THE ROLE OF GLASS IONOMER CEMENT IN CLASSICAL PRIMARY STAPEDOTOMY; A SIX-MONTH PROSPECTIVE STUDY

Hany Farouk El-Garem, Yasser Awad Shewel, Ahmed Hesham Galal , Mashrab Muhdhar Omar Saggaf

Department of Otorhinolaryngology , Faculty of Medicine, Alexandria University, Alexandria, Egypt

Introduction

Otosclerosis is an autosomal-dominant, hereditary disease (25-40% penetrance) of the otic capsule, in which compact bone is remodeled to vascularized, spongy bone, causing stapes fixation and HL. Patients usually present in their 2nd-4th decades of life, with gradual onset, slowly progressing bilateral, assymtrical HL. They may have hyperacusis Willisi, low monotonous speech, tinnitus and/or vertigo. Clinical findings are a negative Rinne, a falsely lateralized Weber's tests, and normal otoscopy (or rarely, Schwartze sign). PTA reveals gradual low – high frequencies CHL, ABG widening, and Carhart's notch (2KHz), with excellent SDS and As type tympanogram. Surgical treatment remains gold-standard, however, malcrimping accounts for 85% of revision surgery.

Aim of the work

The aim of this 6-month, randomized, prospective study was to compare hearing results between GIC-intervened otosclerotic patients and non-GIC intervened ones during the crimping step of primary stapedotomy, at the Otorhino-laryngology Department in Alexandria Main University Hospital.

Patients and Methods

Thirty patients diagnosed with otosclerosis were randomly selected at the out-patient clinic, 15 of who were assigned to intervention group A, and the other 15 to control group B. Classical primary stapedotomy was the primary intervention for both groups, with additional augmentation of the incus – prosthesis attachment only in Group A patients using GIC. The duration of follow up was 2 months. Mean thresholds were used measured at 0, 1, 2, and 4 KHz frequency levels and used to calculate the primary outcome measurements, which were ABG closure, hearing gain and residual ABG, and plotted on charts to depict audiograms for overall observation Statistical data sets used to compare outcomes were mainly Chi-square and independent t-tests. Results significance was judged at the 5% level.

Results

Overall, the patients' age ranged between 19 – 55 years with more patients aged between 20 – 50 years in group, amd male–to–female ratio of approximately 1:1.3. Bilateral otosclerosis was seen mainly in both studied groups, with 66.7% iincidence of moderately severe CHL, 60% incidence of tinnitus and 13.3% incidence of vertigo. From thr 30 operated ears, (60%) were right and (40%), all surgically confirmed with stapes fixation, 6.7% (1 patient) with LPI erosion, and accidental TMP occurring in 13.2%. CTN had to be severed in 6.7% (1 patient) from group B, resulting in dysgeusia post-operatively. Ossicular discontinuity occurred in 6.7% from group B also, postoperatively, and no complications occurred in group A. Hearing gains were more in GIC-intervened subects, with more patients achieving better closure, comparad non-GIC intervened, with significantly less residual ABG in group A. *(p=0.007*). Post-operative mean ± SD ABG was considerably less in group A than B across the 4 frequencies, but not statistically significant *(p=0.12)* as shown below:

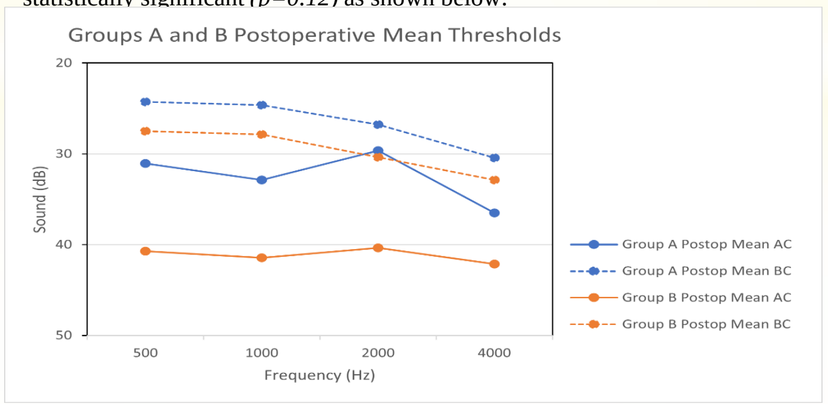

Figure (1): Comparison between the two studied groups regarding post-operative mean thresholds at 500, 1000, 2000, 4000 Hz

Table (1): Comparison between the two groups regarding postoperative Mean ABG, ABG closure, hearing gain and residual ABG measurements.

PRIMARY HEARING MEASURES		Group A (n=15)	Group B (n=15)	p-value
Postoperative ABG (0.5, 1, 2, 4KHz)	Min. – Max.	0 – 16.9	0 – 33.8	0.12
	Mean ± SD	6.2 ± 6.0	13.9 ± 13.2	
ABG closure (dB)	Min. – Max.	-8.75 – 19.4	-5 – 37.5	0.099
	Mean ± SD	4.4 ± 9.8	11.8 ± 13.8	
Categories of ABG closure (No.)	Up to 10 dB	11 (73.3%)	7 (46.7%)	0.12
	10 – 20 dB	4 (26.7%)	4 (26.7%)	
	Above 20 dB	0 (0.0%)	4 (26.7%)	
	Complete	5 (33.3%)	4 (26.7%)	
	Overclosure (BC)	2 (13.3%)	0 (0.0%)	
	SNHL (BC)	0 (0.0%)	0 (0.0%)	
Functional Success (dB)	Min. – Max.	25.8 – 41.2	21.2 – 73.8	0.88
	Mean ± SD	32.2 ± 5.6	40.0 ± 19.7	
Hearing Gain (dB)	Min. – Max.	20.8 – 53.3	1.67 – 46.7	0.313
	Mean ± SD	31.9 ± 11.3	27.3 ± 13.2	
Residual ABG (dB)	Min. – Max.	0 – 16.9	0 – 33.8	0.104
	Mean ± SD	5.6 ± 6.1	13.8 ± 13.2	
Categories of Residual ABG (No.)	0 dB	7 (46.7%)	6 (40.0%)	0.007*
	0-10 dB	6 (40.0%)	0 (0.0%)	
	10-20 dB	2 (13.3%)	5 (33.3%)	
	>20 dB	0 (0.0%)	4 (26.7%)	

Table (2): Comparison between preoperative and postoperative ABG for each studied group A and B:

GROUP	VALUE CHARACTERS	Preoperative ABG Values (dB) (n=15)	Postoperative ABG Value (dB) (n=15)	p-value
A	Min. – Max.	21.2 – 53.8	0 – 16.9	< 0.001
	Mean ± SD	35.0 ± 10.1	6.2 ± 6.0	
B	Min. – Max.	35.6 – 50	0 – 33.8	< 0.001
	Mean ± SD	40.7 ± 5.0	13.9 ± 13.2	

Conclusion

GIC can improve hearing outcomes and potentially reduce postoperative complications, and should be considered in routine practice.