Welcome to issue 139 of Respiratory Research Review. “Begin at the beginning’, the King said very gravely, ‘and go on till you come to the end: then stop” (Lewis Carol, Alice in Wonderland).

With this quote, Andy Bush and Adrian Custovic start their outstanding editorial on breastfeeding, asthma, rhinovirus infections, obesity, candidate genes, the Universe and COPD, a state-of-the-art review of our current understanding of asthma, which allocates priorities and challenges dohoma. For example, not all individuals reach near-normal maximal lung function in early adulthood. Some start off with a lower baseline and even if they don’t smoke, end up with a diagnosis of COPD later in life. With expert skill, the title of their editorial gives the key message: ‘Formula one: best is no formula’; or, as the article details, breastfeeding by asthmatic mothers has a protective effect for their infants and this protective effect is abrogated when formula milk, rather than complementary foods, is introduced. Read on, if you wish to hear their opinion on the ‘contradictory and hopelessly impractical advice’ mothers receive, or ‘the failure of breast feeding promotions’ and their passion to ‘get it right for little lungs’ or we are heading towards an ‘Armageddon of COPD death’.

‘Drugs don’t work in patients that don’t take them’, is a less prosaic and yet still accurate statement from the former US General Surgeon, Everett Koop. It may even be worse in respiratory medicine, as our inhalers suffer the same adherence issues and, as reviewed in Respiratory Research Review in Feb 2017 (issue 133), there has been no improvement in inhaler technique over the last 30 years. We are reviewing a few articles that address this issue. It is great to see that the European Respiratory Society together with other major European Societies is working to put therapy adherence on the political agenda. This editorial reminds us to explore the phenotypes of nonadherence as this will influence our interventions. Erratic nonadherence (forgetfulness) may respond to reminders, social support, simplifying regimens or linking it to daily habits; Intelligent nonadherence (conscious decision not to take medication due to side effects or lack of belief in benefit) may respond to shared decision making, motivational interviewing, reimbursement and linking to personal goals; unwitting nonadherence (lack of knowledge) is a particular problem in respiratory medicine and may respond by working together with all health providers to review inhaler techniques.

The impact of the Melbourne thunderstorm asthma events in November 2016 has been compared to 150 bombs exploding across Melbourne; 9900 patients presented to hospital, more than 2300 calls were made to emergency lines, with one call every 4.5 seconds, and a total of nine deaths were recorded and many more patients had hypoxic brain damage (Intern Med J 2017). Asthma is not harmless, and as the Royal College report in ‘Why asthma still kills’, almost half of patients with a fatal asthma event were diagnosed with mild-to-moderate asthma and many were not prescribed an ICS. We may be in the middle of a major change on how we treat asthma. The first three articles of this review address all the issues of β-agonist overuse. Helen Reddel and colleagues challenge the accepted need for long-term medications for largely asymptomatic conditions like hypertension and hypercholesterolemia to reduce future risk of adverse outcomes. In NZ, we doctors prescribe over 1 million SABAs (short-acting β-agonists) each year; maybe the time is right to review this practice. Hopefully, the articles selected will assist in clinical decision making, including the brand new guidelines in performing methacholine challenge testing to confirm or exclude asthma as a diagnosis; they even include a seven-point table on qualifications needed to perform bronchial challenge testing (Eur Respir J 2017).

We hope you enjoy the selection and are looking forward to comments or questions.

Kind regards
Professor Lutz Beckert
lutzbeckert@researchreview.co.nz

Abbreviations used in this issue
BAL = bronchoalveolar lavage
COPD = chronic obstructive pulmonary disease
FEV = forced expiratory volume
ICS = inhaled corticosteroid
Ig = immunoglobulin
IL = interleukin
L/SABA = long/short-acting β-agonist
QOL = quality of life

In this issue:

- Excessive SABA prescriptions in asthma management
- β-agonist overuse common in high-risk asthma
- Basing decisions to start ICSs on symptom frequency
- Association between asthma control and cost
- Inhaler technique reminders to improve retention of skills
- Breastfeeding, maternal asthma and wheezing
- Re-evaluating diagnoses in adults with physician-diagnosed asthma
- Aspiration in the asthmatic airway
- Benralizumab reduces oral glucocorticoid use in severe asthma
- Add-on mepolizumab improves severe eosinophilic asthma

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Beta-agonist overuse and delay in obtaining medical review in high risk asthma

Authors: Pilcher J et al.

Summary: This was a secondary analysis of data from a 24-week trial that randomised 303 patients with high-risk asthma to combination budesonide/formoterol inhaler according to a single maintenance and reliever therapy regimen or fixed-dose budesonide/formoterol with salbutamol as reliever (‘standard’) regimen. Inhalers were fitted with electronic monitors to accurately measure medication use. The thresholds for high, marked and extreme β-agonist use-days were defined in the single maintenance and reliever therapy arm as >8, >12 and >16 actuations of budesonide/formoterol in >4 maintenance doses, respectively, and in the standard arm as >16, >24 and >32 actuations of salbutamol, respectively. The respective mean proportions of days in which high, marked and extreme β-agonist overuse occurred without medical review within 48 hours were 0.94, 0.94 and 0.94 in the single maintenance and reliever therapy group, and the respective values in the ‘standard’ group were 0.92, 0.90 and 0.94. In both groups, in ≥90% of days when β-agonist overuse occurred, patients failed to follow-up with medical professionals within 48 hours as advised.

Comment: This study from Wellington is based on individual electronic monitors measuring actual SABA and ICS/LABA use. They provide personalised data compared with observational data, which have linked an overuse of SABA, or SABA dispensing of more than 1.4 containers per month, to increased death rates. The Wellington group report that around 90% of participants overused their reliever medications, 80% of all exacerbations seem to resolve without a course of steroids and, bottom line, even in a clinical trial setting, patients did not follow the written advice to seek medical help when using β-agonists excessively.

Reference: NPJ Prim Care Respir Med 2017;27(1):33

Abstract

Independent commentary by Professor Lutz Beckert.

Professor Lutz Beckert is the Head of Department of Medicine at the University of Otago, Christchurch. He is also a Respiratory Physician at Canterbury District Health Board with particular clinical interests in interstitial lung disease, pulmonary vascular disease, respiratory physiology and COPD (chronic obstructive pulmonary disease). Lutz is happy to be contacted to discuss research ideas either as a sounding board or considering future collaborations.

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**Should recommendations about starting inhaled corticosteroid treatment for mild asthma be based on symptom frequency**

**Authors:** Reddel HK et al.

**Summary:** Outcomes were reported for a post hoc analysis of the START study, involving patients aged 4–66 years with recent-onset, mild persistent asthma to assess early intervention with budesonide 400µg (200µg for participants aged <11 years) once daily (n=3577) versus placebo (n=3561) on long-term asthma control. For budesonide versus placebo: i) time to first severe asthma-related event (hospital admission, emergency treatment or death) was longer across symptom frequency subgroups (respectively hazard ratios 0.54 [95% CI 0.34, 0.86], 0.60 [0.39, 0.93] and 0.57 [0.41, 0.79] for 0–1, >1–≤2 and >2 symptom-days per week; p=0.94 for interaction); ii) the decline in postbronchodilator lung function was less at 3 years of follow-up (p=0.32 for interaction); iii) severe exacerbations requiring oral or systemic corticosteroids were reduced (respectively rate ratios 0.48, 0.56 and 0.66 for 0–1, >1–≤2 and >2 symptom-days per week; p=0.11 for interaction); and iv) prebronchodilator lung function was significantly higher and symptom-free days significantly more frequent with no differences between the symptom subgroups. The data were similar when participants were classified by any guideline’s criterion as so-called persistent versus so-called intermittent asthma.

**Comment:** For the last 25 years, asthma guidelines have suggested that ICSs should be used for patients with persistent asthma; however, for patients with intermittent asthma, as-needed SABAs were recommended. The evidence base for this advice is lacking and no long-term safety data for this approach are available. In a post hoc analysis of the START study, the authors demonstrated that low-dose budesonide halved the long-term risk of serious asthma events, reduced the decline in lung function and improved day-to-day symptoms. Bottom line: these findings challenge the long-standing assumption on β-agonist use and suggest that ICSs should be prescribed to reduce population risk of death.

**Reference:** Lancet 2017;389(10,065):157–66

**Abstract**

**Association between asthma control and asthma cost**

**Authors:** Nguyen HV et al.

**Summary:** This longitudinal study compared healthcare costs between primary-care patients achieving optimal versus suboptimal asthma control based on Asthma Control Test scores while on an asthma care programme. Compared with participants with suboptimal asthma control, those whose asthma was controlled spent more per doctor visit (US$36) on drugs for their asthma but less per doctor visit (US$48) in total costs (p<0.01 for both). Obese participants accrued greater savings by achieving asthma control than normal bodyweight participants (p<0.05).

**Comment:** This study and the excellent editorial are both from colleagues in Singapore, which has a fee-for-service primary healthcare system. Paraphrasing Sanjay Chotirmall’s words, the authors demonstrate that the investment in prophylactic therapy improves the long-term outcomes of asthma and so decreases the cost to the individual patient. Patients with better asthma control spent more on asthma medications; however, their total cost incorporating indirect costs like treatment of exacerbations, unscheduled healthcare visits and loss of earnings was about 30% lower. The authors’ bottom line: is patients who adhere to prescribed regimens may use more medications; however, their total care costs less.

**Reference:** Respirolgy 2017;22(3):454–9

**Abstract**

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Effect of novel inhaler technique reminder labels on the retention of inhaler technique skills in asthma

Authors: Basheti IA et al.

Summary: Ninety-five patients with asthma using controller medication (Accuhaler or Turbuhaler) were assessed for inhaler technique and randomised into active and control groups in this single-blind study; all participants were instructed in accurate inhaler technique, and those in the active treatment groups also received inhaler labels highlighting their initial errors. The respective mean inhaler scores at baseline in the Accuhaler and Turbuhaler active groups and Accuhaler and Turbuhaler control groups were 5.3, 4.7, 5.5 and 4.2 and the respective mean Asthma Control Test scores were 13.9, 12.1, 12.7 and 14.3. All participants scored 9/9 for inhaler technique after training. Declines in inhaler technique scores at 3 months were significantly smaller in the active groups than the control groups (mean differences −1.04 [p=0.022] and −1.61 [p=0.003] for the Accuhaler and Turbuhaler groups, respectively). Symptom control improved significantly from baseline in both groups, but reminder labels were associated with less reliever medication in the active versus control groups (2.19 vs. 3.42 puffs per day [p=0.002]).

Comment: Here colleagues from Jordan had previously shown that a brief education on inhaler use was highly effective in improving technique and asthma outcomes. Unfortunately, only a few months later, patients reverted to old habits and reported difficulties in inhaler use. In this study, the authors randomised the patients following education to be provided with a simple sticker attached to the inhaler device summarising the key points of correct usage. Patients with the sticker had better technique after 3 months. Bottom line: a label with key points of correct inhaler usage is an inexpensive, feasible, scalable intervention to improve inhaler technique.

Reference: NPJ Prim Care Respir Med 2017;27(1):9

Breastfeeding, maternal asthma and wheezing in the first year of life

Authors: Azzad MB et al.

Summary: The association between being breastfed and wheezing at ages 3, 6 and 12 months was explored in 2773 infants from the longitudinal birth cohort CHILD (Canadian Healthy Infant Longitudinal Development) study; 21% of the mothers were asthmatic and 46% breastfed their infants for ≥12 months, and 21% of the infants experienced wheezing. Breastfeeding by mothers with asthma for ≥12 vs. <6 months was associated with a lower rate of infant wheezing (adjusted rate ratio 0.52 [95% CI 0.35, 0.77]). Compared with no breastfeeding at 6 months, infant wheezing was reduced by exclusive breastfeeding (adjusted rate ratio 0.38 [95% CI 0.20, 0.71]) and partial breastfeeding supplemented with complementary foods (0.63 [0.43, 0.93]), but not when supplemented with formula (0.89 [0.61, 1.30]). There were no significant associations among mothers without asthma.

Comment: These researchers learned from previous studies to articulate the correct question in their CHILD study to untangle some of the previous inconsistencies. They documented a strong dose-dependent protective association between breastfeeding and wheeze in the first year of life, particularly in mothers with asthma. Younger mothers breastfed less and higher rates of wheezing were observed in infants of younger mothers. I strongly recommend reading the outstanding and free editorial by Andy Bush and Adnan Custovic. Bottom line: breastfeeding reduces wheeziness by 63%; however, this effect is negated when formula milk, but not complementary foods, is introduced.

Reference: Eur Respir J 2017;49(5):1602019

Abstract
Reevaluation of diagnosis in adults with physician-diagnosed asthma

Authors: Aaron SD et al., for the Canadian Respiratory Research Network

Summary: This Canadian investigation recruited 701 adults with asthma established within the prior 5 years. The primary outcome was the proportion of participants in whom a diagnosis of current asthma could be ruled out, defined as participants who exhibited no evidence of acute worsening of asthma symptoms, reversible airflow obstruction or bronchial hyper-responsiveness after having all asthma medications gradually tapered off (over four study visits) and after a study pulmonologist established an alternative diagnosis. Of the 613 participants who completed the study, current asthma was ruled out in 33.1%. Serious cardiorespiratory conditions were identified in 12 participants who had previously been misdiagnosed, and after an additional 12 months of follow-up, 181 participants continued to exhibit no clinical or laboratory evidence of asthma. Fewer than half of participants (43.8%) in whom current asthma was ruled out underwent testing for airflow limitation in the community at the time of initial diagnosis, compared with 55.6% of those whose asthma diagnosis was confirmed.

Comment: In this Canadian study, the researchers recruited 613 adults with asthma after random digit dialling more than 16,000 adults. The authors systematically offered spirometry with an inhaled bronchodilator. If they didn’t have 200mL and 12% reversibility, a methacholine bronchial challenge test was offered, and if negative, the medication was downtitrated. If a further methacholine test 3 weeks off medications was still negative, asthma was ruled out. There are three conclusions: 1) stepping treatment down as per guidelines is safe; 2) not all patients with adult-onset asthma appear to have asthma lifelong; and 3) bottom line, if asthma is not confirmed with reversible airflow limitation, the diagnosis is wrong in 44%.

Reference: JAMA 2017;317(3):269–79

Abstract

The potential role of aspiration in the asthmatic airway

Authors: Hunt EB et al.

Summary: This study focused on airway pepsin as a biomarker of adverse clinical outcome and disease severity in the asthmatic lung. The researchers sought to determine whether aspiration occurs in patients with asthma and, if so, whether it correlates with asthma control. On the morning of bronchoscopy, 78 patients with asthma completed the ACQ (Asthma Control Questionnaire)-7, were tested for fractional exhaled nitric oxide levels and undertook spirometry to characterise their level of asthma control. Barium swallow with provocation was performed to assess for predisposition to aspiration. BAL pepsin level was measured as a marker of aspiration. Asthma disease severity was characterised as mild (35.8%), moderate (21.7%) or severe (42.3%). Pepsin was detectable in BAL in 46 of the patients, but the levels did not differ by disease severity. Moreover, detectable pepsin was not associated with asthma control, FEV1, ACQ-7 score or exacerbation frequency. The results were similar in a model adjusted for smoking history, body mass index, proton pump inhibitor use, eosinophil count and IgE. When stratified into eosinophilic or neutrophilic asthmatic populations, there were no relationships with detected pepsin levels. A positive barium swallow did not correlate with BAL pepsin level. Neither univariate nor multivariate analyses identified any significant associations between barium swallow result and ACQ-7 score, asthma severity, exacerbation frequency or FEV1.

Comment: About 10% of patients with asthma have persistent symptoms despite optimal therapy. In this article, researchers from Ireland, England and Canada explored the role of reflux disease in patients with symptomatic asthma. They recruited 78 patients with mild, moderate and severe asthma, and explored the role of reflux disease with a barium swallow and pepsin on bronchoscopic BAL. The correlations between asthma control, lung pepsin level and aspiration on barium swallow were so poor that the authors concluded that even in non-acid reflux, bottom line, reflux disease may not be an important comorbidity in patients with asthma symptoms.

Reference: Chest 2017;151(6):1272–8

Abstract

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Efficacy of mepolizumab add-on therapy on health-related quality of life and markers of asthma control in severe eosinophilic asthma (MUSCA)

Authors: Chupp GL et al.

Summary: In this multinational phase 3b trial, patients aged ≥12 years with severe eosinophilic asthma and a history of ≥2 exacerbations requiring treatment in the prior 12 months, despite regular ICS plus other controller use, were randomised by country to receive subcutaneous mepolizumab 100mg (evaluable n=274) or placebo (evaluable n=277) every 4 weeks for 24 weeks added to standard care. Compared with placebo, mepolizumab was associated with a significant improvement over 24 weeks in baseline St George's Respiratory Questionnaire total score (least squares mean difference −15.6 vs. −7.9 [p<0.0001]). There were no deaths and the rates of ≥1 on-treatment adverse events were similar in the respective mepolizumab and placebo arms (70% and 74%), as were the rates of on-treatment serious adverse events (5% and 8%).

Comment: Current biological therapies are all designed to assist the management of patients with severe asthma; they include monoclonal antibodies targeting IgE (omalizumab), IL-5 (mepolizumab, benralizumab and reslizumab) or IL receptors 4, 5 and 13 (e.g. benralizumab). In this study, a group of American and Dutch researchers explore the role of the anti-IL-5 antibody, mepolizumab, and demonstrated that it not only allowed reduction in steroid therapy, but it also improved health-related QOL. Bottom line: mepolizumab shows a clinically relevant improvement in lung function, asthma control and QOL in severe eosinophilic asthma.


Abstract

Oral glucocorticoid-sparing effect of benralizumab in severe asthma

Authors: Nair P et al., for the ZONDA Trial Investigators

Summary: This study randomised 220 adults with severe asthma to receive subcutaneous benralizumab 30mg every 4 or 8 weeks (with the first three doses administered every 4 weeks) or placebo for 28 weeks. Asthma control was maintained in all patients. Benralizumab significantly reduced the median final oral glucocorticoid dose from baseline (primary endpoint) by 75% at week 28, as compared with just 25% in the placebo group (p<0.001 for both). Benralizumab administered every 4 weeks and every 8 weeks resulted in annual exacerbation rates that were lower than the rate with placebo (0.83 and 0.54, respectively, vs. 1.83 [p<0.003]). At 28 weeks, FEV1, FEV1/FVC, and 12-month cumulative exacerbation rates were significantly lower with benralizumab (p<0.05) compared to placebo; some showed significant changes in favour of benralizumab whereas others showed no significant changes. Adverse events occurred at similar rates in the three treatment groups.

Comment: The principle target group for biological therapies is the 5–10% of asthmatics who are not controlled on combination inhaler therapies after addressing technique, adherence and comorbidities. The best overview on how these therapies fit into the inflammatory cascade of asthma, i.e. somewhere between corticosteroid and bronchodilators, is by Brian Lipworth and Sunny Jabbar (Lancet Respir Med 2017;5:614–5), however, every journal has published an editorial and viewpoints. In this study, the humanised monoclonal antibody against the α-subunit of the IL-5 receptor, benralizumab, has been tried on patients with severe oral steroid-dependent asthma. Bottom line: benralizumab allowed a reduction in the oral steroid dose in severe asthma.


Abstract

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- Contraindicated in patients with a hypersensitivity to pirfenidone or any of the excipients.
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- Common: Cough, dyspnoea, cold symptoms, upper respiratory tract infection, headache, rhinitis, sinusitis.
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**Usage:**
- For the treatment of idiopathic pulmonary fibrosis (IPF). Esbriet (pirfenidone) 267 mg oral capsule is a provascular matrix metalloproteinase inhibitor approved in Europe for the treatment of IPF. Esbriet has published an editorial and viewpoints. In this study, the humanised monoclonal antibody against the α-subunit of the IL-5 receptor, benralizumab, has been tried on patients with severe oral steroid-dependent asthma. Bottom line: benralizumab allowed a reduction in the oral steroid dose in severe asthma.