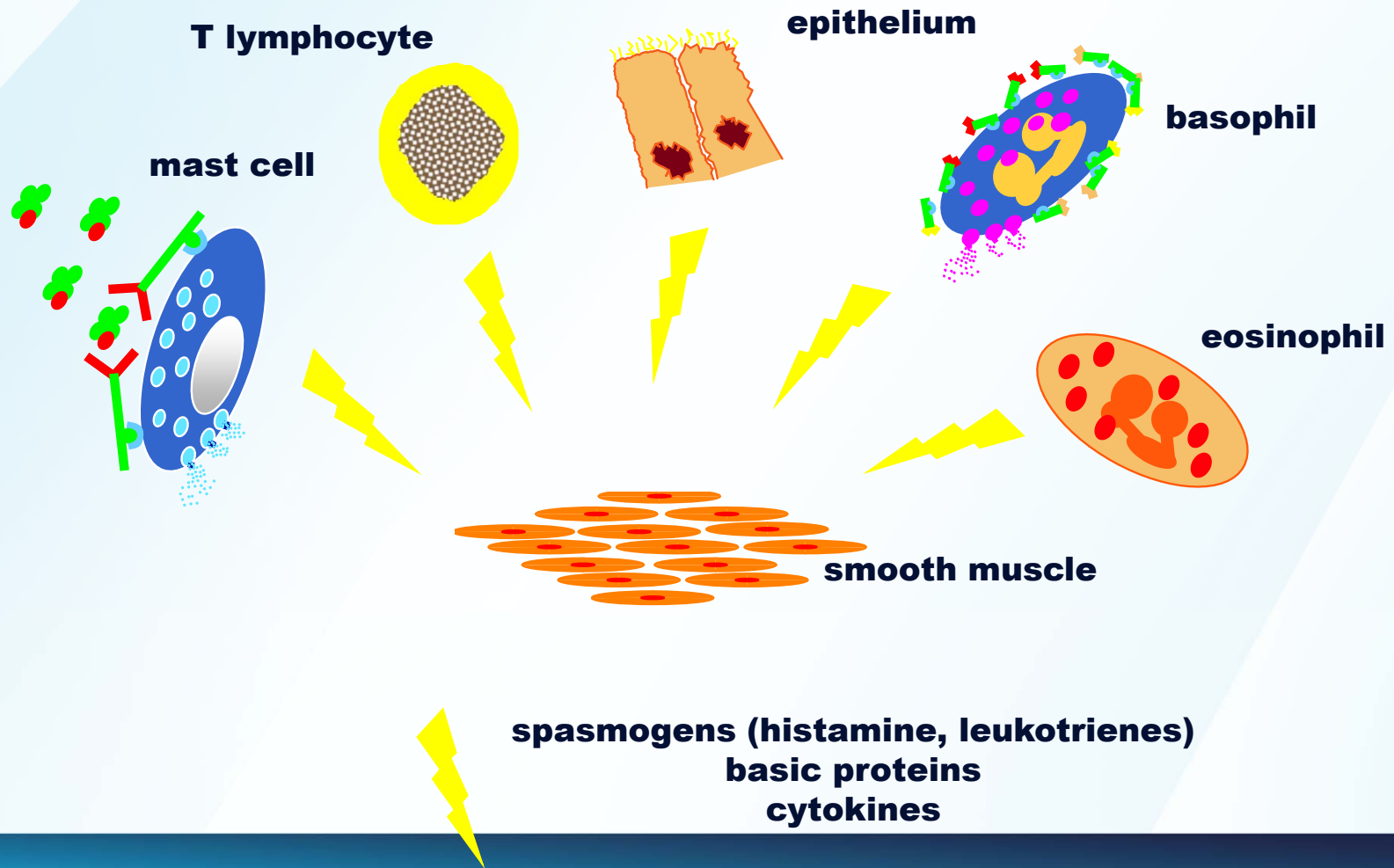


Before



10 Minutes After  
Allergen Challenge

# Effetti delle cellule infiammatorie sul muscolo liscio bronchiale



**Panel 3: Henry Hyde Salter's description of asthma and its effect on the individual<sup>34</sup>**

"...but not only is asthma not an uncommon disease, but it is one of the direst suffering; the horrors of the asthmatic paroxysm far exceed any acute bodily pain; the sense of impending suffocation, the agonizing struggle for the breath of life, are so terrible that they cannot even be witnessed without sharing in the sufferer's distress. With a face expressive of the intensest anxiety, unable to move, speak, or even make signs, the chest distended and fixed, the head thrown back between the elevated shoulders, the muscles of respiration rigid and tightened like cords, and tugging and straining for each breath that is drawn, the surface pallid or livid, cold and sweating—such are the signs by which this dreadful suffering manifests itself...he only knows that a certain percentage of his future life must be dedicated to suffering; he cannot make an engagement except with a proviso, and from many occupations of life he is cut off; the recreations, the enjoyments, the indulgences of others are not for him; his usefulness is crippled, his life is marred; and if he knows anything of the nature of his complaint, he knows that his suffering may terminate in a closing scene worse only than the present."

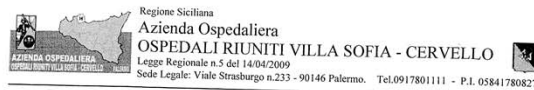
*Pavord I et al. Lancet 2017*



# AC, donna di 51 anni, mai fumatrice, asma dall'adolescenza.

## Peggioramento clinico negli ultimi 2 anni (diversi accessi in P.S., sintomi scarsamente controllati da terapia ICS/LABA ad alte dosi)

### Poliposi nasale, MRGE, eccesso ponderale.



PRONTO SOCCORSO - P.O. V. CERVELLO  
Verbale n. 008032

Pagina 1 di 2  
Accettazione 23/01/2014 09:52  
Ora Ingresso PS 23/01/2014 11:02  
Dimissione 23/01/2014 14:53

Sig. [redacted] Sesso Femmina  
Nato a [redacted] # 24/12/1972  
Domiciliato a PALERMO in VIA S. FRAGAPANE N. 10  
Residente a PALERMO in VIA S. FRAGAPANE N. 10  
Cod. Sanitario Cod. Fiscale VNZDNL72T64G273X Tel. 0916840683  
Nazionalità ITALIA Professione Casalinga  
Modalità di arrivo AUTONOMO  
Sintomo RIF. DISPNEA E FAME D'ARIA IN PAZ. CON STORIA DI ASMA BRONCHIALE ALLERGICO.  
Proven. paziente ALTRO  
Modalità di trauma  
Triagista CIOLINO GIUSEPPE Colore Triage GIALLO  
Medico Accettante ROTOLO GASPARE ANTONIO

Rilevi rilevati  
23/01/2014 09:54 CIOLINO GIUSEPPE FREQUENZA CARDIACA 84 bpm r  
23/01/2014 09:54 CIOLINO GIUSEPPE SAT. O2 99% in a.a.  
23/01/2014 09:56 CIOLINO GIUSEPPE PRESSIONE ARTERIOSA 125/75

Anamnesi  
23/01/2014 11:19 ROTOLO GASPARE AN NON ESIBITA DOCUMENTAZIONE ASMA BRONCHIALE. NEGA DI ESSERE INCINTA. RIFERISCE DI AVERE PRATICATO TERAPIA CON ZITROMAX E VELAMOX (?) SINDA A QUALCHE GIORNO ADDIETRO. VIENE IN PRONTO SOCCORSO PER INCREMENTO DELLA DISPNEA E TOSSE CON ESPETTORATO BIANCASTRO. NON FEBBRE.

Esame Obiettivo  
23/01/2014 11:20 ROTOLO GASPARE AN PZ COLLABORANTE, LUCIDA, ORIENTATA. DISPNOICA A RIPOSO. AL TORACE: REPERTO DI BRONCOSPASMO DIFFUSO. ATTIVITA' CARDIACA RITMICA NORMOFREQUENTE. PAO 120/70 MMHG.  
23/01/2014 12:05 ROTOLO GASPARE AN EGA IN A.A. -> PH 7.465 PCO2 30.9 PO2 65.6 SO2 95.2 LAC 0.7 HCO3 21.9

Prestazioni  
23/01/2014 11:02 897 VISITA GENERALE  
23/01/2014 12:19 91492 PRELIEVO DI SANGUE VENOSO

Laboratorio  
23/01/2014 14:33 ESEGUITI ESAMI EMATOCHIMICI: VEDI ALLEGATI  
23/01/2014 14:33  
23/01/2014 14:36

Radiologici  
23/01/2014 12:20 87441 RX TORACE

Consulenza  
VC - PNEUMOLOGIA 1  
23/01/2014 13:25 897 CONSULENZA PNEUMOLOGICA



PRONTO SOCCORSO - P.O. V. CERVELLO  
Verbale n. 023727

Pagina 1 di 3  
Accettazione 09/03/2014 10:43  
Ora Ingresso PS 09/03/2014 11:52  
Dimissione 10/03/2014 13:09

Sig. [redacted] Sesso Femmina  
Nato a PALERMO # 24/12/1972  
Domiciliato a PALERMO in VIA S. FRAGAPANE N. 10  
Residente a PALERMO in VIA S. FRAGAPANE N. 10  
Cod. Sanitario Cod. Fiscale VNZDNL72T64G273X Tel. 0916840683  
Nazionalità ITALIA Professione Casalinga  
Modalità di arrivo ACCOMPAGNATO DA:  
Sintomo RIF. DISPNEA IN PAZ CON STORIA DI ASMA BRONCHIALE ALLERGICO  
Proven. paziente ALTRO  
Modalità di trauma  
Triagista LIBRO FABIO Colore Triage GIALLO  
Medico Accettante D.ssa GUZZETTA GIUSEPPA

Rilevi rilevati  
09/03/2014 10:45 LIBRO FABIO FREQUENZA CARDIACA 90 bpm rit  
09/03/2014 10:45 LIBRO FABIO SAT. O2 95 % in aa  
09/03/2014 10:46 LIBRO FABIO PRESSIONE ARTERIOSA 110/80 mmhg  
09/03/2014 11:40 LIBRO FABIO FREQUENZA CARDIACA 100 bpm  
09/03/2014 11:40 LIBRO FABIO SAT. O2 94 % in aa  
10/03/2014 09:00 ROTOLO GASPARE AN PRESSIONE ARTERIOSA 105/65 mmhg  
10/03/2014 09:01 ROTOLO GASPARE AN SAT. O2 95% con O2 a 2 V

Anamnesi  
09/03/2014 11:52 GUZZETTA GIUSEPPA RIFERITA DISPNEA DA STANOTTE E DOLORE IN EMICOSTATO DESTRO, IN PZ CON STORIA DI ASMA

Esame Obiettivo  
09/03/2014 11:55 GUZZETTA GIUSEPPA PZ. DISPNOICA TORACE REPERTO DI BRONCOSPASMO TONI CARDIACI NETTI IN SUCCESSIONE RITMICA  
09/03/2014 12:45 GUZZETTA GIUSEPPA RX TORACE TENUE ADDENSAMENTO ILIARE (MERCADANTE GISELLA GILDA)  
09/03/2014 17:01 RESTIVO PANTALONE IT 37.4°C. SAO2 IN OSSIGENOTERAPIA 96%.  
09/03/2014 19:37 RESTIVO PANTALONE SAO2 IN OSSIGENOTERAPIA 96%. REPERTO BRONCOPASTICO E DISPNEA A RIPOSO.

Prestazioni  
09/03/2014 11:52 897 VISITA GENERALE  
09/03/2014 11:59 91492 PRELIEVO DI SANGUE VENOSO  
10/03/2014 11:17 91492 PRELIEVO DI SANGUE VENOSO

Laboratorio  
09/03/2014 12:48 ESEGUITI ESAMI EMATOCHIMICI: VEDI ALLEGATI  
09/03/2014 13:33  
10/03/2014 12:26

Radiologici  
09/03/2014 17:03 87441 RX TORACE



PRONTO SOCCORSO - P.O. V. CERVELLO  
Verbale n. 024800

Pagina 1 di 2  
Accettazione 12/03/2014 12:30  
Ora Ingresso PS 12/03/2014 16:32  
Dimissione 12/03/2014 22:24

Sig. [redacted] Sesso Femmina  
Nato a PALERMO # 24/12/1972  
Domiciliato a PALERMO in VIA S. FRAGAPANE N. 10  
Residente a PALERMO in VIA S. FRAGAPANE N. 10  
Cod. Sanitario Cod. Fiscale VNZDNL72T64G273X Tel. 0916840683  
Nazionalità ITALIA Professione Casalinga  
Modalità di arrivo AUTONOMO  
Sintomo TORAN PER IL PERSISTERE DELLA SINTOMATOLOGIA VERBALE N° 23727  
RILEVI  
Proven. paziente ALTRO  
Modalità di trauma  
Triagista CUCCHIARA GIOVANNI Colore Triage GIALLO  
Medico Accettante Dott. VAGLICA SAVERIO

Rilevi rilevati  
12/03/2014 12:32 CUCCHIARA GIOVANNI PRESSIONE ARTERIOSA 160/80  
12/03/2014 12:32 CUCCHIARA GIOVANNI FREQUENZA CARDIACA 102  
12/03/2014 12:32 CUCCHIARA GIOVANNI SAT. O2 97  
12/03/2014 22:20 ROTOLO GASPARE AN SAT. O2 99% in a.a.  
12/03/2014 22:21 ROTOLO GASPARE AN PRESSIONE ARTERIOSA 100/65 mmhg a dx

Anamnesi  
12/03/2014 16:51 VAGLICA SAVERIO RITORNA PER IL PERSISTERE DEL DOLORE EMITRACE DX. PROBABILE ASMA ESTRINSECA. UDIVERSII ACCESSI IN PS PER ANALOGA SINTOMATOLOGIA -> ULTIMO ACCESSO INDICATO IL RICOVERO MA PER MANGANZA DI POSTI LETTO HA RIFIUTATO OSSERVAZIONE

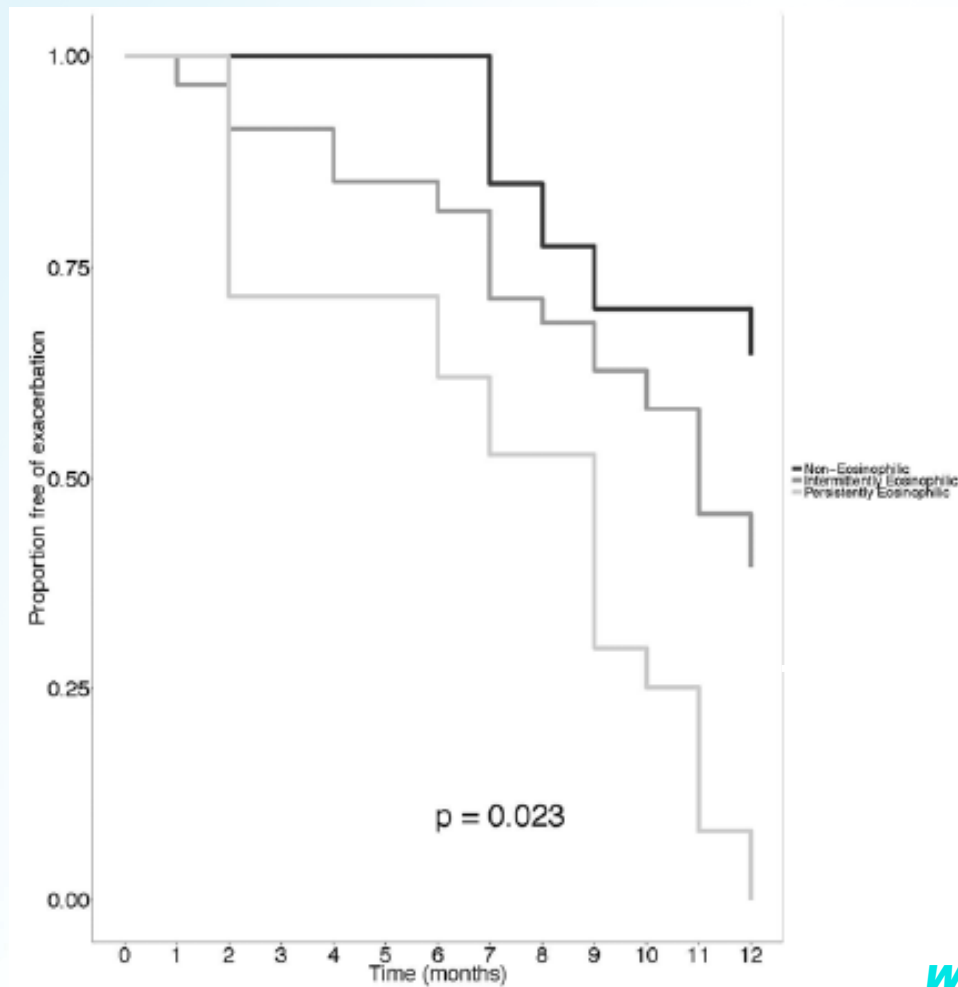
Esame Obiettivo  
12/03/2014 16:55 VAGLICA SAVERIO BRONCOSTENOSI DIFFUSA, DOLORE TRA IV E VI SPAZIO INTERCOSTALE DX SULL'ASCPELLARE MEDIA E ANTERIORE, NON LESIONI ERPETICHE

12/03/2014 22:07 ROTOLO GASPARE AN DA REFERITO TAC:-> Indagine eseguita in urgenza, nelle sole condizioni di base. Non significative alterazioni della densita' pare ncilmale aventi carattere di attivita'. Il di volume medio. Non versamento pleurico e/ o faldie di prx. La trachea ed i bronchi principali sono pervi. Note di spandilartriosi dorsale. Nodulo ipodensso di circa 1,8 cm, nella mammella di destra.

12/03/2014 22:11 ROTOLO GASPARE AN. IN ATTO ASINTOMATICA. D-DIMERO 110. SI ESEGUE ECO: SOVRAPPONIBILE A QUELLO ESEGUITO IL 10 MARZO. AL TORACE: MV RIDOTTO + MODESTO BRONCOSPASMO. PAO 100/65 MMHG A DX E A SX (N.B.: SI TRATTA DI VALORI PRESSORI GIÀ NOTI ALLA PAZIENTE).

Prestazioni  
12/03/2014 16:32 897 VISITA GENERALE  
12/03/2014 16:53 91492 PRELIEVO DI SANGUE VENOSO  
12/03/2014 20:13 91492 PRELIEVO DI SANGUE VENOSO  
12/03/2014 22:20 8952 ELETTROCARDIOGRAMMA

# Exacerbation risk in severe asthma is stratified by the inflammatory phenotype



Walsh CJ et al. CEA 2016

## benralizumab

### Outcomes

The primary efficacy endpoint was the annual asthma exacerbation rate ratio versus placebo, which is summarised as total number of exacerbations  $\times$  365.25 / total duration of follow-up within the treatment group

## mepolizumab

### PRIMARY OUTCOME

The primary outcome was the annualized frequency of clinically significant exacerbations, which

### Outcomes

The primary endpoint was the frequency of clinical asthma exacerbations per patient during the 52 week

## reslizumab

### OUTCOMES

The primary efficacy end point was the occurrence of an asthma exacerbation, as previously defined, during the 12-week intervention period. Second-

## dupilumab

# **AGENDA**

**le “peculiarità” della definizione**

**i “consigli” per prevenire le riacutizzazioni**

**i “diversi” approcci terapeutici**

**due considerazioni personali...**



## Definizione di riacutizzazione

**Le riacutizzazioni di asma consistono in un marcato, spesso progressivo deterioramento dei sintomi di asma e dell' ostruzione bronchiale, che compaiono **nello spazio di ore o giorni**, e che possono durare fino a settimane, e che in genere richiedono un **cambiamento della attuale terapia**.**

## **Facciamo chiarezza...**

### **Fattore temporale:**

- **evento acuto vs. graduale peggioramento**

### **Diagnosi clinica:**

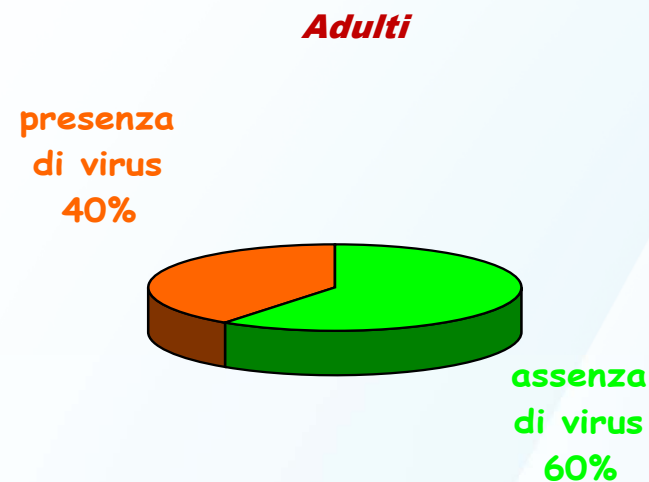
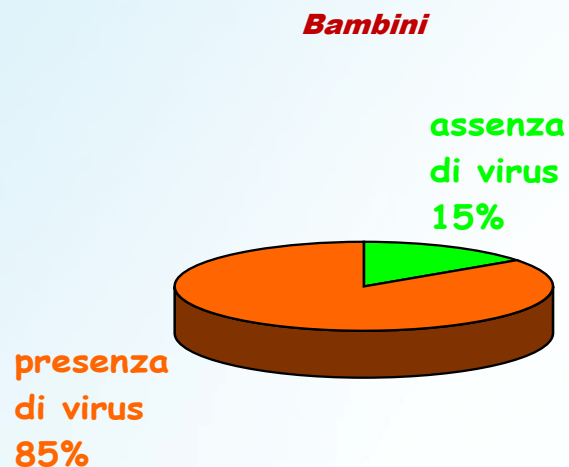
- **assenza di biomarcatori o di test funzionali**

### **Gravità in funzione della terapia:**

- **short-acting vs. steroide vs. ospedalizzazione**

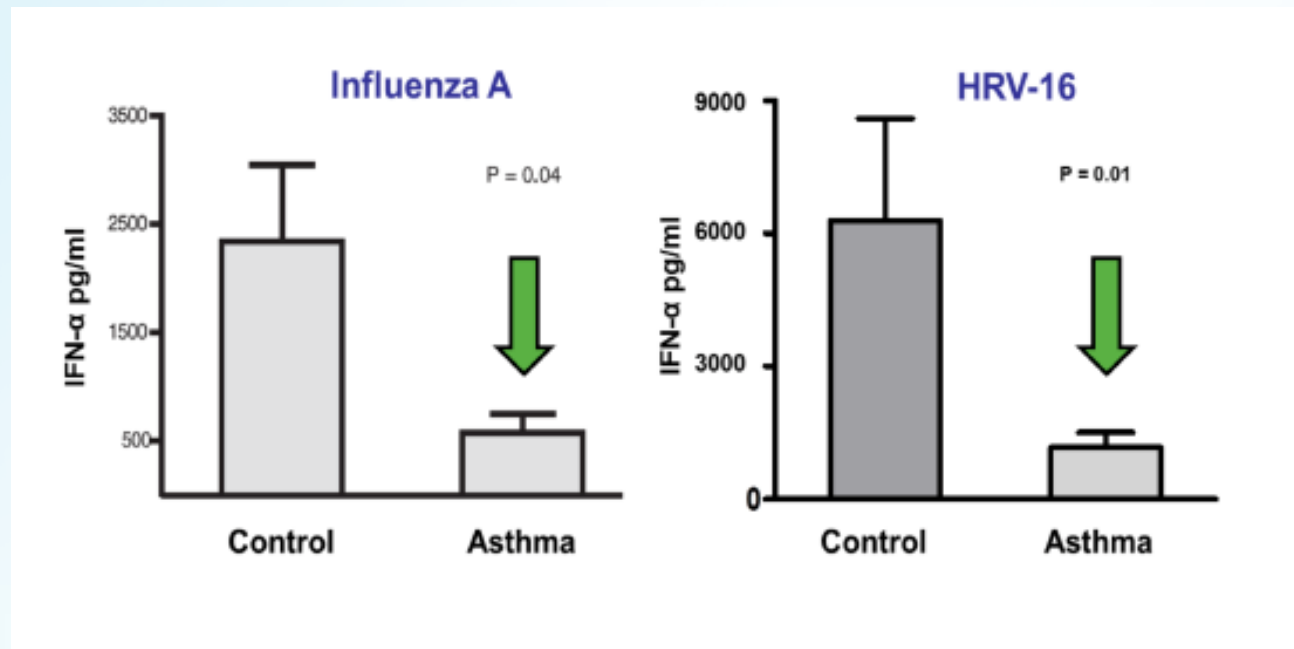
## Riacutizzazioni asmatiche e virus

- **Almeno il 40% delle riacutizzazioni asmatiche negli adulti sono scatenate da infezioni virali**
- **Nel 60% dei casi il virus responsabile è il rinovirus (raffreddore comune)**



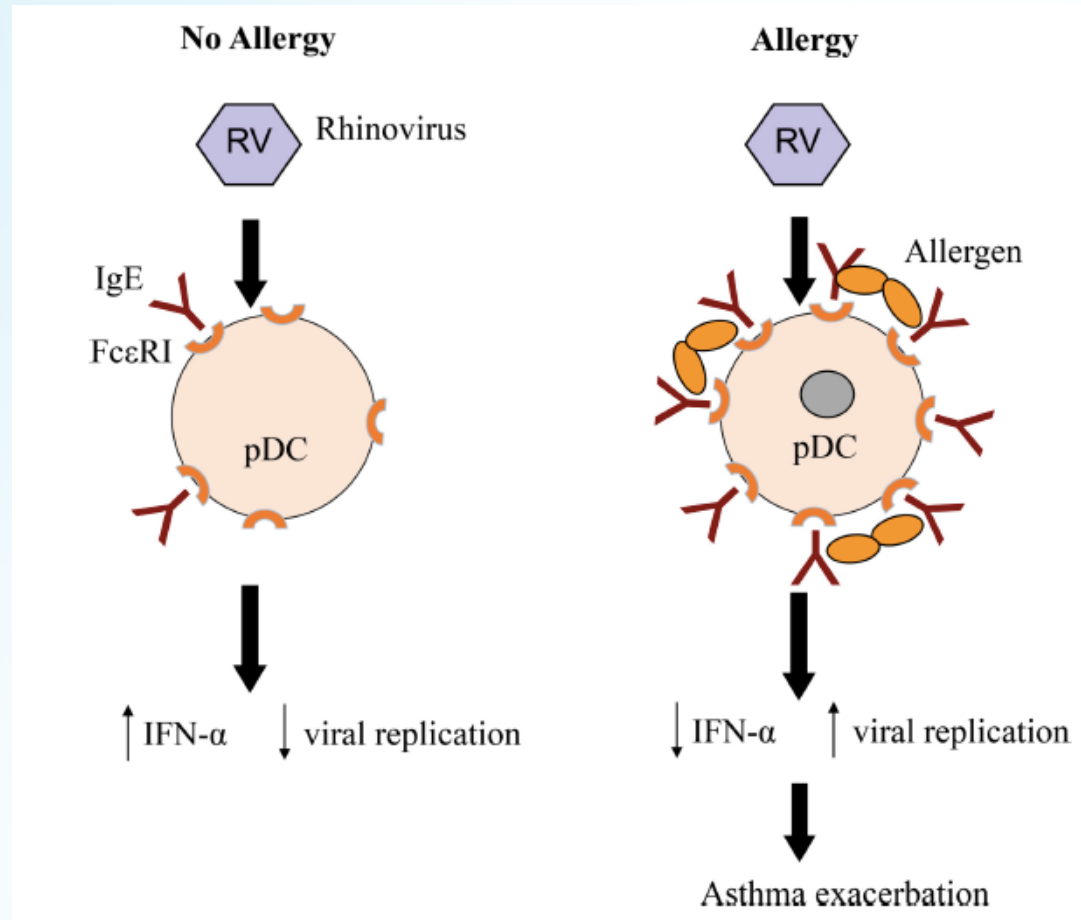
*Corne JM, et al. Lancet 2002; Johnston SL et al. Br Med J 1995*

# Le cellule dendritiche nell'asma secernono livelli ridotti di IFN- $\alpha$ in risposta ad esposizione virale



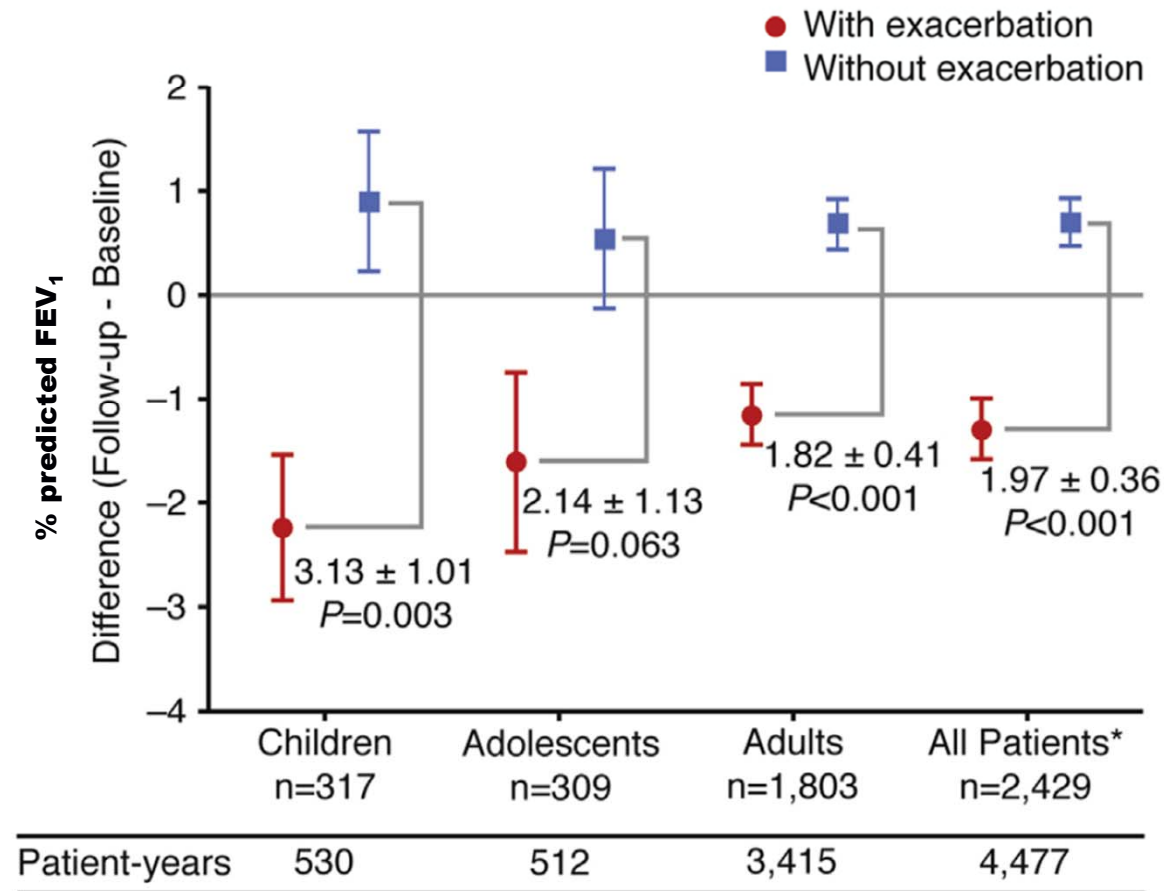
*Gill et al. J Immunol 2010*

# Nell'asma il legame IgE-recettore inibisce la produzione di IFN- $\alpha$ favorendo la replicazione virale

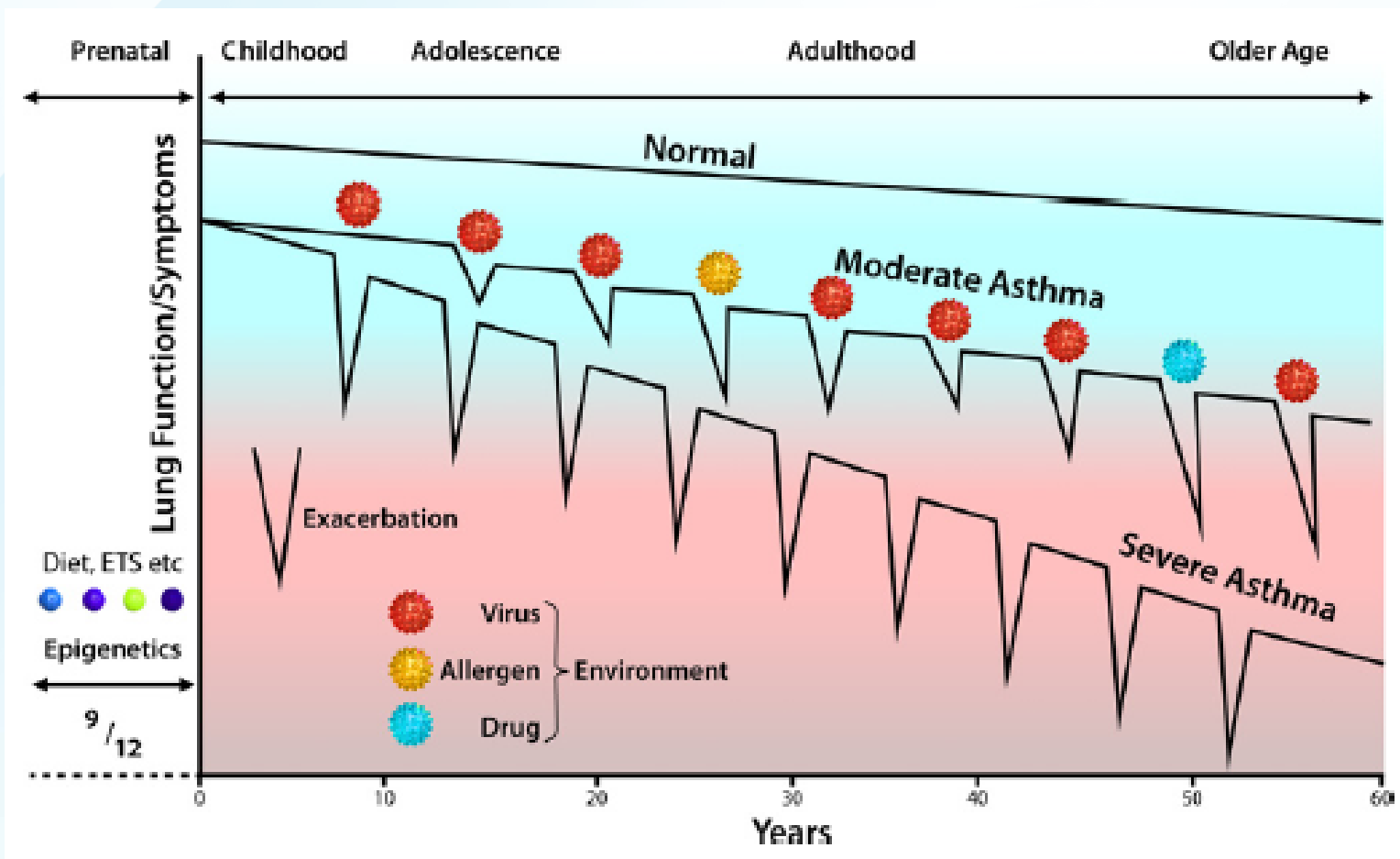




# Riacutizzazioni e funzione polmonare (TENOR – 3 year follow-up)



# Riacutizzazioni e declino funzionale nell'asma



**Table 1. Classifications of Severity of an Asthma Exacerbation**

Degree of severity	Symptoms and signs	Peak Expiratory Flow (PEF) (or FEV <sub>1</sub> )	Clinical course
Mild	Dyspnea only with activity (assess tachypnea in young children)	PEF ≥ 70 percent of predicted or personal best	Usually treated at home Prompt relief with inhaled short-acting beta <sub>2</sub> agonist Possible short course of oral systemic corticosteroids
Moderate	Dyspnea interferes with or limits usual activity	PEF 40 to 69 percent of predicted or personal best	Usually requires office or emergency department visit Relief from frequent inhaled short-acting beta <sub>2</sub> agonist Oral systemic corticosteroids; some symptoms last for one to two days after treatment begins
Severe	Dyspnea at rest; interferes with conversation	PEF < 40 percent of predicted or personal best	Usually requires emergency department visit and likely hospitalization Partial relief from frequent inhaled short-acting beta <sub>2</sub> agonist Oral systemic corticosteroids; some symptoms last for more than three days after treatment begins Adjunctive therapies are helpful
Subset: life threatening	Too dyspneic to speak; perspiration	PEF < 25 percent of predicted or personal best	Requires emergency department visit/hospitalization; possible intensive care unit Minimal or no relief from frequent inhaled short-acting beta <sub>2</sub> agonist Intravenous corticosteroids Adjunctive therapies are helpful

## **Asma instabile (“brittle asthma”)**

**Tipo 1:** attacchi ricorrenti su asma non controllato nonostante terapia ad alte dosi

**Tipo 2:** attacchi improvvisi e molto gravi su asma apparentemente controllato

**Tipo 3:** asma grave in paziente con “brittle personality” (problemi psicosociali)

# AGENDA

**le “peculiarità” della definizione**

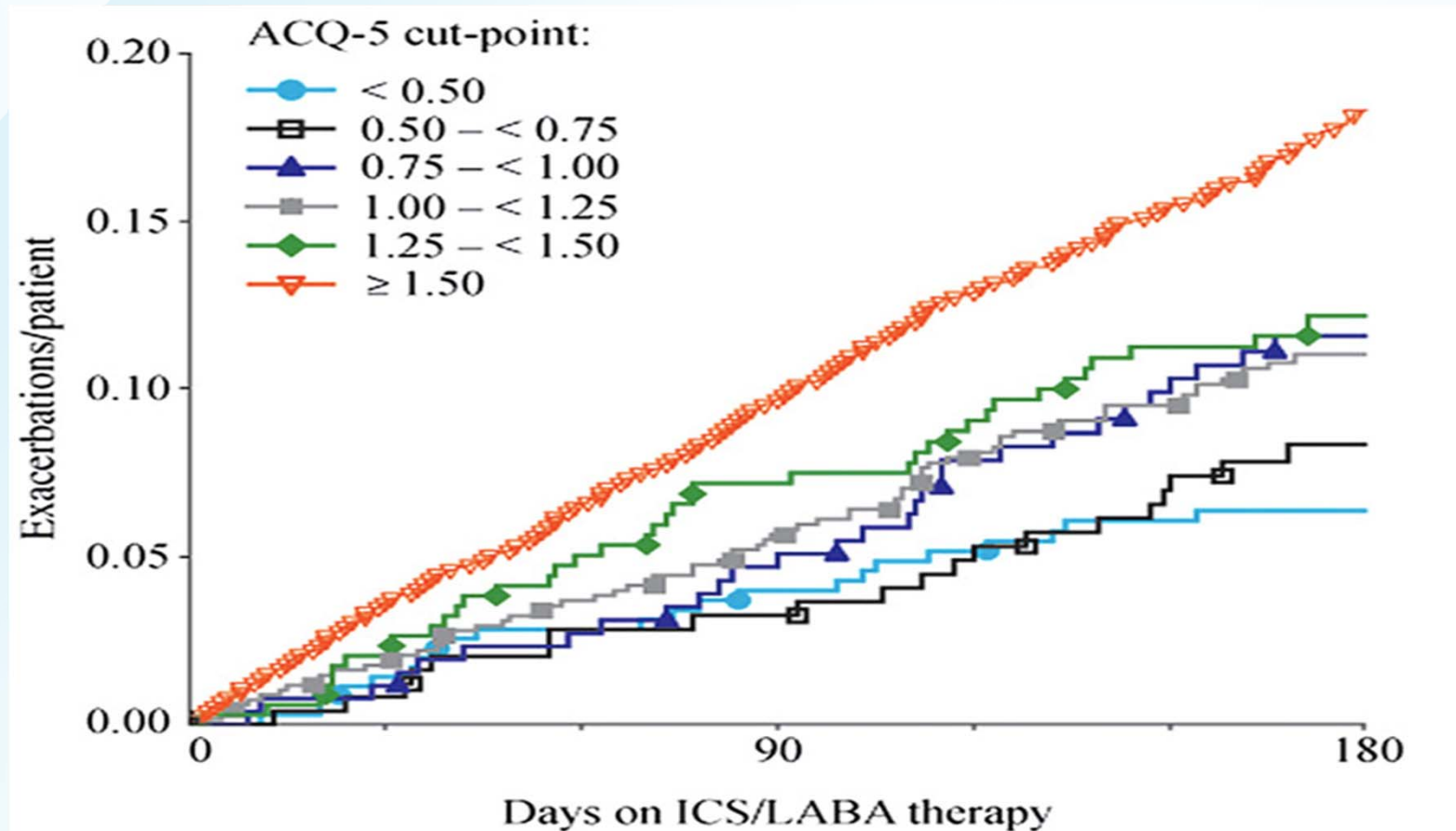
**i “consigli” per prevenire le riacutizzazioni**

**i “diversi” approcci terapeutici**

**due considerazioni personali...**



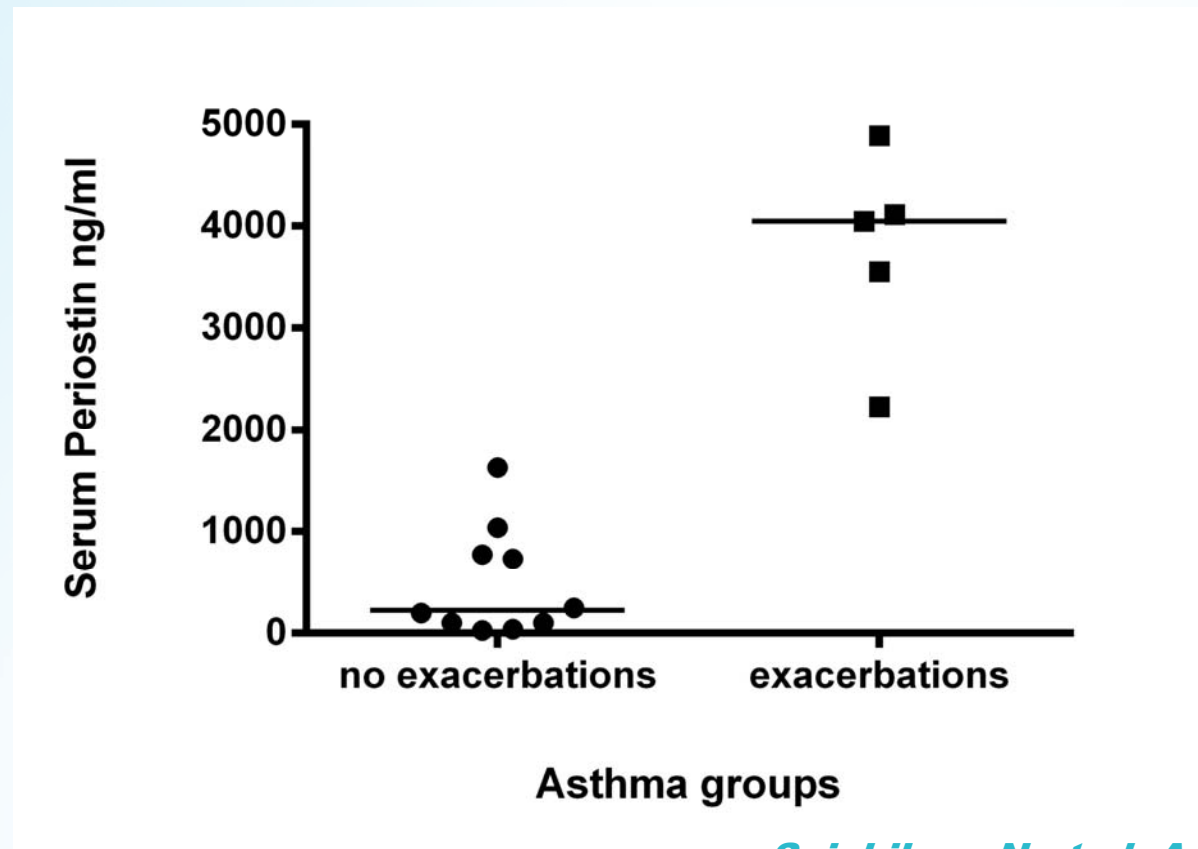
# Controllo di malattia e rischio di riacutizzazione



Bateman et al. JACI 2010

# I livelli di periostina predicono le riacutizzazioni

15 pazienti con asma moderato/severo, follow-up 1 anno



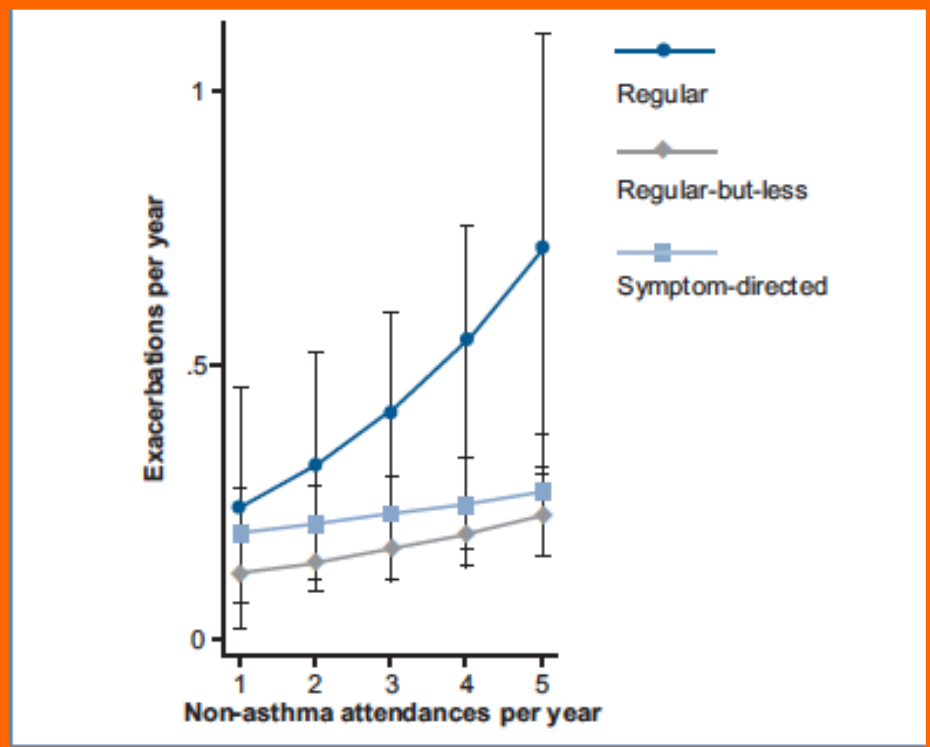
*Scichilone N et al. Asthma Res Pract, 2016*

RESEARCH PAPER

Frequency of non-asthma GP visits predicts asthma exacerbations: an observational study in general practice

\*Michael E Hyland<sup>a,f</sup>, Sue Blake<sup>d,f</sup>, Margaret

...<sup>c,f</sup>, Clare Seamark<sup>d,f</sup>, ...  
...<sup>d,f</sup>



## Non respiratory symptoms in asthma as possible predictors of exacerbations

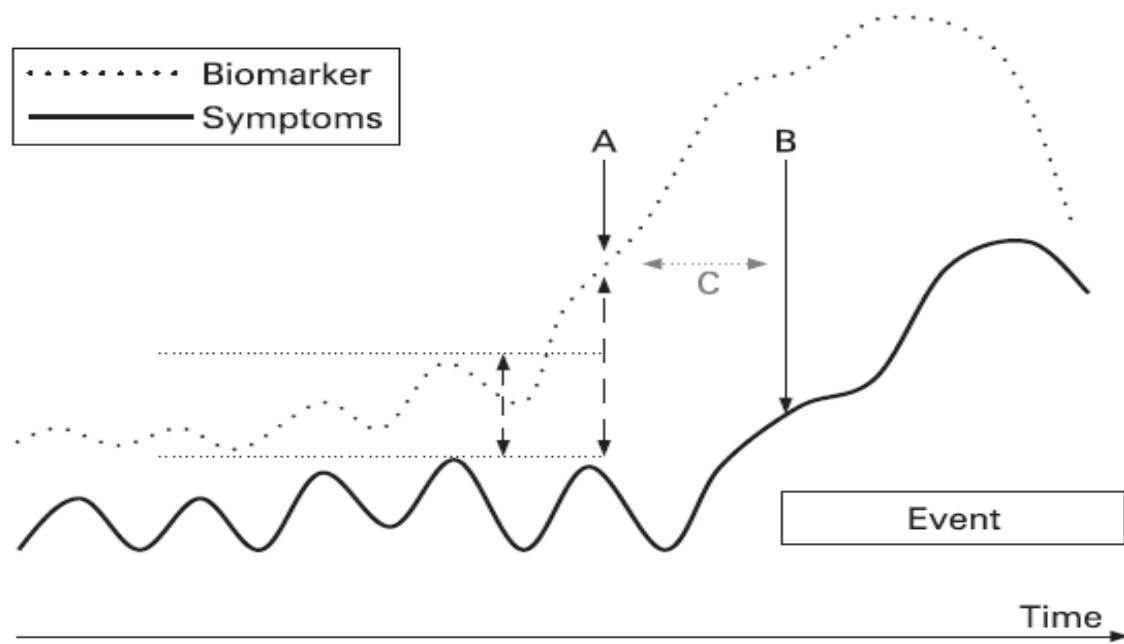
Gennaro Liccardi, MD<sup>a</sup>, Gennaro Baldi, MD<sup>b</sup>,  
 Adriano Berra, MD<sup>c</sup>, Emanuela Carpentieri, MD<sup>d,e</sup>,  
 Marina Cutajar, MD<sup>f</sup>, Maria D'Amato, MD<sup>g</sup>,  
 Mario Del Donno, MD<sup>e</sup>, Bruno Del Prato, MD<sup>h</sup>,  
 Ilenia Folletti, MD<sup>i</sup>, Federica Gani, MD<sup>j</sup>,  
 Domenico Gargano, MD<sup>k</sup>, Domenico Giannattasio, MD<sup>l</sup>,  
 Michele Giovannini, MD<sup>m</sup>, Antonio Infantino, MD<sup>n</sup>,  
 Carlo Lombardi, MD<sup>o</sup>, Mario Lo Schiavo, MD<sup>p</sup>,  
 Francesco Madonna, MD<sup>q</sup>, Mauro Maniscalco, MD<sup>r</sup>,  
 Antonio Meriggi, MD<sup>s</sup>, Manlio Milanese, MD<sup>t</sup>,  
 Carmen Montera, MD<sup>p</sup>, Antonio Pio, MD<sup>p</sup>,  
 Maria Russo, PhD<sup>a</sup>, Antonello Salzillo, MD<sup>a</sup>,  
 Patrizia Scavalli, MD<sup>u</sup>, Nicola Scichilone, MD<sup>v</sup>,  
 Bruno Sposato, MD<sup>w</sup>, Anna Stanziola, MD<sup>g</sup>,  
 Antonio Starace, MD<sup>x</sup>, Alessandro Vatrella, MD<sup>y</sup>,  
 Gennaro D'Amato, MD<sup>a</sup>, and Giovanni Passalacqua, MD<sup>z</sup>

### *Clinical Implications*

- In patients with ascertained bronchial asthma, the occurrence of nonrespiratory symptoms before attacks is common (63.27%).
- An early recognition of nonrespiratory symptoms could be useful to predict a possible worsening of bronchial obstruction.

TABLE I. Distribution of n-RS (%) in 510 patients, according to asthma severity\*

nRS	Moderate or severe persistent asthma	Intermittent or mild persistent asthma	All patients
Anxiety	34	37	36
Headache	28	23	26
Abdominal pain	1	3	2
Weakness	13	4	9
Depression	5	0	3
Impaired sleep	4	8	7
Nicturia	7	0	5
Chest pain	11	7	9
Excitement	13	6	10
Nonlocalized pain	4	4	4
Hunger	3	4	3
Lack of appetite	5	5	5
Fever	1	3	2
Nausea	1	5	4
Urticaria	3	0	2
Palpitation	28	23	26
Heartburn	11	7	10
Generalized itching	22	30	25
Reflux	9	10	10
Flushing	2	3	2
Swelling	7	7	7
Dry mouth	11	11	11
Drowsiness	9	4	5
Daze	10	5	7
Sweating	13	16	14
Tremor	8	9	9
Dizziness	6	11	8



**Figure 2** Using a biomarker to predict future clinical event or status. A, Point at which biomarker rises beyond “normal range” and the signal is meaningful. B, Point at which symptoms become apparent. C, Interval of time during which intervention may be applied. This needs to be greater than the time required for an intervention to abort or modify the exacerbation. The time interval may be days or years depending on the disease (eg, asthma or chronic obstructive pulmonary disease), the event or outcome (eg, exacerbation or chronic respiratory failure).



# **AGENDA**

**le “peculiarità” della definizione**

**i “consigli” per prevenire le riacutizzazioni**

**i “diversi” approcci terapeutici**

**due considerazioni personali...**

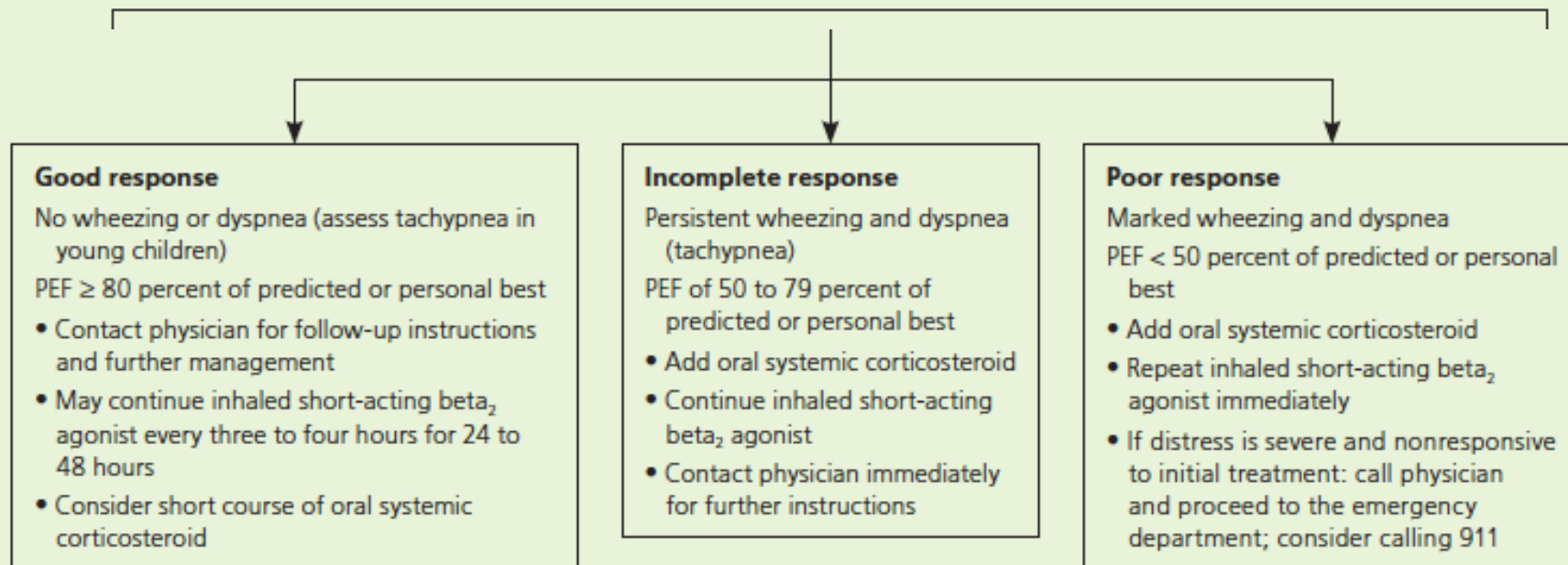
## Section of Therapeutics and Pharmacology

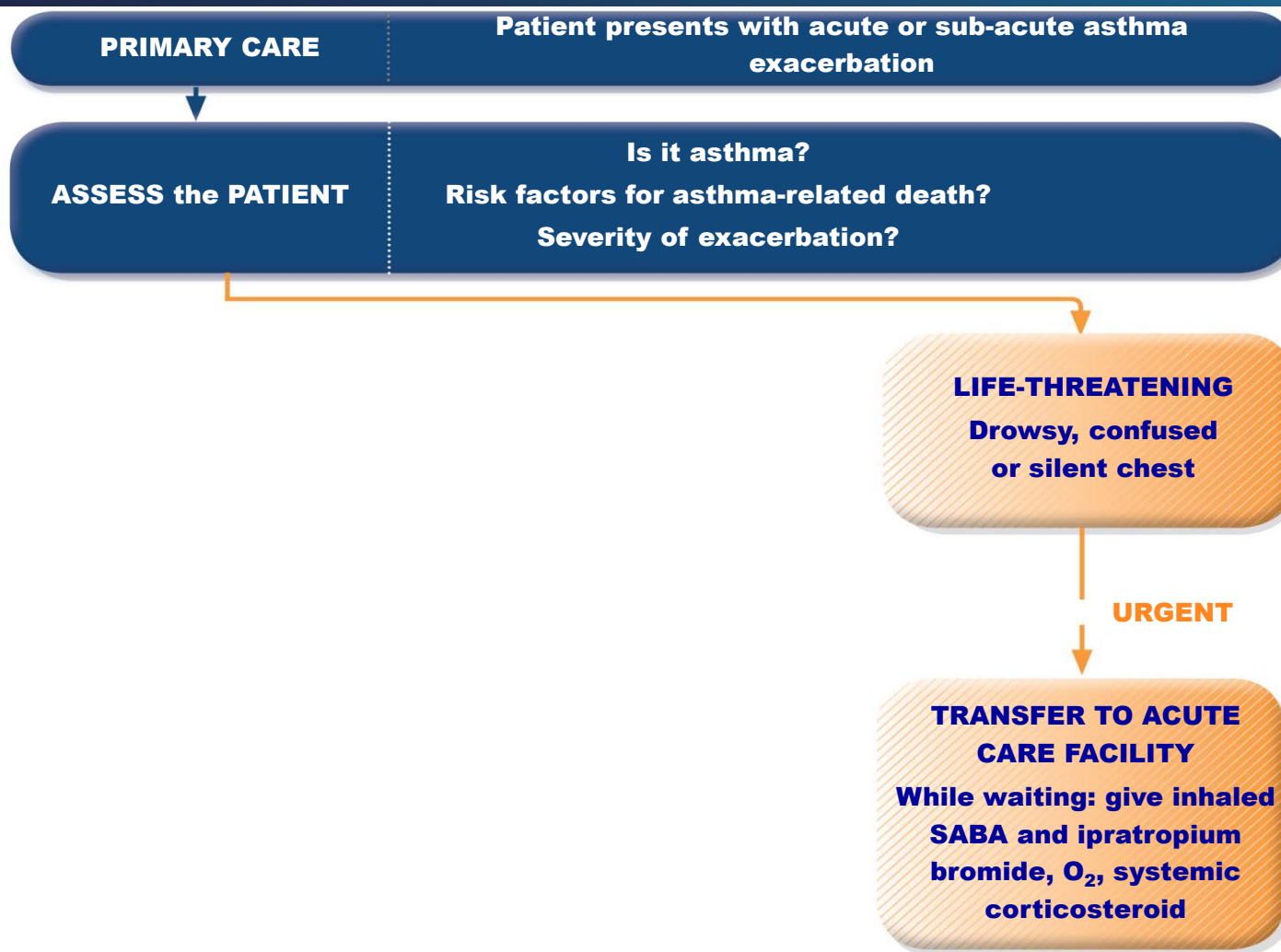
President—J. H. BURN, M.D.

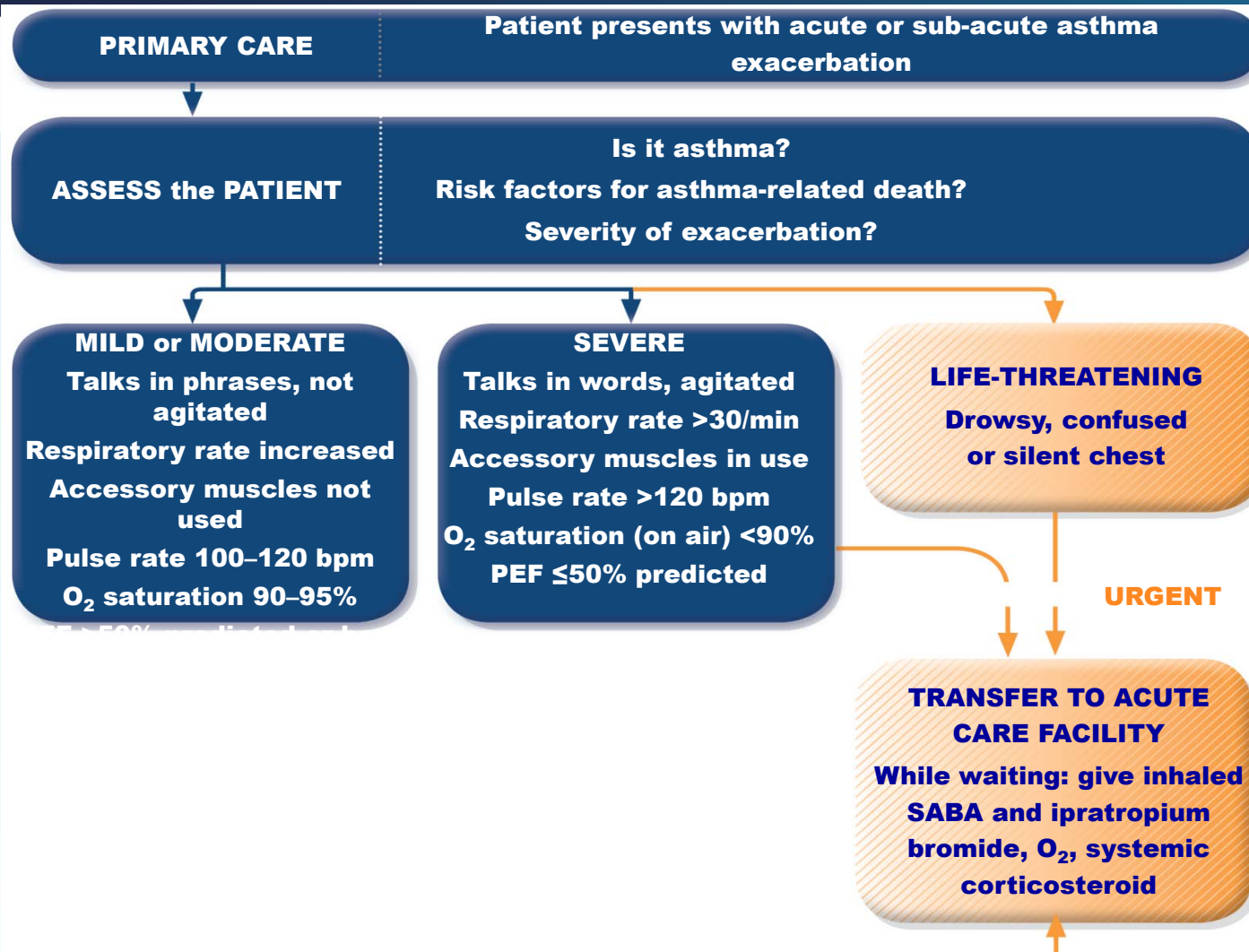
*Abstract.*—About four years ago I began the investigation of an obscure pharmacological problem which, though interesting enough from a theoretical standpoint, offered no hope that any result of general importance might emerge from it. In the course of the work a number of new observations have been made which, taken together, suggest that adrenaline in circulation in the body has a function in relation to the sympathetic system not hitherto assigned to it. The results indicate that the efficiency of the sympathetic nerve (that is to say the size of the response elicited by a given impulse passing down a sympathetic nerve) depends upon the amount of adrenaline in circulation in the blood. The pathological application of this arises from the consideration that in some persons the amount of adrenaline in circulation may be below normal; some evidence derived from asthmatic patients is in support of this, and there is some evidence that the amount of adrenaline in the blood of different cats differs. If the amount of adrenaline in different persons does indeed vary, it follows that those persons in whom the amount of circulating adrenaline is abnormally low will possess a relatively inefficient sympathetic system; they will be predisposed to asthma. Should any chronic inflammatory change develop, leading either to a direct or to a reflex diminution of the bronchiolar air way, these patients will be unable to dilate their bronchioles and will suffer an asthmatic attack. The conception of the predisposing cause of asthma as being a deficient secretion of adrenaline which enfeebles the sympathetic nerves suggests fresh methods of treatment for the alleviation of the disease, by the addition to the diet of the precursors of adrenaline.

# Gestione delle riacutizzazioni di asma in medicina generale

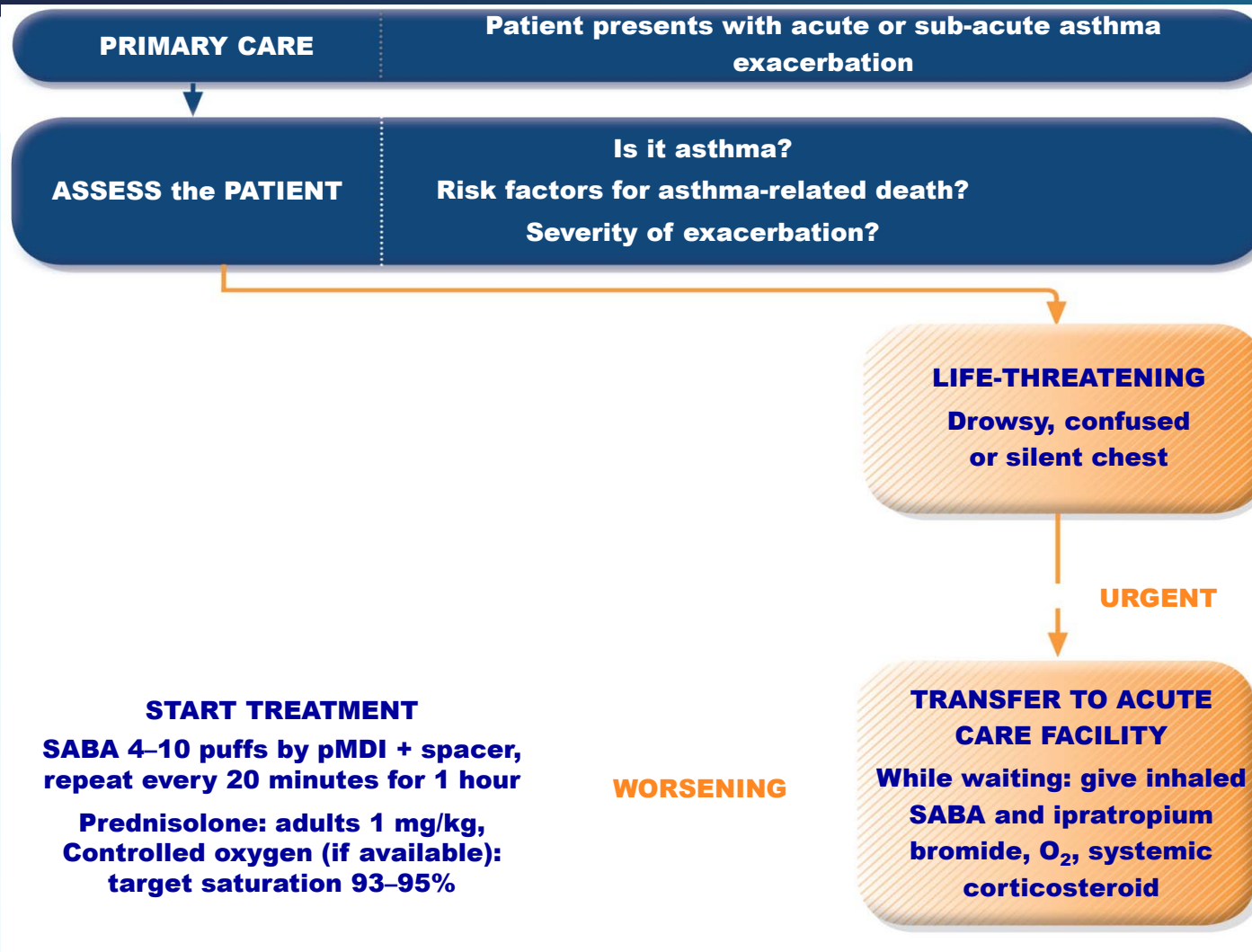
## Management of Asthma Exacerbations: Home Treatment













G Model  
AUCC-358; No. 0



ELSEVIER

Review Pa  
Noninva  
systema

Elyce Gree  
Dr Paras Ja  
Dr Maree E

## A B S T R A C T

**Background:** Asthma is a chronic disease characterised by reversible airway obstruction caused by bronchospasm, mucous and oedema. People with asthma commonly experience acute exacerbations of their disease requiring hospitalisation and subsequent utilisation of economic and healthcare resources. Non-invasive ventilation has been suggested as a treatment for acute exacerbations of asthma due to its ability to provide airway stenting, optimal oxygen delivery and decreased work of breathing.

**Objectives:** This paper is a systematic review of the available published research focused on the use of noninvasive ventilation for the treatment of acute exacerbations of asthma to determine if this treatment provides better outcomes for patients compared to standard medical therapy.

**Method:** Database searches were conducted using EBSCOhost, MEDLINE and PubMed. Search terms used were combinations of 'noninvasive ventilation', 'BiPAP', 'CPAP', 'wheez\*' and 'asthma'. Articles were included if they were research papers focused on adult patients with asthma and a treatment of noninvasive ventilation, and were published in full text in English. Included articles were reviewed using the National Health and Medical Research Council (Australia) evidence hierarchy and quality appraisal tools.

**Results:** There were 492 articles identified from the database searches. After application of inclusion/exclusion criteria 13 articles were included in the systematic review. Studies varied significantly in design, endpoints and outcomes. There was a trend in better outcomes for patients with acute asthma who were treated with noninvasive ventilation compared to standard medical therapy, however, the variability of the studies meant that no conclusive recommendations could be made.

**Conclusion:** More research is required before noninvasive ventilation can be conclusively recommended for the treatment of acute exacerbations of asthma.

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**i “diversi” approcci terapeutici**

**due considerazioni personali...**

# Patient and physician asthma deterioration terminology

**RIACUTIZZAZIONE**

**ATTACCO D'ASMA**

**PAZIENTI**

**24%**

**97%**

**MMG**

**77%**

**65%**

**STESSO SIGNIFICATO?**

**PAZIENTI**

**38%**

**MMG**

**97%**

*Blaiss et al. Allergy Asthma Proc 2012*

# La comunicazione atto terapeutico

- **Migliora la comprensione del trattamento**

(Roter et al. 1987; Hall et al. 1988)

- **Aumenta la soddisfazione del paziente**

(Williams et al. 1998; Safran et al. 1998; Kinnersley et al. 1999)

- **Migliora la collaborazione al trattamento**

(Butler et al. 1996; Safran et al. 1998; Svensson et al. 2000)

- **Incide sullo stato di salute**

(Ong et al. 1995; Stewart 1995; Maly et al. 1999; Mead & Bower 2002; Joosten et al. 2008)

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## Asthma Management Failure: A Flaw in Physicians' Behavior or in Patients' Knowledge?

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### Why do **doctors** and patients not follow guidelines?

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#### **Purpose of review**

The aim of this review is to evaluate the factors related to the doctor and the patient that could make following the guidelines difficult. It also underlines the importance of the adherence to guidelines themselves in order to ameliorate both the control of healthcare and the patients' quality of life.

#### **Recent findings**

Following guidelines not only depend on factors related to guidelines themselves,





## **ASTHMA: FROM POPULATION-LEVEL TO PATIENT-LEVEL «PERSONALIZED THERAPY»**

- *Population-level medication choices*, e.g. for national formularies or managed care organizations. These aim to represent the best option for most patients in the population. For each treatment step, a 'preferred' controller medication is recommended that provides the best benefit to risk ratio (including cost) for both symptom control and risk reduction. Choice of the preferred controller is based on group mean data from efficacy studies (highly controlled studies in well-characterized populations) and effectiveness studies (from pragmatically controlled studies, or studies in broader populations, or strong observational data),<sup>133</sup> as well as on safety data and cost.
- *Patient-level medication choices*: choices at this level also take into account any patient characteristics or phenotype that may predict a clinically important difference in their response compared with other patients, together with the patient's preferences and practical issues (cost, ability to use the medication and adherence).



# STATO DI SALUTE

**È una quantificazione standardizzata dell'impatto di malattia e negli studi clinici è considerato uno dei principali *outcome*.**

**Lo stato di salute come concetto di elevata complessità viene valutato indirettamente e richiede l'applicazione di questionari appropriati.**

	<b>Instrument Type</b>	<b>Domains</b>
SGRQ	disease-specific	symptoms, activities, psychosocial impact
CRQ	disease-specific	dyspnea, emotional function, fatigue, mastery
SF-36	generic	physical and social function, mental health, energy/vitality, health perception, physical and mental role limitation, pain

**Patient-Reported Outcomes to  
support medical product labeling  
claims: FDA perspective**



**PROs provide an unique perspective on medical therapy,  
because some effects of a health condition and its  
therapy are known only to patients**

*Patrick DL, et al 2007*



## **HRQoL and Other PROs in the European Centralized Drug Regulatory Process: A Review of Guidance Documents and Performed Authorizations of Medicinal Products 1995 to 2003**

**There was a trend toward increasing HRQL and other PRO claims in regulatory documents of pharmaceutical products in recent years, with the proportion exceeding 30% from 1999 to 2003.**

*Szende A. et al. Value Health, 2005*

# The Expert Patient and Chronic Respiratory Diseases

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The concept of “expert patient” refers to a patient who has a deep understanding of his/her disease and treatment options. These patients are now considered as partners who can interact effectively with health professionals in the management of their condition, on care delivery, and be involved in the design and conduct of research initiatives. This role is becoming increasingly important and specific requirements need to be met to ensure a potentially important role to improve patient care.

## The expert patient: towards a novel definition



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Experience of illness and knowledge of disease make the expert patient an empowered partner for health professionals <http://ow.ly/x8vbj>

Chronic diseases have become a major burden in many developed countries. Physicians and policy makers manage patients and set clinical as well as research goals. In recent years, however, it has become progressively apparent that, as the patients are the ones living with the disease, their views and wishes should be considered, and healthcare should be more patient-centred. Many guidelines stress the importance of patient education, especially now that patients have easy access to information through the internet, mass media, educational activities in hospitals, communities and patient groups. Those living with common conditions such as chronic obstructive pulmonary disease (COPD) and asthma, and even rare pulmonary disorders, progressively acquire both experience and knowledge of their condition. The importance of patient involvement not only in their own management but also in health policy planning and decision-making is now being emphasised in Europe. Task forces are beginning to include patients in their expert panels when setting guidelines.