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A Study to Compare the Efficacy of palatal Electrical Stimulation with Non-Swallowing Exercises vs Palatal Electrical Stimulation with Swallowing Exercises in Patients with Dysphagia Following Acute Stroke

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ABSTRACT

Aim and objective: Stroke is one of the leading causes of mortality worldwide and in India the prevalence of stroke among younger individuals is high compared with other countries, Dysphagia occurs commonly in ischaemic stroke as well as haemorrhagic stroke and this study which reveals the importance of physiotherapeutic interventions in treating dysphagia in stroke patients. The study is to compare the effects of palatal electrical stimulation with Non swallowing exercises VS Palatal electrical stimulation with swallowing exercises in patients with dysphagia following acute stroke.

Methodology: 20 stroke patients (13 males and 7 females) between the age group of 30 to 70 years with post stroke dysphagia were recruited with GUSS score between 4 to 7. 20 subjects were randomly divided into two groups. Group A divided into 10 subjects who received palatal electrical stimulation with swallowing exercises. Group B divided into 10 subjects who received palatal electrical stimulation with Non-swallowing exercises.

Study design: This study design is based on Comparative study design and carried out in Hospitals around Chennai and home care patients. The Guggling swallowing Scale and Dysphagia Severity Rating Scale were studied for 2 weeks and 5 sessions per week was done. The included criteria is Acute stroke patients with swallowing difficulty, Age between 30 to 70 years, Medically stable patients and Patients on Ryle's tube. The Exclusion criteria is Stroke patients with cognitive impairment, Brainstem stroke, Patients with tracheostomy, Stroke more than 6 months duration and Patients with pulmonary complications

Results: The patients were screened initially with GUSS scale. The pre- test mean values for experimental and control group are found to be 5.50 and 6.10 respectively. The post- test mean values for experimental and control group are found to be 13.40 and 10.10 respectively. There is significant effect of treatment group A (Control Group) in decreasing the value of DSRS ($t = 9.00$, $p = 0.000 < 0.05$). In addition, the mean value of DSRS has decreased from 8.50 to 5.80, which confirms that Control Group (A) is significantly effective in decreasing the value of DSRS score.

Conclusion: The results of this study suggest that stroke patients with dysphagia benefit from palatal electrical stimulation and exercises. But combined method of palatal electrical stimulation and Non-swallowing exercises proved to be more superior and effective treatment for the acute stroke patients with dysphagia than treating with combined method of palatal electrical stimulation and swallowing exercises.

Keywords: Dysphagia, Stroke, GUSS, DSRS.

INTRODUCTION

WHO defines stroke as a clinical syndrome consisting of rapidly developing clinical sign of focal or global disturbances of cerebral function lasting for more than 24 hours. Stroke is one of the leading causes for mortality and morbidity worldwide. In India, the prevalence of stroke among younger individuals is high (18-32% of all stroke cases) compared with other countries. Men are more likely to have stroke than women, the male/female sex ratio for India is 7:1 [1,2]. This may be due to differences in risk factors such as smoking and drinking which are more prevalent among men in India compared with women [3].The mean onset of stroke for men in India ranges from 63-65 for men and 57-68 for women [4]. The Global Burden of Disease Study estimated a population-based annual stroke incidence of India to be 89/100,000 in 2005, which is projected to increase to 91/100,000 in 2015 and to 98/100,000 in 2030.

Stroke is divided into two broad categories based on its pathophysiology. Ischaemic strokes are caused by either cerebral thrombosis or embolism and account for about 50%–85% of all strokes worldwide. Haemorrhagic strokes are caused by subarachnoid haemorrhage or intracerebral haemorrhage and account for 1%-7% and 7%-27% respectively of all strokes worldwide [5]. The effects of stroke is determined by the extent and location of lesion in brain. Classic stroke symptoms include the acute onset of unilateral paralysis, loss of vision, speech impairment, dysphagia, memory loss, impaired reasoning ability, coma, or death [6].

Stroke is the leading neurologic cause for dysphagia and about 42 –67% patients present with dysphagia within 3 days of stroke. 40% or more patients with unilateral hemispheric stroke may have swallowing difficulties. Depending on the stroke severity, approximately 20 to 80 percent of stroke patients have a swallowing abnormality.[7] Swallowing problems can affect as many as one in three patients in the period immediately after stroke in India. Swallowing dysfunction after stroke is commonly present in 30-60% patients with acute stroke. Dysphagia following stroke is associated with increased risk of complication such as aspiration pneumonia, dehydration and increased mortality [8]. Dysphagia is considered as an independent marker of poor outcome following stroke and may lead to decreased functional outcome among stroke patients.

[9] Documented bilateral activation of the anterior cingulate gyrus and the supplementary motor area at 1 to 1.5 seconds before the onset of volitional water swallowing. [10] Found the differences in the swallowing response between dysphagic patients with right hemispheric brain lesion and those with left hemispheric brain lesion. He also found that patients with right hemisphere involvement, aspiration was more apparent. [11] Has discussed that cortical representation of the pharyngeal and oesophageal muscles are asymmetrically organized.

A variety of treatments have been developed for improving the ability to swallow among stroke patients. [12] Had found that volitional swallowing and electrical stimulation of the submental musculature can bidirectionally modify the corticobulbar excitability and motor projections and therefore improves swallowing biomechanics. [13] Demonstrated that somatosensory stimulation in the form of electrical current applied over the pharynx changed the excitability of the corticobulbar projection and induced cortical reorganization in patients with post stroke dysphagia. [14] showed that electrical stimulation to be a safe and effective treatment for dysphagia due to stroke. So, there is the need of study to compare the effects of palatal electrical stimulation and non- swallowing exercises Vs palatal electrical stimulation and swallowing exercises in patients with dysphagia following acute stroke

MATERIALS AND METHODS

This study is based on Comparative Study Design. It was conducted in Hospitals around Chennai and home care patients. The Data will be collected from in patients department of various hospitals and Home care patients in and around Chennai, Acute stroke patients will be included in the study based on the fulfilment of inclusion criteria. The purpose of the study will be explained to all the subjects and consent from each subject will be obtained, the subjects were randomly assigned.

Sample size - 20 stroke patients between the age group 30-70 years were recruited with GUSS score between 4 to 7. The subjects were screened for eligibility to participate in the study, and are counselled regarding the study. They were explained about the purpose of the study and their role in the study. After screening the subjects, they were asked to sign the informed consent.

20 subjects with dysphagia following acute stroke were recruited and randomly divided into two groups. Group A divided into 10 subjects who received palatal electrical stimulation with swallowing exercises. Group B divided into 10 subjects who received palatal electrical stimulation with non-swallowing exercises. The treatment duration is 30 minutes per session. Total duration of treatment is 2 weeks i.e., 5 days /week. The subjects in both the groups were received 8-10 sessions. The Dysphagia Severity Rating Scale (DSRS) and Guggling Swallowing Scale (GUSS) were studied.

Sampling Criteria

S.no.	Inclusion criteria	Exclusion Criteria
1	Acute stroke patients with swallowing difficulty.	Stroke patients with cognitive impairment
2	Age – 30 to 70 years	Brainstem stroke
3	Both Male and Female	Patients with tracheostomy
4	Medically stable patients	Stroke more than 6months duration
5	Patients on Ryles tube	Patients with pulmonary complications

PROCEDURE

All the patients were initially screened with GUSS and the initial score was noted. Total score of GUSS was 20 and its components are deglutition, cough, drooling and voice change. Base line value for GUSS scale for patients included in the study is from 4 to 7. Followed by preparing the patient for electrical stimulation with the position of supine lying with head flat. Skin resistance lowering- the anterior aspect of the neck is cleaned with alcohol swab.

Instructions were given to the patient regarding the stimulation and asked to perform voluntary swallowing movement during the stimulation. Palatal stimulation was given for a period of ten days once daily. The parameters for stimulation were Current-faradic and Contraction-90. The placement of electrodes-on either side of midline above the lesser horns of the hyoid bone (anterior neck)

Fig.1. Palatal stimulation

Fig.2. Palatal stimulation

Non-Swallowing exercises was given for a period of ten days once daily under supervision and asked to perform twice daily by the patient. The parameters were Frequency 3times per day.

Shaker Exercise - Lying on the back on the bed. Keeping shoulders flat against the bed, and lifting up the head, bringing the chin down to the chest. Keeping the head lifted for 60 seconds, and then lower the head and rest for 60 seconds. (10 reps).

Lip Exercises - Lip Press - Tightly close upper and lower lip against each other for 5 seconds, (repeat 10 times).

Fig.3. Shakers exercise

Fig.4. Lip press exercise

Fig.5. Tongue to the right

Fig.6.Tongue to the left

Fig.7.Tongue pushing forward

Fig.8.Tongue push upwards

Tongue Side to Side - Move tongue out of mouth, rotate tongue tip to left side of mouth, hold for 5 seconds, then to right side of mouth, hold for 5 seconds, (repeat 10 times). Tongue Push Forward - Open mouth and move tongue such that tongue tip rests against the lower lip, patient attempts to move tongue forward, hold for 5 seconds, (repeat 10 times). **Tongue Push Up** - Extend tongue out of mouth, patient attempts to move tongue upward against the upper lip, hold for 5 seconds, (repeat 10 times).

Fig.9. Supraglottic swallow manoeuvre

Fig.10.Masaka manoeuvre

Fig.11.Mendelson manoeuvre

Swallowing exercises was given for a period of ten days once daily under supervision and asked to perform twice daily by the patient. The parameters were Frequency 3 times per day and the duration is 10 days.

The super-supraglottic swallow: This manoeuvre involves a person holding a tight breath, swallowing while keeping the airway tightly closed, then immediately coughing after the swallow, (repeat 10 times).

Masako manoeuvre: This manoeuvre involves swallowing while protruding the tongue beyond the lips and holding it between one's teeth for 3-5 secs (repeat 10times).

Mendelsohn manoeuvre: This manoeuvre involves holding the larynx for 3–5 seconds after swallowing, when the larynx is raised upward. Patients were asked to hold the larynx after swallowing (repeat 10 times). After the treatment duration of 10 days, GUSS was re-evaluated and score was noted.

Data Analysis and Statistics

Statistics

This study was done on 10 patients. The patients comprised of both males and females. The patients were screened initially with GUSS scale. The pre-test mean values for experimental and control group are found to be 5.50 and 6.10 respectively. The post- test mean values for experimental and control group are found to be 13.40 and 10.10 respectively. Mean & Standard deviation for Continuous variables, namely Age, GUSS and DSRS. Intra Group Analysis – Paired Samples t-test and Inter Group Analysis – Independent Samples t-test

Test to be applied: Paired Sample t-test

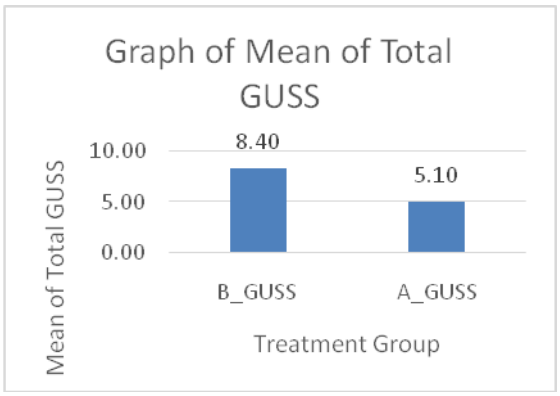
Test Statistic: $t = \frac{\mu_d - 0}{s_d / \sqrt{n}}$

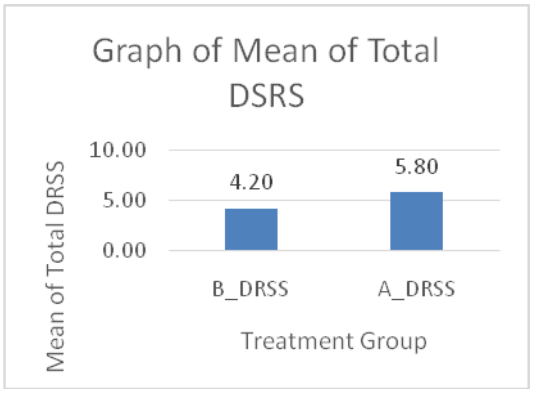
Test to be applied: Independent Samples t-test

Test Statistic:

$$t = \frac{\overline{X}_1 - \overline{X}_2}{S\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}, \text{ where S = Pooled S.D} = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}}$$

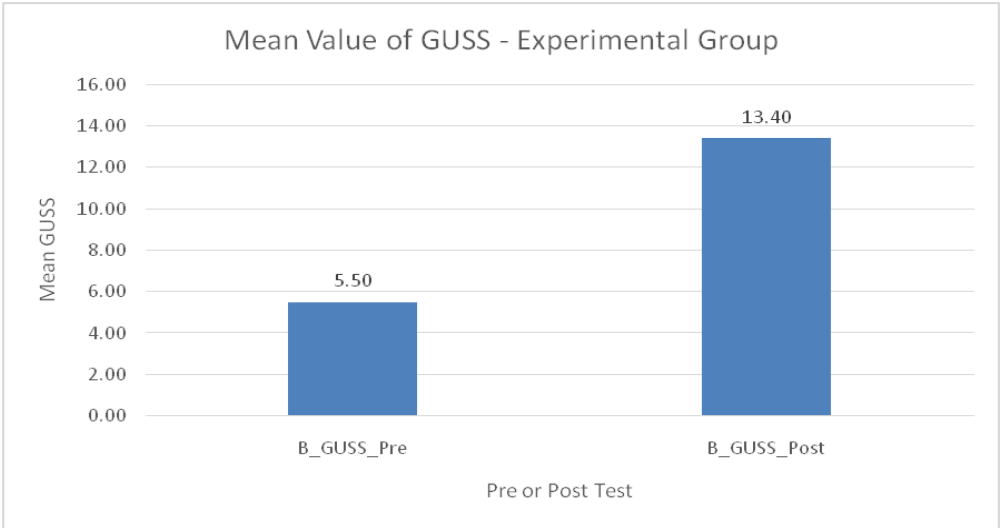
Descriptive Statistics of Age	Experimental Group	Control Group	Gender Distribution	Experimental Group	Control Group
Min	32	35	Male	6 (60%)	7 (70%)
Max	70	70	Female	4 (40%)	3 (30%)
Mean	50.60	53.30	**Total**	**10 (100%)**	**10 (100%)**
SD	13.36	12.63			





Paired t-test:

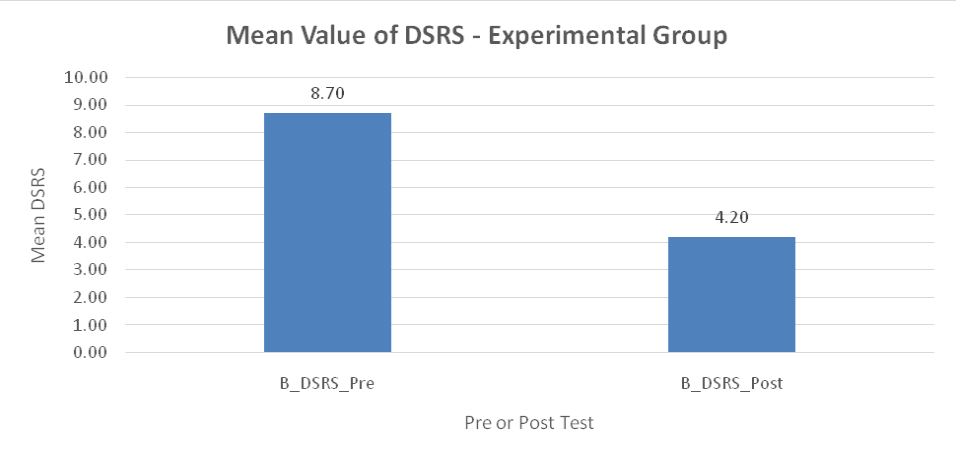
	B_GUSS_Pre	***B_GUSS_Post***
Mean	5.50	13.40
SD	1.27	3.27
Variance	1.61	10.71
Observations	10.00	10.00
Pearson Correlation	0.67	
Hypothesized Mean Difference	0	
Df	9	
t Stat	-9.60	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.83	
P(T<=t) two-tail	0.000	
t Critical two-tail	2.26	



The evidence is sufficient to conclude that there is significant effect of treatment group B (Experimental Group) in increasing the value of GUSS (t = -9.60, p = 0.000 < 0.05). In addition, the mean value of GUSS has increased from 5.50 to13.40, which confirms that Experimental

Paired t-test:

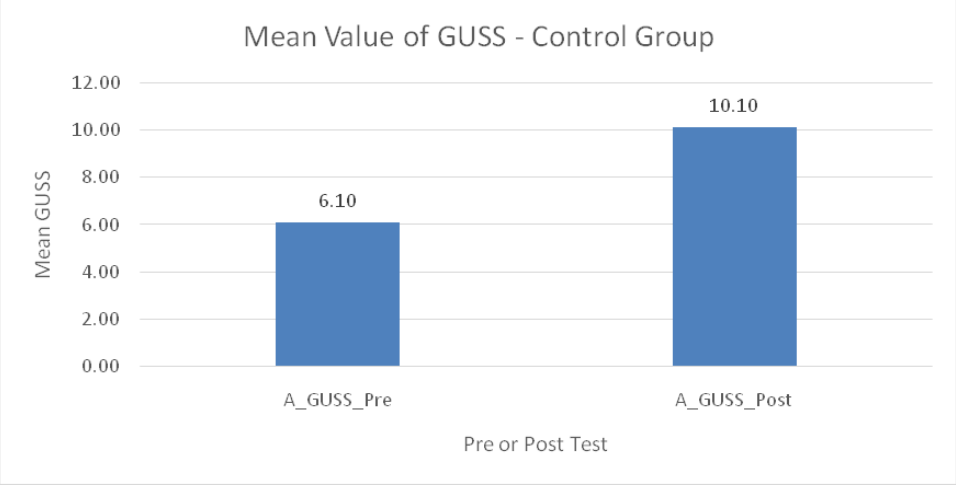
	B_DSRS_Pre	***B_DSRS_Post***
Mean	8.70	4.20
SD	0.95	1.48
Variance	0.90	2.18
Observations	10.00	10.00
Pearson Correlation	0.84	
Hypothesized Mean Difference	0	
Df	9	
t Stat	16.74	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.83	
P(T<=t) two-tail	0.000	
t Critical two-tail	2.26	



The evidence is sufficient to conclude that there is significant effect of treatment group B (Experimental Group) in decreasing the value of DSRS (t = 16.74, p = 0.000 < 0.05). In addition, the mean value of DSRS has decreased from 8.70 to 4.20, which confirms that Experimental Group (B) is significantly effective in decreasing the value of DSRS score.

Paired t-test:

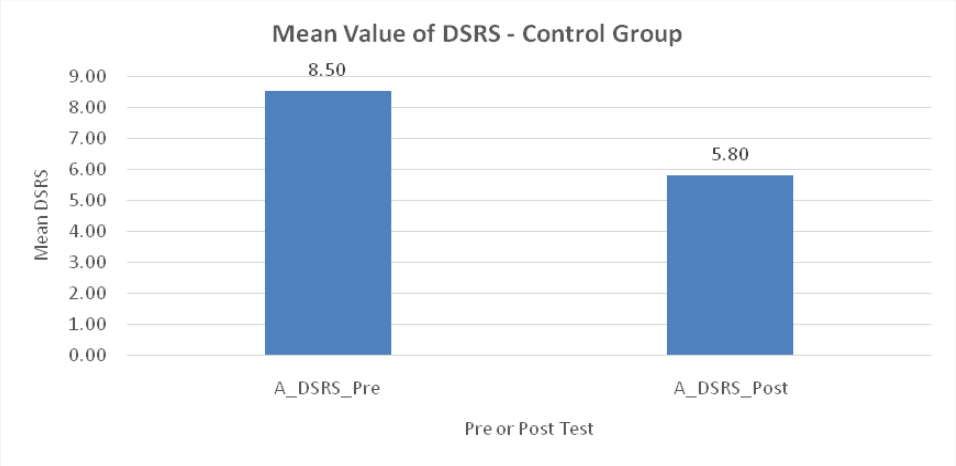
	A_GUSS_Pre	***A_GUSS_Post***
Mean	6.10	10.10
SD	1.10	2.08
Variance	1.21	4.32
Observations	10.00	10.00
Pearson Correlation	0.63	
Hypothesized Mean Difference	0.00	
Df	9.00	
t Stat	-7.75	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.83	
P(T<=t) two-tail	0.000	
t Critical two-tail	2.26	



The evidence is sufficient to conclude that there is significant effect of treatment group A (Control Group) in increasing the value of GUSS (t = -7.75, p = 0.000 < 0.05). In addition, the mean value of GUSS has increased from 6.10 to 10.10, which confirms that Control Group (A) is significantly effective in increasing the value of GUSS score.

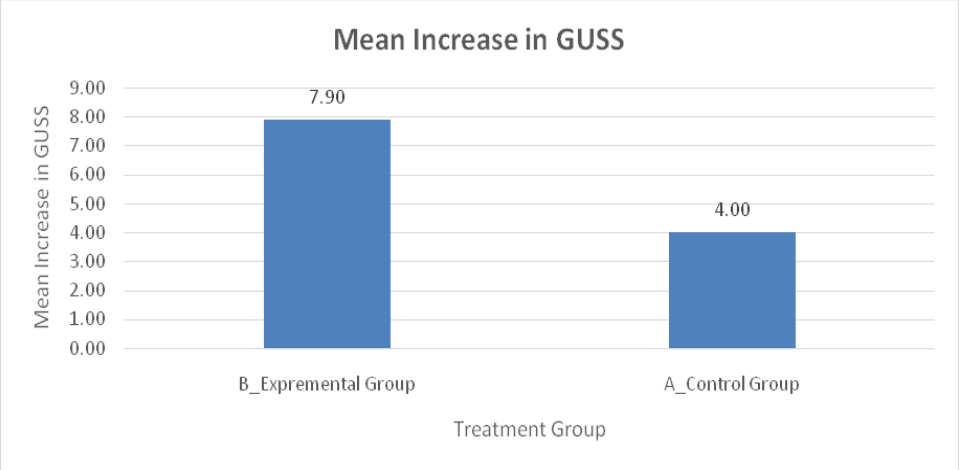
Paired t-test:

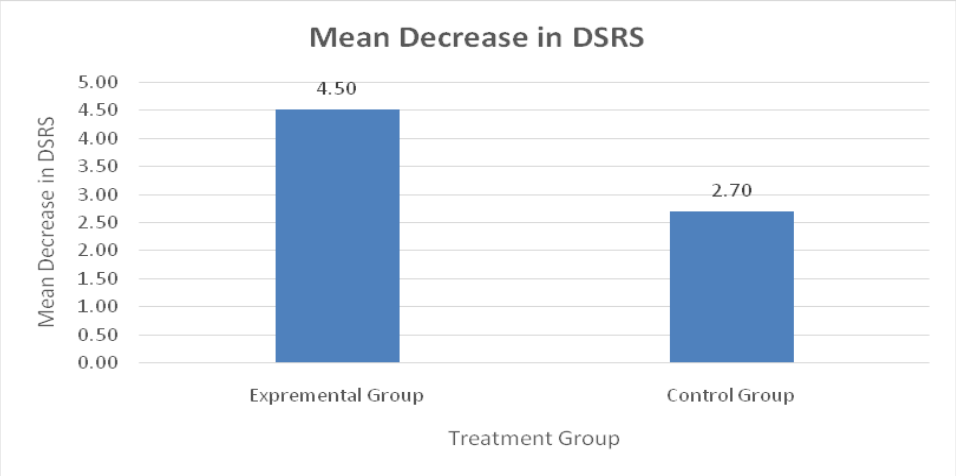
	A_DSRS_Pre	***A_DSRS_Post***
Mean	8.50	5.80
SD	0.85	1.40
Variance	0.72	1.96
Observations	10.00	10.00
Pearson Correlation	0.75	
Hypothesized Mean Difference	0.00	
Df	9.00	
t Stat	9.00	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.83	
P(T<=t) two-tail	0.000	
t Critical two-tail	2.26	



The evidence is sufficient to conclude that there is significant effect of treatment group A (Control Group) in decreasing the value of DSRS (t = 9.00, p = 0.000 < 0.05). In addition, the mean value of DSRS has decreased from 8.50 to 5.80, which confirms that Control Group (A) is significantly effective in decreasing the value of DSRS score.

	B_GUSS_Diff	***A_GUSS_Diff***
Mean	7.90	4.00
SD	2.60	1.63
Variance	6.77	2.67
Observations	10	10
Pooled Variance	4.72	
Hypothesized Mean Difference	0	
Df	18	
t Stat	4.02	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.73	
P(T<=t) two-tail	0.001	
t Critical two-tail	2.10	





There is significant difference between two treatments (A and B) in terms of average reduction in DSRS ($t = -4.47$, $p = 0.000 < 0.05$). In addition, the mean decrease in DSRS by Treatment B (4.50) is greater than that of Treatment A (2.70). Hence, we conclude that Experimental Group (B) is significantly effective than Control Group (A) in terms of mean reduction in DSRS.

DISCUSSION

Stroke as a clinical syndrome consisting of rapidly developing clinical signs of focal or global disturbances of cerebral function lasting for more than 24 hours, Stroke is one of the leading causes for mortality and morbidity worldwide. Dysphagia is a disruption of bolus flow through the mouth and pharynx, Injury to swallowing areas of motor cortex will result in dysphagia. causes the risk of aspiration of food and fluids in airways, malnutrition, weakness and weight loss increasing mortality rate following stroke. In this study, patients are assessed through GUSS and DSRS scale for dysphagia following acute stroke. A sample of 20 subjects fulfilling the inclusion criteria have randomized into 2 groups of 10 each. All participants were clearly explained about the treatment procedure.

Group A- underwent palatal electrical stimulation with swallowing exercises. Group B- underwent palatal electrical stimulation with non-swallowing exercises for two weeks. The informed consent was obtained from all participants and they underwent treatment for 2 consecutive weeks. The outcome measures were recorded on before and after the treatment using GUSS and DSRS scale on the last day of treatment. The main objective of this study is to compare the effectiveness of palatal electrical stimulation with swallowing exercises Vs palatal electrical stimulation with non-swallowing exercises.

The aim of the study was to select patients with stroke having swallowing difficulty and to analyse, compare the influence between palatal stimulation and Non-swallowing exercises for the experimental group and palatal stimulation and swallowing exercises for the control group. It was hypothesized that combined treatment of palatal stimulation and Non-swallowing exercises would be more beneficial than providing palatal stimulation and swallowing exercises in dysphagia following acute stroke.

Comparing the values of group A and group B

Table 1 represents on comparing group A and group B using independent sample t-test there is significant difference between two treatments (A and B) in terms of average improvement in GUSS ($t = 4.02$, $p = 0.001 < 0.05$). In addition, the mean increase in GUSS by Treatment B (7.90) is

greater than that of Treatment A (4.00). Hence, we conclude that Experimental Group (B) is significantly effective than Control Group (A) in terms of mean improvement in GUSS.

Table 2 represents on comparing group A and group B using independent t-test there is significant difference between two treatments (A and B) in terms of average reduction in DSRS ($t = -4.47$, $p = 0.000 < 0.05$). In addition, the mean decrease in DSRS by Treatment B (4.50) is greater than that of Treatment A (2.70). Hence, we conclude that Experimental Group (B) is significantly effective than Control Group (A) in terms of mean reduction in DSRS.

(15) proved that changes in corticobulbar excitability induced by neuromuscular electrical stimulation of the submental muscle group are frequency and dose dependent and only occur after neuromuscular electrical stimulation triggered by volitional swallowing.(16) showed that neuromuscular electrical stimulation combined with thermal tactile stimulation is a better treatment for patients with swallowing disorders after stroke than thermal tactile stimulation alone. (17) found that rehabilitative swallowing therapy and neuromuscular electrical stimulation therapy showed a positive effect in the treatment of persistent dysphagia in stroke patients, while neuromuscular electrical stimulation was statistically significant.

(18) found that effortful swallowing coupled with electrical stimulation increases the degree of hyoid elevation in healthy volunteers and thereby activation of submental muscles during swallowing.(19) Demonstrated that one session of somatosensory stimulation in the form of an electrical current applied to the pharynx changed the excitability of the corticobulbar projection and induced cortical reorganization in patient with poststroke dysphagia.

(20) Showed that electrical stimulation on the neck may produce an effect by preventing atrophy of the swallowing muscles, it is believed that the effect is enhanced by inducing a repeated swallowing motion, which can elicit motor learning and this can be indirectly demonstrated by cortical reorganization.

Table 3 shows when we compare the pre and post- test means of GUSS in group B non -swallowing exercises with palatal stimulation the results conclude that there is significant effect of treatment group B (Experimental Group) in increasing the value of GUSS ($t = -9.60$, $p = 0.000 < 0.05$). In addition, the mean value of GUSS has increased from 5.50 to 13.40, which confirms that Experimental Group (B) is significantly effective in increasing the value of GUSS score.

Table 4 shows when we compare the pre and post- test means of GUSS in group B non -swallowing exercises with palatal stimulation the results conclude that the evidence is sufficient to conclude that there is significant effect of treatment group B (Experimental Group) in decreasing the value of DSRS ($t = 16.74$, $p = 0.000 < 0.05$). In addition, the mean value of DSRS has decreased from 8.70 to 4.20, which confirms that Experimental Group (B) is significantly effective in decreasing the value of DSRS score.

(21) showed that non swallowing exercises to have favourable long term effects by improving the strength of the suprahyoid muscles over time and increasing the opening of the upper oesophageal sphincter in patients with dysphagia. (22) conducted three RCT trial proving tongue strengthening exercise along with other non-swallowing exercises was affecting in reducing the risk of aspiration and improved swallowing capacity in dysphagic patients.

(23) proved that decline in tongue pressure from anterior to posterior direction on median line, which would be expected for propulsion of the bolus from the oral cavity into the pharynx and interfere with enveloping and transferring the bolus between the dorsum and palate, thus reducing pre pharyngeal swallow efficiency.(24) showed in a study that there

was significantly less aspiration post-therapy in patients receiving the Shaker exercises. With traditional therapy, there were several significant increases from pre- to post-therapy, including superior laryngeal movement and superior hyoid movement on swallowing, indicating significant improvement in swallowing physiology.

Group A to find the effectiveness of palatal electrical stimulation with swallowing exercises

Table 5results when we compare the pre and post- test means of GUSS in group A swallowing exercises with palatal stimulation the results conclude that the is a significant improvement in treatment group A (Control Group) in increasing the value of GUSS ($t = -7.75$, $p = 0.000 < 0.05$). In addition, the mean value of GUSS has increased from 6.10 to 10.10, which confirms that Control Group (A) is significantly effective in increasing the value of GUSS score.

Table 6results when we compare the pre and post- test means of DSRS in group A swallowing exercises with palatal stimulation the results conclude that the is a significant improvement in treatment group A (Control Group) in decreasing the value of DSRS ($t = 9.00$, $p = 0.000 < 0.05$). In addition, the mean value of DSRS has decreased from 8.50 to 5.80, which confirms that Control Group (A) is significantly effective in decreasing the value of DSRS score.

[25] A well-designed a small RCT (cross sectional design) demonstrating limited beneficial effects of the Mendelsohn manoeuvre in improving the swallow in stroke patients.[26] In a meta-analysis showed that there were n studies that investigate the long term effects of supra glottis swallow manoeuvre although it is known that it has immediate effects on laryngeal and hyoid excursion.

CONCLUSION

The intra-group analysis showed that both Experimental Group and Control Group are significantly effective in terms of improvement in GUSS and in terms of reduction in DSRS. The inter-group analysis showed that Experiment Group (B) is significantly effective than Control Group (A) in terms of mean improvement in GUSS and mean reduction in DSRS. Hence, we conclude that the Experiment Group (B) is better than Control Group in terms of both the measures, namely GUSS and DSRS.

The results of this study suggests that stroke patients with dysphagia benefit from palatal electrical stimulation and exercises. But combined method of palatal electrical stimulation and Non-swallowing exercises proved to be more superior and effective treatment for the acute stroke patients with dysphagia than treating with combined method of palatal electrical stimulation and swallowing exercises.

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Conflict of Interest: None

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Ethical Approval: Approved

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