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Original Research Article

A study to compare the outcomes of laser myringotomy and conventional incision myringotomy

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ABSTRACT

Background: The objective of the study was to compare the outcomes of laser myringotomy and incision myringotomy in terms of operating time, patency of opening, hearing improvement, and disease recurrence.
Methods: This study is a prospective study done among 35 children and 68 ears. All cases which were diagnosed to have otitis media with effusion were randomly assigned into two groups: group 1 was treated with diode laser myringotomy and group 2 was treated with conventional incision myringotomy without grommet insertion. These patients were followed up at regular intervals and compared in terms of operating time, patency of opening, recurrence of disease and hearing improvement.
Results: Diode laser myringotomy took an average operating time of 6.38 minutes and the patency of opening was maintained for an average of 13.59 days, compared to the average operating time for incision myringotomy of 9 minutes, and the patency of opening being 12.35 days. These differences were statistically significant ($p<0.0001$ for operating time and $p=0.041$ for patency of opening). Hearing improvement was also found to be better in laser myringotomy group ($p=0.021$).
Conclusions: Diode laser myringotomy is an effective, easy and less time-consuming modality than incision myringotomy for the treatment of otitis media with effusion.

Keywords: Otitis media with effusion, Diode laser myringotomy, Incision myringotomy, Patency of opening

INTRODUCTION

Otitis media with effusion is defined as the chronic accumulation of mucus within the middle ear and sometimes the mastoid air cell system.[1] It is also known as serous otitis media, secretory otitis media, mucinous otitis media, glue ear, blue drum, tubotympanitis, tympanic hydrops or exudative catarrh. It is the leading cause of conductive hearing loss in the pediatric population.[2] It is a very common problem among children and even young adults necessitating surgeries in many of the cases.

Hearing plays an important role in speech development in children.[5] Hence, otitis media with effusion with hearing loss may have adverse effects on cognitive, linguistic and communicative skills in a child.[3] It presents with varied clinical features like hearing loss, ear ache, fullness in the ear, and may be even asymptomatic. It can result in various sequelae like chronic suppurative otitis media, adhesive otitis media, retraction pocket, cholesteatoma formation, atrophic tympanic membrane, tympanosclerosis and even sensorineural hearing loss. A high index of suspicion is mandatory for the early and prompt diagnosis of the disease, thereby preventing the delayed sequelaes.

It is accepted that mild forms of the disease resolve spontaneously and the remaining cases can be treated either conservatively or surgically.[4] Surgical intervention

is done when there is effusion lasting for more than 4 months, failure of medical treatment, and also depends on the hearing status of the patients.[2] The main aim of surgical treatment is to provide drainage of effusion and middle ear ventilation.[2]

Incision myringotomy and ventilation tube insertion is the accepted and has been the most common surgical treatment procedure. It was for the first time described by Dr. Armstrong in 1954.

Laser myringotomy in human ears was first introduced by Goodel in 1979. It has been recommended as an alternative surgical procedure for otitis media with effusion. Recent advances in laser technology have made this procedure feasible in the office setting and useful in the operating room. Lasers commonly used for myringotomy are diode laser, CO2 laser, argon laser, Nd: YAG laser. It is important to take a wise decision regarding the method of surgical treatments for otitis media with effusion keeping in mind the advantages and disadvantages of each.

Hence, this study is undertaken to compare the outcomes of treatment of otitis media with effusion using diode laser and conventional incision myringotomy.

METHODS

The study design was prospective comparative study. The study group included children aged between 4 yrs and 12 yrs suffering from secretory otitis media. Children with history of ear discharge, previous myringotomies and sensorineural hearing loss were excluded from the study. Among total of 35 children, two groups comprising 34 ears each were formed. The first group (Group 1), underwent myringotomy using diode laser. The other group (Group 2) underwent myringotomy with conventional incision method.

All the children were subjected to pure tone audiometry, nasopharyngeal imaging for adenoid hyperplasia and tympanometry. All the children, except one, underwent myringotomy combined with adenoidectomy.

Diode laser with 400micron fibre and 5-watt setting was used in laser group. For incision myringotomy, politzer myringotome was used and 2 mm radial incision was given. After aspirations of secretions, N-acetyl cysteine (0.5ml) was instilled in the ears in both groups.

The patients were regularly followed up and outcomes in terms of patency of myringotomy opening, hearing improvement, and recurrence of disease were compared.

The patients were randomly allocated. Non-parametric tests and Kolmogorov-Smirnov test for normality of data was used. Quantitative variables were compared using independent T-test/mann-whitney test between two groups and kruskal wallis test was used to compare patency of opening. Qualitative variables were correlated using chi-square test/fisher's exact test. P value<0.05 was considered statistically significant. Statistical packages for Social Science (SPSS) version 21.0 was used.

RESULTS

Our study was conducted among a total of 35 patients and 68 ears. Both ears of 33 patients and one ear of the other 2 patients were considered in our study after fulfilling the inclusion and exclusion criteria. All the ears taken in for our study were randomly divided into two groups: group 1 underwent laser myringotomy and group 2 underwent incision myringotomy.

Out of 68 ears considered, only 29.41% presented with complaints of hearing impairment in each group. Among the total 68 ears considered for our study, majority didn't have the complaints of hearing impairment (Table 1).

Table 1: Age group distribution.

Hearing impairment	Group 1 N (%)	Group 2 N (%)	Total (%)
No	24 (70.59)	24 (70.59)	70.59
Yes	10 (29.41)	10 (29.41)	29.41
Total	100.00	100.00	100.00

In our study, among the 34 patients taken for laser myringotomy, the mean hearing loss in PTA was 26.23 dBHL with a standard deviation of 6.3. In contrary, in the incision myringotomy group, the mean hearing loss in PTA was 22.86 dBHL with a standard deviation of 5.53. The highest hearing loss in group 1 was 34.5 dBHL and in group 2, it was 32.5 dBHL.

In the present study, in group 1, the mean operating time was less than that of group 2. The P value was <0.0001, which indicates that it is statistically very significant. This suggests that laser myringotomy needs significantly less operating time (Table 2).

Table 2: Comparison of operating time in two groups.

Operating time (min)	Group 1	Group 2	P value
Sample size	34	34	<0.0001
Mean±Standard deviation	6.38± 1.23	9±1.15	
Median	6	10	
Min-Max	5-8	7-10	
Inter quartile Range	5 – 8	8 - 10	

In the postoperative PTA at the end of 2 months, the mean hearing improvement in each group were compared with adding appropriate standard deviations. The p value on comparison was 0.021, which was statistically

significant, indicating a better hearing improvement in group 1 (Table 3).

Table 3: Comparison of hearing improvement in two groups.

Hearing improvement (dbhl)	Group 1	Group 2	P value
Sample size	34	31	0.021
Mean±Standard deviation	13.12± 5.52	10.16± 4.39	
Median	13.42	10	
Min-Max	2.5-23.75	1-18	
Inter quartile range	9-17	6.562-13	

Regarding patency of myringotomy opening, in group 1 the mean patency of myringotomy opening was 13.59 days with a standard deviation of 1.67. In group 2, the mean patency of myringotomy opening was 12.35 days with a standard deviation of 3.01. In group 1 and group 2 , the maximum duration of myringotomy patency was found to be 14 days and the minimum duration was found to be 7 days. The p value was found to be 0.041 which was statistically significant, showing increased duration of patency of the myringotomy opening in group 1 (Table 4).

The recurrence of the disease was assessed by otoscopic findings and postoperative tympanometry, done at the end of 2 months. There was no recurrence in group 1 at the end of 2 months and in group 2, there was recurrence in one ear which constituted about 2.94 % of the total cases. The p value after calculation was found to be 1 which was not statistically significant (Table 5).

Table 4: Comparison of patency of myringotomy opening in two groups.

Patency of opening (days)	Group 1	Group 2	P value
Sample size	34	34	0.041
Mean ±Standard deviation	13.59± 1.67	12.35± 3.01	
Median	14	14	
Min-max	7-14	7-14	
Inter quartile range	14 - 14	14 - 14	

Among the 34 ears taken for laser myringotomy in group 1, there were no noticeable postoperative complications. In group 2, six ears developed tympanosclerotic patches in the pars tensa which was noticed at the end of one month postoperatively. After statistical analysis, we found that the p value was 0.024 which was significant. Hence, in our study, it was found that there was an increased incidence of tympanosclerotic patches following incision myringotomy when compared to laser myringotomy (Table 6).

Table 5: Comparison of disease recurrence in two groups.

		Surgical procedure(ear)		Total	P value
		Group 1	**Group 2**		
		N (%)	**N (%)**	**N (%)**	
Disease recurrence	No	34 (100.00)	33 (97.06)	67 (98.53)	1.000
	Yes	0 (0.00)	1 (2.94)	1 (1.47)	
Total		34 (100.00)	34 (100.00)	68 (100.00)	

Table 6: Comparison of surgical complications in two groups.

		Surgical procedure (ear)		Total	P value
		Group 1	**Group 2**		
		N (%)	**N (%)**	**N (%)**	
Complications	Nil	34 (100.00)	28 (82.35)	62 (91.18%)	0.024
	Tympanosclerotic patches	0 (0.00)	6 (17.65)	6 (8.82%)	
Total		34 (100.00)	34 (100.00)	68 (100.00)	

DISCUSSION

Otitis media with effusion is one of the leading causes of conductive hearing loss in the pediatric population. It is a very common problem among children and even young adults necessitating surgeries in many of the cases.

Among the 68 ears taken for our study, 29.41% presented with symptoms of hearing impairment. We found in our study that because the study population was in the paediatric age group, significantly appreciable symptoms like ear ache was found to be the most common presenting complaint rather than hearing loss.

In a research conducted by Varsak et al on the prevalence of otitis media with effusion among school age children, it was found that the most common presenting complaint was hearing impairment in (33%).[6] Reddy observed that hard of hearing was one of the major complaints in cases of otitis media with effusion.[7]

All of these surgeries were done under general anaesthesia considering the age of the children. In the present study, in group 1, the mean operating time was 6.38 minutes with a standard deviation of 1.23. In group 2, the mean operating time was 9 minutes with a standard deviation of 1.15. The p value after statistical analysis for this was found to be <0.001, which indicates that it is statistically very significant. There were no intraoperative complications in both the groups, except for minimal bleeding which was noted in group 2 when compared to group 1, which would have resulted in an increased operating time in group 2. The surgical field with laser myringotomy was quite bloodless.

In the same article published by Yousaf et al on the comparative study on laser and incision myringotomy in otitis media with effusion, all the 98 ears considered in the study were divided into 2 groups: 48 ears were treated by laser myringotomy and 50 ears were treated by incision myringotomy.[3] It was found that 54% hearing improvement was present in laser myringotomy group and only 24% improvement in incision myringotomy group.

In the present study, the mean hearing loss in the preoperative PTA was 26.23 dBHL in group 1 and in group 2, it was 22.86 dBHL. At the end of 2 months follow up period, a postoperative PTA was done for all patients included in our study to assess the hearing improvement. It showed a mean value of 13.6 dBHL in group 1 and a mean value was 13.95 dBHL in group 2. We also found that the mean hearing improvement in group 1 was 13.12 dBHL and in group 2, it was 10.16 dBHL. The p value on comparison was 0.021 which was statistically significant; hence this showed that there was better hearing improvement in ears in group 1, which underwent laser myringotomy when compared to incision myringotomy.

In group 1 (laser myringotomy) the mean patency of myringotomy opening was 13.59 days and in group 2, the mean patency of opening was 12.35 days. The p value was found to be 0.041 which was statistically significant. Hence, we proved that the myringotomy opening remained patent for longer time in the ears in group 1 treated with laser myringotomy compared to those treated with incision myringotomy.

We found that there was no disease recurrence (disease resolution at the end of 2 months) in laser myringotomy group at the end of 2 months and in group 2, there was recurrence in one ear. The p value after calculation was found to be 1 which was not statistically significant. Similar observations were made by Yousaf et al, where it was found that laser myringotomy showed longer patency of myringotomy opening, helping in resolution of middle ear effusion and less chance of disease recurrence.[3] In this study, the middle ear effusion recurrence was found to be 46 % in laser myringotomy group and 76% in incision myringotomy group. Hence, it is possible that even though the myringotomy opening remained patent for longer time in laser myringotomy when compared to incision myringotmy, it didn't have a significant effect on disease recurrence in each group. Disease recurrence can be determined by many other associated factors, one of the important factors among which is allergy.

Among the 34 ears which underwent laser myringotomy, there were no complications noted postoperatively, whereas among the 34 ears which underwent incision myringotomy, 6 ears developed tympanosclerotic patch in the pars tensa noticed at the end of 2nd month. After statistical analysis, we found that p value was 0.024, which was significant. This led us to the conclusion that incision myringotomies even without ventilation tube insertion are significantly associated with myringosclerosis, when compared to laser myringotomy.

Yousaf et al observed that there was a higher incidence of complications like intraoperative bleeding, persistent otorrhoea, persistent perforation, and atrophic scar in incision myringotomy group compared to the laser myringotomy group.[3] They found that intra-operative bleeding occurred in no ear operated with LM in group-1 as against 8 (16%) ears treated with IM. One ear (2.08%) in LM group and 4 (8%) ears in IM group developed ear discharge. Two ears (4.16%) had atrophic scar and 1 ear (2.08%) had persistent perforation in laser myringotomy group. In incision myringotomy group, 10 ears (20%) had retraction of tympanic membrane, two ears (4%) had persistent perforation which had developed otorrhoea postoperatively and two ears (4%) had hypertrophic scar due to delayed healing having ear discharge.

CONCLUSION

The surgical outcomes of diode laser myringotomy in the treatment of otitis media with effusion is found to be superior to that of incision myringotomy in terms of less operating time, better hearing improvement and longer patency of myringotomy opening. No significant difference in disease recurrence is noted between the two groups. Even though the incidence of intrao-perative complications were comparable between laser and incision myringotomy, the incidence of postoperative myringosclerosis is more with incision myringotomies. Diode laser myringotomy is an effective, easy and less time-consuming modality than incision myringotomy for the treatment of otitis media with effusion.

Further controlled clinical trials need to be conducted on a larger group of population with a longer follow up, in order to understand and implement laser myringotomy as

a sole and effective treatment for otitis media with effusion.

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