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Technical Report: Evidence for the Diagnosis and Treatment of Acute Uncomplicated Sinusitis in Children: A Systematic Overview

John P. A. Ioannidis, MD*‡§, and Joseph Lau, MD*§

ABSTRACT. *Objective.* **To evaluate and analyze the existing evidence for the diagnosis and treatment of acute uncomplicated sinusitis in children.**

Design. **A systematic overview and meta-analysis considered all pertinent studies with at least 10 children younger than 18 years with acute symptoms of <30 days and without serious complications.**

Outcomes. **Clinical improvement rates for intervention studies of antibiotics or ancillary measures; concordance of diagnostic tests (expressed as likelihood ratios).**

Results. **Of 1857 citations originally reviewed, we identified 21 qualifying studies, compared with 450 reports on complications of acute sinusitis and 233 nonsystematic reviews of the subject. The qualifying studies included 5 randomized, controlled trials and 8 case series on antibiotic therapy, 3 randomized, controlled trials on ancillary treatments, and 8 studies with information on diagnostic tests (including 3 therapeutic trials). Definitions and inclusion criteria were heterogeneous across studies. The pooled clinical improvement rate with antibiotics was 88% (177/202) in randomized, controlled trials and 92% (318/345) in nonrandomized studies; the improvement rates on no antibiotics were 60% and 80%, respectively. Improvement rates were significantly higher in nonrandomized studies (Mantel-Haenszel odds ratio: 1.79; 95% CI: 1.05–3.04, stratified for use of antibiotics). Data on ancillary measures were sparse and heterogeneous. In studies comparing clinical findings with plain film radiography, the pooled rate of abnormal radiographic findings against a clinical diagnosis of sinusitis was 73% (596/814; range: 55% to 96% between studies). There was poor concordance between clinical criteria, plain radiographs, ultrasonography, computed tomography, and fluid on aspiration in all available paired assessments (all positive likelihood ratios were ≤4 and all negative likelihood ratios were ≥0.2).**

Conclusions. **Good, high-quality evidence for acute uncomplicated sinusitis in children is limited. Diagnostic modalities show poor concordance, and treatment options are based on inadequate data. More evidence is needed for defining the optimal treatment and diagnostic methods for this common condition.** ***Pediatrics*** **2001;108(3). URL: http://www.pediatrics.org/cgi/content/full/108/3/e57;** ***clinical practice guideline, bacterial sinusitis, literature review.***

ABBREVIATIONS. OR, odds ratio; CT, computed tomography.

INTRODUCTION

Acute sinusitis is one of the most common community-acquired infections.[1–6] One investigator estimated that there are as many as 1 billion episodes (viral, bacterial, or other) occurring each year in the US population.[2] The condition is even more common in children than in adults. Given the frequency of this condition, the costs associated with its diagnosis and medical treatment (either antibiotics or ancillary measures) are large.[3] However, evidence on the diagnosis and management of this common condition is limited and fragmented.

In 1997, the Agency for Healthcare Research and Quality contracted with the New England Medical Center Evidence-based Practice Center to produce an evidence report, titled "Diagnosis and Management of Acute Sinusitis." A supplemental analysis to include nonrandomized trials for the pediatrics population was added to this contract when only 2 relevant randomized studies were found that studied exclusively pediatric populations. Although randomized studies are more likely to provide unbiased information, nonrandomized evidence may provide additional information and is needed when randomized data are sparse.

In this study, we systematically identified and analyzed all the accumulated evidence that pertains to the diagnosis and therapeutic management of acute uncomplicated sinusitis in children. The main questions addressed in this study are: 1) What is the evidence for the efficacy of various antibiotics in children with a diagnosis of acute sinusitis? 2) What is the evidence for the efficacy of various ancillary, nonantibiotic regimens in children with acute sinusitis? 3) What is the diagnostic accuracy and concordance of clinical symptoms, radiography, and other imaging methods and sinus aspiration for the diagnosis of acute sinusitis in children?

METHODS

Definitions

The definition of uncomplicated sinusitis excludes cases in which clinically evident neurologic, soft tissue, or other complications were present. Acute sinusitis is defined typically by a duration of symptoms of <30 days. We did not attempt to sepa-

From the *New England Medical Center Evidence-based Practice Center, Boston, Massachusetts; ‡Clinical Trials and Evidence-Based Medicine Unit, Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece; and §Division of Clinical Care Research, New England Medical Center, Tufts University School of Medicine, Boston, Massachusetts.

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

rate bacterial from nonbacterial cases in the considered reports. Cures and failures were recorded as defined by each individual study: "cure" generally meant resolution of all signs and symptoms, and "failure" generally signified no change or worsening of signs and symptoms. "Improvement" was typically used for intermediate changes, although some studies used the term without a distinction from "cure."

The reference standard for the diagnosis of acute uncomplicated bacterial sinusitis is sinus aspiration and culture; this is infrequently used because it is invasive, cumbersome to perform, and time-consuming. Other diagnostic parameters (clinical presentation, plain-film, and ultrasound) were compared to assess concordance rather than as proof of diagnostic accuracy.

Inclusion Criteria

Published reports on acute sinusitis qualified for inclusion regardless of study design if they studied at least 10 children younger than 18 years, or if subgroups of age younger than 18 years could be readily identified in the presented data. Studies of subacute and chronic sinusitis were excluded. Subgroup data on acute sinusitis (with at least 10 children) from reports in which chronic and acute sinusitis or other infections were considered, qualified for inclusion. Studies limited to complications (neurologic, local soft tissue, or other) of acute sinusitis were excluded.

Search Strategy

We searched Medline using a broad search strategy covering from January 1966 through March 1999. The word sinusitis was used in the search as a text word and as a medical subject heading. We then limited the search results to human studies and English language that included pediatric patients using the terms "infant, newborn," "infant," "child, preschool," "child," and "adolescence." The titles and abstracts of the citations produced by the search were screened for articles that may have data on treatment of acute sinusitis in the pediatric population.

As part of a previous project,[7,8] we also had retrieved all published randomized, controlled trials on the management of acute uncomplicated sinusitis in all age groups. This collection of randomized, controlled trials had been generated based on Medline searches complemented by Excerpta Medica searches, perusal of the Abstracts for the Interscience Conference on Antimicrobial Agents and Chemotherapy, review of bibliographies of retrieved studies, and communication with technical experts and colleagues in the field. Randomized, controlled trials were included in this collection with no foreign language restrictions. All identified randomized, controlled trials were screened for the presence of data in children.

Statistical Analysis

Given the paucity and heterogeneity of the data for specific questions, we did not attempt the application of formal meta-analytic techniques in most circumstances.[9] When possible, rates were combined across different studies and heterogeneity was assessed with a χ^2 statistic. Odds ratios (ORs) for efficacy (clinical improvement) also were estimated by the Mantel-Haenszel formula stratified per antibiotic use.

For diagnostic modalities, we expressed concordance by using the positive likelihood ratio, which is calculated as

$$\text{positive likelihood ratio} = \text{sensitivity}/(1 - \text{specificity})$$

and the negative likelihood ratio, which is calculated as

$$\text{negative likelihood ratio} = (1 - \text{sensitivity})/\text{specificity}.$$

The positive likelihood ratio gives an estimate of how much more common a specific diagnostic finding in the positive group is versus the negative group, when positive and negative are defined by a different diagnostic standard. For example, a sensitivity of 50% with specificity of 90% corresponds to a positive likelihood ratio of 5. The higher the positive likelihood ratio, the better the concordance of the 2 diagnostic modalities. A positive likelihood ratio of 1 indicates that there is no concordance at all. There are no absolute cutoffs, but positive likelihood ratios between 1 and 5 are generally suggestive of poor concordance, while positive likelihood ratios >20 suggest strong concordance. The positive likelihood ratio can take values up to infinity. The inverse considerations hold true for the negative likelihood ratio, where good concordance is shown by diminishing values. A negative likelihood ratio of 1 also shows lack of concordance. Again, there are no absolute cutoffs, but negative likelihood ratios between 0.2 and 1 are generally suggestive of poor concordance, while negative likelihood ratios <0.05 suggest strong concordance.

All reported *P* values are 2-tailed.

RESULTS

Retrieved Reports

The Medline strategy produced 1857 articles (Fig 1). Of those, 1719 were rejected on the basis of their title and abstracts. Notably, these included 450 articles on complications of acute sinusitis and 233 nonsystematic review articles without apparent primary original data. One hundred thirty-eight articles were retrieved in full and examined because the possibility that they might qualify could not be excluded from the title and/or abstract alone. A total of 21 studies qualified for inclusion.[10–30]

Of 68 randomized, controlled trials on antibiotic treatment of acute sinusitis that we identified in the more extended search, only 5 dealt with exclusively a pediatric population.[10–14] These 5 trials are among the 21 identified qualifying reports. For 30 additional

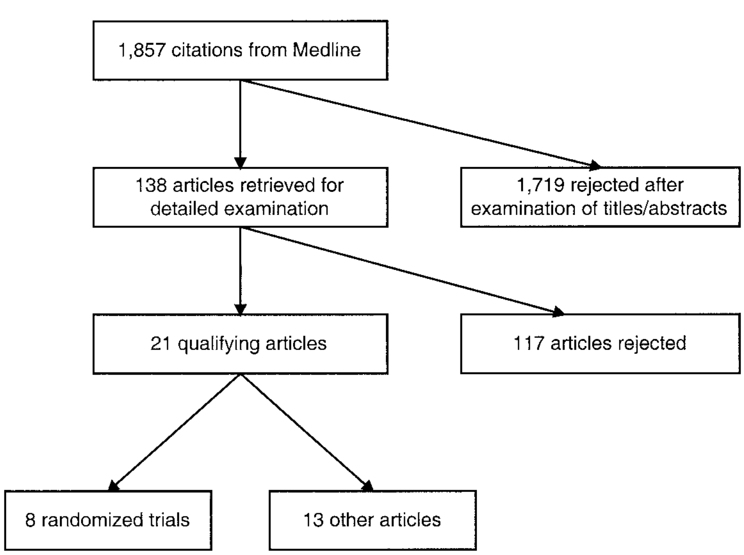

Fig 1. Flowchart for the selection of articles for the systematic review.

randomized, controlled trials, the age range of the enrolled patients extended to younger than 18 years, but no separate data on children younger than 18 years were available, and the majority of the patients were presumably adults. For 23 of these 30 trials, the lower age limit was between 12 and 17 years, and for another 5 trials it was 10 or 11 years.

Of the 12 randomized, controlled trials on ancillary measures identified as part of the extended search, there were only 3 trials (with a total of 243 patients) that studied the efficacy of ancillary measures in the treatment of acute sinusitis in exclusively pediatric populations.[15–17] The age range of the remaining 9 trials extended to as young as 9 to 20 years (younger than 12 years in 7 of them), but no separate data on the pediatric population were provided and the majority of the enrolled patients were presumably adults (upper age limit: 62 years to undefined).

Efficacy of Antibiotic Interventions

The efficacy of various antibiotic interventions was addressed in 5 randomized, controlled trials[10–14] and 8 nonrandomized studies[18–25] (Table 1). These 13 qualifying studies were published between 1970 and 1997 and with 2 exceptions had been conducted at single centers by pediatricians or otolaryngologists. Nine of the 13 reports, including 6 of the 8 nonrandomized studies, originated outside the United States. Pharmaceutical sponsorship was clearly mentioned in 4 reports. The largest case series had 106 patients, and the largest randomized, controlled trial had 93 patients. Overall, 255 children had been studied in the 5 randomized, controlled trials, and 418 children had been studied in the 8 nonrandomized studies. Eight of the 13 reports did not specify the duration of symptoms. Puncture for aspiration/irrigation was performed in 6 studies in selected children. Positive radiographic findings (typically combinations of air-fluid level, opacification, and/or mucosal thickening criteria) were required for the diagnosis of acute sinusitis in 9 of the 13 studies. Clinical symptoms and signs were typically the other mainstay of diagnosis, but there was large variability on how sinusitis was diagnosed as well as on the

TABLE 1. Studies of Antibiotic Treatment and Ancillary Measures in the Management of Acute Sinusitis in Children*

Author (Year)	*N*	Age (Years)	Abnormal Radiograph	Clinical Symptoms and Signs	Antibiotic	Duration (Days)	Ancillary Measures
ANTIBIOTICS							
Randomized							
Ficnar (1997)[10]	27	½–12	Required	Yes, but not specified	Azithromycin	3	ND
	18				Azithromycin	5	ND
Careddu (1993)[11]	25	2–14	ND	Not mentioned how diagnosed	Brodimoprim	8	ND
	27				Amoxicillin/clavulanate	8?	ND
Wald (1986)[12]	28	2–16	Required	Nasal discharge or cough >10 d required	Amoxicillin/clavulanate	10	Antihistamines
	30				Amoxicillin		
	35				Placebo		
Wald (1984)[13]	27	1–16	Required	Specified severe or persistent symptoms	Amoxicillin	10	Antihistamines
	23				Cefaclor		
Jeppesen (1972)[14]	7†	6–10	Required	Secretions, edema, dilated vessels on sinoscopy	Pivampicillin	7–30	Decongestant + lavage
	8†				Placebo		
Case series							
Hager (1980)[18]	30	1–12	Required	Red and swollen mucosa with discharge	Co-trimazine	10	ND
Helin (1982)[19]	61	1–15	Required	Various reported	Penicillin v	10	Nose drops and PPA
	16				Pivampicillin	10	Nose drops and PPA
	15				Erythromycin	10	Nose drops and PPA
Nylen (1972)[20]	25	5–15	Not required	Yes, but not specified	Penicillin	10	Decongestants for 7 d
Gurses (1996)[21]	39	5–14	Required	Various reported	Cefuroxime	7	ND
Herz (1977)[22]	106	6–17	Required	Various reported	Doxycycline	10–28	ND
Puhakka (1986)[23]	14	0–15	Not required	Purulent drainage; transillumination (required?)	Cefadroxil	7–17	ND
McLean (1970)[24]	25	4–15	Required	Various reported	Various	14–21	ND
Aitken (1998)[25]	68	1–5	Not required	Nasal congestion/drainage ± cough >9 d required	Various	various	ND
	19				None		
ANCILLARY							
Barlan (1997)[15]	43	2–14	Not required‡	Required specified major and minor criteria§	Amoxicillin/clavulanate	21	Budenoside
	46	1–15					Placebo
Revonta (1982)[16]	50	4–10	Not required‖	No symptoms of sinusitis except for rhinorrhea	Amoxicillin	10	PPA + lavage
	36						PPA only
McCormick (1996)[17]	34	1–18	Required	Symptom score used; components not mentioned	Amoxicillin	14	Triple combination
	34						Placebo

* PPA indicates phenylpropanolamine; ND, no data available.
† Number of sinuses.
‡ Abnormal in 68/89 of patients performed.
§ At least 2 of 3 major criteria (purulent nasal discharge, pharyngeal drainage, cough) or 1 major and 2 of 9 prespecified minor criteria were required for the diagnosis.
‖ Radiograph abnormalities were seen in 168/452 children who came for adenoidectomy or adenotonsillectomy without having any clinical symptoms of sinusitis.

prevalence of various specific symptoms and signs as reported in the various studies.

An array of antibiotics were tested, while a placebo arm was present in 2 randomized, controlled trials and a "no antibiotic" treatment group was considered in 1 of the case series. The duration of treatment varied between 3 and 28 days. The 2 shorter courses (3 and 5 days) were with azithromycin, which retains high drug levels for several days after its discontinuation.[10] All other studies used at least 7 days of therapy. Decongestants were either reported to be routinely prescribed or their use was not mentioned at all.

The response to treatment typically was assessed after 7 to 14 days, but it also was assessed at 21 days and 1 month in 2 early studies.[19,24] Cure, improvement, and failure rates are shown in Table 2. Overall, using the available data we estimated that the clinical improvement rate with antibiotics was 88% in randomized, controlled trials (177/202) and 92% (318/345) in nonrandomized studies. The rate of improvement on no antibiotics was 66% (33/50). It was 60% (21/35) in a randomized trial and 80% (12/15) in an observational study. The only randomized trial that compared antibiotics with placebo and provided cure rates found significantly better efficacy for antibiotics.[12] There were no significant differences in the efficacy of various antibiotic regimens in direct randomized comparisons. Overall, there was a trend for higher improvement rates in the nonrandomized studies compared with the randomized studies (OR: 1.79; 95% CI: 1.05–3.04; $P = .03$ stratified for antibiotic use). Improvement rates were higher in nonrandomized studies versus randomized studies in the stratum of patients receiving antibiotics (OR: 1.66) and in the stratum of patients not receiving antibiotics (OR: 2.67). Improvement rates did not differ significantly between the various individual studies.

Data on outcome as documented by the performance of follow-up images were available from 5 studies; overall 81% (269/333) of images (plain film radiography or ultrasound) improved. Reporting of safety data were limited; the frequency of discontinuations of treatment attributable to side effects was mentioned per arm in only 5 studies.[11,12,18,22,23] In all, there were 7 discontinuations attributable to side effects among 233 (3%) patients treated with antibiotics. In 1 placebo-controlled trial, the discontinuation rate attributable to side effects was 6 of 58

TABLE 2. Clinical and Imaging Outcome Measures for Studies of Antibiotic and Ancillary Interventions*

Author Year	Antibiotic	Ancillary Measures	Cure	Improvement	Failure	Imaging Improved
ANTIBIOTICS						
Randomized						
Ficnar (1997)[10]	Azithromycin (3 d)	ND	23/24	23/24	1/24 (relapse)	ND
	Azithromycin (5 d)	ND	18/18	18/18	0/18	ND
Careddu (1993)[11]	Brodimoprim	ND	24/25	24/25	1/25	ND
	Amox/clavulanate	ND	23/27	23/27	4/27	ND
Wald (1986)[12]	Amox/clavulanate	Antihistamines	ND	21/28	7/28	ND
	Amoxicillin		ND	25/30	5/30	ND
	Placebo		ND	21/35	14/35	ND
Wald (1984)[13]	Amoxicillin	Antihistamines	ND	23/27	4/27	16/22
	Cefaclor		ND	20/23	3/23	18/22
Jeppesen (1972)[14]	Pivampicillin	Ephedrine chloride and lavage	ND†	ND†	ND†	ND
	Placebo		ND‡	ND‡	ND‡	ND
Case series						
Hager (1980)[18]	Co-trimazine	ND	23/28	26/28	2/28	ND
Helin (1982)[19]	Penicillin V	Nose drops and PPA	53/61	53/61	8/61	51/61
	Pivampicillin	Nose drops and PPA	14/16	14/16	2/16	14/16
	Erythromycin	Nose drops and PPA	12/15	12/15	3/15	12/15
Nylen (1972)[20]	Penicillin	Decongestants for 7 d	12/25	ND	ND	ND
Gurses (1996)[21]	Cefuroxime	ND	ND	36/39	3/39	ND
Herz (1977)[22]	Doxycycline	ND	77/106	100/106	6/106	80/106
Puhakka (1986)[23]	Cefadroxil	ND	13/14	13/14	1/14	ND
McLean (1970)[24]	Various	ND	20/21	20/21	1/21	14/14
Aitken (1998)[25]	Various	ND	37/43	44/45	1/45	ND
	None		10/14	12/15	3/15	ND
ANCILLARY						
Barlan (1997)[15]	Amox/clavulanate	Budenoside	ND§	ND§	ND§	ND
		Placebo	ND§	ND§	ND§	ND
Revonta (1982)[16]	Amoxicillin	PPA + lavage	No SX	No SX	No SX	62/72‖
		PPA only	No SX	No SX	No SX	36/49‖
McCormick (1996)[17]	Amoxicillin	Triple combination	ND¶	ND¶	ND¶	ND
		Placebo	ND¶	ND¶	ND¶	ND

* PPA indicates phenylpropanolamine; ND, no data available; SX, symptoms.
† Outcome data provided as mean (standard deviation) time to recovery: 7.86 (3.69) days in the antibiotic group.
‡ Outcome data provided as mean (standard deviation) time to recovery: 6.38 (1.45) days in the control group.
§ Outcome data given as cough and nasal discharge scores per week in the 2 groups (budenoside was superior to placebo only at the second week).
¶ Outcome data given as clinical and radiography scores (there was no difference at 3 and 14 days from onset of treatment).
‖ Outcomes based on ultrasound (all other studies in the table used plain radiographs to assess improvement of imaging).

patients with antibiotics versus 2 of 35 patients with placebo (risk ratio: 1.8; 95% CI: 0.4–8.5).

Bacteriologic response with sinus aspirates obtained before and after treatment was assessed only in 2 studies. In the study by Ficnar et al,[10] eradication was achieved with azithromycin in 3 of 3 patients who had isolated pathogens. Puhakka et al[23] used sinus aspirates and exudates from sinus ostia for culture; information on the 2 sampling modes is not presented separately. In addition, the results on eradication are mixed with those of other infections and thus are not interpretable.

Efficacy of Ancillary Measures

Of the 3 trials qualifying for inclusion regarding the efficacy of ancillary measures (Table 1), 1 trial enrolled children who had sinusitis on the basis of ultrasonography, in the absence of any symptoms, and addressed the value of lavage as adjunctive therapy to amoxicillin and a decongestant.[16] The other 2 trials addressed, in a double-blind fashion, the efficacy of steroid or combination agents (nasal spray budenoside[15] and a combination of nasal oxymetazoline in addition to oral liquid brompheniramine and phenylpropanolamine,[17] respectively) against placebo.

None of the 3 studies used the categorization "cure-improvement-failure" for clinical outcomes (Table 2). The study on lavage used strictly ultrasonographic criteria. The other 2 studies used composite clinical and/or radiologic scores, and there was no statistically significant difference found at any of the addressed time points, except for a superiority of budenoside over placebo at the end of 2 weeks in terms of the clinical score. It should be noted that in this study,[15] only 89 of the 151 enrolled patients were followed up adequately to be included in the analysis.

Concordance of Diagnostic Methods

We were able to identify only 5 studies that addressed the comparative diagnostic accuracy of at least 2 procedures used as diagnostic tools in children with acute sinusitis (Table 3). In addition, 2 of the randomized, controlled trials on therapeutic measures provided data on percentage of abnormal radiographs among children with a clinical diagnosis of sinusitis[12,15]; a third trial[16] addressed the presence of aspiration fluid in the setting of abnormal ultrasonography without any symptoms being present. Thus, a total of 8 studies qualified for considerations pertaining to diagnostic concordance.

These diagnostic studies were very heterogeneous. Five of the 8 originated outside the United States. In several of them, radiology and/or otolaryngology specialists authored the reports, rather than general pediatricians. The study population was usually not adequately defined in terms of duration of symptoms, except in 2 randomized, controlled trials.[12,15]

Of the 7 studies in which some or all patients had clinical symptoms or signs, plain film radiography was performed in 6, while plain films were considered to be worthless in a study of infants. In these 6 studies, the rate of abnormal plain film radiography findings (typically opacification, mucosal thickening, and/or air-fluid level) against a clinical diagnosis of sinusitis ranged from 55% to 96%. These rates were statistically significantly different across the various studies ($P < .001$). The pooled rate was 73% (596/814). The largest component of this variability is probably attributable to variability in the clinical definition of sinusitis. This could be discerned easily in the only study that used different thresholds for the clinical definition.[30] When the subgroup of children who had only 1 of the 3 criteria of purulent secretion, history of upper respiratory secretion, and sinus pain or tenderness were considered, radiographic abnormalities were present only in 22/79 cases (28%). When 2 or 3 of these criteria were present, radiographic abnormalities were noted in 75/96 cases (78%). The likelihood ratios are shown in Table 4.

Similar rates of abnormal radiographs also were seen in the 2 randomized, controlled trials that used

TABLE 3. Studies of Concordance of Diagnostic Tests for Acute Uncomplicated Sinusitis in Children*

Author	*N*	Age (Years)	Aspiration	Abnormal Plain Radiograph	Other Imaging	Clinical Diagnosis
Kogutt[26]	100	1/2–14	Not done	96/100†	Not done	Various signs and SX reported
Watt-Boolsen[27]	86 (155 sinuses)	3–12	Done	114/155	Not done	Not specified
Van Buchem[28]	79 ("sinusitis")	2–12	Done	80/124	Ultrasound	Clinical impression of "sinusitis"
	68 ("rhinitis")		Not done	Not done	Not done	Clinical impression of "rhinitis"
Glasier[29]‡	15 with URI SX	<1	Not done	Not done	CT scan	Upper respiratory infection SX
	85 without URI SX			Not done	CT scan	No upper respiratory infection SX
Revonta[16]§	86	4–10	Done	Not done	Ultrasound	No children had sinusitis-specific SX
Jannert[30]	175	0–15	Not done	97/175	Not done	Purulent secretion, URI in previous 2 weeks, sinus pain or tenderness
Wald[12]	171	2–16	Not done	136/171	Not done	Nasal discharge or cough not improving >10 d
Barlan[15]	89	1–15	Not done	69/89	Not done	Major criteria: purulent nasal discharge, pharyngeal drainage, cough; 9 minor criteria‖

* URI indicates upper respiratory infection; SX: symptoms.
† Includes 5 children with pansinusitis in the setting of immunodeficiency.
‡ CT scan was performed on infants for unrelated reason, none were diagnosed a priori with "sinusitis" per se, but a subgroup was clinically diagnosed with upper respiratory infection.
§ Ultrasound was performed in the absence of clinical symptoms for sinusitis in 452 children referred for adenoidectomy or adenotonsillectomy.
‖ Two major or 1 major and 2 minor criteria required.

strict clinical criteria for the diagnosis of acute sinusitis. Wald et al[12] defined sinusitis by the presence of any nasal discharge and/or cough that were not improving for 10 to 30 days. Barlan et al[15] defined sinusitis by the presence of at least 2 of 3 major criteria (purulent nasal discharge, pharyngeal discharge, cough) or 1 of them plus 2 of 9 minor ones with duration of at least 7 days. In these 2 randomized, controlled trials, abnormal radiographs were seen in 136/171 (80%) and 69/89 (78%) of children with a clinical diagnosis, respectively.

The other 3 studies that offer data on radiography and clinical diagnosis do not specify a priori explicit criteria for the clinical diagnosis of acute sinusitis. One study simply lists the percentage of various symptoms,[26] while another[27] does not give any clinical information on signs and symptoms. The third study[28] states that the distinction between "sinusitis" and "rhinitis" was left to the impression of the clinician. Interestingly, the "rhinitis" group did not differ from the "sinusitis" group in the prevalence of fever, purulent secretion, sinus tenderness, or headache.

In a study of infants (newborn to 12 months of age), plain film radiographs were considered worthless and thus only computed tomography (CT) scans were evaluated.[29] Excluding cases of sinus hypoplasia, evidence of CT involvement of the maxillary sinus(es) had an 87% (13/15) sensitivity, but only 41% (28/69) specificity against the clinical impression of upper respiratory infection symptoms. The positive predictive value is only 13/54 (24%), and the negative predictive value is 28/30 (93%). The respective figures for the ethmoid sinus(es) were sensitivity of 67% (10/15) and specificity of 61% (46/75), positive predictive value of 10/39 (26%) and negative predictive value of 46/51 (90%). Thus the concordance of CT scan and clinical impression in infants is very poor.

One study[16] found good correlation between ultrasonographic findings and retrieval of fluid on aspiration: 68 of 72 sinuses with ultrasonographic abnormalities yielded fluid on aspiration, but aspiration was not attempted in any control group without ultrasonographic abnormalities. Cultures of the aspirate from 59 sinuses yielded microbial pathogens in less than half the cases (26/59). The only study[28] to compare ultrasonography with plain film radiography and sinus fluid abnormalities among children with a clinical picture of sinusitis[28] found very low concordance between these diagnostic techniques (Table 4). Finally, abnormalities of plain film radiography had a poor concordance even with the simple presence of fluid in one study[27] (Table 4).

DISCUSSION

This study evaluated the available randomized and nonrandomized evidence on the diagnosis and management of acute sinusitis in children. Compared with the frequency of this common condition, the amount of high-quality evidence regarding diagnosis and treatment is remarkably limited. Most randomized data on adolescents may have been inextricably merged with data on adults in previous studies, and it is unclear whether adolescents should differ from adults in the diagnosis and management of acute sinusitis. However, for children younger than 12 years, evidence is sparse. Furthermore, it is hazardous to extrapolate evidence from adults to children given that children have a different and continuously changing anatomy and a higher incidence of viral upper respiratory tract infections.

There are few data on how to accurately diagnose acute sinusitis in childhood. Clinical criteria may not be very reliable. Plain film radiography shows only modest concordance with clinical diagnosis, and the concordance depends largely on how a clinical diagnosis is defined. Other imaging modalities have no clear role in the diagnosis of uncomplicated acute bacterial sinusitis. A decision analysis suggests that imaging studies may not be cost-effective for any level of previous suspicion of acute bacterial sinusitis.[7]

Although 1 small trial has shown superiority of antibiotics over placebo,[12] its applicability to settings where sinusitis is defined by different criteria is uncertain. The available evidence also suggests that the

TABLE 4. Concordance of Diagnostic Findings on Imaging and Aspiration Tests: Positive and Negative Likelihood Ratios*

Study	Evaluated Diagnostic Test and Finding	Reference Test and Finding	Positive Likelihood Ratio	Negative Likelihood Ratio
Jannert	Plain radiograph: any abnormality†	Clinical criteria: 2–3 vs 1 of pus, upper respiratory secretion, sinus pain/tenderness	2.8	0.3
Glasier	CT scan of maxillary sinuses in infants: opacification‡	Clinical diagnosis: upper respiratory infection	1.5	0.3
Glasier	CT scan of ethmoid sinuses in infants: opacification‡	Clinical diagnosis: upper respiratory infection	1.7	0.5
Van Buchem	Ultrasound: any abnormality	Plain radiograph: any abnormality†	1.7	0.9
Van Buchem	Ultrasound: any abnormality	Sinus aspirate: nonclear fluid	0.5	1.2
Van Buchem	Plain radiograph: any abnormality†	Sinus aspirate: nonclear fluid	1.1	0.9
Van Buchem	Sinus aspirate: nonclear fluid	Sinus aspirate: pathogenic microorganisms	0.9	1.0
Van Buchem	Sinus aspirate: >3 leukocytes per visual field	Sinus aspirate: pathogenic microorganisms	4.0	0.9
Watt-Boolsen	Plain radiograph: any abnormality†	Sinus aspirate: any fluid	2.7	0.2

* (See "Methods" for details on the calculation of positive and negative likelihood ratios).
† Typically including mucous thickening, opacification, or air-fluid level.
‡ Excluding hypoplasia.

various antibiotics, among the several used for children with sinusitis, do not differ in their efficacy; nevertheless, given the sparse evidence and the high rate of spontaneous resolution, modest differences could have been missed. Furthermore, no studies have been reported in the era of increased resistance among isolates of *Streptococcus pneumoniae* and bacteriologic response data are almost nonexistent. There is no convincing evidence to support the use of ancillary treatment with decongestant-antihistamines and limited evidence on the use of steroids.

Therapy for children with acute uncomplicated sinusitis is controversial. The rates of spontaneous resolution are high. Antibiotics have been shown to be superior to placebo in a population defined by symptoms of nasal discharge or cough that were not improving for at least 10 days and positive radiographs.[12] Perhaps obtaining a radiograph would not be necessary if these clinical criteria exist for >10 days because almost 80% of these children would have a positive radiograph. Empirical treatment with antibiotics may be warranted in such cases. However, there is no evidence to support the use of antibiotics in other groups of children, such as those without nasal discharge or cough, those with shorter duration of symptoms, or those with improving symptoms. Spontaneous recovery rates in these groups are likely to be too high for antibiotics to offer any meaningful benefit. Finally, if antibiotic treatment is prescribed in acute, uncomplicated cases of sinusitis, evidence supports the use of amoxicillin, unless there is a history of allergy to β-lactams. Currently, there is insufficient evidence to support the use of newer, broad-spectrum antibiotics,[31] although increasing rates of antibiotic resistance should prompt the performance of properly designed studies.

Finally, the current evidence does not offer any clear indication for the use of ancillary measures. Although routinely used, there is no strong evidence from randomized, controlled trials to justify the use of antihistamines and decongestants in children. Evidence for the use of steroids comes from a single small trial.[15] More data are needed to evaluate the usefulness of these agents.

The strongest message emanating from this report is the lack of standardized clinical criteria for defining acute bacterial sinusitis in children as well as the paucity of high-quality evidence for establishing the diagnosis and optimal management of this condition. Despite the presence of an extensive bibliography on sinusitis in children, actual evidence and primary data on the diagnosis and management of acute uncomplicated sinusitis are limited. We encountered 450 reports on complications of sinusitis, mostly case reports or case series. Although it is important to know about the rare complications of this disease, it is questionable whether all these case reports and small case series give us useful information when there is comparatively only a handful of studies that deal with the common uncomplicated forms of the infection. In addition, there were 233 nonsystematic review articles compared with approximately 20 primary studies with analyzable original data. The paucity of primary data may be attributable to the difficulties in applying the necessary rigorous diagnostic methodologies to generate high-quality information in children. Additional well-designed prospective studies are much needed to establish optimal diagnostic procedures and management of children suspected to have acute bacterial sinusitis.

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John P. A. Ioannidis and Joseph Lau

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