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Title Page

Full Title of Article:
Suprascapular Nerve Block For Shoulder Pain In the First Year After Stroke: A Randomised Controlled Trial

Cover Title:
Suprascapular Nerve Block For Post Stroke Shoulder Pain

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Abstract

Background and Purpose: Shoulder pain is a common complication after stroke which can impede participation in rehabilitation and has been associated with poorer outcomes. Evidence based treatments for hemiplegic shoulder pain are limited. Suprascapular nerve block (SSNB) is a safe and effective treatment of shoulder pain associated with arthritic shoulder conditions, but its usefulness in a stroke population is unclear.

Methods: We undertook a randomised controlled trial assessing the effectiveness of SSNB in a population of 64 stroke patients (onset < 1 year) with hemiplegic shoulder pain. The primary outcome was pain measured on a visual analogue scale (VAS). Secondary outcomes were disability (Modified Rankin Scale, Croft Disability Index) and quality of life (EuroQol Health Questionnaire). All participants were assessed prior to randomisation, and at 1, 4 and 12 weeks post intervention. Both groups continued with routine therapy.

Results: Whilst both intervention and control groups demonstrated reduction in pain score, participants who received SSNB consistently demonstrated superior, statistically significant pain reduction compared to placebo. Mean VAS reduction in the SSNB group was over 18mm greater than participants receiving placebo injection. The number needed to treat with SSNB to reduce one stroke survivor's pain by 50% at four weeks is 4. No significant differences in function or quality of life were observed. No adverse events were reported.

Conclusions: Suprascapular nerve block is a safe and effective treatment for patients with hemiplegic shoulder pain.

Clinical Trial Registration Information: This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) - ACTRN12609000621213.

Text

Introduction:

Shoulder pain is a distressing complication of hemiplegia[1] and is one of the four most commonly reported medical complications of stroke[2]. The aetiology of hemiplegic shoulder pain is multifactorial[3,4] and contributions have been described from biomechanical changes[1,5], spasticity[6,7] and central-pain mechanisms[8,9].

Population based studies suggest that approximately one quarter of stroke survivors develop hemiplegic shoulder pain[10,11], though higher rates of 52-54% have been reported in large studies using retrospective[12], prospective[13] and literature review[14] methodologies. Hemiplegic shoulder pain is associated with reduced functional ability[15], a higher incidence of depression[15], interference with rehabilitation and an increased length of hospitalisation[16].

Despite the high incidence and significant impact of shoulder pain post stroke, there is little robust evidence to inform clinical practice[17,18] with reviews examining the management of hemiplegic shoulder pain concluding that further efforts are required to examine intervention options[1,17,18].

Published systematic reviews have not included information on the use of suprascapular nerve block (SSNB) as an intervention type due to the emerging nature of this procedure in stroke populations and a lack of robust trials. Since commencement of this trial, two small trials have been published in this field[19,20]. Comparison of SSNB with intra-articular steroid injection[20] did not demonstrate either treatment to be superior, whilst in a preliminary study[19] of ten people,

comparison of SSNB with ultrasound treatment trended toward greater improvement in the SSNB group. Conclusions regarding the efficacy of SSNB are unable to be drawn from these studies due to small numbers, absence of power analysis and absence of placebo control.

Suprascapular nerve block has been shown to be a safe[21] and efficacious treatment for shoulder pain associated with rheumatoid arthritis and degenerative shoulder conditions[22,23,24]. It is unclear whether the results of these trials can be generalised to people with non-arthritic shoulder pain. The objective of our study was to compare the effect of SSNB to placebo on shoulder pain in a population of stroke survivors in the first year after stroke. The secondary objective was to examine the effects on function and quality of life.

Methods:

The study design is a parallel group, randomised, placebo controlled trial. Sixty four participants gave written informed consent and were randomly assigned to an experimental group (suprascapular nerve block) or placebo group (normal saline injection). A protocol paper was published at commencement[25].

Setting

Participants were recruited from acute stroke and rehabilitation wards across Adelaide, South Australia between 2009 and 2012. Ethics approval was granted for all sites, including

Repatriation General Hospital, Flinders Medical Centre, The Queen Elizabeth Hospital, Hampstead Rehabilitation Centre, Griffith Rehabilitation Hospital and Calvary Rehabilitation Hospital. Participants were recruited following education sessions and provision brochures to each facility.

Participants and Eligibility Criteria

Participants were required to be aged over 18 years with a diagnosis of acute stroke within the previous 12 months, and to report hemiplegic shoulder pain with a minimum VAS of 30 mm (100 mm scale). Minimum pain score was selected in the clinical context that invasive interventions are not routine for mild pain. Exclusion criteria included significant cognitive impairment (Mini-Mental State Examination < 23) or language deficits (inability to follow 2-stage command, limited English) that might affect the reliability of responses to outcome measures scales. Hypersensitivity to injection agents excluded participation.. Following protocol publication and trial commencement, authors decided to exclude palliative patients, as it was deemed unethicial to knowingly offer placebo during palliation.

Randomisation, Treatment Allocation and Blinding

A computer generated randomised number sequence allocated participants to either the intervention or the control group. Randomisation was managed by a Clinical Trials Pharmacist external to the study. Allocation was assigned after baseline assessment. The principal investigator (ZA) was responsible for eligibility assessment, consent, baseline assessment and injection of all participants. Where she was involved in treating the participant, consent was obtained by another investigator. All outcome assessments were completed by one

physiotherapist who was masked to treatment allocation. Participants and treating staff remained masked to allocation.

Interventions

Participants were randomly assigned to receive either a suprascapular nerve block or a placebo subcutaneous normal saline injection. The principal investigator (ZA) was responsible for syringe preparation, and was aware of the allocation as the injection technique and appearance of syringe contents varied between groups. Both groups continued to receive routine therapy Syringe size and needle gauge (10ml syringe and a 21 gauge 38mm needle) were consistent across both groups. Blinding of participants was maintained by consistent preparation and positioning of all patients, and and all received a 2ml subcutaneous infiltration of 1% lidocaine prior to injection.

The experimental group received a suprascapular nerve block injection with 1ml of 40mg/ml methylprednisolone and 10ml 0.5% bupivacaine hydrochloride. The technique used for SSNB has been used in a prior trial[22]. Anatomical landmarks were used to determine injection site into the supraspinous fossa (please see http://stroke.ahajournals.org). The needle was introduced parallel to the scapula blade and the syringe contents slowly injected into the enclosed space of the supraspinous fossa. The placebo group received an injection of 5 ml normal saline infiltrated subcutaneously to the same region of the shoulder.

Outcomes

Participants were assessed prior to randomisation and at 1, 4, and 12 weeks following injection. Demographic data collected included age, gender, dominance, duration since stroke, stroke type and location. The primary outcome of pain was measured using a vertical Visual Analogue Scale (VAS). This measure involves a 100mm vertical line anchored with the extremes of subjective pain. Self-perceived pain severity is rated and recorded in millimetre readings[26]. The VAS is easy to use, readily reproducible[27], validated in a stroke population[28] and a commonly used in prior research. A minimum VAS change of 20mm is reportedly required to achieve clinically significant pain reduction for patients with initial pain scores >60 mm[26]. Secondary outcomes of disability and quality of life were measured using the Modified Rankin Scale[29], Croft Disability Questionnaire[30], and the EuroQol Health Questionnaire[31]. The Croft Disability Questionnaire includes twenty-two questions regarding disability associated with shoulder pain. This validated measure was chosen due to applicability in a more dependent population. The minimal level of detectable change (90% confidence) is defined as 3 points.

Sample Size and Statistical Analysis

A prospective sample size calculation, previously described in protocol paper[25], calculated that a sample size of 26 participants per group was required to achieve a statistically and clinically significant difference between the two groups (power 80%, alpha 0.05). Minimally significant clinical change in VAS was set at 20mm. Allowing for an attrition rate of 20% to accommodate deaths and withdrawals, we aimed to recruit a total of 66 participants, 33 per group.

Research into the efficacy of SSNB in shoulder pain associated with rheumatoid arthritis[22] demonstrated a mean VAS difference of 22.9mm at one week, with the intervention superior to

placebo. This study was used to assist in the development of the power calculation, with the hypothesis that treatment with SSNB would reduce hemiplegic shoulder pain by the minimally important clinical change of 20mm when compared to placebo injection.

All data entry was completed by a research assistant masked to allocation. Data was exported into IBM SPSS (version 20) for statistical analyses on an intention to treat basis. Independent samples t-tests, Mann-Whitney U tests and Chi-square test of association were used to compare groups at baseline. Repeated measures were analysed using a generalized linear mixed model due to advantage in dealing with missing values (maximum likelihood analysis)[32] and the robust approach to calculation of effect. Results of primary outcomes are expressed as means with 95% confidence intervals. The level for statistical significance for hypothesis tests was set at 0.05. Linear regression analysis was performed to assess potential associations in responding patients. EQ-5D weights were derived using the Australian general population algorithm[33].

Results:

Of 129 persons assessed for eligibility, 64 were enrolled and randomised into two groups (Figure 1). Reasons for exclusion are tabulated in online supplement (please see http://stroke.ahajournals.org). The mean time from stroke onset to trial referral was 12 weeks; 11(SD 8) weeks for control group and 13(SD 9) weeks for intervention group. The mean difference between scheduled and actual follow up was less than one day for all time points.

Three participants in the control group were lost to follow up. One further control participant was not available for follow up at four weeks, but was available at subsequent time points. One participant from the control group and three from the intervention group were unable to be contacted at 12 weeks. A total of 29 participants in the intervention group and 28 in the control group completed the trial with an overall attrition rate of 11%.

The demographic characteristics of participants at baseline were similar across groups (Table 1). The groups were well matched on stroke severity (NIHSS), motor weakness of the affected upper limb, and pain severity (VAS). Percentages of infarct versus haemorrhage were comparable, and Oxfordshire stroke classification demonstrated equivalent numbers of anterior and posterior circulation strokes. Potentially confounding factors such as spasticity and subluxation were also similar. No gender-based differences were detected.

Primary Outcomes

Results for the primary outcome of pain (VAS) are summarised in Table 2 and Figure 2. Mean pain scores at baseline were comparable across the groups ($p=0.379$). Pairwise contrasts between groups were statistically significant at all follow up time points, with the SSNB group consistently demonstrating greater mean VAS reduction when compared to placebo ($p=0.02$ at Week 1, $p=0.01$ at Week 4, $p=0.02$ at Week 12). Linear regression analyses were performed to assess associations and predictors of responders. There were no statistically significant associations between any of the variables assessed; namely age, gender, spasticity (Modified Ashworth Scale), stroke severity (baseline NIHSS) or disability (Croft Disability Index).

Secondary Outcomes

There were no differences between groups at any follow up time point in the secondary outcomes of disability and quality of life which were assessed with Modified Rankin Scale (mRS), Croft Disability Scale and EuroQol Health Questionnaire (EQ-5D). Both the intervention and control groups recorded a mean mRS score of 4(SD 1) at baseline. The majority of participants in both groups had a mRS of 3 or 4 (moderate – moderately severe disability) at all time points. The mean change in Croft Disability Index was non-significant between groups and at each follow up time point. EQ-5D weights for both groups reflected improved health-related quality of life over time, independent of effect from group allocation.

No adverse effects were reported.

Discussion

Comparable clinically important variables at baseline reflected successful randomisation. Whilst there was a higher proportion of total anterior circulation strokes (TACS) in the control group, the composite of total and partial anterior syndromes (TACS and PACS) was evenly distributed (81.3% in control group, 84.4% in intervention group). It is possible that subjective pain report in participants with TACS may have been influenced by higher cortical dysfunction, though the authors accounted for this in exclusion criteria. Whilst the difference of 4.12mm in baseline VAS between groups did not reach clinical or statistical significance, it could indicate a potential

confounding factor. The mean time between stroke onset and enrolment was similar between groups, in keeping with the typical nadir of hemiplegic shoulder pain at the 2-3 month mark[34].

A single SSNB injection provides superior reduction in hemiplegic shoulder pain in comparison to placebo injection. The SSNB group demonstrated a mean VAS reduction of approximately 37mm, with an 18mm difference between intervention and control groups, maintained at each assessment. The definition of a minimal clinically important change on the 100mm VAS has been debated; papers report clinical importance from as little as 12mm[35]-15mm[36], up to 30mm[37,38]. In our pre-trial protocol we aimed for a VAS change of 20mm to reach a robust level of clinical importance[26]. In order to consider our results in a clinically relevant context, data were subsequently reviewed to assess the percentage of responders who achieved criteria for patient defined successful[37] pain reduction of 50% and 30mm. The 4 week time point was taken to be of highest clinical interest, given the known pharmacodynamics of the active injection agent. At 4 weeks, 78% of all participants receiving SSNB reported any improvement in symptoms, with 80% of these responders demonstrating $\geq$ 20mm VAS pain reduction. The number needed to treat with SSNB to achieve a clinically significant pain reduction of 50% in one person was 4 (95%CI 3-29) at four weeks and 4 at twelve weeks (95%CI 2-25).

The marked placebo response (mean change of 25mm) is expected[39] in a subjective outcome trial utilising a sham injection, and is consistent with other studies of SSNB[22]. A degradation of this effect over follow up might have been expected[22] and we hypothesize that the maintained placebo response over time may reflect the natural history of hemiplegic shoulder pain as compared to degenerative shoulder conditions.

Despite significant pain reduction, there was no impact on the secondary outcomes of function and quality of life. . The self reporting of health-related quality of life following stroke is affected by multiple factors, and improvement in a single variable of pain was insufficient to improve overall quality of life. Pain reduction may allow for more intensive therapies which could impact future independence.

Suprascapular nerve block is not a new intervention[40]. There has been an increasing body of literature in non-stroke populations, describing the SSNB as a simple, successful and reproducible intervention. As evidenced by results of this trial, the breadth of application of this intervention continues to expand. The suprascapular nerve involves a high proportion of sympathetic fibres, and supplies 70% of pain fibres to the shoulder.. The mechanism of initial pain reduction is attributed to blocking these sensory fibres[23] and reducing nociceptive input to the central nervous system[20]. Lack of degradation of treatment effect by 3 months suggests an additional potential mechanism in this population. It has been postulated[22] that there may be a reduction in central sensitisation secondary to diminished nociceptive stimulus as a potential effect of SSNB. This is in keeping with more recent studies which have identified features consistent with somatosensory sensitisation in patients with HSP, suggesting both nociceptive and neuropathic components[9] of pain.

Strengths and Limitations

This is the first randomised controlled study to investigate SSNB as a treatment for hemiplegic shoulder pain. We recruited from stroke and rehabilitation settings across the city and believe our findings are generalisable to clinical practice. A single injector and single outcome assessor

throughout this study reduced the risk of variations in technique and assessments. In future studies, alternatives to the Croft Disability Index could be considered. In practice, this questionnaire did not clearly delineate between disability secondary to hemiplegia and limitations secondary to pain.

The major limitation of this trial is that it is a small study with a comparatively short follow up period of 3 months. Estimation of treatment effect may be greater in this current study given the influence of a smaller sample size[41]. Further work is required with larger sample size, with the aim of identifying characteristics of clinical responders and clarifying the mechanism of therapy effect in this population.

Summary / Conclusion:

Suprascapular nerve block is a safe and effective treatment option for patients with hemiplegic shoulder pain in the first year after stroke. The intervention is easily reproducible in the clinical setting, offering a practical and important advance for this patient population.

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Conflict of interest statement / disclosures:

All authors state that there are no conflicts of interest to declare.

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Tables

Table 1. Baseline characteristics of participants with hemiplegic shoulder pain

Baseline Variable	Control (n=32)	Intervention (n=32)
Age in years		
0-65	16 (50%)	15 (46.9%)
66-79	13 (40.6%)	19 (28.1%)
80+	3 (9.4%)	8 (25%)
Number (%) male	15 (46.9%)	21 (65.6%)
Number (%) right hemisphere stroke	21 (65.6%)	23 (71.9%)
Number (%) right hand dominant	26 (81.3%)	29 (90.6%)
Duration post stroke in weeks *mean (SD)*	11 (8)	13 (9)
NIHSS* *mean (SD)*		
Total[†] NIHSS	8 (4)	7 (3)
Motor score[‡] affected arm	2 (1)	2 (1)
Stroke Type		
Number (%) Infarct	29 (90.6%)	27 (84.4%)
Number (%) Haemorrhage	3 (9.4%)	5 (15.6%)
Oxfordshire classification[§]		
TACS	10 (31.3%)	6 (18.8%)
PACS	16 (50.0%)	21 (65.6%)
LACS	4 (12.5%)	2 (6.3%)
POCS	1 (3.1%)	2 (6.3%)
Other	1 (3.1%)	1 (3.1%)

Number with subluxation (%)	10 (31.3%)	10 (31.3%)
Modified Rankin Scale *mean (SD)*	4 (1)	4 (1)
Croft Disability Q *mean (SD)*	12 (5)	12 (4)
Modified Ashworth Scale		
0	16 (50%)	16 (50%)
1	11 (34.4%)	11 (34.4%)
2	5 (15.6%)	2 (6.5%)
3	0 (0%)	2 (6.5%)

Values are number (%) unless otherwise stated
*NIHSS = National Institute of Health Stroke Scale
[†]NIHSS total score 5-15 = moderate severity stroke
[‡]NIHSS motor score upper limb of 2 = some effort against gravity, limb cannot get to or be maintained at 90°
[§]Oxfordshire Classification: TACS = total anterior circulation syndrome; PACS = partial anterior circulation syndrome; LACS = lacunar syndrome; POCS = posterior circulation syndrome

Table 2. VAS pain scores between groups by treatment allocation

Time point	Control Mean (95% CI)	Intervention Mean (95% CI)	Pairwise Contrast Control-intervention	P value
Baseline	73.03 (66.10-79.99)	68.91 (62.25-75.56)	04.12	0.379
1 week	47.90 (36.58-59.21)	29.78 (19.29-40.23)	18.12	**0.02***
4 weeks	49.73 (40.62-58.83)	31.69 (21.40-41.97)	18.04	**0.01***
12 weeks	46.20 (34.63-57.78)	28.14 (17.81-38.46)	18.06	**0.02***

* Statisically significant

Sequential Bonferroni adjusted significance level is 0.05

Confidence interval bounds are approximate

Figure 1. Flow of Participants Through Study

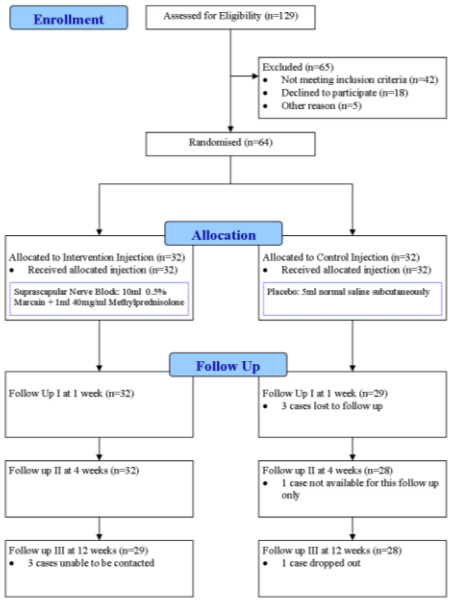

Figure 2: VAS pain scores between groups by treatment allocation