

# Evidence Supporting Endoscopic Sinus Surgery in the Management of Adult Chronic Rhinosinusitis: A Systematic Review

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## ABSTRACT

**Background:** Evidence-based medicine calls for a critical evaluation of the scientific evidence for treatments of disease. This report synthesizes the available evidence on the use of endoscopic sinus surgery (ESS) in the management of adult chronic rhinosinusitis (CRS) examining the clinical question: “In adults with CRS who have failed medical management, does ESS improve symptoms and/or quality of life (QOL)?”

**Methods:** The American Rhinologic Society and the American Academy of Otolaryngology–Head and Neck Surgery convened a steering committee composed of the authors. Primary research articles evaluated for this report were identified using appropriate search terms and a Medline search. Two authors

independently reviewed each article. Articles were assigned an evidence level based on accepted guidelines (level 1 = randomized trials; level 2 = prospective cohort studies with comparison group; level 3 = case-control studies; level 4 = retrospective case series; level 5 = expert opinion).

**Results:** We identified 886 abstracts to review, retrieved 75 articles for full review, and included 45 articles in our report. The vast majority of articles represented level 4 evidence (n = 42) and two articles represented level 5 evidence. One article was identified that qualified for level 2 evidence. All of these articles generally supported the finding that ESS improves symptoms and/or QOL in adult patients with CRS.

**Conclusion:** There is substantial level 4 evidence with supporting level 2 evidence that ESS is effective in improving symptoms and/or QOL in adult patients with CRS. Future research efforts should focus on prospective studies that include appropriate comparison groups in their design. (American Journal of Rhinology 19, 537–543, 2005)

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Given the substantial quality of life (QOL) morbidity associated with chronic rhinosinusitis (CRS), it is perhaps not surprising that endoscopic sinus surgery (ESS) is performed ~200,000 times per year.<sup>1</sup> Although a relatively low risk procedure, complications, even serious ones, have been reported in the literature. Additionally, the costs associated with management of CRS, including ESS, are on the order of billions of dollars per year if one considers the cost of medication and surgery, lost work time, and productivity.<sup>2</sup>

Like all therapeutic interventions, it is helpful to view ESS through the evidence based-medicine (EBM) paradigm

to help understand its appropriate role in the management of patients with CRS. *Practicing EBM* is a process whereby the clinician integrates their clinical experience and expertise with the best studies from systematic, scientific research while considering societal and patient values. By “best studies,” EBM means clinically relevant research, especially studies conducting patient-centered clinical research. The process of practicing EBM requires that a clinical question is asked and the “best studies” or evidence addressing this question are identified, appraised, and understood. The clinician then incorporates the recommendations from this evidence into the decision-making process.<sup>3</sup>

Since the widespread introduction of ESS in the 1980s, numerous articles examining its effectiveness have been published in the form of case series, prospective studies, and even randomized trials. The general perception is that ESS is effective in cases of CRS that are refractory to medical management; however, a systematic review of the evidence in the literature has not been performed to date. In keeping with the concept of EBM, the American Academy of Otolaryngology–Head and Neck Surgery and the American Rhinologic Society convened a panel to perform a rigorous systematic review of evidence for ESS in adult CRS addressing the focused clinical question: “In adults with CRS who have failed medical management, does ESS improve symptoms and/or QOL?” It is our hope that such a review will help otolaryngologists understand the current evidence and provide insight into the most appropriate design of future studies. Furthermore, such evidence would allow otolaryngologists to more effectively counsel patients when consideration is given to ESS for management of CRS refractory to medical therapy.

## MATERIALS AND METHODS

The American Academy of Otolaryngology–Head and Neck Surgery and the American Rhinologic Society convened a panel to examine evidence for treatments in the field of rhinology. With input from each of the panelists, the following question was formulated: “In adults with CRS who have failed medical management, does ESS improve symptoms and/or QOL?” In this case, the index disease was CRS, intervention was ESS, and outcomes were patient-reported symptoms and/or QOL as measured by general health status instruments or disease-specific QOL instruments developed to measure outcome in CRS.

### Literature Search

Studies for the literature review were identified primarily through a MEDLINE search of the English language literature published between 1966 and January 2004. A second group of studies were identified by reviewing the bibliography of initially selected papers to search for pertinent articles that were missed by the MEDLINE search.

Search terms for the MEDLINE search included: ESS, CRS and ESS, sinusitis and ESS, maxillary antrostomy, nasal polyposis and ESS, nasal polyps and QOL, endo-

scopic ethmoidectomy, ESS and complications, nasal polyposis and complications, CRS and complications, sinusitis and QOL, ESS and QOL, and surgery and recurrent acute sinusitis. Of these search terms, the following are National Library of Medicine Medical Subject Heading terms: endoscopic, sinus, surgery, sinusitis, nasal polyps, QOL, and complications.

### Selection of Articles for Inclusion

The Medline search yielded 886 titles and abstracts. The titles and abstracts were screened by the panel to identify articles that addressed the focused clinical question. Of these citations, appropriate full-length articles were further examined. Additional articles were identified through review of the bibliography of the initial articles to compose the final list of full-length articles to be reviewed.

### Assigning Levels and Grade to Articles and Evidence

In the process of an EBM review, each of the identified articles is reviewed and assigned a *level* of evidence. The level of evidence is an indication of where a particular article falls in the hierarchy of evidence strength. For instance, randomized controlled trials (level 1) are considered to be stronger evidence than prospective, controlled, non-randomized studies (level 2), which in turn are stronger than case-control studies (level 3; *e.g.*, retrospective study with comparison group), which in turn are stronger than case series (level 4; *e.g.*, retrospective chart review), which in turn are stronger evidence than expert opinion or case reports (level 5). The designated level of a study can be debatable. For example, a prospective study examining outcomes of ESS may be considered either level 2 or level 4 evidence. To determine which level is most appropriate, important considerations include whether the study incorporates a comparison group and whether rigorous methodology has been used such as prestudy power analysis.

Additionally, the aggregate of articles, each with their assigned level of evidence, can be assigned a *grade* of evidence. Evidence grade is an overall determination based on the levels of evidence that are present. Therefore, grade A evidence indicates that there are level 1 studies addressing the clinical question, grade B evidence indicates levels 2 and 3 studies, grade C evidence indicates level 4 studies, and grade D evidence indicates level 5 studies.

Each article was independently reviewed by at least two members of the panel. After gathering the appropriate information to be included in the evidence table, each reviewer independently determined whether the article addressed the focused clinical question and, if so, assigned an evidence level to the article. When opinions differed as to whether an article addressed the clinical question or when evidence levels for an individual article were discrepant, the panel jointly reviewed the article to develop consensus. Then, the aggregate of evidence was reviewed to assign an evidence grade for the overall body of evidence addressing

the focused clinical question. Evidence levels and grade were assigned according to EBM parameters.<sup>4</sup>

## RESULTS

The Medline search yielded 886 titles and abstracts. Of these citations, 62 full-length articles were selected by the panel for further review. An additional 13 articles were identified through review of the bibliography of the initial 62 articles so that the final number of full-length articles reviewed was 75.

Thirty of the 75 articles did not address the clinical question and therefore were not assigned a level of evidence. Forty-five articles were assigned an evidence level by two independent panelists. Independent reviewers agreed on the appropriate level in 41 of 45 articles. Articles with discrepant level assignment were reviewed by the panel and consensus was achieved for appropriate level in all cases.

An evidence table (Table I) was constructed including all 45 articles addressing the focused clinical question. Of the 45 articles, 42 articles represented level 4 evidence and 2 articles represented level 5 evidence. One article (Gliklich and Metson, 1997<sup>19</sup>) was assigned level 2 evidence.

Within the 42 articles representing level 4 evidence, not all were retrospective case series. Eleven studies were prospective, uncontrolled studies. Of these prospective studies, five used validated QOL instruments as outcome measures.

## DISCUSSION

We have performed a systematic review of the published literature addressing a focused clinical question related to the use of ESS to treat medically refractory CRS. This systematic review was performed rigorously and methodically in accordance with the principles of EBM. Our results indicate that the evidence supporting ESS in adult CRS is primarily level 4 evidence with one level 2 study and a few level 5 studies providing additional support. Our assigned evidence grade is a “B” if one is willing to offer this based on one level 2 study. Alternatively, grade C may be applied if corroborating level 2 studies are required.

EBM is said to be the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.<sup>3,4</sup> The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research. It is important to recognize that even the highest-quality evidence can not answer every question or be applicable to every patient. At the same time, without inclusion of current best evidence, our practice may become outdated. EBM is not a new process as clinicians have always striven to combine their clinical expertise and their patients’ values with the best available evidence from the literature. However, it is clear that the interest in EBM has grown exponentially since the coining of the term in the early 1990s (from 1 MEDLINE citation in 1992 to 2957 in February 2000) with a clear increasing emphasis in teaching the concept of EBM to medical students.<sup>5</sup>

Otolaryngology–Head and Neck Surgery has a long history of publishing clinical research evidence. Rosenfield notes that >75% of the articles in major otolaryngology journals report clinical research,<sup>6</sup> one-half of which make treatment recommendations. However, >80% were uncontrolled retrospective case series (level 4); more often than not, necessary sample size had not been predetermined and was inadequate to achieve statistical power, a feature particularly true of studies reporting surgical treatments. This is grades “C” and “D” evidence, which may cause regulators and payers to question the effectiveness of such procedures. Clearly, there are gaps in the evidence to suggest that systematic flaws exist in the production of clinically relevant evidence.<sup>7</sup> One major reason cited for this is that the major funders of clinical research, the National Institutes of Health and the medical products industry, do not focus on supporting such research.<sup>7</sup>

Our systematic review did not identify any level 1 studies addressing our focused clinical question. Level 1 studies, for the most part, require randomization that can be quite challenging to apply in surgical clinical trials. Any number of significant obstacles to randomization is encountered including patient and surgeon preferences, difficulties in blinding surgical procedures, and ethical concerns of “sham” or placebo operations. However, these obstacles have not prevented other randomized trials in ESS from being performed. Ragab *et al.* published a randomized controlled trial (level 1 study) comparing ESS to medical therapy in CRS.<sup>8</sup> Because the patients did not receive antibiotic therapy or failed standard medical therapy before randomization, the study does not address our focused clinical question and is not included in our evidence table. In addition, this study was performed in the United Kingdom and whether a similar trial could be performed in the clinical research environment in the United States is debatable.

Our systematic review identified one study that could be considered level 2 evidence.<sup>19</sup> This prospective study uses a validated outcome measure and incorporates a comparison group in its design. Although these types of “outcomes studies” typically occupy the bottom tier of level two studies (*i.e.*, level 2c), they typically require rigorous methodology such as validated outcomes measures and prestudy power analysis determination.

However, there is a large body of observational data that support the effectiveness of ESS in the management of adult CRS. In this evidence report, 32 retrospective studies describe improvement in symptoms after ESS with up to 10 years follow-up. Furthermore, 11 prospective studies describe improvement after ESS and 5 of these show statistically significant improvement using validated QOL instruments. However, observational studies have been the subject of criticism including accusations of data dredging, confounding, and bias.<sup>9</sup> Must all interventions intended to prevent ill health be subjected to the rigorous evaluation of randomized controlled trials? Smith and Pell, in their publication entitled, “Parachute Use to Prevent Death and Ma-

TABLE I

Evidence Table for ESS in Adult CRS

Reference/Year	Evidence Level	No. of Patients	Outcome Measure	Comments
Austin and Hicks 1993 <sup>12</sup>	4	64	Symptom improvement	Age range, 11–66 yr
Batra <i>et al.</i> 2003 <sup>13</sup>	4	17	Symptom improvement	Asthma evaluated
Chambers <i>et al.</i> 1997 <sup>14</sup>	4	182	Symptom VAS	
Colclasure <i>et al.</i> 1993 <sup>15</sup>	4	300	Symptom improvement	Complications evaluated; age range, 5–82 yr
Damm <i>et al.</i> 2002 <sup>16</sup>	4	279	Symptom improvement	Prospective
Durr and Desrosiers 2003 <sup>17</sup>	4	51	SF-36; QF-ROM (translated RSOM)	Prospective, validated outcome instrument; 1996 AAO definitions used
Frisch <i>et al.</i> , 1995 <sup>18</sup>	4	62	Symptom and endoscopic improvement	Endoscopic outcomes evaluated
Gliklich and Metson, 1997 <sup>19</sup>	2	108 ESS 62 Medical tx	SF-36; CSS	Prospective with comparison group (medical therapy); validated outcome instrument
Hartog <i>et al.</i> 1997 <sup>20</sup>	4	34 ESS	Symptom improvement; endoscopy	Prospective; compares ESS to sinus irrigation
Hoffman <i>et al.</i> 1989 <sup>21</sup>	4	114	Symptom improvement	
Hoffman <i>et al.</i> 1990 <sup>22</sup>	4	100	Symptom improvement	Complications evaluated; Age range 11–80
Hoffman <i>et al.</i> 1993 <sup>23</sup>	4	31	Symptom improvement; TyPE	Prospective
Hoffman <i>et al.</i> 1994 <sup>24</sup>	4	31	SF-36; TyPE	Prospective; validated outcome instrument
Ikeda <i>et al.</i> 1999 <sup>25</sup>	4	22 ESS; 6 control	Symptom improvement	Case-control study; asthma evaluated
Jakabsen and Svendstrup 2000 <sup>26</sup>	4	237	Symptom improvement; endoscopy	
Jones <i>et al.</i> 1998 <sup>27</sup>	4	49	SNOT-20	Prospective; validated outcome instrument
Kamel <i>et al.</i> 1989 <sup>28</sup>	4	66	Symptom improvement	Evaluates maxillary sinusitis
Kennedy <i>et al.</i> 1987 <sup>29</sup>	4	75	Symptom improvement, antrostomy patency	
Kennedy 1992 <sup>30</sup>	4	50 Prospective 70 Retrospective	Symptom questionnaire; endoscopy	Prospective and retrospective
Kennedy <i>et al.</i> 2000 <sup>31</sup>	5			Expert opinion
King <i>et al.</i> , 1994 <sup>32</sup>	4	43	Symptom improvement; endoscopy	Evaluates revision ESS
Kloppers <i>et al.</i> 1987 <sup>33</sup>	5	50	Symptom improvement	Expert opinion
Kupferberg <i>et al.</i> 1997 <sup>34</sup>	4	26	Symptom improvement	Focuses on allergic fungal sinusitis
Lazar <i>et al.</i> 1993 <sup>35</sup>	4	513 Adults	Symptom improvement	Complications evaluated
Levine 1990 <sup>36</sup>	4	250	Symptom improvement	Complications evaluated
Lund <i>et al.</i> 1991 <sup>37</sup>	4	24	Symptom improvement (VAS); olfactory testing, ciliary function, rhinometry	

for Trauma Related to Gravitational Challenge: Systematic Review of Randomized Controlled Trials,” humorously make the point that common sense might be applied when

considering the potential risks and benefits of interventions.<sup>10</sup> They conclude that “everyone might benefit if the most radical protagonists of EBM organized and partici-

TABLE I

Continued

Reference/Year	Evidence Level	No. of Patients	Outcome Measure	Comments
Lund and Scadding 1994 <sup>38</sup>	4	200	Symptom improvement (VAS); olfactory testing; ciliary function; rhinometry	Prospective
Marks and Shamsa 1997 <sup>39</sup>	4	115	Symptom improvement	
Matthews <i>et al.</i> 1991 <sup>40</sup>	4	155	Symptom improvement	
Nayak <i>et al.</i> 2001 <sup>41</sup>	4	30 ESS	Symptom VAS	Study compares ESS to another surgical technique; prospective
Nishioka <i>et al.</i> 1994 <sup>42</sup>	4	20	Symptom improvement	Evaluated asthma and ER visits
Park <i>et al.</i> 1998 <sup>43</sup>	4	79	Symptom improvement	Evaluated asthma, ER visits
Penttila <i>et al.</i> 1994 <sup>44</sup>	4	73	Symptom improvement	Compares ESS versus C-L; 1 year f/u
Penttila <i>et al.</i> 1997 <sup>45</sup>	4	66 ESS	Symptom improvement	Compares ESS versus C-L; 5–9 yr f/u
Rice 1987 <sup>46</sup>	4	100	Symptom improvement	Age range, 11–75 yr
Schaitkin <i>et al.</i> 1993 <sup>47</sup>	4	91	Symptom improvement	
Senior <i>et al.</i> 1998 <sup>48</sup>	4	72	Symptom improvement	Long-term f/u Kennedy 1992; evaluates medication use
Smith and Brindley 1993 <sup>49</sup>	4	200	Symptom improvement	Age range, 11–75 yr
Sobol <i>et al.</i> 1998 <sup>50</sup>	4	393	Symptom improvement	
Stammberger and Posawetz 1990 <sup>51</sup>	4	500	Symptom improvement	Heterogeneous population; long-term f/u
Unlu <i>et al.</i> 1994 <sup>52</sup>	4	40 ESS	Symptom improvement; endoscopy	Compares ESS vs C-L
Uri <i>et al.</i> <sup>53</sup>	4	34	Symptom improvement, endoscopy	Asthma evaluated
Venkatachalam <i>et al.</i> 2002 <sup>54</sup>	4	25 ESS	Symptom improvement	Compares ESS vs conventional surgery
Vleming and deVries 1990 <sup>55</sup>	4	165	Symptom improvement; endoscopy	
Winstead and Barnett 1998 <sup>56</sup>	4	125	SF-36	Prospective; validated outcome instrument

VAS = visual analogue scale; SF-36 = Medical Outcomes Study 36-item short form health survey; QF-ROM = Quebec French–rhinosinusitis outcome measure; RSOM = rhinosinusitis outcome measure; AAO = American Academy of Otolaryngology–Head and Neck Surgery; CSS = chronic sinusitis survey; TyPE = Technology of Patient Experience survey; SNOT-20 = Sinonasal Outcome Test 20 item survey; ER = Emergency Room; C-L = Caldwell-Luc; f/u = follow-up.

pated in a double-blind, randomized, placebo-controlled, crossover trial of the parachute.”

The principles of EBM were designed to foster an understanding of the best therapies for our patients rather than to inhibit them. EBM was designed to allow evidence and our clinical expertise to meld and provide our patients with the best available treatments. We must recognize the obstacles to performing randomized clinical trials in addressing surgical interventions such as ESS and also recognize the shortcomings of the current evidence for ESS in the man-

agement of CRS. It is clear that a major strength of the randomized control trials, for instance, is in its inclusion of a comparison group.

Moving forward, it seems most prudent for studies of ESS to be designed to include a comparison group. One study in this systematic review arguably provides level 2 evidence as a result of including a comparison group. Furthermore, diagnostic criteria for CRS established by the American Academy of Otolaryngology task force should be used to define the index disease.<sup>11</sup> Finally, outcome mea-

asures should include a validated QOL instrument, because these are readily available and incorporated into prospective clinical research on CRS.

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