Title: Lap-tray and triangular sling are no more effective than a hemi-sling in preventing shoulder subluxation in those at risk early after stroke: a randomised trial.

Authors:

1. Louise Ada, PhD, Professor, Discipline of Physiotherapy, The University of Sydney, Australia
2. Anchalee Foongchomcheay, PhD, Chulalongkorn University, Thailand
3. Birgitta Langhammer, PhD, Professor, Oslo and Akershus University College of Applied Sciences, Norway
4. Elisabeth Preston, PhD, Discipline of Physiotherapy, The University of Canberra
5. Rosalyn Stanton, PhD student, Discipline of Physiotherapy, The University of Sydney
6. John Robinson, Discipline of Medical Radiation Sciences, The University of Sydney
7. Serene Paul, PhD, The George Institute for Global Health, Sydney Medical School, The University of Sydney, , Sydney, Australia.
8. Colleen G Canning PhD, Associate Professor, Discipline of Physiotherapy, The University of Sydney, Australia

Correspondence:

Name	Louise Ada
Department	Discipline of Physiotherapy
Institution	The University of Sydney
Country	Australia
Email	Louise.ada@sydney.edu.au

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ABSTRACT

BACKGROUND: Shoulder subluxation is a common secondary impairment of the upper limb following stroke. A range of supportive devices are used in rehabilitation to prevent shoulder subluxation, including hemi-slings and firm supports, such as arm troughs, however, there is little evidence regarding their efficacy.

AIM: To determine whether a modified lap-tray during sitting and a triangular sling during standing is more effective than a hemi-sling in preventing shoulder subluxation, pain, contracture and upper limb activity limitation after stroke.

DESIGN: A prospective, randomised trial with concealed allocation, assessor blinding and intention-to-treat analysis.

SETTING: Three inpatient rehabilitation units in Australia and Norway.

POPULATION: Forty-six acute stroke survivors within 3 weeks of stroke who were at risk of subluxation.

METHOD: The experimental group used a modified lap-tray while sitting and a triangular sling while standing to support the affected arm for four weeks. The control group used a hemi-sling while sitting and standing. The primary outcome was amount of shoulder subluxation on X-ray. Secondary outcomes were upper limb activity, pain and contracture.

RESULTS: There was no significant difference between groups in terms of shoulder subluxation (MD -3 mm, 95% CI -8 to 3). There was a trend for the experimental group to develop less pain at rest (MD -0.7 out of 10, 95% CI -2.2 to 0.8) and during shoulder external rotation (MD -1.7 out of 10, 95% CI -3.7 to 0.3) and a trend towards having less contracture of shoulder external rotation (MD -10 deg, 95% CI -22 to 2). There was no significant difference between groups in terms of other contractures and activity of the upper limb.

CONCLUSION: A lap-tray during sitting combined with a triangular sling during standing is no more effective than a hemi-sling in preventing subluxation, pain, contracture and activity limitation in acute stroke survivors at risk of shoulder subluxation.

CLINICAL REHABILITATION IMPACT: The use of a lap-tray during sitting and triangular sling during standing is not indicated as an alternative to the hemi-sling to prevent shoulder subluxation in patients after stroke, so alternative strategies with proven efficacy, such as electrical stimulation, should be considered.

INTRODUCTION

Shoulder subluxation is a common secondary impairment of the upper limb following stroke. After stroke, as a result of muscle paralysis, the gravitational pull on the humerus causes stretching of the capsule of the glenohumeral joint resulting in inferior displacement[1]. The prevalence of shoulder subluxation is related to the degree of paralysis in the upper limb. In patients after stroke with no upper limb strength, the prevalence has been reported as 81%[2], 60%[3] and 56%[4]. The prevalence is lower (40%) in people after stroke with some upper limb strength[5], and even lower in those who regain full upper limb strength within one month (7-15%)[6,7]. Shoulder subluxation may cause shoulder pain[8,9,10,11] and hinder the recovery of upper limb activity[12] due to the incongruence between the head of the humerus and the glenoid fossa making elevation of the arm difficult[13].

A range of supportive devices are used during stroke rehabilitation attempting to prevent shoulder subluxation. These devices aim to eliminate the downward pull of gravity on the humerus, while awaiting recovery of muscle strength. Supportive devices include slings as well as attachments to wheelchairs. Slings with the elbow in flexion (eg, triangular sling, hemi-sling) can be worn when standing and walking as well as in sitting, but have the disadvantage of holding the shoulder in internal rotation and elbow in flexion thus predisposing the arm to contracture. Slings with the elbow in extension (eg, Bobath sling) attach to the affected upper arm and the opposite shoulder or arm, leaving the arm unrestrained so that it can be used for daily activities. Attachments to wheelchairs, such as lap-trays and arm troughs, provide support to the shoulder from underneath the elbow when sitting, but provide no support when standing and walking.

The Cochrane systematic review on supportive devices found only one small quasi-randomised trial examining the efficacy of a hemi-sling (ie, a collar-and-cuff type sling going around the neck and attaching to the forearm at two points) in preventing subluxation[14]. However, the review found that firm supportive devices could re-position the head of the humerus in the glenoid fossa temporarily. Specifically, arm troughs and lap-trays attached to wheelchairs immediately reduced existing subluxation by 13.7 mm compared with 4.2 mm for slings that offered support via a bent elbow[14]. The review concluded that further randomised trials were required to determine the effectiveness of supportive devices for prevention of shoulder subluxation[14]. Despite this recommendation, this is the first randomised trial to be carried out investigating the efficacy of supportive devices in preventing shoulder subluxation after stroke.

Prevention of shoulder subluxation should be considered an important part of upper limb rehabilitation. Since recovery of muscle strength around the shoulder takes time, it is important to have an ongoing strategy in place early after stroke to prevent shoulder subluxation while therapy focuses on increasing muscle activity. The Cochrane Systematic Review on supportive devices suggests that a lap-tray and a triangular sling have the most potential to prevent subluxation[14]. Therefore, these two devices were combined and tested in a randomised trial against usual practice. A survey of physiotherapy practice in Australia indicated that the usual practice was for a physiotherapist to apply a hemi-sling for the prevention of subluxation[15]. Therefore, the research questions for this study were:

In patients early after stroke who are at risk of shoulder subluxation,

1. Is four weeks of a modified lap-tray during sitting and a triangular sling during standing more effective than a hemi-sling at preventing subluxation in the affected shoulder?
2. Is it more effective than a hemi-sling at preventing pain and contracture in the affected shoulder, and improving upper limb activity after 4 weeks?

Since the prevalence of shoulder subluxation is related to the degree of paralysis in the upper limb, patients were considered to be at risk of subluxation of the shoulder if the upper limb muscles were very weak, in particular the muscles of the upper arm. Given there is no clear evidence regarding the effectiveness of supportive devices to prevent the development of shoulder subluxation, and that shoulder subluxation has a significant negative effect on upper limb outcome after stroke, this study should provide evidence on which to base rehabilitation.

MATERIALS AND METHOD

Design

A prospective, multicentre, single-blind randomised trial was carried out. People after stroke with a paralysed or very weak upper limb were recruited on admission to rehabilitation at 3 different centres, two in Australia and one in Norway. Participants were randomly allocated into a control or experimental group. Randomisation was stratified according to severity since it has been found to affect outcome[16]. Item 6 (upper arm function) of the Motor Assessment Scale for Stroke[17] was divided into two severity strata: 0 and 1-3. Random permuted blocks were used so that after every block (of between 6-10 participants), the experimental and control groups contained equal numbers. The computer-generated sequence of allocation was revealed by a phone call off-site and therefore independent and concealed from the person recruiting participants. For 4 weeks during waking hours, the experimental group received a lap-tray and triangular sling while the control group received usual care which was a hemi-sling. Outcomes were measured at baseline (0 weeks) and immediately after the cessation of intervention (4 weeks) by a measurer blinded to group allocation. To ensure blinding, measurers were therapists who worked remote to the rehabilitation unit and participants were asked not to reveal details of their intervention. Data analysis was performed using intention-to-treat analysis. The study was approved by the Human Research Ethics Committees of each of the centers involved in the study. Informed consent was obtained from participants prior to data collection.

Participants

Stroke survivors were included if they were within 3 weeks of their first stroke, aged between 50 and 85 years, had a hemiparesis or hemiplegia clinically diagnosed, and had significant weakness and disability of the upper limb (defined as < 4 out of 6 on Item 6 of the Motor Assessment Scale for Stroke)[17]. They were excluded if they had severe cognitive and/or language deficits which precluded them from giving informed consent, or if they had previous pathology of the shoulder.

Intervention

The experimental group received a modified lap-tray and a triangular sling to support the affected upper limb. The lap-tray was attached to the armrest of the wheelchair or chair at the level of the armrests to support the affected forearm whenever the participant was sitting. It was modified by attaching a cylinder which the hand was placed around, so that the affected shoulder was positioned in a neutral amount of rotation, the forearm in a neutral amount of rotation, the wrist in some extension and the web space around the cylinder (Figure 1a). The triangular sling was fitted every morning, but was only used to position the arm during standing and walking (Figure 1b). Whenever the participant was sitting, the upper limb was removed from the triangular sling and supported by the lap-tray. The triangular sling remained around the participant's neck in preparation for further standing (Figure 1a).

The control group received usual care for the prevention of subluxation which was to wear a hemi-sling during waking hours. The sling was fitted every morning, such that one cuff was placed at the affected elbow and the second cuff was placed at the affected wrist, and was worn during sitting, standing and walking (Figure 1c).

In all other respects, usual care was provided for the affected shoulder. Both groups received exercises aimed at increasing muscle strength and coordination, routinely provided as part of their multidisciplinary rehabilitation. Exercises were selected at the discretion of the treating physiotherapist, and were implemented for up to 10 min/day, reflecting standard practice for patients after stroke with significant activity limitation.

Outcome measures

The primary outcome was shoulder subluxation measured on x-ray and reported in mm. Participants were seated in a chair without armrests, with the arm hanging freely by the side with the elbow extended. A steel ball bearing of known size was taped halfway along the clavicle to act a reference point. Antero-posterior plane x-rays of both shoulders were taken at a focal field distance of 1 metre. Shoulder subluxation was quantified using the method described by Prévost et al[18] which measures the shortest perpendicular distance in millimetres between the most superior part of the head of the humerus and the inferior portion of the glenoid fossa of the affected arm. The amount of subluxation was determined by subtracting the distance in the affected shoulder from that in the unaffected shoulder, by a radiographer blinded to group allocation.

The secondary outcomes were pain, contracture and upper limb activity. Pain was measured using a 10-cm visual analogue scale when the participant was at rest, as well as during passive external rotation of the shoulder, where 0 was no pain and 10 was extreme pain.

Contracture was determined by measuring the difference in range of motion between the intact and affected sides. Shoulder external rotation, forearm supination, wrist extension and hand web space were measured because these are common sites of contracture in people after stroke and the lap-tray had been modified to place these joints on some stretch compared with the arm resting in the lap. An inclinometer was used to measure range of motion of shoulder external rotation, forearm supination and wrist extension. The goniometer was set to zero when the shoulder, forearm and wrist were in the anatomical position and then the joints moved to their end of range of motion and measured in degrees. End of range was defined either as the point when further movement was limited by pain or resistance. Hand web space was measured using a set of standardised cylinders ranging from 4 to 8 cm in diameter. Cylinders of increasing sizes were placed between the thumb and the index finger. The size of the largest cylinder where the web space could maintain contact with the cylinder was recorded.

Upper limb activity was measured using Items 6, 7 and 8 of the Motor Assessment Scale for Stroke[17], summed and reported as a score from 0 to 18, where 0 was no upper limb activity and 18 was very good activity.

Data analysis

All analysis was by intention-to-treat. Statistical significance was set at 0.05. Mean difference (95% CI) between groups was determined for change in shoulder subluxation, pain, contracture, and upper limb activity from baseline to 4 weeks. The sample size was determined to reliably detect a large effect (ie, 0.8 by Cohen's definition), with 80% power at a two-tailed significance level of 0.05.

RESULTS

Flow of participants, therapists, centres through the trial

The flow of participants through the trial is summarised in Figure 2. Forty six participants (26 male, 20 female) aged 69 (SD 10) years old participated in the trial. Twenty-three participants were allocated to the experimental group and 23 were allocated to the control group. Outcomes were collected for 100% of participants, except for subluxation where measures were collected for 96% of the experimental group and 96% of the control group.

Characteristics of the participants at baseline are presented in Table 1. Participants were recruited to the trial 16 (SD 10) days after a stroke and at this time had little spasticity, moderate sensory loss and 17 deg loss of external rotation in their affected shoulder. Experimental and control groups were similar in terms of age, sex, time to admission into the trial, side of hemiparesis, spasticity and sensory loss.

Three rehabilitation units participated in the trial, two in Australia and one in Norway. Two were referred patients from an on-site acute stroke unit, and one from an on-site acute neurology unit. One site in Australia recruited 67% of participants (Table 1). All centres recruited similar numbers of experimental and control participants.

Compliance with trial method

Physiotherapists treating the participants were asked to observe participants twice every weekday, in the morning and evening, and to indicate on a recording sheet whether the set-up of either the lap-tray and triangular sling, or hemi-sling, was correct, not correct, or not observed. If the set-up was not correct, the physiotherapists re-applied the devices according to the instructions. Of the 46 participants, 16 recording sheets were missing, so 30 recording sheets were used to calculate compliance to the intervention. Of 1012 observations, 880 events were correct, 132 events were incorrect and 99 events were not observed. On average, there was 87% compliance to intervention during the four week period.

Effect of intervention

The results of the intervention are presented in Table 2. There was no significant difference between groups after 4 weeks of intervention in terms of shoulder subluxation (MD -3 mm, 95% CI -8 to 3, Cohen's d = 0.3). There was a trend for the experimental group to develop less pain at rest (MD -0.7 out of 10, 95% CI -2.2 to 0.8) and during shoulder external rotation (MD -1.7 out of 10, 95% CI -3.7 to 0.3). There was no significant difference between groups in terms of contracture of forearm supination (MD -5 deg, 95% CI -17 to 7), wrist extension (MD 1 deg, 95% CI -7 to 9) or webspace (MD 0 cm, 95% CI -1 to 1), but a trend towards the experimental group having less contracture of shoulder external rotation (MD -10 deg, 95% CI -22 to 2). There was no significant difference between groups in terms of activity of the upper limb (MD -1.0 out of 18, 95% CI -2.6 to 0.6).

DISCUSSION

This prospective, multicentre, single-blind randomised trial found that in acute stroke survivors with significant motor impairment of the upper limb, a modified lap-tray during sitting and a triangular sling during standing was no more effective than a hemi-sling at preventing subluxation in the affected shoulder after 4 weeks. There was also no effect of the lap-tray and triangular sling on contracture of three joints (forearm supination, wrist extension, hand web space) or upper limb activity. There was some suggestion that the lap-tray and triangular sling may prevent pain and shoulder external rotation contracture.

The stratified randomization ensured that those with more severe impairment were allocated evenly across groups. Even though both groups were at high risk of shoulder subluxation due to severe weakness and activity limitation, on average there was only 4 mm of subluxation two weeks after stroke and this had only increased to 7 mm four weeks later. That is, participants did not develop much subluxation during the intervention phase of the trial. This may indicate that both the lap-tray and the hemi-sling were effective in preventing shoulder subluxation or that early active rehabilitation is sufficient to prevent subluxation. However, rehabilitation did not improve upper limb activity, with participants scoring only 2 out of 18 on the Motor Assessment Scale for Stroke[17] after four weeks of intervention, indicating that they remained very weak and disabled.

There was a trend for the lap-tray in sitting and triangular sling in standing to result in less pain at rest and during movement. On average, participants had little pain at rest, scoring only 1.0 cm out of 10 at four weeks. There was more pain on movement, with the difference between groups at four weeks (1.7 cm out of 10) being clinically meaningful[19]. However, a larger sample would be required to have sufficient power for this result to be statistically significant.

Despite participants in the experimental group being positioned in more external rotation of the shoulder, forearm supination, wrist extension and thumb conjunct rotation than the control group, there was no effect on the development of contracture. Contracture was quite severe at the beginning of the trial and became more severe over time. This may be because, even though the muscles were on some stretch across the joints, this was not enough to counteract the effect of severe weakness and disability which still remained four weeks later. It may also be because participants were not positioned at the end of available range of motion and that prevention of contracture requires passive and/or active movement through joint range, which these participants were unable to perform. There was a suggestion that participants in the experimental group developed less shoulder external rotator contracture, in the realm of 10 deg. However, the control group had more severe external rotation contracture at baseline and therefore may have been more likely to develop further contracture.

This study has both strengths and limitations. Potential bias was reduced by using a concealed randomisation process that was stratified for severity to allocate participants to groups, so that the control and experimental groups were similar for nearly all characteristics at baseline. The assessors were blinded to group allocation, data were available for 100% of participants for all but one outcome, and 96% of participants for that outcome. Intention-to-treat analysis was also employed. These aspects of the trial increased the rigour of the findings. The limitations of the study were, first, the number of participants was small. However, there was enough power because if we use 5 mm of subluxation as the effect we are trying to detect[14], then the CI only just crosses it, suggesting that there is only a very small chance that lack of power is responsible for the finding. It is more likely that there really is little effect. Second, the participants and therapists could not be blinded, therefore are a potential source of bias.

CONCLUSION

There are several clinical implications of this study. First, the use of a lap-tray during sitting and triangular sling during standing is not indicated as an alternative to the hemi-sling to prevent shoulder subluxation or pain in patients after stroke with a paralysed or very weak upper limb. Second, the use of a lap-tray that positions the upper limb in shoulder external rotation, forearm supination, wrist extension and thumb conjunct rotation is not indicated to prevent contracture of these muscle groups in stroke survivors with a paralysed or very weak upper limb. Finally, alternative strategies with proven efficacy, such as electrical stimulation[20], should be considered in order to prevent shoulder subluxation in people early after stroke who are very weak and disabled. Furthermore, cyclical electrical stimulation not only prevents subluxation, but also increases strength and activity[21].

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