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Balance After Stapedectomy

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***Abstract*---**Objective: To investigate the impact of stapedectomy on the vestibular system and analyze the relation of the vestibular changes to the operational and audiological properties.Patients and Methods: This is a prospective Cohort study including 50 otosclerosis patients underwent stapedectomy operation. Who were frequented on the ENT outpatient clinic of Elgalaa Military Medical Complex. The patients were investigated preoperatively, one week and one month postoperatively. Results: Preoperative and postoperative audiological assessment revealed that pure tone average was improved in 49 patients (98%) and remained constant in 1 patient (2%), no sensorineural hearing loss occurs among the study patients. After the first post-operative week, 2 patients (4%) showed decreased pure tone average scores that improved 1 month postoperatively to more than the pre-operative scores. Bone conduction average threshold was improved in 39 patients (78%), remained constant in 4 patients (8%) and decreased in 7 patients (14%). Sensory Organization Test (SOT) composite and vestibular scores at the first postoperative week testing improved in only 1 patient (2%) and diminished in 49 patients (98%) with stastically insignificant difference. However; at One month

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postoperatively, they recovered at least to preoperative level. Neither patient characteristics, nor audiological findings were found to be correlated with vestibular changes. Conclusions: Stapedectomy causes a temporary balance loss in a high percentage of patients which then recover to their former levels in the first postoperative month.

***Keywords*---**otosclerosis, stapedectomy, vestibular findings, posturography.

Introduction

Otosclerosis, also known as otospongiosis, is a primary disease of the otic capsule that leads to stapes ankylosis (HadjKacem et al., 2011). Hearing loss is the main symptom. Complaints of continuous tinnitus and eventual vertigo are also observed. Otosclerosis is considered an autosomal dominant disease (Rondini-Gilli et al., 2002).

Otosclerosis consists of one or several circumscribed foci of new, softer, and more vascular bone that replaces the remarkably avascular endochondrial bone of the adult labyrinthine capsule. There is simultaneous and continuous resorption of perivascular bone (otospongiosis) and deposition of immature and collagen deficient bone (otosclerosis) within a focus. It is an active remodeling process of bone that occurs within the endochondrial layer of the temporal bone, which under normal circumstances undergoes virtually no remodeling following development. Otosclerosis can occur independently at the stapes footplate, cochlear capsule, or both, which result in different clinical presentations and histopathological changes (Andres Makarem et al., 2008).

Histopathologically, the otosclerosis process is divided into two phases including the early phase and the late phase. Increased vascularity, hyperemia and bone resorption characterize the early phase. In the late phase, the reabsorbed bone is replaced with dense sclerotic bone (de Souza et al., 2016).

Treatment for otosclerosis includes surgery, medical treatment, and sound amplification, alone or in combination. Otolaryngologists should analyze each patient individually and decide which treatment will provide the best functional outcomes (de Souza et al., 2016). The aim of this study was to investigate the impact of stapedectomy on the vestibular system and control of the balance with the use of CDP, and analyze the relation of the vestibular changes to the operational and audiological properties.

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Patients and Methods

The present study included 50 otosclerosis patients underwent stapedectomy operation, males were prominent than females; 36 (72%) and 14 (28%), average age 38.32 ± 10.74 year; range, 21 to 50 year. Revision cases were not included. Diagnosis of Clinical Otosclerosis was done according to the criteria of *Committee of Hearing and Equilibrium (1995):* Progressive conductive or mixed hearing loss

with positive Carhart notch (the largest increase in bone conduction threshold (around 15 dB) occurs at 2 KHz).Normal tympanic membrane (by pneumatic otoscopy, tympanometry and acoustic reflexes.No evidence of middle ear inflammation.

Exclusion criteria: Neurological manifestations (by history and examination).Past history of ear operations.Past history of external or middle ear problems.Past history of head trauma. Past history of ototoxic drugs intake. The prescence of preoperative or postoperative imbalance was reported. Patients underwent Pure tone audiometry (PTA); Air conduction thresholds tested through the following frequencies 0.25-8 KHz. Bone conduction thresholds (BCT) tested through 0.5, 1, 2 & 4 KHz. Postoperative air–bone gap was calculated by subtracting postoperative bone conduction from postoperative air conduction. A deviation in the bone conduction threshold of more than 10 dB from normal was accepted as sensorineural loss. Acoustic immittance testing It included tympanometry and acoustic reflex threshold measurement. Preoperatively, 1 week and 1 month postoperatively.

Vestibular work up

Patients were tested with Computerized Dynamic Posturography (CDP) (Balance master; NeuroCom, International, Clackamas, USA). Patients underwent sensory organization test as the balance test preoperatively. Postoperatively the test was repeateated after the first week and after the first month. Patients were asked to maintain their balance under six different conditions which were derived by manipulating visual surround by closing the eyes or swaying the visual surround and by manipulating support surface by anteroposterior sway of the moving platform (Table 1). Averages of three trials were taken for all six positions of the test. Torsional forces exerted by patients' feet are measured and compared with responses from an age-appropriate group of persons without symptoms. The findings were classified into patterns from the combination of results for the different test conditions.

Table 1
Sensory test conditions (C1-6) of sensory organization test

Test Condition	Vision	Surround	Platform
	EO, eyes open; EC, eyes closed.		
C1	EO	Fixed	Fixed
C2	EC	Not Applicable	Fixed
C3	EO	Sway-referenced	Fixed
C4	EO	Fixed	Sway-referenced
C5	EC	Not Applicable	Sway-referenced
C6	EO	Sway-referenced	Sway-referenced

Statistic analysis

Data were collected in a master sheet, coded, entered and analyzed using both SPSS version 22 medical statistics software and Microsoft Excel v. 2016. ROC curve analysis was performed by MedCalc Version 11.3 for Windows (MedCalc

Software bvba). The threshold of significance was fixed as 5% level student t-test (t) and A value of $P < 0.05$ was considered statistically significant.

Results

Table (2)
Age and sex distribution of the study patients

	Mean ± SD	Range
Age (years)	38.32 ± 10.74	21 – 50
Gender	Number (N)	Percent (%)
Males	36	72.0
Females	14	28.0
Laterality	Number (N)	Percent (%)
Right	22	44.0
Left	28	56.0
Total	50	100

x^2 = Chi square test

Table 2; showed that males were more prominent than females 36/14 (72/28%). They all have a middle age ranged from 21 to 50 years with mean ± SD of 38.32 ± 10.74 years. As regard laterality, left ear had the upper hand than the right ear 28/22 (56/44%). This is illustrated in the next figures.

Table 3
Comparison of preoperative and postoperative pure tone audiometry air conduction thresholds (mean ±SD) of the affected ear of the study patients

PTA (KHz)	Preoperative	Postoperative		Significance	
		1 week	1 month	t-test#	P value
0.25	51.8 ± 9.99	24.2 ± 11.44	18.96 ± 10.4	7.621	P < 0.001*
0.50	51.0 ± 11.95	21.7 ± 11.00	16.6 ± 9.49	7.96	P < 0.001*
1.0	52.0 ± 11.47	20.3 ± 12.09	15.7 ± 9.37	8.24	P < 0.001*
2.0	49.1 ± 11.81	21.7 ± 10.48	16.0 ± 9.26	6.45	P < 0.01*
4.0	50.8 ± 14.96	22.9 ± 12.54	17.1 ± 9.69	6.52	P < 0.01*
8.0	52.8 ± 14.39	27.5 ± 16.36	23.5 ± 16.17	5.64	P < 0.01*

- P > 0.05 = statistically non-significant difference.
-*P < 0.05 = statistically significant difference.
-*P < 0.01 = statistically highly significant difference.
-*P < 0.001 = statistically very highly significant difference.

Table 3; showed that the comparison of preoperative and postoperative pure tone audiometry of the affected ear. They all showed statistically highly significant values (P <0.01).

Table 4
Comparison of pre- and post-operative regarding PTA average of the study patients

PTA average	Preoperative	Postoperative		Significance	
		1 week	1 month	t-test#	P value
Mean	50.7	21.7	16.4	7.76	P < 0.001*
± SD	17.63	20.57	19.62		
Range	28.8 – 68	10.75 – 68.8	7.5 – 48.8		

Table 4; showed that the comparison of preoperative and postoperative pure tone audiometry of the affected ear. The mean ± SD of PTA was 50.7 ± 17.63, preoperatively decreased to 21.7.43 ± 20.57 at 1 week postoperatively and further decreased to 16.4 ± 19.62 at 1 month postoperatively with very high statistically significant value (p < 0.001).

Table 5
Comparison of preoperative and postoperative bone conduction thresholds (mean ±SD) of the study group in the affected ears of the study patients

BCT (KHz)	Preoperative	Postoperative		Significance	
		1 week	1 month	t-test#	P value
0.5	12.9 ± 4.96	14.4 ± 7.26	10.5 ± 4.43	1.833	P < 0.05*
1.0	14.4 ± 5.31	13.8 ± 6.02	10.3 ± 6.02	2.645	P < 0.05*
2.0	23.7 ± 7.68	17 ± 6.39	11.7 ± 4.91	5.251	P < 0.01*
4.0	14 ± 4.63	15.7 ± 7.89	10.7 ± 5.05	2.241	P < 0.05*
Average	16.3 ± 5.9	15.2 ± 6.86	10.8 ± 5.04	2.93	P < 0.05*

Table 5; showed that the comparison of preoperative and postoperative bone conduction thresholds of the affected ear. They all showed statistically significant values (p < 0.05).

Table 6
Comparison of preoperative and postoperative air-bone gap (ABG) levels (mean ±SD) in the affected ears of the study patients

ABG (KHz)	Preoperative	Postoperative		Significance	
		1 week	1 month	t-test#	P value
0.5	38.1 ± 11.4	7.1 ± 12.6	5 ± 9.48	9.95	P < 0.001*
1.0	37.6 ± 11.5	6.1 ± 12.3	4.6 ± 9.19	9.12	P < 0.001*
2.0	25.4 ± 9.52	5.5 ± 12.6	3.3 ± 6.52	8.17	P < 0.01*
4.0	35.5 ± 13.2	6.5 ± 11.5	5.4 ± 9.94	9.27	P < 0.001*
Average	34.68 ± 9.05	6.86 ± 11.03	4.84 ± 8.46	8.77	P < 0.01*

Table 6; showed that the preoperative and postoperative air-bone gap (ABG) thresholds of the affected ear. They all showed statistically significant values (p <0.05).

Table 7
Incidence of vertigo pre- and post-operative among the study patients

Vertigo	Preoperative		Postoperative		Significance	
	No.	%	No.	%	Chi square	P value
Present	9	18	2	4	8.6	p < 0.05*
Absent	41	82	48	96	8.325	p < 0.05*

Table7; showed that the incidence of vertigo among the study patients. Pre-operative vertigo was reported in nine patients (18%). Postoperatively; Seven patients (14%) recovered completely, while two patients (4%) reported that they still suffering from vertigo.

Table 8
Comparison of preoperative and postoperative as regard consecutive components of the sensory organization test (SOT) values (mean ±SD) of the study patients

SOT	Pre-operative	Postoperative		Significance	
		1 week	1 month	t-test#	P value
Somatosensory	95.1 ± 2.8	93.1 ± 4.3	94.7 ± 3.2	0.45	P > 0.05
Visual	83.1 ± 3.3	80.8 ± 4.4	82.3 ± 4.9	0.013	P > 0.05
Vestibular	75.04 ± 5.9	70.04 ± 7.1	75 ± 6.3	0.94	P > 0.05
Preference	94.2 ± 5.2	90.2 ± 6.2	93.4 ± 5.3	0.31	P > 0.05
Composite	82.4 ± 5.05	76.16 ± 6.12	85.24 ± 3.95	1.11	P > 0.05

Table 8; showed that comparison between preoperative and postoperative results of the consecutive components of the sensory organization test (SOT) of the study patients. After the first postoperative week, vestibular component of the SOT and composite score average decreased, while; at the first postoperative month testing, results returned to the preoperative values with stastically insignificant difference ($P > 0.05$).

Discussion

In the present study; males were more prominent than females 36/14 (72/28%). They all have a middle age ranged from 21 to 50 years with mean ± SD of 38.32 ± 10.74 years. As regard laterality, left ear had the upper hand than the right ear 28/22 (56/44%).

The number of patients in this study was 50 patients. Age of this study patients could be compared to other studies as the range in Özmen et al. (2009))was 18 – 55 years with mean of 41 ± 9 year and a mean of 48 ± 12 years in Blijleven et al. (2019) study. In the present study, males were prominent than females; 36 (72%) and 4 (28%), respectively, however in other studies; females were prominent than males; Blijleven et al. (2019) study had 39 of 66 females (59%) and Özmen et al. (2009) had 27 of 33 females (81.8%).

All cases in the present study had undergone single stapedectomy. As regarding air conduction pure tone audiometry thresholds; the mean of PTA average was 50.7 ± 17.63, preoperatively decreased to 21.7 ± 20.57 at 1 week postoperatively and further decreased to 16.4 ± 19.62 at 1 month postoperatively with statistically very high stastically significant value ($p < 0.001$). Preoperative and postoperative audiological assessment revealed that pure tone average was improved in 49 patients (98%) and remained constant in 1 patient (2%), no sensorineural hearing loss occurs among the study patients. After the first post-operative week, 2 patients (4%) showed decreased pure tone average scores that improved 1 month postoperatively to more than the pre-operative scores.

In comparison to other studies; the present study results agreed with different studies results; 59 dB and 41 dB in preoperative and postoperative assessment, respectively in Blijleven et al. (2019); 50 dB and 26 dB respectively in Mahafza et al. (2013); 59 dB and 46 dB respectively in Vincent et al. (2010); 60 dB and 43 dB, respectively in Babighian & Albu (2009) study; 62 dB and 49 dB, respectively in Gros et al. (2005) study.

The present study results also agreed with Özmen et al. (2009), who reported that audiological results of the operation were generally successful with a mean 21 ± 14 dB gain in air conduction thresholds. Kujala (2010), also reported that postoperatively; no significant sensorineural hearing loss occurs. As regarding bone conduction average threshold of the affected ear; bone conduction average threshold showed a statistically significant value ($P < 0.05$) Bone conduction average threshold was improved in 39 patients (78%), remained constant in 4 patients (8%) and decreased in 7 patients (14%).

Other studies agrees with the present study about the post stapedectomy improvement of the mean bone conduction average thresholds; 23 and 19 dB in preoperative and postoperative results, respectively in Vincent et al. (2010) study; 30 dB and 29 dB, respectively in Bakhos et al. (2010) study; 28 dB and 29 dB, respectively in Babighian & Albu (2009) study; while Blijleven et al. (2019), reported no difference between preoperative and postoperative bone conduction thresholds (the mean bone conduction average threshold was 25 dB).

Regarding the air-bone gap (ABG) of the affected ear; the air bone gap average showed stastically very high significant difference ($p < 0.001$) (as shown in table 7). 47 patients (94%) were improved, one patient (2%) remained constant and 2 patients (4%) showed increase in air bone gap average scores. Postoperative ABG was ≤ 10 dB in 4 patients (8%), between 10 and 20 dB in 10 patients (20%), more than 20 dB in 2 patients (4%). Complete air bone gap closure was achieved in 34 patients (68%).

Similar to the present study; Blijleven et al. (2019), reported improvement of hearing outcomes after stapes surgery in 66 otosclerosis cases. The mean preoperative ABG was 33 ± 11 decreased to 13 ± 7 dB at follow up from 6-8 weeks postoperatively and to 15 ± 8 dB at follow up of 12 weeks postoperatively. Mahafza et al. (2013), studied 104 patients underwent stapes surgery and reported that postoperative air bone gap was ≤ 10 dB in 79 (76.0%) patients, between 10 and 20 dB in 10 (9.6%) patients, and between 20 and 30 dB in four (3.8%) patients. These results are considered very good and comparable with most studies with a limited number of cases Alessandrini et al. (2009).

Nash et al. (2018), reported that both air conduction and air-bone gap significantly improve between 6 weeks and 6 months postoperatively. The mean gain in air-conduction threshold was 18 dB, mean postoperative air-bone gap was 15 dB, and mean gain in air-bone gap was 19 dB. Air-bone gap closure to 10 dB or less was achieved in 38% of cases and air-bone gap closure to 20 dB or less in 80% of cases. None of the included cases suffered from a profound sensorineural hearing loss postoperatively. Also, Bakhos et al. (2010), reported different results

as the pre-operative and postoperative air bone gap was 56 dB and 42 dB, respectively.

On studying the incidence of vertigo among the studied patients, it showed that vertigo was present in 9 patients (18%) preoperatively. 36 patients (72%) reported vertigo one week postoperatively. One month postoperatively; thirty four patients (68%) recovered completely, while two patients (4%) reported that they still suffering from vertigo with a statistically significant difference ($P < 0.05$).

The two patients who reported the prescence of vertigo one month postoperatively were among the nine patients suffered from preoperative vertigo, while; all the patients who developed vertigo (for the first time) one week postoperatively reported the disappearance of vertigo one month postoperatively. Kujala (2010), explained the post operative vertigo is most likely due to irritation of the otolith organ and semicircular canals.

There exists no standard test for human vestibular disorders. CDP provides an objective measurement of the response of the balance system but is not able to localize a lesion or determine its etiology. Patients having problems in the fifth and sixth conditions of the SOT have a vestibular deficiency pattern. Vestibular deficiency pattern occurs in acute, severe or uncompensated unilateral or bilateral vestibular deficits (Hain, 2020).

As regards sensory organization test (SOT) of the studied patients, the mean preoperative value was 82.4 ± 5.05, 1 week postoperatively was 76.16 ± 6.12 and 1 month postoperatively was 85.24 ± 3.95. SOT composite and vestibular scores at the first postoperative week testing improved in only one patient (2%) and diminshed in fourty nine patients (98%) (including all the thirty four patients who reported postoperative vertigo) with stastically insignificant difference ($P < 0.05$). However; at One month postoperatively, they recovered at least to preoperative level (including the two patients who reported still prescence of vertigo).

The present study SOT results were comparable to that of Özmen et al. (2009), who found that all patients were asymptomatic preoperatively when considering the vestibular system; however, eight of them got low SOT scores on vestibular examination. Postoperatively 82% of the patients had vestibular complaints in variable severity. By the end of the first week, all but one patient become asymptomatic. This patient recovered by the end of postoperative second week. However, a drop in SOT scores was encountered at the first week testing. One month after the operation, all patients were asymptomatic and SOT scores recovered at least to preoperative level. Audiological outcome was not influenced by the degree of balance disorder

The present study results also agreed with Singh et al. (2018), who evaluated 80 clinically diagnosed Otosclerosis patients underwent small fenestra stapedotomy by either conventional or CO_2 Laser assisted technique. Vestibular function was assessed objectively by measuring sway velocity using modified clinical test of sensory interaction on balance by static posturography. Subjective measurement of balance was done using Vestibular balance subscore of Vertigo Symptom Score (VSS-sf-V). The outcome measures were compared pre-operatively, at the first and

fourth week post-operatively. All patients had vestibular deficit 1 week post-operatively in the form of increased sway velocity and symptom scores, which reduced by 4 weeks after Stapedotomy.

Similar findings were reported by Kujala et al. (2010), who observed vertigo, in 27% of the patients one week after a stapedotomy operation. All but one of their patients became asymptomatic after one month.

In the present study; one week preoperatively 9 (18%) patients reported prescence of vertigo. One week post operatively; the SOT composite score decreased in 49 (98%) patients. Among these patients; 36 (72%) reported prescence of vertigo (including the nine patients who reported pre operative vertigo), 2 (4%) patients showed diminished PTA average and ABG average thresholds, 17 (34%) patients had diminished BCA thresholds. One month post operatively; the SOT composite score was better than the preoperative level in 15 (30%) patients and reached the preoperative level in 35 (70%) patients. 2 (4%) patients only reported that vertigo is still present while 34 (68%) patients reported that vertigo disappeared completely, 49 (98%) patients showed improved PTA average and ABG average thresholds and 39 (78%) patients had improved BCA thresholds (all of them to more than the preoperative levels) and 1 patient (2%) regained the preoperative hearing level.

Conclusion

Stapedectomy causes a temporary balance loss in a high percentage of patients which then recover to their former levels in the first postoperative month.

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