Learning curve in Endoscopic Tympanoplasties: a prospective study based on outcomes of 141 cases.

RUNNING TITLE – Learning Curve in 141 Endoscopic TPLs.

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Title: Learning curve in Endoscopic Tympanoplasties: a prospective study based on outcomes of 141 cases.

Key points:

1. The overall success rate for TEES tympanoplasty was 83%
2. A learning curve of approximately 60 cases was evident, with success in the final 33% of cases being 93.5%
3. The only significant factor affecting the tympanoplasty success rate was the year since starting TEES.
4. Hearing outcomes are related to pre-operative ABG, ossicle erosion, and COM risk factors, but not to the level of experience in TEES.
5. TEES has comparable outcomes, efficacy and complications to microscopic or combined techniques

Keywords: endoscopic ear surgery, TEES, tympanoplasty, outcomes, success rate, learning curve, chronic otitis media.

Level of Evidence: 3.

Acknowledgments: none.

1. OBJECTIVES

Trans-canal endoscopic ear surgery (TEES) was introduced in the 1990s and since then, an increasing number of studies has described the various applications and safety of the endoscopic approach[1-3]. The main advantages of TEES are the magnification of the surgical field, the improved visualisation of anatomical recesses, the avoidance of external incisions and mastoid drilling, the reduction in pain, operation time and improved quality of life[4]. Our study aimed to analyse the TEES outcomes to identify the effect of a learning curve.

2. DESIGN

2.1 Study design & Setting

A prospective study of TEES tympanoplasties performed in one centre by a single senior otologist, from 2014 when TEES was introduced till 2018. All the patients had chronic otitis media (COM) with or without cholesteatoma.

STROBE reporting guidelines have been followed in conducting this study.

2.2 Statistical analysis

Dependant variables were: tympanoplasty success (intact tympanic membrane and non-discharging ear (yes/no)), and hearing gain (dB) as a secondary outcome measure. Independent variables are highlighted in Table 1.

Analyses included univariate (UVA) Chi-Squared tests and general linear models, and multivariate (MVA) general linear models, with Bayesian information criterion (BIC) factor extraction. Variance inflation factor was utilised to identify co-variates. Cartilage use and ossicular reconstruction required exclusion from MVAs as they demonstrated too much co-variance when analysed in conjunction with other variables. A moving average (MA) assessment was performed with an analysis of the relationship using Spearman's rank correlation coefficient. Statistical testing was performed with the use of R statistical software through RStudio (version 1.1.463). P values <0.05 were considered statistically significant.

2.3 Surgical technique

The Procedures were performed using 14 cm rigid endoscopes (Storz®, Tuttlingen Germany), and HD 3CCD chip cameras (Stryker®, Kalamazoo USA). The operations performed were myringoplasties, tympanoplasties, atticotomy or atticoantrostomy, with or without ossiculoplasty. In 106 cases, the graft material used was tragal cartilage-

perichondrium. Temporalis fascia was used in 3 and porcine submucosa graft (Biodesign®, Cook medical) was used in 34 and details are not available in one (Tab 1).

3. PARTICIPANTS

141 tympanoplasties were performed, which included 76 females and 65 males, with a mean age of 33 years (5-77), 71 were on the left and 70 on the right side (Tab 1). Operations in which a graft was not performed and patients who had less than 6 months of follow-up or incomplete information were excluded.

3.1 Post-operative follow-up

Patients' first follow up was normally after 20 days in cases requiring packing removal. All patients were then reviewed at 3, 6, 12 months, and every 12 months for the next 5 years in cases of cholesteatoma.

3.2 Data collection

All data were entered prospectively in the Common Otology Audit (http://www.ear-audit.net/), a web-based international database, tailored to collect and monitor results of ear operations. If required, the data was verified using electronic patient records. Audiological outcomes were calculated according to the AAO-HNS standards[5].

3.4 Ethical considerations

This project was approved as a clinical audit, and therefore ethical approval was not required.

4. MAIN OUTCOME MEASURES

Intact tympanic membrane was the main outcome measure, audiological improvement was used as a secondary measure.

5. RESULTS

5.1 TEES outcomes

The overall success rate for intact tympanic membrane was of 83%, reaching 93.5% in the last 2 years (Fig. 1). The mean hearing gain was of 4.25 dB. Mean follow-up was of 22 months. Comparing TEES tympanoplasties outcomes to non-endoscopic procedures

(microscopic and combined) performed in the same centre, no significant difference was noted, both for the success rates with complete closure of perforation (OR 0.91, 95% CI 0.43-1.89, p=0.791) and the hearing gain obtained (HR 0.28, 95% CI 0.01-13.3, p=0.519).

5.2 Factors affecting tympanoplasty outcomes

Analysing outcomes on UVA, TEES success rate was solely affected by the operative year (χ2=12.3, df=4, p=0.015). However, this did not maintain significance on MVA.

There were no significant differences due to age, laterality, site and size of perforation, discharging ear, type of graft and presence of cholesteatoma or ossicular erosion (table 1).

Not surprisingly, the greater post-operative hearing gain was associated with a wider pre-operative ABG (HR 1.83, 95% CI 1.52-2.21, p<0.005), larger perforation size (HR 1.19, 95% CI 1.09-1.31, p<0.005), and perforation type (i.e. single site or multisite) (HR 0.001, 95% CI 0-0.21, p=0.012), in UVA. In MVA, improved hearing outcomes were associated with a wider pre-operative air-bone gap (ABG) (adj. HR 2.28, 95% CI 1.84-2.82, p<0.0005), absence of ossicular erosion (adj. HR 0.0003, 95% CI <0.005-0.03, p<0.005) and the presence of risk factors for chronic otitis media (adj. HR 4608, 95% CI 2.31-9160432, p=0.032)

5.3 Learning curve

The operative success was significantly affected by the year of operation (Fig. 1A). However, the presence of a learning curve becomes more apparent when analysing the data by thirds, thus obtaining numerically equal groups. Success rate becomes 75%, 80.9%, 93.5%, with each progressive third (Fig. 1B). Moving averages confirms this, with a significant improvement over time (S=55178, p=<0.005), and evidence of flattening of the learning curve after approximately 60 cases (Figure 2). No clear relationship was established between hearing gain and the operator experience. The mean hearing gain was of 7.2db, 2.8dB, 4.1dB in the 1st, 2nd and last thirds, respectively. MA confirms the absence of a significant relationship between hearing gain and the learning curve.

Over the study period, there was a trend of increased use of TEES from 48% of all ear surgeries in the first year (2014) to 78% in the fifth year (2018). At the same time, the rate of microscope only procedures dropped from 47% to 8% of cases (Figure 3). There were 38 cases where the procedure had to be converted to a microscopic approach: the reason for conversion was predominantly the presence of cholesteatoma extending beyond the level of

mid-point of the lateral semi-circular canal (89% of converted cases). Other rarer causes were narrow external auditory canal (n=3) and glomus tympanicum (n=1).

5.4 TEES Complications

Post-operative complications included 9 wound infections, 7 myringitis, 2 external ear canal granulations and one case of neuropathic pain and tinnitus. These appear to be similar to the complication rates occurring in microsurgical procedures, either in the literature or in our hospital[6].

6. DISCUSSION

The success of tympanoplasty usually depends on several factors, such as patient and operative variables[7,8]. This study shows the presence of an operative learning curve of approximately 60 cases, having accounted for other potential confounding factors. A significant difference has been found between the healing rates according to the year in which the patient was operated on. However, this was non-linear, with an initial high success rate (86%), decreasing in subsequent years to 65% and 74% respectively, before improving again to 92-94% success rates in the final two years (Figure 1A). This suggests the presence of a learning curve accounting for the differing success rates over the years, with a decrease in success rates as more challenging cases were adopted in the 2nd and 3rd years e.g. higher number of patients with actively discharging ears - which may account for the apparent trend. The learning curve becomes more evident when analysing outcomes by data thirds (Figure 1B), and using MA analyses, with 60 patients required before flattening of the learning curve (Figure 2). Also, poorer TEES operative results correlated with larger pre-operative ABG, which likely relate to more advanced pathology.

A secondary outcome measure for the study was the amount of hearing gain achieved. A large pre-operative ABG was the most statistically significant predictor of greater hearing gain as expected, having a greater conductive defect to correct. Ossicular erosion was found to negatively correlate with hearing gain, even with ossiculoplasty. When these results are taken in combination, it indicates that the greatest hearing gain is achieved through tympanic membrane repair, especially if the perforation is large (Tab. 1). Finally, the greater hearing gain was associated with the risk factors for chronic otitis media. The authors have postulated that it may be that these patients were more likely to have an active ear, and therefore to

achieve improvement in the operated ear. Hearing gain post-operatively was not affected by the operative learning curve.

The majority of the unsuccessful cases had a pinhole perforation with a dry ear, rather than significant re-perforation. Furthermore, complication rates were low in the TEES group and comparable to the patients who had microsurgery. This highlights the safety of endoscopic tympanoplasty, with similar results in the literature[7,9,10].

While our study shows the learning curve of endoscopic ear surgery, it also emphasises the importance of continued microscope-assisted operating, allowing the surgeon to tailor the operation to the patients' needs.

One of the main limitations of this study is that the operations were performed by a single surgeon. Therefore, applicability to a broader cohort needs to be assessed.

7. CONCLUSION

Trans-canal endoscopic ear surgery demonstrated comparable outcomes to microsurgery. As with any surgical technique, TEES has a learning curve. In our experience, the effect of the learning curve is overcome after 60 cases.

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Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Table 1: **TEES Operative outcomes and hearing gain by factor.**

TEES operative outcomes and hearing gain by factor							
Factor		**Operative Outcome**		**% Success**	**p-value (outcome)**	**Hearing Gain (dB)**	**p-value (hearing gain)**
		Success	**Failure**				
Sex	Male	55	10	84.6	0.633	+6.5	0.145
	Female	62	14	81.6		+3.0	
Age (years)		33	33	-	0.943	-	0.539
Operation Year	2014	12	2	85.7	**0.015**[b]	+6.5	NS
	2015	17	9	65.4		+5.1	
	2016	23	8	74.2		+3	
	2017	36	3	92.3		+7.7	
	2018	29	2	93.5		+1.5	
Laterality	Left	59	12	83.1	0.97	+5	0.808
	Right	58	12	82.9		+4.4	
Risk factors present	Yes	11	0	100	0.989	+9.4	**0.032**
	No	106	24	81.5		+4.2	
Smoker	Yes	80	17	82.5	0.813	+5.6	0.604
	No	37	7	84.1		+4.3	
Perforation size (%)		34.3	32.9	-	0.796	-	**<0.005**
Perforation category[a]	Single	68	12	85	0.233	+2.3	**0.012**
	Multi	32	10	76.2		+9.1	
	NA	17	2	-		-	
Cholesteatoma	Yes	38	6	86.4	0.547	+1.6	0.086
	No	79	17	82.3		+6.1	
	NA	0	1	-		-	
Ossicle erosion	Yes	57	8	87.7	0.245	+3.7	**<0.005**
	No	57	14	80.3		+5.4	
	NA	3	2	-		-	
Otorrhoea	Yes	43	10	81.1	0.544	+4.0	0.655
	No	74	13	85.1		+5.1	
	NA	0	1	-		-	
Pre-operative ABG (dB)		21.1	23.9	-	0.264	-	**<0.005**
Autograft	Yes	91	15	85.8	0.102	+5.7	0.121
	No	25	9	73.5		+1.3	
	NA	1	0	-		-	

Table 1: Displaying operative outcomes and hearing gain in TEES, categorised by factor assessed. Success is defined as successful closure of the perforation. The displayed p value is calculated from univariate analysis general linear models (GLMs), and highlighted in bold if significant. If significance is maintained on multivariate analysis, then the multivariate GLM (BIC extraction) p-

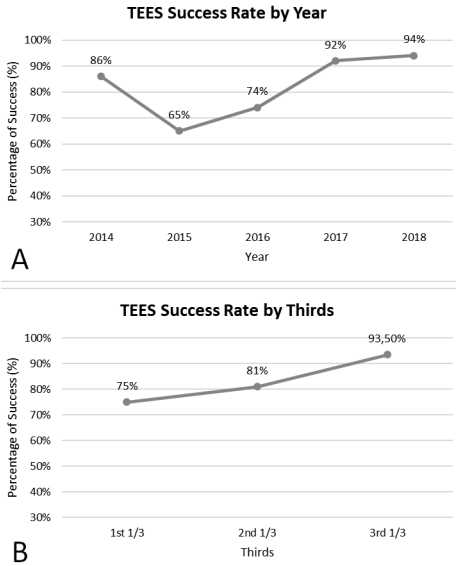
value is displayed underlined. Missing data is identified within the table under the category 'NA'. [a]Perforations categorised into single quadrant or >1 quadrant. [b]Result displayed calculated from Chi-square test.

FIGURES LEGEND

Figure 1: TEES success rate variation by year (%) [A] and dividing the cases by progressive thirds (%) [B].

Figure 2: Moving average success rates for TEES, over time, by case cohorts of 25 patients each.

Figure 3: Tympanoplasty approaches trends (%) over time (years).



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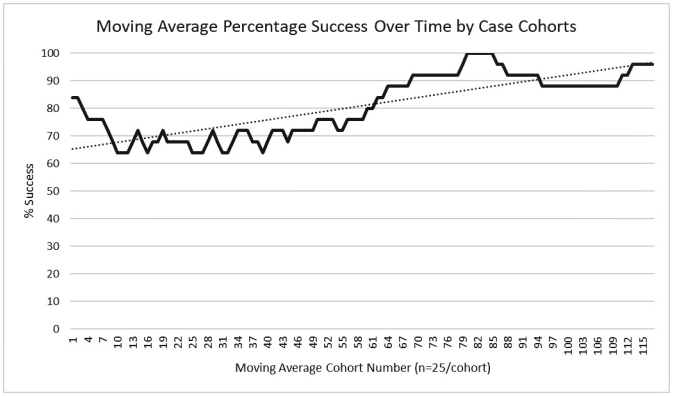

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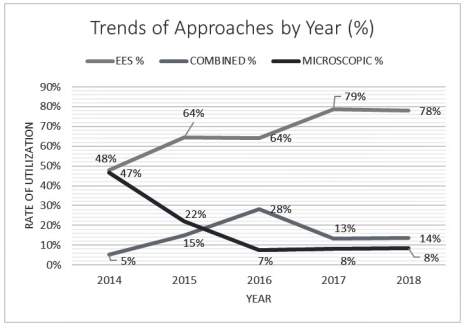

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