The SAInT study: a protocol for a randomized controlled trial of steroid injection for subacromial pain syndrome using the anterolateral versus posterior approach

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Aims

Steroid injections are used for subacromial pain syndrome and can be administered via the anterolateral or posterior approach to the subacromial space. It is not currently known which approach is superior in terms of improving clinical symptoms and function. This is the protocol for a randomized controlled trial (RCT) to compare the clinical effectiveness of a steroid injection given via the anterolateral or the posterior approach to the subacromial space.

Methods

The Subacromial Approach Injection Trial (SAInT) study is a single-centre, parallel, two-arm RCT. Participants will be allocated on a 1:1 basis to a subacromial steroid injection via either the anterolateral or the posterior approach to the subacromial space. Participants in both trial arms will then receive physiotherapy as standard of care for subacromial pain syndrome. The primary analysis will compare the change in Oxford Shoulder Score (OSS) at three months after injection. Secondary outcomes include the change in OSS at six and 12 months, as well as the Pain Numeric Rating Scale (0 = no pain, 10 = worst pain), Disabilities of Arm, Shoulder and Hand questionnaire (DASH), and 36-Item Short-Form Health Survey (SF-36) (RAND) at three months, six months, and one year after injection. Assessment of pain experienced during the injection will also be determined. A minimum of 86 patients will be recruited to obtain an 80% power to detect a minimally important difference of six points on the OSS change between the groups at three months after injection.

Conclusion

The results of this trial will demonstrate if there is a difference in shoulder pain and function after a subacromial space steroid injection between the anterolateral versus posterior approach in patients with subacromial pain syndrome. This will help to guide treatment for patients with subacromial pain syndrome.

Take home message

- The Subacromial Approach Injection Trial (SAInT) will provide evidence to guide which approach to use for steroid injections in the treatment of subacromial pain.
- The findings of this trial may help to improve clinical outcomes in the management of subacromial pain syndrome.

Bone & Joint Open

Introduction

Shoulder pain is a common symptom, with an estimated 15 patients per 1,000 presenting to their general practitioner (GP) with shoulder pain every year.[1] Subacromial pain syndrome may account for a substantial proportion of cases with shoulder pain attributed to a variety of causes, including inflammation or degeneration of the subacromial structures.[2] The diagnosis of subacromial pain syndrome is clinical based on the symptoms and signs. Shoulder pain over the deltoid muscle area and difficulty in performing overhead activities are some of the symptoms associated with subacromial pain syndrome.[2] Steroid injections are commonly used in the treatment of subacromial pain as well as other shoulder conditions,[3] as part of the management ladder.[4,5] Although subacromial pain syndrome has multiple potential underlying causes (such as subacromial impingement, rotator cuff tendinopathy, rotator cuff tears, subacromial bursitis, and calcific tendinopathy), which often co-exist, the injection management of subacromial pain syndrome may be the same no matter what the underlying specific pathology.[2] Such injections may be administered by a wide variety of clinicians including GPs, physiotherapists, rheumatologists, and orthopaedic surgeons.[6,7] In a survey of 157 consultant shoulder surgeons who were members of the British Elbow and Shoulder Society (BESS), subacromial steroid injection was used by 95% for the management of subacromial impingement. Furthermore, 86% of surgeons repeated the injection if the patient failed to respond to a previous injection by their GP. Most respondents would consider a combination of subacromial injection along with physiotherapy for at least three months before proceeding with surgery.[7]

Identifying factors that influence the effectiveness of subacromial injections may help to guide clinical practice and improve patient care. One such factor may be the approach via which the injection is administered into the subacromial space. Subacromial injections may be administered via different approaches to the subacromial space and can be broadly divided into anterior, posterior, or lateral (including the anterolateral) approaches.[4] The aim of such injections is to infiltrate the subacromial bursa, which is thought to be the origin of the subacromial pain.[8] Previous studies have assessed the location of the subacromial bursa, as well as the accuracy of various injection approaches in relation to where the tip of the needle used to administer the injection is in the subacromial space, and where the injectate is administered.[9–15] However, there is limited evidence examining the clinical effectiveness of the anterolateral versus posterior approach for improving symptoms and function. In this study, we are evaluating the anterolateral versus posterior approach to the subacromial space, as we feel that these are the two most commonly used approaches for injections to the subacromial space. These approaches are also the ones that have been extensively investigated previously with regards to accuracy of needle insertion.

Beals et al[9] conducted an anatomical study in 17 fresh-frozen cadavers, and showed that the subacromial bursa occupied the anterior half of the anteroposterior distance of the acromion, and its margins extended to 2 cm or more from the acromion's anterolateral corner. Such an anterior location of the bursa suggests that it may be reached more easily via the anterolateral or anterior approach, and this is supported by various cadaveric as well as in vivo clinical studies. Sardelli and Burks[10] assessed the ability of a standard needle to reach the subacromial bursa through three commonly used approaches. A total of 30 patients without a rotator cuff tear underwent arthroscopic evaluation of their shoulder, and a spinal needle was inserted into the subacromial space via an anterior, lateral, or posterior approach, without shaving or otherwise disturbing the bursa, and the distance of the tip of the needle, i.e. the subacromial bursa, to the skin was determined. The mean distance of the bursa to the skin was 2.9 cm (SD 0.6) with anterior needle placement, 2.9 cm (SD 0.7) with the lateral approach, and 5.2 cm (SD 1.1) with the posterior approach. It was thus concluded that the distance from the skin to the subacromial bursa using the anterior or lateral approach is within reach of a standard 22- or 25-gauge needle, while the distance to the subacromial bursa from a posterior approach was almost double and hence may not be reachable with such a needle. Of interest, there was no correlation between the distance to the subacromial bursa and the patient's BMI with either approach. It was suggested that a longer needle may improve the accuracy of placement when approaching the subacromial bursa from a posterior approach, but a standard-length needle may suffice when approaching the bursa via the lateral or anterior approach. Marder et al[11] conducted a trial whereby 75 shoulders were randomly assigned to receive a subacromial injection containing radiopaque contrast, steroid, and local anaesthetic through an anterior, lateral, or posterior approach. The accuracy of injection was assessed using radiographs and was 92% for the lateral approach, 84% for the anterior approach, but only 56% for the posterior approach ($p = 0.006$). Furthermore, the accuracy of injection was lower in females compared to males ($p < 0.006$). In males, there were no differences between the routes, with accuracy rates of 93% for the lateral, 92% for the anterior, and 89% for the posterior approach. In contrast, in females the accuracy of injection was significantly lower for the posterior (38%) compared to the anterior (77%) or lateral (91%) approach ($p < 0.050$). Based on these findings, it was concluded that the anterior and lateral routes of subacromial bursal injection were more accurate than the posterior route, especially in females.

The accuracy of the anterolateral approach and the ability of fluoroscopy to assess this reliably have been questioned by Mathews and Glousman,[12] who attempted to inject the subacromial bursa in 40 cadaveric shoulders with radiocontrast via an anterolateral or posterior approach. A total of 20 shoulders were also injected with methylene blue and subsequently dissected. The anterolateral approach was accurate as determined by fluoroscopy in 18 cases (90%), but in only six of ten shoulders (60%) as determined by dissection. The posterior approach was accurate as determined by fluoroscopy in 16 shoulders (80%), and in eight of ten cases (80%) as determined by dissection. The authors concluded that the accuracy rates of the anterolateral and posterior approaches to subacromial bursa injections did not differ significantly, and that the anterolateral approach may result in the injected solution being located medial to the medial boundary of the subacromial bursa, which may not be accurately assessed by fluoroscopy.

There is conflicting evidence whether the accuracy of injecting the subacromial bursa is related to the improvement

in clinical outcomes. Henkus et al[13] assessed the accuracy of subacromial bursa injections by a posterior or anteromedial approach. Overall, 33 patients with clinical signs of subacromial impingement had an injection of steroid, local anaesthetic, and contrast followed by MRI to determine the actual site of injection. The bursa was randomly infiltrated posteriorly (n = 17) or anteromedially (n = 16). A total of 13 injections (76%) were found to be in the subacromial bursa with the posterior approach, and ten (69%) with the anteromedial approach. On some occasions, other structures were found to be injected instead of the bursa, such as the rotator cuff. The confidence of the orthopaedic surgeon with regards to the accuracy of where the injection was administered correlated positively with the MRI findings in only 66% of cases. Injection of the subacromial bursa resulted in a significant improvement in pain (p = 0.004) and functional scores, while injection in the bursa and rotator cuff muscle led to a significant increase in pain (p = 0.032) with no change in clinical scores. The authors concluded that injections of the subacromial bursa are inaccurate, despite the clinician being confident as to their administration. In contrast to the study by Henkus et al,[13] a study by Yamakado[14] suggested that the exact site of administration of the injectate may not be related to its effect on subacromial pain. A total of 56 shoulders with subacromial impingement signs underwent a subacromial injection of steroid, local anaesthetic, and radiological contrast via the lateral approach. Plain radiographs were used to determine the structure reached by the injection, while impingement pain was assessed before and 15 minutes after the injection. Overall, 39 of 56 injections (70%) were considered to have reached the subacromial bursa; 12 (21%) entered the deltoid muscle, two (4%) were in the glenohumeral joint, and three (5%) were subcutaneous. However, the subacromial bursal and intra-deltoid injections showed no significant differences in pain reduction (1.5 vs 1.7 in the Neer impingement sign and 1.6 vs 1.6 in the Hawkins impingement sign). It was thus concluded that a high proportion of subacromial injections miss the subacromial bursa, but despite this an improvement in impingement pain can still be achieved. Along similar lines, Ganokroi et al[15] randomly assigned 50 shoulders to a mid-lateral or posterior subacromial steroid injection, and reported that the accuracy of injecting the subacromial bursa was 92% with the mid-lateral approach versus 68% with the posterior approach (p < 0.034). However, the University of California Los Angeles (UCLA) shoulder score[16] and visual analogue scale pain score improved in both groups at 30 minutes post injection compared to just prior to the injection, with no significant difference between the two approaches (p > 0.05). The latter two studies have thus questioned the necessity of specifically injecting the subacromial bursa compared to injecting anywhere in the subacromial space.

It is obvious from the above discussion that there is uncertainty as to the influence of the exact location of administering the injectate and the improvement in clinical outcomes, especially whether there is a need to inject the bursa at all. Hence, understanding the clinical effectiveness of each approach on patients' symptoms would be of immense value. In relation to this, Ogbeivor[17] undertook a systematic review to compare the effectiveness of the anterior, lateral, and posterior injection approaches in the treatment of subacromial impingement syndrome. He concluded that the evidence for the superiority of any one method of subacromial injection approach over the other is unclear in clinical practice, and called for further research into this area.

There is thus a sparsity of high-quality evidence comparing the effectiveness of various injection approaches in the management of subacromial pain syndrome. In a randomized trial, Ogbeivor et al[18] compared the effectiveness of the lateral and posterior subacromial injection approaches for the treatment of subacromial impingement syndrome in an outpatient community musculoskeletal service. They reported greater improvement in daytime pain when using the lateral compared to the posterior approach between weeks zero and eight post injection (difference of 1.4 points on an 11-point Numerical Pain Rating Scale (NPRS)[19] between the two approaches (95% CI 0.3 to 2.6; p = 0.018)). There were no statistically significant differences between the groups with regards to night-time pain, shoulder function, and functional scores (as determined by the Shoulder Pain and Disability Index).[20] There was a statistically and clinically significant difference (p = 0.001) within the groups for all clinical outcomes between weeks zero and eight, and between weeks zero and 12. However, that trial compared the mid-lateral approach to the subacromial space rather than the anterolateral approach, which our proposed trial aims to evaluate. Furthermore, all injections were done by a single physician, which may limit the wider applicability of its findings.

Understanding the effectiveness of the various approaches to the subacromial space and the differences in outcomes would provide an evidence-based determination as to the best choice of approach. Furthermore, when faced with a patient who had previously undergone a subacromial steroid injection without substantial improvement in symptoms, it may allow the clinician to determine whether this was due to the approach employed, and hence the need to repeat the injection using an alternative approach, or whether it could be attributed to a lack of efficacy of the injectate to improve the patient's symptoms.

Given the limited available information as to the effectiveness of the different approaches of subacromial injection, the proposed trial aims to provide evidence to guide clinical practice. This trial may provide information to help effectively treat subacromial pain syndrome and improve resource allocation.

The overall objective is to determine if there is a difference in the effectiveness of a steroid injection, given for shoulder subacromial pain syndrome, when administered via an anterolateral compared to a posterior approach. Effectiveness will be measured in relation to objective improvements in pain and function. The null hypothesis is that there is no difference between the two approaches.

Methods

This is a single-centre, parallel, two-arm randomized clinical trial, carried out at Blackpool Victoria Hospital, Blackpool, UK. The trial is expected to take a total of 60 months or until recruitment is complete. The trial started recruiting in December 2020. The trial takes place at a single-site NHS Foundation Trust. Trial management will be conducted by the research and development team at Blackpool Teaching Hospitals NHS Foundation Trust.

Eligibility

The inclusion criteria is patients diagnosed with shoulder subacromial pain syndrome based on clinical symptoms and signs, aged ≥ 18 years, who have capacity to give valid consent for participation, and can complete the follow-up. In order to reflect routine clinical practice, patients with a previous injection will be included without a limit as to the number of previous injections having been administered.

The exclusion criteria is patients aged < 18 years, lacking capacity/unable to give valid consent for participation, full-thickness rotator cuff tear diagnosed on either ultrasound scan or MRI, unable to complete follow-up, and unable to speak or read English. The duration of symptoms prior to treatment will not influence recruitment. We will exclude full-thickness rotator cuff tears, as they are considered a different entity whereby there is communication between the subacromial space and glenohumeral joint (hence a larger distribution area of the injectate), and whereby the biomechanics of the shoulder may be altered, contributing to the patient's symptoms.

Consent

Informed written consent will be obtained during the initial clinic visit or subsequently, after the patient has had adequate time to read the information leaflet, digest the information, and ask any questions they may have, as well as express their views/wishes.

Randomization

After enrolment, study participants will be randomized to either the anterolateral or posterior injection approach on a 1:1 basis. We will be using blocked randomization with random block sizes of four, six, and eight. The randomization sequence will be generated using the R software package 'blockrand'.[21] Patients will be randomized by the selection of sealed envelopes with one of the two approaches listed inside. The envelopes will be generated in advance by the research team and will be unidentifiable once sealed.

Blinding

Patients and clinicians will not be blinded to treatment allocation to maintain a pragmatic approach to the patient's journey. However, the treatment modality will be coded in final analysis so that the statistician remains blinded to which treatment is which until analysis is complete.

Post-recruitment withdrawals

Patients will be free to withdraw from the study at any time. The patient will continue to receive standard care if unable to continue in the study for whatever reason. If the patient fails to attend the follow-up clinic visit, then a letter will be sent to the patient and copied to the GP as is done routinely when a patient does not attend. A follow-up appointment will then be booked for the nearest possible date. If participants withdraw from the study, any information already obtained will be included in the analysis of the study.

Decline to participate

During the study, the number of patients assessed for eligibility and reasons for any exclusion will be recorded.

Pre-treatment assessment

Patients who present to the orthopaedic outpatient department and are subsequently diagnosed with shoulder subacromial pain syndrome may be treated with a steroid injection along with a course of physiotherapy. Diagnosis of subacromial pain syndrome will be based on clinical examination along with any radiological investigations (plain radiographs, ultrasound, MRI as per the discretion of the treating clinician). The exclusion of a full-thickness rotator cuff tear will be based on either ultrasound scan or MRI according to the discretion of the treating clinician. Eligible participants who consent to participate in the trial will then be randomly allocated to the anterolateral or posterior approach.

Trial intervention

Participants will be randomly allocated to one of two groups: 1) Group one – subacromial space injection administered via the anterolateral approach – given about 1 cm below and behind the anterior edge of the acromion with the needle aiming towards the under surface of the acromion (10 ml syringe containing 10 ml of 0.25% Marcaine with 40 mg triamcinolone using a 40 mm 21-gauge needle); 2) Group two – subacromial space injection administered via the posterior approach – given about 1 cm inferior and medial to the posterolateral acromial edge with the needle pointing towards the anterolateral aspect of the acromion (10 ml syringe containing 10 ml of 0.25% Marcaine with 40 mg triamcinolone using a 40 mm 21-gauge needle).

The injections will be administered by clinicians trained and experienced in administering such injections (clinic orthopaedic consultant, extended scope physiotherapy practitioners, and senior orthopaedic doctors).

Physiotherapy rehabilitation

Following both injections, patients will be taken through a protocol of physiotherapy. The frequency of appointments with physiotherapy will depend on the patient's symptoms and clinical progression. Physiotherapy will be delivered in line with previously published guidance,[22,23] but therapists are allowed to use other methods as per their discretion.

Follow-up

Participants will be seen in clinic three months after their injection to review their progress and collect follow-up data for the primary and secondary outcome measures. If clinic attendance is not possible, assessment will be completed via phone or post. Further follow-up data will be collected at six and 12 months after the injection in person (if patient is attending clinic as part of routine care), or via phone or post.

Primary outcome measures

The primary outcome measure of this study is the Oxford Shoulder Score (OSS)[24] at three months post injection. The OSS is a 12-item patient-reported outcome measure of the participants' subjective assessment of their pain and ability to perform activities of daily living (ADLs). Each item has five response categories scored from 0 (worst/most severe symptoms) to 4 (best/fewest symptoms), giving a range of overall scores for the OSS from 0 (worst) to 48 (best). It is widely used in clinical studies to assess outcomes after

surgical and non-surgical interventions, and is considered to be reliable and valid.

Secondary outcome measures

Secondary outcome measures include assessment of how much pain the patient experienced during the injection and how much pain the patient has 20 to 30 minutes after having the injection using a NPRS of 0 to 10 (0 = no pain, 10 = worst pain), which will be completed prior to the patient leaving the clinic. The 11-item NPRS features a horizontal bar numbered 0 to 10, and requires the patient to select the number which best reflects the severity of their pain. The NPRS has been shown to be a reliable and valid measure of pain intensity in patients suffering from a large variety of pain conditions.[19]

Further secondary endpoints include the OSS at six months and one year, and pain using the NPRS, Disabilities of Arm, Shoulder and Hand questionnaire (DASH),[25] and 36-Item Short-Form Health Survey (SF-36),[26] all at three months, six months, and one year.

The DASH outcome measure is a 30-item questionnaire that assesses the ability of a patient to perform certain upper limb activities.[25] It is a self-reported questionnaire whereby patients can rate difficulty and interference with daily life on a five-point Likert scale. This is rescaled into a total score which gives a minimum score of 0 (least disability) and maximum score of 100 (most disability).

The SF-36 consists of 36 items that assess eight health concepts, namely physical functioning, role limitations caused by physical health problems, role limitations caused by emotional problems, social functioning, emotional wellbeing, energy/fatigue, pain, and general health perceptions.[26] The SF-36 score ranges from 0 to 100, with higher scores indicating better health.[27]

Power and sample size

We will be measuring the OSS before injection and at three months post injection in each patient, to compare the change in OSS (three months vs pre-injection) between the two trial arms. We calculated that 43 patients in each group are needed based on 80% power for a paired *t*-test, detecting a minimal clinically relevant difference of six points and a two-tailed significance level of 0.05 with a SD of 9.1 (the SD for change in OSS at 12 weeks from baseline was obtained from a previous study of steroid injection for shoulder pain).[28] This accounts for 10% attrition between baseline and three months as documented in the previous study.[28] The study from which the relevant parameters for sample size calculation were derived was a UK study injecting the subacromial space using steroid, and in which most patients had rotator cuff tendinopathy (one of the commonest causes of subacromial pain syndrome).[28]

Statistical analysis

Baseline demographic and clinical variables will be reported by treatment group using summary statistics including mean, median, frequency, SD, and IQR as appropriate to the data type. Baseline characteristics will be analyzed with comparison between the arms of the study for descriptive purposes only.

In terms of the primary outcome, the change in OSS from baseline to three months post injection will be compared between the two groups using either the independent-samples *t*-test or Mann-Whitney U test, with the final choice depending on exploration of the data. The same approach will be adopted for secondary outcomes. All analysis will be performed according to the intention-to-treat principle.

Adverse events

Safety reporting will be recorded for each participant starting at the time of the initial clinic visit up until the final follow-up date at 12 months after their injection. As both types of approach for the subacromial injection are commonly used in current NHS practice, serious adverse events are not expected. If an adverse event occurs in a trial participant, the chief investigator will review the adverse event and adjudicate the relatedness of the event to the intervention. Any serious adverse event thought to be related to the trial will be reported to the Research Ethics Committee.

Data management

Information about study subjects will be kept confidential and managed according to the requirements of the Data Protection Act and UK Policy Framework for Health and Social Care Research 2017.[29,30] Data recorded on a password-protected Trust computer will be stored securely until the study is published. This will be within a maximum of five years from the final patient visit, after which all such data will be permanently destroyed.

Trial organization and oversight

The ongoing management of the trial will be the responsibility of the local research and development team at Blackpool Victoria Hospital, UK, with regular meetings to assess progress during the recruitment phase of the study. They will ensure that all staff involved will be adequately trained.

Quality control

The research and development team will continually monitor the quality of all aspects of the study, including consenting, randomization, and data collection. The study will be conducted as per the study protocol, ethics committee approval, and Good Clinical Practice. The study was approved by the North-West – Greater Manchester West Research Ethics Committee (REC reference: 19/NW/0012, IRAS project ID: 249246), and was registered with clinicaltrials.gov (Identifier NCT04965376).

Dissemination

Results of the study will be presented locally and at national and international meetings. Results will be published in a peer-reviewed journal, and data from the study will be shared with patients in the future to help them decide between the different treatment options for subacromial pain syndrome.

Social media

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