Doctoral thesis in Tehran university of medical science

Title:

Evaluation of Middle Ear ossicular Chain Reconstruction in 1987 – 1996 and Comparing the Results of applying Incus by PORP or TORP at Amir Aalam Hospital

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Abstract: Various natural or synthetic materials are used for middle ear ossicular chain reconstruction. Each material is found to have its own advantages and disadvantages. This study provides a report on cases of middle ear reconstruction and compares the results of applying Incus (homologous of autologous) with plastipore TORP or PORP.

The total of 153 operations done by Dr. Khorsandi for middle ear reconstruction at Amir Aalam Hospital during 1987 - 1996, have been reviewed and evaluated. The aim was to find out about the frequency of prosthesis extrusion and post-surgery hearing results during the evaluation period.

To compare the results in patients, they were first divided into 2 groups: Group 1 included the patients who underwent surgery by applying Incus (homologue or autologue). The Group 2 lists the patients who underwent surgery by using plastipore PORP or TORP.

Out of the 82 cases of surgeries evaluated in the first group of patients, 2 cases of

prosthesis extrusion were identified. In the second group, there were 14 cases of extrusion out of 53 tympanoplaties which, compared to the results of the first group, statistically shows a considerable difference (P = 0/00010). In other words, as far as audiometric result is concerned, the first group shows 19 cases of therapeutic failure, while such failure in the second group is 29 cases which is statistically indicative of a considerable difference (P = 0.00952). We have also separately evaluated the results of operations done by TORP with Incus - TORP that shows a considerable difference of P = 0.00952.

Considering the noticeable differences observed in the results of using natural or synthetic materials in middle ear reconstruction, and in view of the costs of synthetic prostheses, the significance of returning to and opting for the use of natural materials becomes more apparent and imperative.

Introduction: A considerable number of patients in this country suffering from chronic middle ear infections in most cases come to physicians at a relatively progressed stage of the problem with damaged middle ear ossicles. Most of these patients are either young or are in their middle age. Therefore, middle ear reconstruction should be dealt with as a significant issue.

The aim of this study is to evaluate the frequency of various ossiculoplasty techniques in patients at Amir Aalam Hospital. It also aims to follow up post-surgery results, to compare the results of applying Incus as Incus Interposition or Incus – TORP by plastipore PORP and TORP prostheses so that, by showing the efficiency of returning to the nature, solutions are sought and offered for further assurances on the safety of using low cost homologous tissues in middle ear reconstruction.

Materials & Methods: This survey has been accomplished on retrospective descriptive and analytic basis, by studying the files of the patients who underwent middle ear reconstruction (mostly as 2^{nd} stage tympanoplasty) operations by Dr. Khorsandi at Amir Aalam Hospital during 1987 – 1996. The information was compiled by using the questionnaires prepared in advance, and the information available in the files of the said patients and the audiometric filing system of the hospital. Also applied in some cases are the information that became available by either directly calling the patients or writing to them and making appointments for follow - up and audiometry in the hospital.

All those patients who had surgery during the said period have been studied, but the ones whose audiometric results were not available were excluded from the analysis. As a matter of fact, 53 patients in PORP and TORP prosthetics groups, and 82 patients in Incus Group were studied. The surgeries were all done by Dr. Khorsandi. The surgeries performed on left or right ear of the same patient were studied separately. In the case of the patients who underwent revision tympanoplasty (in de said period), the second surgery has been ignored and skipped for the survey. **Spss** software was used for the

analysis. The results were compared by using T-test and Chi - Square.

Findings:

A total 153 cases of tympanoplasty surgeries have been reviewed.

Sex: Out of this total number, 73 cases were female and 79 cases were male patients, with one case unknown for sex!

Age: the average age was 29/83 with SD = 10/13. The youngest patient was 13 years old and the oldest one was 62.

Side of operation: 80 cases were left ear surgery and 71 were right ear surgery, while 2 cases are unknown for side of ear!

Type of surgery: second stage tympanoplasty surgeries in 124 cases, 7 cases were performed as single – stage, and 16 cases of surgeries were revision. Six cases were unknown for this classification.

In 88 cases in previous operation posterior wall were maintained (CWU). In 47 cases, the surgeries were accomplished by removing the posterior wall (CWD). 18 cases are unknown for this classification.

Pathology of cholesteatoma detected in 89 cases, tympanosclerose in 28 cases, granulation tissue in 15 cases, adhesive otitis in 7 cases and 14 unknown pathology.

Follow up: The average length of post-surgery follow up in patients was 28/24 months

The frequency of different ossiculoplasties is illustrated in table 1.

The average air- bone gap (in 0.5,1,2,4kHz) before surgery was 39.38 dB (SD = 7/19). Minimum was 15 dB and Maximum was 60 dB.

Average air- bone gap (in 0.5,1,2,4 kHz) after surgery was 22/84 dB (SD= 14/2). Minimum was complete closure of A-B gap and Maximum was 60 dB .

The audiometric results on the basis of post-surgery air-bone gap are divided into 3 groups: Good (ABG < 20 dB), Satisfactory (ABG 20 – 30 dB) Failure (ABG >30 dB).

To analyze and evaluate the results, the patients were divided into 2 groups.

The first group(T1) included Incus -TORP and Incus-interposition. There were totally 82 cases.

Group 2 (T2) includes plastipore PORP and TORP cases which were 53 cases in total. There were 2 cases of prosthesis extrusion in the first group. Such extrusion in the 2^{nd}

group was 14 cases which statistically show a considerable difference (p = 0.00010).

The audiometric results in the said 2 groups based on the said classification are shown in table No. 2 which is also indicative of a considerable difference (P = 0.00092).

The frequency of prosthesis extrusion in the 2 groups of plastipor TORP and Incus-TORP were analyzed separately. 2 extrusion cases from 53 cases of incus – TORP and 5 extrusion of 25 cases of TORP was detected in follow up period (fischer – exact – test = 0/03145)

The audiometric results obtained in the said 2 groups is shown in the table No. 3 which is also considerable and meaningful (P = 0.01058).

The results obtained by the foregoing analysis and evaluation is indicative of differences and similarities, if compared to the results mentioned in texts and articles available on this matter. As for homologue/autologue bone (Incus-TORP and Incus interpostion) the overall result and the amount of extrusion are similar to what reported in the text i.e. about 1 percent extrusion, and 77 percent acceptably good result have been achieved (over an average period of 28 months).

As for PORP and TORP, the amount of extrusion is 26 percent and the amount of success is only 44 percent which are indicative of a less satisfactory result if compared to the statistics reported by foreign sources (amount of extrusion reported in the articles is 10 percent for plastipore and 19 percent for gold prosthesis). In justifying this matter perhaps a relatively longer follow-up period of our study can be referred to. In most cases, the figures and statistics reported by foreign sources are the results of short – term studies done with a one-year follow-up, while in most cases extrusion occurs in the 2^{nd} and the 3^{rd} years after the operation.

The said figures indicate that the results of PORP and TORP are by far poorer and less satisfactory in long terms. On the other hand, compared to TORP, the results of Incus - TORP show a considerable difference. The frequency of TORP extrusion during the follow up period was 20% which is high and considerable, if compared to the 4% extrusion of Incus - TORP.

The post-surgery audiometric results of Incus – TORP obtained during the follow up period was 77 percent good to satisfactory. In TORP cases, it was 48 percent good to satisfactory, which are considerable from statistics point of view.

Such difference becomes more conspicuous if the results of Ossiculoplasty with TORP and Incus – TORP are taken into consideration, particularly if the costs of TORP and Incus – TORP are taken into account. These are the reasons why Plastipore prostheses have been gradually put aside and deleted over the recent years.

Incus – TORP is a combination of low cost glass piston with the patient's own Incus or homologue ossicle. The prosthesis can be easily modified for appropriate form and size at the operating room. Although it's time- consuming but it is worth the effort, because of its better hearing result and lower cost.

Prosthetic displacement is to be considered as the most significant factor behind therapeutic failure (in addition to pathologic recurrence) in treatment by Incus autograft or homograft but in most cases this problem is remarkably reduced, thanks to technical improvements and surgical skills. However, despite the presence of such likely side effect, the 77 percent rate of success revealed by the study is a satisfactory figure which equals the figures available for the best prosthesis i.e. Hydroxyapatite TORP (that is 66 percent).

The most significant problem of using homograft tissues is transmission of infectious diseases, particularly *prions* (causing Creutz-Feldt Jacob disease) and HIV virus.

Fixation methods with *formalin* effectively sterilize autologous tissues against all known bacterial, fungal and viral factors. All infectious factors will be eliminated by putting the sample in 4% *formalin* solution within 24 hours. The most effective method of preventing the infection is to place the bone in autoclave (1) for at least 1 hour and then preserve in suitable liquid such as 70 % alcohol (4).

Based on the foregoing it can be concluded that autograft bone is always the best choice which is available in most cases. Incus can be applied in homologue graft already prepared.

Obviously, Ossiculoplasty techniques can not address and solve all problems faced in middle ear reconstruction. Hope there will be better prostheses or techniques in the future. If synthetic bone (hydroxyapatite) is the most ideal artificial material then natural bone should be the first choice for Ossiculoplasty and a combination of natural bone with a cheap synthetic prosthesis can be an excellent choice .

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