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The contribution of flexible endoscopy for diagnosis of acute bacterial rhinosinusitis

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Abstract This prospective controlled study ascertained the contribution of flexible endoscopy (FE) for diagnosis of acute bacterial rhinosinusitis (ABRS) in a group of consecutive adult patients who had symptoms suggestive of ABRS and in whom sinus radiography (SRG) and FE were accomplished. We adopted for analysis the 2007 updated European guidelines on rhinosinusitis and computed the sensitivity and specificity of FE against SRG. Positive diagnosis was entertained when FE showed purulent material within sinus drainage area and/or SRG demonstrated air–fluid level, complete opacification, or at least 6 mm mucosal thickening. Of a total of 179 patients initially included in this study, 104 had clinical criteria compatible with guidelines for ABRS. Of them, 43 (41.3%) had positive FE and SRG, 17 (16.3%) had positive FE and negative SRG, and vice versa in 9 (8.7%); both modalities were negative in 35 (33.7%). FE yielded sensitivity of 82.7 ± 5.24% (95% CI: 72.41–92.97%) and specificity of 67.3 ± 6.50% (95% CI: 54.56–80.06%). Age, gender, symptom duration, pre-referral antibiotics, and treatment by primary/secondary physician were not associated with positive or negative diagnosis of ABRS. Of 75 patients who were excluded from the analysis, 33 (44%) had positive diagnosis of ABRS established by FE and/or SRG. The finding that clinical criteria had moderate predictive value (66.3%) highlights the need for objective measures for diagnosis of ABRS. In absence of feasible gold standard and considering that guidelines do not recommend SRG for routine diagnosis, FE serves as an indispensable ancillary tool for establishing ABRS.

Keywords Acute bacterial rhinosinusitis · Flexible endoscopy · Sensitivity · Sinus radiography · Specificity

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Introduction

Acute bacterial rhinosinusitis (ABRS) is manifested by inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, the fluids within these cavities, and/or the underlying bone [1]. This common condition is known to complicate 0.5–2.5% of patients with viral rhinosinusitis [2]. Data show that in 1996, in the US alone, the impact of acute or chronic rhinosinusitis on healthcare costs was considerable, with direct expenditures for hospitalizations, office visits, and medications approaching $3.5 billion [3]. In 2006, the annual rate of ambulatory care visits for ABRS was 4.82 million [4].

Although a considerable number of patients with ABRS improve spontaneously [5], the decision to prescribe antibiotics is commonly based on the assumption that treatment may hasten symptom resolution [6] and prevent rare but potentially life-threatening complications. Given the difficulties inherited in differentiating between bacterial and viral rhinosinusitis, a number of imaging and laboratory modalities have been used to increase the likelihood of a correct diagnosis of ABRS [7–10]. The gold standard test is direct sinus puncture with aspiration and culture of retained fluids, yet because of its invasive nature, it is in most cases impractical for routine clinical practice.

Another standard reference test whose sensitivity and specificity rates for diagnosis of ABRS were computed is sinus radiography (SRG) (76 and 79%, respectively) [11]. The contribution of flexible endoscopy (FE) to the assessment of adult ABRS has not yet been fully determined.

In a study of 117 ABRS patients, where the sensitivity and specificity of FE were compared with known values for SRG [11], no firm conclusion was reached as to whether FE is a better diagnostic tool than SRG [12]. In the current study, we chose SRG as a reference standard test against which the sensitivity and specificity of FE for diagnosis of ABRS were computed.

Materials and methods

Study subjects

A prospective controlled study of 181 consecutive adult patients aged 18 years and older, who were treated at the outpatient ear, nose, and throat (ENT) clinic of Meir Medical Center and the ENT clinic of Clalit Health Services (healthcare maintenance organization), Kfar Saba, between May 5, 2003 and January 1, 2006, for a variety of symptoms and signs suggestive of ABRS and in whom SRG and FE were performed, was initiated. Initially included were patients who had a combination of the following: nasal obstruction, purulent anterior/posterior nasal drip, facial pain or pressure sensation, upper toothache, headache, bothersome cough, anosmia, otalgia/sensation of pressure in the ear accompanied by the following constitutional signs and symptoms: temperature elevation or weakness, tiredness, or malaise. Patients were referred for consultation by general practitioners, family physicians, internists, and community otolaryngologists or were self-referred. Another source of referral was emergency room patients sent for consultation to the outpatient ENT clinic. Excluded were patients whose symptoms lasted longer than 4 weeks, those who received systemic corticosteroid treatment in the month before diagnosis, and those who had previous sinus surgery. Excluded were also patients with the following modifying factors: cystic fibrosis, immotile cilia disorders, ciliary dyskinesia, severe anatomic nasal abnormalities, and immunodeficiency.

The study protocol was approved by the Institutional Review Board of Meir Medical Center. All patients signed an informed consent form before enroling in the study.

Study design

A case-report form was developed, covering patients' background data and symptoms associated with the current episode, duration of symptoms before diagnosis, type of referral (self-referred/referred by other physicians), and antibiotic treatment before referral.

FE was accomplished by means of a flexible fiberoptic endoscope (3.4 mm Olympus ENF-P3, Olympus Opto-Electronics Co., Tokyo, Japan) attached to a halogen light source (LS-3525, Contec Medical Ltd., Ramat Hasharon, Israel). Reprocessing techniques were followed meticulously and maintenance, manual cleaning with a powerful enzymatic liquid detergent (Aniozyme DLT 5%, Anios Laboratories, Lille, France), and immersion in high-level disinfectant [Cidex OPA solution (ortho-phthalaldehyde 0.55%), Johnson & Johnson Medical Limited, Gargrave, UK] were performed according to known guidelines [13, 14]. Before administration of FE to the drainage areas of the sinuses, patients were advised about the advantages and disadvantages of local anesthetics with or without vasoconstrictors and were given a choice as to whether to use these agents or not. FE was preferred over rigid nasendoscopy because: (1) it provides good visualization of the sinus drainage areas, (2) from our experience, most patients tolerate well the procedure, with no need for local anesthetic and/or vasoconstrictor agents in each case, and (3) it is suitable for difficult access cases. SRG included Water's view (i.e., occipitomental projection) to evaluate the maxillary sinuses and Caldwell's view (i.e., occipitofrontal projection) to evaluate the frontal sinuses. A third lateral view was occasionally obtained to assess the sphenoid sinus.

FE examinations were performed by a single examiner (G.B.), who was blinded to radiologic findings. SRG was reviewed in a blinded fashion by staff radiologists.

Criteria for analysis

For screening criteria for diagnosis of ABRS, we adopted the 2007 updated guidelines formulated in the European position papers on rhinosinusitis and nasal polyps [15, 16]. Accordingly, ABRS was defined as inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which was nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip) accompanied by facial pain/pressure including headache/dental pain and/or reduction or loss of smell with persistent symptoms after 10 days or longer, or increase of symptoms after 5 days.

Air–fluid level in the maxillary or frontal sinuses, complete opacification of the maxillary sinus, or mucosal thickening of the maxillary sinus of at least 6 mm, measured as the nearest distance from the air–mucosal interface to the most lateral part of the sinus wall, was considered as positive SRG. The diagnosis was confirmed endoscopically when purulent or mucopurulent material was noted in any

of the drainage areas of the frontal, maxillary, ethmoid, and sphenoid sinuses; thus, providing indirect evidence for the existence of bacteria [8]. Serous or mucoid drainage or congested turbinates without frank purulence were not indicative of bacterial infection.

Data analysis

A diagnosis of ABRS was entertained when FE and/or SRG was positive. The association between positive diagnosis (i.e., positive FE and/or SRG) and negative diagnosis (i.e., negative FE and SRG) of ABRS and patients' age, gender, symptom duration, pre-referral antibiotics, and treatment by primary/secondary care physician were made by the Pearson chi-square test for categorical variables and the independent *t* test for continuous variables. The parameter treatment by primary/secondary care physician refers to the possibility whereby G.B. served as primary or secondary treating physician depending on the referral procedure (self-referral or referral by another physician, respectively). SRG was considered the reference test against which the sensitivity and specificity of FE for diagnosis of ABRS were estimated; 95% confidence intervals (CIs) were calculated for both scores. Measurements were expressed as mean ± SD; *P* values lower than 0.05 were considered significant.

Results

Of the 181 patients who were initially recruited for this study, 2 patients refused to sign the consent form required for study entry. Seventy-five were excluded due to insufficient diagnostic criteria for diagnosis of ABRS. In 30 patients, duration of symptoms was less than 10 days or symptoms did not increase after 5 days. In the remaining 45, symptoms were incompatible with the criteria for ABRS (Fig. 1). Of the 104 patients who formed the study population for this prospective analysis, 29 (27.9%) had their symptoms worsened after 5 days and 75 (72.1%) had symptoms persisting for 10 days and longer. Thirty-three (31.7%) were men and 71 (68.3%) were women; age ranged between 18 and 89 years (mean age, 44 ± 19.9 years). All patients readily tolerated the FE procedure and no residual after-effects were reported. The mean duration of symptoms before diagnosis was 15.3 ± 7.8 days, with no significant difference between men and woman in this respect (16.2 ± 8.5 days vs. 14.8 ± 7.4 days, respectively, $P = 0.377$). Thirty-one patients were self-referred, while 73 were referred by other physicians. Forty-eight patients were given antibiotics before referral.

The combined results of diagnostic FE and SRG for ABRS are shown in Fig. 1. Positive FE and positive SRG were in 43 patients (41.3%), positive FE and negative SRG in 17 patients (16.3%), and negative FE and positive SRG in 9 patients (8.7%). In the remaining 35 patients (33.7%), both tests were negative. Thus, objective evidence by FE and/or SRG was found in only 69 of 104 patients (66.3%); in a third (33.7%) of the patients both modalities failed to demonstrate ARBS. Forty-three of 52 patients with positive SRG had positive FE, showing that in reference to SRG, FE has a sensitivity of 82.7 ± 5.24% (95% CI: 72.41–92.97%). Of 52 patients with negative SRG, 35 had negative FE showing a specificity of 67.3 ± 6.50% (95% CI: 54.56–80.06%).

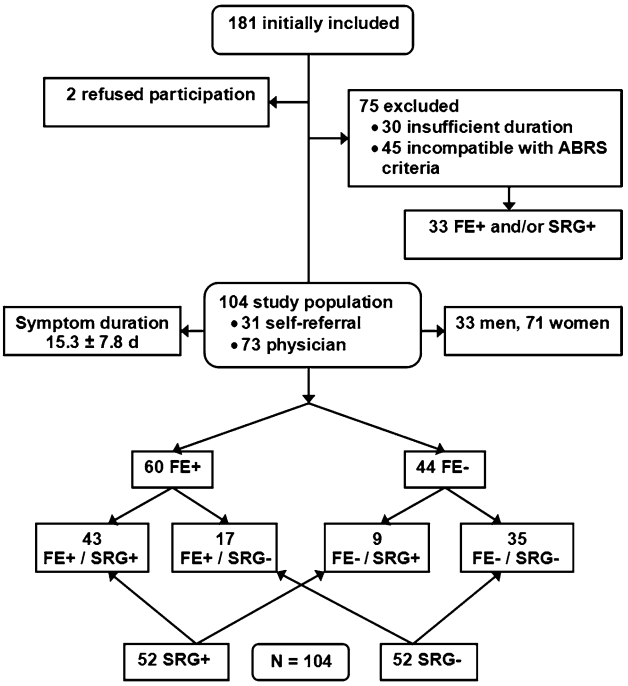

Fig. 1 Patient flow diagram (*ABRS* acute bacterial rhinosinusitis, *FE* flexible endoscopy, *SRG* sinus radiography)

No association was found between positive and negative diagnosis and age and duration of symptoms (mean ± SD, 44.1 ± 20.2 years vs. 43.8 ± 19.8 years, $P = 0.939$; and 14.9 ± 7.7 days vs. 15.9 ± 7.9 days, respectively, $P = 0.520$). Gender was also not significantly associated with positive or negative diagnosis [18/33 (54.5%) and 15/33 (45.5%) for men vs. 51/71 (71.8%) and 20/71 (28.2%) for women, $P = 0.083$, respectively]. Similar findings were found for patients receiving pre-referral antibiotics [34/69 (49.3%) for a positive diagnosis vs. 14/35 (40%) for a negative diagnosis, $P = 0.370$]. Analysis by referral group showed that positive diagnosis of self-referred patients (23/31, 74.2%) and that of patients referred by another physician (46/73, 63%) were also not significantly different ($P = 0.270$).

It is of note that of 75 patients, who were excluded from the study due to insufficient symptom duration or symptom

incompatibility with criteria for diagnosis, 33 (44%) had positive diagnosis of ABRS established by FE and/or SRG.

Discussion

For more than a decade, there is an ongoing debate over the validity of clinical practice guidelines for diagnosis and treatment of ABRS. Past recommendations applying major and minor symptoms [1] were discontinued due to lack of prospective trials for validation [17]. The 2007 updated guidelines of the European position paper on rhinosinusitis and nasal polyps clinical criteria was formulated to identify, monitor, and manage an adult with rhinosinusitis [15, 16]. The 2007 American clinical practice guidelines for adult sinusitis is a second set of clinical criteria, requiring three symptoms: purulent nasal drainage accompanied by nasal obstruction and facial pain/pressure/fullness, which have been shown to correlate with high sensitivity and specificity of ABRS, over a 10-day disease course. The primary purpose of these guidelines was to improve the diagnostic accuracy of adult rhinosinusitis and reduce inappropriate use of antibiotics [17, 18]. Evidently, most patients with ABRS are seen in primary care clinics and thus diagnosis mainly remains clinical and treatment empiric. Given the lack of immediate precise objective diagnostic tests such as FE or imaging to further define sinusitis, patients do not always receive adequate workup to accurately differentiate between acute viral rhinosinusitis and ABRS, leading to under- or over-diagnosis of this ailment.

We recognize that the current European and American guidelines do not recommend imaging studies for routine diagnosis of ABRS [16, 17]. It was also stated that sinus radiographs are not cost-effective for initial management strategy [19]. Yet, imaging, which was shown to be more sensitive than clinical examination for diagnosis of ABRS [19], is a well-documented reference standard test for the diagnosis of this ailment [7, 20–22] and is broadly used by primary and secondary care physicians [23]. Contrary to the wealth of data on SRG, little is known about the contribution of flexible FE that is a safe, radiation-free, rapidly implemented, and relatively inexpensive office procedure endorsed by both European and American current guidelines as an objective ancillary tool for diagnosis of ABRS [16, 17] in a variety of populations including pregnant women. It was used for the diagnosis of acute and chronic rhinosinusitis in a number of studies [12, 24, 25], allowing clear visualization of the sinus drainage regions.

In a previous study, the estimated sensitivity and specificity of FE for diagnosis of ABRS was 80 and 94%, respectively. Although estimates seemed better than those of SRG (76 and 79%, respectively [11]), the CIs were quite wide and no firm conclusions as to which test was better for diagnosis of ABRS could be made [12]. In the present study, we examined the sensitivity and specificity of FE against SRG and found that of 52 patients with a positive SRG, 43 displayed positive FE yielding a high sensitivity of 82.7%. This high correlation between SRG and FE demonstrates that in most cases of positive SRG (with air–fluid level, total opacification, or mucosal thickening), a positive FE characterized by purulent discharge from sinus apertures is expected, indicating that patients with positive SRG have a high chance of having positive FE. On the other hand, of 52 patients with negative SRG, only 35 had negative FE and 17 had positive FE yielding a relatively low specificity of 67.3%. The considerable disagreement between negative SRG and negative FE, with a third of the patients (17/52, 32.7%) with negative SRG displaying positive FE, indicates that an appreciable number of patients who in fact have ABRS could have been otherwise diagnosed endoscopically. This attests to the contribution of FE in the decision making-process, particularly if SRG is negative. Other investigators reported that a negative SRG has a markedly high negative predictive value of 90–100% and is helpful in ruling out ABRS [26, 27]. Given the disagreement about the role of SRG for diagnosis of this common ailment, further research is warranted.

It was shown that after preparation with local anesthetic spray and a vasoconstrictor, rigid endoscopy (used with a 2.7-mm caliber) was preferable over FE (used with a 3.4-mm caliber), in terms of visualization of more intranasal structures. Yet, in cases with difficult access (e.g., a deviated nasal septum) both tools are needed [28]. In comparison with rigid instruments, FEs do not tolerate high processing temperatures and cannot be autoclaved, thus require unique consideration with respect to decontamination [13]. However, FE is superior to rigid endoscope with regard to patient's comfort and tolerance and provides good visualization of the major sinus drainage routes (middle meatus, frontal recess and sphenoethmoidal recess), with no need to use local anesthetic and/or vasoconstrictor agents [29] for each case.

The ratio of male-to-female in our population was 1:2.2. This finding is in agreement with reports that women use more health care services than men [30]; nevertheless, we found that males and females had a similar proportion of positive and negative diagnosis of ABRS accomplished by SRG and FE. Likewise, the distribution of age, duration of symptoms compatible with clinical diagnosis of ABRS, and use of antibiotics were also not significantly different between patients having positive or negative objective findings. This similar proportion of positive and negative objective findings in the antibiotic and in the non-antibiotic treated patients demonstrates that inclusion of the former group of patients did not bias the results of our study. Of

note is that the mean duration of symptoms of our patients (15.3 ± 7.8 days) was similar to that recommended by the EPOS primary care guidelines, advocating that non-resolution of clinically diagnosed acute rhinosinusitis after 14 days should prompted consideration of referral to specialist care [16].

The finding that the proportion of patients with ABRS was higher in specialty clinics than in primary care clinics [31] may raise questions about whether our findings apply to primary care setting. Indeed, a majority of the patients was referred by primary care physicians and only a minority who sought treatment at the ENT clinic was self-referrals. However, the lack of significant difference in the proportion of positive and negative objective findings between referred and self-referred patients lends support to the notion that a fortnight and longer after onset of symptoms, the outcomes of objective findings in specialty care clinics apply to those in primary care clinics.

The contribution of clinical criteria for diagnosis of ABRS based on type and number of symptoms presented and on their duration, classifying patients as highly likely to have ABRS, is crucial to the selection process for treatment. However, it cannot be ignored that as many as a third of our patients (35/104, 33.7%), who fulfilled the clinical criteria for ABRS, demonstrated negative objective radiographic and endoscopic findings. This disagreement between subjective and objective diagnostic measures may stem either from low specificity of the clinical predictors or from low sensitivity of the objective measures. In a former study, it was shown that FE had a fairly high (80%) estimated sensitivity [12]. Analysis of our current data also revealed that in 8.7% of the patients (9/104), SRG was positive although FE was negative. Given these observations, it can be argued that the combined diagnostic efficacy of both objective diagnostic measures is high. All of these may suggest that solely relying on clinical criteria for diagnosis of ABRS is associated with high rate of false positive results and may lead to over-diagnosis and over-treatment contributing to antibiotic resistance. It was found that the accuracy of clinical criteria was estimated to be only 40–50% [32]. Others also reported that clinical predictors are less sensitive than SRG [33, 34]. Interestingly, of 75 patients, who were excluded from the study due to insufficient symptom duration or symptom incompatibility with criteria for ABRS, 33 (44%) had positive diagnosis established by FE and/or SRG; thus, once again demonstrating the problems inherited in clinical criteria and the need for objective measures for diagnosis of ABRS.

In conclusion, the data showed that clinical criteria had moderate predictive value (66.3%). This highlights the need for objective non-invasive measures to diagnosis ABRS. Considering that aspiration puncture, the gold standard, and SRG are either impractical and/or not recommended for routine diagnosis, respectively, FE may serve as an indispensable ancillary tool for establishing ABRS.

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Conflict of interest statement The authors declare no conflict of interest for this study.

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