

## TO EVALUATE THE OUTCOME OF TYMPANOPLASTY TYPE I USING DRY AND WET TEMPORALIS FASCIA GRAFT: A RANDOMIZED CONTROL TRIAL.

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### Abstract

**Aim:** to evaluate the outcome of tympanoplasty type I using dry and wet temporalis fascia graft.

**Methods** The present Randomized control trial was conducted in the Department of ENT, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar . Among 100 patients attended the OPD of the ENT and diagnosed with chronic suppurative otitis media. Patients were divided into 2 groups of 50 each: one group underwent dry graft tympanoplasty and the other underwent wet graft tympanoplasty.

**Results:** The dry graft and wet graft groups had overall surgical success rates of 82 and 88 per cent, respectively; this finding was not statistically significant. A statistically significant high fibroblast count was observed in wet grafts.

**Conclusion:** The present study concluded that the dry or wet temporalis fascia graft did not affect the outcome of type I underlay tympanoplasty significantly. However, using wet temporalis fascia could shorten the duration of surgery in type I underlay tympanoplasty.

**Keywords:** tympanoplasty; wet graft, dry graft, temporalis fascia

### Introduction

Chronic otitis media is a widespread disease of developing countries such as India, especially in rural areas, and the prevalence ranges from 2% to 15%.<sup>1</sup>

Tympanoplasty is a commonly performed surgical procedure to close perforations of the tympanic membrane in chronic otitis media. It is performed to eradicate disease from the middle ear cleft and to reconstruct the hearing mechanism with or without tympanic membrane grafting.<sup>2</sup>

In 1960, Hermann introduced the use of a temporalis fascia graft in tympanoplasty.<sup>3</sup> Shea introduced the underlay technique of tympanoplasty at the same time that Hermann introduced the temporalis fascia graft.<sup>4</sup> A year later, in 1961, Austin and Shea modified this technique by incorporating a tympanomeatal flap elevation.<sup>5</sup> In 1973, Glasscock described the use of a post-auricular approach for underlay tympanoplasty; this is now a standard procedure worldwide.<sup>6</sup> An impressive success rate of more than 90 per cent is routinely observed with this technique.<sup>7</sup>

Since then, it has become the most widely used graft for tympanoplasty, as it is strong, durable, and easy to procure and handle.<sup>8,9</sup> It has the added advantages of a low metabolic rate and high collagen content.<sup>10,11</sup> However, the

type of temporalis fascia graft to use (i.e. dry or wet) remains controversial.

A recent review of the literature suggested that the nature of the graft, whether it is dry or wet, might influence the outcome of tympanoplasty.<sup>12-14</sup> A dry graft might give poor results, as it rehydrates and shrinks, leading to alterations in its position relative to the perforation. It is hypothesised that a fresh wet graft is histologically more viable, on account of the greater number of fibroblasts, which promote wound healing, leading to better graft uptake.<sup>15,16</sup>

An extensive internet search revealed scarcity of the data. Thus, the present comparative interventional study was carried out at tertiary care facility to evaluate the success rate of tympanoplasty type I using dry and wet temporalis fascia graft.

### Materials and methods

#### Study Design

The present Randomized control trial was conducted in the Department of ENT, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar. Among 100 patients attended the OPD of the ENT and diagnosed with chronic suppurative otitis media.

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After

explaining the purpose and details of the study, a written informed consent was obtained.

### Inclusion Criteria

- Patients above 18 years of age of either sex
- Patients presented with chronic suppurative otitis media
- Patients with a dry ear for a period of at least four weeks
- Patients with air–bone gap below 30 dB
- Patients who has signed the informed consent

### Exclusion criteria

- Patients who has not signed the informed consent
- Patients having any kind of acute and chronic systemic illness

### Sample Selection

50 subjects in each arm to achieve 80% power of study and level of significance 0.05 were recruited for the study.

The minimum sample size for each group was calculated using the formula:

$$n = (Z_{\alpha/2} + Z_{\beta})^2 * 2 * \sigma^2 / d^2,$$

where  $Z_{\alpha/2}$  is the critical value of the Normal distribution at  $\alpha/2$ ,  $Z_{\beta}$  is the critical value of the Normal distribution at  $\beta$ ,  $\sigma^2$  is the population variance<sup>1</sup>, and  $d$  is the hypothesized difference between the two study groups. Assuming equal group sizes to achieve a power of 80% and a two-sided confidence level of 95%, the study required a sample size ranging from 16 to 50 for each group. Assuming a non response rate of 10%, the minimum required sample size was 40. Therefore, a sample size of 50 for each group was included in the study.

Groups

Group A: underwent underlay tympanoplasty with a dry graft

Group B: underwent underlay tympanoplasty with a wet graft

### Methodology

#### Data collection

All the cases were subjected to a detailed clinical investigation. Specifically, relevant history and clinical examination were meticulously recorded in a proforma. Hearing was evaluated using pure tone audiometry, at frequencies of 0.5, 1, 2 and 3 kHz. All patients underwent routine tests for pre-anaesthetic check-up.

#### Operatively

Thereafter, all patients underwent type I tympanoplasty under local anaesthesia, performed by a single surgeon (the first author). The grafts were procured via a post-auricular incision. For those patients who underwent a dry graft procedure, the graft was pressed in a graft press and

dried with a hair dryer for 3–5 minutes just prior to insertion in the middle ear.

For those who underwent a wet graft procedure, the temporalis fascia graft was procured after tympanomeatal flap elevation, just before placement in the middle ear. A small piece of temporalis fascia (dry or wet) was cut at the time of surgery and sent to the pathology department preserved in formalin for a fibroblast count (see the Fibroblast count methodology section below).

Post-operatively

Patients were prescribed antibiotics (amoxicillin), analgesics (diclofenac plus paracetamol) and an anti-allergic (levocetirizine) for 7 days. All patients were discharged on post-operative day 1. The external auditory canal pack and the post-auricular stitches were removed on post-operative day 7.

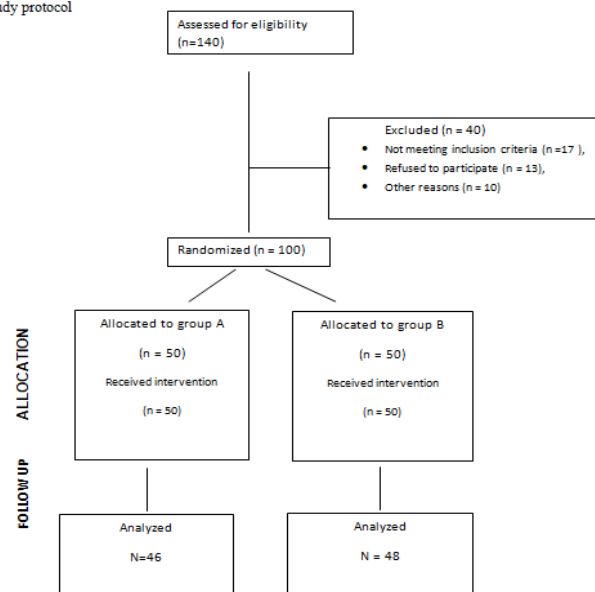
Follow-up and outcome

Regular follow up was maintained in the ENT department on day 7 post-operatively, and again after 3 weeks, 3 months and 6 months. Repeat pure tone audiometry was conducted after six months to assess hearing improvement. The surgical and audiological results were recorded.

Statistical analysis

The data was entered in the form of a data matrix in Microsoft Excel® and analysed statistically using IBM® SPSS® version 20.0.0. Descriptive statistics were calculated as frequencies for categorical variables and means and standard deviation for continuous variables. The association between the categorical variables was explored using Pearson chi-square test or fisher's exact test where as applicable. The difference of continuous variables, among two groups was explored using independent samples t-test. P-value of <0.05 was considered statistically significant for the purpose of the study.

Study protocol



## Results

**Table 1:** demographic profile of the study population

Variables	Group A	Group B
Age (years)	32.16±4.61	33.01±3.83
*p-value	p≥0.05	
Gender		
Male	28 (56.0%)	26 (52.0%)
Female	22 (44.0%)	24 (48.0%)
Total	50 (100.0%)	50 (100.0%)
**p-value	p≥0.05	

Test applied: \*student t-test and \*\*chi-square test

**Table 2:** comparison of fibroblast count between the groups

Fibroblast Count	Group A	Group B
0-9	9 (18.0%)	3 (6.0%)
≥ 10	41 (82.0%)	47 (94.0%)
Total	50 (100.0%)	50 (100.0%)
p-value	p≤0.05 (sig.)	

Test applied: chi-square test

**Table 3:** comparison of outcome between the groups

Outcome	Group A	Group B
Surgical success	41 (82.0%)	44 (88.0%)
Audiological success	32 (64.0%)	37 (74.0%)
Complications	0	0
p-value	p≥0.05 (NS)	

Test applied: chi-square test

## Discussion

Wormald and Alun-Jones, in 1991, were the first to highlight the concept of temporalis fascia graft shrinkage.<sup>17</sup> However, the exact clinical implication of this finding was emphasised by England et al. in 1997.<sup>13</sup> These authors promulgated that when a dry graft is placed in the wet physiological environment of the middle ear, it will shrink and lose contact with the remnant margins of the tympanic membrane under which it is tucked, especially anteriorly, and cause graft failure.

Indorewala also observed shrinkage and thickening of the temporalis fascia graft in an experimental study conducted on dogs in 2002.<sup>18</sup> Chow and Wei advocated that a large-sized graft be harvested in accordance with this concept of temporalis fascia graft shrinkage.<sup>19</sup>

It has been argued that better closure rates are obtained by using a wet graft, on account of increased fibroblast count. This is based on the assumption that fibroblasts lay down collagen for a reparative process in the wound, with formation of a granulation tissue matrix to allow the spread of epithelialisation, which thereby promotes successful graft uptake.<sup>14-16</sup> However, in this study, the success rates of dry and wet grafts were not significantly different with respect to their relative fibroblast counts

Currently, limited information is available in the medical literature regarding the influence of dry and wet grafts on tympanoplasty success. Previous studies found no statistically significant difference in the success of graft uptake with dry or wet grafts.<sup>14,15</sup> Recent studies also found good perforation closure results when using dry and wet graft.<sup>20,21</sup> Our study results were also sound in similarity with these findings.

## Strength and limitation

As a single-institution study, the data reflected experience of our geographical area, and may not be generalisable. Further, selection bias and confounding may have impact the outcome.

The present study is unique in its evaluation of the effect of fibroblast count on tympanoplasty. This study amalgamates the realities of clinical practice with independent statistical validation of data, and contributes further to the sparse medical literature available on the impact of dry and wet grafts on tympanoplasty.

## Conclusion

The present study concluded that the dry or wet temporalis fascia graft did not affect the outcome of type I underlay tympanoplasty significantly. However, using wet temporalis fascia could shorten the duration of surgery in type I underlay tympanoplasty. Concerns that the fibroblast count of temporalis fascia may beneficially affect success rate have not been substantiated in clinical reports thus offer debate and impetus for future research on the subject.

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