

Original Research Article

EFFECT OF VIBRATORY INHIBITION AND PELVIC STABILIZATION EXERCISE ON TONE, BALANCE AND GROSS MOTOR FUNCTION IN SPASTIC CEREBRAL PALSY- A COMPARATIVE STUDY

Abstract

Objectives- Cerebral palsy is one of the leading causes of movement and posture disorders. Recently, Vibration therapy as a treatment method in clinical practice has been used as a complementary approach. This study compared the effects of Segmental Muscle Vibration and Pelvic Stabilization Exercises on Muscle Tone, Balance, and Gross Motor Function in spastic CP children.

Material and Method- A total of 20 children with Spastic Cerebral Palsy, of both sexes (age range of 4-6 years) were included in the study. The Children were randomly assigned into two groups. Group A received Segmental Muscle Vibration along with conventional treatment i.e. Passive Stretching Exercise and Group B received Pelvic Stabilization Exercise along with conventional treatment for 40 minute, 3 times a week for 3 weeks. Outcome measures include Modified Ashworth Scale, Pediatric Balance Scale and Gross Motor Function Measure-88 for measuring Tone (spasticity), Balance and Gross Motor Function.

Results- A significant improvement in all variables ($p < 0.05$) was observed in each group, with greater improvement in tone, balance and gross function indices in group A.

Conclusion- From the results we concluded that both the Segmental Vibration Inhibition Therapy and Pelvic Stabilization exercise yielded a clinically significant improvement in spastic CP; but Segmental Vibration Inhibition Therapy shows more improvement in reduction in tone, improvement in balance and gross motor function.

Keywords- Cerebral palsy, balance, posture, gross motor function, segmental muscle vibration and pelvic stabilization exercise.

INTRODUCTION

Cerebral Palsy (CP) is a group of permanent disorders of the movement and posture, which causes activity limitation that is attributed to non-progressive disturbances that occurred in the developing fetus or infant brain (Levitt Sophie & Addison Anne, 2019). It is the most common childhood disability. Approximately 2-2.5 cases per birth are the worldwide prevalence of cerebral palsy. It is estimated that in India at around 3 cases per 1000 live births, however being a progressing or developing country the actual real figure may be much higher than probable figures. There are about 25 lakh Cerebral Palsy children in India as per the last statistical documentation (Kathy, J., 2013). In Cerebral Palsy central nervous system damage is occurring which causes various disorders in neuromuscular, musculoskeletal and sensorial systems (Gunel MK. et al., 2014). The pathophysiology of Cerebral Palsy depends on birth; it can happen before birth or shortly after birth by various causes and risk factors. The causes of CP vary from child to child which includes very low birth weight, multiple births and intrauterine infection. One of the major causes of CP is brain damage which is caused by anoxia, abnormal development of the brain, perinatal stroke, intracranial bleeding, excessive neonatal asphyxia, hypoglycemia, or neurotrophic virus (Hagberg et al. 2016). CP has many clinical risk factors during pregnancy like genetic mutations and probable environmental triggers such as bacterial and viral intrauterine infection, antepartum hemorrhage, intrauterine growth restriction (IUGR), tight nuchal cord and threatened miscarriage (MacLennan, A.H et al., 2015).

Cerebral palsy is classified according to the parts of the body involved and by the clinical description of tone and involuntary movements. (a) According to an area of the body (distribution) showing impairment CP is -Monoplegia, Diplegia, Hemiplegia, and Quadriplegia; (b) Classification according to perceived clinical signs includes Spastic, Dyskinetic, Hypotonic, Ataxic, Mixed Type (Levitt, S. & Addison, A., 2019). Among perceived clinical signs Spastic CP is the most common type. According to the latest researches, 93.75% of the patients have Spastic Cerebral Palsy (Vyas A.G et al., 2013). Spasticity is a result of the upper motor lesion and can cause secondary disorders such as scoliosis, knee contractures hip, dislocation, torsional-alignments of the femur and tibia, etc (Sanger et al., 2003). Spastic Cerebral Palsy is associated with delayed development of mechanisms of postural stabilization and postural adjustments of the head and trunk as well as the pelvic and shoulder girdles. The deviation of pelvic alignment

Comment [MOU1]: Inconsistent with the rest of your in-text references. Please change for consistency.

Comment [MOU2]: Should include a reference.

Comment [MOU3]: Sentence is awkwardly worded, recommend rearranging for clarity to an international audience.

Comment [MOU4]: This term is not widely understood by an international audience, suggest using million, if I understand the term correctly.

Comment [MOU5]: Always use "person first" language so as not to define children by their disability. Suggest "children with cerebral palsy". Please see for further explanation: Crocker, A.F., Smith, S.N., 2019. Person-first language: are we practicing what we preach?. *Journal of Multidisciplinary Healthcare* Volume 12, 125-129. doi:10.2147/jmdh.s140067

Comment [MOU6]: I would not call a reference from 2013 the latest research. Either revise sentence or reference, please.

Comment [MOU7]: Please provide a reference.

in the standing positions is a common problem in children with cerebral palsy. Such children retain an anterior pelvic tilt due to the contracture of the Iliopsoas muscles as well as weakness in the trunk flexors and hip extensors. Impaired postural control limits a child's re-active balance control, which is the ability to recover from unexpected threats to stability (Himmelman, et al., 2007).

Comment [MOU8]: Again, a reference, please.

Spastic Cerebral Palsy can be managed by Surgical and Conservativetreatment approaches. Surgical Management shows various orthopedic and neurosurgeries. On the other hand, Conservative management includes Medical Management and Physiotherapy Management. In Medical Management, different symptoms of Spastic CP can be treated by Antispastic Drugs (Lin, J.P. 2004). These medications have risks and the potential side effects also. They are not currently considered a permanent solution for muscle spasticity in children with cerebral palsy (Molenaers, G. et al., 2010). Another effective method of Conservative Management is Physiotherapy. In which different therapeutic goals of children with cerebral palsy are to improve or established independent mobility, promote functional movement, to improve performance of Activity of daily living (Gates, P. E. et al., 2012).

Comment [MOU9]: Please add a space here.

There are many Pelvic Core stabilization programs for children with Cerebral palsy to improve their fine and gross motor functional movements which include various exercises. In addition, this type of program can improve gait, postural control, balance, stability, and reduced muscle tone (Dodd, K. J. et al., 2002). Recently, use of vibration therapy is increased for achieving therapeutic or physical performance goals (Novak, et al., 2013, Stark, C. et al., 2010 & Ruck, J. et al., 2010). In which Segmental Muscle Vibration (SMV) is one of the latest type which is used to improve motor function and inhibit spasticity (Caliandro, P. et al., 2012). In this technique by using a mechanical device a vibratory stimulus is given to a specific muscle which induces the generation of Ia fiber inputs as an outcome of the activation of muscle spindle primary endings (Annino, G. et al., 2019). Therefore, the purpose of this study was to compare the effects of SMV and pelvic stability program on tone, balance and gross motor function in children with spastic CP, with an intervention period of 3 weeks.

Comment [MOU10]: Sentence fragment. Please convert to a complete sentence.

Comment [MOU11]: Please reference the many pelvic core stabilization programs.

Comment [MOU12]: Please update this reference to Novak's updated version. Please see: Novak I, Morgan C, Fahey M, et al. State of the evidence traffic lights 2019: systematic review of interventions for preventing and treating children with cerebral palsy. *Current neurology and neuroscience reports*. 2020;20(2):1-21. Additionally, please note that the 2019 article presents limited evidence for the use of vibration as proposed in this manuscript. I would add the systematic review here by Ritzman et al.: Ritzmann, R., Stark, C., Krause, A., 2018. Vibration therapy in patients with cerebral palsy: a systematic review. *Neuropsychiatric Disease and Treatment* Volume 14, 1607-1625.. doi:10.2147/ndt.s152543

Comment [MOU13]: Are you really able to say this with a 10 year-old reference. Please reconsider statement or reference.

MATERIALS AND METHODS

An experimental study was conducted at the SGT Medical College Hospital & Research Institute, Gurugram Haryana, India. The Institutional Ethical Clearance of SGT university Faculty of Physiotherapy was obtained prior to the study (Ethical Number: SGTU/FOP/2020/36).

Sample size calculation: A sample size of 34 was calculated using the G- power software with 10% power and 95% confidence interval.

Inclusion Criteria: Subjects with Spastic cerebral palsy, Age group 4-6 years (Katusic, A. *et al.*, 2013), Able to ambulate i.e Independent or assisted and Based on Gross Motor Function Classification System (GMFCS) criteria level I-III. (Rosenbaum, P. L. *et al.*, 2008) were included in the study

Exclusion Criteria: Participants were excluded if they had been on antispastic drugs in the last six months, had undergone any orthopedic or neurosurgery within the previous 12 months, moderate to severe intellectual disabilities, experienced a seizures episode within the past 12 months, Cognitive impairment, inability to comply with the required procedure and any musculoskeletal problem like muscle disease, congenital limb deficiency etc. (Park, C. *et al.*, 2017)

Outcome measures: Baseline and post outcome measurements included the Modified Ashworth Scale, Pediatric Balance Scale and Gross Motor Function Measure-88 for measuring Tone (spasticity), Balance and Gross Motor Function. Pre data was taken before beginning of treatment and Post data was taken at the end of 3rd week.

Procedure

The sample of 34 subjects was selected from the population on the basis of inclusion and exclusion criteria. 4 subjects were excluded (not meeting the inclusion criteria) and 10 subjects were lost to follow up out of 34 subjects. Total 20 Subjects fulfilled the protocol and were equally divided into two groups (figure 1). The parents/guardian of subjects who were included in the study was explained about the nature of the study. Assessment of the subject was taken after the written consent was signed by the parents/guardian of the subjects. Pre readings of the Modified Ashworth scale, GMFM-88, pediatric balance scale were taken at baseline i.e. before starting the intervention for both the groups. The treatment protocol of 40min/day for 3 days a week for a period of 3 weeks was given to both groups. After treatment at the end of the 3rd

Comment [MOU14]: The standard power is 80%. Why would you only use 10%. What effect size did you use in G-power and how did you determine the effect size? Please provide more details here.

Comment [MOU15]: Please provide a readers with percentages of children GMFCS Levels I, II, or III in each group. This will allow us to see that the groups are balanced or that they are not balanced. Did you use any stratification techniques when assigning children to groups to avoid having all of the children with GMFCS I - and with better potential for change at this age- in the vibration group? Without this information the reader could assume that the vibration group made more progress in three weeks time because they had higher potential which puts the validity of your study into question.

Comment [MOU16]: Please provide information as to how the children were initially diagnosed with CP (Prect's GMA at 12-14 weeks gestation, MRI, HINE, by a neurologist?). I am concerned as to how it was determined these children did indeed have CP with misdiagnosis affecting the validity of the study).

Comment [MOU17]: Please use parallel structure when writing items in a series. See: Lingard, L., Watling, C., 2021. The Power of Parallel Structure, in: Story, Not Study: 30 Brief Lessons to Inspire Health Researchers as Writers. Story, N...

Comment [MOU18]: Please add more information, including referencing each test and briefly (1-2 sentences per test) providing information for the validity and reliability of each test for this population with references.

Comment [MOU19]: While high attrition is common in pediatric research, 33% is a very concerning attrition rate. Please describe the reasons these participants were lost and if any modifications were made in the statistic...

Comment [MOU20]: In the abstract you mention the subjects were randomly assigned to the groups. Please provide evidence of random assignment or change the abstract.

Comment [MOU21]: I recommend using "participants" rather than "subjects" throughout this manuscript, as the children and their families had an active role in this research.

Comment [MOU22]: Please provide rationale for this dosage. Is this a common dosage? Is this dosage representative of an intensive burst of therapy?

week, Post readings were taken through the Modified Ashworth scale, GMFM-88, Pediatric Balance Scale.

Interventions

Group A (*Segmental muscle vibration + Passive Stretching exercises*)

Children with Cerebral Palsy in Group A received Segmental Muscle Vibration along with conventional treatment i.e. Passive Stretching Exercise. For the Segmental vibration of the muscles, a Hand Vibrator of frequency 50Hz was used as an Intervention (Murillo, N. et al. 2011). The target muscles i.e. Gluteus Maximus, Gluteus Medius, Biceps Femoris, and Gastrocnemius [19] were given a segmental muscle vibration for five minutes on each muscle with a rest time of one minute in between the muscle. A Passive Stretch of 20 seconds was given on each targeted muscle i.e. Gluteus Maximus, Gluteus Medius, Biceps Femoris, and Gastrocnemius with five repetitions each. 30 Seconds of rest was given in between each muscle after the Passive stretching exercise (Eken, MM. et al., 2019).

Group B (*Pelvic stabilization exercises + Passive Stretching exercises*)

Children with Cerebral Palsy in Group B received Pelvic Stabilization Exercise along with conventional treatment i.e. Passive Stretching Exercise. Pelvic stabilization exercises like Clam, leg lift, Tabletop leg lift, Tabletop arm lift, Bridging. Each exercise was given for 10 repetitions for a 10-second hold with assistance. A Passive Stretch of 20 seconds was given on each targeted muscle i.e. Gluteus Maximus, Gluteus Medius, Biceps Femoris, and Gastrocnemius with five repetitions each. 30 Seconds of rest was given in between each muscle after the Passive stretching exercise (Pelvic (hip) Girdle. Exercise Sheet, 2018).

Comment [MOU23]: Who administered the tests? Licensed physical therapists, graduated students, ...? How are they qualified? Was test reliability explored- a minimum of inter-rater reliability should be documented. Were the assessors blinded to the treatment groups to control for bias?

Also, we have no idea if this treatment had any lasting effect. A second post-treatment time-point really should be taken to determine any lasting impact of the treatment.

Comment [MOU24]: In order for others to replicate the interventions, I recommend that the authors comply with the TIDieR checklist. Please see: Hoffmann, T.C., Glasziou, P.P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D.G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S.E., Dixon-Woods, M., Mcculloch, P., Wyatt, J.C., Chan, A.-W., Michie, S., 2014. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 348, g1687–g1687. doi:10.1136/bmj.g1687
In particular, there needs to be more information on the specific vibrator used in this. We need to know who provided the intervention- a physical therapist, PT student, research assistant? How was treatment fidelity monitored? The authors also need to define what is meant by "conventional treatment" as, without documentation, we do not know how the other treatments could have interfered with the study interventions.

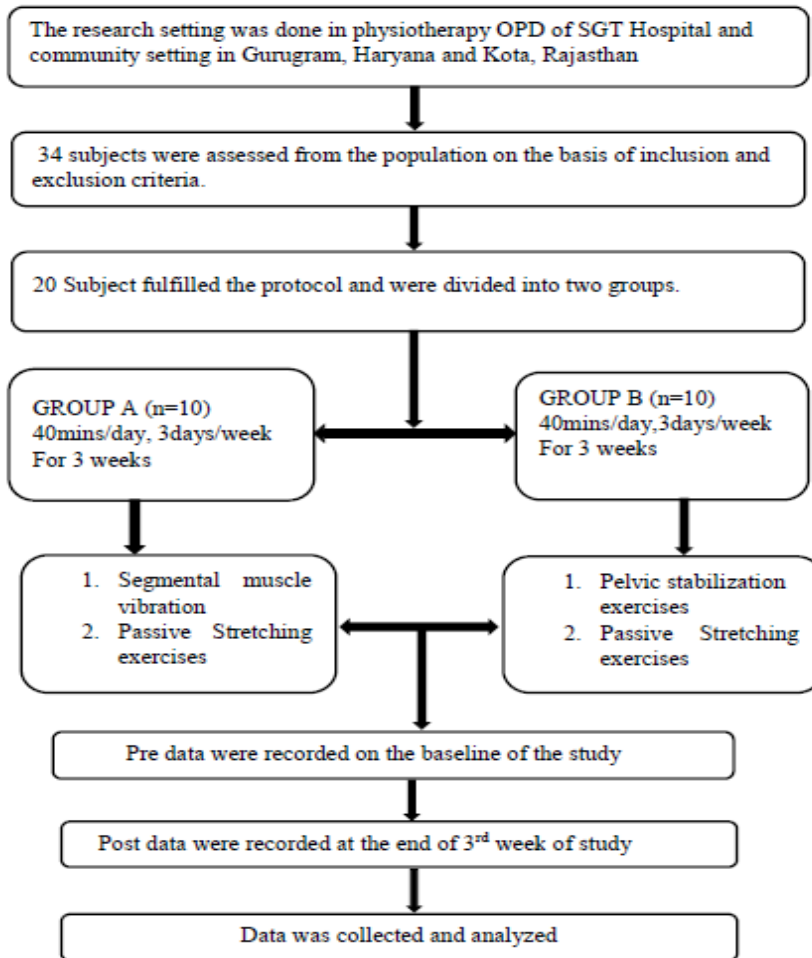


Figure 1: Flowchart of demonstrates the experimental design of the study.



Figure 2: Segmental vibration for Gluteus Maximus, Gluteus Medius, Biceps Femoris and Gastrocnemius muscle in spastic CP.



Comment [MOU25]: Please label the pictures and provide a key as to what is taking place in each picture for all pictures provided. These pictures add significantly to the article.

Figure 3: Pelvic stabilization exercises (Starting and end position for clam)



Figure 4: Pelvic stabilization exercises (Leg lift tabletop, tabletop arm lift, leg lift and Bridging exercise)

STATISTICAL ANALYSIS

Statistical Analysis was done using software package SPSS 24.00 for window 7 version. The analysis for demographic characteristics was done in frequency and percentage while Wilcoxon test was used to compare mean of data of pre and post intervention within the group and Mann Whitney test was used to compare the mean of data of pre and post intervention in between the group A and B. The p -value < 0.05 was considered to be statistically significant.

RESULT

Table 1 shows the comparison of mean and standard deviation (SD) of age among Group A and B. The mean and standard deviation 5.2 ± 0.788 were found in Group A and mean and standard deviation 4.9 ± 0.875 were found in Group B. There was no significant difference of age was found among both Group with t value 0.805.

Table 2 Shows Comparison of Mean value of Modified Ashworth Scale (MAS) at Pre intervention and Post intervention i.e. Baseline and end of 3rd week of subjects within Group A

Comment [MOU26]: Please re-write this section to flow through your results without just describing your tables. Additionally, more information needs to be given in a caption for each table to allow it to stand alone.

and Group B. In Group A there were significant difference of Gluteus Maximus (p-value 0.025), Biceps Femoris (p-value 0.003) and Gastrocnemius (p-value 0.046) were found in the study with t-value 2.236, 3.00, 2.00 respectively. There was no significant difference of Gluteus Medius (p-value 1.89) with t-value 1.89 was found in the study. Whereas in Group B there was significant difference of Biceps Femoris (p-value 0.014) was found in the study with t-value 2.449. Rest were non-significant.

Table 3 describes the Comparison of means of Muscle Tone (G.max, G.med, Biceps Femoris & Gastrocnemius) of Pre and Post intervention between the group A and B. The mean and standard deviation of pre and post intervention data of Gluteus Maximus 2.65 ± 0.58 and 2.3 ± 0.57 , Gluteus Medius 2.55 ± 0.51 and 2.15 ± 0.81 , Biceps Femoris 2.15 ± 0.81 and 2.15 ± 0.67 , Gastrocnemius 3.55 ± 0.60 and 3.35 ± 0.58 were found between the Group A and B. There was significant difference found in Biceps Femoris of pre and post data (p-value 0.045 and 0.021) with t-value 2.317 and 2.317. Rest was non-significant.

Table 4 shows Comparison of t-value and p-value of Pediatric Balance Scale at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects within Group A and Group B. There was significant difference of balance (p-value 0.005) found in study with t-value 2.821.

Table 5 Shows Comparison of Mean value of Pediatric Balance Scale at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects between Group A and Group B. The mean and standard deviation of pre intervention 33.70 ± 5.19 and post intervention 38.15 ± 4.62 of Balance were found in the study. There was no significant difference of pre and post intervention of balance in between the groups was found in the study. (p-value > 0.05)

Table 6 Describes Comparison of t-value and p-value of GMFM-88 at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects within Group A and Group B. There was significant difference gross motor function measure (p-value 0.005) and t-value 2.803 in Group A whereas in Group B there was significant difference of gross motor function measure (p-value 0.005) found in study with t-value 2.803 were found in the study.

Table 7 Shows Comparison of Mean value of GMFM-88 at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects between Group A and Group B.

Comment [MOU27]: Please look up and provide the minimally clinically important difference for your sample. This should be reported for well established motor tests. This allows the reader to determine if the change from time A to time B was clinically meaningful to the children and their families.

The mean and standard deviation of pre intervention 71.40 ± 6.99 and post intervention 76.46 ± 6.69 of Gross motor function were found in the study. There were no significant difference of pre and post intervention of gross motor function measure in between the group were found in the study. (p -value >0.05) with t - value 0.756 and 0.545.

Parameter		Mean	Standard Deviation (SD)	t value	P value
Age	Group A	5.2	0.788	0.805	$p>0.05$
	Group B	4.9	0.875		

Table 1: Comparison of Mean and Standard Deviation (SD) of Age among Group A and Group B

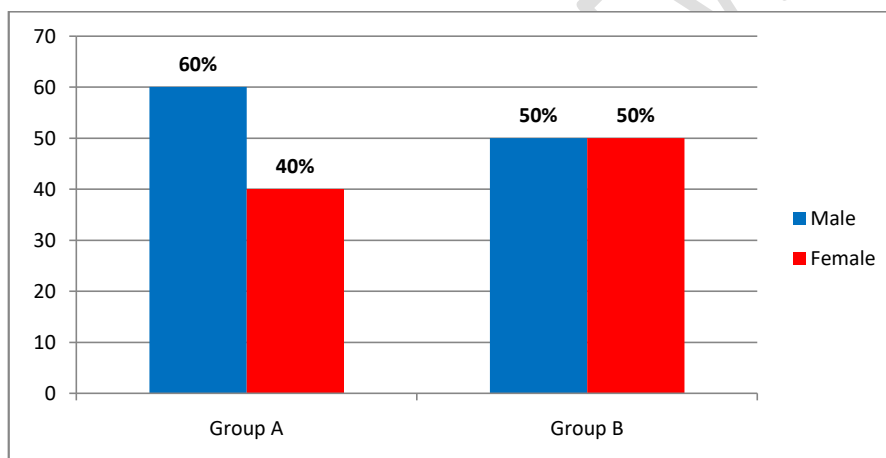


Figure 5: Gender Distribution among Group A and B.

MAS		Group A		Group B	
		t value	P value	t value	P value
Pre (Baseline) vs Post (end of 3 rd Week)	G Max.	2.236	0.025	1.414	0.157
	G Med.	1.89	0.059	1.732	0.083
	Biceps Femoris	3.00	0.003	2.449	0.014
	Gastrocnemius	2.00	0.046	0.0	1.000

Table 2: Comparison of t-value and p- value of Modified Ashworth Scale (MAS) at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects within Group A and Group B.

MAS		Group A vs Group B		
		Mean±SD	t value	P value
Pre (Baseline)	G Max.	2.65 ± 0.58	0.559	0.576
	G Med.	2.55 ± 0.51	0.438	0.661
	Biceps Femoris	2.15 ± 0.81	2.007	0.045*
	Gastrocnemius	3.55±0.60	1.834	0.067
Post (end of 3rd Week)	G Max.	2.3 ± 0.57	1.535	0.125
	G Med.	2.15 ± 0.81	0.846	0.397
	Biceps Femoris	2.15 ± 0.67	2.317	0.021*
	Gastrocnemius	3.35 ± 0.58	0.559	0.576

Table 3: Comparison of Mean value of Modified Ashworth Scale (MAS) at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects between Group A and Group B.

Pediatric Balance Scale	Group A		Group B	
	t-value	p-value	t-value	p-value
Pre (Baseline) vs Post (end of 3 rd Week)	2.821	0.005*	2.803	0.005*

Table 4: Comparison of t-value and p- value of Pediatric Balance Scale at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects within Group A and Group B.

Pediatric Balance Scale	Group A vs Group B		
	Mean ± SD	t-value	p-value
Pre (Baseline)	33.70 ± 5.19	1.146	0.252
Post (end of 3 rd Week)	38.15 ± 4.62	0.00	1.0

Table 5: Comparison of Mean value of Pediatric Balance Scale at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects between Group A and Group B.

GMFM-88	Group A		Group B	
	t-value	p-value	t-value	p-value
Pre (Baseline) vs Post (end of 3 rd Week)	2.803	0.005*	2.803	0.005*

Table 6: Comparison of t-value and p- value of GMFM-88 at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects within Group A and Group B.

GMFM-88	Group A vs Group B		
	Mean ± SD	t-value	p-value
Pre (Baseline)	72.99 ± 6.60	0.756	0.449
Post (end of 3 rd Week)	75.42 ± 6.90	0.605	0.545

Table 7: Comparison of Mean value of GMFM-88 at Pre intervention and Post intervention i.e., Baseline and end of 3rd week of subjects between Group A and Group B.

DISCUSSION

Spasticity was considered a primary limiting impairment in people with cerebral palsy (Aisen, M. L. *et al.*, 2011). According to various studies many interventional experiments were conducted to reduce spasticity and to improve associated factors, in neurological condition like, cerebral palsy.

The present study was conducted to find out the effect of segmental muscle vibration and pelvic stabilization exercises on spasticity and gross motor function in spastic cerebral palsy. The data was collected pre and post intervention i.e. before and after 3 weeks. The data was analyzed in which the Descriptive analysis describes about the age distribution among both the group i.e.

Group A and Group B. Age group of 4-6 years was taken in the study. In Group A 20% of 4 years, 40% of 5 years and 40% of 6 years were taken. Whereas in Group B 40% of 4 years, 30% of 5 years and 30% of 6 years were taken in the study. The comparison of mean and standard deviation (SD) of age among Group A and B was done. The mean and standard deviation 5.2 ± 0.788 were found in Group A and mean and standard deviation 4.9 ± 0.875 were found in Group B. In Gender Distribution 60% male and 40% females were in Group A and 50% male and 50% females were in group B.

Role of Segmental Vibration and pelvic stabilization Exercise in improving Muscle Tone in Spastic Cerebral Palsy

The comparison of mean value within the Group A and B was done. The statistically difference between the t-value and p-value at Baseline Vs end of 3rd week i.e., for Gluteus Maximus, Gluteus Medius, Biceps Femoris & Gastrocnemius were 2.236, 1.89, 3.00, 2.00 and 1.414, 1.732, 2.449 and 0.0 for group A and B respectively. It reveals that there was a significant difference for Gluteus Maximus, Biceps Femoris & Gastrocnemius in group A. The result achieved from the comparison between the mean value of MAS Score between Group A and Group B at Pre and Post Intervention i.e., Baseline and end of 3rd week was 2.65 ± 0.58 and 2.3 ± 0.57 and, 2.55 ± 0.51 and 2.15 ± 0.81 , 2.15 ± 0.81 and 2.15 ± 0.67 , 3.55 ± 0.60 and 3.35 ± 0.58 for Gluteus

Comment [MOU28]: Please reference these various studies.

Comment [MOU29]: While spasticity is discussed in the introduction, it is not stated as clearly as in the discussion. Please re-write portions of the introduction to include an emphasis on using vibration for spasticity management.

Comment [MOU30]: Please re-write these sentences to reduce redundancy and to improve the flow. While the rest of the article seems as if it was written by a native English speaker, it feels as if either their was writing fatigue when the authors came to this section or that a different author wrote this section. Please re-write to match the quality of writing in the rest of the article.

Comment [MOU31]: As stated before, this section needs a smaller emphasis on sex and age and a greater emphasis on GMFCS Levels per group which need to please be reported.

Maximus, Gluteus Medius, Biceps Femoris & Gastrocnemius respectively. The comparison of mean value between Group A and Group B was done, the statistically difference between the t-value and p-value at Pre and Post Intervention i.e., Baseline and end of 3rd week was 0.559 and 1.535, 0.438 and 0.846, 2.007 and 2.317, 1.834 and 0.559 respectively. It reveals that there was a significant difference of Pre and Post Intervention i.e., Baseline and end of 3rd week 0.045 and 0.021 for Biceps Femoris and rest were found non-significant. Park C. et al., (2017), Caliandro P. et al., (2012), Katusic A. (2013) were also found that there were significant effect of vibration therapy on tone (spasticity).

Comment [MOU32]: This information should be included in the results section, not the discussion.

Role of Segmental Vibration and pelvic stabilization Exercise in improving Balance in Spastic Cerebral Palsy

The comparison of mean value within the Group A and B at baseline Vs end of 3rd week were 2.821 and 2.803 respectively. It reveals that there was a significant difference between the baseline and end of 3rd week scores within the groups. And comparison of mean value between Group A and Group B was done, the statistically difference between the t-value and p-value at baseline Vs end of 3rd week were 1.146 60 and 0.00. It reveals that there was no significant difference for balance between Group A and Group B were found. El-Shamy SM., (2013), Dudoniene V. et al., (2017), Saquetto M. et al., (2015) were found that there were significant effect of vibration therapy on balance in the study.

Role of Segmental Vibration and pelvic stabilization Exercise in improving Gross Motor Functions in Spastic Cerebral Palsy

The comparison of mean value within the Group A and B was done, the statistically difference between the t-value and p-value at baseline Vs end of 3rd week 2.803. It reveals that there was a significant difference between the baseline and end of 3rd week scores within groups. The comparison of mean value between Group A and Group B was done, the statistically difference between the t-value and p-value at baseline Vs end of 3rd week were 0.756 and 0.605. It reveals that there was no significant difference for Gross Motor Function between balance of Group A and Group B were found. (p value ≥ 0.05). Katusic A. et al., (2013) Dudoniene V. et al., (2017), Jung Y. et al., (2020) concluded that vibration stimuli are significantly improves Gross motor performance in children with Cerebral Palsy.

Present experimental study of three weeks was proved significant improvement in spasticity, balance and gross motor function in both the groups. The result of above study supporting the hypothesis that treatment through segmental vibration therapy with conventional treatment would lead to reduction in spasticity, improvement in balance and gross motor functions. Ruck. *et al.*, (2013) have demonstrated that vibration therapy is safe and has some effect on mobility in children with cerebral palsy, but there still is a need of standardized methods. Ibrahim *et al.*, (2014) in their study also found that the vibration therapy decreased spasticity and improve motor functions after 12 week treatment program.

Comment [MOU33]: I do not believe you can make this statement based on your paragraph above regarding the non-significant change in GMFCS levels across the 3 weeks. Also, it needs to be said that any changes were only temporary as the study design did not allow for any follow-up assessment at later timepoints.

The present study has explained that when using Segmental vibration therapy in combination with conventional interventions like stretching, muscle tone, mainly, improved more significantly than with exercises alone in spastic hemiplegic cerebral palsy. This was also supported by Tavernese *et al.*, (2013), who reported that the use of SMV on the Biceps Brachii and Flexor Carpi Ulnaris of the affected side of their participants who had suffered a stroke, along with physical therapy, produced a significant improvement in normalized jerk and reaching motion and this effect was maintained at the participants' 2-week post treatment evaluation. In summary both group have shown significant improvement in balance and gross motor function. But group A has shown more significant reduction in spasticity. Hence segmental vibration therapy has shown significant improvement in variables given in the study.

Comment [MOU34]: Again, this statement is too strong. What would have happened if you included the children who dropped out of the study. Would their data support this claim? Also, again, please better describe what is considered "conventional interventions" in this study.

Limitation(s)

Very limited Age group was included in the study. Intervention is used on limited muscles and for short duration of interval and Treatment protocol. Home Exercises were not prescribed and the Sample size was small.

Comment [MOU35]: Please expand on the limitations to include a lack of analysis on subjects lost and no post-treatment follow-up.

CONCLUSUION

The present study suggested that in children with spastic hemiplegic cerebral palsy both the Segmental Vibration Inhibition Therapy and Pelvic Stabilization exercise yielded a clinically significant improvement; but Segmental Vibration Inhibition Therapy shows more improvement in reduction in tone, improvement in balance and gross motor function.

Comment [MOU36]: Again, please more accurately reflect your findings. You did not find a significant improvement in GMFM scores between the groups.

Future Recommendation(s)

Future research is needed to evaluate the effect of segmental muscle vibration therapy on large sample size with proper home exercise program. Age group range should be increase in future study with long treatment protocol that means more than 3 weeks.

REFERENCES

- Aisen, M. L., Kerkovich, D., Mast, J., Mulroy, S., Wren, T. A., Kay, R. M., & Rethlefsen, S. A. (2011). Cerebral palsy: clinical care and neurological rehabilitation. *The Lancet Neurology*, *10*(9), 844-852.
- Annino, G., Alashram, A. R., Alghwiri, A. A., Romagnoli, C., Messina, G., Tancredi, V., & Mercuri, N. B. (2019). Effect of segmental muscle vibration on upper extremity functional ability poststroke: A randomized controlled trial. *Medicine*, *98*(7).
- Caliandro, P., Celletti, C., Padua, L., Minciotti, I., Russo, G., Granata, & Camerota, F. (2012). Focal muscle vibration in the treatment of upper limb spasticity: a pilot randomized controlled trial in patients with chronic stroke. *Archives of physical medicine and rehabilitation*, *93*(9), 1656-1661.
- Children and Young People., (2018). Pelvic (hip) Girdle. Exercise Sheet. *Children's Physiotherapy Service*
- Dodd, K. J., Taylor, N. F., & Damiano, D. L. (2002). A systematic review of the effectiveness of strength-training programs for people with cerebral palsy. *Archives of physical medicine and rehabilitation*, *83*(8), 1157-1164.
- Dudoniene, V., Lendraitiene, E., & Pozeriene, J. (2017). Effect of vibration in the treatment of children with spastic diplegic cerebral palsy. *Journal of Vibroengineering*, *19*(7), 5520-5526.
- Eken, M. M., Brændvik, S. M., Bardal, E. M., Houdijk, H., Dallmeijer, A. J., & Roeleveld, K. (2019). Lower limb muscle fatigue during walking in children with cerebral palsy. *Developmental Medicine & Child Neurology*, *61*(2), 212-218.
- El-Shamy, S. M., & Abd El Kafy, E. M. (2014). Effect of balance training on postural balance control and risk of fall in children with diplegic cerebral palsy. *Disability and rehabilitation*, *36*(14), 1176-1183

- Gates, P. E., Banks, D., Johnston, T. E., Campbell, S. R., Gaughan, J. P., Ross, S. A., & Tucker, C. (2012). Randomized controlled trial assessing participation and quality of life in a supported speed treadmill training exercise program vs. a strengthening program for children with cerebral palsy. *Journal of pediatric rehabilitation medicine*, 5(2), 75-88.
- Günel MK, Türker D, Ozal C, Kara OK., (2014). Physical management of children with cerebral palsy. *Cerebral Palsy: Challenges for the Future*. 19:29
- Hagberg, H., Edwards, A. D., & Groenendaal, F. (2016). Perinatal brain damage: the term infant. *Neurobiology of disease*, 92, 102-112.
- Himmelmann, K., Beckung, E., Hagberg, G., & Uvebrant, P. (2007). Bilateral spastic cerebral palsy—prevalence through four decades, motor function and growth. *European Journal of Paediatric Neurology*, 11(4), 215-222.
- Ibrahim M. M., Eid M., Moawd S. A. Effect of whole-body vibration on muscle strength, spasticity, and motor performance in spastic diplegic cerebral palsy children. *The Egyptian Journal of Medical Human Genetics*, 15, 2014, p. 173-179
- Jung, Y., Chung, E. J., Chun, H. L., & Lee, B. H. (2020). Effects of whole-body vibration combined with action observation on gross motor function, balance, and gait in children with spastic cerebral palsy: a preliminary study. *Journal of Exercise Rehabilitation*, 16(3), 249.
- Kathy Jones., (2013). Incidence of Cerebral Palsy Remains Constant in India on Indian Health News.
- Katusic, A., Alimovic, S., & Mejaski-Bosnjak, V. (2013). The effect of vibration therapy on spasticity and motor function in children with cerebral palsy: a randomized controlled trial. *NeuroRehabilitation*, 32(1), 1-8.
- Levitt, S., Addison, A., (2019). *Treatment Of Cerebral Palsy and Motor Delay* (6th ed) UK WILEY Blackwell.
- Lin, J.P. (2004) The assessment and management of hyper tonus in cerebral palsy: a physiological atlas ('road map'). In Management of the Motor Disorders of Children with Cerebral Palsy (eds D. Scrutton, D. Damiano, and M. Mayston), pp.85–104. *Clinics in Developmental Medicine* No.161. Mac Keith Press, London.

- MacLennan, A. H., Thompson, S. C., & Gecz, J. (2015). Cerebral palsy: causes, pathways, and the role of genetic variants. *American journal of obstetrics and gynecology*, 213(6), 779-788.
- Molenaers, G., Van Campenhout, A., Fagard, K., De Cat, J., & Desloovere, K. (2010). The use of botulinum toxin A in children with cerebral palsy, with a focus on the lower limb. *Journal of children's orthopaedics*, 4(3), 183-195.
- Murillo, N., Kumru, H., Vidal-Samsó, J., Benito, J., Medina, J., Navarro, X., & Valls-Sole, J. (2011). Decrease of spasticity with muscle vibration in patients with spinal cord injury. *Clinical neurophysiology*, 122(6), 1183-1189.
- Novak, I., McIntyre, S., Morgan, C., et al. (2013) A systematic review of interventions for children with cerebral palsy: state of the evidence. *Dev. Med. Child Neurol.*, 55, 885– 910.
- Park, C., Park, E. S., Choi, J. Y., Cho, Y., & Rha, D. W. (2017). Correction: immediate effect of a single session of whole body vibration on spasticity in children with cerebral palsy. *Annals of rehabilitation medicine*, 41(4), 722.
- Rosenbaum, P. L., Palisano, R. J., Bartlett, D. J., Galuppi, B. E., & Russell, D. J. (2008). Development of the gross motor function classification system for cerebral palsy. *Developmental Medicine & Child Neurology*, 50(4), 249-253.
- Ruck J., Chabot G., Rauch F. Vibration treatment in cerebral palsy: A randomized controlled pilot study. *Journal of Neuronal and Musculoskeletal Interactions*, Vol. 10, Issue 1, 2010, p. 77-83.
- Sanger, T.D., Delgado, M.R., Gaebler-Spira, D., et al., (2003) Classification and definition of disorders causing hypertonia in childhood. *Pediatrics*, 111, e89–97.
- Saquetto, M., Carvalho, V., Silva, C., Conceição, C., & Gomes-Neto, M. (2015). The effects of whole body vibration on mobility and balance in children with cerebral palsy: a systematic review with meta-analysis. *Journal of musculoskeletal & neuronal interactions*, 15(2), 137.
- Stark, C., Nikopoulou-Smyrni, P., Stabrey, A., Semler, O., & Schoenau, E. (2010). Effect of a new physiotherapy concept on bone mineral density, muscle force and gross motor function in children with bilateral cerebral palsy.

- Tavernese, E., Paoloni, M., Mangone, M., Mandic, V., Sale, P., Franceschini, M., & Santilli, V. (2013). Segmental muscle vibration improves reaching movement in patients with chronic stroke. A randomized controlled trial. *NeuroRehabilitation*, 32(3), 591-599.
- Vyas, A. G., Kori, V. K., Rajagopala, S., & Patel, K. S. (2013). Etiopathological study on cerebral palsy and its management by ShashtikaShaliPindaSweda and SamvardhanaGhrita. *Ayu*, 34(1), 56.

UNDER PEER REVIEW