Research Article

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AYURVEDA MANAGEMENT OF SPASTICITY IN CHILDREN WITH CEREBRAL PALSY: A RANDOMIZED CONTROLLED TRIAL

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Received on: 21/06/17 Accepted on: 02/08/17

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DOI: 10.7897/2277-4343.085234

ABSTRACT

Cerebral Palsy (CP) is most common and exorbitant form of chronic motor disability that begins in childhood and spasticity is the most common movement disorder in children with CP. Incidence of CP is 3.6 per 1000 live births with a male: female ratio of 1.4:1. Randomized control trial 1 -12 years. of either sex. 30 cases were selected from OPD and IPD of National Institute of Ayurveda, Jaipur for the study; that were satisfied the inclusion and exclusion criteria. They were randomly divided in three groups each comprising 10 patients. In Group A was administered Trial Drug (Shishu Kalyan Ghrita) and Panchkarma procedure [Abhyanga (massage) & Shashtishali Pinda Sweda (sudation)], in Group B Kala Basti (therapeutic enema) (Anuvasana Basti: Dhanvantar taila and Asthapana Basti: Dashmool Kwath) and Panchakarma procedure and in Group C Physiotherapy (Control group) were administered. Assessment was done by Ashworth scale for spasticity. Very significant results were seen in group A while intergroup comparison shows statistically significant gain of Group A over Group C. Ayurveda management with Shishukalyan Ghrita and Panchkarma procedures including Abhyanga with Dashmoola Taila, Shashtishali Pinda Sweda have proved to be a better, safe and cost-effective treatment modality for improving the spasticity of children with Cerebral palsy.

Keywords: Cerebral Palsy, Shishukalyan Ghrita, Ashworth scale for spasticity, Ayurveda

INTRODUCTION

Today developmental disabilities are emerging as a new problem of society. When disability is discussed predominantly in children, about a quarter of chronic childhood problems are neurological in origin. Cerebral Palsy (CP) is the leading cause of disability that begins in childhood, making them physically and mentally handicapped and socially apart. CP is not a single disease but it is a symptom complex. It is a broad term encompassing a group of non-progressive, non-contagious condition that causes motor impairment syndrome characterized by abnormalities in movement, posture and tone ("Cerebral Palsy" National Centre on Birth Defects and Developmental Disabilities, Oct 3-2002).

Data from the Centers for Disease Control and Prevention (CDC) indicate that the incidence is 3.6 per 1000 live births with a male: female ratio of 1.4:1[1]. In India it is reported that incidence of CP is 3 per 1000 live births[2]. Its pathology lies in developing brain chiefly cerebrum, brain stem, gyri, middle cerebral artery, thalamus, basal ganglia, cerebellum etc.

Swedish Classification (SC) of CP mentioned 4 Subtypes viz. spastic, ataxic, dyskinetic and mixed. All types of CP are characterized by abnormal muscle tone, reflexes, motor development and coordination. In this entire sub type, spastic CP accounts for major portion of 70% to 80%[3].

There is no any definite cure available for CP. Stem cell transplantation procedure, Baclofen intrathecal injection[4], Botulinum toxin type A injection[5], Selective dorsal Rhizotomy[6] (SDR) Orthotic devices such as ankle-foot orthoses (AFOs), Hyperbaric oxygen therapy[7] (HBOT), Neuroplasticity are the newer advancements under trial in the management of CP.

Even though there is no direct reference in Ayurveda classics regarding CP, but conditions with similar aetiopathology are described very clearly in many texts. Inappropriate Ritu (Fertile period), Kshetra (Uterus), Ambu (Ahara rasa nutrients) and Bija[8] (sperm and ovum), Dauhrida Avamanana[9] (negligence of urges during Dauhrida stage of pregnant women), Garbhopaghatkarbhava[10] (Dont's in Antenatal period), incompatible Garbha Vriddhikarabhava[11] (embryonic growth factors) are some etiological factors responsible for disease. Consequently, Cerebral Palsy may also be considered as Dhatukshayajanya Vata Vyadhi (disorders due to Vata).

MATERIAL AND METHODS

Study design: Randomized controlled trial (RCT).

Selection of Cases : For the study, diagnosed cases of Spastic CP of the age group of 1 to 12 years of either sex was selected after evaluating them clinically, from O.P.D. and I.P.D. of PG Department Balaroga, National Institute of Ayurveda, Jaipur.

Number of cases : 30 cases were registered and screened for the study and were randomly divided in three groups each comprising 10 patients.

Inclusion Criteria

1. Age group of 1 to 12 years of either sex.
2. Diagnosed Case of spastic cerebral palsy without seizures.

Exclusion Criteria

1. Progressive neurological disorder.
2. Presence of Seizures.

Discontinuation Criteria

1. Parent/Guardian is not willing to continue the treatment.
2. Patient develops life threatening complication during treatment.
3. Any other severe illness.

Assessment Criteria

Modified Ashworth Scale for spasticity

Grouping and Interventions

Table 1: Grouping and interventions

Group	Intervention	Period
Group A	Shishukalyan Ghrita- 0.25 ml/ kg/ day in two to three divided doses	90 days
	Abhyanga (massage) - With Dashmoola Taila 15-20 minutes per day.	90 days
	Shashtishali Pinda Sweda- 30-35 minutes per day.	90 days
Group B	Kala Basti (therapeutic enema) - Anuvasana Basti with Dhanvantara Taila and Niruha Basti with Dashmoola Kwatha.	15 days
	Abhyanga (massage) - With Dashmoola Taila 15-20 minutes per day.	90 days
	Shashtishali Pinda Sweda- 30-35 minutes per day.	90 days
Group C	Physiotherapy 30-35 minutes daily	90 days

Institutional Ethics Committee clearance

Present research work approved by Institutional Ethics Committee with approval No. IEC/ ACA/ 2015/ 32

Trial Duration: The trial was conducted for ninety days.

Statistical Analysis

The information gathered on the basis of above observations was subjected to statistical analysis using GraphPad Instat. Software Version 3.10. As the criteria selected for analysis were non parametric hence 'Wilcoxon matched pairs test' was applied for statistical improvement analysis in the clinical features of Cerebral palsy in single group and for statistical status of intergroup differences of clinical features 'unpaired Mann-Whitney Test' was applied.

RESULT

Table 2: Effect on spasticity in Right upper limb of Group A, Group B and Group C

Group	Mean (n=10)			% Change	S.D. (±)	S.E. (±)	'P' Value	Result
	BT	AT	Diff.					
Group A	1.50	0.70	0.80	53.33	0.350	0.111	<0.01	**V.S.
Group B	1.35	0.95	0.40	29.63	0.316	0.100	<0.05	*S.
Group C	1.50	1.10	0.40	26.67	0.394	0.125	<0.05	*S.

BT: Before Treatment, AT: After Treatment

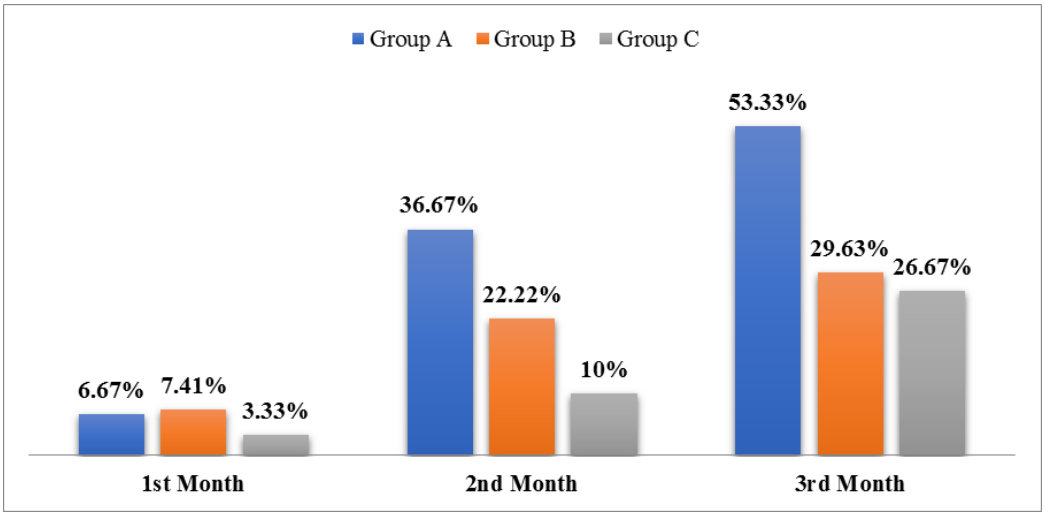
The effect of treatment observed in group A at the end of 3rd month was 53.33% change which was statistically very significant ($p<0.01$). The effect of treatment observed in group B at the end of 3rd month was 29.63% change which was statistically significant ($p<0.05$). The effect of treatment observed in group C at the end of 3rd month was 26.67% change which was significant ($p<0.05$).

Table 3: Intergroup comparison of Ashworth scale readings of effect on spasticity in Right upper limb in all three groups Kruskal-Wallis Test (Nonparametric ANOVA)

Sr.No.	Group	N	Sum of Ranks	Mean of Ranks	KW	'p' Value	Remarks
1	A	10	209.00	20.900	6.636	0.0362	*S.
2	B	10	128.00	12.800			
3	C	10	128.00	12.800			

Kruskal-Wallis Test (Nonparametric ANOVA) shows that the $P < 0.05$, considered significant. Variation among Group medians is significantly greater than expected by chance.

Dunn's Multiple Comparisons Test shows there is non-significant difference in action of intervention used in group A, group B and group C.



Graph 1: Improvement in Ashworth scale readings of effect on spasticity in Right upper limb in Group A, Group B, Group C

Table 4: Effect on spasticity in Left upper limb of Group A, Group B and Group C

Group	Mean (n=10)			% Change	S.D. (±)	S.E. (±)	'P' Value	Result
	BT	AT	Diff.					
Group A	1.40	0.85	0.55	39.28	0.284	0.090	<0.01	**V.S.
Group B	1.45	1.00	0.45	31.03	0.158	0.050	<0.01	**V.S.
Group C	1.55	1.20	0.35	22.58	0.337	0.107	<0.05	*S.

BT: Before Treatment, AT: After Treatment

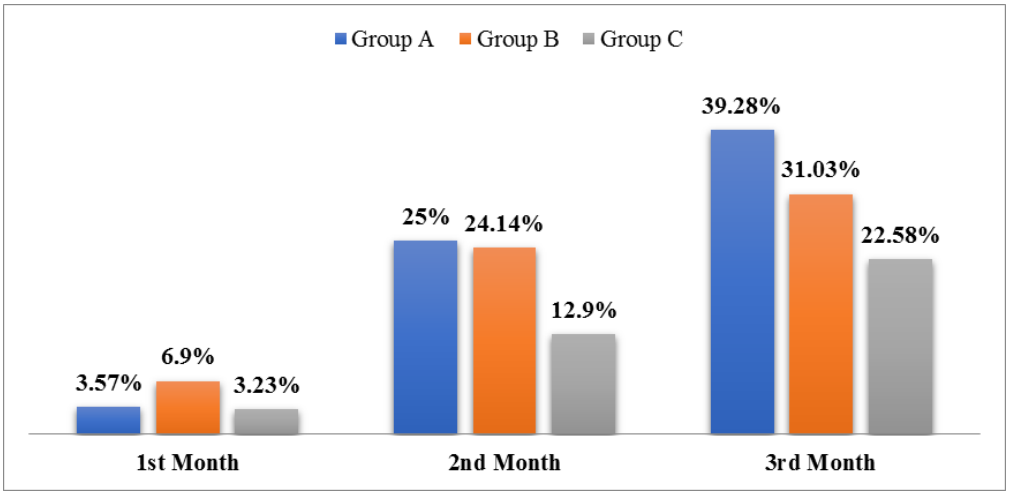
The effect of treatment observed in group A at the end of 3rd month 39.28% change which was statistically very significant (p<0.01). The effect of treatment observed in group B at the end of 3rd month 31.03% change which was statistically very significant (p<0.01). The effect of treatment observed in group C at the end of 3rd month 22.58% change which was statistically significant (p<0.05).

Table 5: Intergroup comparison of Ashworth scale readings of effect on spasticity in Left upper limb in all three groups, Kruskal-Wallis Test (Nonparametric ANOVA)

Sr.No.	Group	N	Sum of Ranks	Mean of Ranks	KW	'p' Value	Remarks
1	A	10	205.00	20.500	7.540	0.0231	*S.
2	B	10	142.50	14.250			
3	C	10	117.50	11.750			

Kruskal-Wallis Test (Nonparametric ANOVA) shows that the P <0.05, considered significant. Variation among Group medians is significantly greater than expected by chance.

Dunn's Multiple Comparisons Test shows there is non-significant difference in action of intervention used in group A and Group B, there is significant difference in action of intervention used in group A than Group C and there is non-significant difference in action of intervention used in group B and Group C.



Graph 2: Improvement in Ashworth scale readings of effect on spasticity in Left upper limb in Group A, Group B & Group C

Table 6: Effect on spasticity in Right lower limb of Group A, Group B and Group C

Group	Mean (n=10)			% Change	S.D. (±)	S.E. (±)	'P' Value	Result
	BT	AT	Diff.					
Group A	1.90	1.25	0.65	34.21	0.474	0.150	<0.01	**V.S.
Group B	1.95	1.50	0.45	23.08	0.369	0.117	<0.05	*S.
Group C	1.55	1.05	0.50	32.26	0.236	0.074	<0.01	**V.S.

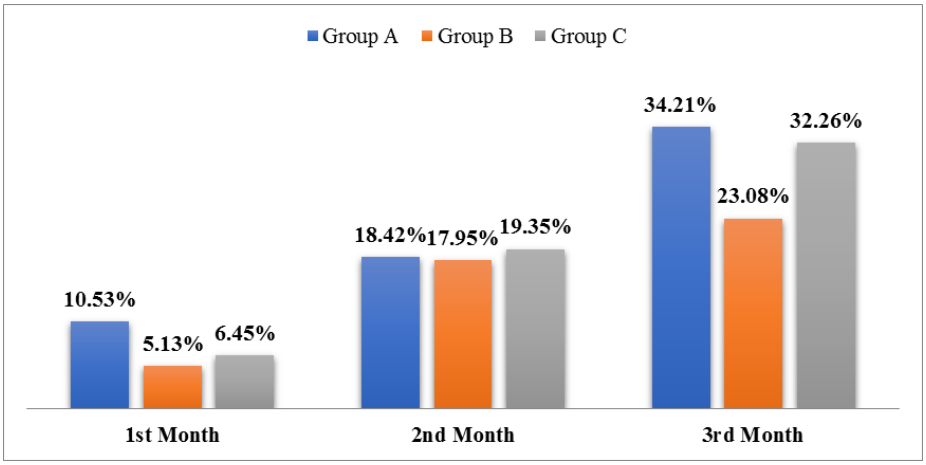
BT: Before Treatment, AT: After Treatment

The effect of treatment observed in group A at the end of 3rd month 34.21% change which was statistically very significant (p<0.01). The effect of treatment observed in group B at the end of 3rd month 23.08% change which was also statistically significant (p<0.05). The effect of treatment observed in group C at the end of 3rd month 32.26% change of which was statistically very significant (p<0.01).

Table 7: Intergroup comparison of Ashworth scale readings of effect on spasticity in Right lower limb in all three groups, Kruskal-Wallis Test (Nonparametric ANOVA)

Sr.No.	Group	N	Sum of Ranks	Mean of Ranks	KW	'p' Value	Remarks
1	A	10	176.50	17.65	1.221	0.543	N.S.
2	B	10	138.50	13.85			
3	C	10	150.00	15.00			

Kruskal-Wallis Test (Nonparametric ANOVA) shows that the P >0.10, considered non-significant. Variation among Group medians is significantly greater than expected by chance.



Graph 3: Improvement in Ashworth scale readings of effect on spasticity in Right lower limb in Group A, Group B & Group C

Table 8: Effect on spasticity in Left lower limb of Group A, Group B and Group C

Group	Mean (n=10)			% Change	S.D. (±)	S.E. (±)	'P' Value	Result
	BT	AT	Diff.					
Group A	1.85	1.15	0.70	37.84	0.422	0.133	<0.01	**V.S.
Group B	1.90	1.30	0.60	31.57	0.394	0.125	<0.01	**V.S.
Group C	1.60	1.00	0.60	37.50	0.211	0.067	<0.01	**V.S.

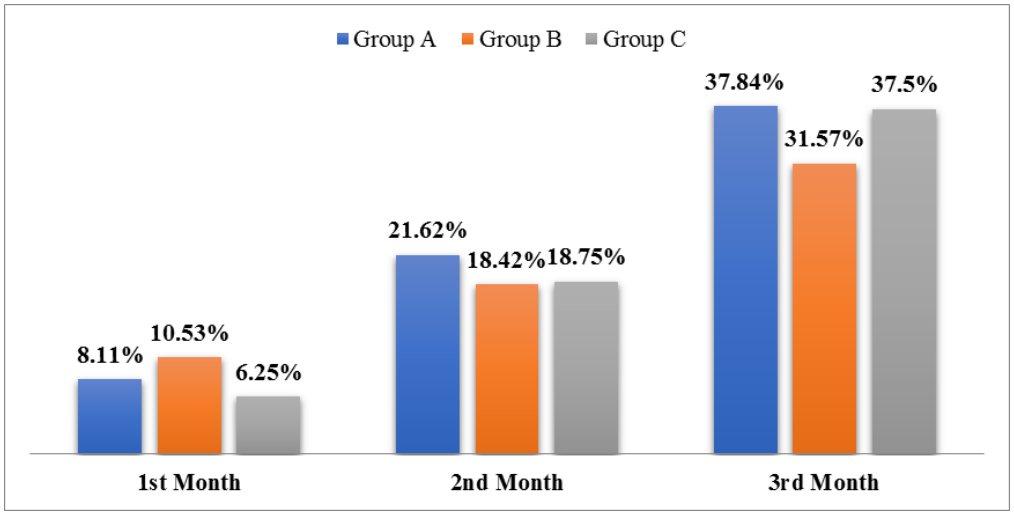
BT: Before Treatment, AT: After Treatment

The effect of treatment observed in group A at the end of 3rd month 37.84% change which was statistically very significant (p<0.01). The effect of treatment observed in group B at the end of 3rd month 31.57% change which was statistically very significant (p<0.01). The effect of treatment observed in group C at the end of 3rd month 37.50% change which was very significant (p<0.01).

Table 9: Intergroup comparison of Ashworth scale readings of effect on spasticity in Left lower limb in all three groups, Kruskal-Wallis Test (Nonparametric ANOVA)

Sr.No.	Group	N	Sum of Ranks	Mean of Ranks	KW	'p' Value	Remarks
1	A	10	170.00	17.00	0.708	0.702	N.S.
2	B	10	155.00	15.50			
3	C	10	140.00	14.00			

Kruskal-Wallis Test (Nonparametric ANOVA) shows that the P >0.10, considered non-significant. Variation among Group medians is significantly greater than expected by chance.



Graph 4: Improvement in Ashworth scale readings of effect on spasticity in Left lower limb in Group A, Group B & Group C

DISCUSSION

In the upper limb examination group A showed no results at first month in bilateral upper limbs while at the end of 3rd month very significant changes seen bilaterally, while in other two groups the results at the end of study was significant for bilateral upper limbs. At the end of trial in group A right upper limb responded quite extra in comparison to left upper limb.

Reason for same is one Right sided hemiplegic case was there in group A, and overall spasticity was on higher side in right upper limb as compared to left upper limb (though the difference was statistically insignificant; $p>0.10$), thus giving better change in spasticity as compared to left upper, but the change in both limbs were statistically very significant.

Group A (Panchkarma procedure along with oral drug) had quite significant gain over group C (Physiotherpy) ($p<0.05$) in bilateral upper limbs. But group B had contributed equally as compared to group C. Not only the Ayurveda management was found to be equally effective as physiotherapy in spasticity, but also Ayurveda management have shown improvement quite earlier than physiotherapy, this can be attributed to mild stretching effect during Abhyanga and Shashtishali Pinda Sweda along with relaxed muscle due to oleation and sudation effect.

Effect of treatment in group A and group C over spasticity in lower limbs were bilaterally very significant. While as in group B significant results were found bilaterally at end of study. The mean before treatment was higher than upper limb so the improvement was seen with mild change in mean, but found to be very significant with p value near to the periphery of the minimum gain needed to be very significant.

In the intergroup comparison, Group A and group B has non-significant gain over group C bilaterally in lower limbs, but improvement in terms of percentage was approximately same in group A and group C. So Ayurveda management found equally effective as compare to control group. In upper limbs where muscles are comparatively smaller than in lower limbs have shown better results for Ayurveda management but here muscles are larger hence active stretching of muscle possible in physiotherapy have shown earlier results in control group, but active and continuous Ayurveda management is equally effective in long term as compared to physiotherapy showing efficacy of the management in spasticity.

CONCLUSION

Present study shows strong association of History of Birth asphyxia and fetal distress was observed in the present study. No specific relation was observed in mother's age of conception, birth order, type of delivery and presentation, and place of delivery with causation of cerebral palsy (CP).

The results of the present study showed that Group A i.e. Shishukalyan Ghrita along with Abhyanga followed by Shashtishali Pinda Sweda shown statistically very significant ($p<0.01$) improvement in Ashworth scale for spasticity in all four limbs. Group B i.e. Kala Basti along with Abhyanga followed by Shashtishali Pinda Sweda shown statistically very significant ($p<0.01$) improvement in Ashworth scale for spasticity in Left upper and lower limbs; while it shows statistically significant ($p<0.05$) result in Ashworth scale for spasticity in Right upper and lower limbs. Group C which is control group has shown very significant ($p<0.01$) result in Ashworth scale for spasticity in bilateral lower limbs; while it shows statistically significant ($p<0.05$) improvement in Ashworth scale for spasticity in bilateral upper limbs. In intergroup comparison Group A is statistically significant over Group C in Ashworth scale for spasticity in right upper limb.

No untoward side effect was noticed during the trial of any drug or procedure. Ayurveda management with Shishukalyan Ghrita and Panchkarma procedures including Abhyanga with Dashmoola Taila, Shashtishali Pinda Sweda have proved to be a better, safe and cost effective treatment modality for managing and improving the spasticity of children with Cerebral palsy.

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Cite this article as:

Aniket Palande and Nisha Kumari Ojha. Ayurveda management of spasticity in children with cerebral palsy: A randomized controlled trial. Int. J. Res. Ayurveda Pharm. 2017;8(5):14-19 http://dx.doi.org/10.7897/2277-4343.085234

Source of support: Nil, Conflict of interest: None Declared