

EVIDENCE-BASED TREATMENT OF CHRONIC RHINOSINUSITIS

Livije Kalogjera and Tomislav Baudoin

Department of Otorhinolaryngology/Head & Neck Surgery, Sestre milosrdnice University Hospital Zagreb, Croatia

SUMMARY – Although chronic rhinosinusitis is one of the most common chronic disorders, and major advances in minimally invasive surgery and potent antimicrobial and anti-inflammatory conservative treatment have been accomplished in the past decade, evidence for the most effective treatment of chronic rhinosinusitis is still lacking. Randomized controlled trials, which provide the best possible evidence in terms of testing the efficacy of chronic rhinosinusitis treatment, are too few. Those that have been done so far, have proven advantages of endoscopic sinus surgery over classic radical surgery in terms of providing better health related quality of life. Case controlled studies of endoscopic sinus surgery have shown a 91% (73.0%-97.5%) improvement with a major complication rate of 1.6%. Still, at longterm follow up, improvement rate drops to 50% in revision cases and in patients with systemic disease (allergy, asthma). Further improvement in surgical failures can be achieved with longterm topical steroid and low-dose macrolide treatment. Conservative treatment, which includes aggressive long-term steroid and antibiotic therapy, with permanent nasal saline douches and short-term decongestants, has proved successful in half of the treated patients, yet with a shorter follow up. However, only few of clinical trials are randomized controlled trials, and placebo-controlled studies have not recognized significant advantage of any conservative treatment. The level of evidence for the treatment for pediatric sinusitis is satisfactory, and meta-analysis of conservative treatment has been cited in the Cochrane Library Database. Meta-analysis of surgical treatment for pediatric sinusitis yields a success rate of 88% with a mean follow up of 3.7 years and major complication rate of 0.6%.

Key words: Sinusitis –surgery; Chronic diseases; Evidence based medicine

Chronic rhinosinusitis (CRS) is regarded as one of the most common chronic diseases with a significant impact on the quality of life and cost of health care in the developed world. Major advances in ever less traumatic surgical procedures on the one hand and development of potent antimicrobial and anti-inflammatory medication on the other hand have created a dilemma in defining treatment strategies for chronic rhinosinusitis in the past two decades. Randomized controlled trials (RCT) with their prospective definition of methods and outcome measures, double-blind assessment of outcomes and unbiased selection of subjects and controls provide the best possible

evidence for deciding the value of a medical or surgical intervention. A lot of case series deal with CRS treatment, both conservative and surgical⁶, but only a few randomized controlled trials meet adequate inclusion and exclusion criteria to provide data for meta-analysis of randomized controlled trials, as only such a study is considered as the highest level of evidence. Such meta-analysis is needed as a guideline for evidence-based treatment options, yet the problem is that only a few RCTs evaluated topical steroids, no RCT dealt with longterm low-dose antibiotic concept of treatment for CRS and the placebo effect of endoscopic sinus surgery was not measured, so a controlled trial of the improvement rate following sinus surgery compared to conservative treatment does not exist in the literature at the moment.

The concept of functional endoscopic sinus surgery (FESS), the Messerklinger technique, world-wide spread

Correspondence to: *Livije Kalogjera, M.D., Ph.D* Department of Otorhinolaryngology/Head & Neck Surgery, Sestre milosrdnice University Hospital, Vinogradska c. 29, HR-10000 Zagreb, Croatia
E-mail: kalogjera@sfzg.hr

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by efforts of Stammberger and Kennedy, was broadly accepted in the '80s and evaluated in numerous prospective and retrospective case controlled studies or nonrandomized clinical trials. The functional approach to rhinosinusitis hypothesized recovery of the diseased sinus mucosa by enabling ventilation through the natural ostia and restoring mucociliary clearance achieved by minimally invasive endoscopic technique^{4,5}. Treatment outcomes for endoscopic sinus surgery (ESS) were reviewed by Terris and Davidson⁶ in 1994, analyzing 10 large series (level II and III) with a total of 1,713 patients, which showed a 91% (73.0%-97.5%) improvement rate. Subjectively, 63% of patients reported a very good result, 28% good result, and 9% an unsatisfactory result. Twelve percent of patients required revision surgery. Major complications occurred in 1.6% of patients. The cited review is not a meta-analysis of RCT, so its results cannot be used as Ia level of evidence. The problems of performing RCT in evaluating surgical treatment are numerous and affect all surgical disciplines⁷. It seems that surgeons are not well educated in clinical research, funding of RCT in surgery is hardly comparable to those supported by pharmaceutical industry, and surgeons are probably lacking training, expertise and desire to perform RCT. The placebo effect of surgery is great, and blinding of patients and surgeons is particularly difficult⁷. Ethical problems should be considered if placebo surgery is performed. If RCT is a study designed (and supported) ideally to evaluate drug treatment, and not surgery, more appropriate experimental design to test surgical treatment should be applied (like prospective matched-pair trials)⁸.

On the other hand, aggressive, longterm, conservative treatment of persistent sinusitis is being on trial during the last decade and is expected to modify indications for sinus surgery as well as the accumulated knowledge on poor prognostic factors¹. However, although RCT is much easier to perform to test conservative (drug) management, double blind placebo controlled trials for such treatment are few, and meta-analysis of these trials would probably face the problem of uniformity of scoring system and treatment modality.

The situation is different for pediatric population, with a meta-analysis of conservative treatment in Cochrane Library Database⁹, and a meta-analysis of surgical outcomes (although not of RCTs)³³. Antibiotic treatment seems to be helpful at short- to medium-term⁹, and surgery has proved successful in the meta-analysis of 8 published series (+ authors' 50 patients with unpublished data) in 922 children operated with FESS¹⁰. The success rate was 88% with a mean follow-up of 3.7 years and major complica-

tion rate of 0.6%. Patients with systemic disease (like cystic fibrosis or immunodeficiency) were excluded.

Controlled clinical trials use at least one objective instrument to support improvement in subjective parameters, such as CT scans^{11,12}, olfactometry¹³⁻¹⁶, mucociliary transport^{17,18}, inflammatory cell infiltration and activity^{19,20}; however, as the diagnosis of rhinosinusitis is based on symptoms, consequently the outcomes are usually measured by symptom relief and improved health-related quality of life (HRQL)^{21,22}. It is well established that most of objective and subjective parameters in CRS do not correlate significantly²². A long list of symptom scores/quality of life instruments are now available, e.g., Rhinoconjunctivitis Outcome Measurement (RSOM-31)²³, Sinonasal Outcome Test-20 (SNOT-20)²⁴, Chronic Sinusitis Survey (CSS)¹¹, Sinonasal Assessment Questionnaire (SNAQ-11)²⁵, Child Health Questionnaire (CHQ)²⁶, Rhinosinusitis Disability Index (RSDI)²⁷, SNOT-16²⁸, Short Form 36²⁸, most of them validated and compared in several studies^{24-26,28,29}. A lot of other questionnaire forms for HRQL have been created, with the idea to be population specific or more sensitive, but their value is supported mostly by their creators³⁰.

Considering surgical trials on chronic rhinosinusitis, those presenting level Ib statement of evidence (RCT) are either comparing different surgical techniques (radical surgery *vs.* ESS), or more or less traumatic and advanced-technology-applied (power instrumentation) modifications of Messerklinger technique. Considering outcomes of sinus surgery, two trials (level Ib) by Pentilla *et al.* have compared ESS and radical, Caldwell Luc approach (C-L) one year following surgery and longterm outcomes^{31,32}. Interestingly, the first study revealed significant improvement in obstruction, rhinorrhea and improved smell in the ESS group as compared with C-L group (global evaluation showed marked improvement in 50.7% of the C-L group and in 76.7% of the ESS group)³¹, but the outcomes in another trial demonstrated different improvement rate 5-9 years postoperatively, i.e. 82% of the C-L and 76% of the ESS patients, respectively. Revision surgery was done in 20% of ESS group and 18% of C-L group³². Postoperative cheek pain and sensations to changes in temperature were noted in 23% of C-L group. Histopathology of the same groups was done by Forsgren *et al.* (level IIb), indicating greater reduction in inflammatory parameters in the mucosa of the maxillary sinus after C-L than after ESS one year after the surgery³³. Another randomized controlled clinical study (level Ib) by Unlu *et al.* revealed superiority of ESS (40 patients) to C-L (37 patients), where both CT

scans and endoscopy were used as outcome measures³⁴. A randomized controlled trial (38 patients, bilateral disease, side randomized) comparing chronic maxillary sinusitis outcomes following middle (MMA) and inferior (IMA) meatal antrostomy showed no significant difference³⁵, in contrast to the results of Lund³⁶, who analyzed longterm nasal symptom scores for two types of antrostomy, proving superiority of MMA. The outcomes for purulent rhinitis and loss of smell showed significant improvement following ESS preceded by maxillary sinus irrigation as compared with those obtained by sinus irrigation alone after one-year observation for chronic maxillary sinusitis in a trial (Ib) conducted by Hartog *et al.*³⁷ Scores for other sinusitis symptoms did not differ significantly.

Trials comparing outcomes of medical *versus* surgical + medical treatment for nasal polyposis (Ib) proved the benefit from surgery only in some patients^{38,39}. A randomized controlled study (Ib) compared results following oral and topical steroid with subsequent surgery on one side, using the other side as control, with a follow-up of 12 months. Surgery resulted in additional improvement of nasal obstruction and secretion scores, but only 25% of the patients were willing to have surgery on the conservative-only treated side³⁸. A randomized, double blind, placebo controlled study (Ib) demonstrated significant improvement in all outcome measures (subjective scores, olfaction, peak expiratory flow) following topical steroid treatment, and subsequent surgery was needed in a low proportion of patients³⁹.

The outcomes of subsequent medical treatment to prevent failure/recurrence in the operated patients have been tested in numerous clinical trials. As appropriate control, when treated conservatively, is easier to achieve than for surgery alone, it may be concluded that RCTs would give evidence for best postoperative treatment. Still, sample size and planning in such trials remain a problem. In some studies controls are another group of patients, but in some contralateral side of the active treatment serves as a control, which may not be appropriate for the models where medication can affect the other side. An example of such a model is RCT by El Naggar *et al.*¹³ on the effect of post-polypectomy nasal treatment with beclomethasone on olfaction, where the difference between the treated and control sides was insignificant (unilateral nasal steroid treatment reduces inflammation contralaterally). Intraoperative administration of i.v. corticosteroid during sinus surgery in 24 children resulted in significantly less maxillary sinus mucosal edema, less ethmoid scarring, and a lower incidence of closure of maxillary ostium at second look after

Table 1. Levels of evidence according to evidence-based medicine guidelines

Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

2-3 weeks, compared to placebo treated controls (Ib)⁴⁰. A double blind placebo controlled study (Ib) was performed to test whether intranasal budesonide application was effective in reducing symptoms in 26 previously operated patients allergic to house dust mite with persistent rhinorrhea and pain/pressure resistant to oral antibiotic and nasal steroid treatment. Significant reduction in sinusitis symptoms was accomplished in the active treatment group, but also in eosinophil count and cells expressing IL-4 and IL-5 mRNA⁴¹. Although nasal steroids are the gold standard in postoperative care, proven by several RCTs⁴², significant protection from polyp recurrences was demonstrated for nasal capsaicin and furosemide treatment, as shown in a RCT by Zheng *et al.*⁴³ (Ib level) and Passali *et al.*⁴⁴ (Ib level), respectively. In a prospective nonrandomized trial of patients with persistent sinusitis symptoms conducted by Cervin *et al.*¹⁷ (IIb), twelve of 17 patients were considered responders to treatment with longterm low-dose macrolide (erythromycin and clarithromycin, for up to 1 year in responders after 3-month trial) after surgery. After one-year treatment, they showed significant improvement in subjective and endoscopy scores, and in saccharin transition time but not in CBF and nitric oxide. In a nonrandomized prospective study by Katsuta *et al.*¹² with 3-month roxithromycin in patients with persistent rhinosinusitis with nasal polyposis, subjective improvement was 50.3% and 51.8% on CT scans and 59.1% at endoscopy. Electron microscopy of sinus mucosa revealed apoptosis of plasma cells and reduced fibroblast proliferation following treatment. An open label prospective trial (level III) with nasal amphotericin B in patients with

persistent rhinosinusitis indicated improvement in 75% of patients⁴⁵. Longterm antibiotics combined with oral and topical steroids with nasal irrigations gave improvement in a higher percent of patients and time to relapse was shorter in previously operated patients and nasal polyposis, while atopy, asthma and persistent ostiomeatal obstruction did not tend to early relapse, as demonstrated in a retrospective study of 40 patients (level III)⁴⁶. Earlier RCT on topical steroid + erythromycin (short-term) did not produce evidence for such treatment, although some scores were significantly improved⁴⁷. Expensive treatment with the anti-inflammatory agent filgrastim in patients irresponsive to any CRS treatment failed to prove significant efficacy in RCT⁴⁸.

In conclusion, we may say that trials representing high level statements of evidence for efficacy of rhinosinusitis surgery are missing, as it has been already reviewed by Lund in 2001⁴⁹. Few rhinosurgical studies are designed as RCTs, and those that are should be of higher quality. The lack of consistency between the studies (inclusion-exclusion criteria, staging, scores, questionnaires, etc.) and small samples for evidence-based statistics are the main features of these trials. The learning curve of endoscopic rhinosurgeon should be established, before we can compare results from different studies. Although we have evidence that ESS is a safe procedure that improves sinusitis symptom scores and HRQL in low-risk adult patients, the outcomes seem to be better than for conservative treatment only at long-term. High-risk patients should be treated with aggressive longterm conservative treatment pre- and postoperatively, and should represent a different group on study evaluation. In pediatric patients, there is a strong evidence that antibiotic treatment gives short-term to midterm benefit in children with persistent rhinosinusitis. Results are better for pediatric ESS. Similar effort to perform meta-analysis of raw data on numerous patients operated on with ESS in the adult population is needed.

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Sažetak

NA DOKAZIMA ZASNOVANO LIJEČENJE KRONIČNOG RINOSINUSITISA

L. Kalogjera i T. Baudoin

Iako je kronični rinosinusitis jedna od najčešćih kroničnih bolesti, a u prošlom su desetljeću postignuti veći pomaci u minimalno invazivnoj kirurgiji, kao i u pojačanoj antimikrobnoj i protuupalnoj konzervativnoj terapiji, još uvijek nedostaju dokazi o najdjelotvornijem liječenju kroničnog rinosinuitisa. Premalo je randomiziranih kontroliranih studija koje pružaju najbolje moguće dokaze u smislu ispitivanja učinkovitosti liječenja kroničnog rinosinuitisa. Dosad provedene studije dokazale su prednosti endoskopske operacije sinusa pred klasičnog radikalnom kirurgijom, jer osigurava bolju zdravstvenu kvalitetu života. Kontrolirane studije endoskopske kirurgije sinusa pokazale su 91.%-tno (73,0%-97,5%) poboljšanje sa stopom većih komplikacija od 1,6%. Međutim, uz dugotrajnije praćenje stopa poboljšanja opada na 50% kod ponovno ispitanih slučajeva i u bolesnika sa sistemskim bolestima (alergija, astma). U slučajevima gdje operacija zakaže daljnje poboljšanje može se postići dugotrajnim liječenjem topičnim steroidima i niskim dozama makrolida. Konzervativno liječenje, koje uključuje agresivnu dugotrajnu terapiju steroidima i antibioticima uz trajnu primjenu nazalnom ispiranja fiziološkom otopinom i kratkoročno sredstvima za dekongestiju, pokazalo se je uspješnim u polovice tako liječenih bolesnika, no uz kraće vrijeme praćenja. Međutim, tek je nekoliko randomiziranih kontroliranih kliničkih studija, dok placebo kontrolirane studije nisu dokazale nikakvu značajnu prednost bilo koje konzervativne terapije. Razina dokaza za liječenje sinusitisa u djece je zadovoljavajuća, a meta-analiza konzervativnog liječenja navedena je u Cochrane Library Database. Meta-analiza kirurškog liječenja sinusitisa u djece pokazuje stopu uspješnosti od 88% uz prosječno vrijeme praćenja od 3,7 godina i stopu ozbiljnijih komplikacija od 0,6%.

Ključne riječi: