

risk reduction is important in evaluating drug therapy and assessing clinical usefulness for intervention. The relative risk reduction is a necessary measure of clinical significance. Absolute risk reduction has shortcomings with respect to clinical usefulness. The reciprocal of absolute risk reduction is the number of patients needed to treat in order to prevent one complication of the disease. This is useful, as it emphasizes the effort needed in order to accomplish a treatment target. It also enables us to estimate the cost of treatment. There is, however, an important consideration when evaluating the number needed to treat. This number can vary drastically depending upon the study population and therefore should *not* be used for comparison between drugs in the absence of a head-to-head trial.

My article quoted a 30% reduction in the relative risk of hip fracture with risedronate. Dr Larocque states that the relative risk reduction of 30% was obtained by subgroup analysis. This is not the case. The 30% reduction was obtained from the overall data. The subgroup analyses identified a 40% reduction in women with osteoporosis as described in the article. A 60% reduction was seen in those women who also had pre-existing vertebral fractures at baseline.

In the PROOF trial evaluating calcitonin therapy,² a dose response was not seen. The reasons for this are not clear and could have been related to the drop-out rate. Clearly, what was statistically significant was a reduction in vertebral fracture with the 200-IU dose, on which basis calcitonin was approved by both the Food and Drug Administration and the Health Protection Branch for treatment of osteoporosis.

We must remember that results from clinical research are very carefully considered by both the Food and Drug Administration and the Health Protection Branch, and the possibility of “chance” alone contributing to the data is excluded by detailed statistical

analysis in well-designed clinical trials with fracture as a primary outcome.

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Is expensive medicine worth it?

Having myself done a review of the literature on the same subject, I read with interest the article¹ by Dr Papsin and Ms McTavish, “Saline nasal irrigation,” in the February issue of *Canadian Family Physician*.

I had undertaken this research because residents were prescribing “Hydrasense” for acute rhinosinusitis to patients at our walk-in clinic. Because we were working in a disadvantaged area, I wondered whether studies supported such an expense for these patients.

As the authors mentioned in their “Quality of evidence” section at the beginning of the article, most studies on this subject are small and not placebo-controlled. The best study I found was the one by Adam et al² cited as reference 14 by the authors. It showed no difference in outcome whether patients were treated with a hypertonic nasal solution, an isotonic nasal solution, or observation for acute rhinosinusitis. I concluded there was no evidence base for asking patients to buy such an expensive product.³

Papsin and McTavish’s objective was to review the literature for clinical trials of the efficacy of saline nasal irrigation. The authors did not mention, as is usual in this type of research, what criteria they used to include or reject articles. It seems that they retained all the articles they found. I cannot understand why certain articles (cited as references 8, 22, 23, and 25), which they

describe in the text, are not included in Table 1, “Clinical studies of saline irrigation.”¹

I found the section on rhinosinusitis weak both in its literature review and in its content. I was shocked that the authors ended this section by describing without comment the study by Seppely and Krayenbuhl (reference 22).⁴ The authors reported the conclusions without analyzing or criticizing them. I tried to obtain the article by Seppely and Krayenbuhl, but it was published in a journal not listed on MEDLINE. The authors’ summary suggests the study was not randomized and not placebo-controlled and did not mention the inclusion criteria or which antibiotic was used. The authors suggest that most patients got better with only 5 days of antibiotic therapy, rather than the usually recommended 10-day treatment, because nasal irrigation was given with 5 days of antibiotics: “Frequent nasal lavage can reduce the length of antibiotic therapy.” What we must understand when we do a literature review on the subject of acute rhinosinusitis is that, in most studies of antibiotics versus placebo, most patients get better while receiving placebo and that there is often no difference in rates of improvement—it is not surprising, then, that the patients in this study got better with only 5 days of antibiotics.⁵⁻¹¹

If we want to reduce antibiotic resistance, we should simply refrain in general from prescribing antibiotics during the first few days of acute rhinosinusitis (unless it is a question of severe sinusitis, which was excluded by the antibiotic-placebo studies). The role of nasal irrigation remains to be defined.

The section on allergic rhinitis would have been interesting, but there again the authors only described and did not analyze the two studies of Georgitis.^{12,13} The authors used the first of these studies to affirm: “Nasal irrigation has been recommended as an adjunct therapy to flush out mucus and irritants and improve the flow of

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air through the nose.” Georgitis’ conclusion is quite different: “Rhinitis symptoms improved after vapor treatments *but not with nasal irrigation*. Patients preferred the molecular water vapor treatment over the large particle vapor treatment and nasal irrigation by 2:1 margin. This study demonstrated the usefulness of heated vapor treatments in improving rhinitis symptoms and nasal airflow.”

In the second study of Georgitis, the fact that 6 hours after nasal irrigation levels of histamine were reduced, does not imply that patients are clinically better. Papsin and McTavish conclude that section by reporting: “The investigators concluded that nasal irrigation had a long-term effect on mediator production and was, therefore, a useful therapy for allergic rhinitis.”¹ Georgitis’ conclusion is more guarded: “This study demonstrated the usefulness of large particle vapor treatment and saline solution irrigation in reducing inflammatory mediators in nasal secretions and indirectly supports the clinical efficacy of these treatments for chronic rhinitis.”

There is nothing in the literature to back up our prescribing nasal solutions for acute or allergic rhinosinusitis. Isotonic solutions do not appear to be harmful, although certain patients complain of a burning sensation (13% in the study by Adam et al²). Doctors who want to suggest this treatment to patients can give them a very simple home recipe: 1.25 mL of salt in 250 mL of boiling water.

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