© 2017 EDIZIONI MINERVA MEDICA Online version at http://www.minervamedica.it

ORIGINAL ARTICLE

A randomized controlled trial on the immediate and long-term effects of arm slings on shoulder subluxation in stroke patients

Anke van BLADEL^{1, 2}*, Gert LAMBRECHT^{1, 2}, Kristine M. OOSTRA², Guv VANDERSTRAETEN 1, 2, Dirk CAMBIER 1

¹Department of Rehabilitation Sciences and Physiotherapy, Ghent University, Ghent, Belgium; ²Department of Physical and Rehabilitation Medicine, Ghent University Hospital, Ghent, Belgium

*Corresponding author: Anke van Bladel, Department of Rehabilitation Sciences and Physiotherapy, Ghent University, Campus Heymans (1B3), De Pinte-laan 185, 9000 Ghent, Belgium. E-mail: anke.vanbladel@ugent.be

ABSTRACT

BACKGROUND: Arm slings are often used in clinical practice to support the hemiplegic arm aiming to prevent or treat glenohumeral subluxation. Evidence supporting the corrective effect of slings on subluxation is scarce and long-term studies are lacking, AIM: The aim of this study was to determine both the immediate and long-term effect on acromiohumeral distance using the Actimove® sling

and Shoulderlift and to determine the effect of slings on pain and passive range of motion of the shoulder in stroke patients with glenohumeral subluxation

DESIGN: Randomized control trial.

SETTING: Hospital inpatients. POPULATION: Stroke patients

METHODS: Twenty-eight stroke patients, with severe upper limb impairments, were randomly allocated to 3 groups (Actimove, Shoulderlift, No sling). Patients wore their supportive device for 6 weeks and no sling in the control group. Immediate and postinterventional effect on acromiohumeral distance was measured using sonography. Pain (VAS), ROM (goniometry), spasticity (Modified Ashworth Scale), Fugl-Meyer Assessment and trunk stability (TIS) were also assessed before and after the intervention.

RESULTS: The level of immediate correction of both slings was different at baseline and after 6 weeks (0 weeks: Shoulderlift 63%, Actimove 36%; 6 weeks: Shoulderlift 28%, Actimove 24%). Comparing the level of subluxation over time shows a distinct decrease in subluxation but only for the control group (-37.59% or 3.30 mm). Subluxation remained the same in the Actimove group (-2.77% or 0.27 mm) but increased in the Shoulderlift group (+12.44% or 1.03 mm). After 6 weeks, the Actimove group reported more pain at rest (P=0.036). ROM for abduction and external rotation decreased in 2 groups and remained un-altered in the Shoulderlift group.

CONCLUSIONS: Results of immediate correction varied. Subluxation seemed to reduce in patients that did not wear a sling. CLINICAL REHABILITATION IMPACT: The (assumed) presence of subluxation may not benefit from wearing an arm sling which may itself inhibit active correction. If a sling is indicated the Shoulderlift may be preferable to the Actimove sling.

(Cite this article as: van Bladel A, Lambrecht G, Oostra KM, Vanderstraeten G, Cambier D. A randomized controlled trial on the immediate and long-term effects of arm slings on shoulder subluxation in stroke patients. Eur J Phys Rehabil Med 2017;53:400-9. DOI: 10.23736/S1973-9087.17.04368-4) Key words: Stroke - Orthotic devices - Shoulder dislocation - Shoulder pain.

Temiplegic shoulder pain (HSP) is one of the most H common and functionally incapacitating complications after stroke. Incidence varies from 5% to 84% with an average incidence of 55%.¹⁻³ The presence of HSP often leads to a decreased quality of life, longer hospitalization and potentially, it may undermine the crucial early phase in the rehabilitation process and therefore have a negative impact on long-term treatment outcome.⁴⁻⁷

Due to the complex shoulder anatomy and biomechanics, the eventual cause of HSP is considered multifactorial,⁴ although glenohumeral subluxation (GHS) is often identified as a possible and major cause. Not-

withstanding the presence of GHS in 17-66% of stroke patients ^{2, 8, 9} and the suspected relationship with HSP, the correlation cannot always be identified.8-11 However, a higher prevalence of GHS in patients with HSP is often reported.^{4, 12-17} Despite the ongoing debate on the causal relationship between GHS and HSP, the presence of a subluxation is commonly accepted to be associated with poor upper limb function ^{18, 19} and also as an important risk factor for developing a shoulderhand syndrome²⁰ or other complications (limited range of motion [ROM], plexus brachialis injuries, adhesive changes and subacromial impingement).9,19 In view of the potential risk for dysfunction, the relationship with HSP and its role in these complications, the search for appropriate preventative and corrective measures for GHS remains a permanent clinical and scientific challenge. Despite insufficient evidence supporting the beneficial effect of shoulder slings in the prevention of subluxation,²¹ decrease of pain or increase of function and the lack of long-term studies on the effect of such arm slings, these slings are often used in clinical practice. They aim to support the arm by functioning to counteract the downward pull of gravity on the humerus of the paralyzed arm and thereby prevent or treat a subluxation and/or avoid (further) trauma.^{2, 8, 22-24} Aside from the more obvious aims for the upper limb. some authors also propose effects of these slings on parameters of balance ²⁵ and gait.²⁶⁻²⁸ Unfortunately, they may also encourage learned non-use and facilitate unwanted synergic flexion patterns of the arm.²⁹ They may also cause disturbance in the body schematic with an arm in flexion or a limitation of sensory input and they may create the potential for the onset of contractures over time.^{2, 30}

Although the use of an arm sling in stroke patients seems to be a logical and sensible common therapeutic intervention, scientific indications are available that individual reconsideration of its use in clinical practice is warranted. The type of sling, its introduction and method of application — in view of the possible negative implications for the patient — should be assessed. As no standard guidelines are available, therapists often have to rely on their own subjective judgment and previous experience (if any) on how best to approach the selection, introduction and application of a sling with a particular patient. Data on the corrective impact of a sling on GHS would therefore be invaluable and benefit therapeutic advancement.

van BLADEL

This study will compare 2 different types of slings. The Actimove[®] sling (BSN medical SA-NV, Leuven, Belgium) supports the forearm of the patient, thus indirectly attempting to immobilize and support the shoulder. The Shoulderlift brace (V!GO, Wetteren, Belgium) is an extension of the Pellenberg retractionelevation bandage supporting the shoulder joint directly, *i.e.* proximally allowing the arm to move freely. Assessing the sling correction of GHS can be performed by radiographic evaluation of the acromio-humeral distance (AHD) in a reliable and valid way.^{22, 31} However, ultrasonographic evaluation of the GHS is also a reliable method that can be used to measure GHS in stroke patients 32, 33 and will therefore be used in this study. It is less costly, without radiation exposure, often more clinically accessible and safe in application.³⁴ Kumar et al. described this method as also reliable and valid, when performed by a trained physiotherapist (Figures 1, 2).33

The aims of this study are therefore two-fold:

— to determine the immediate and long-term effect on acromiohumeral distance (AHD) using the Actimove[®] sling and Shoulderlift by ultrasonography;

— to investigate the effect of wearing a sling on hemiplegic shoulder pain and passive ROM of the shoulder.





Figure 1.—Actimove sling

ARM SLINGS ON SHOULDER SUBLUXATION IN STROKE PATIENTS

Materials and methods

Participants

Twenty-eight stroke patients were recruited from 3 different rehabilitation centers in Belgium. Only adult stroke patients after a first stroke with a unilateral upper limb hemiparesis were eligible to participate. All had to be able to sit upright in a chair with a back support but no arm support for at least 30 minutes. Patients with a score of \geq 3 on the muscle testing Medical Research Council Scale for the supraspinatus or deltoideus muscles, other neurological conditions, former shoulder problems on the hemiplegic side or severe cognitive impairments were excluded.

Patients were randomly allocated into three different groups: a control group without a sling (with proper positioning of the arm during the day and on request of the patient a supportive device during gait), a group wearing the Actimove[®] Sling and a third group wearing the Shoulderlift. Randomization was performed by extracting a number 1, 2 or 3 (that corresponded to the 3 groups) for each patient. To assure the blinding procedure envelopes were prepared before the intervention. An independent person, who was not informed about the meaning of the numbers, was asked to draw the envelopes. Devices were fitted by trained physiotherapists, nursing staff or family members. Participants wore their device for a period of 6 weeks during the active time of the day, but not when lying in bed and not during formal therapy sessions. Therapy compliance was not systematically assessed, however all team members were informed about the procedure and controlled the patient's compliance. All patients, independent of the assigned study group, received an equal standard rehabilitation program. Related to the severely impaired upper limb the therapy program focused on avoiding complications (e.g. spasticity, contractures, pain) and active exercises adjusted to the level of impairment. Furthermore patients were involved in physiotherapy focusing on balance (sitting and standing) and gait. Physiotherapeutic interventions were based on a mix of different approaches (e.g. Bobath concept, Motor Learning Programme, PNF). All patients received occupational therapy and if needed speech therapy and/ or cognitive training. All recruited patients agreed to participate in the study and signed an informed consent form prior to their participation. The study received approval from the Medical Ethics Committee of the Ghent



Figure 3.-Flowchart of sample.

University Hospital (Prof. Dr. D. Matthys; EC/2013/991; 19/11/2013) and was registered on ClinicalTrials.gov (Identifier: NCT02102269) (Figure 3).

Procedure

All measurements, primary (AHD and pain) and secondary (passive ROM, spasticity, Trunk Impairment Scale, Fugl Meyer assessment upper limb), were performed at onset of the study and after 6 weeks of treatment. Baseline demographic data (age, sex, time after stroke, type of stroke, side of paresis) are presented in Table I.

Sonographic examination of the AHD

Patients were seated in a chair, with a back support but without arm supports and with their feet positioned flat on the floor. The humerus was in the neutral position with respect to flexion-extension and ab- and adduction with the elbow flexed to 90° and in neutral forearm rotation. If necessary, the arms were supported with a cushion, but support was not allowed at the elbow to eliminate the influence on the shoulder joint. Depending on

van BLADEL

0 1			,		
	Shoulderlift	Actimove	No sling	Р	
N.	10	9	9		
Age (y)	47±14	62±12	56±9	0.033*,a	
Sex (m/f)	6/4	6/3	5/4		
Time post stroke (w)	10.30±3.74	9.44±5.39	8.44±4.22	0.498^{\ddagger}	
Type stroke (isch/hem)	6/4	7/2	6/3		
Side Paresis (L/r)	5/5	4/5	5/4		
FMUE (/66)	8.70±7.85	7.13±4.05 (1 missing)	8.33±6.58	0.941‡	
FMUE_SE (/36)	7.20±3.62	6.63±3.20 (1 missing)	6.89±4.40	0.947‡	
TIS	14.78±4.24	10.50±6.74 (1 missing)	11.33±6.23	0.279‡	
Pain questionnaire (/35)	26±2.55	25±4.24	25.88±10.76	0.321+	

 TABLE I.—Demographic data and baseline variables (mean±standard deviations).

FMUE: Fugl Meyer Assessment Upper Extremity; FMUE_SE: Fugl Meyer Assessment Upper Extremity_ Shoulder Elbow part; TIS: Trunk Impairment Scale. ^aOne way ANOVA; 'Kruskal Wallis Test. *P<0.05.

the measurement the shoulder was positioned in neutral or internal rotation (Figure 4).

Sonographic measurements were performed by the same, trained, physiotherapist using a Colormaster 128 EXT-IZ (Telemed UAB, Vilnius, Lithuania). The ultrasound transducer was placed over the lateral border of the acromion along the longitudinal axis of the humerus to determine the AHD. The distance between the lateral border of the acromion and the humeral head was defined in two different ways: the shortest distance to the humeral head ³⁵ and the distance to the nearest margin of the superior border of the greater tubercle.³⁶

AHD was measured in the non-hemiplegic shoulder and in the hemiplegic shoulder. The level of subluxation (dAHD1) was defined by subtracting the AHD of the non-affected side from the AHD of the affected side. AHD was re-measured immediately after applying the supportive device. The level of correction (dAHD2) was calculated by subtraction of AHD without and with the supportive device. To compare both slings, only the measurements in internal rotation were used since, when wearing the Actimove sling, positioning in the neutral position was impossible. When applying the Shoulderlift brace sonographic examination could only be performed when patients wore the Pellenberg retraction elevation bandage. Wearing the shoulder section as well would make it impossible to position the transducer over the acromion (Figure 4).

Pain

Pain intensity was assessed using a visual analogue scale. Patients were asked to score the intensity of their

Figure 4.—Standardized position of sonographic examination.

shoulder pain during the last 72 hours at rest, during activities and at night on a scale from 0 to 10.³⁷ To examine other dimensions of pain such as frequency and appreciation of comfort of the position of the arm in different situations, a questionnaire was used. Since not all questions of the Shoulder Rating Questionnaire are suitable for stroke patients, only specific questions about the intensity were used from this Shoulder Rating Questionnaire.³⁸ Patients had 5 options to answer questions about the frequency and intensity of possible shoulder pain and to evaluate comfort of the arm in different positions. The total available score of the questionnaire was 35.

Secondary outcome measures

Passive ROM of the shoulder and elbow were measured using a manual goniometer with the patients in the supine position. The degrees of pain free ROM were noted for shoulder flexion, abduction, external rotation and elbow extension. Spasticity in the upper limb was evaluated using the Modified Ashworth Scale (MAS) again with patients in the supine position. Trunk control was evaluated using the Trunk Impairment Scale (TIS). This test contains 3 subscales (static, dynamic sitting balance and trunk coordination) and the score ranges from 0 to 23.³⁹ The Fugl Meyer assessment was used to quantify motor deficits of the upper limb.^{40, 41} Both the

ARM SLINGS ON SHOULDER SUBLUXATION IN STROKE PATIENTS

total score of the upper limb section and the shoulder *Effect on acromiohumeral distance* elbow score were used in statistical analysis.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences, version 23 (SPSS 23.0). Normal distribution was examined using a Shapiro Wilk Test. A one-way ANOVA was used to compare the mean level of subluxation between groups at onset and after the intervention. To compare the mean level of subluxation between onset and the end of the intervention for all groups a general linear model with repeated measures analysis was performed. An independent samples *t*-test was used to compare the mean level of correction between groups at the onset and after the intervention period. Depending on normality a Kruskal Wallis Test or a one-way ANOVA was used to compare the means of the demographic data and clinical measurements between groups at the start and end of the intervention. To compare the means of the clinical measurements between onset and after the intervention for the different groups a Wilcoxon Signed Ranks test was used. Correlations between the variables were analyzed using a Spearman correlation coefficient test. Probability values lower than 0.05 were considered statistically significant in all tests.

Results

Demographic data

Of the 59 patients screened for eligibility, 32 were included in the study. One patient decided to end her participation prematurely since she found wearing the Actimove sling to be uncomfortable. Three other patients were excluded, two of them because there was no subluxation present at the start of the intervention and one because the patient was not compliant with the protocol. Demographic data and baseline variables are summarized in Table I.

Groups were comparable for the variables time post stroke, arm function, trunk control and pain. A significant difference was detected for age (P=0.033) with the Shoulderlift group being younger compared to the control and the Actimove group. However, no correlation could be detected between age and hemiplegic shoulderpain.

At the onset there was no significant difference between groups for the level of subluxation and for immediate correction on applying the sling. The Shoulderlift tended to correct the level of subluxation by 63% while the Actimove sling corrected it by 36%. After a period of 6 weeks there was no significant difference between groups, neither for the level of subluxation nor for correction after applying a sling. Correction at this posttreatment period was reduced to 28% for the Shoulderlift group and to 24% for the Actimove group (Table II).

A general linear model with repeated measures, performed to determine the time group interaction effect, resulted in a significant difference for the subluxation measured in internal rotation (Figure 5A; P=0.025). In the Shoulderlift group dAHD1 increased during the period of 6 weeks, implying an increment in subluxation of 12.44% (1.03 mm). Acromiohumeral distance in the Actimove group remained relatively the same over time showing only a small reduction in subluxation of 2.77% (0.27 mm) after six weeks. In the control group a clearly larger decrease of acromiohumeral distance was noted implying a reduction in subluxation of 37.59% (3.30 mm).

For the measurements in the neutral position the same result was obtained but the level of significance was not reached (Figure 5B; P=0.154).

Clinical measurements and correlations

An overview of all clinical measurements at the onset and after 6 weeks is provided in Table III.

At the start of the study there was no statistical difference between groups for all pain variables. After 6 weeks the patients in the Actimove group reported more pain at rest (P=0.036) compared to the other two groups. When evaluating the pain scores over the period of 6 weeks no significant changes could be detected. According to the questionnaire, patients reported most pain during excercise, tranfers and daily care in all groups. Pain and the level of subluxation in all 3 groups was not correlated. Spasticity in the upper limb was low before and after 6 weeks. No relevant differences could be detected between groups at both times and no significant evolution was detected over a period of 6 weeks. Besides no relevant correlations could be detected between spasticity and shoulder pain nor for the

ARM SLINGS ON SHOULDER SUBLUXATION IN STROKE PATIENTS

		/ 5	1	/
	Shoulderlift	Actimove	No sling	Р
dAHD1 (0w, neutral position)	8.54±4.80	9.14±4.02	8.73±4.65	0.961
dAHD1 (0w, internal rotation)	8.28±4.99	9.73±3.53	8.78±5.12	0.810
dAHD2 (0w internal rotation)	5.21±2.35	3.49±2.35		0.154
dAHD1 (6w, neutral position)	9.99±5.92	8.66±7.00	5.89±5.19	0.368
dAHD1 (6w, internal rotation)	9.31±5.70	9.46±5.43	5.48±3.09	0.203
dAHD2 (6w, internal rotation)	2.57±2.08	2.31±2.94		0.844
dAHD1= AHD affected side – AHD non-affect	ed side = level of subluxation: dAHD	2= AHD affected side – AHD a	iffected side with $sling = corrections$	ection

TABLE II.—Subluxation (dAHD1) and correction (dAHD2) at onset (0w) and after 6 weeks in mm (mean \pm standard deviations).

level of subluxation. At onset all groups were comparable for ROM. No statistical significant changes could be detected in ROM (all directions) between onset and 6 weeks for all groups. It was noted that, in contrast with the Shoulderlift group. ROM of abduction and external rotation decreased in the Actimove and control group. Only the ROM of shoulder abduction correlated significantly with pain intensity (VAS) during activities measured at the end of the intervention (Table IV). Upper limb function (FMUE) at the start was comparable for all groups. Patients in the Shoulderlift and control group increased their score significantly (P<0.05). Upper limb function scores and level of subluxation were not correlated (Tables III-V).

Discussion

Arm slings are often used to support the hemiplegic arm in an attempt to counteract the downward pull of gravity on the humerus in order to reduce or prevent a possible subluxation. Due to the lack of long-term studies investigating the effect of arm slings on subluxation we have attempted to address this by examining the immediate and long-term effect on acromiohumeral distance using the Actimove® sling and Shoulderlift.

Effect on acromiohumeral distance

In clinical practice the hemiplegic arm can be supported in various ways. Wheelchair attachments appear to provide the best correction for GHS with a mean correction of 15 mm.23, 42 However, using wheelchair attachments is no longer useful when patients become ambulatory. Also, side effects such as inadequate stimulation to perform transfers independently, skin problems due to friction or even overcorrection of subluxation



Figure 5.—Evolution of the level of subluxation (mm) over 6 weeks in internal rotation (A) and neutral position (B).

have been reported.^{22, 43} Moreover in the case of patients with severe neglect or cognitive impairments the hemiplegic arm can fall off the lapboard due to visual and/or sensory inattention. Often ambulatory patients with hypotonia and severe paresis or HSP are prescribed an arm sling.⁴² However, there is insufficient evidence regarding the preventive ²¹ and corrective function of these slings.²³ There are some observational studies that have measured the immediate effect of shoulder devices on subluxation.8, 22 The average amount of subluxation was 12 mm, measured from X-rays. Overall immediate

This

ARM SLINGS ON SHOULDER SUBLUXATION IN STROKE PATIENTS

TABLE III.— (Iverview of	clinical	measurements	mean±stand	ard	deviations)).
---------------	-------------	----------	--------------	------------	-----	-------------	----

	Shoulderlift	Actimove	No sling	Р
VAS rest 0 w	1.14±1.86	0	0.22±0.67	0.082
VAS rest 6 w	0.71±1.89	2.63±3.16	0	0.036*
VAS activity 0 w	4.86±2.27	5.75±2.12	2.78±2.59	0.050
VAS activity 6 w	2.29±2.63	4.38±2.39	2.44±2.01	0.157
VAS night 0 w	0.71±1.89	1.88 ± 2.95	1.56±3.00	0.639
VAS night 6 w	2.00±2.65	1.88±3.04	0	0.104
Questionnaire 0 w	26.00±2.55	25.00±4.24	25.88±10.76	0.321
Questionnaire 6 w	26.33±3.39	24.33±5.51	28.63±2.26	0.389
ROM flexion 0 w	110.5±24.99	106.11±35.34	128.33±28.06	0.273
ROM flexion 6 w	104.5±23.51	92.78±25.63	113.33±24.49	0.320
ROM abduction 0 w	92.5±13.18	83.89±15.37	97.78±21.08	0.398
ROM abduction 6 w	93.00±12.52	78.33±23.45	89.44±13.33	0.219
ROM ext rot 0 w	25.50±28.72	$14.44{\pm}17.04$	25.56±16.48	0.393
ROM ext rot 6 w	24.50±28.13	2.22±14.17	13.89±13.64	0.108
TIS tot 0 w	14.78±4.24	10.50±6.74	11.33±6.23	0.279
TIS tot 6 w	16.78±2.86	13.13±6.40	14.44±5.83	0.330
FMUE 0 w	8.70±7.85	7.13±4.05	8.33±6.58	0.941
FMUE 6 w	12.30±10.55	8.38±5.21	12.78±12.28	0.828
FMUE SE0 w	7.20±3.62	6.63±3.20	6.89±4.40	0.947
FMUE_SE 6 w	9.20±5.12	7.63±4.21	9.56±7.33	0.837

VAS: Visual Analogue Scale; ROM: range of motion; TIS: Trunk Impairment Scale; FMUE: Fugl Meyer Assessment Upper Extremity; FMUE_SE: Fugl Meyer Assessment Upper Extremity_Shoulder Elbow part; *P<0.05.

TABLE IV.—Correlations between pain intensity during activities and limited passive range of motion for shoulder abduction at 6 weeks per group.

	Shoulderlift	Actimove	No sling
Correlation coefficient P	-0.797 0.032*	-0.755 0.030*	-0.687 0.041*
Spearman correlation coeffic	cient: *P<0.05		

TABLE V.—P values for intra-group differences for the clinical measurements, subluxation (dAHD1) and correction (dAHD2).

	Shoulderlift	Actimove	No sling
VAS rest	0.581+	0.066 [‡]	0.317‡
VAS activity	0.072+	0.306 [‡]	0.524‡
VAS night	0.180+	1.000‡	0.109 [‡]
Questionnaire	0.786*	0.785 [‡]	1.000‡
ROM flexion	0.228‡	0.326‡	0.072*
ROM abduction	0.705‡	0.157‡	0.498 [‡]
ROM ext rotation	0.498 [‡]	0.065+	0.096‡
TIS tot	0.027*+	0.042*+	0.011*+
FMUE	0.042*+	0.066+	0.043*+
FMUE SE	0.043*+	0.066‡	0.042*+
dAHD1 (neutral)	0.115¥	0.761¥	0.039*¥
dAHD1 (internal rot)	0.375¥	0.078^{F}	0.041*¥
dAHD2 (internal rot)	0.017*¥	0.382¥	

reduction was 8 mm. When comparing different slings a mean correction of 13 mm was noted for the slings that support the arm in flexion compared to 4 mm for the slings that do so in extension.^{23, 42}

The present study compared the immediate and longterm effects of two different arm slings on the GHS in hemiplegic patients. The characteristics of the Shoulderlift stimulate the use of the hemiplegic arm when function recovers and allows the patient to counterbalance weight-shift in ambulation.²⁴ The Actimove sling on the other hand supports the arm via an immobilizing approach. Due to the low number of patients in each arm our results should be interpreted with caution. Nevertheless, they indicate a different corrective function for the two slings at the times of measurement of AHD. An immediate correction of 63% (5.21 mm) was noted for the Shoulderlift and 36% (3.49 mm) for the Actimove sling. So in contrast to the literature,^{21, 23} our extension sling appears to establish a better correction than the flexion sling. When repeating the measurement 6 weeks later, the Shoulderlift only corrects 28% (2.57 mm) and the Actimove sling 24% (2.31 mm). This reduction might be explained technically in that the materials, from which the slings are manufactured, lose their

van BLADEL

(elastic) quality overtime and thereby potentially, their corrective properties.

Surprisingly our results indicate that not wearing a sling reduces the subluxation (subtracting the AHD of the non-affected side from the AHD of the affected side) over time in comparison to patients who did wear an arm sling. The level of subluxation remained approximately equal when wearing the Actimove sling and even increased when wearing the Shoulderlift. A possible explanation for this is that patients without a supportive sling are more attentive to the position of their arm during daily activities and are actively engaged in muscle activity to preserve glenohumeral congruence. Meanwhile, patients who wear a sling describe a secure feeling as their arm is supported and cared for (passively). They do not have to look actively after their arm and muscular activity is not required.25 EMG recordings of the shoulder muscles is mandatory to confirm our hypothesis. Improvement of upper limb function during the period of intervention also provided an indication of the differences we observed, but no correlation could be detected between upper limb functional changes and the level of subluxation. This result did not support our hypothesis that the improvement of upper limb function might explain the reduction of subluxation in the control group. Active control (to take care of a paralyzed limb) might therefore be the most acceptable explanation given this result. Thus, the presence of subluxation might not always be an absolute indication to use an arm sling. Informing the patient, the careers and family members on how to position and handle the hemiplegic arm might be more important together with early active strengthening exercises for stabilizing the shoulder muscles. We are aware that these findings need to be confirmed by larger studies, nevertheless we do believe that these results could be of clinical importance.

Effect on clinical measurements

Regarding HSP the present study showed no correlation between the pain variables and the level of subluxation. After 6 weeks, patients in the Actimove group reported more pain during activity than the patients in the Shoulderlift or control group, although this was not significant. Possibly this minor difference could be explained by the limited pain free passive ROM of external shoulder rotation in the Actimove group. The interrelationship of limited passive shoulder abduction, external rotation and HSP has been described elsewhere.4, 17, 19, 44-46 Roosink et al. describes a bi-directional relationship between restricted passive ROM and persistent shoulder pain beginning from 3 months post stroke. Restricted joint motion could be a critical element to address in order to break the vicious circle of post stroke shoulder pain.28 In contrast to the Shoulderlift and control group, patients in the Actimove group had the most restricted ROM for external rotation and shoulder abduction after 6 weeks. Since the arm in this sling is positioned in internal rotation against the body during most of the day, this almost permanent fixed position may possibly lead to muscle and/or capsule tightening and even contractures.23 This could also be an explanation for the increased pain during activities since too much internal rotation in the shoulder is known to increase the risk of impingement during active and passive movements of the arm.^{47, 48} Only in the Shoulderlift group the passive ROM of shoulder abduction and external rotation could be preserved suggesting that this sling may be the better option for patients who do need to wear a sling. Patients not wearing a sling should be discouraged from holding their arm against their abdomen whilst walking to prevent the decrease of external rotation. A possible compensation is to position the arm in their pocket during walking.²⁵ The correlation between less external rotation and increased pain during activities was confirmed in our results.

Limitations of the study

To our knowledge this is the first study that investigates the immediate and long-term effect of arm slings using sonography. However, due to the small sample size our results should be interpreted with caution. Post hoc power analysis for the change in AHD distance over 6 weeks, showed a medium effect size (f=0.47) with a power of 67%. With containment of the given size effect obtaining a power of 80% would warrant a total sample of 39 patients implying that we would have had to add 3 or 4 patients per group. Sonography is a reliable and valid method to measure the AHD ^{35, 36} even in stroke patients,^{32, 33} but it did present some difficulties. For example, patients with severe limitation of external rotation in the shoulder could not be positioned in the neutral rotation. The greater tubercle of the humerus

This document is protected by international copyright laws. No additional reproduction is authorized. It is permitted for personal use to download and save only one file and print only one copy of this Article. It is not permitted to make additional copies (either sporadically or systematically, either printed or electronic) of the Article for any purpose. It is not permitted to distribute the electronic copy of the article through online internet and/or intranet file sharing systems, electronic mailing or any other means which may allow access to the Article. The use of all or any part of the Article for any Commercial Use is not permitted. The creation of derivative works from the Article is not permitted. The use of all or any part of the Article for any Commercial Use is not permitted. The creation of derivative works from the Article is not permitted. The production of reprints for personal or commercial use is not permitted to remove, cover, overlay, obscure, block, or change any copyright notices or terms of use which the Publisher may post on the Article. It is not permitted to frame or use framing techniques to enclose any trademark, logo or other proprietary information of the Publisher.

was not always visible on the sonographic image. Particularly when performing the measurement in internal rotation and maintaining the position of the transducer along the longitudinal axis of the humerus, the tubercle could not be seen. When dealing with a large person or a severe subluxation the transducer was too small to cover the subluxed distance and this resulted in some missing data.

An immediate correction of a sling can be influenced by various elements (sling as such, brand new material, increased attention to the limb,...). Repeating the measurement a few hours after application, to determine the intrinsic corrective character and 'settling' of the sling was lacking in this study. This should be investigated in future studies.

Also, limitations in the use of a visual analogue scale for pain in stroke patients should be taken into consideration. Not all patients were able to score their pain due to language problems or cognitive impairments. Furthermore, in stroke patients, self-reported pain often underestimates the extent of pain found during physical examination of the shoulder.⁴⁹

Conclusions

The present findings indicate that not wearing a sling is related to AHD reduction, whereas wearing the sling does not seem to prevent pain and shoulder subluxation. Therefore, prescribing a sling might not be the preferred treatment approach since it may actually inhibit active correction.

The Shoulderlift tends to provide better initial correction than the Actimove sling. However, both slings seem to lose their corrective functioning ability over time.

Due to the small sample size our results should be interpreted with caution and further research is necessary to confirm our findings.

References

- Kalichman L, Ratmansky M. Underlying pathology and associated factors of hemiplegic shoulder pain. Am J Phys Med Rehabil 2011;90:768-80.
- Turner-Stokes L, Jackson D. Shoulder pain after stroke: a review of the evidence base to inform the development of an integrated care pathway. Clin Rehabil 2002;16:276-98.
- Demirci A, Ocek B, Koseoglu F. Shoulder pain in hemiplegic patients. J PMR Sci 2007;1:25-30.

- Aras MD, Gokkaya NK, Comert D, Kaya A, Cakci A. Shoulder pain in hemiplegia: results from a national rehabilitation hospital in Turkey. Am J Phys Med Rehabil 2004;83:713-9.
- Chae J, Mascarenhas D, Yu DT, Kirsteins A, Elovic EP, Flanagan SR, et al. Poststroke shoulder pain: its relationship to motor impairment, activity limitation, and quality of life. Arch Phys Med Rehabil 2007;88:298-301.
- Barlak A, Unsal S, Kaya K, Sahin-Onat S, Ozel S. Poststroke shoulder pain in Turkish stroke patients: relationship with clinical factors and functional outcomes. Int J Rehabil Res 2009;32:309-15.
- Adey-Wakeling Z, Liu E, Crotty M, Leyden J, Kleinig T, Anderson CS, *et al.* Hemiplegic Shoulder Pain Reduces Quality of Life After Acute Stroke: A Prospective Population-Based Study. Am J Phys Med Rehabil 2016;95:758-63.
- Zorowitz RD, Hughes MB, Idank D, Ikai T, Johnston MV. Shoulder pain and subluxation after stroke: correlation or coincidence? Am J Occup Ther 1996;50:194-201.
- Ikai T, Tei K, Yoshida K, Miyano S, Yonemoto K. Evaluation and treatment of shoulder subluxation in hemiplegia: relationship between subluxation and pain. Am J Phys Med Rehabil 1998;77:421-6.
- Paci M, Nannetti L, Taiti P, Baccini M, Rinaldi L. Shoulder subluxation after stroke: relationships with pain and motor recovery. Physiother Res Int 2007;12:95-104.
- 11. Bender L, McKenna K. Hemiplegic shoulder pain: defining the problem and its management. Disabil Rehabil 2001;23:698-705.
- Lindgren I, Jonsson AC, Norrving B, Lindgren A. Shoulder pain after stroke: a prospective population-based study. Stroke 2007;38:343-8.
 Pompa A, Clemenzi A, Troisi E, Di Mario M, Tonini A, Pace L, et
- Pompa A, Clemenzi A, Troisi E, Di Mario M, Tonini A, Pace L, *et al*. Enhanced-MRI and ultrasound evaluation of painful shoulder in patients after stroke: a pilot study. Eur Neurol 2011;66:175-81.
- Kim YH, Jung SJ, Yang EJ, Paik NJ. Clinical and sonographic risk factors for hemiplegic shoulder pain: A longitudinal observational study. J Rehabil Med 2014;46:81-7.
- Blennerhassett JM, Gyngell K, Crean R. Reduced active control and passive range at the shoulder increase risk of shoulder pain during inpatient rehabilitation post-stroke: an observational study. J Physiother 2010;56:195-9.
- Huang YC, Liang PJ, Pong YP, Leong CP, Tseng CH. Physical findings and sonography of hemiplegic shoulder in patients after acute stroke during rehabilitation. J Rehabil Med 2010;42:21-6.
- Roosink M, Renzenbrink GJ, Buitenweg JR, Van Dongen RT, Geurts AC, Mj IJ. Persistent shoulder pain in the first 6 months after stroke: results of a prospective cohort study. Arch Phys Med Rehabil 2011;92:1139-45.
- Hanger HC, Whitewood P, Brown G, Ball MC, Harper J, Cox R, *et al.* A randomized controlled trial of strapping to prevent post-stroke shoulder pain. Clin Rehabil 2000;14:370-80.
- Lo SF, Chen SY, Lin HC, Jim YF, Meng NH, Kao MJ. Arthrographic and clinical findings in patients with hemiplegic shoulder pain. Arch Phys Med Rehabil 2003;84:1786-91.
- Dursun E, Dursun N, Ural CE, Cakci A. Glenohumeral joint subluxation and reflex sympathetic dystrophy in hemiplegic patients. Arch Phys Med Rehabil 2000;81:944-6.
- Nadler M, Pauls M. Shoulder orthoses for the prevention and reduction of hemiplegic shoulder pain and subluxation: systematic review. Clin Rehabil 2017;31:444-53.
- Brooke MM, de Lateur BJ, Diana-Rigby GC, Questad KA. Shoulder subluxation in hemiplegia: effects of three different supports. Arch Phys Med Rehabil 1991;72:582-6.
- Ada L, Foongchomcheay A, Canning C. Supportive devices for preventing and treating subluxation of the shoulder after stroke. Cochrane Database Syst Rev 2005:CD003863.
- Dieruf K, Poole JL, Gregory C, Rodriguez EJ, Spizman C. Comparative effectiveness of the GivMohr sling in subjects with flaccid upper limbs on subluxation through radiologic analysis. Arch Phys Med Rehabil 2005;86:2324-9.
- 25. Acar M, Karatas GK. The effect of arm sling on balance in patients with hemiplegia. Gait Posture 2010;32:641-4.

- Yavuzer G, Ergin S. Effect of an arm sling on gait pattern in patients with hemiplegia. Arch Phys Med Rehabil 2002;83:960-3.
- Hesse S, Herrmann C, Bardeleben A, Holzgraefe M, Werner C, Wingendorf I, et al. A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: a preliminary study. J Rehabil Med 2013;45:623-9
- 28 Han SH, Kim T, Jang SH, Kim MJ, Park SB, Yoon SI, et al. The effect of an arm sling on energy consumption while walking in hemiplegic patients: a randomized comparison. Clin Rehabil 2011;25:36-42. Stolzenberg D, Siu G, Cruz E. Current and future interventions for
- glenohumeral subluxation in hemiplegia secondary to stroke. Top Stroke Rehabil 2012:19:444-56.
- 30 Murie-Fernandez M, Carmona Iragui M, Gnanakumar V, Meyer M, Foley N, Teasell R. [Painful hemiplegic shoulder in stroke patients:
- causes and management]. Neurologia 2012;27:234-44. Prevost R, Arsenault AB, Dutil E, Drouin G. Rotation of the scapula and shoulder subluxation in hemiplegia. Arch Phys Med Rehabil 1987;68:786-90.
- 32. Park GY, Kim JM, Sohn SI, Shin IH, Lee MY. Ultrasonographic measurement of shoulder subluxation in patients with post-stroke hemiplegia. J Rehabil Med 2007;39:526-30
- Kumar P, Bradley M, Gray S, Swinkels A. Reliability and validity of ulir asonographic mesurements of acromion-greater tuberosity distance in poststroke hemiplegia. Arch Phys Med Rehabil 2011;92:731-6.
- 34 Azzoni R, Cabitza P, Parrini M. Sonographic evaluation of subacromial space. Ultrasonics 2004;42:683-7
- 35. Desmeules F, Minville L, Riederer B, Cote CH, Fremont P. Acromiohumeral distance variation measured by ultrasonography and its association with the outcome of rehabilitation for shoulder impingement syndrome. Clin J Sport Med 2004;14:197-205.
- 36 Seitz AL, Michener LA. Ultrasonographic measures of subacromial space in patients with rotator cuff disease: A systematic review. J Clin Ultrasound 2011;39:146-54.
- Turner-Stokes L, Jackson D. Assessment of shoulder pain in hemiple-
- gia: sensitivity of the ShoulderQ. Disabil Rehabil 2006;28:389-95. Vermeulen HM, Boonman DC, Schüller HM, Obermann WR, van Houwelingen HC, Rozing PM, *et al.* Translation, adaptation and vali-38

dation of the Shoulder Rating Questionnaire (SRQ) into the Dutch language. Clin Rehabil 2005;19:300-11.

- Verheyden G, Nieuwboer A, Mertin J, Preger R, Kiekens C, De 39 Weerdt W. The Trunk Impairment Scale: a new tool to measure motor impairment of the trunk after stroke. Clin Rehabil 2004;18:326-34.
- Poole JL, Whitney SL. Motor assessment scale for stroke patients: concurrent validity and interrater reliability. Arch Phys Med Rehabil 1988.69.195-7
- 41. Duncan PW, Propst M, Nelson SG. Reliability of the Fugl-Meyer assessment of sensorimotor recovery following cerebrovascular accident. Phys Ther 1983;63:1606-10.
- Foongchomcheay A, Ada L, Canning CG. Use of devices to pre-42 vent subluxation of the shoulder after stroke. Physiother Res Int 2005;10:134-45
- Spaulding SJ. Biomechanical analysis of four supports for the sub-luxed hemiparetic shoulder. Can J Occup Ther 1999;66:169-75. 43
- Lindgren I, Lexell J, Jonsson AC, Brogardh C. Left-sided hemipare- $\Delta \Delta$ sis, pain frequency, and decreased passive shoulder range of abduction are predictors of long-lasting poststroke shoulder pain. PM R 2012:4:561-8
- 45 Rajaratnam BS, Venketasubramanian N, Kumar PV, Goh JC, Chan YH. Predictability of simple clinical tests to identify shoulder pain after stroke. Arch Phys Med Rehabil 2007;88:1016-21.
- Niessen M, Janssen T, Meskers C, Koppe P, Konijnenbelt M, Veeger 46 D. Kinematics of the contralateral and ipsilateral shoulder: a possible relationship with post-stroke shoulder pain. J Rehabil Med 2008:40:482-6
- 47 Flatow EL, Soslowsky LJ, Ticker JB, Pawluk RJ, Hepler M, Ark J, et al. Excursion of the rotator cuff under the acromion. Patterns of subacromial contact. Am J Sports Med 1994;22:779-88.
- Niessen MH, Veeger DH, Meskers CG, Koppe PA, Konijnenbelt MH. 48 Janssen TW. Relationship among shoulder proprioception, kinematics, and pain after stroke. Arch Phys Med Rehabil 2009;90:1557-64.
- Dromerick AW, Edwards DF, Kumar A. Hemiplegic shoulder pain 49 syndrome: frequency and characteristics during inpatient stroke rehabilitation. Arch Phys Med Rehabil 2008;89:1589-93.

Congresses .-- International congress on Neurorehabilitation and Neural Repair (May 2015): "Shoulder subluxation in stroke patients: measuring the immediate effect of on arm sling using sonography (a preliminary cross-sectional study)"

Acknowledgements.-Our grateful thanks go to Dr. Chris Truyers of the Rehabilitation Hospital of Inkendaal and to Dr. Annick Debuysscher of the hospital AZ Nikolas in Sint Niklas for participating in patient recruitment. A special thanks to all physiotherapists, occupational therapists and nurses from the 3 rehabilitation centers for assisting with patient compliance.

Conflicts of interest.-The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript. Article first published online: January 30, 2017. - Manuscript accepted: January 25, 2017. - Manuscript revised: January 13, 2017. - Manuscript received: June 17, 2016