

EFFECT OF HIGH VOLTAGE PULSED GALVANIC STIMULATION FOR CONSTIPATION IN ACUTE STROKE –A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

BACKGROUND: Constipation is a common symptom among patients with Acute Stroke leading to increased morbidity and mortality. It is associated with increased length of hospital stay, poor neurological outcome and development of more complications. This can negatively affects the Physical, Social functioning and Quality of Life in patients with Acute Stroke

AIM: To assess the effect of High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercise for Constipation in patients with Acute Stroke.

METHODS: The study included 28 individuals, 14 in each group with acute stroke and age >18 years. All the patients were recruited using Rome II criteria. The intervention included High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercises with Diet Modification for 30 minutes, 3 sessions per week over a period of 3 weeks. Patients were assessed at baseline and at the end of the intervention, using Patient Assessment of Constipation–Symptom Questionnaire and Patient Assessment of Constipation Quality of Life questionnaire.

RESULTS: There was a statistically significant change in all the outcome measures in both groups with p value <0.0001, but Patient Assessment of Constipation–Symptom score showed more improvement in Group A with p value <0.05 when compared between two groups.

CONCLUSION: The study concluded that both High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercises were beneficial in the improvement of symptoms and Quality of Life in subjects with Constipation in Acute Stroke

Keywords: High Voltage Pulsed Galvanic Stimulation, Acute stroke, Constipation, Conventional Physiotherapy Exercises.

I. INTRODUCTION

Stroke is a Cerebrovascular episode wherein the bloodstream to the brain is substantially altered and it leads to sudden loss of neurological functioning.¹ The prevalence of Stroke is globally increasing with a predictable 70 million new cases anticipated by 2030. In 2015, after Ischemic Heart Disease, Stroke accounted for 6.3 million deaths and ranked second in the list of deaths due to any disease.²

The severity and symptoms of the Stroke depends on the site and size of the lesion, speed of occlusion and the collateral arterial blood flow. The Red flags of Stroke involve precipitous numbness or weakness on one side of the body, difficulty in Speech and Language, Communication or Understanding, Visual Disturbances, severe

Headache, Dizziness, Nausea and Vomiting. The other most frequently reported symptoms are altered Sensations on the paretic side, Constipation, Balance and Gait problems.³

Recently studies have revealed that constipation is a major problem in Acute Stroke which affects patients Social Life, Quality of Life and activity of daily living. Based on the Stages of Stroke, 41.6% had Constipation in Acute phase, 31.5% Sub Acute phase and 22.6% in Chronic phase. It has been noted that constipation is important co-morbid factor in Acute Stroke.⁴ As Constipation is associated with Anxiety, Depression, Embarrassment, Irritation, immobility and dependence on others.⁵ It also causes Painful Bowel movements, Bloating and Straining during defecation. Consequently, patients develop more dependency on caregivers leading to decline in Quality of Life.⁶ Studies have proven Pharmacological treatment, Exercises and Diet Modification helps in relieving the Constipation. But Studies have also reported that the long term use of medicines leads to decrease in gut motility.⁷ The literature shows that High Voltage Pulsed Galvanic Stimulation is effective in treating Constipation in various condition.⁸ It is the treatment of choice for Acute Pain, Constipation, Postoperative Pain, Reduction of Muscle Spasms, Direct Stimulation of Deep Nerves and Muscle Strengthening.⁹

As there is dearth in literature on the comparative effect of HVPGS and Conventional Physiotherapy Exercise with Diet Modification on symptoms and Quality of Life, the current study intends to determine and compare the effectiveness of High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercise for Constipation in patients with Acute Stroke.

II. MATERIALS AND METHODS:

The study was a Randomized Clinical Trial conducted in tertiary care hospital, Belagavi, Karnataka from 1st April 2019 to 31st March 2020. The ethical clearance was obtained from the Institutional Ethical Committee. All participants were given the informed consent in writing before participating in this study. The participants were recruited using Rome II criteria with age > 18 years, both gender, able to understand the commands and First onset of Stroke. Subjects with Cardiovascular or Respiratory disorders, history of Structural diseases in the rectum or colon, Disturbance of Consciousness, any Congenital, Malignant, Autoimmune and Neurological conditions (apart from stroke) were excluded from the study.

The Sample size calculated was Thirty-four (28), based on the previous literature considering effect size. All the subjects were randomly allocated using Convenience sampling into Group A (14) and Group B (14). All the outcome measures were recorded by the therapist prior to the intervention (Baseline measures) and post intervention (i.e. after 4 weeks).

Outcome Measures

1. Patient Assessment of Constipation–Symptom Questionnaire(PAC-SYM): PAC-SYM was used to measure the severity of symptoms of Constipation and has intra-rater, inter-rater and test-retest reliability of 0.70. It is a 12 item scale with each item consisting of a five-point likert scale ranging from 0 to 4, with 0 indicating absence of symptom and 4 very severe symptoms. It takes approximately 5 minutes to complete.¹⁰

2. Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire: The PAC-QOL was used to measure the Quality of Life and has intra-rater, inter-rater and test-retest reliability of 0.93. It contains 28 items which are grouped into 4 subgroup: Physical Discomfort, Psychosocial Discomfort, Worries and Satisfaction. It takes about five minutes to complete. The total score ranges from 0-96 where lower the scores indicate better quality of life.¹¹

Intervention:

Group A: High Voltage Pulsed Galvanic Stimulation was given for 30 minutes, 3 sessions per week over a period of 3 weeks. The starting position of the subject was in supine lying. The two non adhesive carbon electrodes was placed on the external oblique and transverse abdominal muscle where maximum visible contraction was seen.⁹

Group B: Conventional Physiotherapy Exercises were given for 30 minutes, 3 sessions per week over a period of 3 weeks. The starting position of the subject was in supinelying. The Isometric Abdominal Muscle Training was performed by subjects in which voluntary isometric contraction of the upper abdomen and the simultaneous relaxation of the lower abdomen was done.¹² The subjects performed abdominal massage by slow circular

clockwise movements, along the line of the colon, applying constant moderate pressure to the abdomen with the hand on each point for 1 min, beginning with the ascending colon and moving toward the sigmoid colon.¹³

Both the groups were recommended to follow Dietary Modification which include a Fibre Intake of 25gm and Fluid Intake of (1-2 litres of water) every day.¹⁴

III. STATISTICAL ANALYSIS:

SPSS version 23 was used for the statistical analysis. The homogeneity of the data was checked using the Chi Square Test for gender, age and BMI. The Comparison of two groups (Group A and Group B) with mean age and BMI was done by using Independent -T Test. The comparison of the pre intervention and post intervention of the outcome measures such as PAC-SYM and PAC-QOL within the group was done by using Dependent T Tests and between the groups was done by using Independent -Test.

IV. RESULTS:

The total number of males and females in Group A was 5 (35.71%) & 9 (64.29%) and in Group B was 7(50%) &7(50%),respectively. The mean age of the subjects in Group A was 61.21± 5.86 and Group B was59.36±11.96. The mean age and Gender showed no statistical difference in both the Groups with p value >0.4451 and p >0.6062 which represented homogeneity of the subjects. The mean BMI of Group A was 28.05± 2.68 and Group B was 25.81± 2.74 which showed significant statistical difference with p value<0.05which indicated non-homogeneity of the subjects. [Table 1]

Table 1: Demographic data including Gender distribution, Age distribution, and BMI in group A and group B

Factor		Group A	Group B	P-value
Gender	Female	5 (35.71%)	7 (50%)	0.4451
	Male	9 (64.29%)	7 (50%)	
Age (Years)		61.21± 5.86	59.36 ± 11.96	0.6062
BMI (Kg/m ²)		28.05± 2.68	25.81± 2.74	0.0382*

In Group A, the mean PAC-SYM score pre intervention was 20.36 ± 9.37 and post intervention was 12.07± 8.05. In Group B, the mean PAC-SYM score pre intervention was 20.64± 10.83and post intervention was 16.29±10.09. The p value for PAC-SYM score was statistically highly significant (p<0.0001*) & (p<0.0002*) within the group. [Table 2]

In Group A, the mean PAC-QOL score pre intervention was64.57±13.74 and post intervention was 53.29± 11.10. In Group B, the meanPAC-QOL pre intervention was 20.64±10.83 and post intervention was 16.29±10.09. The p value for PAC-QOL score was statistically highly significant (p<0.0001*) &(p<0.0007*) within the group. [Table 2]

Table 2: Comparison within the Group A and Group B respect to pretest and posttest scores of PAC-SYM andPAC-QOL:

OUTCOME MEASURES		Pre	Post	P-value
Group A	PAC-SYM	20.36 ± 9.37	12.07± 8.05	<0.0001*
	PAC-QOL:	64.57± 13.74	53.29± 11.10	<0.0001*
Group B	PAC-SYM	20.64± 10.83	16.29± 10.09	<0.0002*
	PAC-QOL:	58.36± 9.44	50.00± 7.37	0.0007*

The mean difference of PAC-SYM score for Group A was 8.29 ± 4.25 and for Group B was 4.36± 3.13. The mean difference of PAC-QOL score for Group A was 11.29 ± 7.01 and for Group B was 8.36±7.14.The comparison of PAC-SYM andPAC-QOL scores between the groups showed statistical significant difference for

PAC-SYM scores with p value ($p < 0.0098^*$); but p value for PAC-QOL scores was ($p > 0.2836$) respectively, which was not statistically significant. [Table 3]

Table 3: Comparison between the Group A and Group B with respect to posttest scores of PAC-SYM and PAC-QOL:

OUTCOME MEASURE	Group A	Group B	P-value
PAC-SYM	8.29 ± 4.25	4.36 ± 3.31	0.0098*
PAC-QOL:	11.29 ± 7.01	8.36 ± 7.14	0.2836

Difference = Post - Pre; * indicate significance;

V. DISCUSSION:

The present study reports that significant improvement was observed in symptoms of Constipation and Quality of Life in terms of PAC-SYM and PAC-QOL scores with High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercises in subjects with Acute Stroke.

Improvement observed in PAC-SYM score is significantly more in subjects treated with High Voltage Pulsed Galvanic Stimulation. The possible reason for this significant improvement can be due to HVPG current, which has a short duration with low frequency, leads to stimulation of deep neuro-endocrine nerves. The stimulation of neuro-endocrine nerves helps in improving the interaction and communication between the Brain-Gut Axis, thereby increasing the gut motility and improving the bowel frequency in Stroke patients.¹⁵ Thereby, decrease in symptoms like painful bowel movements, bloating, rectal bleeding, burning and enhance the peristaltic movements of the intestine, leading to increase in bowel frequency. A study carried out by Giuseppe Chiarioni et al to evaluate the long-term effects of HVPG Stimulation in patients with Pelvic Floor Dyssynergia and severe Constipation in 30 patients, which showed significant improvement in muscle strength and function of pelvic floor muscle, leading to decrease in constipation symptoms.¹⁶

In addition improvement in PAC-SYM score in subjects with Conventional Physiotherapy Exercises group could have been due to Abdominal Exercises which causes indirect synergic activation between the pelvic floor and the lower abdominal muscles, leading to defecation.¹² The slow circular clockwise movements along the line of the colon in Abdominal Massage which, helps to promote colonic and rectal motility to train intestinal function.¹³ A Randomized Clinical Trial was carried out by C. A.G. Silva et al to evaluate the effect of abdominal isometric Training, Abdominal Massage and Diaphragmatic Breathing with medical treatment in patients with Chronic Functional Constipation, which showed that after 6 weeks of treatment, the frequency of bowel movements was higher in the Physiotherapy Group than in the Medication Group.¹²

Both groups could have also benefited in constipation symptoms, due to the Dietary modification which was given. The Diet Modification helps by increasing the stool bulk, the osmotic load and accelerates colon transit time in gut which, led to better outcome in terms of bowel movements frequency and stool consistency.¹⁷ A Systemic Review was done by S.S.C Rao et al to examine the effect of Dietary Modification in Chronic Constipation and Irritable Bowel Syndrome patients, which showed dietary modification aids in reduction of colon transit time hence, improvement in symptoms of Constipation.¹⁷

The PAC-QOL score was significantly improved in Group A. The probable explanation for this improvement could be due to the kind of stimulation observed in HVPG, in which the monophasic pulse with a double peak configuration current caused recruitment of type I and II muscle fibres, thereby increasing the strength of abdominal muscles.¹⁸ This in turn increases the abdominal pressure, leading to reduction in bloating, feeling of heaviness in stomach, increase in appetite and less hard stools. As a result, there is a reduction in irritation, disappointment, tension and dependence on others in these patients.¹⁹ Norman Sohn et al conducted a study in which HVPGS stimulation was given in Anorectal region for Levator ani Syndrome wherein a significant improvement was observed in Quality of Life and symptoms of Constipation.⁹

PAC-QOL also showed improvement in the Group B. The reasonable explanation for this could have been the Neurological Effect of Conventional Physiotherapy Exercises which helps in activation of stretch receptors and reinforcing the Gastrocolic Reflex, causing an increase in motility of the Gastrointestinal Tract.²⁰ Moreover, it also activates the Parasympathetic Nervous System which is highly involved in digestion leading to reduction in straining of stool, embarrassment and less dependence on bedpan use, therefore enhancement of quality of life in patients with Constipation after Stroke.¹³ A study carried out by T W J Janssen et al. to evaluate the effect of Abdominal Massage for Constipation in Neurological conditions suggested that Abdominal Massage had a positive effect in improving Quality of Life and symptoms of Constipation.²⁰

The limitation of the study is short duration of the study and no blinding of evaluators or participants.

Future scope: Studies can be taken up to assess long term effect of High Voltage Pulsed Galvanic Stimulation in Acute Stroke subjects with Constipation.

VI. CONCLUSION:

The present study concludes that High Voltage Pulsed Galvanic Stimulation and Conventional Physiotherapy Exercises were beneficial in the betterment of symptoms and Quality of Life in subjects with Constipation in Acute Stroke. Furthermore it was observed in between group comparison, High Voltage Pulsed Galvanic Stimulation was more advantageous than Conventional Physiotherapy Exercises in terms of symptoms improvement.

List of abbreviations

BGA- Brain Gut Axis.

HVPGS- High Voltage Pulsed Galvanic Stimulation.

PAC- QOL- Patient Assessment of Constipation Quality of Life.

PAC- SYM - Patient Assessment of Constipation Symptom.

BMI - Body Mass Index

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