

A comparative study between haemocoagulase and adrenaline in achieving hemostasis in tympanoplasty

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Abstract

Background: Bleeding is a major setback during the ear surgery. Haemostasis with drugs plays major role in the prevention of bleeding during surgery. The present study compared the haemostatic effect of adrenaline with haemocoagulase in type 1 tympanoplasty. **Materials and Methods:** This is a prospective double-blind study done on 100 patients admitted in Department of Otorhinolaryngology in MVJ Medical College and Research Hospital from November 2014 to September 2016. Selected patients were divided into 2 groups Group-I (cotton balls soaked in 1 ml of adrenaline) Group-II (cotton balls soaked in about 1ml of haemocoagulase). The time taken during surgery from elevation of flap to placement of graft and number of cotton balls used during surgery were assessed and the efficacy of both the drugs in controlling bleeding and attaining haemostasis were noted. Surgeries performed in all the patients in the study was by the same surgeon. **Results:** In this study 52% were males and 48% were females with majority of patients between the age group 31 to 40 years. The duration of ear perforation was 7.5 years with majority of patients presenting with large central perforation (51%). Majority of patients had normal middle ear mucosa (68%) compared to congested middle ear mucosa. The number of cotton balls used with adrenaline was 6 and with haemocoagulase was 8. The average time taken for surgery was 38 minutes with adrenaline and 43 minutes with haemocoagulase. **Conclusion:** It is concluded in our study that adrenaline is a better middle ear haemostat when compared to haemocoagulase irrespective of the middle ear mucosa (normal/congested) in type 1 tympanoplasty

Key Words: Adrenaline, haemocoagulase, haemostat, tympanoplasty, middle ear, cotton balls.

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Received Date: 14/09/2018 Revised Date: 13/10/2018 Accepted Date: 06/11/2018

DOI: <https://doi.org/10.26611/1016825>

Access this article online

Quick Response Code:	Website: www.medpulse.in
	Accessed Date: 24 November 2018

INTRODUCTION

Bleeding is a major drawback in all surgeries, especially in ear surgeries. Even a small amount of bleeding can disturb the field while doing surgery under microscope. It is important to attain a bloodless field during ear surgery. Even capillary ooze can make the field messy affecting the duration and efficacy of the surgery. Haemostasis can

be achieved by topical methods including simple manual pressure with gauze or cotton balls soaked with adrenaline, administration of haemostatic agents like haemocoagulase etc. Use of adrenaline-soaked cotton balls is the gold standard in middle ear haemostasis. Capillary bleeding leads to decrease in supply of oxygen and nutrients and may lead to impaired healing. In our study we have compared both adrenaline and haemocoagulase for attaining haemostasis. Haemocoagulase topical solution is an enzyme complex based fundamentally on coagulative and antihemorrhagic properties of fractions isolated from poison of snake Bothrops jararaca or bothrops atrox. It acts by accelerating the conversion of fibrinogen to fibrin polymer and promotes the interaction of platelets with fibrin clot to coagulate the blood¹. Haemocoagulase solution reduces blood clotting time significantly², enhances capillary network formation and hastens wound healing concomitantly arresting capillary bleeding. It is

known that haemocoagulase is devoid of antigenic capacity and does not cause the appearance of immunologic phenomenon³. Considering all these therapeutic uses of sterile haemocoagulase solution “A comparative study between haemocoagulase and adrenaline in type1 tympanoplasty” was conducted at MVJ Medical College and Research Hospital, ENT Department to evaluate its usefulness in middle ear surgeries.

MATERIALS AND METHODS

Study Settings: The study was conducted in Department of Otorhinolaryngology, MVJ Medical College and Research Hospital between Nov 2014 to Sep 2016. It is a prospective study.

Inclusion Criteria

- Patients undergoing type1 tympanoplasty in MVJ medical college and research hospital.
- Age group between 15 years to 50 years
- Normotensive patients.
- Patients giving consent to undergo study.

Exclusion Criteria

- Patients not willing to undergo the study.
- Patients with suspected labyrinthine fistula
- Patients with history of coagulation disorders.
- Patients with ishchemic heart disease on aspirin treatment.

Procedure

The patients were selected based on the inclusion and exclusion criteria. The selected patients were divided into two groups. Group-I (on whom cotton balls soaked in 1 ml adrenaline were used) and Group-II (on whom cotton balls soaked in 1 ml haemocoagulase were used). All the patients were explained about the study and procedure in detail and informed consent was obtained. The surgery was done under general anesthesia. The operating ear was painted using povidone iodine, methylated spirit and then draped ensuring complete asepsis. Local infiltration with 3ml (xylocaine 2% with 1:100000 adrenaline in 1:1 dilution) were administered in post aural and 0.5ml in each quadrant of EAC for all the cases. Through the post aural William wildes incision temporalis fascia graft harvested and preserved. Under the microscope/endoscopic vision tympanic membrane perforation visualized and edges freshened. Incision taken in the canal 7 mm lateral to annulus from 6 0 clock to 12 0 clock position. Tympano meatal flap elevated and middle ear entered and inspected for ossicles, mobility of ossicles, round window reflex, middle ear mucosa. Temporalis fascia graft placed using underlay technique. Abgel placed in the middle ear to support the graft. Tympanomeatal flap repositioned and EAC filled with medicated gelfoam. Post aural incision closed in 2 layers,

mastoid dressing applied. Surgeries of all the patients included in the study were performed by the same surgeon. The specified drugs (adrenaline/haemocoagulase) mentioned in the study are used to achieve haemostasis from tympanomeatal flap elevation till graft placement. The amount of drug used during the procedure and the time taken for the procedure are considered.

Statistical Analysis: Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square was used as test of significance. Continuous data was represented as mean and SD. Independent t test was used as test of significance to identify the mean difference between two groups. p value <0.05 was considered as statistically significant.

RESULTS

The mean age of Group-I is 33.80 and Group-II is 32.60 was not statically significant (p>0.45). Males were more in group-I (n=29) compared to females (n=23) but in group-II females were more (n=25) compared to males (23). The gender distribution between the groups was not significant (Table-1). 7.5 was the mean duration of tympanic membrane perforation which was less in group-II. Right side tympanic membrane perforation was more in group-I compared to group-II. Maximum number (n=17) had middle ear mucosa congestion compared between the group-I and group-II. Lt conductive hearing loss was maximum in group-I (22) and group-II (26). Least was B/L conductive hearing loss R>L. More number of cotton bolls was used in group-II compared to Group-I. More time was taken for surgery in group-II patients than group-I patients. 25 were in group-I and 26 in group-II had large central tympanic membrane perforation. In group-II no patient had medium size PI and AI and Small AS (Table-3). Significant number of cotton balls was used in group-II compared to group-I for middle ear tympanoplasty (Graph-1).

Table 1: Demographic data

Demographic data	Group-I	Group-II	p value
Age (MEAN±SD)	33.80±8.40	32.60±11.0	0.45
Gender			
Male	29	23	
Female	23	25	
Duration of tympanic membrane perforation (Y) (MEAN±SD)	7.5±4.0	7.3±3.7	0.89

Table 2: Comparison of clinical observations between the groups

Observations	Group-I	Group-II	P value
Side of tympanic membrane perforation			
Left	24	27	0.67
Right	28	21*	0.04
Middle ear mucosa			
Congested	15	17	0.89
Normal	37	31*	0.04
Tuning fork test findings			
L CHL	22	26	
R CHL	27	22	
BL CHL R>L	1	0	
BL CHL L>R	2	0	
Pure tone audiometry findings			
PTA right side (MEAN±SD)	33.80±10.3	34.80±12.20	0.67
PTA left side (MEAN±SD)	32.30±13.6	30.10±12.70	0.56
Number of Cotton balls used (MEAN±SD)	6.00±1.29	7.15±2.02*	0.04
Time taken for surgery (min) (MEAN±SD)	37.19±3.30	42.89±6.60*	0.032

(*p<0.05 significant)

Table 3: Location of tympanic membrane perforation between the groups

Tympanic membrane perforation	Group-I	Group-II
Large central	25	26
Medium ASandAI	11	6
Medium size AalandPI	4	3
Medium size in PSandPI	1	1
Medium size PI andAI	1	0
Small AI	3	4
Small AS	1	0
Small PI	5	7
Small PS	1	1

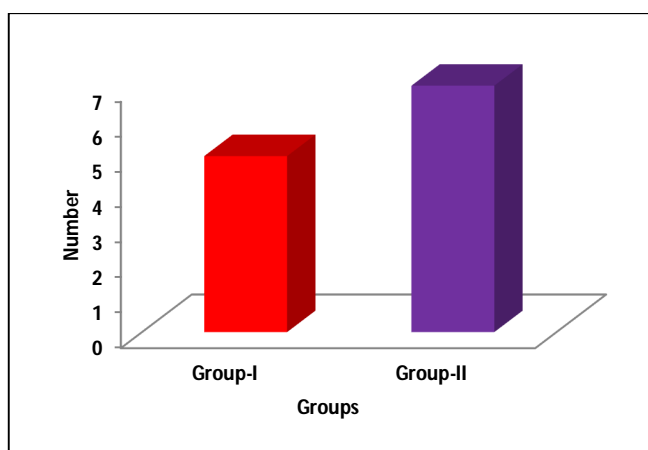


Figure 1: Number of cotton balls used in both groups with respect to middle ear mucosa

DISCUSSION

Chronic suppurative otitis media is a long-standing infection of a part or whole of the middle ear space characterized by ear discharge and permanent changes in tympanic membrane. Treatment of chronic otitis media includes ear toileting, topical and systemic antibiotics and surgical treatment to eradicate the disease and to close the perforation⁴. Bleeding is a major drawback in all ear surgeries. Even a small amount of bleeding can disturb the field while doing surgery under microscope. It is important to attain a bloodless field during ear surgery. Even capillary ooze can make the field messy affecting the duration and efficacy of the surgery. In middle ear surgeries haemostasis can be achieved by topical methods including simple manual pressure with gauze or cotton balls soaked with adrenaline. Use of adrenaline soaked cotton balls are the gold standard in middle ear hemostasis. Adrenaline is a hormone and a neurotransmitter, also called as Epinephrine and comes under the group of catecholamine. It is a sympathomimetic with both Alpha and Beta adrenergic receptor agonist effects. Arterioles in mucosa display vasoconstriction due to alpha receptor predominant stimulation. Adrenaline is used in various medical conditions including cardiac arrest, anaphylaxis, bronchospasm and to control bleeding in various surgical procedures like tonsillectomy⁵, ear surgeries etc. Adrenaline is known to produce palpitations, tachycardia, arrhythmia, anxiety, headache, tremor, hypertension and acute pulmonary edema⁶. Haemocoagulase is the enzyme complex present in south American snakes species “Bothrops Jarararca and Bothrops Atrax”. This enzyme complex has extensive clinical application in arresting the capillary bleeding and promoting wound healing. In surgical procedures like Adenotonsillectomy, Ophthalmic surgeries⁷, cosmetic surgeries, Dental extraction, to prevent pulmonary hemorrhage¹³, in treating sudden deafness^{8,9}, in bleeding disorders¹⁰ like Haemophilia A and B and Thrombocytopenic purpura, in controlling internal and external hemorrhages like epistaxis, malena and haemetemesis. Haemocoagulase is well tolerated. It is devoid of antigenic capacity and does not cause the appearance of immunologic phenomenon¹¹. In this study a comparison was made between the action of Haemocoagulase and Adrenaline in attaining haemostasis in type 1 tympanoplasty. A total number of 100 subjects were included in this study and they were divided into two groups as group A (Haemocoagulase) and group B (Adrenaline). In our study done on 100 patients. 9 patients were under the age group of 20 years, 37 patients were between the age group of 21 to 30 years, 37 patients were between the age group of 31 to 40 years and 17 patients were above the age of 40 years. Majority of

subjects (74%) in both the groups were in the age group 21 to 40 years. Occurrence was found to be less in older age groups. No significant difference was observed between two groups with respect to age. In a study conducted by Sanjeev kumar goud *et al*¹² out of 112 patients with chronic otitis media 74.1% of patients belong to age group 11 to 40 years. Occurrence was found to be less in older age groups. In study conducted by Sharankumar Shetty¹³ out of 50 patients included in the study 80% belonged to age group between 11-30 years. In a study done by Shrikrishna BH *et al*¹⁴ the age of patients ranged from 10 years to 50 years. Most (83.3%) of the affected cases were in age group of 10-30 years. The highest number of patients were between 21 to 30 years of age (56.67%), followed by 26.67% in the age group of 10 to 20 years. About 10% patients were in the age group of 31 to 40 years and 6.7% in the age group of 41 to 50 years. The above studies are showing that most of the patients belonged to age group between 21 to 30 years, similar results were found in our study. In our study (52%) were males and (48%) were females. (29 patients in group A where adrenaline was used and 23 patients in group B where haemocoagulase was used) the study consisted of 48 female patients (23 patients in group A where adrenaline was used and 25 patients in group B where haemocoagulase was used) There was no significant difference in gender distribution between two groups. In a study conducted by Adoga *et al*¹⁵ in 2011 on Bacterial isolates in chronic suppurative otitis media, out of 75 patients included in the study 50 were males and 47 were females suggesting no significant difference in incidence of chronic otitis media in both sex. According to Sanjeev kumar goud *et al*¹⁶ 43% were males and 57% were females in his study. In another study by Sharan kumar shetty¹⁷, 48% cases were males and 52% were females. Similar results were found in our study. In our study it was observed that there was significant increase in number of cotton balls used in patients with congested mucosa compared to patients with normal mucosa. We observed that between the two groups with respect to middle ear mucosa significant difference was observed in number of cotton balls used. i.e higher number of cotton balls (8 cotton balls) was required in hemocoagulase group in both normal and congested middle ear mucosa. *P value <0.001 (independent t test) is statistically significant: it suggests in normal middle ear mucosa adrenaline group patients required less cotton balls. *P value 0.003 (independent t test) is statistically significant: it suggests in congested middle ear mucosa adrenaline group patients required less cotton balls. In our study we observed that there was a significant difference in the time taken during surgery. Patients with congested mucosa required more time compared to patients with

normal mucosa. Similarly between the two groups with respect to middle ear mucosa significant difference was observed. i.e., Higher duration was required for surgery in hemocoagulase group (42.89 mins) with respect to Normal and Congested Mucosa respectively. *p value 0.002 (independent t test) is statistically significant: it suggests in normal middle ear mucosa adrenaline group patients time taken for surgery was lesser compared to haemocoagulase group. *P value <0.001 (independent t test) is statistically significant: it suggests in congested middle ear mucosa, in adrenaline group patients time taken for surgery was lesser compared to haemocoagulase group. Mehmet Haksever *et al*¹⁸ conducted a comparative study between inlay. butterfly cartilage tympanoplasty and conventional underlay tympanoplasty on 72 patients. Average time duration of Inlay butterfly cartilage tympanoplasty was found to be 29.9± 5 minutes. Average time duration for conventional type 1 tympanoplasty was 58 ± 12 minutes

CONCLUSION

It is concluded in our study that adrenaline is a better middle ear haemostat when compared to haemocoagulase irrespective of the middle ear mucosa (normal/congested) in type I tympanoplasty.

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Source of Support: None Declared
Conflict of Interest: None Declared

