

## Study of Effectiveness of Shoulder Elbow Wrist Hand Orthosis in the Management of Glenohumeral Subluxation in Post-stroke Hemiplegic Patients

G. Sonachand Sharma<sup>1</sup>, Y. Nandabir Singh<sup>2</sup>, Ak. Joy<sup>3</sup>, Bimol Singh<sup>4</sup>, Alex T Touthang<sup>5</sup>, Tamphaleima Devi<sup>6</sup>

### Abstract

**Objective:** Study of effectiveness of shoulder elbow wrist hand orthosis in the management of glenohumeral subluxation in post-stroke hemiplegic patients.

**Methods:** Design: Randomised control trial.

**Setting:** Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences (RIMS), Imphal.

**Participants:** Post-stroke hemiplegic patients (n=120) having glenohumeral subluxation (GHS) as confirmed by x-ray.

**Duration:** One and half years (August 2010 to January 2012).

**Intervention:** Control group (n=60) received routine rehabilitation programme for hemiplegic practice in the Department of PMR, RIMS while the experiment group (n=60) received shoulder elbow wrist hand orthosis in addition to rehabilitation programme.

**Outcomes:** Grade of glenohumeral subluxation using x-ray.

**Results:** Experiment group showed reduction in the glenohumeral subluxation which is statistically significant when compared to control group (p<0.001).

**Conclusions:** Use of upper limb orthosis in addition to routine rehabilitation programme can effectively reduce glenohumeral subluxation in post-stroke hemiplegic patients.

**Key words:** Glenohumeral subluxation (GHS), shoulder elbow wrist hand orthosis (SEWHO), Post-stroke hemiplegic patients.

### Introduction:

A good shoulder function is essential for effective hand function, as well as for performing multiple

tasks involving mobility, ambulation, and activities of daily livings (ADL). One of the common sequelae of stroke is shoulder dysfunction subsequently leading to disability. Hemiplegic shoulder pain (HSP) is the one which causes shoulder dysfunction occurring in 16-72% of stroke survivors<sup>1</sup>. Studies reported appearance of HSP as early as 2 weeks with an average occurrence between 2 and 3 months of post-stroke<sup>2</sup>.

The glenohumeral subluxation(GHS) is among the commonly cited cause for HSP with a reported incidence of up to 81% in hemiplegic patients<sup>3</sup>. GHS in hemiplegia is defined "as a non-traumatic, partial or total change of relationship between the scapula and the humerus in all directions and in all planes, as compared with the non-affected shoulder, that appeared after stroke"<sup>4</sup>. GHS may have a role in the pathogenesis of HPS by stretching the local neurovascular and musculoskeletal tissues. The possible mechanisms for occurrence of GHS in stroke are: (1) loss of support from the deltoid and supraspinatus to the head of humerus, (2) scapular downward rotation due to paralysis of seratus anterior,

#### Authors' affiliation:

<sup>1</sup> MBBS, MD PMR

<sup>2</sup> MBBS, MS(Ortho), Professor, PMR

<sup>3</sup> MBBS, MD, DNB, PhD (PMR), Professor and Head, PMR

<sup>4</sup> MBBS, MD PMR

<sup>5</sup> MBBS, Post graduate trainee, PMR.

<sup>6</sup> MBBS, Post graduate trainee, PMR.

Department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences (RIMS), IMPHAL, Manipur, Pin-7951004.

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#### Correspondence:

Dr. Y. Nandabir Singh Professor, Department of Physical Medicine and Rehabilitation, RIMS, Imphal. E-mail: gschandsharma@gmail.com, drynsingh70@yahoo.com.

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rhomboids and trapezius, (3) drooping of trunk towards hemiplegic side due to loss of righting reflex, and (4) downwards traction by the weight of the upper limb. Because the subluxed shoulder is unstable, care must be taken to support the flail shoulder in upright position. Treatment to reduce this subluxation should focus on achieving trunk alignment and glenohumeral joint stability<sup>5</sup>.

Objective documentation of subluxation requires radiographs with a patient in upright position. It is suggested that patient showing early radiologic signs of subluxation might be most likely to get benefit from early orthotic intervention<sup>6</sup>.

The ideal approaches for treating GHS which have been proposed are:

1. Careful positioning and handling of the paralyzed limb<sup>7</sup>.
2. Strapping<sup>8</sup>.
3. Use of slings<sup>9</sup>.
4. Electrical stimulation<sup>10</sup>.

Many authors have studied the effectiveness of different types of mechanical approaches in the management of GHS in post hemiplegic patients. In our present set up, we have been treating the hemiplegic patients only with rehabilitation exercise programmes and proper and careful positioning of the paralysed limb. In our country so far there are limited studies on orthotic intervention. So, this study is designed to see the effect of shoulder elbow wrist hand orthosis (SEWHO) in the management of GHS in post-stroke hemiplegic patients.

### Materials and Methods:

It is a randomised controlled trial conducted in the Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, Manipur with study period of 1 year and 6 months. Altogether 120 patients of post-stroke hemiplegia were studied with following inclusion criteria: (1) Stroke patient within 3 months of attack, (2) hemiplegic patient having GHS and (3) age between 18 and 60 years. Exclusion criteria in the study were: (1) patient unable or not willing to give consent, (2) recurrent stroke, (3) comatose patients, (4) recent fracture of humerus/clavicle, (5) severe arthritis affecting shoulder joint and (6) severe comorbid conditions like uncontrolled diabetes, chronic renal failure, coronary artery disease, etc.

There were two groups in the study namely A (control group) and B (intervention group). The group allocation was done by block randomisation method using block of two. The procedure was as follows: (1) A block size of 2 was chosen, (2) possible balanced combinations with C (control) and T (treatment) subjects were calculated as (TC, CT), and (3) blocks were randomly chosen to determine the assignment of all 120 participants<sup>11</sup>. This procedure resulted in 60 participants in both the control and treatment groups.

The routine rehabilitation physiotherapy programme was given to both the groups. It includes:

- (a) Positioning: The shoulder to be positioned in 90 degree abduction and external rotation and elbow flexed at 90 degree while the patient on bed.
- (b) Range of motion exercise: Passive range of motion exercises of the shoulder in flexion, abduction, internal and external rotations to be taught to the patient's care-giver. This is to be done thrice daily, with 10-20 repetitions per session.
- (c) Bed mobility and transfer techniques.
- (d) Careful handling.

Group B also received SEWHO which was made in Orthotic Unit of Department of PMR, RIMS, Imphal. In this orthosis, position of upper limb was elbow flexion at 90 degree, forearm in full supination, wrist dorsiflexion at 40-45 degree, thumb in abduction and metacarpo-phalangeal, interphalangeal joints in extension, so called reflex inhibitory position. The SEWHO was made to be applied only when the patient is in upright position ie, sitting, standing and moving around and for a maximum period of 6 months to see its effect.

### Outcome Measures and Follow-up:

The GHS was assessed through radiological examination by taking x-ray anteroposterior view of both the shoulders in erect posture with weight of limb working as traction. X-ray was taken at the time of diagnosis of GHS, subsequently at 3 months and 6 months of follow-up to reduce radiation hazard. In the x-ray, the GHS was measured in following 4 grades (Fig 5)<sup>12</sup>.

1. V- shaped widening
2. Moderate subluxation
3. Advance subluxation
4. Dislocation

**Steps of making SEWHO: Step 1: Making of negative cast [Fig1(a) to Fig 1(c)]**



**Fig 1(a) - Negative Cast**



**Fig 1(b) - Negative Cast**



**Fig 1(c) - Negative Cast**

**Step 2: Making of positive cast [Fig 2(a) & 2(b)]**



**Fig 2(a) - Positive Cast**



**Fig 2(b) - Positive Cast**

**Step 3 : Making of final orthosis- SEWHO [ Fig 3(a) to 3 (b) & 4]**



**Fig 3(a) - SEWHO**



**Fig 4 - Patient with SEWHO**



**Fig 3(b) - SEWHO**

Follow-up of the cases was done at 1st month, 3rd month then at 6th month (Fig 6 & 7).The approval of the ethical committee was taken from the Institutional Ethics Committee, RIMS, Imphal, Manipur.

**Statistical Analysis:**

All analyses were performed using Statistical Package for Social Science SPSS software 16 version. Chi-square was used for the comparison between the groups. A significant level of 0.05 was used for all comparisons.

## Results :

A total of 120 patients of stroke fulfilling the inclusion criteria were studied. The control group consisted of 50 females and 10 males with average age of  $54.7 \pm 6.9$  years while the intervention group consisted of 45 females and 15 males with average age of  $56.1 \pm 9.4$  years. At first follow-up, 5 patients (3 in intervention, 2 in control), at second follow-up, 14 patients (8 in intervention, 6 in control), at third follow-up, 18 patients (8 in intervention, 10 in control) and at last follow-up, 21 patients (11 in intervention, 10 in control) were lost subsequently for the complete follow-up. There were no statistically significant differences between groups in terms of baseline characteristics as shown in Table 1. Males were 25 (20.8%) and females were 95 (79.2%). Majority of the patients, 27 in intervention and 31 in control were having post-stroke duration less than 1 month at the initiation of study. Cerebral infarct constituted 80% in intervention, 75% in control groups whereas haemorrhage constituted 20% in intervention and 25% in control group. Majority of the patients ie, 45 (80%) in intervention group and 44 (73%) in control group had left sided hemiplegia. Majority of cases, 43 in intervention and 39 in control had HSP. GHS with grade 3 was present in 54 patients in intervention and 52 in control group. At the 1st follow-up, majority of intervention group were in GHS grade 1 (36.8%) and 2 (59.6%) while in the control group maximum number of patients were in GHS grade 3 (79.3%).

This difference was found to be statistically significant ( $p=0.001$ ) (Table 2). At second follow-up, majority of intervention group (75.0%) was in GHS grade 1 while the maximum of control group (92%) were in GHS grade 2 and 7(13.5%) of intervention group did not have GHS, however no patient of control group achieved neither grade 0 nor 1 GHS. This finding was found to be statistically significant ( $p=0.001$ ) (Table 3). At 3rd follow-up, maximum number of patients in intervention group (75.0%) were in GHS grade 1 while majority of control group (86%) were still in GHS of grade 2 and the finding was found to be statistically significant ( $p=0.001$ ) (Table 4). At the end of last follow-up, majority (69.4%) of the intervention group were not having GHS (grade 0) while maximum (82.0%) of the control group were still having GHS grade 2 and the finding was found to be statistically significant ( $p=0.001$ ) (Table 5). The proportion of participants who did not have GHS (grade 0) were more in the intervention group as compared to those in the control group at all the levels of duration of hemiplegia. This difference was statistically significant at all the levels except when the duration was 1-2 months (Table 6). Majority of intervention with infarct were not having GHS (grade 0) while maximum of control group with infarct were in GHS grade 2. And maximum of patients with haemorrhage did not have GHS in the intervention group while in control group, majority of patients with haemorrhage were in GHS grade 2. These differences were found significant ( $p < 0.001$ ) (Table 7).

**Table 1:** Baseline Characteristics of the Study Groups

Variables	No of cases		P-value	
	Intervention (n = 60)	Control (n = 60)		
Sex:	Male	15(25%)	10(16.6%)	0.261
	Female	45(75%)	50(83.3%)	
Duration:	≤ 1 month	27(45%)	31(51.6%)	0.709
	>1 to ≤ 2 months	7(11.6%)	5(8.3%)	
	>2 to ≤ 3 months	26(43.3%)	24(40%)	
Side of limb involved:	Right	15(25%)	16(26.6%)	0.835
	Left	45 (75%)	44(73.3)	
Type of lesion:	Infarct	48(80%)	45(75%)	0.521
	Haemorrhage	12(20%)	15(25%)	
HSP:	Present	43(71%)	39(65%)	0.432
	Absent	17(28.3)	21((35%)	
GHS grade:	0	0(0%)	0(0%)	0.552
	1	0(0%)	0(0%)	
	2	4(6.6%)	7(11.6%)	
	3	54(90%)	52(86.6%)	
	4	2(3.3%)	1(1.6%)	

P-value <0.05 is taken as significant

**Table 2:** *Difference in Outcome between the Groups at 1st Follow-up*

GHS grade	No of cases		P- value
	Intervention (n = 60)	Control (n = 60)	
0	0(0.0)	0(0.0)	0.001
1	21(36.8%)	0(0.0)	
2	34(59.6%)	12(20.7%)	
3	1(1.8%)	46(79.3%)	
4	1(1.8%)	0(0%)	
Total	57	58	

P-value <0.05 is taken as significant

**Table 3:** *Difference in Outcome between the Groups at 2nd Follow-up*

GHS grade	No of cases		P- value
	Intervention (n = 60)	Control (n = 60)	
0	7(13.5%)	0(0.0)	0.001
1	39(75.0%)	0(0.0)	
2	5(9.6%)	50(92.6%)	
3	0(0.0)	4(7.4%)	
4	1(1.9%)	0(0.0)	
Total	52	54	

P-value <0.05 is taken as significant

**Table 4 :** *Difference in Outcome between the Groups at 3rd Follow-up*

GHS grade	No of cases		P - value
	Intervention (n = 60)	Control (n = 60)	
0	7(13.5%)	0(0.0)	0.001
1	39(75.0%)	6(12.0%)	
2	5(9.6%)	43(86.0%)	
3	0(0.0%)	1(2.0%)	
4	1(1.90%)	0(0.0)	
Total	52	50	

p-value <0.05 is taken as significant

**Table 5 :** *Difference in Outcome between the Groups at the Last Follow-up*

GHS grade	No of cases		P - value
	Intervention (n = 60)	Control (n = 60)	
0	34(69.4%)	0(0.0)	0.001
1	14(28.6%)	8(16.0%)	
2	0(0.0)	41(82.0%)	
3	1(2.0%)	1(2.0%)	
4	0(0.0)	0(0.0)	
Total	49	50	

P-value <0.05 is taken as significant

**Table 6:** Outcome Measure of GHS in the Study Groups at Last Follow-up by Duration of Hemiplegia

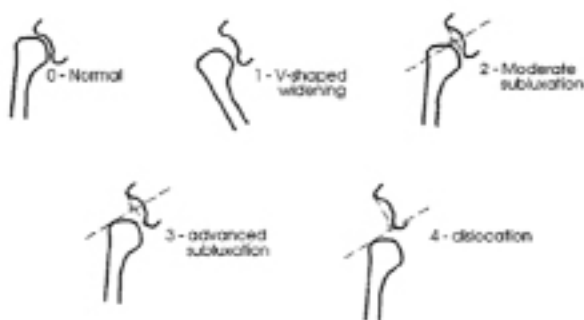
Duration	Grades of GHS	No of cases		Total	P - value
		Intervention (n = 60)	Control (n = 60)		
≤ 1 month:	0	16(69.5%)	0(0)	16	0.001
	1	6(26%)	2(7.6%)	8	
	2	0(0)	23(88.4%)	23	
	3	1(4.3%)	1(3.8%)	2	
	Total	23	26	49	
>1 to ≤ 2 months:	0	4(100%)	0(0)	4	0.30
	1	0(0)	1(33.3%)	1	
	2	0(0)	2(66.7%)	2	
	Total	4	3	7	
>2 to ≤ 3months:	0	14(63.6%)	0(0)	14	0.001
	1	8(36.4%)	5(23.8%)	13	
	2	0(0)	16(76.2%)	16	
	Total	22	21	43	

P-value <0.05 is taken as significant

**Table 7:** Outcome Measure of GHS in the Study Groups at The Last Follow up by Type of the Lesion

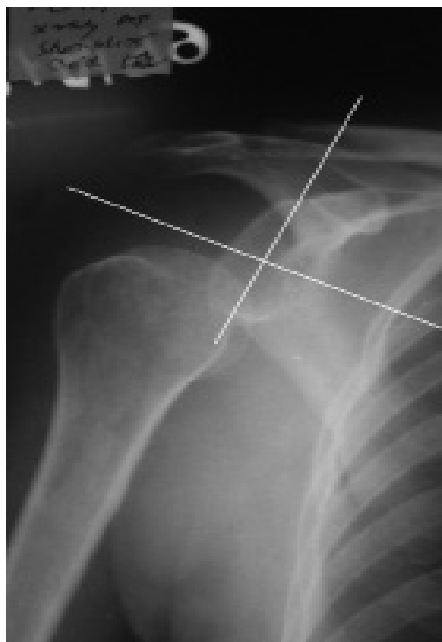
Type of lesion	Grades of GHS	No of cases		Total	p – value
		Intervention (n = 60)	Control (n = 60)		
Infarct:	0	28(73.6%)	0(0)	28	0.001
	1	9(23.6%)	6(17.1%)	15	
	2	0(0)	28(80%)	28	
	3	1(2.6%)	1(2.8%)	2	
	Total	38	35	73	
Haemorrhage:	0	6(45.4%)	0(0)	6	0.001
	1	5(45.5%)	2(13.3%)	7	
	2	0(0)	13(86.7%)	13	
	Total	11	15	26	

P-value <0.05 is taken as significant

**Fig 5 - GHS Measurement**

## Discussion:

The present study revealed that the mean age of the study population were  $56.1 \pm 9.4$  and  $54.7 \pm 6.9$  (age range 41-70 years) among the intervention and control group respectively. Majority of the patients, 27 in intervention and 31 in control were having post-stroke duration less than 1 month at the initiation of study. Similar finding was noted in the study conducted by Hilde *et al*<sup>13</sup> where mean age was 55.6 years. Pizzi *et al*<sup>14</sup> reported a mean age of 65.5 years.



**Fig 6 - Before Intervention**

Cerebral infarct was more common than haemorrhage in both the groups (80% versus 20% in intervention and 75% versus 25% in control). Majority of the patients 45(80%) in intervention group and 44(73%) in control group had left sided hemiplegia. Similar findings were also noted in the study conducted by Joy *et al*<sup>15</sup>.

GHS is a common complication of stroke but, the correlation between GHS and HSP is still controversial. In the present study, out of 120 cases recruited only 82 (68.33%) had HSP at the initiation of study. This finding was similar to the study conducted by Van Langenberghe and Hogan<sup>12</sup>. Another study on hemiplegic shoulder subluxation was conducted by Ikai *et al*<sup>16</sup> where they also concluded that there was no relation between shoulder subluxation and pain. However two mechanisms possible for the correlation between GHS and HSP are: (1) Peri-articular tissue may become overstretched by the weight of the paralysed arm thereby causing pain, since the capsule and ligaments contain high concentrations of pain receptors and (2) overstretching may be the origin of painful ischaemia in the tendons of the supraspinatus muscle and of the long head of the biceps muscle<sup>16, 17</sup>.

Radiographic measurements are considered the best method of quantifying GHS<sup>12</sup>. It is suggested that patient showing early radiologic signs of subluxation might be most likely to get benefit from early orthotic intervention. In this study we also used radiographic measurement for grading GHS.



**Fig 7 - After Intervention**

A number of slings and other supports with different characteristics, design, and function have been described in the literature<sup>18-20</sup> but few studies have assessed their effectiveness in reducing GHS.

In a study conducted by Kieran *et al*<sup>21</sup> three different slings were compared in a group of 10 stroke patients the standard hemisling, the Bobath clavicular sling, and the modified vertical arm sling. The hemisling was found to be better in decreasing vertical and lateral GHS.

Patterson *et al*<sup>22</sup> found that, when correctly applied, all five slings used in their study were effective in reducing GHS (Dennison sling, Dumbbell sling, Harris hemisling, Hook hemiharness, and Zimmer Fashion arm sling).

In a study, Brooke *et al*<sup>23</sup> compared the Harris hemisling, the Bobath sling, and an arm trough/lapboard to assess their efficacy in reducing GHS. Even though improved GHS was found in some cases; no sling that was used consistently prevented subluxation in all cases.

Zorowitz *et al*<sup>24</sup> tested the effectiveness of four different slings in reducing GHS. They found that the only sling that significantly corrected vertical asymmetry was the single-strap hemisling, while total asymmetry was corrected mostly by the Rolyan sling.

Moodie *et al*<sup>25</sup> assessed the effectiveness of five external supports. Two supports used in the sitting position in a wheelchair and the triangular sling (in standing) were

effective; the Bobath roll and the Hook hemi-harness were not effective in reducing GHS.

The use of upper limb orthosis for the management of GHS is not well mentioned in the literature. In the present study, 90% of intervention group had GHS of grade 3 at initiation of the study but majority of them (69.4%) did not have GHS (grade 0) at the end. The proportion of participants who did not have GHS were more in the intervention group as compared to control group when the duration of hemiplegia was less than 1 month showing effectiveness of SEWHO more in the stroke with duration less than 1 month. Majority of patients with haemorrhage and infarct who did not have GHS were also more in the intervention group as compared to control group showing effectiveness of SEWHO both in infarct and haemorrhagic stroke with GHS. The result was found significant statistically when compared to the control group. The possible explanations for improvement in the grades of GHS may be due to following advantages of SEWHO; (1) it keeps the affected upper limb in reflex inhibitory position thereby enhancing the motor recovery, (2) it realigns the subluxed glenohumeral joint in its anatomical position, (3) it supports the paralysed upper limb during upright position and (4) it keeps the subluxed shoulder joint in a secured position thereby preventing the complications which may arise due to malhandling of the paralysed shoulder during transfer. However, natural process of motor recovery in post-stroke patient may also contribute to the reduction of the GHS.

All the patients who were recruited could not be followed up till the end of the study. A total of 21 cases, 11(17.3%) in intervention and 10 (16.6%) in control were lost for the complete follow-up. The difference was however not statistically significant. On further communication through telephone, 10 were completely alright while remaining 11 died of second stroke and other complications which make them to lose for the follow-up.

To our knowledge, the current study is the first randomised controlled trial study conducted to see the effectiveness SEWHO in comparison with physiotherapy treatment for the management of GHS in post-stroke hemiplegic patients. The use of custom made SEWHO in less than 3 months post-stroke patients having GHS significantly reduce the degree of subluxation when used in combination with the physiotherapy programme and it is effective than the physiotherapy alone in the management of GHS.

The limitations of the current study are; (1) non-blinded study, where neither the patients nor the observer were blinded, (2) small sample size, (3) limited outcome measure, x-ray was the only outcome measure being used in the study and (4) limited statistical tool for analysis. Future work incorporating these factors would enrich our current knowledge regarding effectiveness of SEWHO in the management of GHS in post-stroke hemiplegic patients.

## Conclusions:

The custom made shoulder elbow wrist hand orthosis (SEWHO) when use along with routine rehabilitation programmed can effectively reduce degree of shoulder subluxation in hemiplegic patient having GHS during early post stroke period less than 3 month duration.

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