Equine versus bovine pericardium in transmeatal underlay myringoplasty.

EQUINE VERSUS BOVINE PERICARDIUM IN TRANSMEATAL UNDERLAY MYRINGOPLASTY

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ABSTRACT

Objective. Many different grafting materials have been proposed in myringoplasty. The aim of this study was to evaluate the results obtained in transmeatal underlay myringoplasty using bovine and equine pericardium. The results were compared with those obtained by using autologous temporalis fascia.

Methods. The study group consisted of 52 patients affected by tympanic perforation. Twenty-nine patients were randomly selected for treatment with bovine pericardium and 23 for equine pericardium. A group of 14 patients was treated with autologous temporalis fascia.

Results. Closure of the perforation was achieved in 19 of 29 patients (66%) treated with bovine pericardium, in 19 of 23 (83%) treated with equine pericardium and in 13 of 14 (93%) treated with autologous fascia. The best functional results in patients who gained closure of the perforation were obtained by means of equine pericardium.

Conclusions. The overall long-term tympanic closure rate demonstrates that equine pericardium has a greater take rate than bovine pericardium. The results obtained are inferior to those obtained with autologous fascia, but this technique is less aggressive. The higher success rate with equine pericardium may be due to the fact that it is thinner and easier to handle and model than bovine pericardium.

Key words: graft materials, myringoplasty

Introduction.

The primary aim of myringoplasty is restoration of tympanic membrane integrity (1). This result could be accomplished by means of surgical techniques based on the positioning of connective tissue in the site of the eardrum perforation with the purpose of stimulating skin and mucosal regeneration, leading to a permanent defect closure.

Myringoplasty can be differentiated on the basis of the positioning of the graft (underlay, overlay), of the approach (transmeatal, endoaural, retroauricular), of the graft material (autologous temporalis fascia [AF], other tissues) and of the kind of anesthesia (local, general). The principal failures in myringoplasty are re-perforation of the esrdrum, anterior blunting, lateralization or thickening of the graft, iatrogenic cholesteatomas and eardrum retraction. The causes of re-perforation are rejection of the graft, infection with graft necrosis, and poor anterior adaptation of the graft, whereas late re-perforations are principally attributed to atrophy of the tympanic membrane or episodes of acute otitis media. Age, size and site of the perforation, condition of the ear, status of the controlateral ear and grafting materials are considered factors influencing the success rates of myringoplasty (2). The influence of these prognostic factors on the outcome differs among authors; this could be explained by the different surgical techniques adopted.

The kind of graft has been considered a relevant aspect in determining the outcome of myringoplasty. From the first reports in the 1950s, many different grafting materials have been proposed in myringoplasty, such as skin, fat, vein, allografts and xenografts.

The autologous temporalis fascia (AF) graft soon became the standard, as it is today, because of its availability in the operative field and its superior qualities, which led to higher success rate (2-4). Nowadays the temporalis graft take rate, according to literature reports, ranges from 77% to 97%, mostly depending on surgeon's experience and adopted technique; in particular, according to some authors, anatomic success, if an overlay technique is adopted, seems to be greater than that with an underlay technique (5-7).

Several kinds of allografts have also been tested as an alternative to AF. AlloDerm, for instance, showed a similar success rate (88%), with several advantages, including eliminating donor morbidity and reducing operative time (8,9). Bovine pericardium (BP; (Tutopach, Tutogen Medical, Alachua,Florida) has been used since 1982 (10-12) and more recently equine pericardium (EP;

Audiomesh, Audiotechnologies, Gossolengo, Italy) initially designed for arterial, ventricular septal (13) and dural reconstruction (14), has been proposed as an alternative to other allografts. Equine Pericardium is a transparent 0.2 mm thick membrane, slimmer than BP (0.4 mm thick) and therefore easier to position. The reason for this difference is the industrial process which makes EP collagen layers compact, reducing its starting thickness.

The aim of this study to compare transmeatal underlay myringoplasty (TUM) results obtained by using, as graft material BP and EP, in order to find, between them, the better option when AF is not available. In general, AF harvesting is always possible, even in case of second surgery, by means of a larger incision toward the vertex; this approach, however, increases the risk of complications and patient discomfort. We have also compared results obtained with BP and EP with those obtained with AF in order to determine the reliability of these grafts in relation to the material most used in myringoplasty.

Patients and Methods. The study group consisted of 52 patients with tympanic membrane perforation and consecutively submitted to TUM by the same surgeon (R.A.). Patients affected by middle ear cholesteatoma or retraction pocket were excluded from the study. Other kinds of miryngoplasty, which represent a larger amount of operations in our Department, were excluded from the study because in those cases BP and EP are only occasionally utilized - above all in revision surgery when AF is not easily available.

Of the enrolled subjects, ranging in age from 5 to 74 years (mean age, 46 years), 29 (56%) were female and 23 (44%) male. The perforation was at the right ear in 27 cases (52%) and at the left ear in 25 (48%). The site of perforation was posterior in 29 subjects (56%), anterior in 16 (30%), inferior in 3 (6%) and subtotal in 4 (8%).

In our hands, TUM is carried out only if the anterior edge of the perforation can be seen through the external ear canal under the surgical microscope. In each patient admitted to the study, surgery was carried out by removing the border of the perforation. Then we created a posterior tympanic-meatal flap (Rosen incision), and we dislocated the fibrous annulus out of the sulcus; the tympanic membrane was elevated and gently detached form the handle of the malleus. The graft was placed under the annulus and the tympanic membrane remnants (underlay technique) and over the malleus handle and the middle ear cleft was filled with fibrin sponge. The operation ended with external meatus packing

with sponge.

In 7 patients (13%) an ossicular chain suffering was observed. The ossicular lesion was located at the malleus in 2 cases (4%), at the incus in 1 (2%), at the incus and malleus in 1 (2%) and at the incus and stapes in 1 (2%). In these cases, we have always carried out ossiculoplasty at same time by means of remodelled incus. Preoperative otorrhea was present in 10 patients (19%).

Twelve patients (23%) had previously undergone myringoplasty.

The TUM was carried out in local anesthesia in 47 cases (90%) and under general anesthesia in 5 (10%).

The kind of graft, BP or EP, was randomly chosen, and patients gave an informed consent to the study. In 29 cases (56%) we utilized BP, and in the remaining 23 (44%) the graft was EP.

Each patient underwent preoperative pure tone audiometry . Air and bone conduction thresholds refer to the average threshold at 0.5, 1, 2 and 3 KHz. The average (±SD) air and bone conduction thresholds were 41 ± 18 dB and 21 ± 13 dB, respectively, and the average air-bone gap was 17 ± 9 dB.

In the same period, we operated on 14 patients with the same technique (TUM) using AF, harvested through a skin incision above the pinna. In this group, ages ranged from 10 to 64 years (mean age, 44 ± 18 years); 7 (50%) were female and 7 (50%) were male, the perforation was in the right ear in 8 cases (57%) and at the left ear in 6 (43%) and the site of perforation was posterior in 9 cases (64%), anterior in 4 (29%) and inferior in 1 (7%). Ossicular chain damage was observed in 3 patients (21%). The ossicular lesions were all located at the incus. Even in these cases, we always carried out ossiculoplasty at the same time by means of remodelled incus. Preoperative otorrhea was present in 2 patients (14%). In this group 2 patients (14%) had been previously undergone myringoplasty. The mean air and bone conduction thresholds in this group were respectively 39 ± 17dB and 21 ± 13 dB, and the average air-bone gap was 17 ± 9 dB.

Each patient was follow up 1 week and again 1 month after surgery; later routine follow-up was carried out after 6 months and then every year. Follow-up consisted of otoscopy and pure tone audiometry. The mean follow-up period was 33 months (range, 14 to 51 months). The postoperative pure tone audiometry results refer to the last evaluation available, depending on follow-up period.

Statistical analysis was carried out by means of SPSS statistical package. A probability (p) value of less than 0.05 was selected level of significance.

Results. Table 1summerizes clinical data of the study group. The differences among the three groups (BP, EP, and AF) are significant for the kind of anaesthesia only, because in cases treated with AF there was a prevalence general anaesthesia.

Closure of the tympanic membrane after surgery at the last follow-up was gained in 51 subjects (77%) whereas in the remaining 15 (23%) we observed graft perforation.

Closure of the perforation was achieved in 13 out of the 14 patients (93%) treated with AF, in 19 of 29 patients (66%) treated with BP, and in 19 of 23 patients (83%) treated with EP. Even though the worst results were obtained by using BP, the difference was not significant different on the χ^2 test (Table 2).

Table 3 shows the numbers and the rates of success and re-perforation in relation to the site of preoperative tympanic membrane perforation, otorrhea, previous surgery and kind of anaesthesia. None of these parameters influenced the outcome ($p>0.05$ on the χ^2 test). Even the evaluation of the above-mentioned parameters in relation to the kind of graft did not lead to significant differences.

The mean air conduction threshold in subjects who gained tympanic closure after surgery (51 cases) decreased from 40 ±18 dB to 36 ± 16 dB. The mean bone conduction was unchanged with respect to presurgery values (22 ± 10 dB). The mean air-bone gap decreased from 18 ± 9 dB to 14 ± 10 dB after surgery. Table 4 reports air-bone gap values before and after surgery in relation to the kind of graft. The best improvement of middle ear function was obtained by means of EP; moreover this was the only graft who determined a significant improvement of air-bone gap on the Student's t-test for paired data (within-group analysis) and on the analysis of variance (between group analysis).

Discussion. The aim of this study was to evaluate both the anatomic and functional outcome of myringoplasty obtained with two heterologous materials, BP and EP, by following a randomised protocol. Moreover, it was our purpose to compare the results with those obtained with the most widely used material (AF).

We focused the study on patients who underwent TUM, because this technique, in our hands, is currently carried out without skin incision in order to obtain the graft[2], reducing the trauma and the risk of hemorrhage for the patients.

The overall long-term rate of tympanic membrane closure was 73%, but this value increase to 77% if the results obtained with AF are considered. Although this outcome is slightly lower than those in the literature (15, 16) it has to be considered that TUM has worse result in terms of perforation closure

because of technical factors, as demonstrated in our previous report [2]. However, it offers the advantage of a less aggressive procedure, as outpatient surgery and under local anesthesia, with low risk of worsening after surgery [2]. Although AF grafting can be performed under local anesthesia, too, in our experience its harvesting increases surgical time and morbidity rate; the skin incision and AF harvesting can give rise to bleeding, hematomas, and wound infections. These complications, even if rare, can lengthen the hospital stay, increasing costs. From this point of view, although using xenografts is more expensive (about US 100$ for each biomembrane) than using AF, their usage allows to perform 3 TUMs instead of 2, in the same amount of time. The best result, in terms of tympanic closure, was obtained by using AF (93% of cases), whereas between the two kinds of xenografts, we had better results with the EP rather than BP (83% versus 66%). These differences are not significant, but they are large enough to induce us to prefer EP for future tympanic reconstruction. The type of graft was randomly chosen for the xenografts while AF was utilized above all in case treated in general anaesthesia (for example in younger patients) or if xenografts were temporarily not available; this could be considered a bias in the comparative evaluation between xenografts and AF, although clinical differences among the three groups were not statistically significant and the interest of our study was principally directed to the evaluation of BP and EP.

The higher success rate with EP may be due to the fact that this graft is thinner (0.2 mm vs 0.4 mm) and easier to be handled and model into the proper shape. A previous report on BP in myringoplasty (11) showed better results (90% success rate), but in that study tympanic perforations, looked smaller than in our cases. It is our opinion that the thicker BP may be a better application thancartilage when reinforcement of the tympanic membrane is needed - for example, in presence of retraction pocket. The AF, from this point of view, showed the best results, but it needs skin incision to be harvested, lengthening the operation time and increasing patient discomfort (5, 17).

The three groups created on the basis of the graft material did not differ from each other in age, site of perforation, ossicular chain condition, presence or absence of otorrhea, previous surgery, or average threshold on pure tone audiometry. The only difference was a higher rate of cases treated with AF fascia under general anaesthesia; therefore, the better results obtained could be partly justified by the easier surgical maneuvers allowed by narcosis. However, we can conclude that the results obtained with EP really expresses the higher efficacy of this graft.

Moreover the outcome was not related to the prognostic factors evaluated in the study, such as preoperative otorrhea, type of anesthesia or former myringoplasty, which therefore cannot be considered as negative indicators for surgery with heterologous grafts.

We evaluated hearing function after surgery only in subjects who gained the tympanic membrane closure, because it was our aim to determine the efficacy for sound conduction of the different kind of graft and the failure of surgery does not allow to determine this. As regards the results of TUM in patients who presented a re-perforation , we demonstrated in a previous study that the middle ear condition was the same as previously and that hearing function did not worsen even in case of failure[2].

The air-bone gap in our successful cases improved by 4 dB in the overall sample, but the best improvement was obtained with EP (even better than AF). This graft seems to guarantee a good functional reconstruction of the eardrum because of its optimal thickness and easy modelling, leading to a better positioning under the tympanic perforation. In conclusion our data suggests that AF fascia gives the best results in term of tympanic closure and that, between the two kind of xenografts tested, the best results are obtained with EP. This graft, moreover, gives the best results in term of functional improvement.

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Tab. I. Clinical characteristics of the patients admitted to the study.

Fascia	Age	Side	Site of perforation	Ossicular chain condition	Othorrea	Previous surgery	Anaesthesia	PTA threshold (dB)
Bovine pericardium (29 cases)	47 (DS 17)	R: 16 (55%) L: 13 (45%)	Post: 19 (66%) Inf: 2 (7%) Ant: 7 (24%) Subtotal: 1 (3%)	Intact: 25 (86%) Damaged: 4 (14%)	No: 18 (62%) Yes: 11 (38%)	No: 22 (76%) Yes: 7 (24%)	Local: 26 (90%) General: 3 (10%)	41 (DS 20)
Equine pericardium (23 cases)	49 (DS 20)	R: 11 (48%) L: 12 (52%)	Post: 10 (44%) Inf: 1 (4%) Ant: 9 (39%) Subtotal: 3 (13%)	Intact: 20 (87%) Damaged: 3 (13%)	No: 20 (87%) Yes: 3 (13%)	No: 14 (61%) Yes: 9 (39%)	Local: 20 (87%) General: 3 (13%)	42 (DS 17)
Autologous fascia (14 cases)	44 (DS 18)	R: 8 (57%) L: 6 (43%)	Post: 9 (64%) Inf: 1 (7%) Ant: 4 (29%) Subtotal: 0 (0%)	Intact: 11 (79%) Damaged: 3 (21%)	No: 12 (86%) Yes: 2 (14%)	No: 12 (86%) Yes: 2 (14%)	Local: 6 (43%) General: 8 (57%)	38 (DS 17)
P	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	<0.001	>0.05

. Statistical analysis was carried out with the ANOVA test of the variance for the age and PTA threshold and chi square test for the other parameters.

Table II. Results obtained in relationship to kind of graft.

	Closure		**Perforation**	
	No.	%	No.	%
Bovine pericadium	19	65.5	10	34.5
Equine pericardiumEP	19	82.6	4	17.4
Temporalis fascia	13	92.9	1	7.1

. Number of rate *(in parenthesis)* of tympanic closure or failure in relation to kind of graft. Differences were not significant at the chi-square test ($p>0.05$).

Tab.III. Outcome of myringoplasty in relation to site of preoperative perforation presence of othorrea, previous surgery, and kind of anaesthesia

	Site of preoperative perforation		Othorrea		Previous surgery		Anaesthesia	
	Closure	Reperforation	Closure	Reperforation	Closure	Reperforation	Closure	Reperforation
Bovine pericardium (29 cases)	Post: 14 (74%) Inf: 2 (100%) Ant: 3 (43%) Subtotal: 0 (0%)	Post: 5 (26%) Inf: 0 (0%) Ant: 4 (57%) Subtotal: 1 (100%)	Yes: 7 (54%) No: 12 (67%)	Yes: 4 (46%) No: 6 (33%)	Yes: 4 (57%) No: 15 (68%)	Yes: 3 (43%) No: 7 (32%)	Local: 16 (61%) General: 3 (100%)	Local: 10 (39%) General: 0 (0%)
Equine pericardium (23 cases)	Post: 8 (80%) Inf: 1(100%) Ant: 8 (89%) Subtotal: 2 (67%)	Post: 2 (20%) Inf: 0 (0%) Ant: 1 (11%) Subtotal: 1 (33%)	Yes: 2 (67%) No: 17 (85%)	Yes: 1 (4%) No: 3 (15%)	Yes: 7 (78%) No: 12 (86%)	Yes: 2 (22%) No: 2 (14%)	Local: 16 (80%) General: 3 (100%)	Local: 4 (20%) General: 0 (0%)
Autologous fascia (14 cases)	Post: 9 (100%) Inf: 1 (100%) Ant: 3 (75%)	Post: 0 (0%) Inf: 0 (0%) Ant: 1 (25%)	Yes: 2 (100%) No: 11 (92%)	Yes: 0 (0%) No: 1 (8%)	Yes: 2 (100%) No: 11 (92%)	Yes: 0 (0%) No: 1 (8%)	Local: 6 (100%) General: 7 (87%)	Local: 0 (100%) General: 1 (13%)
Overall sample (66 cases)	Post: 31 (81%) Inf: 4 (100%) Ant: 14 (70%) Subtotal: 2 (50%)	Post: 7 (19%) Inf: 0 (0%) Ant: 6 (30%) Subtotal: 2 (50%)	Yes: 11 (78%) No: 40 (80%)	Yes: 5 (22%) No: 10 (20%)	Yes: 13 (72%) No: 38 (79%)	Yes: 5 (22%) No: 10 (21%)	Local: 38 (73%) General: 13 (93%)	Local: 14 (37%) General: 1 (7%)

Tab. IV. Air-bone gap before and after surgery in relation to the kind of graft .

	Bovine pericardium (19 cases)	Equine pericardium (19 cases)	Autologous fascia (13 cases)	p
Preoperative air-bone gap	22 (10)	16 (9)	17 (9)	>0.05
Postoperative air-bone gap	19 (9)	9 (9)	14 (9)	= 0.005
difference	3	7	3	3
p	>0.05	<0.05	>0.05	

. Table considers only cases that gained the closure of the eardrum. Data refer to the average at 0.5,1,2and 3- kHz. Postoperative air-bone gap was significantly reduced only by using EP either on within-technique analysis or on between-technique analysis on analysis of variance (between group analysis) and on Student's t-test for paired data (within group analysis).