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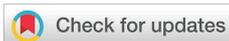
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Research Article

Clinical prognostic index for tympanoplasty (PRIT) in Pediatric patients

Abstract

Objective: Pediatric myringoplasty surgical failure reported is generally attributed to different factors. The purpose of this study is to develop a clinical index based on some of these factors, which will allow surgical prognosis to be predicted.

Methods: This was a cohort study of 148 patients who underwent myringoplasty and received a 6-month follow-up during the period from January 2005 to March 2107 Variables with risk for failure (RR 95%) were introduced into a logistic regression, with those with significance being selected. The following were included for the index: otorrhea, contralateral ear status and marginal perforation (clinical significance), which were assigned values of 6, 3, and 1, respectively, with adjustments being made for age.

The PRIT > 30 or < 30 cutoff point was obtained by means of ROC.

Results: A success rate of 59.6% was reported. Otorrhea, with an OR of 11.859 (95% CI: 2.441-57.626) and an assigned value of 6, contralateral ear abnormal status, with an OR of 2.484 (1.181-5.223) and an assigned value of 3, and marginal perforation, with an OR of 2.717 (.857-8.611) and an assigned value of 1, were included in the PRIT index. Adjustment was made for age, and the cutoff point was established at > 30 (p < 0.001).

Conclusions: Construction of the index was achieved. One shortfall of the study is that only one third of patients were < 7.5 years of age, which might represent a bias. All results correspond to a 6 months follow-up period. Validation will be carried out in a subsequent study.

Introduction

Factors commonly associated with otologic surgery outcome in the pediatric patient are directly related to cranial dimensions of the child and adequate function of the middle ear [1,2], which directly depends on the eustachian tube (ET) and is even further compromised if the patient has any craniofacial malformation such as cleft lip and palate (CLP) [3], or syndromic disorders such as trisomy 21 [4], just to mention some examples [5].

Assessment of the eustachian tube in a perforated ear can be difficult [6] and we can therefore resort to the contralateral ear function to assess both tubes function and their relationship with the nasopharynx [7,8].

Myringoplasty success in children ranges from 35% to 92% [9] and these results are generally attributed to different patient selection criteria [10] and/or surgical success definition

by the author [11]. Some define myringoplasty success solely as integration of the tympanic membrane graft [12]. A more complete definition of success is: 1) Tympanic membrane or graft without evidence of perforation at the last clinic visit. 2) Hearing improvement of at least 20 dB or no auditory threshold decrease, and 3) aerated middle ear space, expressed by a tympanic membrane in anatomic position without atelectasis, retraction or lateralization [13,14]. For the purposes of this study, the latter will be the definition of success.

In 2012, Boronat et al. reported a retrospective cohort of 44 patients with 53.6% of tympanoplasty success, and associated seven logistic regression-obtained variables that intervene in surgical outcome; [15] they proposed these variables as a prognostic model for surgical outcome, but the results were not entirely conclusive owing to the sample size. Dornhoffer [16], analyzed a retrospective cohort of 1000 patients, out of which 129 were pediatric patients, and found discouraging differences between myringoplasty success and patient age at

the moment of surgery [17]. Manning found that ET adequate function was a predictive factor for good surgical outcome [18]. Other factors such as perforation type and size, presence of otorrhea, the surgeon, the surgical technique, etc. have been studied as risk factors for surgical outcomes, but the reports are heterogeneous.

There is no clinical preoperative assessment method that allows for tympanoplasty outcome to be predicted in pediatric patients. We believe that having a tool such as the proposed index, the Prognostic Index for Pediatric Tympanoplasty (PRIT), will be useful for the otorhinolaryngologist, since it is a practical instrument.

Material and Methods

This was an ambispective cohort study carried out at the otorhinolaryngology department of a pediatric tertiary care hospital from January 2005 to May 2017.

Sample size

The calculation is based on events per variable for multivariate analyses, with at least 10 patients per variable in the logistic regression.

Criteria for sample selection

All patients with tympanic membrane perforation for any cause who underwent type I tympanoplasty or myringoplasty were included.

Inclusion criteria

Patients aged 5-16 years, with or without craniofacial alterations, with or without otorrhea, with or without contralateral ear altered status, with or without adenoidectomy, with lateral or medial technique, preoperatively assessed with tonal audiometry or brainstem auditory evoked potentials with latency-intensity curve, with hypoacusis of up to 40 dB were included. Participants also had to have 6-month postoperative audiometric evaluations available, in addition to complete medical records.

Statistical analysis

One hundred and sixty-one patients were included. Descriptive statistics were used for baseline dichotomous variables (gender, time of evolution, perforation size, perforation type, surgeon, cause of perforation, previous adenoidectomy, history of craniofacial malformation and status of contralateral ear), with values expressed as simple frequencies and percentages, and for quantitative variables (age in years), medians and IQR were reported owing to their free distribution.

Bivariate analysis

The gender, perforation site, contralateral ear status, cause of perforation, craniofacial malformation, otorrhea, mucosal status, etc. variables were analyzed using the χ^2 test or Fisher's exact test contrasted with anatomic-functional success. In

the cases where the variable was quantitative or ordinal (age, degree of perforation, pre- and postsurgical auditory threshold), receiver operating characteristics (ROC) curves were constructed to look for cutoff points and make them dichotomous. In all cases, the clinical relevance measure was weighted using the odds-ratio (OR) with the corresponding 95% confidence interval (CI).

Multivariate analysis

Logistic regression was used, with anatomic-functional success as the dependent variable. In this model, those variables that achieved statistical significance in the bivariate analysis were included and variables that in clinical practice constituted a risk factor, such as age and perforation type or size, were added.

Prognostic index model

Possible risk factors were weighed, and those with the highest statistical relevance were assigned a value. Adjustment was made for age, since craniofacial development is regarded by many authors as an important factor for prognosis [19] and a ROC curve was constructed with the purpose to find an optimal cutoff point for the PRIT scale.

The PRIT significance was analyzed using the [2], test, contrasting the resulting cutoff point vs. failure. In all cases, a p-value < 0.01 was considered to be significant. The analyses were carried out using the SPSS 21.0 software.

According to the 2008 Declaration of Helsinki and its subsequent amendments for biomedical research studies involving human subjects [2021], as well as to local regulations on health research [22], this work is classified as minimal risk research.

Results

General characteristics of the population

The cohort included 161 patients of 5 to 16 years and 11 months of age, with tympanic membrane perforation for any cause and superficial hypoacusis, who were programmed for myringoplasty or type I tympanoplasty between January 2005 and March 2017. Thirteen patients were excluded due to some extension of the surgical technique.

To construct the PRIT index, 148 patients were analyzed, out of which 2 (1.42%) were lost to followup at six months. Of the remaining 146 patients, 65.9 (45.20%) were females, the most common cause of perforation was otitis media (75.34%), 47.8% had inferior localization, in 49.3%, the perforation size was 25-50%, and most perforations (89%) were of the central type. No craniofacial malformations were observed in 91.1% of the population and the remaining 8.9% had CLP sequels; adenoidectomy prior to tympanoplasty had only been performed in 50 patients (34.2%).

Fourteen patients with otorrhea were intervened, which accounted for 9.8%, and approximately half of intervened

patients (75, 52.36%) had some type of contralateral ear abnormality, generally tympanic membrane perforation or serous otitis media (Table 1).

Anatomo-functional success

Anatomo-functional success was obtained in 59.6% of cases. For the bivariate analysis of all qualitative variables [2], was calculated, and surgical outcome was observed to be directly affected by otorrhea ($p < 0.0001$), as well as by contralateral ear abnormal status ($p < .024$), with no other variable being significant for surgical outcome. For quantitative variables (mean auditory threshold and age), ROC curves were constructed in order to establish cutoff points. Once the cutoff point was available, quantitative variables were analyzed similarly to the other variables, and were not significant when contrasted with the surgical outcome; however, the age variable remained for the rest of the analysis owing to its biological importance (Table 2).

Table 1: Population demographics.

n= 146 (100%)	Frequency Total (%)	Success n=87 (59.6%)	Failure n= 59 (40.4%)	P
Age * (IQR)		10 (5-16)	11 (6-16)	0.138
Females**	45.2	42 (63.3)	24 (36.4)	0.365
Diagnosis:**				
Post-VT	12.3	59 (62.8)	35 (37.2)	0.316
Traumatic	12.3	10 (55.6)	8 (44.4)	0.667
Infectious	75.34	67 (60.9)	43 (72.9)	0.570
Perforation size***				
0-25 %	16.4	17 (19.5)	7 (11.9)	0.226
25-50%	49.3	43 (49.4)	31 (52.5)	
51-70%	26.7	22 (25.3)	15 (25.4)	
71-100%	7.5	5 (5.7)	6 (10.2)	
Perforation site:**				
Anterior	24.4	25 (62.5)	15 (37.5)	0.660
Posterior	17.8	14 (51.9)	13 (48.1)	0.364
Inferior	47.8	43 (62.3)	26 (37.7)	.525
Subtotal	7.5	5 (45.)	6 (54.5)	0.320
Perforation size**				
< 50%	69.2	62 (71.3)	43 (72.9)	0.854
> 50 %	30.8	25 (28.7)	16 (27.1)	
Craniofacial malformations**				
No	91.1	79 (59.4)	54 (40.6)	0.881
Yes	8.9	8 (61.5)	5 (38.5)	
No adenoidectomy **	65.8	58 (60.4)	38 (39.6)	0.778
Adenoidectomy	34.2	29 (58.0)	21 (42.0)	
Surgeon **				
Resident	38.4	35 (43.2)	21 (37.5)	0.572
Associate specialist	61.6	52 (57.8)	38 (42.2)	
Type of perforation**				
Central	89	79 (60.8)	51(39.2)	0.407
Marginal	11	8 (50)	8 (50)	
Contralateral ear status**				
Normal	48.63	49 (69.0)	22 (31.0)	0.024
Abnormal	51.36	38 (50.7)	37 (49.3)	
Otorrhea**				
No	90.41	85 (64.4)	47 (35.6)	0.000
Yes	9.5	2 (14.3)	12 (85.7)	

All variables reported as simple frequencies, except for age, which is expressed as the median and IQR. The rest of the analysis was carried out with the χ^2 test.

Table 2: Factors associated with failure.

Variable	Failure	RR	95% CI
Otorrhea	35.6%	2.41	1.76 – 3.29
Perforation size >50%	27.1 %	1.015	0.661 - 1.558
Contralateral ear abnormal status	49.3%	1.59	1.05 - 2.41
Adenoidectomy	42.0%	1.06	0.7 – 1.6
No adenoidectomy	39.6%	0.94	0.63 - 1.42
Marginal	50%	1.27	0.75 - 2.18
Craniofacial malformation	38.5%	0.95	0.46 - 1.94
Males	63.6%	1.2	0.8 - 1.8
Chronic otitis media	72.9%	0.87	0.57 - 1.33
Inferior perforation	37.7%	0.92	0.62 - 1.36
Junior surgeon	37.5%	0.89	0.59 - 1.35
Age < 7.5 years	6.8%	0.46	0.79 – 1.37

Factors related to failure

For the multivariate analysis, the selected variables were those that have been commonly reported by other authors as probable factors for failure, including the work that was previously carried out in our department by Boronat et al. in 2012. All variables were analyzed, contrasting them with anatomo-functional success (success of all 3 variables), with the OR being calculated with the corresponding 95% CI (Figure 1).

According to data shown in table 2, failure occurs 2.4 fold more frequently in patients with otorrhea than in those without it (95% CI: 1.76-3.29); patients whose contralateral ear has inflammatory pathology, such as chronic suppurative otitis media or serous otitis media have 1.59fold more failure than patients with a healthy contralateral ear (95% CI: 1.05-2.41) (Figure 1).

Marginal perforation shows that patients with this type of perforation have 1.27 fold higher risk for experiencing failure than those with central perforation (95% CI: 0.752-1.8) ; in spite of the CI crossing the value of 1 , this variable was taken as the third one because, from the clinical point of view, it is regarded as a dangerous perforation.

Integration of variables to the index model

All variables introduced to the regression satisfy the minimum sample size ($n > 10$), and are therefore considered to have statistical power. According to table 3 results, gender, with an OR of 1.570 (95% CI: 0.754 -3.266), perforation size > 50%, with an OR of 0.834 (95% CI: 0.373-1.861) and the age < 7.5 years variable, with an OR of 0.512 (95% CI: 0.196-1.337), are no risk factors for surgery failure (Figure 2). Although dichotomous age has been shown not to be a risk factor, the PRIT index model was adjusted for the age in years.

Elaboration of the PRIT index

With logistic regression-associated values and clinical variables, a PRIT model is proposed. This model weighs

potentially predictive variables according to the ORs significance and, in this case, otorrhea was assigned a value of 6 (OR: 11.59; 95% CI: 2.441-57.626), 3 points were assigned to the contralateral ear abnormal status variable (OR: 2.484; 95% CI: 1.181-5.223) and 1 point to marginal perforation (OR: 2.717; 95% CI: .857-8.611) (Table 3), with a possible score of 0 to 10 points resulting when added up, according to the assessed clinical characteristics. For the creation of the index, this value was adjusted for the age in years, that is, total score was multiplied by the patient's age in years (Table 4).

The PRIT score was calculated for each patient and subsequently, by means of a ROC curve, 30 points was established as the cutoff point, with a sensitivity of 80% and specificity of 80%.

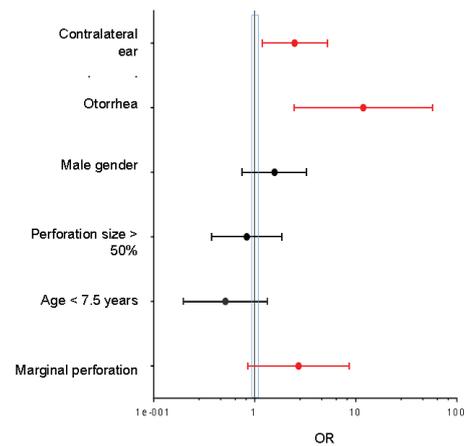
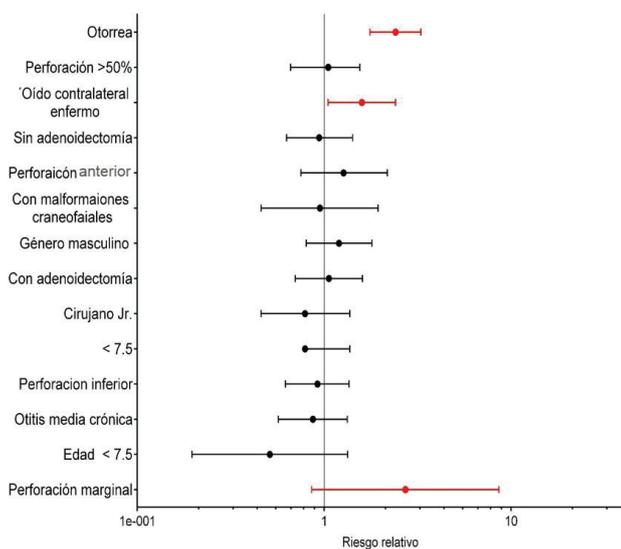


Figure 2: Risk factors for failure. Forest plot showing more clearly that the otorrhea and contralateral ear status variables, as well as marginal perforation, represent risk factors for failure, since the latter does not touch the interval (0.85 - 1.25). OR: odds ratio.

(A)



(B)

Variables resulting from the analysis	Clinical variables proposed for the PRIT
Gender	Age
Type of perforation	Otorrhea
Otorrhea	Contralateral ear status
	Type of perforation
	Perforation size >50%

Figure 1: Variables associated with failure. A. Forest plot showing more clearly those factors that can be associated with failure, as observed by the IC (95%). B. table in the bottom section the clinical variables proposed for the index (PRIT).

Table 3: Logistic regression for the PRIT index construct.

Variable	β	p	OR	95 % CI	
				Lower	Upper
Presence of otorrhea	2.473	0.002	11.859	2.441	57.626
Contralateral ear abnormal status	0.910	0.016	2.484	1.181	5.223
Marginal perforation	0.999	00.090	2.717	0.857	8.611
Gender	0.451	0.228	1.570	0.754	3.266
Perforation size > 50%	-0.182	0.657	0.834	0.373	1.861
Age < 7.5 years	-0.670	0.171	0.512	0.196	1.337
Constant	-2.717	0.009	0.066		

Table 4: Example of the PRIT index clinical use.

PRIT index	Value	Clinical weighing	X age
Contralateral ear abnormal status	1		5 years
Inferior perforation	3	3	
Otorrhea	6	6	
Total		9	45

Clinical use of the PRIT index is hypothetically exemplified above; on both examples, a 5-year-old patient is assessed.

Risk associated to the PRIT value

Age-adjusted clinical significance of the proposed PRIT (< 30 and > 30 points) was analyzed against the failure outcome variable using Pearson's [2], test with a pvalue < 0.001.

The values expressed in table 5 clearly show that patients who obtained a PRIT score > 30 points have a 2.3-fold higher risk for experiencing failure than those with < 30 points.

Discussion

There are numerous articles [23] that try to reach a consensus on the risk factors tympanoplasty failure might be attributed to in the pediatric population [24]. Surgical success obtained in the present analysis is 59.6%, which is similar to that reported by Boronat et al. in 2012, but with regard to risk factors that produce failure there is considerable controversy or lack of homogeneous evidence.

One of the most controversial factors is patient age. The cutoff point in our study was 7.5 years, similar to that reported by Splete [25], where the age to consider surgery is suggested to be above 7 years. By itself, age had no statistical significance, as opposed to findings in a meta-analysis reported in 2015 [26], but when interacting with other variables such as otorrhea, contralateral ear status and type of perforation or marginal perforation [27] (the PRIT model), age was able to significantly predict failure (p < 0.001).

Table 5: Relative risk for failure with the PRIT index.

PRIT	Failure n =59 (40.4%)	RR	95% CI
< 30	33.9%	0.43	0.28 - 0.67
> 30	66.1%	2.3	1.5 – 3.53

Otorrhea has no statistical significance in multiple reports [28], such as the one by Onal in 2005; however, in our study, otorrhea was significant since the beginning of the analysis ($p < 0.001$), and at risk estimation, it was shown to be an important factor for failure (RR: 2.41; 95% CI: 1.76 – 3.29) [29]. Otorrhea was mentioned as a factor that can directly affect surgical outcome by Lin et al. in 2008, but many other studies report having practiced this type of surgeries in patients with otorrhea with good results being obtained. In the multivariate analysis [30], otorrhea was clearly the most relevant variable in the outcome of failure with an OR of 11.859 (95% CI: 2.441–57.626), followed by the contralateral ear abnormal status variable (OR: 2.484; 95% CI: 1.181–5.223).

Craniofacial postnatal development apparently should be taken into account when programming any ear surgery since, at younger ages, the ET function is not fully adequate and, in addition, at pediatric age, its anatomical situation seems to put the patient in disadvantage prior to 7.5 years of age, which is consistent with Boston pediatric hospital experience, where only the age younger than 8 years was reported to be significant for failure [31]. In contrast, other authors claim that age has nothing to do with tympanoplasty outcomes in children [32,33]. On the other hand, Hassman concluded that contralateral ear abnormal status must be taken into account, since it is an indicator of nasopharyngeal pathology that might affect ET correct functioning [34].

The type of perforation is also important. In some textbooks of the specialty, marginal perforations [35] have been referred to as dangerous or insecure perforations, since the remnant eardrum in the tympanic perforation acts as a barrier that prevents squamous epithelium of the duct from migrating to the middle ear [35]. In the logistic regression carried out in this study, the marginal perforation type was found to be the third most relevant variable, in spite of the CI crossing the null hypothesis value of 1, with an OR of 2.717 (95% CI: .857–8.611). This type of perforations have also been associated with failure by Schraff and by Mendes R [35].

Conclusions

Tympanoplasty success was obtained in 59.6% of pediatric patients. The construction of the PRIT model for clinical use in tympanoplasty planning for pediatric patients was achieved ($p < 0.001$). Tympanoplasty failed in 40.4% of patients, and the variables that influenced on the outcome were otorrhea and contralateral ear status. All results correspond to a 6 months follow-up period.

Perspective

Validation of this index is necessary making sure there is

a balance, especially in the sample of groups by age, in order to assess if age really represents a risk for surgical outcomes.

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