The Natural Course of Tympanic Membrane Retractions in the Posterosuperior Quadrant of Pars Tensa: A Watchful Waiting Policy

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Introduction: Tympanic membrane retraction (TMR) is a relatively common otologic finding. Currently, there is no consensus on the optimal treatment of TMR. Some ENT-surgeons advocate surgical correction while others opt for a watchful-waiting policy. Our aim was to investigate the natural course of retraction pockets in the posterosuperior quadrant of the pars tensa in a large cohort of patients.
Methods: An observational retrospective cohort study was conducted including patients of all ages with a posterosuperior pars tensa retraction. Primary outcome measure was difference between audiometry at first and last visits. Secondary outcomes were patients' complaints, otoscopic outcomes (Sade classification), and complications (perforation, ossicular chain damage, and/or cholesteatoma).
Results: A total of 71 patients with 81 ears and a median age of 23 years (IQR 14–47) were included. The median duration of follow-up was 64 months (IQR 44–102). The mean air-bone gap at first and last visits was 17.9 dB (SD 11.3) and 15.5 dB (SD 12.9), respectively, with a mean improvement of 2.4 dB ($p = 0.08$). In 10 ears (12%) the hearing level (air-bone gap) deteriorated with 10 dB or more. Patients who presented with a TMR Sade grade I at first visit had significantly better audiometric outcomes than patients presenting with Sade grade III ($p = 0.001$). Progression to cholesteatoma occurred in one patient (1%), progression to perforation occurred in five patients (6%), and progression to ossicular chain damage occurred in five patients (6%).
Conclusions: Otoscopic findings and audiometric results remained stable in most TMRs without treatment. Additionally, audiometry did not worsen during last follow-up. Progression to cholesteatoma, perforation, or ossicular chain damage was rare. Shared decision making regarding TMRs should include a discussion of a wait-and-see policy. **Key Words:** Cholesteatoma.—Natural history—Pars tensa—Posterosuperior quadrant—Retraction pocket—Tympanic membrane retraction—Wait-and-see policy.

Tympanic membrane retraction (TMR) is a condition in which part of the tympanic membrane is retracted into the middle ear cavity (also called retraction pocket) and is frequently seen in (pediatric) otorhinolaryngology. The prevalence of TMR in children is reported to be 8% to 10%, mostly being mild cases in the pars tensa (Sade classification I) (1). As most (epidemiological) studies have been performed in children, the prevalence of TMR in adults is largely unknown.

Persistent or temporary negative middle ear pressure, which is caused mainly by a dysfunction of the Eustachian tube or by inflammation, is considered a main causal factor in the etiology of TMRs (2,3). TMRs are frequently localized in the posterosuperior quadrant of the pars tensa and in the pars flaccida. One of the proposed explanations for this localization is because the posterosuperior quadrant of the pars tensa lacks a

well-developed circular fibrous layer (3). Furthermore, it is well vascularized and therefore more vulnerable to infiltration of inflammatory cells and mediators. During inflammation, these cells secrete collagenases and elastases that results in damage of collagen fibers, which could weaken the integrity and composition of the tympanic membrane architecture (3,4). The propensity of the pars flaccida and posterior pars tensa to retraction can also be related to the different embryological origin of the eardrum in these specific sites compared with the rest of the tympanic membrane (5).

The first staging system of TMRs was proposed by Sade and Berco (6) in 1976, classifying pars tensa retraction by otoscopic image into stage I till IV, based on the reversibility of the retraction after ventilation. Since then, various authors have proposed other staging systems for which there is no common agreement regarding its clinical utility (6,7). Recent studies have shown that these staging systems do not or weakly correlate to clinical outcomes (8).

Clinically, pars tensa retractions remain stable in the majority of cases without producing any symptoms, and spontaneous recovery occurs in approximately 40% of mild (Sade classification I) cases (9,10). However, when pars tensa retractions become more severe and progressive, they may lead to hearing loss, perforations of the tympanic membrane, erosion of the ossicular chain, and even cholesteatoma. In about 15% of mild cases, TMRs progress into a precholesteatomatous stage (formation of microcholesteatomas in the lamina propria (11)), with around 4% of cases developing to cholesteatoma (12,13). Therefore, correct diagnosis and proper management of pars tensa retractions are essential to prevent middle ear cholesteatoma.

Various management strategies of pars tensa retractions have been proposed and include a wait-and-see policy, ventilation tubes, or tympanoplasty (14,15). Clinical outcomes of the wait-and-see policy are lacking in the literature, especially for adults. Therefore, our aim was to investigate the natural course of pars tensa retractions in a large cohort of patients in which a wait-and see policy was initiated.

METHODS

Study Design and Population

An observational retrospective cohort study was conducted at the Department of Otorhinolaryngology, in the Flevoziekenhuis in Almere, The Netherlands. Patients of all ages were included in our study if they were diagnosed with an oto-endoscopically confirmed retraction in the posterosuperior quadrant of the pars tensa (Fig. 1.). Patients who had synchronous retractions in pars flaccida were also included. Audiometry was performed at baseline and was performed minimally once during follow-up. In all patients, a wait-and-see policy was initiated. Data was retrieved from the Electronic Patients Record for patients diagnosed between March 2001 and April 2019. In this study patients were excluded with:

I. Missing audiograms or missing oto-endoscopic images of the tympanic membrane at either first visit or last visit.
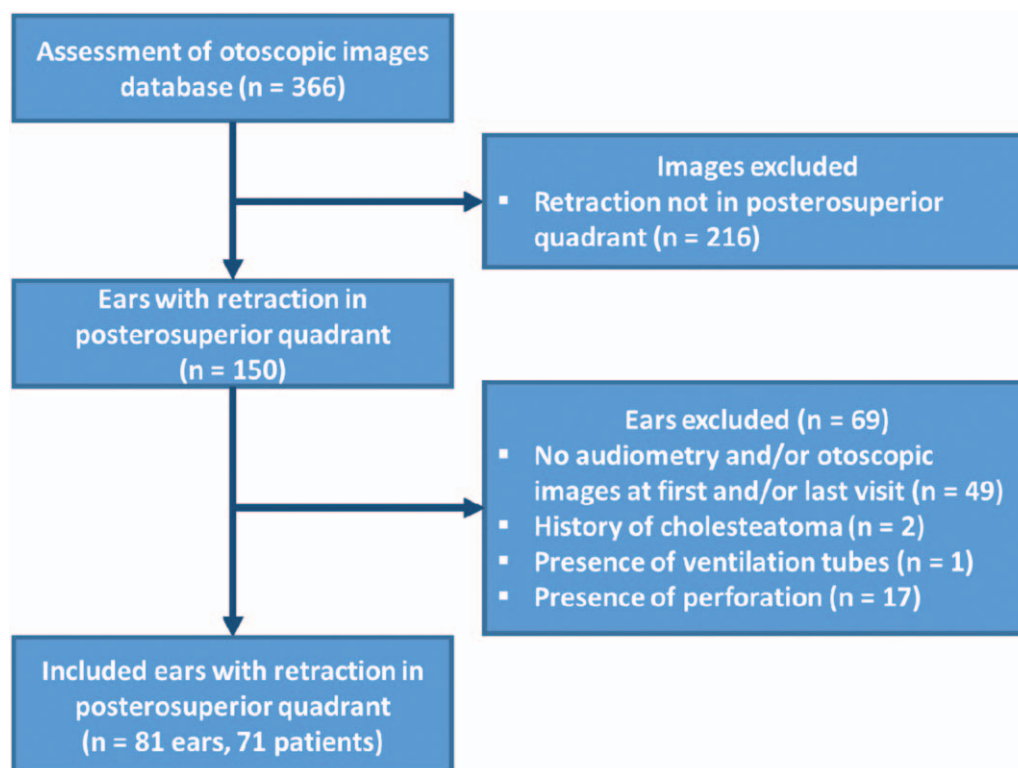

FIG. 1. Flow-chart for inclusion of patients in this study. In total 81 ears (71 patients) have been included while 69 ears were excluded for various reasons.

II. Presence of perforation in pars tensa at initial presentation.

III. Presence of cholesteatoma at initial presentation or a previous history of cholesteatoma.

IV. Presence of ventilation tubes or placement of ventilation tubes at diagnosis according to patients' preference through shared decision making.

This study was in compliance with the ethical principles of the Medical Ethical Review Committee of the Academic Medical Centre, Amsterdam, The Netherlands. Informed consent was not required for this observational study. All data was anonymized and could not be traced back to the patient.

Outcome Measures

The primary outcome in this study was change in hearing levels (air-conduction, bone-conduction, and air-bone conduction). The secondary outcome measurements were patients' complaints, otoscopic outcomes (Sade classification at first and last visits), and complications (progression into perforation, ossicular chain damage, or cholesteatoma). Cholesteatoma was defined according to the EAONO/JOS Staging System on Middle Ear Cholesteatoma as ''a mass formed by the keratinizing squamous epithelium in the tympanic cavity and/or mastoid and subepithelial connective tissue and by the progressive accumulation of keratin debris with/without a surrounding inflammatory reaction'' (16). Ossicular chain damage was determined by the clinical reports written by the otologists in the electronic patient record. Owing to the retrospective nature of the study, the ossicular chain damage was not systematically classified by a grading system such as the Austin-Kartush classification (17).

Pure-tone audiometry was used to assess the level of hearing loss. In this study the high Fletcher-index (1000, 2000, and 4000 Hz) was used to describe hearing results (18). Outcomes were subanalyzed for age, gender, ear localization (left or right), presentation with OME, and Sade classification.

As the present cohort is based on retractions in the pars tensa, otoscopic outcomes were classified using the Sade classification. All the pictures in this study were taken with a 0 degree endoscope (XION, Germany). Oto-endoscopic images were independently reviewed and classified by two researchers (A.B.B. and C.C.A.F.M.V.). Disagreement was resolved by an experienced otologist (J.-W.M.B.). The oto-endoscopic images were taken similarly in each patient, ensuring that both the pars tensa and the pars flaccida were completely visible. All oto-endoscopic images were taken at first visit and during follow-up visits. In patients with multiple follow-up oto-endoscopic images, all the images were checked for abnormalities (e.g., perforations, otitis media with effusion [OME]) and the most recent image was used as final otoscopic outcome.

For this study, an adjusted Sade classification was used, because in a nondynamic oto-endoscopic image a proper distinction between Sade III and Sade IV cannot be made. The Sade III and Sade IV grades were combined in this study. This is due to the inability to perform pneumatic otoscopy to assess whether the retraction pocket is adherent to the promontory.

The adjusted Sade classification we used consists of three grades (Fig. 2):

I. Slight retraction of the tympanic membrane over the annulus.

II. Tympanic membrane touches the long process of the incus or the stapes.

III. Tympanic membrane touches the promontory in the posterosuperior quadrant.

Statistical Analysis

Normally distributed continuous data are presented as means with standard deviations and non-normally distributed continuous data are presented as medians with interquartile range (IQR). Categorical data are presented as frequencies with percentages. Audiometry scores are expressed as mean (SD) and compared with the corresponding baseline scores using paired t tests and Wilcoxon tests as appropriate. Two age categories were used: ≤ 18 years old and > 18 years old. Subgroup analyses were performed for age, ear side, gender, Sade classification, and presentation with OME. Statistical analyses were performed using SPSS Statistics (version 22.0, IBM, New York, NY). A sample size calculation was not performed due to the retrospective nature of this study. A p value < 0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 155 patients with a retraction in the posterosuperior quadrant of the pars tensa were identified. A total of 71 patients and 81 ears with available follow-up data (audiogram and otoscopy) were included in this study (Fig. 1). Baseline characteristics of in- and excluded patients are summarized in Table 1. Patients were of a median age of 23.0 (IQR 14−47) years old, 42 patients (52%) were adults, and 42 patients (52%) were male. The majority of retractions (70%) were limited to the pars tensa, while the other retractions (30%) had involvement of both the pars tensa and the pars flaccida. History of previous middle ear surgery was present in 12 ears (15%) and consisted out of ventilation tubes in 10 ears and tympanotomy in 2 ears. The median duration of follow-up was 64 months (IQR 44−102) and the median time between first and final audiogram was 50.5 months (IQR 24.5−78). In some patients there was a regular clinic visit for follow-up of complaints and otoscopy after the last audiogram.

Audiometry

The mean air bone gap at first and last visits in all patients was respectively 17.9 dB (SD 11.3) and 15.5 dB (SD 12.1). The difference between the air bone gap at first and last visits was +2.4 dB (SD 12.1). This difference was not considered statistically significant ($p = 0.08$, paired T test) (Table 2).

Patients who were 18 years old or younger (Δair-bone gap: 8.0 dB, SD 11.8) had significantly better audiometric outcomes compared with patients older than 18 years old (Δair-bone gap: −1.3 dB, SD 10.7, $p = 0.0001$). Patients presenting with a Sade grade I (Δair-bone gap: 8.3 dB, SD 12.4) had significantly better outcomes than patients presenting with (adjusted) Sade grade III (Δair-bone gap: −2.4 dB, SD 9.0, $p < 0.001$) (Table 2 and Fig. 3).

The subgroup analyses for gender and ear-side were not statistically significant (Table 2). Furthermore, there
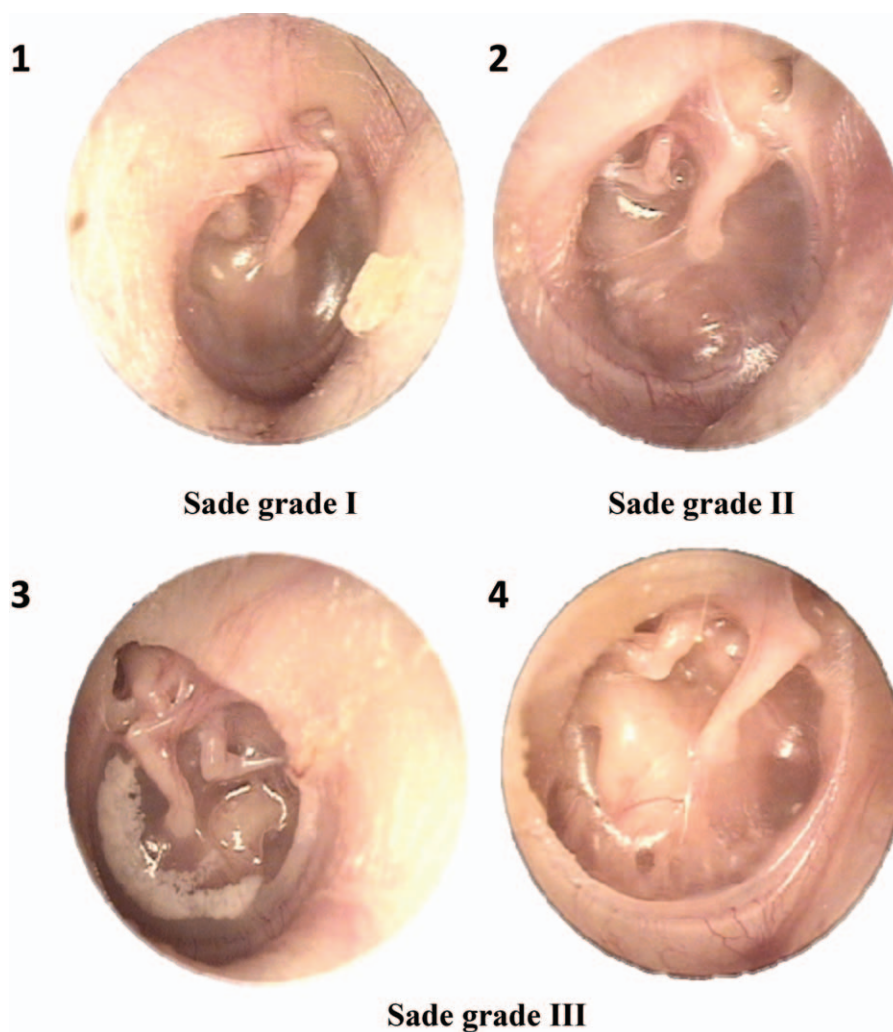
FIG. 2. The adjusted Sade classification used in this study as described in the Methods section. 1: Sade I: mild retraction in the posterosuperior quadrant of the right tympanic membrane. 2: Sade II: retraction in the posterosuperior quadrant of the pars tensa in which the right tympanic membrane touches the incus, with a slight retraction in the pars flaccida. 3: Sade III: retraction in the posterosuperior quadrant of the pars tensa in which the left tympanic membrane touches the incus and the promontory, with a slight retraction in pars flaccida and tympanosclerosis of the anterior edge of the pars tensa. 4: Sade III: subtotal atelectasis of the posterosuperior quadrant of the right tympanic membrane in which the incus and the promontory are clearly visible.

was also no statistical difference between first and last visit audiometry in patients who had worsening progression of the pars tensa retraction compared with those who had stable or improved retractions on otoscopy. In the entire cohort, hearing level (air-bone gap) deteriorated with 10 dB or more in 10 ears (12%). The mean hearing loss (air-bone gap) in these 10 ears with 10 dB or more of hearing level deterioration was −15.7 (SD 4.7). One patient developed cholesteatoma during follow-up; four patients developed (multiple) middle ear infections; two patients had ossicular chain damage; and one patient had adjusted Sade grade IV. The remaining two patients had small conductive losses (±10 dB), and after more accurately measuring the bone-conduction in subsequent testing, this increased the air-bone gap.

Clinical Symptoms, Otoscopic Outcomes (Sade Classification), and Complications

In the initial consultation, 28 patients (35%) presented with subjective hearing loss; 21 patients (26%) presented with otalgia; 18 patients (21%) presented with otorrhea; 8 patients (10%) presented with aural fullness, and 6 patients (7%) presented with other complaints. In total, 76 ears (94%) had improved or stable course (48%) of clinical symptoms. Forty-one ears (46%) had complete remission (34%) or reduction of symptoms (12%). The remaining four patients (6%) had worsened symptoms.

Twenty-two patients (27%) presented with Sade grade I; 29 patients (36%) with Sade grade II, and 30 patients (37%) with Sade grade III. At last visit, 8 patients (10%) had complete resolution of the pars tensa retraction, 16

TABLE 1. *Baseline patients' and disease characteristics.*

Variable	Included Patients	Excluded Patients	*p* Value
Number of ears	81	69	–
Male patients (%)	42 (52%)[a]	29 (43%)[a]	0.30[c]
Age at data collection, median (IQR)	23 (14–47)[a]	27 (13–52.3)[a]	0.81[b]
Age at diagnosis, median (IQR)	14 (7–39)[a]	24 (8.3–43.8)[a]	0.53[b]
Ear side (right, %)	42 (52%)	45 (66%)	0.07[c]
Retraction location			0.34[c]
Pars tensa	57 (70%)	52 (76%)	
Pars tensa and pars flaccida	24 (30%)	17 (24%)	
History of middle ear surgery (yes, %)	12 (15%)	4 (6%)	0.08[c]
Complaints at first presentation			0.27[c]
Otalgy	21 (26%)	14 (20%)	
Aural fullness	8 (10%)	8 (12%)	
Otorrhea	18 (22%)	10 (15%)	
Subjective hearing loss	28 (35%)	28 (39%)	
Other	6 (7%)	9 (14%)	
Presentation with otitis media (yes, %)	12 (15%)	24 (37%)	**0.006** [c]
Treatment with antibiotics (yes, %)	6 (50%)	12 (50%)	
Baseline Sade classification			0.55 [c]
I	22 (28%)	12 (17%)	
II	29 (35%)	26 (40%)	
III	30 (37%)	24 (37%)	
Baseline ossicular chain damage	6 (7%)	2 (3%)	0.23 [c]
Follow-up in months, median (IQR)	64 (44–102)	34 (14–82.5)	**0.008** [b]

Percentages were calculated from the number of ears (n = 81).
[a]Percentage calculated from the total amount of patients (n = 71).
[b]*T* test.
[c]Chi-square test.
Bold is statistically significant (*p < 0.05*).

patients with Sade grade I (20%), and 32 patients (40%) with Sade grade II; 25 patients (30%) with Sade grade III (Fig. 4).

In this cohort, 78 out of 81 (96%) ears had either improved or stable retractions (80%) based on oto-endoscopy. Thirteen ears (16%) had complete resolution (10%) or improvement of the staging of retraction on oto-endoscopy (6%). Three patients (4%) had worsened outcomes on oto-endoscopy (Fig. 4).

Overall, five patients (6%) had progression to perforation after a mean 58.8 months (SD 42.9) of follow-up and 5 patients (6%) had progression to ossicular chain damage after mean 62.4 months (SD 40.0) of follow-up. Ten patients (14%) suffered from OME during follow-up. Eight patients were treated with the combination therapy of hydrocortisone-acetate and bacitracin eardrops. Two patients were treated with a triple combination therapy of dexamethasone, framycetin, and

TABLE 2. *Audiometric outcomes (bone, air conduction, and air-bone gap) at first visit and last visit in all patients (n = 81).*

Parameter	Bone Conduction (dB)		Air Conduction (dB)		Air-Bone Gap (dB)			
	First Visit	Last Visit	First Visit	Last Visit	First Visit	Last Visit	Difference first and last visit	*p* Value
Total (n = 81)	10.3 ± 12.2	9.6 ± 12.9	28.1 ± 14.2	25.1 ± 18.6	17.9 ± 11.3	15.5 ± 12.0	2.4 ± 12.1	0.08[a]
Age ≤ 18 (n = 32)	5.3 ± 5.1	3.2 ± 4.5	25.0 ± 10.9	15.0 ± 9.4	19.7 ± 11.0	11.7 ± 8.3	8.0 ± 11.8	**0.0001** [a]
Age > 18 (n = 49)	13.7 ± 14.8	13.7 ± 14.8	30.2 ± 15.8	31.7 ± 20.0	16.6 ± 11.5	18.0 ± 13.4	−1.3 ± 10.7	
Sade first visit								
I (n = 22)	10.0 ± 12.9	8.9 ± 14.0	28.6 ± 11.7	19.2 ± 16.0	18.6 ± 12.5	10.3 ± 8.4	8.3 ± 12.4	**0.001** [b]
II (n = 29)	9.6 ± 13.9	8.9 ± 14.1	28.2 ± 16.8	24.8 ± 21.7	18.7 ± 11.5	15.9 ± 13.7	2.7 ± 15.7	
III (n = 30)	11.2 ± 10.3	10.8 ± 11.1	27.8 ± 11.5	29.7 ± 16.4	16.5 ± 10.6	18.9 ± 11.4	−2.4 ± 9.0	

The outcomes were subanalyzed for age and Sade classification. Statistical testing was performed on the difference between audiograms of the first and last visits.
[a]*T* test.
[b]ANOVA.
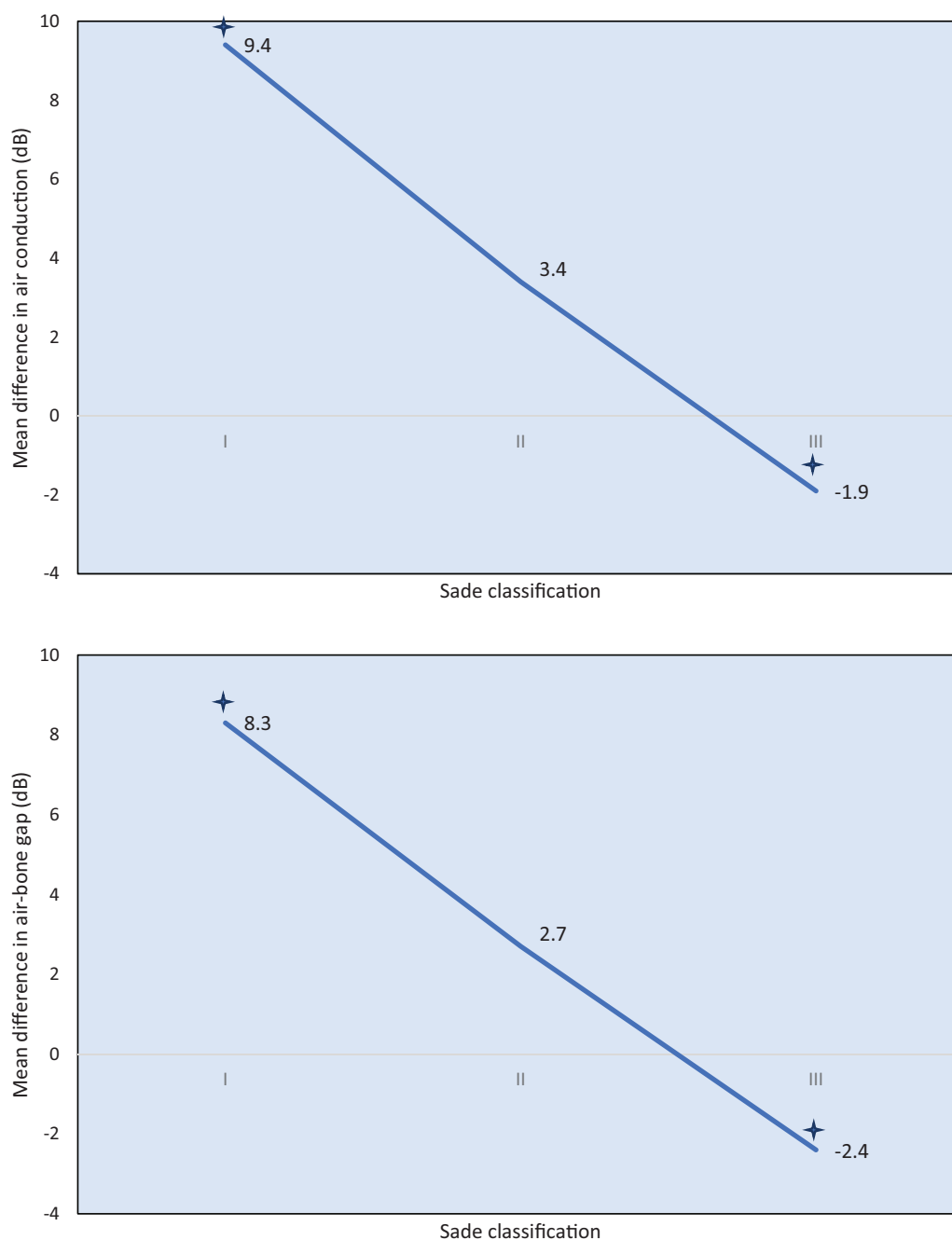Bold is statistically significant (*p < 0.05*).

FIG. 3. The mean difference in air-conduction and air-bone gap between first and last visits by Sade classification at first visit. There was a significant difference between Sade grades in air-conduction (ANOVA, $p = 0.015$) and air-bone gap (ANOVA, $p = 0.015$). ✦: statistical significant difference ($p < 0.05$) between Sade grade I and III.

gramicidin eardrops. The indication for these ear-drops was otorrhea. Reinterventions occurred in 15 (19%) patients, of whom 7 patients received a ventilation tube, 3 patients underwent tympanoplasty, and 4 patients received both. The remaining patient required surgery for the treatment of cholesteatoma. In the seven patients who received a ventilation tube, this was for persistent OME. These patients received the ventilation tubes 23.4 months (SD 19.5) from the start of the wait-and-see policy. The final audiogram was taken after 34.9 (SD 30.3) months and the last clinic visit was at 53.7 months (SD 39.4).

Retraction Pockets in Both Pars Tensa and Pars Flaccida

In 20 ears (29%) there was a retraction in both the pars tensa and the pars flaccida. In this group of patients, 2 (10%) patients presented with Sade grade I; 7 (35%)
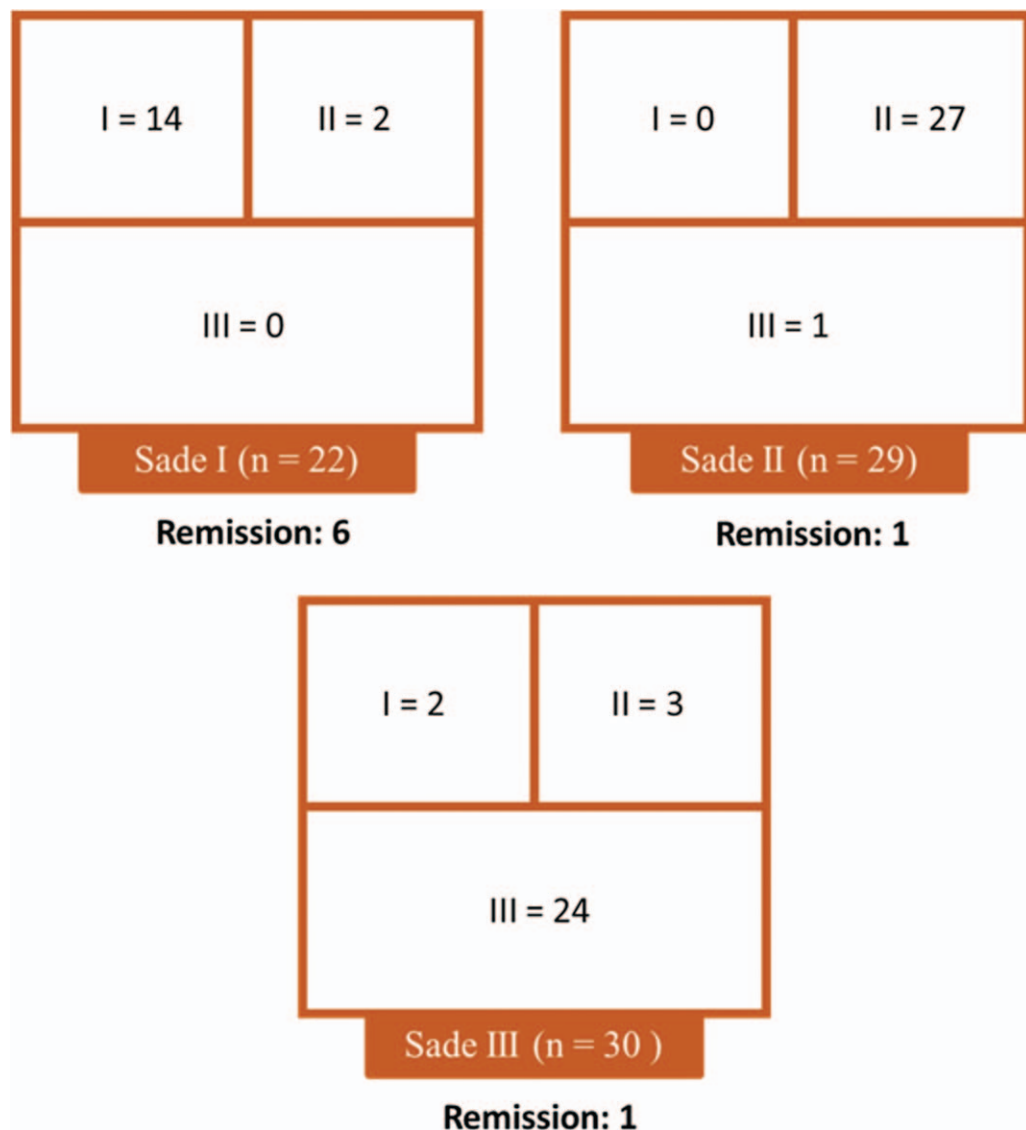
FIG. 4. Distribution of the Sade classification at last visit by Sade classification at first visit. The orange boxes show the number of patients in each of the four Sade classification grades at first visit. The four white quadrants show the distribution of the Sade classification at last visit.

presented with Sade grade II, and 11 patients presented with Sade grade III (55%). At last visit, one patient (5%) was in remission; one patient presented with Sade grade I (5%); seven patients (35%) presented with Sade grade II and 11 patients (55%) presented with Sade grade III. Reintervention occurred in four patients (20%). All four patients received ventilation tubes for OME. Progression to perforation occurred in two patients (10%). Progression to ossicular chain damage also occurred in two patients (10%). There was no progression to cholesteatoma. The mean air-bone gap at first and last visits was 16.6 dB (SD 8.5) and 13.6 dB (SD 10.5), with a mean improvement of +3.0 dB ($p = 0.34$).

Presentation With Otitis Media With Effusion

Twelve patients presented with OME when the TMR was diagnosed. In this group of patients, the mean air-bone gap at first and last visits was 25.3 dB (SD 12.9) and 12.3 dB (SD 8.5), with a mean improvement of +13.0 dB (SD 12.9). In the remaining patients (n = 69), the mean air-bone gap at first and last visits was 16.6 dB (SD 10.6) and 16.1 dB (SD 12.4), with a mean improvement of +0.5 dB (SD 10.9). The difference in hearing gain was statistically significant ($p = 0.001$, T test). Table 3 shows the audiometric results of this cohort without the patients initially presenting with OME. Statistical significance remained between the different Sade grading classifications ($p = 0.02$).

DISCUSSION

Our study describes 71 patients (81 ears) with an oto-endoscopically confirmed retraction in the posterosuperior quadrant of the pars tensa. In this study, there was no

TABLE 3. *Audiometric outcomes (bone, air conduction, and air-bone gap) at first visit and last visit in patients after subgroup analysis (n = 69).*

	Bone Conduction (dB)		Air Conduction (dB)		Air-Bone Gap (dB)			
Parameter	First Visit	Last Visit	First Visit	Last Visit	First Visit	Last Visit	Difference First and Last Visits	*p* Value
Total (n = 69)	11.0 ± 12.8	10.1 ± 13.5	27.6 ± 14.7	26.2 ± 19.6	16.6 ± 10.6	16.1 ± 12.4	0.5 ± 10.9	0.71 [a]
Age ≤ 18 (n = 25)	6.3 ± 5.0	3.6 ± 4.9	22.4 ± 9.0	15.0 ± 9.3	16.1 ± 7.8	11.3 ± 8.1	4.8 ± 9.7	**0.01** [a]
Age > 18 (n = 44)	13.7 ± 15.0	13.8 ± 15.4	30.5 ± 16.5	32.6 ± 21.0	16.8 ± 12.0	18.8 ± 13.7	−2.0 ± 10.7	
Sade first visit								
I (n = 15)	12.6 ± 14.6	11.0 ± 16.0	28.2 ± 12.2	21.1 ± 18.1	15.6 ± 12.8	10.1 ± 9.0	5.5 ± 12.5	**0.02** [b]
II (n = 24)	10.1 ± 14.5	9.1 ± 14.9	27.2 ± 17.4	25.3 ± 23.2	17.1 ± 9.5	16.6 ± 10.8	0.8 ± 10.9	
III (n = 30)	11.0 ± 10.4	10.6 ± 11.2	27.6 ± 13.9	29.6 ± 16.7	16.6 ± 10.8	19.0 ± 11.6	−2.4 ± 9.1	

Patients were removed that presented with otitis media with effusion. Statistical testing was performed on the difference between audiograms of the first and last visits.
[a]*T* test.
[b]ANOVA.
Bold is statistically significant (*p < 0.05*).

progress in hearing loss, audiometric results remained stable, with a minimally insignificant improvement in air bone gap of +2.4 dB (SD 12.1) from an initial air bone gap of 17.9 dB (SD 11.3), $p = 0.08$.

It is difficult to compare results of different management strategies by reviewing the literature because the cohort studied were not similar or comparable. In a report from Borgstein et al. (19), who surgically treated 169 tympanic membrane retractions, the postoperative air-bone gap was slightly better. They found an average air-bone gap improvement of +7.3 dB (air-bone gap) from an initial hearing loss of 13.8 dB (air-bone gap) for the Erasmus grade I–IV patients. The Erasmus classification consists of the following grades; I: tympanic membrane atrophic but not adherent, II: tympanic adherent to the promontory, III: tympanic membrane adherent to incus or stapes, IV: adherent to ossicles with retraction pocket without cholesteatoma (20). However, the baseline characteristics of their cohort were slightly different than this cohort, with a mean age of 9.6 years (SD 3.4). In our subgroup analysis of patients aged 18 years old or younger, an average air-bone gap improvement of +8.0 dB from an initial hearing loss of 19.7 dB (air-bone gap) was found. When comparing these results to the results of Borgstein et al. (19) the audiometric results are similar.

Sade et al. (12) described 308 ears (215 patients) with different types of tympanic membrane retractions who were followed up for average 37 months (range: 12–108 mo). Sixty-eight retractions were found in pars tensa, of which 50 were described as large. Only 1 of the 50 large retractions (2%) progressed into cholesteatoma (average follow-up 34 mo). This is in comparison with our study results; progression to cholesteatoma occurred in one patient (1%).

Parkes et al. (21) described a prospective cohort study of 37 pars tensa retractions in 26 children with cleft palate, a different population that is known for higher risk of OME and Eustachian tube dysfunction, in which a wait-and-see policy was maintained. The median age in this cohort was 15 years (range: 9–21 yr) and the median duration of follow-up was 6.4 years (range: 0.75–7.6 yr). They found that 28 of 37 (76%) retractions had either stable (n = 16) or better (n = 12) outcomes. The incidence of cholesteatoma was 2.6% in an 8.5-year period. In the present cohort 95% of retractions had stable or improvement outcomes on otoscopy.

An argument that has been used against the wait-and-see policy is the possible risk of developing cholesteatoma. However, both our study results and the aforementioned studies show that in the natural course of TMRs the incidence of cholesteatoma is rather low (1–2.6%).

In the patient group aged 18 years old or younger, the level of hearing increases with 8.0 dB (SD 11.8). An explanation for this hearing improvement might be that the middle ear ventilation is improved by the maturation of the Eustachian tube (22,23). Therefore, these children may better regulate the middle-ear pressure, and thus improve or stabilize the retraction. Another possible explanation is that older children are less susceptible to recurrent upper respiratory tract infection and acute OME, as this study had relatively high numbers of older children (n = 26, age > 9 yr old, ≤ 18 yr old). The amount of mild retractions (Sade grade I) was similar in both children (27%) and adults (28%).

Owing to the small numbers of young children (n = 6, age ≤ 9 yr old), it was not possible to make any useful subanalysis in this age subgroup. Larger studies are needed to assess the effect of the wait-and-see policy for this specific age because of the higher rates upper respiratory tract infections and acute OME (24).

Strengths and Limitations

One of the strengths of this study was that it has focused primarily on retractions in the posterosuperior quadrant of the pars tensa, the most commonly affected locations of pars tensa retractions. Furthermore, in all patients oto-endoscopic images and audiometry were

available at first and last visits after a mean follow-up of 64 months. This duration of follow-up is reasonably long and therefore made it possible to assess long-term effects of the wait-and-see policy on audiometric outcomes and progression of the retraction. Also, it allows this study to assess the long-term progression to cholesteatoma and tympanic membrane perforation. Furthermore, this study was the first to be conducted in a cohort consisting of both children and adults.

This study also has a number of limitations that have to be mentioned. First, all the data was retrospectively collected and therefore important baseline characteristics such as cigarette smoking and alcoholic behavior could not be assessed. Owing to missing data we had to exclude 69 ears. After analysis of the excluded patients, it was found that the rate of patients presenting with acute OME was significantly higher in the excluded patient group (37%) compared with the included patient group (15%, $p = 0.006$). Therefore, there might be selection bias as patients with this serious condition are not equally distributed among included and excluded patients. Consequently, this may affect audiometric outcomes in our included patients' group. An explanation for this difference between included and excluded patients might be that patients with acute OME, who were referred by a general practitioner, did not attend the follow-up clinic visit after cessation of complaints. We have therefore subanalyzed the data for OME, because it is thought to give more fragility to the tympanic membrane. In our study, patients presenting with OME had a significantly higher hearing gain (air-bone gap +13.0 dB, SD 12.9) compared with patients not presenting with OME (air-bone gap +0.5, SD 10.9). The relative high gains in the OME group might be explained by cessation of the OME. Another limitation is that the relief of clinical symptoms was based on the physicians' recording on the medical record. These symptoms were not systematically recorded.

Lastly, we recognize the limitations of retrospective analysis of the oto-endoscopic images and the classification by Sade. To be able to classify the retractions using the Sade classification (specifically Sade grades III and IV), it is necessary to perform pneumatic otoscopy to assess whether the retraction is adherent to the promontory. However, it was not systematically recorded in the medical records whether the retraction was adherent and therefore we chose to use an adjusted Sade classification. In this adjusted classification, we chose to only classify what could be visible on the oto-endoscopic image. Therefore, we combined Sade grade III and Sade grade IV into one grade. To reduce the interobserver variation, oto-endoscopic images were assessed by two independent researchers, both researchers had to agree with the final classification. In dubious cases, an experienced otologist assessed and classified the retraction by the Sade classification.

Furthermore, the ossicular chain damage was not systematically collected and was solely based on the descriptions in the medical records and, when the ossicular chain was clearly visible on the oto-endoscopic images. No classification system was used because the entire ossicular chain could not be visualized during otoscopy. Lastly, seven patients in our cohort received ventilation tubes after the wait-and-see policy was initiated. The indication for these ventilation tubes was OME and not for the TMR. These patients with ventilation tubes were not excluded due to the intention-to-treat principle. We have used this principle to mirror expected outcomes seen in real world practice. One excluded patient developed cholesteatoma during follow-up, this patient was excluded due to missing oto-endoscopic images. It was noted in the clinical records that this patient had a retraction and developed cholesteatoma.

Clinical Implications

Based on our data, a wait-and-see policy can be justified in patients with a pars tensa retraction, especially in patients who have mild hearing loss. However, caution should be taken in patients with a pars tensa retraction which involves the promontory (Sade grade III) at the first visit to the otorhinolaryngology clinic. The decision to operate a patient should be individually discussed and be based on the age of the patient, severity of the retraction, and the initial amount of hearing loss. A large prospective study is needed to confirm these results.

CONCLUSION

The majority of tympanic membrane retractions in the posterosuperior quadrant remained stable in terms of audiometric outcomes and otoscopy in patients who did not receive any treatment. Progression to cholesteatoma or perforation was rare in this cohort. Shared decision making regarding TMRs should include discussion of a wait-and-see policy.

REFERENCES

1. Maw AR, Hall AJ, Pothier DD, Gregory SP, Steer CD. The prevalence of tympanic membrane and related middle ear pathology in children: A large longitudinal cohort study followed from birth to age ten. *Otol Neurotol* 2011;32:1256–61.
2. Danner CJ. Middle ear atelectasis: What causes it and how is it corrected? *Otolaryngol Clin North Am* 2006;39:1211–9.
3. Ruah CB, Schachern PA, Paparella MM, Zelterman D. Mechanisms of retraction pocket formation in the pediatric tympanic membrane. *Arch Otolaryngol Head Neck Surg* 1992;118:1298–305.
4. Sade J. Atelectatic tympanic membrane: Histologic study. *Ann Otol Rhinol Laryngol* 1993;102:712–6.
5. Tucker A, Fuchs J, Thompson H. Embryonic origin of the middle ear and its impact on function: Presenting Author: Abigail Tucker. *J Laryngol Otol* 2016;130:S29–129.
6. Sade J, Berco E. Atelectasis and secretory otitis media. *Ann Otol Rhinol Laryngol* 1976;85 (2 suppl 25 pt 2):66–72.
7. Alzahrani M, Saliba I. Tympanic membrane retraction pocket staging: Is it worthwhile? *Eur Arch Otorhinolaryngol* 2014;271: 1361–8.
8. Aimoni C, Cappiello L, Ciorba A, Bovo R, Martini A. Tympanic atelectasis in children and early surgical approach: The Ferrara experience. *J Int Adv Otol* 2011;7:293–8.

9. Jesic SD, Jotic AD, Babic BB. Predictors for sensorineural hearing loss in patients with tubotympanic otitis, cholesteatoma, and tympanic membrane retractions. *Otol Neurotol* 2012;33:934–40.

10. Borgstein J, Gerritsma TV, Bruce IA. Erosion of the incus in pediatric posterior tympanic membrane retraction pockets without cholesteatoma. *Int J Pediatr Otorhinolaryngol* 2008;72:1419–23.

11. Chole RA, Tinling SP. Basal lamina breaks in the histogenesis of cholesteatoma. *Laryngoscope* 1985;95:270–5.

12. Sade J, Avraham S, Brown M. Atelectasis, retraction pockets and cholesteatoma. *Acta Otolaryngol* 1981;92:501–12.

13. Charachon R, Barthez M, Lejeune JM. Spontaneous retraction pockets in chronic otitis media medical and surgical therapy. *Ear Nose Throat J* 1992;71:578–83.

14. Nankivell PC, Pothier DD. Surgery for tympanic membrane retraction pockets. *Cochrane Database Syst Rev* 2010;7:CD007943.

15. Alper C, Olszewska E. Assessment and management of retraction pockets. *Otolaryngol Pol* 2017;71:1–21.

16. Yung M, Tono T, Olszewska E, et al. EAONO/JOS Joint Consensus Statements on the Definitions, Classification and Staging of Middle Ear Cholesteatoma. *J Int Adv Otol* 2017;13:1–8.

17. Austin DF. Ossicular reconstruction. *Arch Otolaryngol* 1971;94: 525–35.

18. Fletcher H, Munson WA. Loudness, its definition, measurement and calculation. *J Acoust Soc Am* 1933;5:82–108.

19. Borgstein J, Gerritsma T, Bruce I, Feenstra L. Atelectasis of the middle ear in pediatric patients: Safety of surgical intervention. *Int J Pediatr Otorhinolaryngol* 2009;73:257–61.

20. Borgstein J, Gerritsma TV, Wieringa MH, Bruce IA. The Erasmus atelectasis classification: proposal of a new classification for atelectasis of the middle ear in children. *Laryngoscope* 2007;117:1255–9.

21. Parkes W, Vilchez-Madrigal L, Cushing S, Papsin B, James A. Natural history of tympanic membrane retraction in children with cleft palate. *J Int Adv Otol* 2018;14:250–4.

22. Canali I, Rosito LPS, Siliprandi B, Giugno C, Costa SSd. Assessment of Eustachian tube function in patients with tympanic membrane retraction and in normal subjects. *Braz J Otorhinolaryngol* 2017;83:50–8.

23. Bylander A, Tjernstrom O. Changes in Eustachian tube function with age in children with normal ears. A longitudinal study. *Acta Otolaryngol* 1983;96:467–77.

24. Teele DW, Klein JO, Rosner B. Epidemiology of otitis media during the first seven years of life in children in greater Boston: A prospective, cohort study. *J Infect Dis* 1989;160:83–94.