

Questions Relating to the Asthma Clinical Guidelines Presentation

1. What proportion of patients initially diagnosed as “asthmatic” turn out to have dysphonia and need speech treatment referrals?

Are you referring to vocal cord dysfunction? In 1983, doctors at National Jewish described a condition that may be confused with asthma. This condition is called vocal cord dysfunction, or VCD. People with VCD will report asthma-like symptoms to their doctors. Symptoms of VCD include: Shortness of breath, intermittent hoarseness and/or wheezing, chronic cough and/or throat clearing, chest and/or throat tightness, “just having trouble getting air in.”

These symptoms are a result of an abnormal closing of the vocal cords (VCD), rather than inflammation of their airways (asthma). Based on these symptoms, many people with VCD may be misdiagnosed with asthma and treated with asthma medications. Since VCD is not asthma, little or no improvement is seen in symptoms. If VCD is still not diagnosed, oral steroids (used in other chronic lung diseases like severe asthma) may be prescribed. While it should be clear why a correct diagnosis of VCD is important, it is also critical to keep in mind that some people have both VCD and asthma, which complicates both the diagnosis and the treatment.

To understand VCD, it is helpful to understand how the vocal cords function. The vocal cords are located at the top of the trachea and vibrate from exhaled air to produce noise and voice. Breathing in and out causes the vocal cords to open, allowing air to flow through the trachea. However, with vocal cord dysfunction, the vocal cords close together, or constrict, during one or both parts of the breathing cycle. This leaves only a small opening for air to flow through the windpipe and causes asthma-like symptoms.

Once diagnosed with VCD, a specific treatment program can begin. If VCD is the only condition, asthma or other medications may be stopped. If both asthma and VCD are diagnosed, asthma medications may be continued, but are often decreased. Treatment for gastroesophageal reflux disease (GERD), laryngopharyngeal reflux, and postnasal drip should be started if these are present.

There are many special exercises and therapies that help control VCD. Speech-language pathology (speech therapy) is a very important part of the treatment for VCD. Special exercises increase awareness of abdominal breathing and relax throat muscles. This enables the patient to have more control of the vocal folds and throat. Learning cough suppression and throat clearing techniques can also be extremely helpful. All of the exercises are aimed at overcoming abnormal vocal cord movements, controlling the vocal folds with the breath stream, and improving airflow into the lungs.

Depends on the dose of ICS used. Clearly the higher the dose the greater the incidence. An article in the “Medical Journal of Australia”, 2003 by Heather Powel and Peter G. Gibson, titled *Inhaled Corticosteroid Doses in Asthma: an evidence –based approach*, the authors found for every 131 people treated with 200 ug of fluticasone daily, one person developed hoarseness /dysphonia. When the higher dose 500 ug of fluticasone daily was used, it took only 23 people to be treated to have one with hoarseness /dysphonia.

2. Youth's > 12: item 8-19 Years (85%) overlaps with previous slide 5-11. Which to follow?

It doesn't appear that it overlaps. The stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual patient needs.

3. What about "step up" treatment in anticipation of seasonal changes, which predisposes patients to exacerbations?

A clinician must understand the patient's seasonal responses to asthma and can be proactive by maximizing therapy before a troublesome season begins, then can step down once the season is over, if asthma is traditionally under better control the rest of the year.

4. What is the criteria when deciding step up one or two steps?

According to the Expert Panel Report 3: the stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual patient needs.

5. Since asthma is an inflammatory disease, is the first step of treatment corticosteroid and quick relief inhaler?

Yes, that is the first step for persistent asthma. Intermittent asthma would require simply the quick relief inhaler, unless the patient has symptoms more than twice a week, nocturnal symptoms more than twice a month, or is using more than two canisters of quick relief inhaler per year.

6. Is a dehydrated patient more prone to an attack? If so, how much more water should an asthmatic drink compared to a healthy individual?

Reference found at: University At Buffalo (1999, June 7). Dehydration Makes Exercise-Induced Asthma Worse, Study By UB Researchers Finds. *ScienceDaily*. Retrieved January 28, 2008, from <http://www.sciencedaily.com/releases/1999/06/990607071643.htm>

Research shows that dehydration may induce bronchospasm even before exercise and make exercise-induced asthma worse. "The message continues to be, 'Drink fluids whenever you get the chance,'" said Frank Cerny, Ph.D., associate professor and chair of the UB Department of Physical Therapy, Exercise and Nutrition Sciences. "If you have asthma, dehydration may make it worse, particularly during exercise." Cerny said that exercise-induced asthma probably is caused by heat and water loss from the airways. "By dehydrating yourself, the airways also become dehydrated," he noted. "We first observed this problem in high-school and college athletes -- that as they became dehydrated, they seemed to have more trouble with their asthma."

Results showed that among the nonasthmatics, hydration status had no effect on the FEV1 before, during or after exercise. However, the FEV1 of the asthmatics was significantly lower, both before and after exercise, when they were dehydrated, compared to their respiratory performance when completely hydrated. Researchers found that the rate of respiratory decline remained the same in the asthmatics during exercise, regardless of their state of hydration, but they started out with less capacity when they were dehydrated, Cerny said. "Asthmatics are more sensitive than nonasthmatics to

dehydration, but we need to investigate this condition further to determine how it affects pulmonary function,” he said.

7. What do you tell the physician who is concerned about the steroid, long-term side effects like osteoporosis, stunted growth or elevated blood sugars for diabetics? Data has not proven that long-term use has had a large impact.

Inhaled corticosteroids (ICS) are much safer than oral steroids, which can cause those effects mentioned above. For information on the safety of ICS, please see the CAMP study and Agertoft and Pederson in the NEJM articles

The Camp study is found at Pediatrics, 2004 Jun, 113 (6) 1693-9 by BacharierLB, etc. “Long-term effect of budesonide on hypothalamic-pituitary-adrenal axis function in children with mild to moderate asthma.” The Agertoft and Pedersen article is located at NEJM. 2000, Oct 12:343(15): 1064-9 “Effect of long-term treatment with inhaled budesonide on adult height in children with asthma”. Both articles are attached to the email.

8. Where can we get more copies of the asthma action plans?

Contact the Asthma Initiative of Michigan toll-free line to request more action plans: 1-866 EZ LUNGS (1-866-395-8647). The action plans (adult and pediatric versions) can be provided free of charge.

9. The physicians will likely want to know where they can get these. Are they free of charge? Where do the physicians order these?

Yes, they can be provided free of charge. Physicians can contact the Asthma Initiative of Michigan toll-free line at 866-EZ-LUNGS (866-395-8647).

10. Please comment on new prescribing guidelines for Serevent and Advair. Will Michigan Medicaid be looking at future claims for these?

When the Department became aware of the concerns with Serevent, the Michigan DUR Board developed a retrospective DUR project. Letters were sent to prescribers with patients on Serevent, alerting them to the concerns. At this time, we do not have a DUR underway with this issue, but maybe it should be revisited. This is the website related to the FDA advisory for Serevent and Advair: FDA warning: www.fda.gov/cder/drug/advisory/LABA.htm, **FDA Public Health Advisory:** Serevent Diskus (salmeterol xinafoate inhalation powder), Advair Diskus (fluticasone propionate & salmeterol inhalation powder), Foradil Aerolizer (formoterol fumarate inhalation powder).

As far as Serevent (salmeterol), it is dangerous if a long-acting beta-agonist (LABA) is used alone. It should never be given to a patient without an inhaled corticosteroid as well (such as Advair, which is a combination of LABA and ICS).

The black box warning for Serevent/Advair is a result of the SMART study. So, what did they do? They recruited patients by advertisements, ensuring a high proportion of patients who might not have been receiving good physician care, gave them either salmeterol or placebo, and then provided only monthly telephone follow up. At this point, we have a group of patients, many of whom were not under good control or receiving regular physician hands-on follow up, who were given a medication that was

purportedly possibly harmful and not monitored other than by telephone calls. They could not be accused of “cherry-picking” their study subjects in this trial.

This "phase one" recruitment ended when it appeared the trial would need over 60,000 participants (over twice what the original power computation indicated because of the relatively low mortality rate in both the control and treatment arms), and the recruitment process shifted to study investigators who recruited their own patients. This change brought about a situation at least resembling how the drug might be used in clinical practice.

There was a marked difference in the outcomes based on the method of recruitment. Thirteen of the sixteen asthma-related deaths occurred in patients recruited in phase one. There were about 15,000 patients in phase one, versus about 11,000 in phase two. The report indicates that there were no statistically significant differences between salmeterol and placebo in any of the primary or secondary outcome measures in the phase two patients.

If there had been no phase one recruitment, there would likely be no black box warning on salmeterol containing products. It should be noted that this trial was terminated early by GSK. Only half of the subjects had been enrolled, and the predefined criteria for terminations had not been met. The reasons given were the disproportionate number of events in African Americans and difficulty in enrollment.

What about the effect of prior or concomitant treatment with an inhaled corticosteroid (ICS) on salmeterol treatment outcomes? This is how salmeterol is currently used according to guidelines. To me, the take-home message from this trial is that long-acting beta-agonists, such as salmeterol, should NEVER be used as monotherapy. When used in combination with inhaled corticosteroids, they should be considered safe.

Questions addressing criteria used for selecting patients and providers that will be targeted in the Academic Detailing Intervention:

11. What about COPD patents? That is information we will use when analyzing patients. You should focus on asthma patients.

We discussed with a medical director and pulmonologist the need to remove patients with COPD. We were advised that the message of the new guidelines is very important; therefore, they recommended casting a broad net and providing the information to prescribers even if the patient may have COPD instead of asthma. We accepted that recommendation.

12. Were any of these physicians visited in the previous asthma detailing project?

It is possible. We did not remove prescribers if they were part of the previous asthma AD project. Again, the message is too important to exclude anyone.

Questions regarding Academic Detailing Visits:

13. What is an NPI #?

The NPI stands for the National Provider Identifier which will be the universal billing provider ID number for all providers billing services to Medicare, Medicaid and other

health plans. Physicians who are being visited by the Academic Detailers are being asked to provide their NPI number on the Detailer Visit Form in place of their DEA number.

14. Are we to leave the form with the MD and trust they will comply?

Yes, you should leave the form with the physician.

15. Which professionals can we meet with if the physician is not available for academic detailing?

Physicians, physician assistants and nurse practitioners