Original Article

International Journal of Neurology and Neurosurgery
Volume 5 Number 1, January - June 2013

Effects of Pneumatic Abdominal Binder and Calf Compression Vs Elastic Compression Bandaging on Orthostatic Hypotension during Tilt Table Standing Following Acute Stroke: A Pilot Randomized Controlled Trial

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Abstract

Background: Orthostatic hypotension (OH) occur early following stroke due to impaired venous return, autonomic instability and paretic limb muscles. This orthostatic hemodynamic stress further exacerbates the existing cerebral damage and delayed functional recovery.

Aim: To compare effects of Pneumatic abdominal binder (PAB) and Pneumatic Calf Compression (PCC) versus Elastic Compression Bandaging (ECB) for OH during tilt table standing in patients with acute stroke.

Methods: 26 (18 male, 8 female) stroke subjects (duration < 4 weeks) with OH as defined by American Academy of Neurology and American Autonomic Society were randomly assigned to receive either experimental- PAB + PCC (n=13) or control- ECB (n=13). Tilt table standing was administered for six consecutive sessions and outcomes were measured pre-post intervention. The hemodynamic responses were measured using Omron™ Digital BP apparatus. The pressure applied using PAB and PCC for the experimental group was maintained at 40 and 30 mm Hg respectively while in the control group ECB was applied to the paretic calf muscles. Primary outcome of percentage of patients who attained orthostatic stability at 60^0 of tilt was considered for between-group comparison using Z test and modified Rankin Functional Scale (MRS) were compared using Mann-Whitney U test using SPSS.13

Results: Comparison of percentage of subjects who had attained orthostatic stability between the groups was significant on the 3rd and 6th day with $p < .05$. Pre-Post median scores for MRS and LOS had no significant difference between the groups.

Conclusion: Application of pneumatic abdominal binder, calf compression found to be improving orthostatic stability in acute stroke rehabilitation. Further large scale studies with long-term follow-up are warranted and necessary.

Keywords: Orthostatic Hypotension in Stroke; Tilt Table Standing; and Pneumatic Compression bandages.

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(Received on 29.04.2013, Accepted on 08.05.2013)

Introduction

Stroke occurs predominantly in the elderly, who are prone to orthostatic hypotension because of the effects of ageing and comorbidity on blood pressure regulation. Lesions of the central nervous system frequently cause disturbances of the cardiovascular and autonomic nervous systems.[1] Disturbances of the Cardiovascular system following acute stroke, include increased sympathetic activity and parasympathetic hypofunction manifesting as transient hypertension and attenuated or

reversed circadian variation in blood pressure and heart rate.[2] In addition, increased blood pressure and hemodynamic variability because of impaired baroreceptor reflex sensitivity has also been reported.[3] In acute stroke, cerebral perfusion is also dependent on systemic blood pressure because of impaired auto regulation of cerebral blood flow.[4]

Prospective studies evaluating OH in acute stroke has reported the incidence rate of 52% and also identified potential risk factors which predisposes OH following stroke are aging, abnormalities of baroreceptor reflexes, contractility of lower limb muscles, co-morbid medical conditions like diabetes mellitus, ischemic heart disease, cardiovascular deconditioning following prolonged immobility, medications with hypo-tensive properties. During early mobilization, the rehabilitation of stroke patients invariably involves putting them in upright position, orthostatic hypotension may have a negative impact on the ability of the stroke subjects to participate in rehabilitation. They also recommend that all elderly stroke patients who have poor functional status with more severe motor weakness should be screened for OH before the start of any rehabilitation programme.[5]

Tilt table standing is one of the methods to reintroduce patients to the vertical position when they are unable to stand. The hypothesised benefits of tilt table standing include increased arousal, facilitation of tone in the antigravity muscles of the lower limbs[6] and improved orthostatic tolerance.[7,8] Normally, about 300-800 ml of blood is forced downward to the capacitance vessels in abdominal area and in the lower extremities during quite standing.[9] The feedback from baroreceptors quickly leads to sympathetic system activation and parasympathetic inhibition, with compensatory rises in heart rate and peripheral resistance, and the contraction of muscles of the lower extremities also aids in decreasing venous pooling and increases venous return.[10] But, in stroke subjects, the failure of such compensatory mechanism leads to hydrostatic pressure difference which in turn results in orthostatic hypotension. During head up tilt, the orthostatic stress leads to decreased cerebral blood flow velocity and silent hypo-perfusion in stroke subjects. This could potentially exacerbate the existing cerebral damage and delayed functional recovery.[11]

The routine management of orthostatic hypotension includes the application of elastic crepe bandages to the lower legs and a simple abdominal binder.[12] The application of pneumatic compression at different capacitance beds, using various types of bandages and garments also prove to be effective in improving the venous return from the capacitance vessels of lower extremity and abdomen, thereby reducing orthostatic hypotension on different population.[13-19]

Hence screening and monitoring of orthostatic hypotension during tilt table standing is of utmost importance in early rehabilitation. To the best of our knowledge, the effective treatment strategies in the management of orthostatic hypotension during tilt table standing in stroke subjects has not been retrieved. We conducted a prospective study in a cohort of stroke patients undergoing inpatient rehabilitation with the aims of (1) documenting the incidence of OH (2) To examine the effectiveness of pneumatic abdominal and calf compression bandages in terms of number of days taken to attain orthostatic stability during tilt table standing in stroke subjects (3) To examine the change in functional outcome scores following management of orthostatic hypotension in stroke subjects.

Materials and Methods

Participants

This study was approved by the scientific committee and the Time bound research ethical committee, Kasturba Medical College, Mangalore. Over a 12-month period, 46 stroke subjects with a first unilateral supra-tentorial involvement associated with ischemic or

hemorrhagic lesions were consecutively admitted to a department of rehabilitation medicine within 1 month of post stroke duration were prospectively enrolled into the study. The diagnosis of a stroke was made by a neurologist in all patients and confirmed on computed tomography scan or magnetic resonance imaging of the brain. The purpose of the study was explained to the stroke subjects on their approval, written informed consent was obtained from them. Subjects were then screened for study criteria presence of orthostatic hypotension (OH) i.e. fall in systolic blood pressure e"20 mmHg or diastolic blood pressure e"10 mmHg during tilt table standing at 60° of tilt, with or without hypotensive symptoms as defined by American Academy of Neurology and American Autonomic Society[20] were randomly allocated into experimental and control group. Subjects were excluded if they had had subarachnoid hemorrhage, ruptured arteriovenous malformation and infections of the brain, a known history of OH, or recurrent stroke, Deep Vein Thrombosis (DVT) in the legs and Left ventricular dysfunction with less than 40% ejection fraction.

Of the 46 stroke subjects screened 26 subjects had orthostatic hypotension and were included in the study (Experimental -13, Control -13). Demographic data and baseline variables of the selected subjects, like post stroke duration, co-morbid illness, Glasgow Coma Scale and the functional status using Modified Rankin Scale at three levels, the day of assessment, end of second week and at the time of discharge were collected by an independent observer.

The OH subjects were then randomized into experimental (pneumatic abdominal binder+pneumatic calf compression bandage) group and control (elastic compression bandage) group by block randomization method. The method of allocation was concealed in sealed opaque envelopes. During tilt table standing, the control group was treated with elastic compression bandage application extending from metatarsal head to the popliteal fossa in a single layer spiral manner with an overlap between each other over the paretic leg , while the experimental group was treated by application of pneumatic abdominal binder containing an inflatable splint, exerting a pressure of 40 mmHg over the abdomen and a compression bandage of pneumatic material containing an inflatable splint over the paretic calf which exerts a pressure of about 30 mmHg.

In order to minimize the effects of postprandial hypotension and circadian variation of blood pressure, the tilt table standing was performed prior to meals or two hours after meals, and same treatment method was continued throughout the study. Both groups were treated with routine physical therapy techniques such as passive movements of hemiplegic lower extremity prior to tilt table standing.

Tilt Table Protocol

subjects were laid supine (0° tilting) on the tilt table for 15 minutes so that the hemodynamic responses come to baseline values and then straps fastened one over the chest and the other over both the knees in order to secure the patient during tilt table standing. The BP apparatus cuff was applied to the non-paretic arm, and then baseline blood pressure and heart rate were measured using Omron (HEM 7111) digital BP apparatus and the validity of the apparatus was established.[21]

The tilt table was progressively inclined from 0° to 30°, 45° and 60°of tilt angle, and maintained in each position for about 5 minutes. Blood pressure and heart rate was measured and recorded at the end of every 1st, 3rd, and 5th minutes using the digital BP apparatus. When there is no drop in BP till the end of 3rd minute the subject was kept in that position for another 2 minutes for cardiovascular adaptation and at the end of 5th minute with no orthostatic distress, the tilt table was inclined to the next higher level of angulations. Whenever there is reduction in systolic blood pressure e"20 mmHg or diastolic blood pressure e"10 mmHg and any symptoms of distress like giddiness, nausea, blurring of

vision, feeble pulse are noted within three minutes, the subject was brought back to the supine position (0°) immediately and those subjects were continued with the same procedure of gradually tilting from 0° to the orthostatic tolerance level, the consecutive day. The subjects in both the groups were weaned off from intervention once they attained orthostatic stability at 60° of tilt.[22]

There were no adverse events occurred for the subjects in both the groups during intervention and hence there were no drop outs in the study. The main outcome measures Number of days taken to attain orthostatic stability and Modified Rankin scale (MRS). The MRS measures independence rather than performance of specific tasks. In this way, mental as well as physical adaptations to the neurological deficits are incorporated. The scale consists of 6 grades, from 0 to 5, with 0 corresponding to no symptoms and 5 corresponding to severe disability.

Statistical Analysis

Data were analysed using Statistical Package of Social Science (SPSS) version 13. The level of significance was set at p value <0.05. Demographic variables such as age, post stroke duration, GCS and gender were analysed using the student's unpaired 't' test and chi square test, respectively. Descriptive statistics was obtained for the nature of stroke, the co-morbid illness, the blood pressure and heart rate parameters. The percentage of number of subjects attaining orthostatic stabilisation on each day was analysed using 'Z' test. Friedman test and Mann Whitney 'U' test were used to analyse within group and between the group comparisons of Modified Rankin scale score respectively.

Table 1: Demographic variables of the subjects in experimental and control groups

Variables	Experimental (Mean ± SD)	Control (Mean ± SD)	p value
Age(Years)	59.77 ± 17.03	63.33±15.83	[a]0.594*
Gender Male/ Female	11/2	7/6	[b]0.144*
Post stroke duration (Days)	14.54 ± 9.95	17 ± 11.1	[a]0.565*
Nature of stroke Hemorrhage/ Infarct	8/5	7/6	
Co morbid illness [c]	9	10	
Side of hemiplegia Right/Left	8/5	6/7	
Glasgow coma scale	11.6 ±4.46	11.4±4.48	[a]0.883*

*- Non significant (NS) SD- standard deviation

a- analysed using student's unpaired 't' test

b- analysed using chi square test

c- diabetes mellitus, hypertension, ischemic heart disease

Results

The mean age of the subjects in experimental group was 59.7± 17 years while in the control group was 63.3 ± 15.8 years. The mean post stroke duration in the experimental group was 14.5 ± 9.9 days while in the control group was 17 ± 11.1 days. In the experimental group, there were 8 hemorrhagic strokes and 5 ischemic strokes. In the control group, there were 7 hemorrhagic strokes and 6 ischemic strokes.Of the total 26 subjects with orthostatic hypotension, 76% had associated illness of Diabetes mellitus; hypertension and ischemic heart disease. The mean GCS score for all the subjects was 11. As there was no statistical difference between the groups (p value>.05) demographic variables of both the groups were similar at baseline.

(Insert Table 1: Demographic variables of the subjects in experimental and control groups)

The percentage of number of subjects stabilised on each day were compared and analysed (Table 2). The result shows that the

Table 2: Analysis of percentage of subjects stabilised on each day

Day	Experimental			Control			Z test	p value
	N	Stabilized		N	Stabilized			
		n	%		n	%		
1	13	2	15%	13	0	0	1.417	0.078
2	11	6	55%	13	3	25	1.450	0.073
3	5	0	0	10	5	50	2.079	0.019*
4	5	1	20	5	1	20	0.179	0.429
5	4	1	25	4	0	0	0.935	0.175
6	3	3	100	4	0	0	2.449	0.007*
7	0	0	0	4	4	100	-	-

*- significant, N – Total no. of subjects, n – No. of subjects stabilized

Table 3: Analysis of Modified Rankin Scale

	Within group analysis		Between group analysis
Mean MRS score	Experimental**	Control**	p value
DOA	5	5	1*
2nd week	4.3±0.6	4.3±0.4	0.7*
DOD	4±1	4.3±0.8	0.4*

MRS-Modified Rankin Scale

DOA-Date of Assessment

DOD-Date of discharge

**-Highly significant (HS)

*-Non- significant (NS)

percentage of subjects who had attained orthostatic stability was significant on the third and the sixth day.

(Insert Table 2: Analysis of percentage of subjects stabilised on each day)

The Modified Rankin Scale functional score was analysed within the group and between the groups as shown in the Table 3. The results showed that the both the experimental group and the control group showed highly significant changes in the functional score of p value 0.001, 0.006 respectively. When compared between the groups there was no significant difference in the functional scores.

(Insert Table 3 Analysis of Modified Rankin Scale Functional score of MRS between the Groups)

Discussion

The aim of the present study was to investigate the effect of pneumatic abdominal and calf compression bandage in the management of orthostatic hypotension during tilt table standing in stroke subjects. In our study, the incidence of orthostatic hypotension was found to be 56% in stroke subjects. Apart from the impairments following stroke, the potential risk factors such as ischemic heart disease, diabetes mellitus, prolonged immobility and anti-hypertensive medications in the subjects would have resulted in the similar finding by Kong et al.[5]

In the present study, the application of pneumatic abdominal and calf compression bandage was found to be effective in terms of number of days taken to attain orthostatic stability compared to that of elastic crepe bandage application. All the subjects in the experimental group had attained orthostatic stability within six days itself, while the control group had taken one more day in addition to it. This could be due to the fact that the pneumatic abdominal compression bandages which exerts a pressure of 40 mmHg at the level of abdomen increases the intra-abdominal pressure, thereby reduces the vein diameter and splanchnic blood volume. This abdomino thoracic blood shift, leads to better filling of the heart and increases stroke volume and cardiac output[13,14,17] and 30 mmHg pressure exerted at the level of calf increases the lower body positive pressure, decreases venous capacitance and facilitates venous return to the heart.[15,16]

In addition, 55% of the subjects in the experimental group attained orthostatic stability on the second day, compared to 25% of the subjects in the control group. The reason for such finding can be attributed to the immediate effect of pneumatic abdominal and calf compression bandages thus favouring the experimental group. The previous studies which investigated the immediate effect of pneumatic compression of different capacitance beds using various kinds of bandages and garments on orthostatic hypotension in different populations also support the above mentioned assumption.[13-17] The above explained findings warrant caution while interpreting, as the other studies have adopted a different kind of pneumatic compression bandage application unlike the procedure that was used in our study.

Interestingly, it is observed that all the subjects in the present study had achieved orthostatic stability within an average of 22 days from the time of onset of stroke whereas, the process of restoring the normal postural cardiovascular responses can take about 20 to 72 days.[23] These findings can be attributed to the method of tilt training, wherein the

subjects are gradually progressed to various angle of inclination and maintained in that degree of tilt for five minutes, thereby allowing cardiovascular adaptation to happen at each degree of tilt.[8] The other factors that would have contributed to the orthostatic stability are the passive movements of the paretic leg, prior to the tilt table standing which improves the venous return from the capacitance vessels of the leg[24] and the facilitation of the muscle tone in the paretic lower limb.[25]

In the analysis of the hemodynamic responses (systolic and diastolic blood pressure and heart rate parameters), it has been found that the difference in parameters from baseline to the point of orthostatic intolerance was minimal in the experimental group compared to the control group. As discussed earlier, the application of pneumatic compression bandages facilitates venous return, thereby, increasing the stroke volume and cardiac output, and also found to increase the peripheral resistance. Hence there is no much change seen in the systolic blood pressure and diastolic blood pressure.

At the time of inclusion, on measuring the functional ability, the subjects in both the groups scored 5 on the Modified Rankin Scale which showed they were severely disabled at the time of assessment; this might have also been one of the contributing factors for orthostatic hypotension. All the subjects in both the groups showed improvement in the functional score of the Modified Rankin Scale at the end of 2nd week and at the time of discharge. This can be attributed to spontaneous recovery of the subjects and effective rehabilitation.[26] There were similar functional changes seen between the groups at 2nd week and time of discharge. This can be due to the failure of the scale to pick up the minimal changes in the functional improvement.[27] Moreover the difference in the number of days taken to achieve orthostatic tolerance was less between the groups which might not have significance in the functional improvement.

Clinical Implication of the Study

This study showed that 56% of patients with a first clinical stroke admitted to a rehabilitation unit had OH. Because the rehabilitation of stroke patients invariably involves putting them in the upright position, we recommend that all stroke patients be screened for OH before the start of any rehabilitation program, especially in those who are elderly, who have more severe motor weakness, and who have a poorer functional status. The application of pneumatic abdominal and calf compression bandage helps in the improvement of orthostatic tolerance and can be used effectively in the routine clinical practice.

Limitations of the Study

There were several limitations to this study. It is a preliminary pilot study effects of these interventions in large sample size should be addressed. One major limitation of this study was that the time of day when blood pressure measurements were taken, apart from at least 2 hours postprandial, was not standardized or fixed. Thus, the timing of drug administration could have influenced blood pressure measurements, especially drugs with hypotensive properties. Another confounding variable due to this no standardization is the phenomenon of within-day variations in blood pressure in response to orthostatism. This is more common in elderly patients and is because of neurovascular instability. The second limitation is that subjects who did not have OH on initial screening were not examined again. Certainly, it is possible that some of them might have developed hypotension later during their stay in rehabilitation. Thus, the actual incidence of OH might have been higher and recovery of lower extremity functions such as muscle tone can also influence the results.

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1. Place of Publication	:	Delhi
2. Periodicity of Publication	:	Quarterly
3. Printer's Name	:	**Asharfi Lal**
Nationality	:	Indian
Address	:	3/258-259, Trilok Puri, Delhi-91
4. Publisher's Name	:	**Asharfi Lal**
Nationality	:	Indian
Address	:	3/258-259, Trilok Puri, Delhi-91
5. Editor's Name	:	**Asharfi Lal** (Editor-in-Chief)
Nationality	:	Indian
Address	:	3/258-259, Trilok Puri, Delhi-91
6. Name & Address of Individuals who own the newspaper and particulars of shareholders holding more than one percent of the total capital	:	**Asharfi Lal** 3/258-259, Trilok Puri, Delhi-91

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