



Research Article

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EFFECT OF MAHAMASHA THAILAM AS SHIROPICHU IN SENSORI-NEURAL DEAFNESS OF CHILDREN UP TO 12 YEARS

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ABSTRACT

Deafness is a condition which affects hearing and other milestones in children. If not detected early and adequate measures taken, delay in language and social development can occur. The trial was aimed to assess the efficacy of Mahamasha thailam as shiropichu in Badhiryam (with special reference to sensori-neural hearing loss) in children up to 12 years. It was also intended to find out the effects on associated speech deficits. The study was carried out in Govt. Ayurveda College Hospital for Women & Children, Poojappura, Thiruvananthapuram as an interventional, open randomized controlled clinical trial. Children with hearing loss associated with recurrent respiratory tract infections, behavioral problems, systemic disorders like diabetes mellitus, osteogenesis imperfecta and tumors like acoustic neuroma were excluded from the study. The total sample population constituted 20 children. Mahamasha thailam as shiropichu was done for 41 days in the study group whereas no treatment was given to the control group. The final assessment showed statistically significant results ($p < 0.01$) in both hearing and speech components like vocabulary and clarity. The treatment could not improve hearing in all children but it clearly arrested progression of hearing loss in all the subjects of study group. In the control group, deterioration in hearing was observed after the follow up period. It can be concluded that Mahamasha thailam as shiropichu arrests the progression of hearing loss and improves vocabulary and clarity of speech in sensori-neural deafness of children up to 12 years.

Keywords: Mahamasha thailam, Shiropichu, Ayurvedic Intervention, sensori-neural deafness, language development

INTRODUCTION

Hearing plays a uniquely important part in our lives. We depend on its efficient functioning as we talk and listen to one another. It is more important in case of children as the child's emotional, cognitive and linguistic development depend on hearing¹. Except for hearing aids and Cochlear implantation², allopathic science does not have much to offer in the management of hearing impairment. The cost of equipments and surgery keeps these beyond the reach of middle- and lower-class population. Professional experience has shown that shiropichu³ (an Ayurvedic therapeutic procedure consisting application of medicated oil on head), has the potential to improve hearing, and further aids language development and learning skills in children. Sensori-neural deafness or Badhiryam⁴ is a condition caused by vata vitiation. As per Ayurvedic texts and clinical experience, Mahamasha thailam⁵ is effective in vata predominant disorders, but its effect on hearing impairment has not been studied previously. So it was decided to study the effect of Mahamasha thailam as shiropichu in Badhiryam (with special reference to sensori-neural hearing loss) in children up to 12 years. The main aim was to know whether Mahamasha thailam as shiropichu was effective in improving hearing. The other objectives were to find out whether this management had effect in associated speech deficits and to assess the long-term effect of the procedure.

MATERIAL AND METHODS

The study was conducted as an interventional, open randomized controlled efficacy clinical trial at Government Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram. Due to non-availability of basic

infrastructure for the assessment of hearing impairment in this hospital, audiometric procedures were carried out at the National Institute of Speech and Hearing (NISH), Thiruvananthapuram, a reputed institute in the field of audiology. Formal permission was sought from the Principal of Government Ayurveda College, Thiruvananthapuram and the Director of NISH, Thiruvananthapuram, before commencing the study. Ethical approval was obtained from the Ethical Committee of Government Ayurveda College, Thiruvananthapuram (Ref No. E2-257-06 AVC dt 12/04/2005 TVM). The patients attending the outpatient department of Government Ayurveda College Hospital for Women and Children, Thiruvananthapuram were screened and those children satisfying the inclusion criteria were selected. The parents were given the study details and an informed consent was obtained. Children with hearing loss associated with recurrent respiratory tract infections, behavioral problems, diabetes mellitus, osteogenesis imperfecta and acoustic neuroma⁶ were excluded from the study. The study period was 18 months and the sample size were 20. The subjects were stratified into three age groups (0-3, 3-6, 6-12 years). The duration of treatment was 41 days with a follow up period of 6 months. The study was carried out considering the safety of the trial drug and procedure. Both are widely used in clinical practice and no adverse effects have been reported so far. Badhiryam has no proven medical management other than amplification using hearing aids and cochlear implantation⁷. So no treatment was given to the control group. All children of both groups underwent speech therapy⁸ at NISH, Thiruvananthapuram.

Mahamasha thaila was prepared by qualified and experienced technical staff in the presence of the researcher at Government

Ayurveda college pharmacy, Thiruvananthapuram.

The children of the study group were admitted in the hospital. The children were made to sit in a room devoid of excess sunlight and wind. A thin cotton piece, 15 x 15 cm was kept over the head. This was covered using a cotton cloth piece with a hole of 2 cm diameter corresponding to the bregma. Another piece of cotton cloth about three cm wide, glued with paste of black gram was used to hold everything in place. This elaborate procedure was performed to ensure that the children did not remove the cotton kept on the head. 45 ml of lukewarm mahamasha thailam was poured from a height of about 5 cm, on the cotton through the hole of the cloth piece over the anterior fontanel region. This was kept for one hour. The whole procedure was done at about 10 am daily for 41 days. Interview in the form of history taking, examination and audiograms were used as research techniques. Different types of audiogram techniques⁹ like BERA, PTA etc. were utilized for different age groups. Audiological evaluation was done free of cost for poor patients and for others at a concession rate at NISH. Both the groups were assessed before study, after 41 days and follow up period for changes in audiograms values, vocabulary levels and clarity of speech.

Statistical analysis

The experimental variable was shiropichu with Mahamasha thailam. The hearing level was the measured variable in the study.

The data was presented by constructing suitable tables and graphs. Paired t- test, Z-test and Mann-Whitney 'U' test was used to compare changes in the mean and standard deviation scores (before and after) between the groups and within the groups.

RESULTS

Of the total children who participated in the trial, 11 were in the age group of 3-6 years, 6 of 6-12 years and the remaining of 0-3 years. 13 of the subjects were males and other females. 15 (75%) belonged to middle class whereas; rest of them belonged to lower socio-economic class.

The distribution of 20 subjects as per disease characteristics was as follows. 13 children (65%) had congenital hearing impairment and 7 (35%) acquired deafness. 5 (25%) children had delayed development of milestones. 17 (85%) had progressive hearing loss.

The data regarding audiogram values and improvement in speech components namely vocabulary and clarity were recorded before, after the study and the follow up period. Results of statistical analysis are as follows.

Effect of Treatment on Audiometric Evaluation

Rt. Ear

Hearing levels of the study group based on audiogram of right ear with mean and standard deviation of 103.8 ± 6 changed to 104.2 ± 6.7 after treatment. When assessed with paired t- test, no significant improvement was seen ($p > 0.05$). In addition, the mean and standard deviation of 104.2 ± 6.7 after treatment changed to 102.3 ± 4.9 after following up period. $p > 0.05$ shows that there was no improvement in the hearing level. The hearing level remained stable. In the control group, the hearing levels based on audiogram of right ear with mean and standard deviation of 100.6 ± 7.4 changed to 100.7 ± 7.7 after 41 days. When assessed with paired t- test, no significant improvement was seen ($p > 0.05$). In addition, the mean and standard deviation changed to 106.9 ± 4.9 after the follow up period. The $p < 0.05$ showed

that the hearing level deteriorated in the absence of treatment. When the percentage change of hearing levels of the right ear of both the groups were compared after 41 days, p value was > 0.05 . Thus, there was no significant difference in the hearing of both groups; however, when we compared the percentage change of hearing levels of the right ear of both the groups after the follow up period, $p < 0.01$. Thus, there was a significant difference in the hearing of both the groups.

Left ear

The hearing levels of the study group based on audiogram of left ear with mean and standard deviation of 103 ± 7.6 changed to 103.4 ± 6.5 after treatment. When assessed with paired t- test, no significant improvement was seen ($p > 0.05$). In addition, the mean and standard deviation of 103.4 ± 6.5 after treatment changed to 101.4 ± 5.8 after follow up. The $p > 0.05$ shows that there is no improvement in the hearing level. The hearing level remained stable. In the control group, the hearing levels based on audiogram of left ear with mean and standard deviation of 101.1 ± 6.0 in the beginning changed to 104.3 ± 6.9 after 41 days. When assessed with paired t- test, a significant difference in the hearing level was seen ($p < 0.05$). In addition, the mean and standard deviation changed to 106.4 ± 6.5 after the follow up period. The $p < 0.01$ shows that there is a considerable change in the hearing level. This proved that the hearing level deteriorated in the absence of treatment. When the percentage changes of hearing levels of the left ear of both the groups were compared after 41 days, p value was < 0.05 . There was a significant difference in the hearing of both groups. The comparison of percentage change of hearing levels of the left ear of both the groups after the follow up period showed that $p < 0.01$, which was significant.

Vocabulary and Clarity of Speech

The subjects reported improvement in the vocabulary levels. The mean and standard deviation before treatment were 7.8 ± 4.6 , which changed to 11.4 ± 4.4 after follow up. The treatment was very effective with regard to vocabulary in the study group ($p < 0.01$). In the control group, the mean and standard deviation before treatment were 5 ± 5 , which turned to 5.4 ± 5.1 after follow up. No significant improvement was noticed in the vocabulary ($p > 0.05$). 70 % of the subjects and 20 % of the controls reported improvement in the clarity of speech. Comparing both the groups, the 'p' value < 0.05 , which was significant. It means that the treatment was effective in improving the clarity of speech.

DISCUSSION

The children recruited into the study were stratified into different age groups (0-3, 3-6, 6-12 years). Such a grouping was done to study the effect of the trial drug based on age difference. The site of application is to be taken into consideration in this context. Up to 18 months of age, the anterior fontanel remains open and there is possibility of increased permeability of the drug. Moreover, the brain development and the acquisition of speech occur very fast in the younger age.

Different audiogram techniques were used in different age groups as children of lower age group (0-3 years) are unable to respond to commands during pure tone audiometric evaluation.

All the subjects had profound hearing loss. After the treatment period of 41 days, no significant improvement in hearing levels was noticed. The treatment was able to improve hearing in only three subjects out of 10, but the progression of hearing loss was arrested in all, which proved the capacity of Mahamasha thailam as shiropichu to prevent further deterioration of the condition. The three children who showed improvement in hearing had acquired deafness whereas all others had congenital deafness.

Shiropichu with Mahamasha thailam was also effective in improving the vocabulary levels and clarity of speech.

Moordha thailam is a form of Bahyasnehana (external application of oil), especially indicated in vatikarogas of shiras. It is capable of producing indriyaprasada (clarity of sense organs). Among moordhnithaila, shirovasti is the best procedure, but considering the practical difficulty in performing Shiropichu in children below 12 years, shiropichu, which is a comparatively simpler procedure, was selected.

Shiropichu is a kind of topical application of oil on head, especially on the fontanel region, for a particular time interval. The skin is permeable to lipids due to the lipid layer present. Thus,

diffusion of the active ingredients may have occurred through the lipid layer of the skin of the anterior fontanel, entered the CSF, and were circulated all over the brain through the C.S.F pathway. Certain changes in the potential differences may have taken place that stimulated the brain, thereby increasing the efficiency in functioning of the auditory area located in the temporal region. This may have spurred neuro development. The oily nature of the drug may have improved the integrity of the cranial bones and transmission of sounds thereby increasing the bone conduction also. Therefore, the hearing remained stable by the combined effect of all these. The stimulation given to the brain resulted in the active functioning of speech centres too, which resulted in improvement in the vocabulary and clarity of speech.

Table 1: Effect of treatment on Audiometric evaluation (Right) in different groups

Group	Stage	Mean	SD	N	Group	mean difference	paired 't'	p
Study	BT	103.8	6.0	10	BT Vs AT	0.3	0.42	p > 0.05
	AT	104.2	6.7	10	BT Vs AFU	1.5	1.60	p > 0.05
	AFU	102.3	4.9	10				
Control	BT	100.6	7.4	10	BT Vs AT	0.1	0.17	p > 0.05
	AT	100.7	7.7	10	BT Vs AFU	6.4	3.06	p < 0.05
	AFU	106.9	4.9	10				

Table 2: Comparison of percentage change in Audiometric evaluation (Right) under different treatment (+): increase (-): Decrease

Group	Study			Control			Mann-Whitney U	p
	Mean	SD	N	Mean	SD	N		
BT and AT	(+) 0.3	2.3	10	(+) 0.1	2.3	10	39	p > 0.05
BT and AFU	(-) 1.4	2.7	10	(+) 6.7	7.2	10	5.5	p < 0.01

Table 3: Effectiveness of treatment on Audiometric evaluation (Left) in different groups

Group	Stage	Mean	SD	N	Group	mean difference	paired 't'	p
Study	BT	103.0	7.6	9	BT Vs AT	0.4	0.48	p > 0.05
	AT	103.4	6.5	9	BT Vs AFU	1.6	0.87	p > 0.05
	AFU	101.4	5.8	9				
Control	BT	101.1	6.0	10	BT Vs AT	3.3	2.26	p < 0.05
	AT	104.3	6.9	10	BT Vs AFU	5.3	3.30	p < 0.01
	AFU	106.4	6.5	10				

Table 4: Comparison of percentage change in Audiometric evaluation (Left) under different treatment (+): increase (-): Decrease

Group	Study			Control			Mann-Whitney U	p
	Mean	SD	N	Mean	SD	N		
BT and AT	(+) 0.5	2.9	10	(+) 3.3	4.6	10	17	p < 0.05
BT and AFU	(-) 1.3	5.2	10	(+) 5.4	5.2	10	9.5	p < 0.01

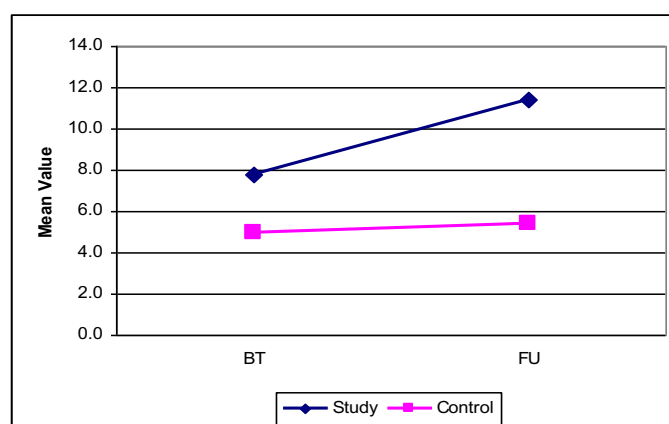


Figure 1: Effect on Vocabulary in both groups

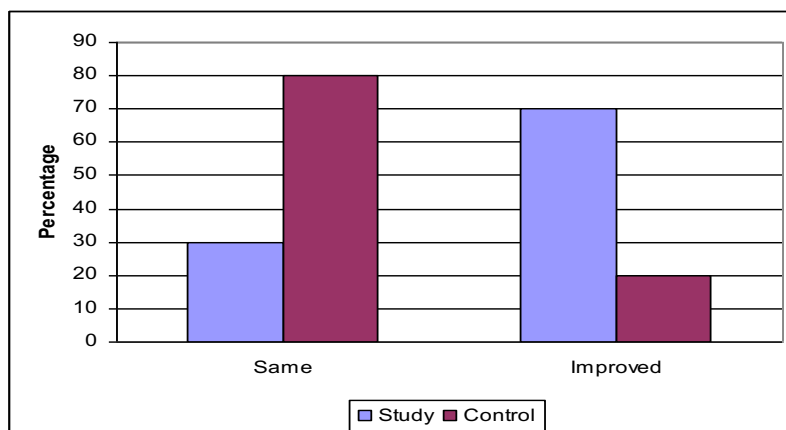


Figure 2: Comparison of percentage levels of clarity of speech

CONCLUSION

There were some limitations of study. The sample size was small. A longer period of follow up could not be kept as the study period was short. The distribution of the intensity of hearing loss was not even. All the subjects of the treated group had profound deafness and all but three of them had congenital deafness. With due consideration to the limitation, the final assessment showed statistically significant results. Even though the treatment was able to improve hearing in only three subjects out of 10, it clearly arrested progression of hearing loss in all. In the control group, where no treatment was given, a deterioration of hearing was observed after the follow up period. Thus it can be concluded that Mahamasha thailam as shiropichu improves hearing and arrests the progression of hearing loss in sensori-neural deafness of children up to 12 years. It also improves vocabulary and clarity of speech and the effects of the procedure-based therapy are stable.

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