

Outcome measurements in clinical research, does it matter?

In the last two decades a tremendous change has evolved in rhinology. Until the 1990's most of our knowledge was based on experience. However since the 90's more and more focus has been placed on measuring our achievements. In 1993 the Cochrane collaboration has started, which is now an established institute of evidence based medicine. If we appraise the field of Rhinology, medical treatments and especially pharmaceutical company trials have led the way. But now measuring our outcomes in a number of different ways starts to influence all parts of our speciality. In this issue of Rhinology, some areas of our speciality that were not always much into evidence, like facial plastic surgery show that more objective measurements can contribute significantly to our knowledge. Niels van Heerbeek shows us for the first time what stereophotogrammetry can teach us in the evaluation of rhinoplasty⁽¹⁾. This method enables the surgical effects on the outside of the nose to be measured. Also of considerable interest is the measurement of functional effects of facial plastic surgery, which can be done by determining the minimum cross-sectional area of the nasal passage by CT scan^(2,3), or digital volume tomography in nasal fractures as described by Bremke et al.⁽⁴⁾. These objective measurements of outcome as well as objective change in "subjective" improvement eg. using quality of life measurements⁽⁵⁾ will help us to compare our results and further define effective and less effective treatment modalities. The time of "in my hands" is over, although we still have some way to go: "rhinoplasty" in Pubmed results in 5635 hits but including quality of life in the search reduces the number to 26 papers, of which only 7 are published in the otorhinolaryngological literature in the English language. This does not imply that papers describing clinical experience are useless. We can learn from experience, e.g. the description of new or modified techniques, especially when long-term results are reported as by Xavier in this issue⁽⁶⁾.

In rhinosinusitis an enormous step forward has been taken in the last decade. The EP3OS paper of 2007^(7,8) describes a tremendous increase in randomized controlled trials in chronic rhinosinusitis compared to what was known in 2005^(9,10). Furthermore since 2007, another 17 trials have been added to the 104 available up to that date⁽¹¹⁻¹⁶⁾. It is also worth noting that non-randomized studies can also contribute to our knowledge. In this issue Nair provides a helpful although not randomized paper on the correlation between symptom severity and CT scan abnormalities⁽¹⁷⁾. Even a prospective case series as described by Danielides, showing that a positive outcome on smell is highly dependent on time of loss of smell before surgery and previous sinus surgery, can give us relevant information⁽¹⁸⁾. Initiatives such as the 'Rhinosinusitis: developing guidance for clinical trials' initiative in the USA⁽¹⁹⁾ and EP3OS

in Europe⁽⁸⁾ that describe outcome measurements and designs of clinical trials will help to improve the quality of our research. The holy grail of evidence-based medicine is certainly not the only way to do research and report⁽²⁰⁾. However, the quality of our studies and papers will certainly increase if we move from "in our hands" to more scientific ways of reporting our (surgery) data. Being as complete and precise as possible in describing our populations and outcomes will further improve our science, our knowledge and last but not least the management of our patients. I call upon all of you to use the checklist from Cochrane or from the papers described above to verify whether your paper contains all relevant data.

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