Are We Adequately Managing Children with Wheeze Using the Standard Case Management Guidelines?

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Introduction: *Prevalence of wheezing is increasing, bronchodilators are sub-optimally utilized and antibiotics are over-prescribed. In Thailand, current case management guidelines based on WHO guidelines, recommend two doses of rapid-acting bronchodilator for children with audible wheeze and fast breathing (FB) and/or lower chest indrawing (LCI).*
Objective: *To document the response of children with wheeze with FB and/or LCI to up to three doses of bronchodilator therapy and followed children whose FB and LCI disappeared for 7 days.*
Material and Method: *We documented response to up to three dose of inhaled salbutamol in consecutively assessed eligible children 1-59 months of age presenting with auscultatory/audible wheeze and FB [WHO defined non-severe pneumonia (NSP)] and/or LCI [WHO defined severe pneumonia (SP)] at the outpatient department of a referral hospital. Data were collected for up to 7 days in responders to bronchodilator therapy.*
Results: *Of 534 children were screened from November 2001 to February 2003, 263(49.3%) had wheeze and NSP and 271(50.7%) had wheeze and SP. Forty-eight children (9%) had audible wheeze. At screening, 224/263 (85.2%) children in the NSP group and 195/271 (72.0%) in the SP group responded to inhaled salbutamol. 86/419 (20.5%) responded to the third dose of bronchodilator. Four hundred and nineteen responders were enrolled and followed up. On follow-up, 14/217 (6.5 %) responders among the NSP group and 24/190 (12.6%) among the SP group showed deterioration. Age 1-11 months at screening was identified as an independent predictor of subsequent deterioration. Two seasonal peaks from December to March and from August to October were documented.*
Conclusion: *A third dose of bronchodilator therapy at screening will improve the specificity of case management guidelines and reduce antibiotic use. Physicians should use auscultation for management of wheeze.*

Keywords: *Child, Wheeze, Bronchodilator, Pneumonia, Antibiotics*

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The prevalence of wheezing (transient or otherwise) in children with or without respiratory infections varies from 13% up to 60% and most children get better with age[1-5]. The common causes of wheeze are bronchiolitis, bronchitis, pneumonia and allergies etc[3-6]. Thailand[7] adapted the World Health Organization (WHO) case management guidelines[8,9] for acute respiratory infection (ARI), which recommend assessment of audible wheeze (without stethoscope) in children with cough and/or difficult breathing. Those with audible wheeze and fast breathing (FB) *i.e.,* WHO defined non-severe pneumonia (NSP) and/or lower chest indrawing (LCI) *i.e.,* WHO defined severe pneumonia (SP), are administered two doses of bronchodilator

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therapy 30 minutes apart. The global asthma guidelines recommend repeated administration of bronchodilator every 20 minutes for the first hour[10]. Children in whom the FB and LCI disappears, are sent home with bronchodilator therapy. Audible wheeze becomes more prominent when the larger airways become narrower[11], but only 30-37% of the wheezing children may have demonstrable audible wheeze[12,13], Current ARI guidelines do not recommend bronchodilator for auscultatory wheeze and many get antibiotics if they have FB or LCI[7,8].

Objective

We conducted a study to document response of children with wheeze (audible and auscultatory) with FB and/or LCI to up to three doses of bronchodilator therapy 15 minutes apart and followed children whose FB and LCI disappeared.

Material and Method

Study population and site

A common protocol was used to collect data in Colombia, Egypt, Ghana, Thailand and Pakistan. Data from Pakistan have been published[13]. This study was conducted prospectively from November 2001 to February 2003 in the outpatient department (OPD) of Queen Sirikit National Institute of Child Health, Bangkok, Thailand. We trained the OPD and study physicians in standard ARI case management[7,8]. The OPD physicians identified consecutive children aged 1-59 months with cough or difficult breathing (Fig. 1) and referred those with wheeze, FB and/or LCI to the study physician for screening. For exclusion criteria see Panel A. The study physician screened the referred children and administered inhaled salbutamol using a metered dose inhaler (MDI) and a volume spacer device to those with FB and/or LCI. Four actuations of salbutamol were released into the spacer device to overcome the electrostatic discharges prior to use by the patient. Up to 3 doses of salbutamol were administered 15 minutes apart according to the clinical response. Each child was reassessed for audible or auscultatory wheeze, FB and LCI. Children were enrolled for follow-up on day 3 and days 5-7, if their FB and/or LCI disappeared after responding to inhaled bronchodilator. Demographic indicators and clinical features were recorded at enrolment and on follow-up. All non-responders to bronchodilator therapy at screening were treated with antibiotics and were reviewed until they were well. To assess seasonal variation, enrolment was continued for more than one calendar year.

Management at home

All responders to bronchodilator were advised two actuations of salbutamol inhaler at home 6 hourly. If children showed deterioration on follow-up, they received either an antibiotic and/or steroid therapy as required.

Outcome measures

Final outcome at follow-up was non-response to inhaled bronchodilator, for details see Panel B.

Sample size and data analysis

A standard formula for single proportion ($n = z^2_{1-\alpha/2} P (1-p)/d^2$) was used for calculating the sample size of 384 children[14], which assumed a 50% prevalence of wheeze, a power of 80% with 95% confidence level.

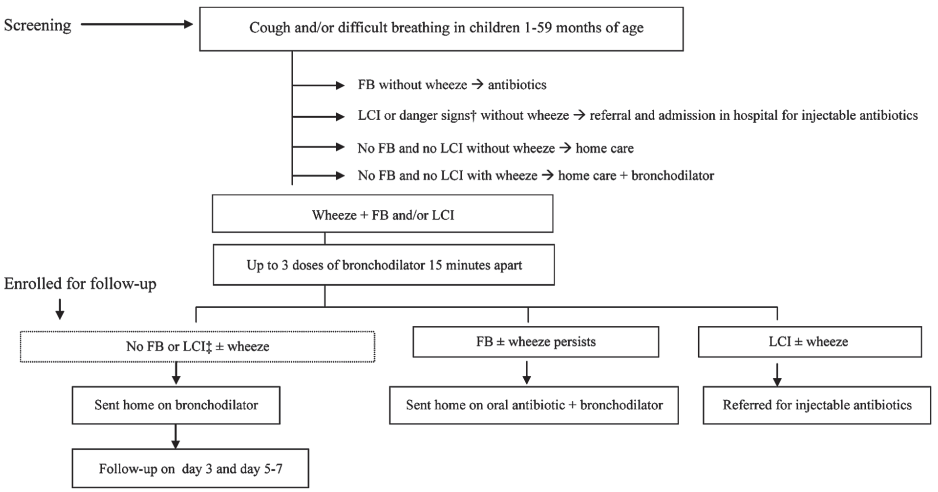
Data were entered twice and validated using EPI INFO and analyzed using SPSS 11.0. The demographic and clinical features of the screened and the

Panel A. Exclusion criteria at screening

- Presence of any WHO defined danger sign[8]
  - Cyanosis
  - Unable to drink
  - Abnormally sleepy or difficult to awake
  - Convulsion
  - Severe malnutrition
  - Stridor in a calm child
- Prior adequate antibiotic treatment in the previous 48 hours
- Complicating acute non-pulmonary or chronic illness
- Living outside the municipal limits of the city
- Refusal of consent
- Previous enrolment in this study

Panel B. Final outcome at follow-up

- Respiratory rate above the age-specific cut off after up to 3 doses
  - ≥ 60 breaths per minute (bpm) for up to 2 months
  - ≥ 50 bpm for 2-11 months
  - ≥ 40 bpm for 12-59 months
- Development of any WHO defined danger sign at any stage
- Development of life-threatening or serious adverse drug reaction
- Receive any antibiotic during the first 48 hours after enrolment
- Change of treatment because of concurrent illness diagnosed subsequent to enrolment



* Children with FB were categorized as non-severe pneumonia. FB is defined as ≥ 60 breaths per minute for up to 2 months of age, ≥ 50 breaths per minute for 2 months up to 11 months of age and ≥ 40 breaths per minute for 12 months up to 59 months of age
† Children with LCI were categorized as severe pneumonia, whereas those with danger signs (inability to drink, convulsions, vomiting everything, lethargy or unconscious, severe malnutrition) were categorized as very severe disease
‡ These patients were enrolled and followed up at day 3 and day 5-7, day of enrolment was considered day-0
Information on all the patients who presented with wheeze and were screened for the study whether they were enrolled or not were recorded by filling the screening form. This data was also analysed
FB: fast breathing, LCI: lower chest indrawing

Fig 1. Flow Chart

enrolled children were compared for initial response to bronchodilator. We used x^2-test for the categorical variables and *t*-test for continuous variables. The estimates of odds ratios (OR) along with 95% confidence interval (CI) were reported for categorical variables, whereas only 2-tailed *p*-values were reported for continuous variables. We calculated the OR along with 95% CI to find out the strength of association between the predictors (*i.e.,* demographic indicators and clinical features) and the outcomes (*i.e.* initial response to bronchodilator and subsequent failures). The OR > 1, with 95% CI excluding 1 was considered statistically significant. Multivariate models were created by stepwise forward logistic regression. For this purpose we recoded some of the continuous variables such as age, duration of illness, temperature, into categorical variables. Variables with *p*-value of 0.1 from the bivariate analysis were included in the model. Statistical significance was taken at the 5% level.

Ethical approval and informed consent

The Institutional Review Boards/Ethical review committees of the hospital, Ministry of Public Health, Thailand and WHO, Geneva approved the study. Written, informed consent was obtained for screening and enrolment after informing the patients' mother/caretaker of the purpose of the study.

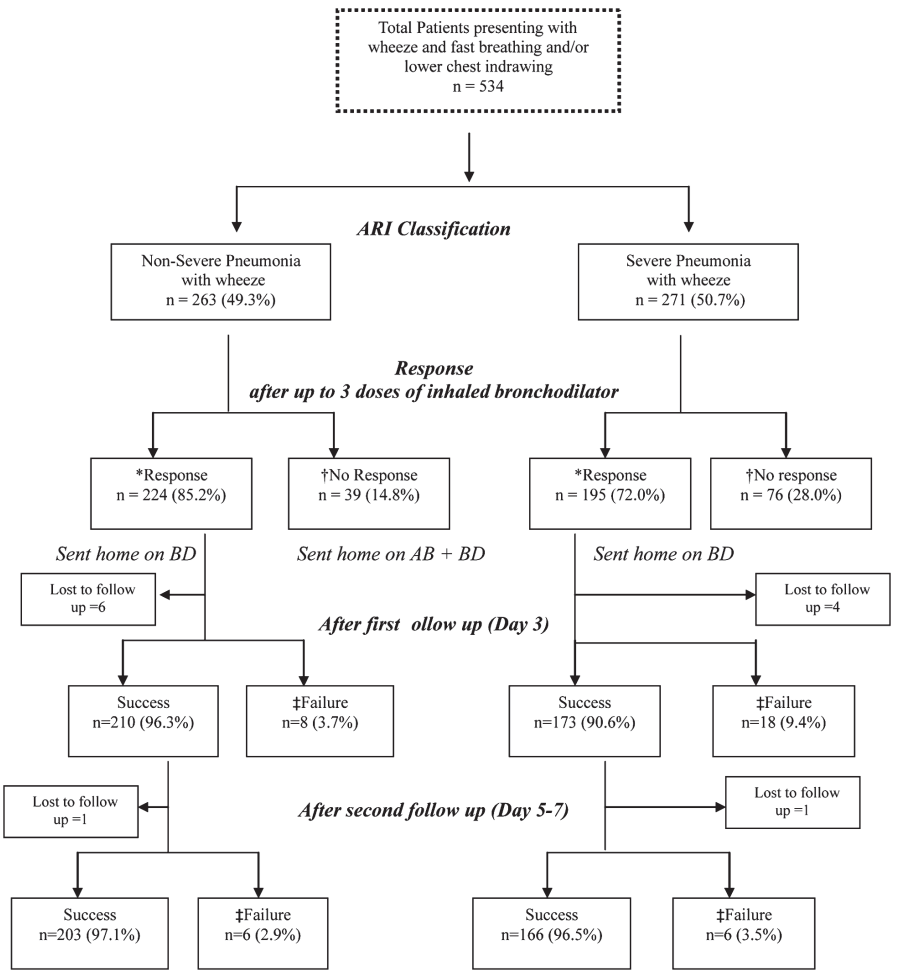
Role of funding source

Department of Child and Adolescent Health and Development, WHO, Geneva funded the study. Dr. Shamim A. Qazi, Medical Officer, contributed to the design of the study, preparing the protocol, data interpretation and preparing the manuscript.

Result

Screening

We screened 534 children with FB and/or LCI along with auscultatory/audible wheeze, of which, 263 (49.3%) were classified as NSP and 271 (50.7%) as SP with wheeze. Only 48 (9%) children had audible wheeze heard without a stethoscope. Overall 419/534 (78.5%) responded to up to three doses of the bronchodilator therapy at screening, 224/263 (85.2%) in the NSP and 195/271 (72.0%) in the SP group (Fig. 2), whereas 115/534 (21.5%) were treated with antibiotics



* 224 responders from non-severe pneumonia and 195 from severe pneumonia group at the time of initial screening
† 39 still had non-severe pneumonia and 76 had severe pneumonia
‡ 14 and 24 showed subsequent deterioration by day 5-7 in non-severe pneumonia and severe pneumonia groups respectively
BD: bronchodilator, AB: antibiotics

Fig. 2 Details of screened cases

plus a bronchodilator. Out of 419 responders at screening, 86 (20.5%) did so after the third dose of bronchodilator therapy, 46/224 (20.5%) in the NSP and 40/195 (20.5%) in the SP group. We documented two seasonal peaks during December-March and August-October in the screened children with wheeze, FB/LCI. Bivariate analysis identified some variables at screening as significantly associated with non-response to bronchodilator therapy (Table 1). However, logistic regression identified age 12-59 months, history of fever, no family history of wheeze, actual temperature > 38.0°C and presence of LCI as the independent predictors for non-response at screening (Table 2).

Enrolment and follow-up

419 responders were enrolled and followed up (Fig. 2). In the NSP group, only 8 (3.7%) continued to have FB at first follow-up and a further 6 (2.9%) at second follow-up. Overall, 203/217 (93.5%) children continued to be well at second follow-up (loss to follow-up 7 cases). In the SP group, 18 (9.4%) non-responders were hospitalized at first follow-up and 6 (3.5%) more at second follow-up. Overall, 166/190 (87.4 %) continued to be well at second follow-up (loss to follow-up 5

Table 1. Comparison of baseline characteristics of responders and non-responders to inhaled bronchodilators at the time of screening (n = 534)

Variables	Responders (n = 419)	Non-responders (n = 115)	OR (95% CI)‡ p-value
Demographic indicators			
Sex			
Male	272 (64.9%)	67 (58.3%)	
Female	147 (35.1%)	48 (41.7%)	1.33 (0.85 to 2.06) 0.22
Age			
1-11 months	122 (29.1%)	20 (17.4%)	
Median (IQR)	7.0 (5.0-9.0)	6.5 (5.0-10.0)	
12-59 months	297 (70.9%)	95 (82.6%)	1.95 (1.12 to 3.42) 0.01
Median (IQR)	25.0 (18.0-34.0)	21.0 (15.0-32.0)	
History and Signs			
Fever	265 (63.2%)	91 (79.1%)	2.20 (1.31 to 3.72) 0.002
Difficult breathing	390 (93.1%)	114 (99.1%)	8.48 (1.22 to 169.1) 0.02
Cough	416 (99.3%)	115 (100%)	0 (0 to 8.19) 0.83
Duration of illness			
Up to 2 days	220 (52.5%)	70 (60.9%)	1.41 (0.90 to 2.19) 0.13
Median (IQR)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	
More than 2 days	199 (47.5%)	45 (39.1%)	
Median (IQR)	3.0 (3.0-6.0)	3.0 (3.0-5.0)	
Past history of wheezing episodes			
None	147 (35.1%)	31 (27.0%)	
One or more	272 (64.9%)	84 (73.0%)	1.46 (0.91 to 2.38) 0.12
No family history of wheeze	273 (65.2%)	88 (76.5%)	1.74 (1.06 to 2.89) 0.02
Presence of audible wheeze	33 (7.9%)	15 (13.0%)	1.75 (0.87 to 3.50) 0.12
Actual temperature (in °C)			
≤ 38.0°C	401 (95.7%)	102 (88.7%)	
Median (IQR)	36.8 (36.2-37.0)	37.0 (36.5-37.3)	
> 38.0°C	18 (4.3%)	13 (11.3%)	2.84 (1.26 to 6.33) 0.008
Median (IQR)	38.7 (38.5-38.9)	38.6 (38.3-39.0)	
Weight for age Z score			
Median (IQR)	-0.30 (-0.89-0.86)	-0.14 (-1.16-0.70)	0.34
Height for age Z score			
Median (IQR)	-0.22 (-1.03-0.52)	-0.36 (-0.84-0.01)	0.35
ARI Classification			
Non-severe pneumonia with wheeze	224 (53.5%)	39 (33.9%)	
Severe pneumonia (lower chest indrawing) with wheeze	195 (46.5%)	76 (66.1%)	2.24 (1.42 to 3.53) 0.001

‡ Odds ratio and 95% CI reported for categorical variables. For continuous variables only p-value are reported

cases). Multiple logistic regression identified only age 1-11 months as independently associated with subsequent deterioration (Table 2). No deaths were recorded in enrolled children.

Discussion

Our data have implications for ARI case management guidelines in Thailand and other countries where wheezing is a common problem[1-5,15,16]. First, FB and/or LCI disappeared with only bronchodilator therapy in a large majority of the children presenting with wheeze and pneumonia and did not need any antibiotic. Second, only 9% of the screened children had audible wheeze, which means that the existing guidelines are not addressing the management of wheeze adequately[7-9]. Third, one-fifth (20.5%) of these wheezing children responded to the third dose of bronchodilator therapy, whereas current guidelines

Table 2. Predictors identified by multivariate logistic regression† of non-response to inhaled bronchodilator at the time of screening and subsequent deterioration until day 5-7 after enrolment

	OR* (95% CI)	p-value
Non-response to inhaled bronchodilator at the time of screening		
Screened patients (n = 534)		
Age 12-59 months	2.23 (1.29 to 3.87)	0.004
History of fever	1.91 (1.14 to 3.20)	0.013
No Family history of wheeze	1.81 (1.10 to 2.96)	0.018
Temperature more than 38.0°C‡	2.96 (1.32 to 6.59)	0.008
Severe pneumonia (lower chest indrawing) with wheeze	2.32 (1.48 to 3.64)	0.0005
Subsequent deterioration until day 5-7 after enrolment		
Enrolled patients (n = 419)		
Age 1-11 moths	1.92 (1.04 to 3.67)	0.04

* Odds Ratio

† For modeling purpose continuous variables such as age and temperature were recoded in to categorical variables. Deterioration included the relapses either on day 3 or 5

‡ Against temperature ≤ 38.0°C

only recommend two doses[7-9]. Finally, the response to bronchodilator therapy became apparent within 15 minutes of bronchodilator therapy and waiting for 30 minutes for re-assessment was not essential, which is the existing recommendation[7-9].

Our data show that there were no deaths in this group of children even when antibiotics were withheld from these children. However, the older children (aged 12-59 months) who have signs of pneumonia from bacteria or atypical pathogens at presentation are a high risk group for non-response to inhaled bronchodilator at the time of screening. According to our analysis, those older children with wheeze and LCI who have fever without family history of wheeze at the time of screening are more likely to fail bronchodilator therapy. It may not be justified to recommend withholding of antibiotics in this subgroup of children. Our results have once again highlighted the fact that the children < 1 year of age are at higher risk of subsequent deterioration. It is quite likely that a large majority of these young children actually have viral bronchiolitis or pneumonia. We know from the results of the Cochrane meta-analysis that the use of bronchodilators in children with bronchiolitis will only have a small benefit[17].

Data from Pakistan[13] reported that at screening, 62% children had FB with wheeze and the rest had LCI with wheeze. 37% of their patients had audible wheeze as compared to 9% in our study. Two-thirds of their children with wheeze and FB and 27% with wheeze and LCI responded to bronchodilator therapy as compared to 85% and 72% responders respectively in our study. In Pakistani children at screening, 15% in the FB and 57% in the LCI group responded to the third dose of bronchodilator as compared to 20.5% each in our study in both groups. At follow-up, 15% Pakistani children in the FB and 38% in the LCI group showed subsequent deterioration as compared to 6.5% in the FB and 12.6% in the LCI group in our study. The difference in audible wheeze rates at both sites could be because our enrolment area was noisy due to its close proximity to a busy OPD and the hospital being situated on a street with heavy traffic or that the patients in Pakistan probably had a more severe disease. The difference in initial response to bronchodilator therapy for the SP group between Thai and Pakistani patient could possibly be due to i) Pakistani patients had a more severe disease, with more audible wheeze resulting in higher non-response rates[11] ii) more, less than one-year infants were enrolled in Pakistan (50%) than in Thailand (26%) iii) possibility of transient conditions associated with diminished airway function at birth[1], and finally iv) more Pakistani patients had high fever (> 38.0°C) which is a risk factor of non-responders at screening[13].

The importance of the follow-up of children who responded to bronchodilator therapy cannot be overstated, as some may deteriorate later. We recommend that children with wheeze and FB/LCI who respond to rapid-acting bronchodilator at screening should be followed up, as some may have need an antibiotic or a short course of steroids. As risk of

mortality in infants is high due to pneumonia, if follow-up is not possible, it would be prudent to treat children with LCI and wheeze conservatively.

One strength of our study was collecting data using a common protocol that was also used by centers in other countries, which would allow us to compare data from various regions of the world. Secondly, we had a very low loss to follow-up rate. One limitation of the study was that it was an open study, without any placebo treatment and without any control group. It is likely that a few children may have spontaneously responded without any bronchodilator therapy[2]. Secondly, we did not collect any microbiology or radiology data. However, as the standard ARI case management guidelines are meant for the first level health facility[7,8], it is impractical to do so in such a situation.

Our data show that there are several potential benefits to improving the management of children with wheeze. First, the current standard ARI guidelines do not recommend auscultation for assessment of wheeze. Our data and that from Pakistan[13] show that if only audible wheeze is employed, a large majority of children with wheeze and FB/LCI will receive antibiotics unnecessarily and many would be hospitalized. It is probable that these children either have a hyperreactive airway disease or early asthma or a self-limiting viral infection[1-5]. Second, less antibiotic use would result in less pressure on antimicrobial resistance[18], fewer antibiotic-related adverse effects,[19,20] cost benefits and less health facility utilization[21]. Third, fewer hospitalizations would reduce the exposure to nosocomial infections and other injection related problems[22]. Fourth, where the physicians staff health facilities they should use auscultation for assessment. Although nurses are trained to use auscultation[23,24], research is needed to evaluate whether they can do this effectively to assess children. Fifth, an interval of 15-20 minutes should be sufficient to evaluate the response to bronchodilator instead of waiting for 30 minutes[7,8].

We recommend that in light of the possible benefits to the children presenting with wheeze, the standard ARI case management guidelines should be revised. Moreover, research is needed in other low and middle resource settings on i) the effectiveness of bronchodilators in children with acute wheeze, ii) the long-term progression of children with acute wheeze and iii) ability of nurses to use auscultation effectively in assessment of children with wheeze. (Word count 2080).

Contributor ship

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Conflict of interest statement:

Shamim A. Qazi works as a medical officer at WHO, which provided financial support for the study. None of the authors have any conflict of interest.

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เราให้การรักษาผู้ป่วยเด็กที่มีเสียงหวีด (wheeze) โดยแนวทางมาตรฐานได้เหมาะสมหรือไม่

สรศักดิ์ โล่ห์จินดารัตน์, ชามิน เอ คาซี, ธัญญณัฐ บุนนาค, ยาเซอร์ บิน นิซาร์, ประวิทย์ เจตนชัย

บทนำ: *อุบัติการณ์ในการเกิดเสียงหายใจหวีดเพิ่มขึ้น มีการใช้ยาขยายหลอดลมในการรักษาต่ำกว่าความจำเป็น ในขณะที่มีการใช้ยาปฏิชีวนะเกินความจำเป็นอย่างไม่เหมาะสม ปัจจุบันประเทศไทยใช้แนวทางการรักษามาตรฐาน ในผู้ป่วยที่มาด้วยอาการไอ และมีเสียงหวีด ตามแนวทางขององค์การอนามัยโลก โดยการพ่นยาขยายหลอดลม ที่ออกฤทธิ์เร็ว ในผู้ป่วยเด็กที่ฟังได้ยินเสียงหวีดร่วมกับหายใจเร็ว และ/หรือชายโครงบุ๋ม ได้ 2 รอบ*

วัตถุประสงค์: *เพื่อดูการตอบสนองของผู้ป่วยเด็ก ที่ฟังได้ยินเสียงหวีดร่วมกับหายใจเร็ว และ/หรือ ชายโครงบุ๋ม ต่อการพ่นยาขยายหลอดลมที่ออกฤทธิ์เร็วได้ถึง 3 รอบ หลังจากนั้น ติดตามผลการรักษาในกลุ่มที่ตอบสนองดีต่อยาขยายหลอดลม เป็นเวลานาน 7 วัน*

วิธีการศึกษา: *ผู้ป่วยเด็กอายุ 1-59 เดือน ที่มารับการรักษาที่แผนกผู้ป่วยนอกของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี ด้วยอาการฟังได้ยินเสียงหวีดด้วยหูฟัง (stethoscope) หรือหูเปล่า ร่วมกับหายใจเร็ว (WHO หมายถึง ภาวะปอดอักเสบไม่รุนแรง) และ/หรือ ชายโครงบุ๋ม (WHO หมายถึง ภาวะปอดอักเสบรุนแรง) ในกลุ่มที่ตอบสนองดีต่อยาขยายหลอดลม จะนัดกลับมาดูอาการเป็นเวลา 7 วัน*

ผลการศึกษา: *ผู้ป่วยเด็กจำนวน 534 คน ที่เข้าร่วมการศึกษาตั้งแต่เดือนพฤศจิกายน พ.ศ. 2544 ถึง กุมภาพันธ์ พ.ศ. 2546 แบ่งเป็นผู้ป่วยในกลุ่มปอดอักเสบไม่รุนแรงร่วมกับเสียงหวีดจำนวน 263 คน (ร้อยละ 49.3) และผู้ป่วยในกลุ่มปอดอักเสบรุนแรงร่วมกับเสียงหวีดจำนวน 271 คน (ร้อยละ 50.7) ในจำนวนนี้มีผู้ป่วย 48 คน (ร้อยละ 9) ที่ฟังได้ยินเสียงหวีดด้วยหูเปล่า โดยไม่ต้องใช้หูฟัง ในช่วงแรก ผู้ป่วยในกลุ่มปอดอักเสบไม่รุนแรง ตอบสนองต่อการพ่นยาขยายหลอดลมที่ออกฤทธิ์เร็วจำนวน 224 คน (ร้อยละ 85.2) และผู้ป่วยในกลุ่มปอดอักเสบรุนแรงตอบสนองต่อยาจำนวน 195 คน (ร้อยละ 72.0) โดยพบว่าผู้ป่วยที่ตอบสนองต่อยาในช่วงแรกจำนวน 419 คนนั้น เป็นการตอบสนองต่อการพ่นยาขยายหลอดลมในรอบที่ 3 จำนวน 86 คน (ร้อยละ 20.5) หลังจากนัดมาติดตาม การรักษาเป็นเวลา 7 วัน พบว่า ผู้ป่วยในกลุ่มปอดอักเสบไม่รุนแรงที่มาติดตามการรักษา 217 คน มีอาการเลวลง จำนวน 14 คน (ร้อยละ 6.5) ในขณะที่ผู้ป่วยในกลุ่มปอดอักเสบรุนแรงที่มาติดตามการรักษาจำนวน 190 คน มีอาการเลวลง จำนวน 24 คน (ร้อยละ 12.6) โดยพบว่าผู้ป่วยกลุ่มอายุ 1 ถึง 11 เดือน เป็นปัจจัยเสี่ยงที่จะมีอาการเลวลงในเวลาต่อมา พบผู้ป่วยที่หายใจมีเสียงหวีดมากในช่วงเดือนธันวาคม ถึง มีนาคม และเดือนสิงหาคม ถึง ตุลาคม*

สรุป: *การให้ยาขยายหลอดลมที่ออกฤทธิ์เร็วเป็นรอบที่ 3 ในผู้ป่วยที่มีเสียงหวีดที่แผนกผู้ป่วยนอก จะช่วยเพิ่มความจำเพาะในแนวทางการรักษามาตรฐานและช่วยลดการใช้ยาปฏิชีวนะเกินความจำเป็น แพทย์ควรพยายามฟังเสียงหวีดโดยหูฟังเพื่อให้การรักษาผู้ป่วยอย่างถูกต้องเหมาะสม*