The “Spoke Sign”

An Otoscopic Diagnostic Aid for Detecting Otitis Media With Effusion

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Objective: To determine the prevalence and diagnostic usefulness of the “spoke sign” (SS), a specific otoscopic finding, in detecting the presence of pediatric middle ear effusion (MEE).

Methods: The SS was defined as a dull gray appearance of the tympanic membrane with engorged vasculature in an arrangement similar to the spokes of a bicycle wheel, covering 50% or more of the inferior tympanic membrane by area. An observational screening test study was performed prospectively with enrollment of consecutive pediatric patients scheduled for tympanostomy tube placement. Intraoperatively, the presence or absence of SS was noted before myringotomy and that of MEE was noted after myringotomy. Statistical analysis was performed to determine the value of SS as a predictor of MEE, with myringotomy as the criterion standard. Videos taken before myringotomy were subsequently shown to independent pediatricians and otolaryngology residents to analyze interrater concordance in evaluating the presence of SS.

Results: Seventy-six patients (150 ears) were included in the study. Forty-nine patients (64%) had SS in at least 1 ear. The sensitivity, specificity, positive predictive value, and negative predictive value for the SS for MEE were 100% (79/79), 93% (66/71), 94% (79/84), and 100% (64/64), respectively. The Fleiss $\kappa$ score for interrater concordance among pediatricians was 0.21 (residents) to 0.24 (staff), and that among otolaryngology residents was 0.61 (all $P < .001$).

Conclusions: The presence of SS may represent a useful adjunct in the detection of pediatric MEE, with high measured sensitivity and specificity. Incorporation of SS in clinical practice may require focused training to detect this specific examination finding.


Otitis media is a common chronic disease of childhood. Some studies\(^1\) have estimated that up to 40% of children experience recurrent or persistent otitis media. Unlike acute otitis media, which commonly presents with fever, earache, and occasionally drainage from the ear, otitis media with effusion (OME) is usually asymptomatic. However, it is well established that OME predisposes to recurrent infection and causes conductive hearing loss. In addition, Rosenfeld et al\(^2\) demonstrated that OME is associated with quality-of-life impairment in children aged 6 months to 12 years, as measured by Otitis Media 6, a 6-item quality-of-life survey representing the domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns. Furthermore, Boruk et al\(^3\) demonstrated that OME adversely affects caregiver well-being, in that most caregivers were nervous or agitated at least “some of the time” because of their child’s ear problems, 29% lost sleep “a good amount of time,” and 56% had to change their daily activities. It is commonly believed that, because OME causes conductive hearing loss, it results in speech delay. However, longitudinal studies in this area have yielded no consensus on the matter. Some studies indicated that early childhood OME is associated with poorer expressive language\(^1,4\) and mathematics performance in school\(^,5\) as well as with impairments of receptive language and verbal aspects of cognition.\(^6\) Several other studies indicated that no such associations exist.\(^6,8\)

Because OME can be asymptomatic or can have nonspecific symptoms, diagnosis relies heavily on physical examina-
tion. In younger children, physical examination is challenging because it is frequently limited by a small and narrow external auditory canal, cerumen impaction that obstructs the view of the tympanic membrane (TM), and resistance to examination by the patient.

Myringotomy continues to be the criterion standard for determining the presence of middle ear effusion (MEE). This maneuver is not possible in the clinic setting with the pediatric patient, where TM mobility as assessed by pneumatic otoscopy is considered to be the most sensitive indicator. However, accurately performing pneumatic otoscopy in the pediatric patient is considerably more challenging than simply obtaining a view of the TM by otoscopy. Tympanometry can be a useful adjunct in diagnosing OME, but it is not widely available outside of the audiologist’s office. Given the challenges of performing pneumatic otoscopy and the lack of widespread accessibility to other adjuncts, it would be useful to better define diagnostic criteria with nonpneumatic otoscopy so that providers can be best equipped to diagnose OME with the basic tools in their office.

Myringotomy is widely accepted as the criterion standard of diagnosis of MEE because the middle ear space can be directly visualized and effusion can be suctioned. Tympanostomy tube placement is therefore an ideal opportunity to critically evaluate the diagnostic usefulness of otoscopic findings. The primary objective of this study was to determine whether the presence of a specific finding on otoscopy, namely, the spoke sign (SS), is a valid predictor of the presence of MEE in children, using myringotomy as the criterion standard. We used the term spoke sign because of the resemblance to the appearance of a bicycle wheel. Our hypothesis was that the SS is a good indicator of the presence of serous MEE. If this hypothesis can be statistically validated, this study may serve to improve the effectiveness of otoscopic physical examination techniques in determining the presence of MEE.

Institutional review board approval was obtained before initiation of our study. This was an observational screening test study with myringotomy as the criterion standard. Consecutive patients who were scheduled to undergo myringotomy and tympanostomy tube placement for chronic otitis media were enrolled. Exclusion criteria were craniofacial anomalies (eg, cleft palate and trisomy 21), presence of a tube at the time of the operation, TM perforation, and obscuring myringosclerosis. The operations were performed without any change to the standard binocular microscope-assisted tympanostomy tube placement technique. Before making the myringotomy, the appearance of the TM and the presence or absence of the SS were noted, using the standard definition. Then, after making the myringotomy, the presence or absence of MEE was noted. These data were recorded in a de-identified manner, and statistical analysis was performed once data collection was complete to avoid bias and to determine the prevalence, sensitivity, specificity, positive predictive value, and negative predictive value. This analysis was performed on a per-ear basis and a per-patient basis. For the per-patient basis, a patient with 1 ear positive for either the SS or an MEE was considered positive for the analysis and only patients without an SS or MEE on either side were considered negative.

We defined the SS as a dull gray appearance of the TM with prominent, engorged vasculature of the TM in a radial fashion, similar to the spokes of a bicycle wheel, covering at least 50% of the dependent, inferior portion of the TM by area. We arrived at describing the concept of the SS by noting, after hundreds of ear tube placements in the operating room, that as hyperemia, the first of the classically described stages of acute suppurative otitis media, develops, the vessels of the TM become engorged and there is inflammation of the middle ear. When MEE is present at this stage, as it is almost universally, it can cause a dull appearance of the TM by color, further enhancing the visibility of the engorged blood vessels, which, from their origin at the umbo, take on the pattern similar to spokes on a bicycle wheel. This visual pattern is easily detected with routine otoscopy.

A series of video clips of the appearance of the TM before making the myringotomy was obtained so that interrater concordance could later be analyzed by having a group of independent pediatricians (staff and residents) and otolaryngologists view the videos and note whether they believed the SS to be present. The quality of each video was also rated by these independent physicians, and the data from the 10 highest-quality videos were used for analysis of interrater concordance, which was calculated using the Fleiss κ, a statistical measure (ranging between 0 and 1) used to assess the reliability of the agreement between a fixed number of raters. Statistical analysis was performed with the assistance of computer software (Stata, version 8.2; StataCorp). The null hypothesis was rejected at P < .05.

Seventy-six patients were enrolled. The mean age was 2.13 years (range, 0.9-10.0 years) and 31 patients (41%) were female. Among the 76 patients, 150 ears were evaluated, of which only 2 were excluded because of excessive myringosclerosis. Figure 1 demonstrates an intraoperative photograph of a normal TM. By contrast, Figure 2 demonstrates a TM with an SS; the overall dull gray appearance and the prominent, engorged radial vas-

Figure 1. Normal tympanic membrane.
Otitis media with effusion is a common condition in the pediatric population that can affect hearing levels and impair quality of life but can be difficult to diagnose in an otherwise asymptomatic patient. Determining its presence or absence using physical examination is an important factor in the management of OME in pediatric patients. Defining and validating a specific physical examination finding on otoscopy to help diagnose OME may greatly benefit the practice of pediatric medicine and otolaryngology. The American Academy of Family Physicians, American Academy of Otolaryngology—Head and Neck Surgery, and American Academy of Pediatrics Subcommittee on Otitis Media with Effusion published a practice guideline for the appropriate management of OME in 2004. The committee recommended the use of pneumatic otoscopy to diagnose OME, with the use of tympanometry to confirm the diagnosis if needed. Based on these guidelines, it is essential for the provider to make an accurate diagnosis of OME and be able to monitor it clinically over time. In a random effects analysis of the literature, Takata et al concluded that pneumatic otoscopy offers the best sensitivity (94%; 95% CI, 92%-96%) and specificity (80%; 75%-86%) for diagnosis of OME compared with other methods, such as tympanometry and acoustic reflexometry.

In practice, pneumatic otoscopy can be challenging, especially when training levels of providers in this skill differ. The committee recognized this challenge and recommended tympanometry or acoustic reflexometry to confirm the diagnosis in cases of uncertainty. However, these adjuncts are expensive and not widely available, especially in community-based primary care settings. Physical examination of the ear in the pediatric age group, especially in younger children (aged 1-5 years), is particularly difficult because of small external auditory canals, cerumen impaction that limits or obstructs the view of the TM, and resistance to examination by the patient. Pneumatic otoscopy not only requires an adequate view of the TM but further requires coordination of insufflating air against the TM while maintaining an adequate view long enough to determine the mobility of the membrane.

**COMMENT**

Otitis media with effusion can be seen. Most patients (49 [64%]) had an SS in at least 1 ear. By the examination of the TM by the senior author (S.E.B.), SS was present in 84 ears, of which 79 had MEE (positive predictive value, 94%). All ears that had MEE also had the SS (sensitivity, 100%). With per-ear analysis, this yielded 100% (79/79) sensitivity, 93% (66/71) specificity, 94% (79/84) positive predictive value, and 100% (64/64) negative predictive value. By a per-patient analysis, this yielded 100% (47/47) sensitivity, 93% (27/29) specificity, 96% (47/49) positive predictive value, and 100% (27/27) negative predictive value. Table 1 shows the 2 × 2 tables for a per-ear and per-patient basis that demonstrate the findings of the SS as a predictor of MEE, using myringotomy as the criterion standard.

As the second portion of the study, the interrater reliability of the SS was evaluated. A group of independent pediatricians and otolaryngology residents were briefly educated about this study and provided a short verbal and written definition of the SS. Twenty-seven video clips obtained intraoperatively before myringotomy was performed were then shown to these physicians, who were asked to independently indicate whether they believed the SS to be present based on the description provided and whether they believed MEE to be present. They were also asked to rate the quality of each video on a numeric scale from 1 to 4. Average video quality scores were calculated for each video, and videos with a mean quality rating of 3.0 or higher were used for evaluation to avoid bias from suboptimal video quality. Interrater concordance using Fleiss \( \kappa \) was calculated on the basis of data from these higher-quality videos. Interpretation was based on the ranges of Fleiss \( \kappa \) scores and was categorized as slight (0.01-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80), and almost perfect (0.81-1.00) agreement. Table 2 reports the findings of this analysis. The Fleiss \( \kappa \) for interrater concordance was in the “fair” range among pediatricians, both for determining the presence of the SS and for determining the presence of MEE. The Fleiss \( \kappa \) among otolaryngology residents was in the “substantial” range for determining the presence of SS.

**Table 1. Spoke Sign Compared With Myringotomy, per Ear vs per Patient**

<table>
<thead>
<tr>
<th>Basis</th>
<th>No. With Spoke Sign</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Per ear</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ears with MEE</td>
<td>79</td>
<td>79</td>
</tr>
<tr>
<td>Ears without MEE</td>
<td>5</td>
<td>64</td>
</tr>
<tr>
<td>Total</td>
<td>84</td>
<td>148</td>
</tr>
<tr>
<td><strong>Per patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with MEE</td>
<td>47</td>
<td>47</td>
</tr>
<tr>
<td>Patients without MEE</td>
<td>2</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>49</td>
<td>76</td>
</tr>
</tbody>
</table>

Abbreviation: MEE, middle ear effusion.
Our study sought to establish whether a specific otoscopic finding, the SS, could be validated as a predictor of pediatric MEE, with myringotomy as the criterion standard. The advantage of using the SS in clinical practice is that determining its presence requires only quick visual inspection, and so it is more feasible to perform on a consistent basis in the office setting. The SS was not intended to replace pneumatic otoscopy but to provide a visual cue to augment otoscopy to improve the diagnostic accuracy of the physical examination.

With TM examination by the senior author, the SS has very high rates of sensitivity, specificity, positive predictive value, and negative predictive value, using myringotomy as the criterion standard. It can therefore be a highly useful diagnostic tool in the clinic setting for diagnosing MEE by physical examination alone. Interrater concordance in determining the presence of the SS was in the fair range by Fleiss κ analysis among independent pediatricians, and that among otolaryngology residents was in the substantial range. The same instructions were offered to the group of otolaryngology residents and pediatricians. The difference in their interrater concordance is likely the result of increased focus and training among otolaryngologists to look for specific findings and abnormalities of the TM compared with pediatricians, who are responsible for proficiency in physical examination of the entire body and therefore may not have this same focus in their training. Thus, incorporation of the SS as a marker of pediatric MEE in clinical practice may require focused education and training in evaluating the TM for specific findings such as the SS. With such training, it appears that the SS is a very sensitive and specific marker for pediatric MEE. We are considering a second study to assess the effects of specific training in otoscopy to optimize the usefulness of the SS.

Limitations of this study mainly lie in the fact that the senior author, who established the concept of the SS, was the sole rater of its presence in most of the TMs in the study. However, it was important to initially assess the validity of the SS as a predictor of MEE in the context of an evaluation by an experienced and well-trained rater. This is why subsequent interrater concordance analysis was performed among independent raters and is an essential part of this study. This analysis demonstrated that focused training and education in evaluating a TM for specific findings, such as the SS, may play an important role in being able to successfully use the SS in clinical practice. Further study is required to fully explore the benefits of assessing for the SS in a primary care setting. Although classification with the SS is somewhat subjective, it is simple and appears to offer diagnostic usefulness when assessing for OME in pediatric patients.

In conclusion, the SS is a simple visual diagnostic aid that was found to be present in most pediatric patients with MEE who were undergoing tympanostomy tube placement. The diagnostic performance of the SS in comparison with the criterion standard of myringotomy was excellent, with high measured sensitivity and specificity. Interrater reliability was fair with pediatricians but substantial with otolaryngology residents, indicating a possible need for specific training in otoscopy to optimize the usefulness of the SS.

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Author Contributions: Drs Sridhara and Brietzke had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Sridhara and Brietzke. Acquisition of data: Sridhara and Brietzke. Analysis and interpretation of data: Sridhara and Brietzke. Drafting of the manuscript: Sridhara and Brietzke. Critical revision of the manuscript for important intellectual content: Sridhara and Brietzke. Statistical analysis: Sridhara and Brietzke. Administrative, technical, and material support: Sridhara. Study supervision: Brietzke.

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