

Treatment of Gastro-Esophageal Reflux Disease May improve Surgical Outcomes for Chronic Otitis Media

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ABSTRACT

BACKGROUND

This study has been designed to investigate the clinical association between gastro esophageal reflux disease (GERD) and chronic otitis media (COM) in adults and also the role of GERD treatment on the outcome of COM surgery.

METHODS

In a randomized clinical trial, 58 patients with COM who were candidates for surgery were evaluated for GERD and divided in two groups; GERD positive (case) and GERD negative (control) patients. The GERD positive patients were randomized to either receiving medical treatment for GERD or not prior to surgery. The surgical outcomes were assessed at 3 and 6 months after COM surgery in the three groups.

RESULTS

Fifty-eight (26 males) patients were enrolled. Forty-two (72.4%) of these had GERD according to a validated questionnaire. Three months after surgery auditory recovery in GERD negative patients was significantly higher [16(100%)] than those suffering from GERD [28 out of 42 (66.7%)], $p=0.008$. The figures remained similar at six months follow up as well (100 % vs. 72.5% in GERD negative and positive patients respectively, $p=0.002$).

In the GERD-positive group, 8 of 18 (44.4%) patients who did not receive GERD treatment before tympanomastoidectomy recovered after three months whereas, while 20 of 24 (83.3%) patients who received GERD treatment recovered during this time ($p<0.001$). At six months 44.4% of non-treated GERD patients had auditory recovery as compared to 95.5 % of those treated for GERD ($p<0.01$).

CONCLUSION

Our data show that the effect of GERD on the outcome of COM surgery may be considerable. On the other hand, treating COM patients for GERD medically for two months before tympanoplasty improves the surgical outcomes. Therefore, we suggest that COM patients be evaluated for GERD before undergoing tympanoplasty and if GERD is present, they be treated medically for a couple of months before undergoing surgery.

KEYWORDS

Tympanomastoidectomy; Treatment; GERD; Chronic otitis media; Outcome

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INTRODUCTION

Gastro esophageal reflux (GER) is the backflow of gastric contents into the esophagus. GER may occur in healthy subjects without any complaint or physiologic disturbance. Esophageal disorders or any disturbances of the patient's quality of life due to GER can lead to "gastroesophageal reflux disease, GERD". Heartburn and regurgitation are common complaints. Generally speaking, GERD symptoms have been reported in up to 20% of the population.¹ Various studies in Iran have addressed its prevalence, risk factors and symptoms.²⁻⁴ GERD complications include erosive esophagitis, esophageal ulcers, esophageal stricture, Barrett's esophagus and adenocarcinoma.⁵ Some otorhinolaryngological problems have been related to GERD.⁶⁻⁹ These include hoarseness, laryngitis, post-nasal discharge (PND), throat clearing stridor, laryngospasm and subglottic stricture.¹⁰⁻¹³ Chronic Otitis Media (COM) is one of the common diseases of the middle ear. COM is defined as tympanic membrane perforation due to middle ear infection persisting more than 3 months. Various microorganisms are considered as etiologic agents in COM. Other predisposing factors may also play determining role in persistence of the disease.

Standard treatment for COM is surgery (tympanomastoidectomy). In this procedure irreversible damage to mucosa and bone such as granulation tissue and osteitis are removed to eradicate the infection and make an effective connection between Eustachian tube, middle ear cavity and the mastoid air cells. Perforation of the tympanic membrane and sound conduction system of the middle ear are also repaired.

Recovery is defined as complete repair of the tympanic membrane and securing an effective connection between the Eustachian tube and the middle ear cavity and mastoid. Effective connection means presence of air behind the the tympanic membrane and appropriate movement of the membrane.

Crapko¹¹ and Sone studied the relation between GERD and middle ear effusion. In Velepik¹⁴ study relation between GERD and tubotympanic disorders were assessed.

The purpose of this study is to review the association between GERD and COM and the association between GERD and its treatment on outcome of tympanomastoidectomy.

MATERIALS AND METHODS

Fifty-eight patients with COM, who came to a referral outpatient clinic in Imam Khomeini Hospital, Tehran, Iran and were candidates for tympanomastoidectomy from February 2005 to February 2006, were enrolled in this clinical trial. COM was diagnosed by expert otorhinolaryngologists (AKY, AT) on clinical grounds.

Patients were excluded if they met fell into any of the following categories: presence of cholesteatoma, harboring any neoplasm of the ear, not consenting for surgery, tendency and Satisfaction to the surgery, having COM complications either limited to the temporal bone or beyond, presence of COM in the only hearing ear, having previous surgery on the affected side, harboring any gastrointestinal (GI) cancer, having previous upper gastrointestinal surgery (including open surgery or endoscopic surgery except for cholecystectomy), being uncooperative (mental problems), having esophageal varices on endoscopic examination, using proton pump inhibitors or H₂ blockers during the last two weeks before enrollment or being pregnant.

At first patients' medical history, especially ear problems, and GERD related laryngopharyngeal symptoms were recorded in the ENT clinic and then the patients were referred to the GI clinic in order to be evaluated for GERD. All patients were assessed for GERD symptoms (acid regurgitation and heartburn) and all those having GERD clinically underwent upper GI endoscopy.

Diagnosis of GERD was based on the presence of GERD related complaints or mucosal erosions found on endoscopy. Thereafter, the patients were divided into two groups: GERD positives and GERD negatives. Then the GERD positive patients were randomly assigned into two groups (eight blocks); one group was treated with omeprazole 20 mg two times a day for eight weeks and the other group did not receive any medication for GERD. The randomization process was block randomiza-

tion (blocks of eight) using a computer generated random table. Allocation concealment was central so that the random number would have been opened after the patient was considered eligible and consented to participate in the study.

All patients underwent tympanomastoidectomy by means of standard methods and the patients' outcomes were assessed three and six months after surgery. All of the patients gave informed consent to participate in the study.

Chi-square and Student's t-test were used to compare the groups where appropriate. All of the analyses were done using SPSS 15.0 and the level of significance was set at 0.05.

RESULTS

Forty-two (72.4%) of 58 patients (32 females and 26 males) with COM had GERD. The sixteen GERD negative patients served as controls. Nineteen (45.2%) GERD positive patients and 7 (43.8%) GERD negatives were males ($p=0.91$). Mean age in the GERD positive group was 35.0+/-12.8 years and in the non-GERD group was 39.3+/-13.5 years ($p=0.36$). Nineteen patients (32.8%) had right-sided ear involvement and 11 patients (19%) had left-sided involvement. Twenty-eight patients (48.2%) had bilateral involvement. Twenty (47.6%) GERD positive patients and 8 (50%) GERD negatives had bilateral involvement (p value=0.21). Findings during surgery in the two groups are compared in table-1.

All 16 GERD-negative patients recovered after three months, whereas 28 of 42 GERD-positive patients recovered at three months (100% vs. 66.7% respectively, p -value =0.008). At six months, 29 of 40 GERD-positive patients available for follow-up had recovered (72.5%, $p=0.019$). Within the GERD-

positive group,¹⁸ patients did not receive any GERD treatment and 24 received GERD treatment before surgery (table-2). Treated GERD patients had a significantly higher recovery rate at here months than those who were not treated for GERD before surgery (83.3% vs. 44.4%, $p<0.001$). The same difference was seen at 6 months (87.5% vs. 44.4%, $p<0.001$).

DISCUSSION

In our series 72.4% of COM patients had GERD which is considerably higher than that reported in the Iranian general population.²⁻⁴ This relationship between GERD and COM has been reported by other investigators as well^{8,9,15} which have proposed a possible etiological association between GER and COM.

Our data also shows that GERD positive patients have more unusual findings in their middle ears than the control group. In addition, the rate of obstructed Eustachian tube and fixed ossicles of the middle ear was higher among COM patients with GERD. These findings suggest higher levels of tissue damage in the middle ear of patients having GERD. Whether this is an association or there is a causal relationship, remains to be determined. We also have shown that the recovery rate after tympanomastoidectomy was less among GERD patients than the control group. This could either be due to the damaging effect of gastric refluxate or the fact that these patients had a worse damage to begin with.

We also have shown that although treated and non-treated GERD patients are similar regarding their middle-ear findings during surgery, but treating GERD medically improves outcomes of tympanomastoidectomy significantly and that this effect remains at six months follow-up. A major short-coming

Table 1: Surgical findings in patients with and without GERD.

Finding during surgery	Patient group	positive	Negative	P-value
Unusual finding in the middle ear	non-GERD	1 (6.2%)	15 (93.8%)	0.001
	GERD	39 (92.2%)	3 (7.1%)	
Obstructed Eustachian tube	non-GERD	0 (0.0%)	16 (100%)	0.002
	GERD	18 (42.9%)	24 (57.1%)	
Fixed ossicles	non-GERD	0 (0.0%)	16 (100%)	0.005
	GERD	15 (35.7%)	27 (64.3%)	

Table 2: Surgical findings among medically treated and untreated GERD patients.

Finding during surgery	Patient group	positive	Negative	P-value
Unusual finding in the middle ear	Untreated	17(94.4%)	1(5.6%)	0.73
	treated	22(91.7%)	2(8.2%)	
Obstructed Eustachian tube	Untreated	5 (27.8%)	13 (72.2%)	0.087
	treated	13 (54.2%)	11 (45.8%)	
Fixed ossicles	Untreated	7 (38.9%)	11 (61.1%)	0.71
	treated	8 (33.3%)	16 (66.7%)	

of this study is the relatively small number of cases enrolled. In addition, the non-treated GERD patients did not receive placebo. Therefore, we suggest a larger study with blinding and placebo control to better assess the relationship between COM and GERD and its treatment effect on surgical outcomes for COM.

To conclude, our data supports a potential association between GERD and COM and that presence of GERD and its appropriate treatment may affect outcomes for COM surgery. According to our findings, looking for GERD in COM patients who are about to undergo tympanomastoidectomy and treating GERD if present prior to surgery may help improving surgical outcomes. A placebo-controlled, larger scale study is needed to better assess these findings.

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CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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