

NOVITA' NEL TRATTAMENTO DELLA BRONCHIOLITE

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The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 11, 2006 VOL. 354 NO. 19

Respiratory Syncytial Virus and Recurrent Wheeze in Healthy Preterm Infants

May 9, 2013

The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 11, 2006 VOL. 354 NO. 19

Racemic Adrenaline and Inhalation Strategies in Acute Bronchiolitis

June 13, 2013

PEDIATRICS[®]

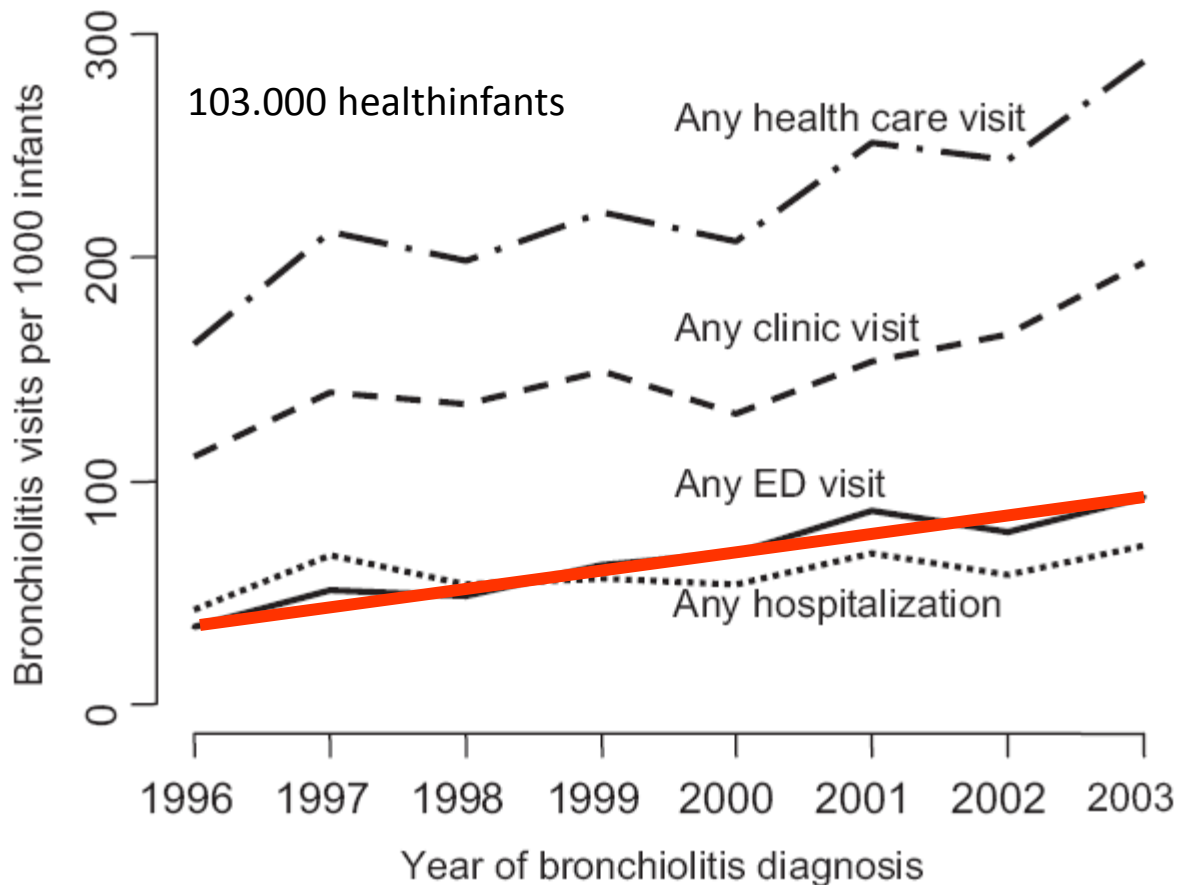
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Oral Dexamethasone for Bronchiolitis: A Randomized Trial

September 4, 2013

Increasing Burden and Risk Factors for Bronchiolitis-Related Medical Visits in Infants Enrolled in a State Health Care Insurance Plan

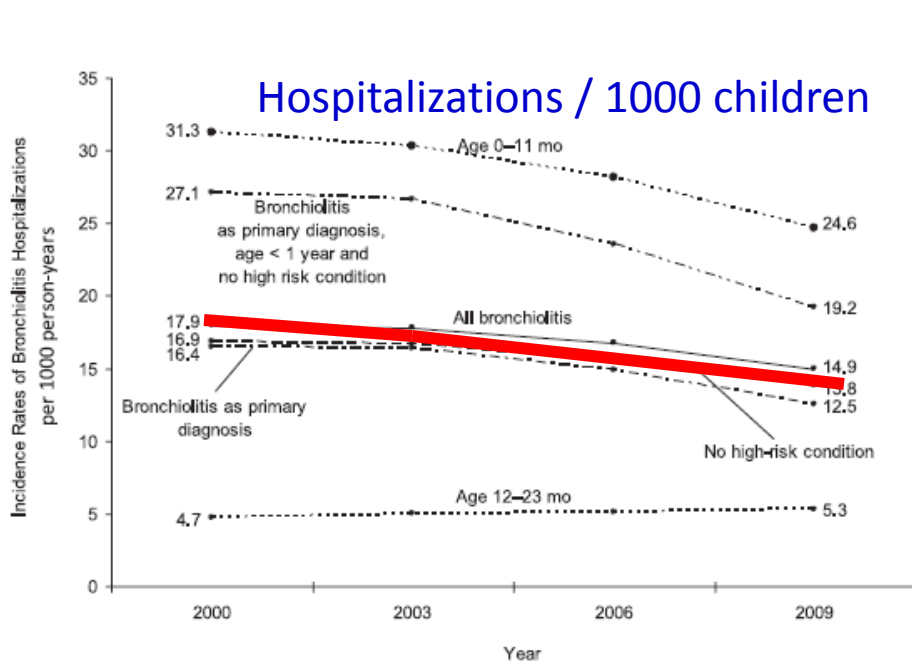
Increasing morbidity and hospitalization over last 15 years



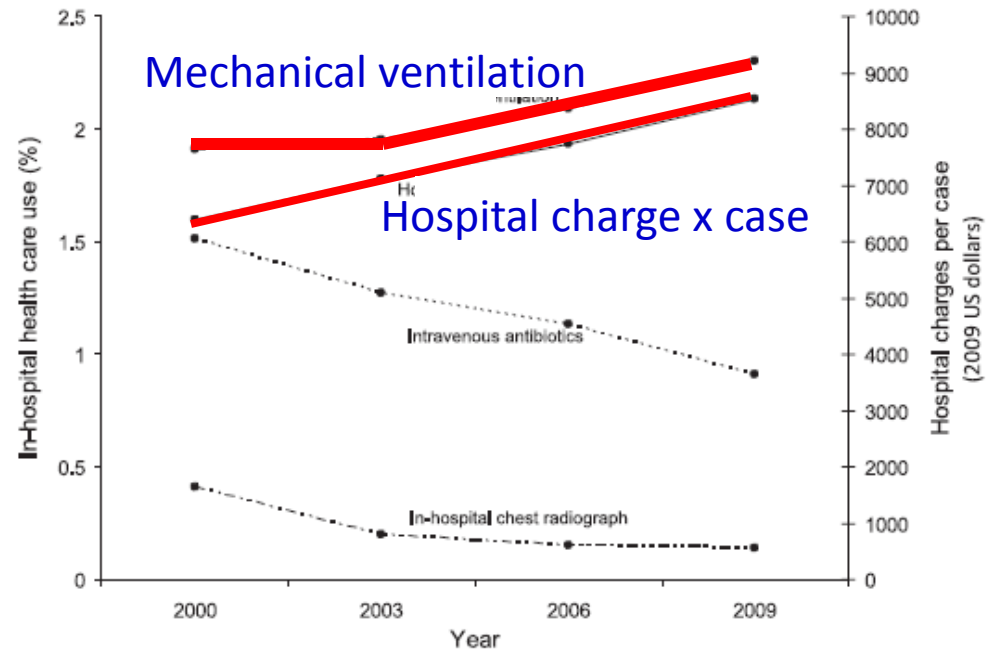
Mean annual rates of bronchiolitis visits increased **41%** from 1996 to 2003

Trends in Bronchiolitis Hospitalizations in the US, 2000–2009

US database (Kids' Inpatients Database)



GOOD NEWS



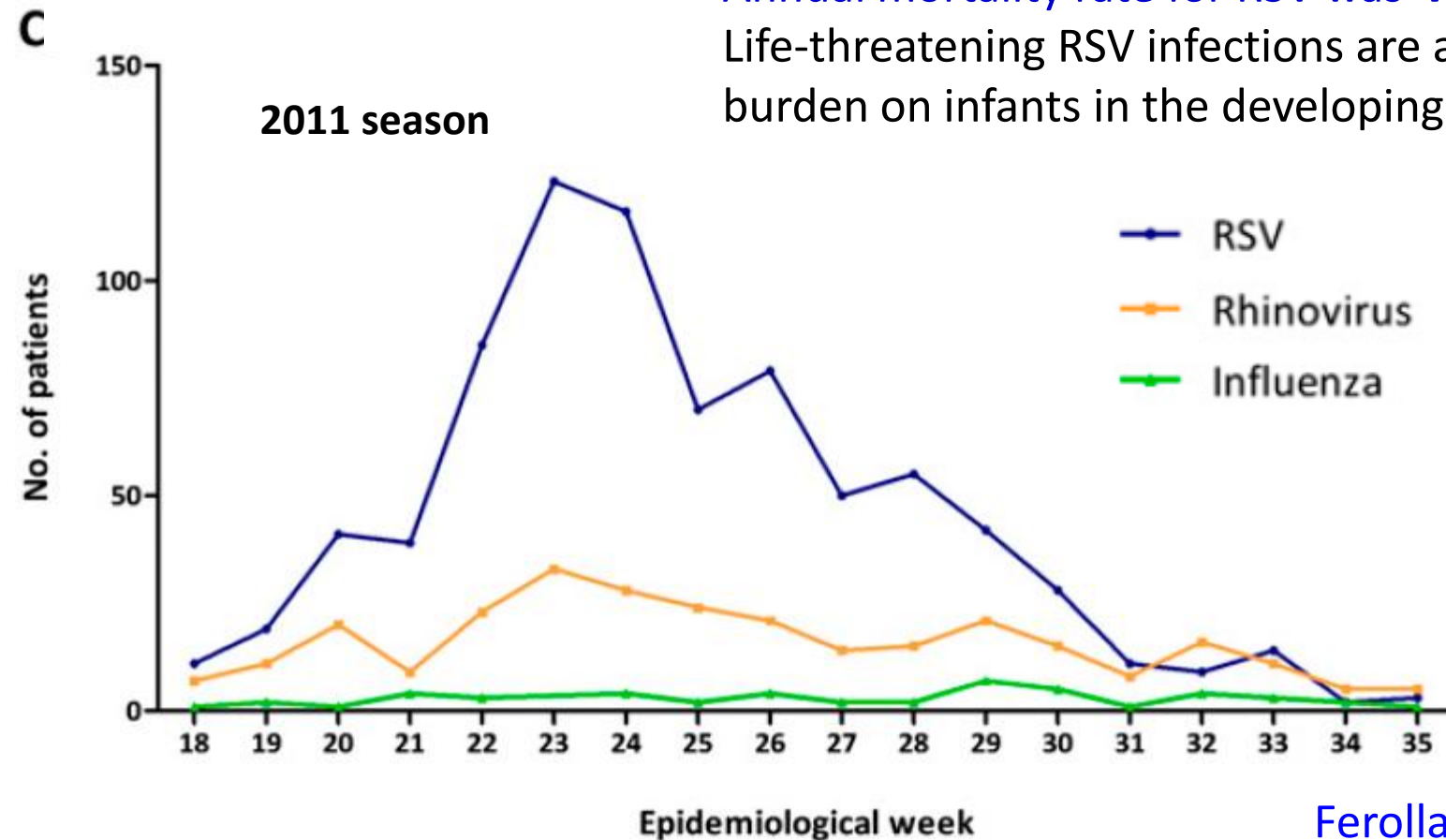
BAD NEWS

BURDEN OF RSV INFECTION IN ARGENTINA

Prospective study in 56,560 children < 2 years.
60% of respiratory infections in hospitalized children (n=1293) were due to RSV.

Annual mortality rate for RSV was **7%**.

Life-threatening RSV infections are a heavy burden on infants in the developing world.



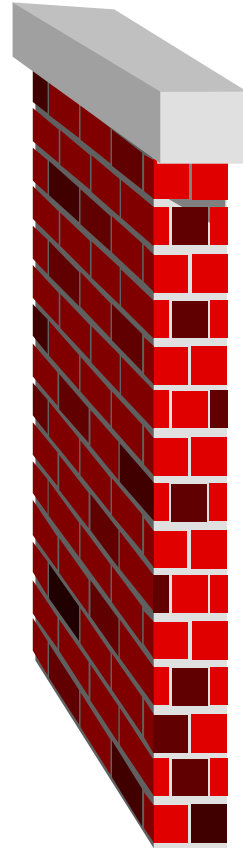
DIAGNOSIS OF BRONCHIOLITIS

UK, Australia
EU (age < 12m)

Bronchiolitis



inspiratory crackles
± wheezing



USA (EU)

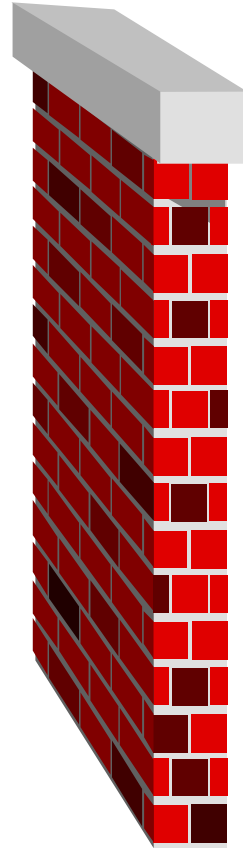
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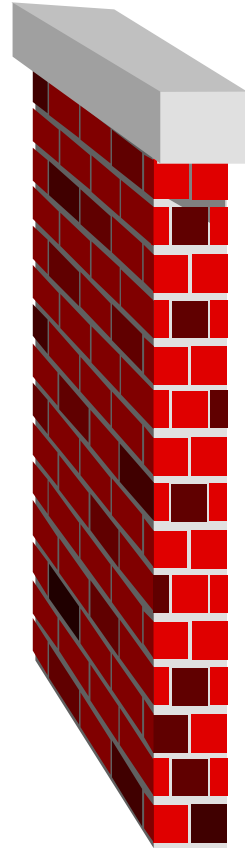
DIAGNOSIS OF BRONCHIOLITIS

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Bronchiolitis



inspiratory crackles
± wheezing



USA (EU)
(age < 2 yrs)

Bronchiolitis



wheezing



Early onset Asthma ???

RSV INFECTION- BRONCHIOLITIS

- Leading cause of hospitalization in infants
 - Up to **3%** of all children in first year of life are hospitalized with bronchiolitis (18% of all hospitalizations in US)
 - **10-12%** need intensive care
- Virtually all children have been infected with RSV by the age of 2 years
- Previous infection does not transmit persistent immunity and reinfection is common and can recur in the same RSV season
- Of RSV infected infants 40% will develop a LRTI

Wright Ped Pulmonol 2011
Glezen Am J Dis Child 1986

RISK FACTORS FOR SEVERE BRONCHIOLITIS

- Prematurity and BPD
- Age less than 12 weeks
- Congenital cardiac illness
- Immunodeficiency

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Pediatrics 2006;118;1774-1793

Diagnosis and management of Bronchiolitis

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Pediatrics 2006;118;1774-1793



Scottish Intercollegiate Guidelines Network



91

Bronchiolitis in children

A national clinical guideline

November 2006



Clinical Questions

Efficacy of pharmaceutical therapies
for **treatment** of bronchiolitis

Role of prophylaxis
in **prevention** of bronchiolitis

Efficacy of pharmaceutical therapies
for **treatment** of bronchiolitis

Management of Bronchiolitis

**When supplemental O₂ is
indicated?**





Supplemental O₂ is indicated when SatO₂
falls persistently < **90%**



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Infants with O₂ saturation levels < **92%** should
receive supplemental oxygen by nasal cannulae or
facemask

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Supplemental O₂ is indicated when

SatO₂ falls < **90%** or < **92%**



Impact on the number of hospitalization!!!

The routine measurement of O₂ saturation may be responsible for the increased admission rates of the last years

Smyth Lancet 2006

Supplemental O2



HOW TO OBTAIN A GOOD MEASUREMENT OF O₂ SATURATION ?

- proper probe and appropriate placement
- avoid movement
- stability of readings pulse amplitude
- vasoconstriction and hypothermia
- ???

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Suctioning of the nares should be performed before to measure O₂ saturation



Nasogastric hydration versus intravenous hydration for infants with bronchiolitis: a randomised trial

Hydration is the mainstay of bronchiolitis treatment

Multicenter randomized trial, infants 2-12 months admitted to hospitals in Australia and NZ

Randomly allocated to - nasogastric hydration (n=323)
- intravenous hydration (n=294)

Results: No differences in length of hospital stay, rate of admission to ICU, adverse events.

Conclusion: Both I.V. and nasogastric hydration are appropriate.

Nasogastric insertion required fewer attempts (failure n=7) than I.V. insertion (failure n= 56).

Medicine	Quality of evidence	Recommendation
Bronchodilators	Bronchodilators have no effect on the course of acute bronchiolitis (high)	Bronchodilators should not be routinely used
Inhaled steroids	Inhaled steroids have no effect on the course of acute bronchiolitis (high)	Inhaled steroids should not be routinely used
Systemic steroids	Systemic steroids have no or minimal effect on the course of acute bronchiolitis (high)	Systemic steroids should not be used
Leukotriene receptor antagonists	Montelukast does not have a beneficial effect on the course of acute bronchiolitis (moderate)	LTRA should not be used
Immunoglobulins	Immunoglobulins have no effect on the course of acute bronchiolitis (high)	Immunoglobulins should not be used
Monoclonal antibodies	RSV-specific monoclonal antibodies do not alter the course of acute RSV bronchiolitis	RSV monoclonal antibodies should not be used
Antibiotics	Antibiotics have no effect on the course of acute bronchiolitis (high)	Antibiotics should not be used
Antiviral treatment	There is little evidence of a positive effect of ribavirin on the course of acute bronchiolitis	Ribavirin should not be used
Chest physiotherapy	Chest physiotherapy has no positive effect on the course of acute bronchiolitis (moderate)	Physiotherapy should not be used
Hypertonic saline	Hypertonic saline may have a beneficial effect on the course of acute bronchiolitis (moderate)	Hypertonic saline may be considered

Treatment of bronchiolitis: state of the art

Liviana Da Dalt^{a,b}, Silvia Bressan^a, Francesco Martinolli^a, Giorgio Perilongo^a, Eugenio Baraldi

Therapeutic options and their clinical implications

Clinical implication

Supportive therapy

Oxygen

Mainstay of therapy in patients with SaO₂ <90–92%

Hypertonic solution

Safe and apparently effective – to be considered

Chest physiotherapy

Not effective

Mist-steam inhalation

Insufficient evidence to show any benefit

Pharmacological therapy

Beta-agonists

Not effective

Adrenaline

Effective to reduce hospital admissions at 24 hours from ER evaluation

Corticosteroids

Not effective

Adrenaline + corticosteroids

Seems to be effective to reduce hospital admission rate at 7 days from ER evaluation

Nebulized deoxyribonuclease

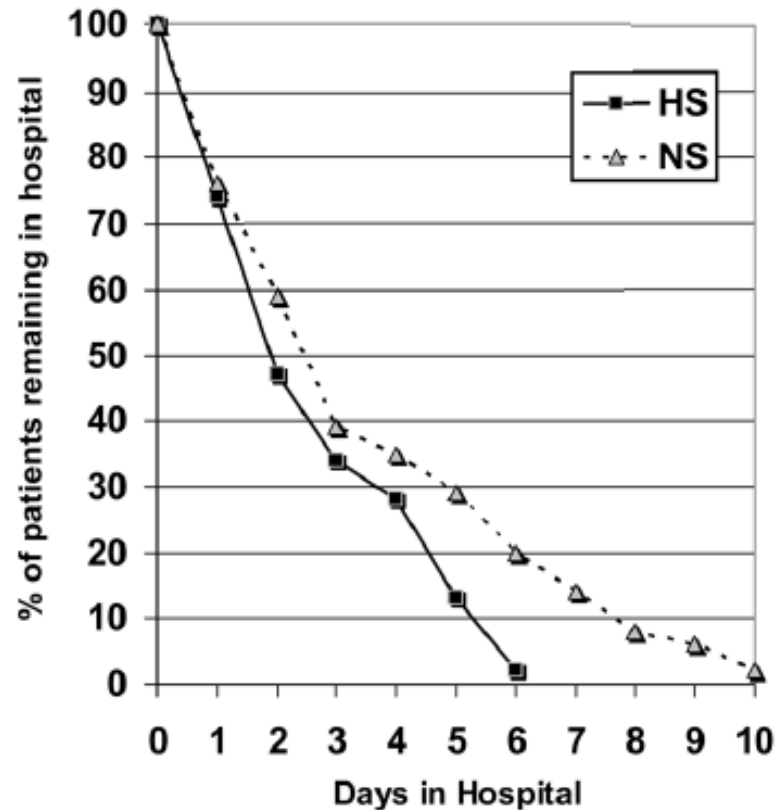
Not effective



Nebulized **Hypertonic Saline** in the Treatment of Viral Bronchiolitis in Infants (< 18 months)

RCT
n=96

4 mL of 3% hypertonic saline vs 0.9% every 6 hrs
(+ albuterol or epinephrine as needed)



26% reduction in the **length of hospitalization** (\$150 million annually)

No adverse effects were observed



Nebulized hypertonic saline (HS) solution for bronchiolitis in infants

- HS improves mucociliary clearance through rehydration of airway surface liquid
- **HS reduces edema of the airways by absorbing water from the mucosa**
- HS breaks the ionic bonds within the mucus gel
- HS increases the ciliary beat frequency



THE COCHRANE
COLLABORATION®

Nebulized hypertonic saline solution for acute bronchiolitis in infants

11 trials involving 1090 infants with mild to moderate acute viral bronchiolitis 4 trials

Current evidence suggests nebulised 3% saline:

- **reduces the length of hospital stay** among infants hospitalised with non-severe acute viral bronchiolitis
- **improves the clinical severity score** in both outpatient and inpatient populations.

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Bronchodilators SHOULD NOT be used routinely in the management of bronchiolitis

- overall, 1 in 4 may have a transient improvement in clinical score
- no impact in the overall course of the illness: some improvement in short-term outcomes (clinical score...) no effects on admission rates and length of hospital stay

A **carefully monitored trial** of α -adrenergic or β -adrenergic is an option

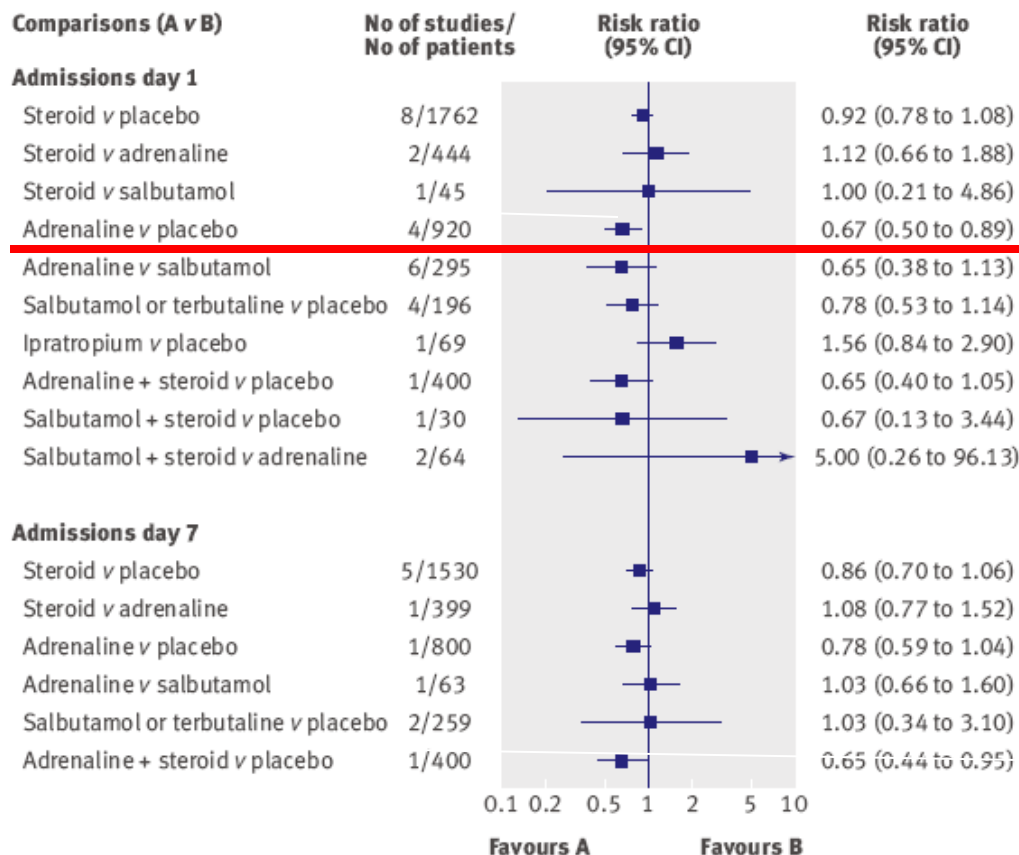


Which bronchodilator?

Epinephrine may be the preferred bronchodilator for this trial in emergency department (0.25 mg/kg/dose).

Epinephrine has demonstrated **slightly better clinical effect** than albuterol possibly related to the **α effect** of the medication.

Steroids and bronchodilators for acute bronchiolitis in the first two years of life: systematic review and meta-analysis



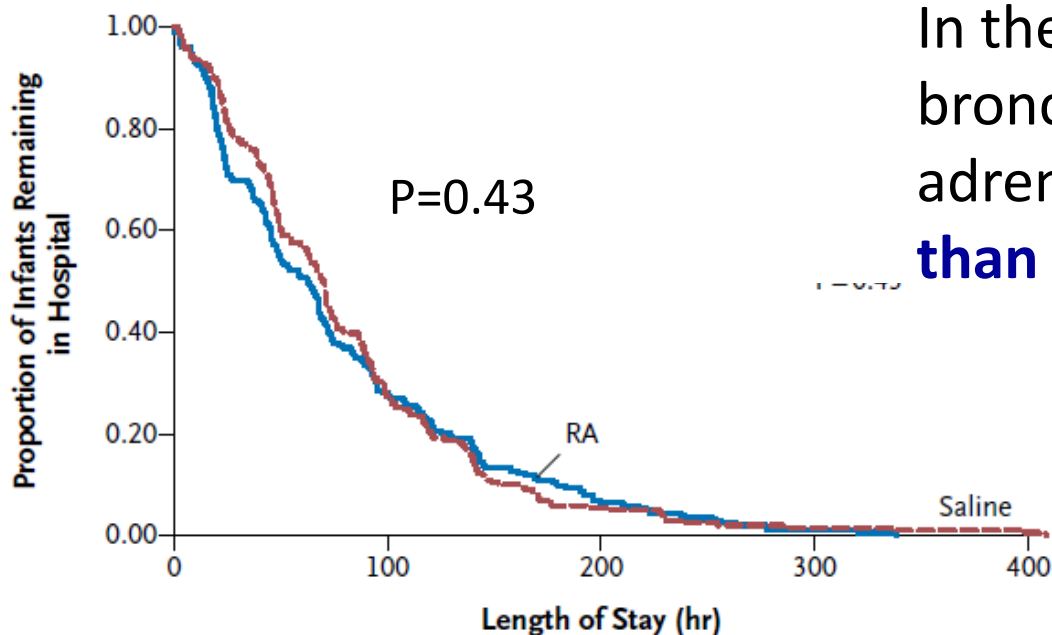
Adrenaline reduced admission on day 1 in the outpatient-emergency setting

BUT no effect for inpatients!

Racemic Adrenaline and Inhalation Strategies in Acute Bronchiolitis

404 infants (mean age 4.2 m.) admitted to a pediatric department inhaled **adrenaline** vs. **saline** (on-demand vs fixed-schedule)
Primary outcome: length of hospital stay

A Inhaled RA or Inhaled Saline



In the treatment of acute bronchiolitis, inhaled racemic adrenaline **is NOT more effective than inhaled saline !!!**

Nebulised Adrenaline at home?

*Because of the lack of studies and potential adverse effects **nebulised adrenaline** is **NOT** recommended in the **home setting***

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Efficacy of pharmaceutical therapies for **treatment** of bronchiolitis

Corticosteroids are NOT recommended for the treatment of acute bronchiolitis

60% hospitalized children with bronchiolitis receive corticosteroids

systemic corticosteroids:

- no benefits were found in length of stay, clinical score or outcomes (Cochrane 2010)

inhaled corticosteroids:

- no benefits in the course of acute disease

inhaled corticosteroids:

- no benefits in the **prevention** of post-bronchiolitic wheeze (Cochrane 2011)

A Multicenter, Randomized, Controlled Trial
of Dexamethasone for Bronchiolitis

600 children (2-12 months) - first episode of bronchiolitis:

20 emergency departments

Excluded children with previous wheeze episodes

Dexamethasone 0.15 mg/kg vs placebo

Outcomes:

Hospital admission after 4 hr of observation

Clinical score

Length of hospital stay

For irreducible people
about steroids

Table 3. Hospital Admission and Changes in Clinical Variables from Baseline to 4 Hours after Intervention.*

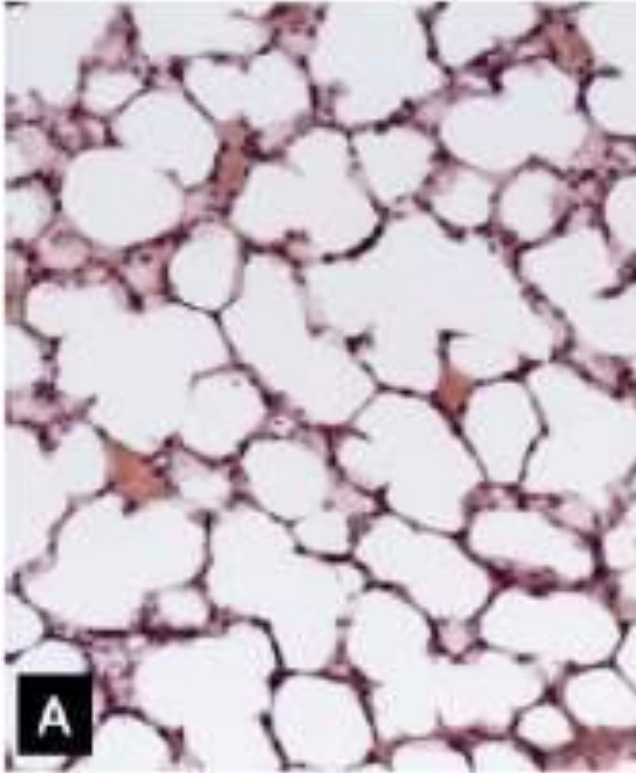
Variable	Dexamethasone Group	Placebo Group	Difference between Groups (95% CI)	P Value
Hospital admission (%)	39.7	41.0	-1.3 (-9.2 to 6.5)	0.74
RACS	-5.3±4.7	-4.8±4.6	-0.5 (-1.3 to 0.3)	0.21
RDAI score	-4.4±3.1	-3.9±3.2	-0.5 (-1.0 to -0.1)	0.03
Respiratory rate (breaths/min)	-8±15	-7±14	-1.0 (-3.0 to 1.0)	0.39
Oxygen saturation (%)	0.3±3.3	<u>0.9±3.2</u>	-0.6 (-1.0 to -0.1)	0.02
Heart rate (beats/min)	-13±24	-5±25	-8.0 (-12.0 to -5.0)	<0.001
Temperature (°C)	-0.6±0.9	-0.2±1.0	-0.4 (-0.6 to -0.3)	<0.001

* Data for all variables except hospital admission are expressed as the change from baseline to 4 hours. RACS denotes Respiratory Assessment Change Score, and RDAI Respiratory Distress Assessment Instrument.

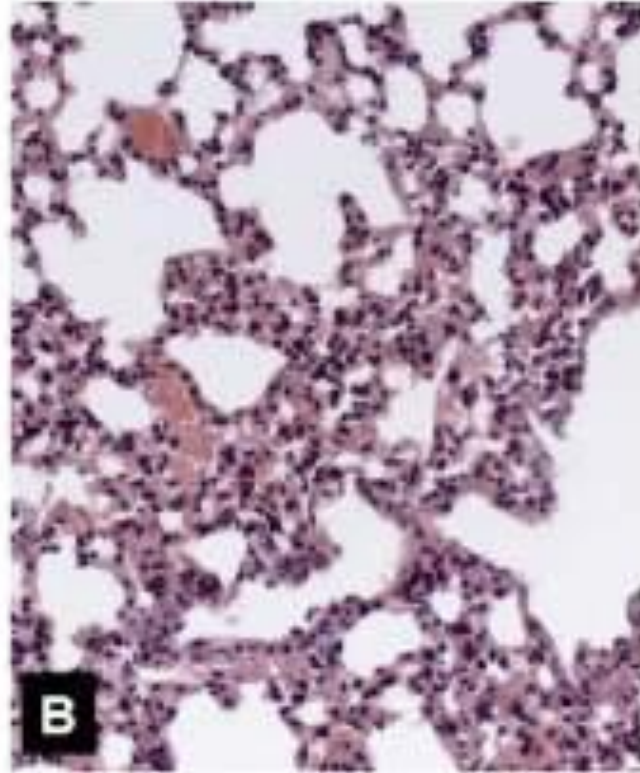
Therapy for Bronchiolitis: When Some Become None

Caroline Breese Hall, M.D.

Immunohistochemistry of lungs on day 7 after infection RSV



Normal



Neutrophils infiltration

GLUCOCORTICOIDS FOR ACUTE VIRAL BRONCHIOLITIS IN INFANTS AND YOUNG CHILDREN

RCTs comparing systemic or inhaled steroids versus placebo in children with bronchiolitis under 24 months.

17 trials - 2596 participants

- ★ Current evidence **does not support** a clinically effect of systemic or inhaled steroids on admissions or length of hospitalisation.

**...AND IN THE CASE OF
BRONCHIOLITIS DETERIORATION?**

...AND IN THE CASE OF BRONCHIOLITIS DETERIORATION?

Nasal CPAP



Assisted Ventilation



PEDIATRIC INTENSIVE CARE

O₂ HFNC

H High Heated Humidified

F Flow

N Nasal

C Cannula



Come agiscono gli alti flussi?

- wash-out dello spazio morto nasale
- riducono la resistenza al flusso inspiratorio
- forniscono pressione positiva che:
 - riduce il carico dei muscoli respiratori
 - mantiene pervi gli alveoli e previene le microatelettasie



High Flow Nasal Cannulae Therapy in Infants with Bronchiolitis



McKieman
J Pediatr 2010

Retrospective study (n=115) comparing seasons with and without HFNC

Required intubation: - **68% (9% vs 23%** in the prior season (P=.043)

PICU length of stay from 6 to 4 days after the introduction of HFNC

Reduced intubation rates for infants after introduction of high-flow nasal prong oxygen delivery



Schibler
Int Care Med 2011

Retrospective study (n=167):

Rate of intubation in bronchiolitis infants **reduced from 37% to 7%**

High Flow Nasal Cannulae Therapy in Infants with Bronchiolitis



McKieman
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Retrospective study (n=115) comparing seasons with and without HFNC

Required intubation: - **68%** (9% vs 23% in the prior season (P=.043))

PICU length of stay from 6 to 4 days after the introduction of HFNC

Setting: Pediatric ICU

**Reduced intubation rates for infants
after introduction of high-flow nasal
prong oxygen delivery**



Schibler
Int Care Med 2011

Retrospective study (n=161):

Rate of intubation in bronchiolitis infants **reduced from 37% to 7%**

High Flow Nasal Cannulae Therapy in Infants with Bronchiolitis



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Retrospective study (n=115) comparing seasons with and without HFNC

Required intubation: - **68%** (9% vs 23% in the prior season (P=.043))

PICU length of stay from 6 to 4 days after the introduction of HFNC

No data available on HFNC in a pediatric ward

**Reduced intubation rates for infants
after introduction of high-flow nasal
prong oxygen delivery**



Schibler
Int Care Med 2011

Retrospective study (n=161):

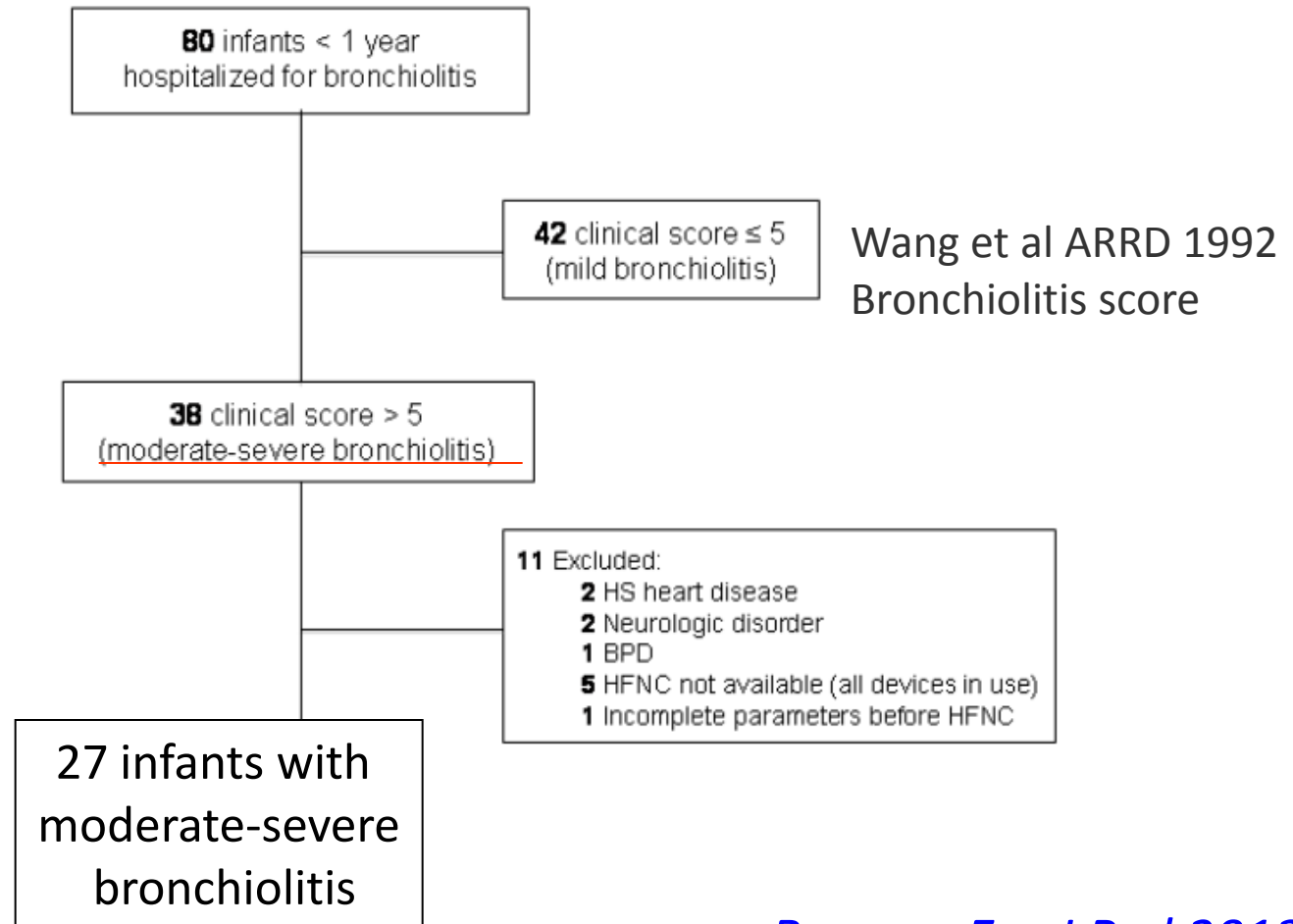
Rate of intubation in bronchiolitis infants **reduced from 37% to 7%**

High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study

Silvia Bressan · Marco Balzani · Baruch Krauss
Andrea Pettenazzo · Stefania Zanconato ·
Eugenio Baraldi



**season
2011-2012**



STUDY DESIGN

Patients: 27 infants with moderate-severe bronchiolitis (first episode)
median age 1.3 months, range 0.3-8.5 months

Aims:

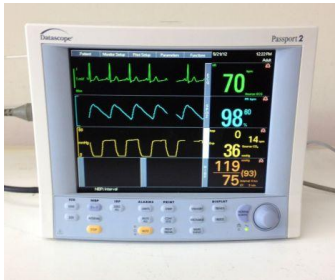
- Feasibility of O₂ HFNC support in a pediatric ward
- Changes in ventilatory parameters before and after HFNC

System: Fisher & Paykel with Optiflow cannulas

Flow rate: weight (in Kg) + 1 (max flow 8 L/min), T 37° C

Monitoring: SatO₂, ETCO₂, RR

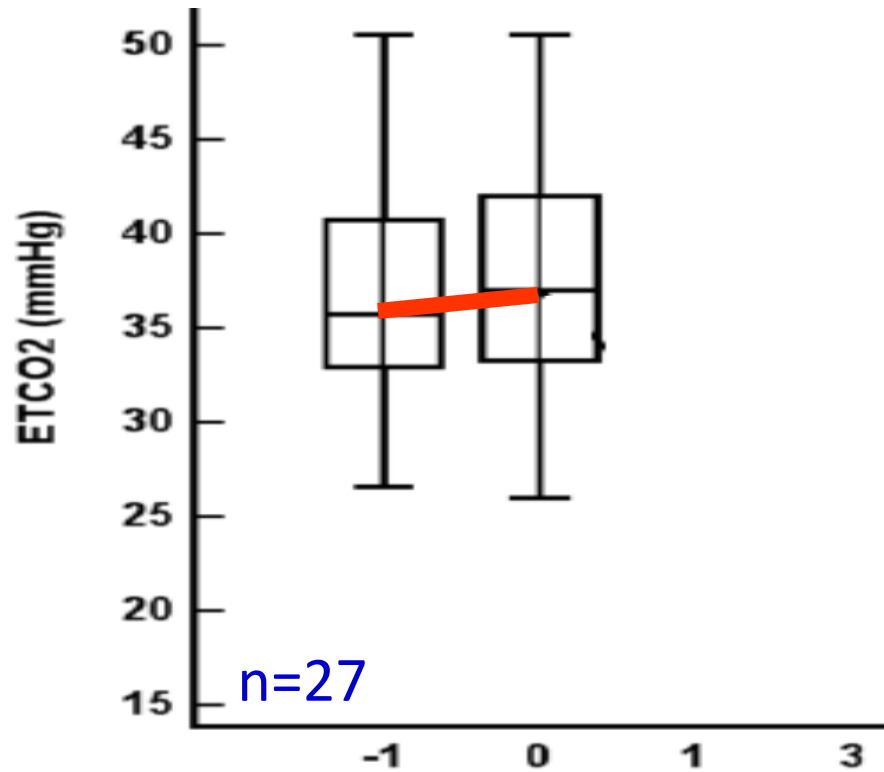
baseline (1 h) – at h 1,3, 6, 12, 24, 36, 48 after starting HFNC



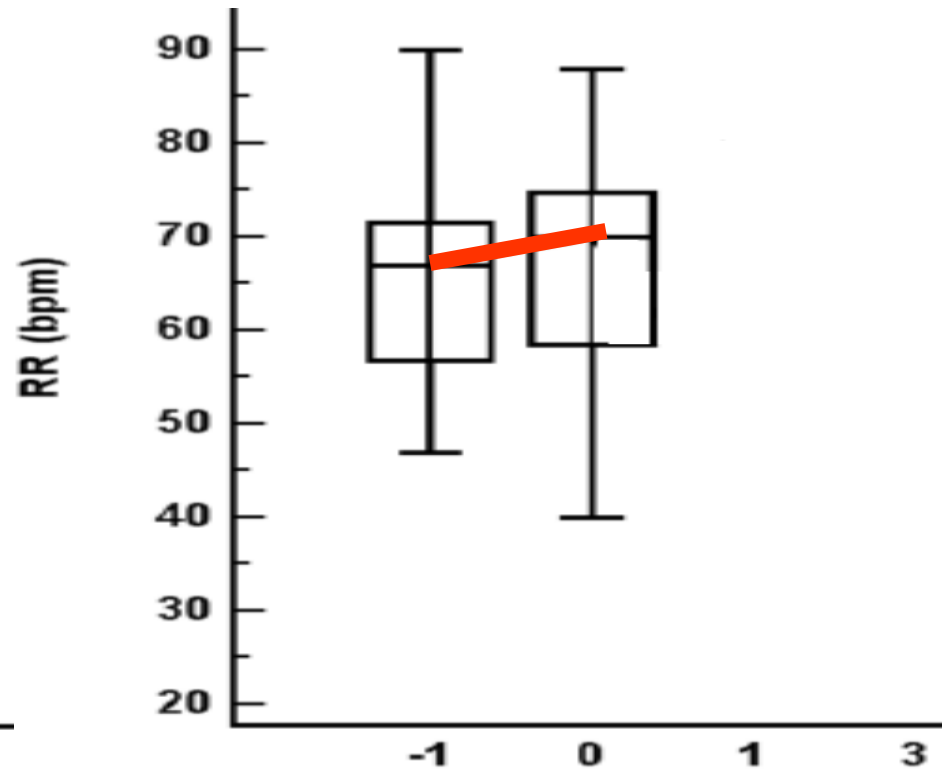
ETCO₂ CapnoLine Philips infant < 10 kg

High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study

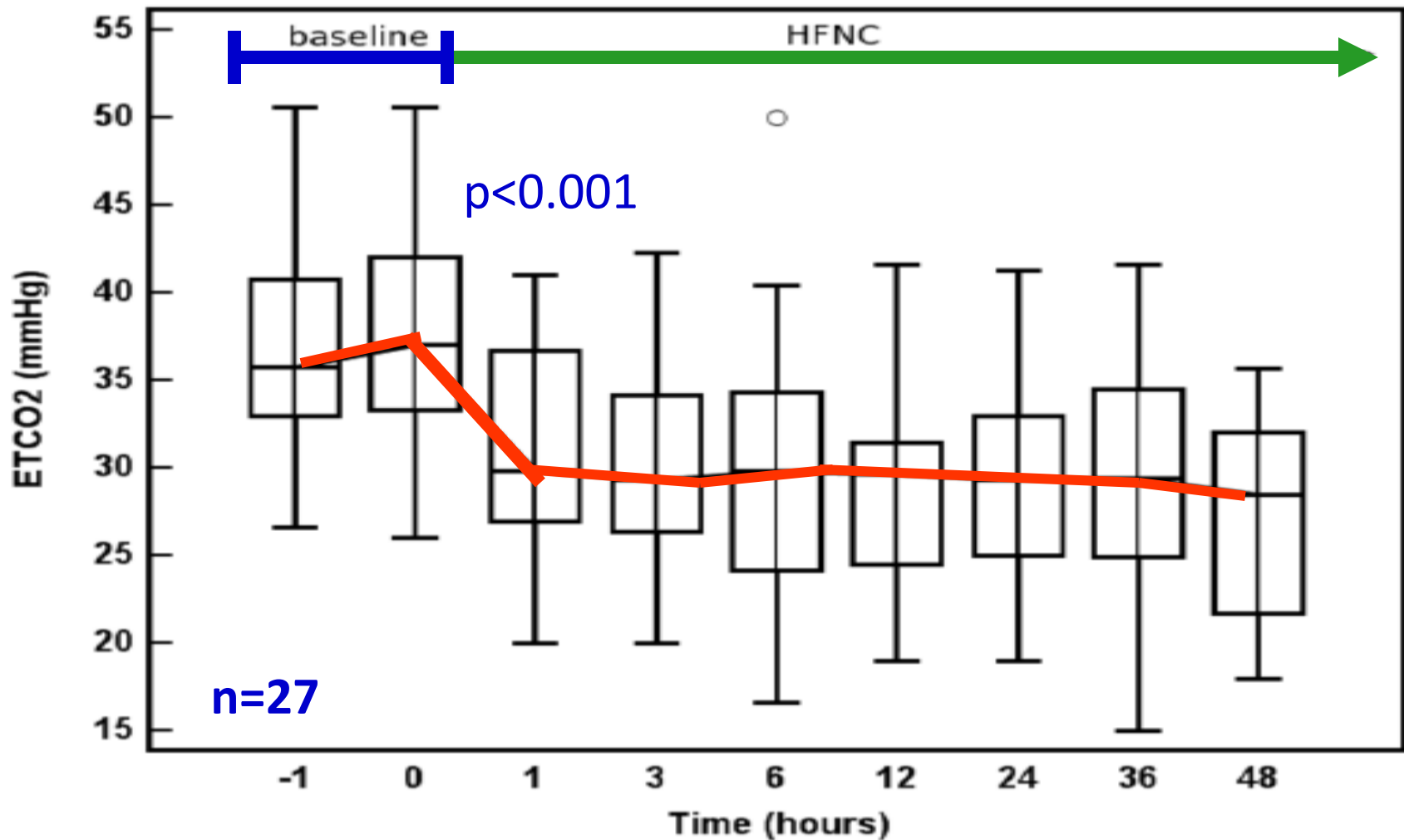
Baseline 1 h



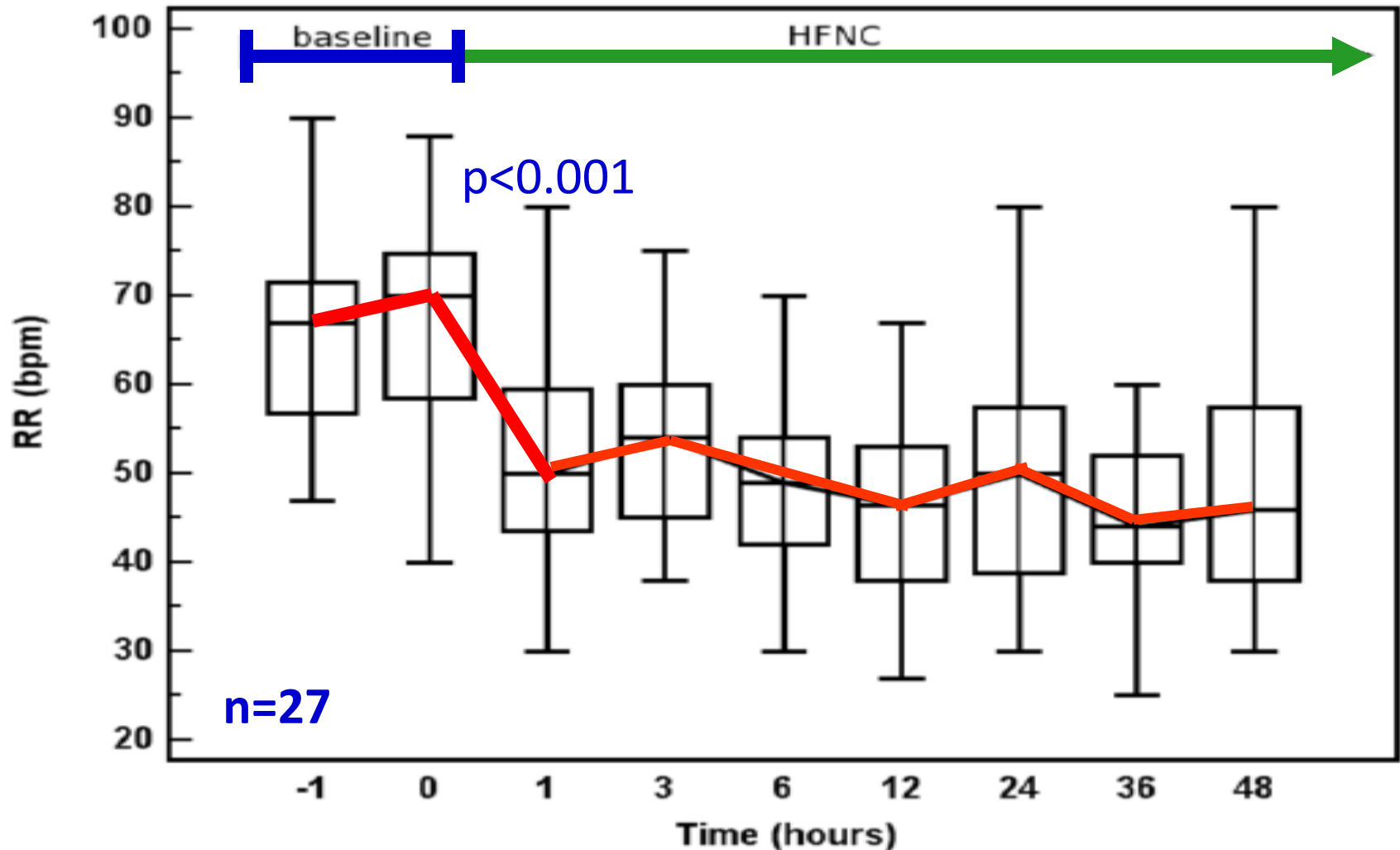
Baseline 1 h



High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study



High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study



High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study



FEASIBILITY AND ADVERSE EVENTS

- None was admitted to the PICU
- No side effects
(pneumothorax, nasal mucosa bleeding, vomiting)

CONCLUSION

HFNC is feasible in a general paediatric ward and it is associated with an improvement of ETCO_2 and RR.



HFNC THERAPY FROM THE EMERGENCY DEPARTMENT TO THE PEDIATRIC WARD –SAFETY AND QUALITY

Patients: 61 HFNC, 33 standard treatment

Aim: to investigate the safety of HFNC treatment in a pediatric ward setting

Flow rate: 2 L/kg/min (max flow 10 L/min)

Results:

feasible in a pediatric ward setting

reduced admission to PICU

no adverse effects



Mayfield, Schibler ATS 2013

...AND IN THE CASE OF BRONCHIOLITIS DETERIORATION?

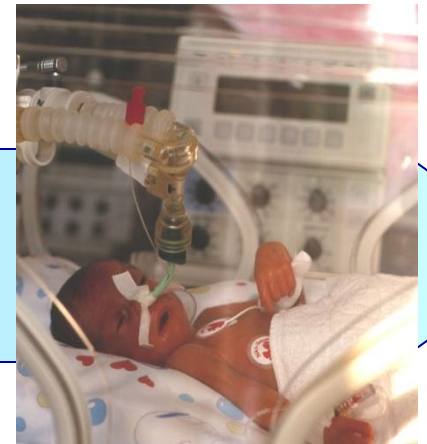
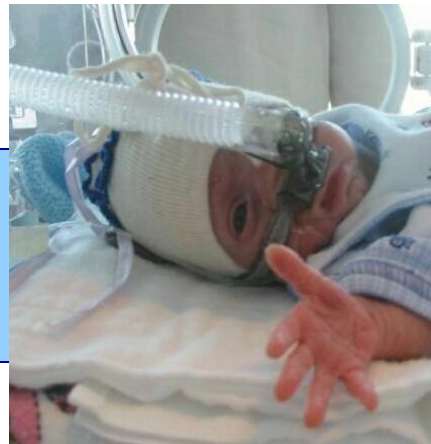
HFNC



**HIGH FLOW NASAL
CANNULAE**

**PEDIATRIC
GENERAL WARD**

Nasal cPAP - Assisted ventilation



**PEDIATRIC
INTENSIVE CARE**

HFNC



**HIGH FLOW NASAL
CANNULAE**

**PEDIATRIC
GENERAL WARD**

**Multicentre randomized
controlled studies are
needed to evaluate:**

- efficacy of HFNC therapy**
- admission to PICU**
- length of hospitalization**
- economic impact**

TRIAL IN CORSO

Study of High-flow Oxygen Therapy Against Standard Therapy in Bronchiolitis RCT

Primary Outcome: Length of hospital stay

University of British Columbia



Comparison of HFNC Versus Standard Nasal Cannula Oxygen Delivery in Infants With Bronchiolitis and Hypoxia

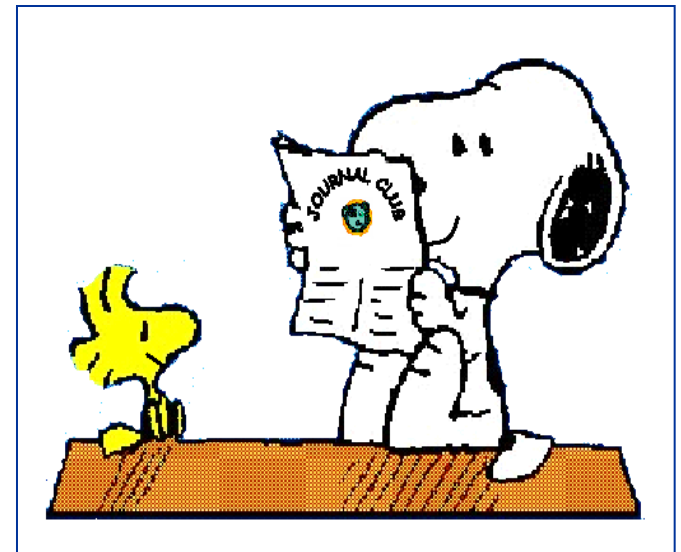
Primary Outcome: Decreases respiratory distress

Secondary Outcome: Length of hospital stay

Children's Hospitals Minnesota



THERAPY FOR BRONCHIOLITIS:
THE HISTORY GOES ON.....

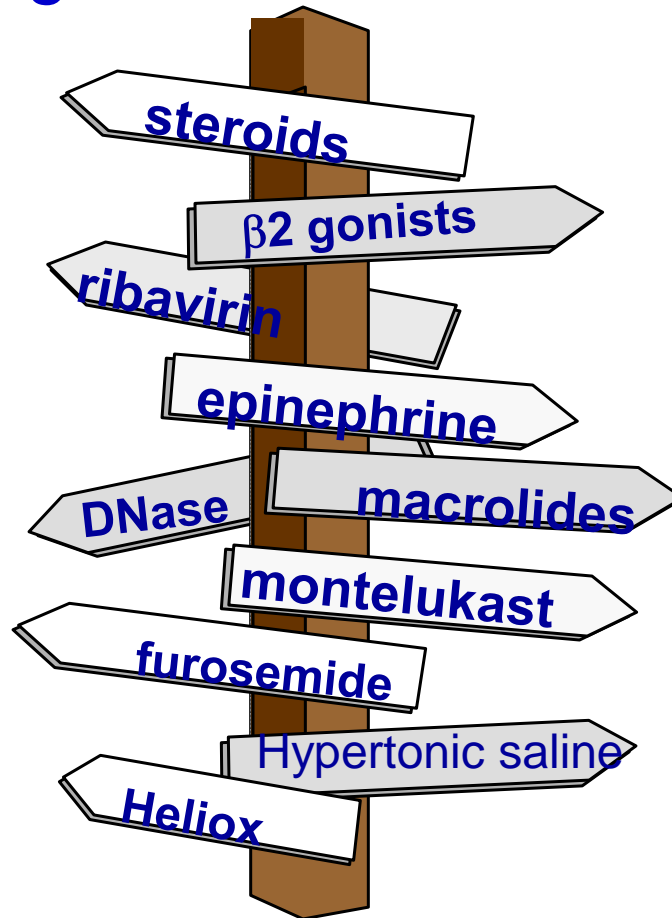


Therapy for Bronchiolitis: When Some Become None

Caroline Breese Hall, M.D.

Withholding therapy is much more difficult than giving it !

NEJM 2007;357:402-4



**Oral Salbutamol for Symptomatic Relief in Mild Bronchiolitis:
A Double Blind Randomized Placebo Controlled Trial**

Gupta et al. Indian Pediatr 2008

**Recombinant Human Deoxyribonuclease
in Infants With Respiratory Syncytial Virus
Bronchiolitis***

Boogaard Chest 2007

**Azithromycin Does Not Improve Disease Course in
Hospitalized Infants With Respiratory Syncytial Virus
(RSV) Lower Respiratory Tract Disease:
A Randomized Equivalence Trial**

Kneyber Pediatr Pulm 2008

**Study of Montelukast for the Treatment of Respiratory
Symptoms of Post-Respiratory Syncytial Virus
Bronchiolitis in Children**

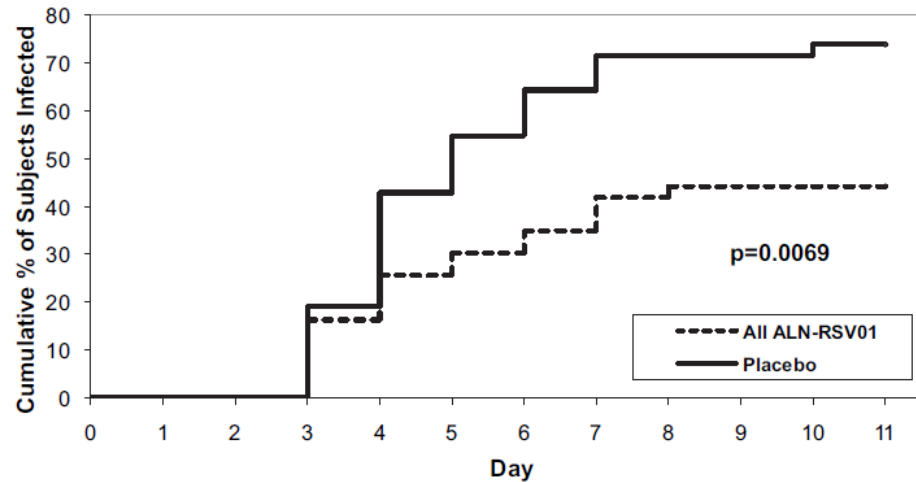
Bisgaard AJRCCM 2008

A randomized, double-blind, placebo-controlled study of an RNAi-based therapy directed against respiratory syncytial virus

Adults (n=88) experimentally infected with wild-type RSV
A **nasal spray of RNA-interference** (ALN-RSV01) or saline placebo was administered for 3 days after RSV inoculation.



Quantitative Culture



Acquisition of infection lower ($p < 0.007$) in ALN-RSV01 treated

**PROOF-OF-CONCEPT FOR A
RNA-I THERAPY IN HUMANS**

RNA-i is a natural mechanism
regulating protein expression

DeVincenzo PNAS 2010



Clinical questions

- 1 Effectiveness of diagnostic tools for **diagnosing** bronchiolitis
- 2 Efficacy of pharmaceutical therapies for **treatment** of bronchiolitis
- 3 Prevention of bronchiolitis and role of specific immunoprophylaxis anti-RSV

Role of prophylaxis
in **prevention** of bronchiolitis

Hands decontamination (alcohol based rubs)
is the most important step in preventing nosocomial spread of RSV

Hands should be decontaminated:

- before and after direct contact with patients
- after removing gloves



Extracorporeal viral survival up to 7 hours !!

Gloves should be used

Stethoscope decontamination!



Prophylaxis with **Palivizumab**
in **PREVENTION** of RSV bronchiolitis

Clinicians may administer Palivizumab prophylaxis:

- to infants and children with CLD < 2 y
- a history of prematurity (<32 gw)
- 32-35 gw + 1 risk factor (child care attendance, siblings < 5yrs) –
- CHD < 2 yrs
- neuromuscular diseases, congenital abnormalities of the airways, immune deficiency (< 1 yr)

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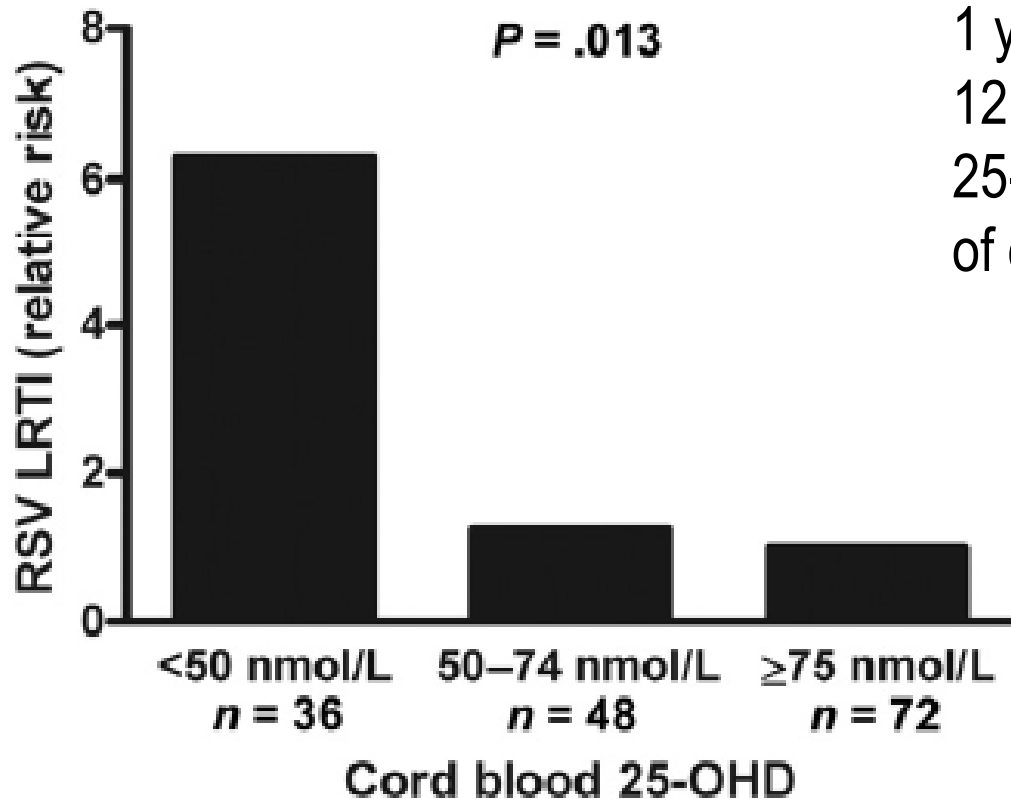


High risk for RSV bronchiolitis in late preterms and selected infants affected by rare disorders: a dilemma of specific prevention



- Prematurity and BPD
- Age less than 12 weeks
- Congenital cardiac illness
- **Immunodeficiency**
- **Chronic pulmonary disease (CF, PCD....)**
- **Neuromuscular diseases**
- **Down syndrome**

Cord Blood Vitamin D Deficiency Is Associated With Respiratory Syncytial Virus Bronchiolitis



n=156 neonates

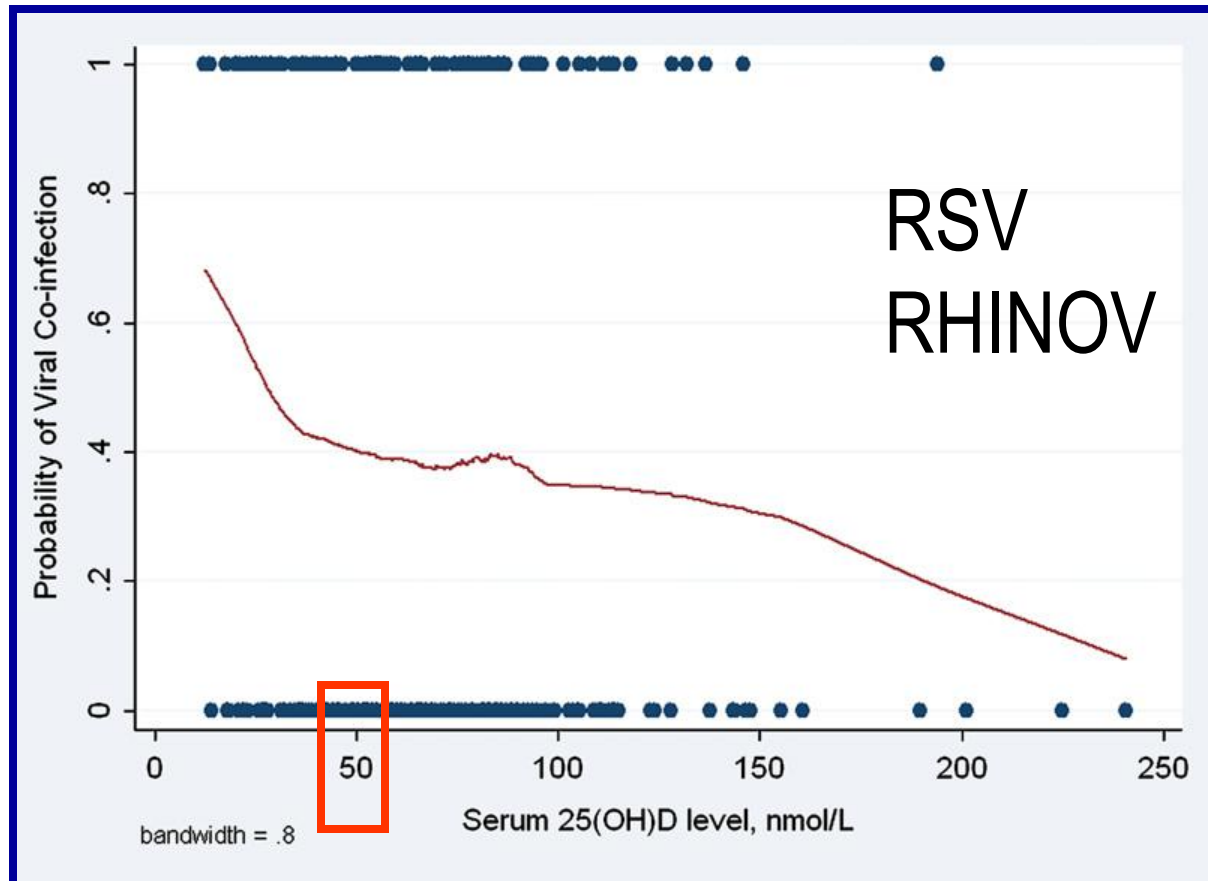
1 y prospective birth cohort

12% developed RSV LTRI

25-OHD < 50: 6 fold increased risk
of developing bronchiolitis

Vitamin D supplementation
during pregnancy may be
useful to prevent RSV-LTRI

LOW SERUM OF VITAMIN D LEVELS ARE ASSOCIATED WITH INCREASED RISK OF VIRAL INFECTIONS IN WHEEZE CHILDREN



284 hospitalized wheeze children

Jartti JACI 2010



TABLE 1. Ca

Life-stage (age and
1–3 yr (M+F)
4–8 yr (M+F)
9–13 yr (M+
14–18 yr (M-
19–30 yr (M-
31–50 yr (M-
51–70 yr (M)
51–70 yr (F)
71+ yr (M+F)
Pregnant or l
14–18 yr
19–50 yr
Infants
0–6 montl
6–12 mon

400 UI a day < 1 year

At least 600 UI a day for children >1 year

upper level: 2500 UI/die 1-3 aa,
 3000UI/die 4-8 aa
 4000 UI/die >9 aa

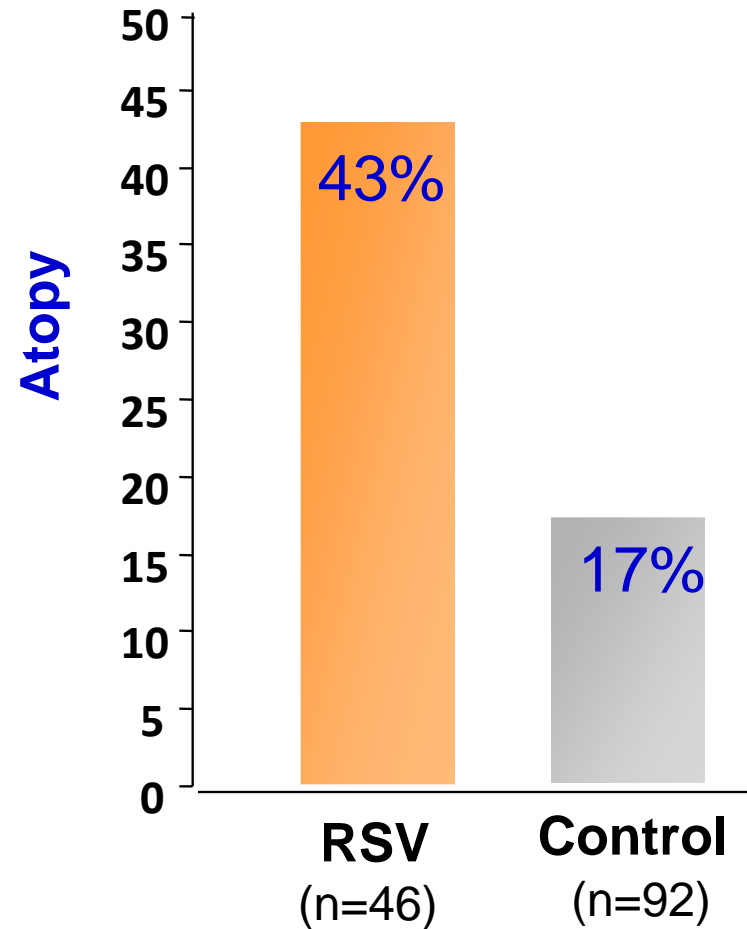
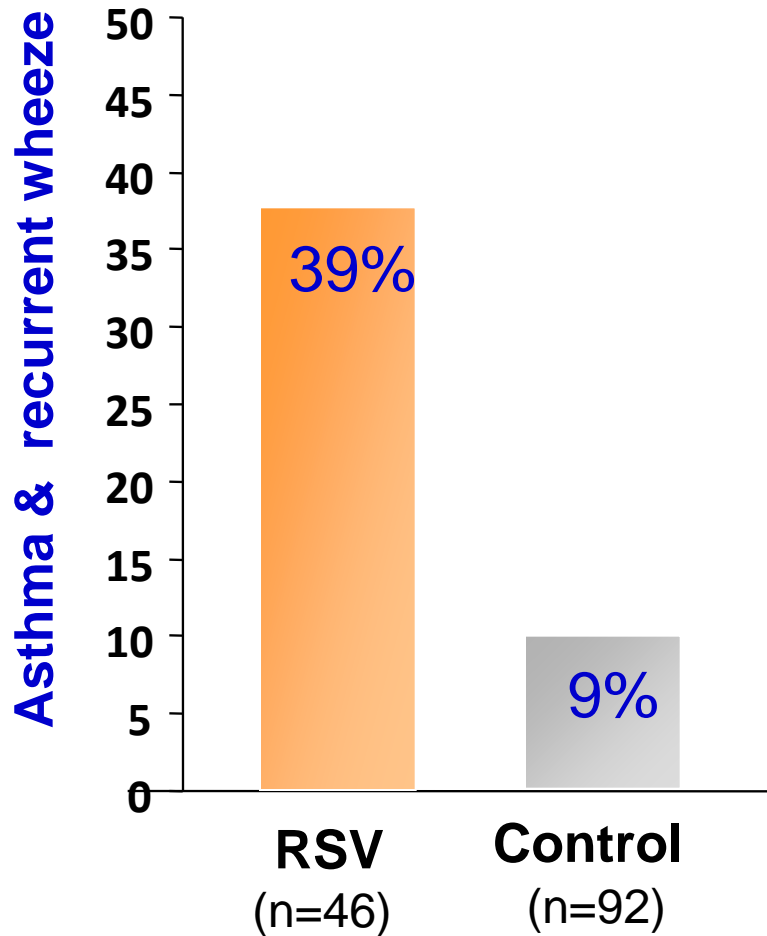
UL (IU/d) ^a
2500
3000
4000
4000
4000
4000
4000
4000
4000
4000
4000
1000
1500

serum level of at least **50 nmol/L** of 25(OH)D as meeting the needs of nearly all children

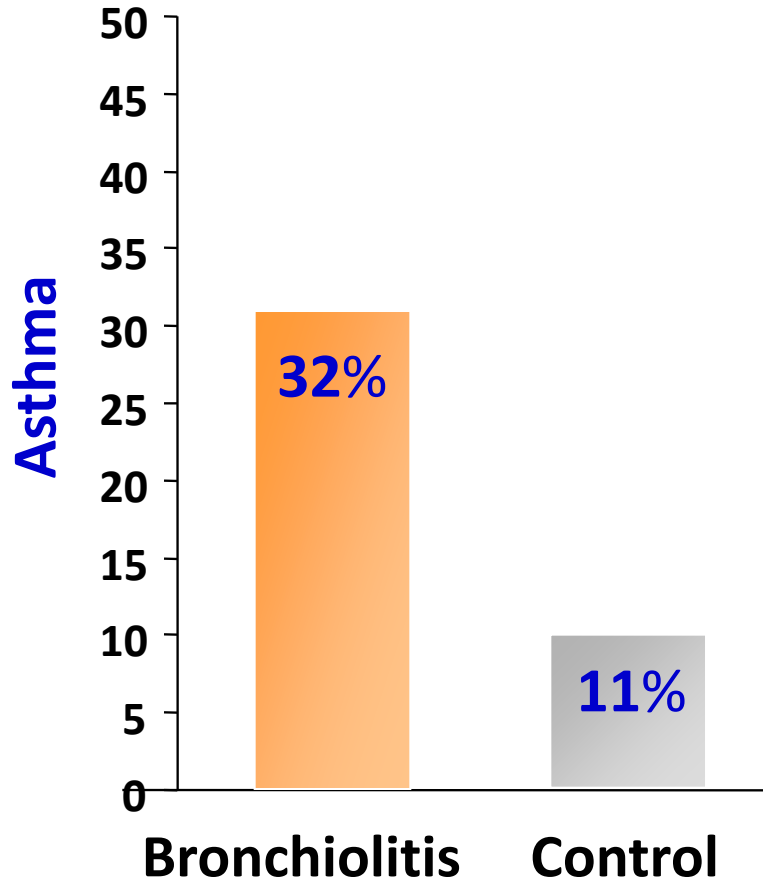
OUTCOME AFTER RSV BRONCHIOLITIS

- ASTHMA development?
- ATOPY development?

Infants hospitalized for RSV bronchiolitis: 18 years follow-up



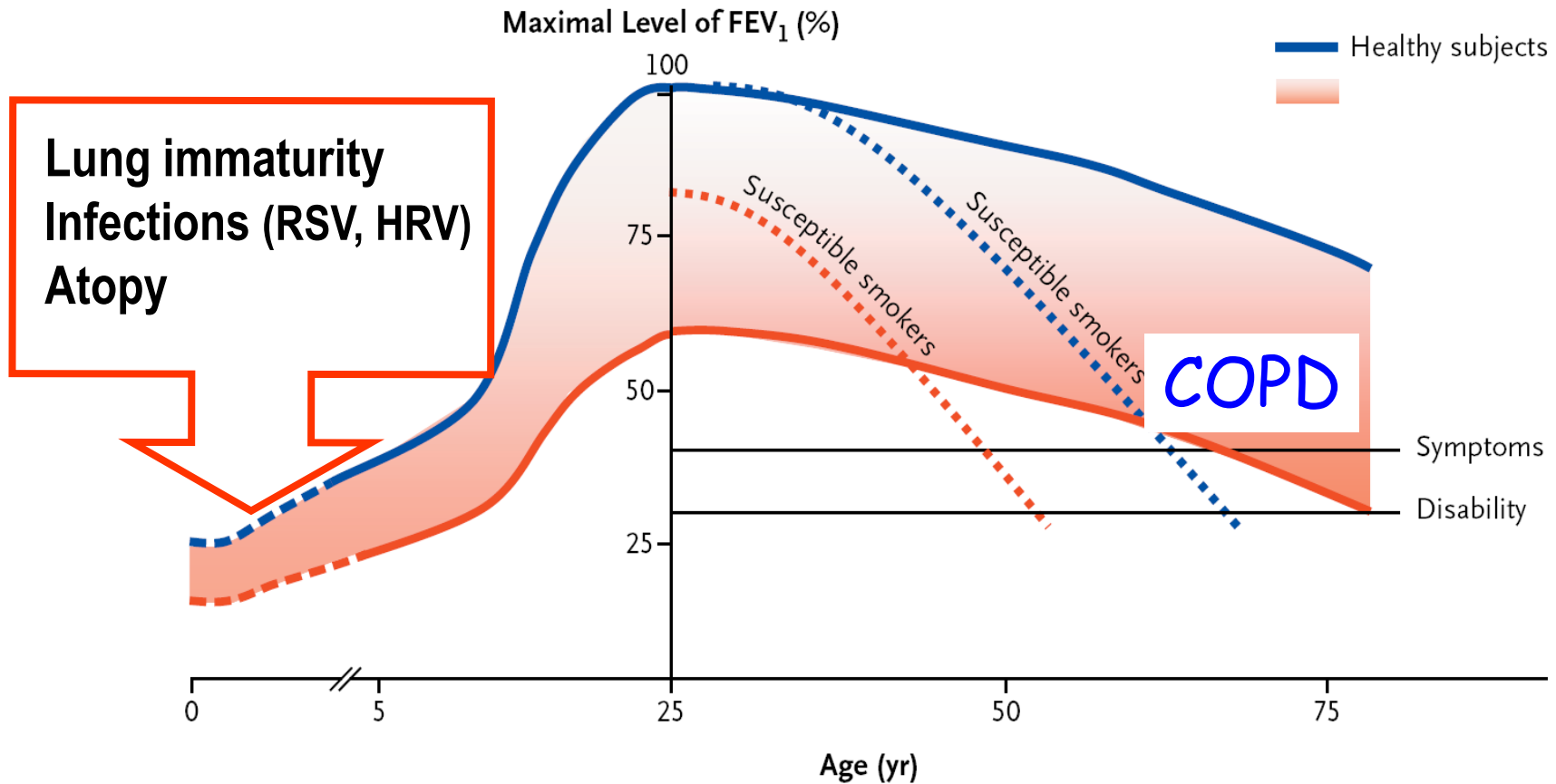
ASTHMA 30 YEARS AFTER HOSPITALIZATION FOR BRONCHIOLITIS



- 70 bronchiolitis children enrolled in 1981-1982 evaluated at the age of 28-31 years (Finland)
- 138 matched controls

Asthma was present in **1/3** of the former bronchiolitis patients

EARLY AIRWAY DAMAGE MAY CAUSE FAILURE TO ACHIEVE OPTIMAL PEAK FUNCTION



Respiratory Syncytial Virus and Recurrent Wheeze in Healthy Preterm Infants

Healthy preterm (33-35 ga) infants
214 Palivizumab vs 215 placebo

Proof-of-concept study

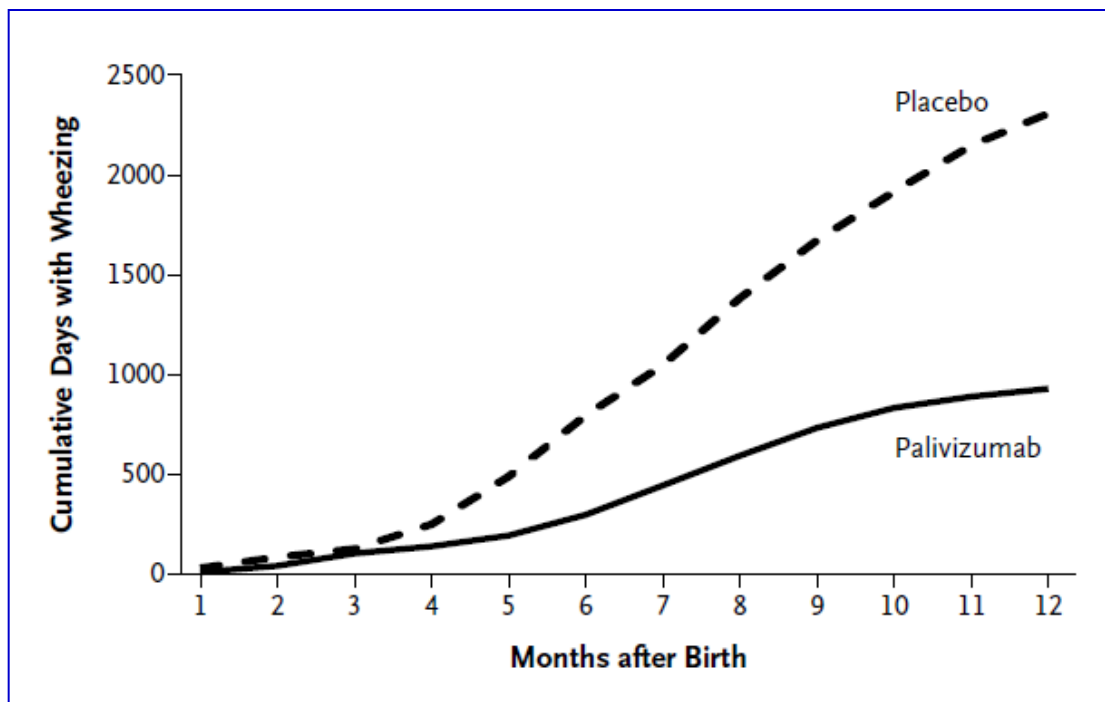


Figure 2. Cumulative Wheezing Days for 429 Preterm Infants during the First Year of Life.

61% reduction in the
n° of wheezing days in
the first year of life
(hospitalization 12% vs 22%)

Some final thoughts.....



- ***Several aspects of bronchiolitis management are still debated***
- ***Attention to children at risk: prematurity , BPD, CHD, immunodeficiency***
- ***Beta-agonists and steroids (systemic and inhaled) are not recommended for routine use***
- ***Hypertonic saline may provide significant benefit***
- ***HFNC O2 therapy is a promising option for moderate-severe cases***
- ***Prevention always and prophylaxis for infants at high-risk***
- ***Significant association between RSV bronchiolitis and long-term development of wheezing up to early adulthood***

SIMRI

società italiana per le malattie
respiratorie infantili



Mark your calendar !

