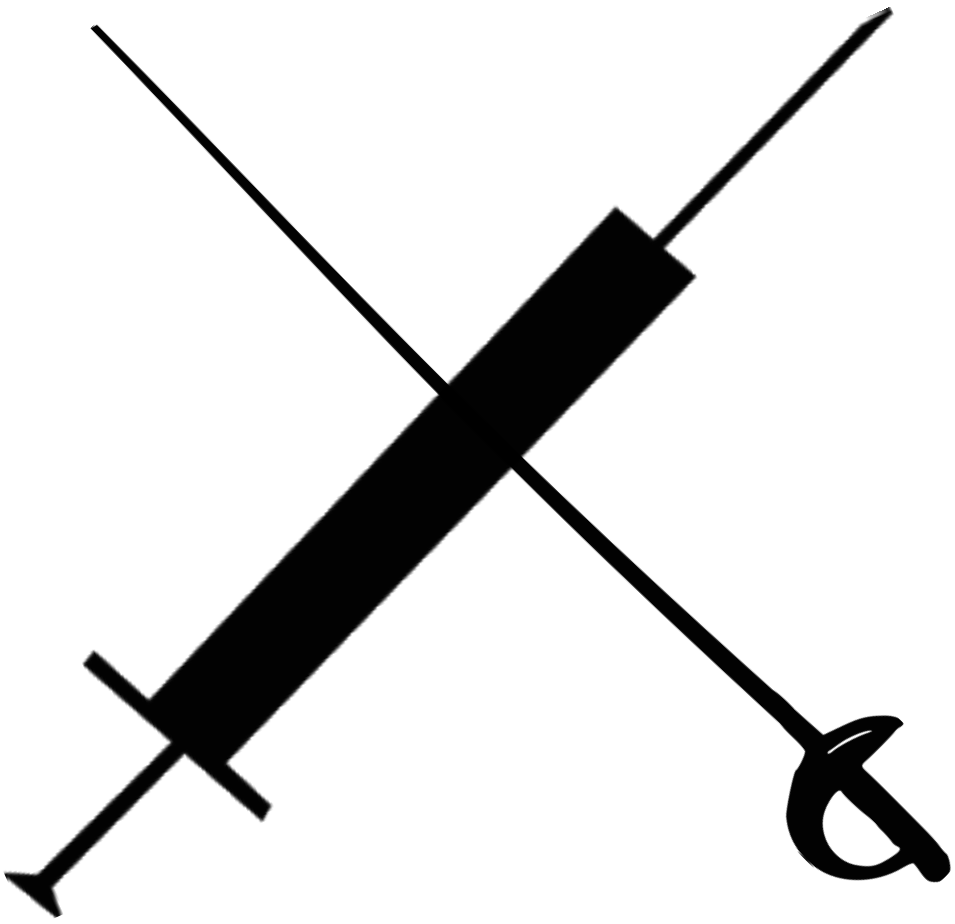
Serratus anterior plane block in addition to protocolised care bundles for patients with rib fractures in the Emergency Department - a randomised control study.

the SABRE study

Study Protocol
Version 2



Trial registration via ANZCTR (*pending*)

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INTRODUCTION.

Lay description

Pain management of the acutely injured patient with rib fractures in the Emergency Department (ED) can be difficult. Severe pain from multiple rib fractures can splint the chest wall, decreasing the ability to clear respiratory secretions and increasing rates of pneumonia. The older person is at increased risk of these complications as well as in-hospital death.

At present, pain relief options include simple analgesics (paracetamol, ibuprofen), opiates (including morphine and fentanyl) or ketamine. In the elderly, many of these medications contribute to in-hospital falls, delirium and constipation and are addictive. Thoracic epidurals are utilised by specialist pain teams however these are contraindicated in anticoagulated patients and not typically available in the ED.

The serratus anterior plane block is an ultrasound-guided, regional anaesthesia technique utilising a single-injection method to anaesthetise the chest wall in patients with multiple rib fractures. They are being utilised at increasing rates across emergency departments worldwide.

The limited evidence available on these blocks suggests they reduce pain scores and may improve respiratory function however, it has not been proven that they are more effective than protocolised rib fracture care bundles including patient-controlled opiate analgesia. The block has not specifically been investigated in an older population.

This study aims to evaluate the effectiveness of an ED-administered, serratus anterior plane block at reducing pain scores in patients with multiple rib fractures following blunt thoracic trauma who are also receiving protocolised rib fracture care (the current standard at participating hospitals) as compared to protocolised rib fracture care alone.

Background & rationale

Rib fractures resulting from blunt thoracic trauma are common injuries presenting to Emergency Departments. Across Australia, hospital admissions for patients with blunt chest wall injuries, such as rib fractures account for more than 35,000 presentations annually[1]. In 2017-18 across New South Wales, 'three or more fractured ribs without flail' was the most common serious injury (23.0%)[2]. They are associated with in-hospital mortality and a variety of complications. Severe pain from rib fractures can impair ventilatory function, decrease the ability to clear respiratory secretions and increase rates of nosocomial pneumonias[3,4]. Elderly patients who sustain blunt chest trauma with rib fractures are much more vulnerable with twice the mortality and thoracic morbidity of younger patients with similar injuries[5]. It is stated that for each additional rib fracture in the elderly, mortality increases by 19% and the risk of pneumonia by 27%[5]. The early management of the pain associated with these injuries can result in a reduction in respiratory complications such as pneumonia.

Protocolised rib-fracture care, such as the "Chest Injury Protocol" (aka. ChIP[6]) include the early implementation of this pain relief combined with physiotherapy, oxygen support and pain team consultation[7]. They have demonstrated reduction in rates of pneumonia in these patients. Patient-controlled opiate analgesia (PCA) is frequently used by these protocols (typically morphine or fentanyl). In particular, in the elderly, these drugs have been associated with in-hospital complications such as delirium, constipation[8] and falls[9].

The serratus anterior plane block (SAPB) is an ultrasound-guided, regional anaesthesia technique that provides analgesia to most of the hemithorax[10]. It is relatively safe and technically simple (on par with ultrasound-guided femoral nerve or fascia iliaca blocks used for hip fracture)[4]. The SAPB is being utilised at increasing rates across emergency departments worldwide. A recent qualitative systematic review reports that single shot thoracic blocks reduce pain scores and opioid consumption when compared with systemic analgesia alone in cardiothoracic surgery, cardiac-related interventional procedures and chest trauma for approximately six to twelve hours[11]. The current evidence available on the SAPB for thoracic trauma which is limited to case series and reports suggests they reduce pain scores and may improve respiratory function[4,12-15]. The block has not specifically been investigated in a dedicated older population.

An anatomical evaluation of the SAPB utilising methylene blue and latex spread in cadavers suggests that this block may not be beneficial for posterior rib fractures, which would require retrograde spread along the intercostal nerve to the paravertebral space[16]. A similar evaluation was performed on cadavers with induced rib fractures which demonstrated a deeper and more posterior spread of SAPB injections when compared to cadavers with intact ribs[17]. There is however a small case series of five patients with posterior rib fractures which reported reduced pain scores and reduced daily opioid consumption when SAPB via catheter technique was placed due to contraindications to thoracic epidural and paravertebral blocks[18]. This discrepancy between anatomic and clinical reporting warrants further investigation in this subgroup of patients.

This study aims to investigate whether the addition of a single-shot, serratus anterior plane block (a one time injection of local anaesthetic) to protocolised, rib-fracture pathway care reduces pain scores and associated complications in patients with clinical or radiologically proven rib fractures and an ongoing analgesic requirement. It will also investigate the specific utility of this block in elderly patients and for posterior rib fractures.

Study Aims/Objectives

The primary objective is to compare pain scores (measured four hours from study enrolment by a verbally administered numerical rating scale[19] or PAINAD score in setting of dementia[20]) in patients who receive a serratus anterior plane block in the ED (in addition to protocolised rib-fracture care) to those who receive protocolised rib-fracture care alone. A target pain score reduction of two or more points[21-23] and an absolute pain score of less than four out of ten[24] have been chosen as this reflects both a ‘clinically significant reduction’ in pain to a level that is ‘no more than mild’[24].

The secondary objectives are to compare these two groups for;

- Average (mean or median) pain scores and ‘change in pain scores from baseline pain’, measured at 4, 12 and 24 hours from study enrolment
- Rates of pneumonia occurrence
- Incidence of delirium in patients aged 65 years or older, using the 4AT Rapid Clinical Test for Delirium
- Total opiate administration (at 24 hours)
- Subsequent rates of regional anaesthesia by inpatient pain service
- Frequency of Local Anaesthetic Systemic Toxicity (LAST) events
- Rates of pneumothoraces (identified on subsequent imaging, post-SAPB)
- Need for and duration of non-invasive ventilation or mechanical ventilation
- ICU and Hospital length of stay
- 30 day mortality
- Quality of life at 30 days from injury

Study investigators & participating institutions

Chief investigator: Dr Christopher Partyka.

Staff Specialist in Emergency Medicine (Liverpool Hospital), Staff Specialist in Prehospital & Retrieval Medicine (NSW Ambulance, Aeromedical Operations), Conjoint lecturer (South Western Sydney Clinical School, University of New South Wales).

Project lead, this includes: drafting the study protocol; ethics application, overall responsibility for the project, analysis and write-up of study findings.

Associate investigator 1: Dr Melanie Berry.

Staff Specialist in Emergency Medicine (Orange Base Hospital), Rural lecturer (Orange Clinical School, University of Sydney).

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 2: Dr Ian Ferguson

Senior Staff Specialist in Emergency Medicine (Liverpool Hospital), Senior Staff Specialist in Prehospital & Retrieval Medicine (NSW Ambulance, Aeromedical Operations), Conjoint senior lecturer and PhD candidate (South West Sydney Clinical School, University of New South Wales).

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 3: A/Prof Stephen Asha.

Senior Staff Specialist and Director of Emergency Medicine Research (St George Hospital), Conjoint Associate Professor (St George & Sutherland Clinical School, University of New South Wales)

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 4: A/Prof Brian Burns.

Staff Specialist and Research Director, NSW Ambulance (Aeromedical Operations), Senior Staff Specialist Emergency Medicine (Northern Beaches Hospital), Clinical Associate Professor (Discipline of Emergency Medicine, University of Sydney).

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 5: Dr. Katrina Tsacalos.

Staff Specialist in Emergency Medicine (The Sutherland Hospital)

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 6: Dr Daniel Gaetani.

Staff Specialist & Co-Director of Emergency Medicine Training (Campbelltown and Camden Hospitals), Conjoint lecturer (University of Western Sydney and University of New South Wales).

Role: contributing to the project design and study protocol. Data entry, analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 7: A/Prof Georgina Luscombe.
School of Rural Health (Dubbo/Orange), Sydney Medical School, University of Sydney.
Role: contributing to the project design and study protocol. Data analysis and interpretation. Contributing to the write-up of study findings.

Associate investigator 8: Professor Kate Curtis.
Professor Trauma and Emergency Nursing (Faculty of Medicine and Health, University of Sydney), Honorary Professorial Fellow (George Institute for Global Health), Director Critical Care Research (Illawarra Shoalhaven Local Health District).
Role: contributing to the project design and study protocol. Data analysis and interpretation. Contributing to the write-up of study findings.

STUDY DESIGN

Study setting and population

This is a multi-centre, prospective, open-label, randomised control study design which aims to include a consecutive patient population of injured persons with clinical or radiologically-proven rib fractures across a range of participating hospitals in NSW. The participating sites who have agreed to participate are Liverpool, Orange Base, Northern Beaches, Campbelltown, St George, Sutherland, Wollongong and Royal Prince Alfred Hospitals. Each of these hospitals have their own established, bundled-care pathway for patients with rib fractures (See Appendix A). Further sites will be approached, and when recruited their details will be supplied to the HREC for approval, and site-specific applications will be completed.

Recruitment processes.

Patients will be captured at the point of hospital admission when they are enrolled in the participating facilities protocolised rib fracture pathway. They will then be screened against a printed eligibility checklist, and those who are eligible for participation will be provided with written and verbal information on the study by either their treating clinician, a study investigator or a member of the in-patient trauma team. They will be given ample opportunity to seek clarification or ask questions of the enrolling clinician.

Patients who are willing to enrol in the study will be asked to provide their formal written consent on a specific study form which will include the SAPB consent (details, procedure, risks and benefits). If the treating physician feels an alternative treatment regimen is necessary, the patient will not be enrolled, although the number of such patients, and reasons for exclusion will be logged for reporting in the trial results. Patients who decline to participate in the study will also not be included in the study but will be recorded on the study's final CONSORT diagram.

Eligibility criteria.

Inclusion criteria:

- All patients aged 16 years or older with clinical or radiologically proven rib fractures
- Clinician qualified to perform SAPB available at time of enrolment

Exclusion criteria:

- Intubated patients
- Prehospital SAPB
- Pregnant women
- Patients transferred for urgent surgical intervention
- Moderate-severe traumatic brain injury (GCS≤13)
- Major concomitant injury identified on imaging;
    - Femoral fracture
    - Spinal fracture
    - Pelvic fracture
    - Intra-abdominal visceral injury ± free fluid

Consent process

Clinical staff working at each of the participating study sites will be educated to screen patients who are admitted to hospital under their 'rib fracture pathway' in order to identify potential participants during their duty periods. Patients will then be screened against an eligibility checklist, and those who are eligible for participation will be provided with verbal and written information about the study, and asked to participate. The written information given in the patient information sheet is comprehensive, and aims to explain the current state of knowledge about rib fracture management, details about the serratus anterior plane block (including the procedures' potential risks and benefits) and what this study hopes to add. The voluntary nature of the study is clearly outlined, and will be reinforced verbally at the time of consent.

Patients who agree to participate will then provide their written consent.

Patients who do not speak English will still be eligible to participate if they can undergo a verbal consent process using a professional medical interpreter which is provided by the hospital to all patients in the Emergency Department and would be simultaneously used to update the patient on their injuries, their clinical management and need for hospital admission. Should phone consent be obtained, two clinical staff must hear this verbal approval and both will co-sign the consent form on behalf of the proxy.

Patients who are deemed (by their treating clinician) to lack the capacity to consent will be excluded from the study, with the exception of patients with a preexisting diagnosis of dementia (as recorded in the patient's clinical record or reported by a care-giver present at the time of hospital admission), so long as they meet all other inclusion criteria and that consent by their proxy (Power of Attorney) can be obtained. This person (the proxy) will also receive the same written and verbal information about the study, and have an opportunity to explore questions as previously described for competent patients. Should phone consent be obtained, two clinical staff must hear this verbal approval and both will co-sign the consent form on behalf of the proxy.

Patients who are unable or unwilling to provide informed consent will not have their clinical care compromised in any way.

Specific patient groups, such as Aboriginal and Torres Strait Island people, people with disabilities, and prisoners are not specifically targeted for this study, but may be recruited by coincidence.

Withdrawal of consent.

Patients may withdraw from the study at any time, and if they choose to do so, they will be asked to sign the revocation of consent section on the Consent Form. If they have already undergone a SAPB at this stage, they will continue to be monitored for side-effects as a matter of participant safety. Once this usual period of monitoring has expired, their ongoing clinical care will be managed by their in-patient, specialist team without prejudice and with full access to the ongoing treatment bundle used at that facility.

Patients who decide not to proceed with the study, will have any data collected to the point of withdrawal included, unless they specifically request otherwise. This is in order to maintain a transparent consort diagram of all screened patients.

Study procedures.

- Patient consented and enrolled into study (see *Figure 1*)
    - Study clock starts at time of enrolment
    - Baseline pain score recorded (see *Outcomes* for more details)
- Patient undergoes computer randomisation to treatment (SAPB plus protocolised rib fracture pathway) or control group (protocolised rib fracture pathway alone)
    - Patients allocated to a SAPB will have this procedure performed as soon as practicable by a qualified clinician (as per Appendix B)
- Primary outcome measured (four hours from study enrolment)
    - Patients in the control arm who have not met the primary outcome are eligible to receive a SAPB as rescue analgesia but only after this four hour mark
    - The need for this rescue block is reviewed & prescribed by the treating bedside clinician so long as a qualified clinician is still available to do so.
- Patient is then admitted to their destination bed with ongoing bundled, rib-fracture care with routine observations per local policy/guideline.
- All clinical care beyond the ED is dictated by the admitting treatment team.
- Delirium screening is performed on all patients aged 65 years or older, by in-hospital treatment team 24-48 hours post-admission.
- Patient follow-up continues until 30 days post-injury at which time;
    1. Mortality or hospital discharge status is recorded *and*
    2. A quality of life screening assessment will be performed via the EQ-5D-5L questionnaire. This will be undertaken by the dedicated study research assistant by telephone (if discharged) or face-to-face interview (if still an in-patient).
- Outside of the data listed above, all study data collected will be via review of clinical records.

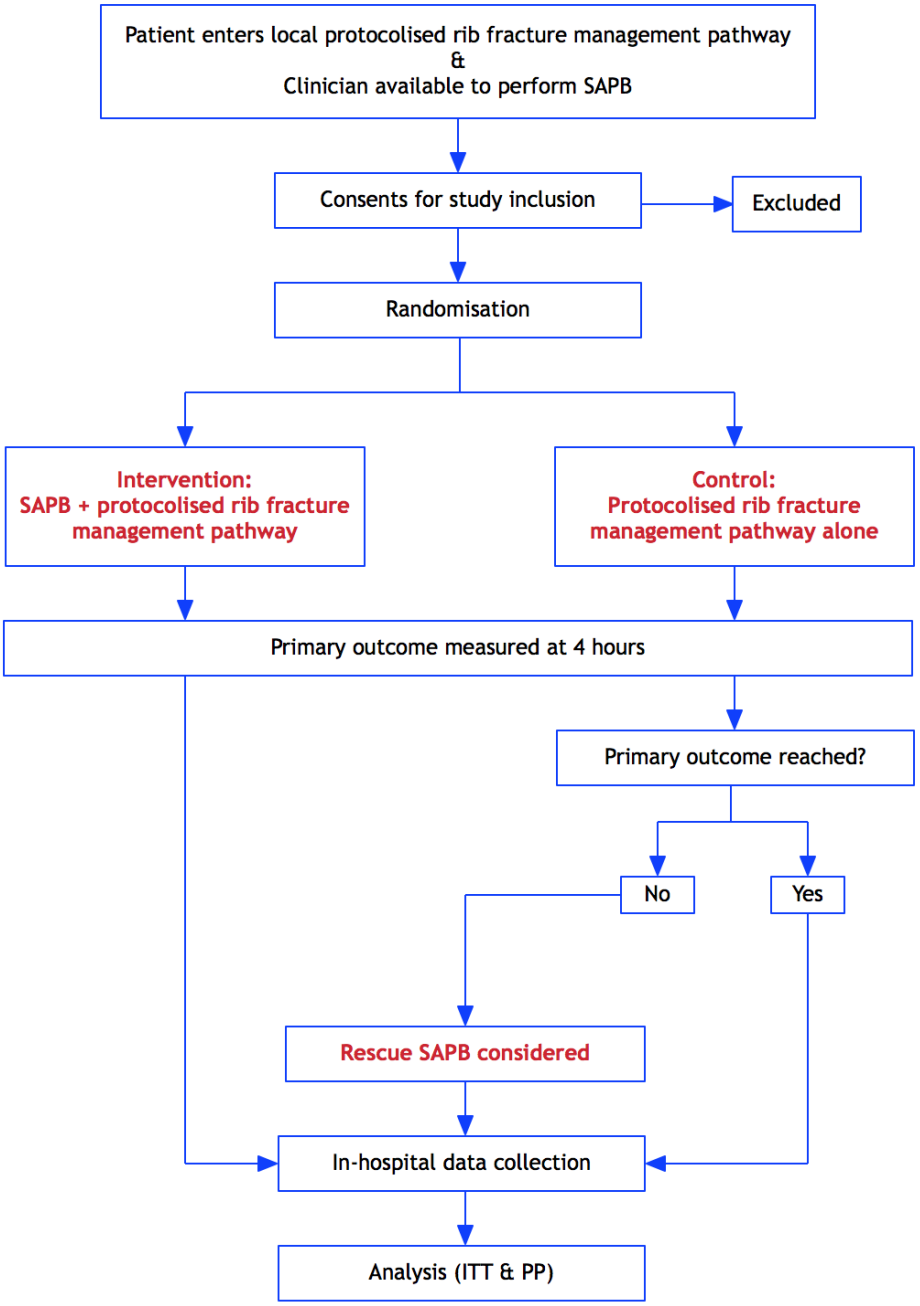

Figure 1. Summary of study procedure and patient allocation.

Randomisation

Participants who fulfil the eligibility criteria and give informed consent will be randomised 1:1 to one of the two groups: SAPB plus protocolised rib fracture pathway management (intervention) or protocolised rib fracture pathway management alone (control). Randomisation will occur in blocks of various sizes (2,4,6) and will be stratified by participating hospital. Owing to the nature of the intervention, it will not be possible to blind participants or investigators to treatment allocation. Statistical analysis will be undertaken in a blinded fashion with the statistician unaware of treatment allocation.

Intervention.

Patients randomised to the treatment arm of the study will receive a single-shot (once only injection) SAPB by a qualified clinician as soon as practicable after study enrolment. The SAPB will be performed in line with Blanco's original description[10], summarised in Appendix B. .

A qualified clinician is one deemed competent to independently perform the SAPB according to local hospital policy. The minimum level of training required is; (1) completion of a standardised online virtual learning module ("*Serratus Anterior Block online learning module (Northern Beaches Hospital)*" link in Appendix B), (2) an in-person education session by the local study investigator which will involve demonstration of relevant sonoanatomy on healthy volunteers and finally, (3) they will perform at least one SAPB supervised by study investigators who will assess suitability for independent practice against a predetermined competency checklist (*see Appendix F)*

The study investigators will be undertaking a concurrent mixed methods assessment of this training program for effectiveness of training and implementation, however this study ("Evaluation of an education program designed to teach serratus anterior plane blocks to emergency medicine clinicians - a mixed methods study") will be detailed in a separate protocol and ethics submission.

Potential benefits to the participant.

Participants who are randomised to standard care will benefit from prompt access to protocolised rib fracture care, as well as close monitoring and access to rescue analgesia if necessary. It is hoped that participants who receive a SAPB may have a reduction in their severity of pain caused by their rib fractures which may also lead to a benefit in respiratory function and may result in a reduction in use of opiate medications and in complications of their use such as constipation and confusion.

Possible risks to the participant.

The SAPB is considered to be a very safe procedure with the most common side effect being localised pain at the site of injection. This pain should be no worse than having a cannula placed in the arm/hand.

The routine use of ultrasound-guidance allows clinicians to accurately insert their needle safely beneath the serratus anterior muscle whilst avoiding other important structures. There is however a very rare chance (<1%) of developing a haematoma from injury to a blood vessel or a pneumothorax from injury to the underlying lung. Pneumothoraces will be monitored closely and if they become symptomatic, they may need to be managed with supplemental oxygen and occasionally by the insertion of an intercostal catheter.

The dose of local anaesthetic is taken from a standardised dosing chart (Appendix B) which is based on body weight. Each dose has been calculated to be well below the toxic dose (three milligrams per kilogram)of ropivacaine. Very rarely (<1%), patients experience unwanted side effects from their local anaesthetic injection. These can include tingling in the extremities or around the mouth, seizures, behavioural disturbance, cardiac dysrhythmias or hypotension. These side effects are routinely monitored for in all patients after local anaesthetic treatment in the emergency department, where the staff are trained to both recognise and treat these complications. Should they occur, these side effects almost always resolve without intervention or treatment.

Rescue SAPB.

To ensure all study participants have access to adequate analgesia for their injuries, a 'rescue SAPB' will be made available to control arm patients in whom the primary outcome (pain score reduction by ≥2 points and a total pain score of less than four out of ten) is not reached at four hours from study enrolment, so long as a qualified clinician is still available to do so.

Any other regional anaesthesia technique will be provided at the discretion of in-patient Acute Pain Services.

Outcomes

Pain measurement.

For the purpose of this study, pain scores will be measured at '*end inspiration following a slow, full (vital capacity) breath*' using one of the two methods below;

- Verbally administered numerical rating scale (score out of '10')
    - '0' is "no pain" and '10' is "worst pain imaginable" (or similar)
- *or* utilisation of the PAINAD score in patients with dementia

Primary outcome.

- Patients will be deemed to meet the primary outcome measure if they have had a pain score reduction of two or more points[21-23] and have an absolute pain score of less than four out of ten[24] measured four hours from study enrolment.
- Should a recorded pain score not fall exactly on a required time-stamp, the pain scores will be designated to that required time stamps if they fall within a 30 minute window of that time (ie. t ±30min). For example a pain score recorded 3 hours and 31 minutes (or 4 hours and 29 minutes) after enrolment will be attributed to the four hour primary outcome measure, and a score recorded at 11 hours and 31 minutes (or 12 hours and 29 minutes) after enrolment will be attributed to the twelve hour secondary outcome measure.

Secondary outcomes.

- Average (mean or median) pain scores and 'change in pain scores from baseline pain', measured at 4, 12 and 24 hours from study enrolment
- Pneumonia: defined by radiological evidence of pulmonary air-space opacification, together with medical record documentation of a clinical diagnosis of pneumonia and treatment with antibiotics[6].
- Total opiate administration in the first 24 hours of admission (measured in morphine milligram equivalents)
- Rates of subsequent regional anaesthesia administered by inpatient pain service
- Local anaesthetic systemic toxicity (LAST) defined by severe neurologic or cardiovascular symptoms within one hour of local anaesthetic administration
- Need for non-invasive ventilation or mechanical ventilation
- ICU and Hospital length of stay
- Delirium: as measured by the 4AT Rapid Clinical Test[25] (Appendix C)
- 30 day mortality

A health economic evaluation will also be undertaken utilising allocated Diagnosis Related Groups to estimate costs per hospital admission as well as quality of life measured at 30 days post-injury by the EQ-5D-5L questionnaire (Appendix D)[26-27]

Subgroup analyses;

1. *Patients ≥65 years of age*
   The potential benefits of the SAPB (SAPB group versus No SAPB groups) will be specifically reassessed in all study patients aged 65 years or older with the inclusion of delirium frequency.
2. *SABP efficacy between anatomic rib fracture locations*
   Patients will be divided into groups designated by the predominant segment of chest wall injury (see Appendix E) and analysed for the potential benefits of SAPB in each segment.

Sample size

Given the paucity of published data on the clinical analgesic effect of PCAs or protocolised, rib fracture pathways we have reviewed a convenience sample of locally treated patients with clinically significant rib fractures receiving an opiate PCA. This sample demonstrated that 12.5% (95% CI 0-35%) of patients would have met our primary outcome. We have elected to use the conservative 35% upper limit of this treatment effect as the baseline proportion. It is expected that approximately 50% of patients receiving a SAPB would meet the primary outcome and that an absolute difference of 20% would be clinically meaningful. Therefore, a figure of 55% has been chosen.

Using these estimates, with a power of 80%, and a significance level set at 0.05, we calculate that a sample size of 96 in each group will be necessary to detect a true difference. To allow for dropouts, approximately 10% will be added to the planned sample size, meaning that a target of 210 patients (105 in each arm) will be recruited.

METHODS: Data collection, analysis and management

A standardised, electronic data collection form (in REDCap, see Data Management below) will be used for initial patient recruitment. This will include data that is not routinely entered into the patients' clinical record, such as height and weight.

Data to be collected.

Identifiable patient markers - Name, date of birth, and medical record number will be recorded, but then concealed in the REDcap database for privacy protection. By coding these identifiers as such in REDCap, it is ensured that it will be obscured when data is exported for analysis, providing a further layer of privacy protection. The storage of data in a re-identifiable (rather than de-identified) manner is preferred, as this may provide opportunities for data-linkage in future studies that may arise.

Patient demographics - hospital, age, sex, height (cm), weight (kg), BMI, smoking status, Charlson Comorbidity index, prior/chronic opiate use, chronic lung conditions (COPD, fibrosis), time of study enrolment.

Injury details - mechanism of injury, time of injury, time of hospital arrival, injuries sustained (incl. number and location of ribs fractured, presence of flail segment, associated haemopneumothoraces, atelectasis on initial imaging), ISS, AIS (thoracic injuries), need for tube thoracostomy.

Details of the SAPB - time of block, hemithorax, plane (deep or superficial), local anaesthetic (drug and dose used), volume administered.

Pain management details - time PCA commenced, pain scores (at baseline, 30 minutes, 1, 2, 4, 12 and 24 hours), opiate requirements, PCA use (demand/supply) days on PCA, further regional anaesthesia details (incl. catheter techniques), naloxone use, LAST complications

Respiratory complications - need for respiratory support (NIV or intubation), ventilator free days, CXR reports (days 1 to 7), need for antibiotics.

Other - 4AT delirium screening tool, ICU and hospital LOS, 30 day mortality, EQ-5D-5L questionnaire, DRG list

Data analysis plan

Patients will be analysed according to their randomised treatment allocation receiving the Serratus anterior plane block in the emergency department (SAPB) or not receiving the block (NSAPB), i.e. using an Intention to Treat (ITT) analysis. Demographic data including age, sex, BMI of patient, co-morbidities (e.g. COPD, heart failure and injury score), will be compared between groups using a t-test or non-parametric equivalent for continuous data and chi-square analysis for categorical data. The central tendency and distribution of normally distributed data will be described with means and 95% confidence intervals, and non-normally distributed data with medians and interquartile range.

Patients will be categorised according to whether or not they meet the primary outcome criteria for pain reduction (reduction of two or more points[21-23] from baseline to 4 hour measure and an absolute pain score of less than four out of ten at 4 hours). The primary outcome measure will be coded as "0" if patients do not meet the criteria and "1" if they do meet the criteria. Comparison of the dichotomised results will be made between the groups (SAPB and NSAPB) and presented as relative risk and absolute relative risk reduction. The study is powered to test if the SAPB is superior to NSAPB.

Separate multivariable regressions will be conducted to explore the relationship between group and change in the dependent variables (a) pain score or (b) in total opioid use from baseline to 4 hours. In addition to group (SAPB or NSAPB) as the independent variable, these models will also control for patient factors (age, sex, Charlson Comorbidity Index, rib fracture numbers, BMI, type of oxygen delivery); and site factors (hospital and CHIP pathway type).

Comparisons between groups (SAPB and NSAPB) on the frequency of complications (opioid related, pulmonary, delirium and LAST) will be performed using chi-square analyses. The following outcome measurements will be compared between the two groups; analgesic use (opiate requirements), procedural complications (LAST and pneumothorax), opioid associated side effects and respiratory complications (including pneumonia, need for oxygen therapy/mechanical support). Patients allocated to the control arm may receive a SAPB as a component of rescue analgesic management. As a result, all secondary outcomes will be analysed using both intention to treat (ITT) and per protocol approaches.

P values < 0.05 will be considered indicative of statistical significance and all analyses will be performed using IBM SPSS software. An interim analysis will be performed six months into the study period to ensure patient safety and appropriate recruitment trajectory is being maintained.

Missing data plan

Missing data will be reviewed and reported on and if less than 5%, a complete case analysis will occur. Any missing data over 5% will be reviewed on a case by case basis. If a variable related to the primary outcome is not available, a last observation carried forward method will be used to impute that missing result.

Data management

All data will be recorded in an electronic case-report form (CRF) using REDCap, a secure web application developed by Vanderbilt University for the development and storage of online databases. This data will be collated from the hospital electronic medical record, trauma registry, medication charts and pain service data. The enterprise imaging repository (EIR) will be used to create the thoracic segment images for patients who undergo thoracic CT imaging (as seen in Appendix E) for the subgroup analysis. The treating medical and/or nursing staff will be responsible for the initial data entry (incl. demographics, injury details, initial pain score), the qualified clinician will record details of their SAPB and all other information will be collected by study personnel from routinely collected, in-hospital data.

The in-built quality control tools of REDCap will be used to scrutinise data quality.

Missing data will be dealt with by interrogation of other sources initially (e.g. nursing notes, patient observation forms), and/or discussion with the treating clinician.

Data storage and record retention

We will adhere to the Australian Code for the Responsible Conduct of Research for the storage and archiving of data. Following the recruitment procedure, or in-patient assessment, hard-copy study documents (which will include Consent Form, the Clinician Enrolment Form, the 4AT assessment tool and the EQ-5D-5L questionnaire) will be taken to and stored in a locked filing cabinet in the Principal Investigator's office of each participating Emergency Department following the patient's admission to hospital. The REDCap database will be stored on a secure server at UNSW with access restricted, by password, to the investigators. The data will be owned by South West Sydney Local Health District, as the study sponsor. At the conclusion of the study, data will be stored securely, and then subsequently disposed of in a time-frame and manner consistent with the regulatory environment at that time (currently for 15 years following the last use of the data).

METHODS: Monitoring

Data monitoring

Data monitoring will occur as part of routine quality assurance undertaken in both study settings, as detailed above.

Harms

Patient safety will be largely monitored by the bedside treating clinicians. Protocolised rib-fracture management is a common occurrence in the participating hospitals where there are established systems to safeguard these injured patients. When a patient receives a SAPB, the treating speciality teams involved in ongoing patient care beyond the Emergency Department will have prior notice and be able to observe for complications such as LAST (local anaesthetic systemic toxicity) or local reactions. If there is any adverse event, the principal investigator will inform the Human Research and Ethics Committee. If there is a serious adverse event, this notification will occur within one working day.

With regard to the SAPB itself; this is considered to be a safe procedure with the most common side effect being local pain at the site of injection. The use of live, ultrasound-guided needle placement will help mitigate complications such as pneumothorax and vascular injury. The standardised ropivacaine dosing (Appendix A) falls well below the three milligram per kilogram toxic dose, so LAST symptoms should not occur.

ETHICS AND DISSEMINATION

Confidentiality and privacy

All data will be stored in a (coded) re-identifiable manner as described above. Confidentiality and privacy will be maintained by secure data storage (see below). Only members of the research team will be aware of and have access to these codes.

Data will be entered into a REDCap data collection form and stored as described above. The re-identifiable code will be marked as an 'identifier', which will ensure that when data is exported to statistical software, it is obscured (letters and numbers replaced by #), as a further safeguard against unintended disclosure.

Permission is sought to store the data in a coded (re-identifiable) manner, rather than in a de-identified manner, as one of the purposes of this database is to facilitate future research. As all of the data collected is accessible from our routine systems, and involves a single episode of care, it would not meet the definition of being a data linkage study. However, it is possible in the future that data linkage could form a part of proposed studies, in which case it would be necessary to have some method of identifying participants. If such studies were undertaken, the necessary ethical approvals would be sought from the appropriate Human Research and Ethics Committee prior to commencement. In addition, ethical approval will be sought for any further studies using these data.

Dissemination policy

The results of research arising from this project will be presented at local and national conferences, and published in a peer-reviewed journal.

PROJECT TIMELINE.

Complete study protocol: September 2020

Ethics submission: September 2020

Local SSA submissions: October 2020

Local site training & accreditation of SAPB: January 2021

Patient enrolment commences: February 2021

Patient enrolment completed: February 2022

Data collection completed: March 2022

Data analysis complete: April 2022

Publication submission: August 2022

BUDGET.

This study has received $60,000 from NSW Institute of Trauma and Injury Management (ITIM), a network within the Agency for Clinical Innovation (ACI) under the 2020 NSW Trauma System Research Grant Scheme.

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APPENDIX A - Summary of rib fracture pathways at participating SABRE sites.

Summary of rib fracture pathways at participating SABRE sites.

	Campbelltown	Liverpool	Northern Beaches	Orange	St George	Sutherland	Wollongong	Royal Prince Alfred
Preexisting protocolised rib fracture pathway	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Inclusion criteria	Age >16 Fractured ribs (radiologically or clinically)	Age >14 Fractured ribs or sternum (radiologically or clinically)	All patients with isolated blunt chest injury (radiological or clinical diagnosis)	All patients with isolated blunt chest injury (radiological or clinical diagnosis)	All patients with isolated blunt chest injury (radiological or clinical diagnosis)	All patients with isolated blunt chest injury (radiological or clinical diagnosis)	All patients with blunt chest injury (proven or suspected rib fractures)	Any patient with high risk rib fracture(s)
Analgesia	Paracetamol NSAID Consider PCA Consider regional anaesthesia	Paracetamol plus PCA or regular oral opiates. Consider NSAID Consider regional anaesthesia	Paracetamol NSAID PCA or regular oral opiates Early regional anaesthesia Consider pregabalin	Paracetamol plus PCA or regular oral opiates Consider NSAID Consider regional anaesthesia Consider pregabalin	Paracetamol, NSAID plus PCA or regular oral opiates (Targin/Oxycodone). Consider regional anaesthesia	Paracetamol NSAID Targin/Oxycodone Consider PCA Consider regional anaesthesia	Paracetamol NSAID Targin/Oxycodone Consider PCA Consider paravertebral block	Paracetamol NSAID Targin/Oxycodone Buprenorphine patch Referral for PCA Consider regional anaesthesia
Routine oxygen therapy	Nasal prong (low-flow)	Nasal prong (low-flow)	Humidified HFNO	Humidified HFNO	Humidified HFNO (35L/min)	Yes. SpO2 target 90-95%	Consider humidified HFNO (50L/min)	Yes. Consider humidified HFNO (SpO2<94% on O2)
High risk criteria	Flail segment ≥ 4 ribs (<70 yr) *or* ≥2 rib (≥70 yr) Hypoxia Lung contusions (on CXR/CT) Haemopneumothorax Assoc. polytrauma First rib fracture	Flail segment ≥4 ribs *or* ≥2 signif displaced fractures Chest wall deformity or defect Signif displaced sternal fracture Hypoxia Lung contusions (on CXR/CT) Chronic respiratory or cardiac failure Age ≥65	Central flail Peripheral flail w/ ventilatory failure Off-ended rib fractures Signif. haemothorax (>1L initially or >200ml/hr for 2-4 hours) Signif SC emphysema Persistent PTx despite ICC Tracheobronchial injury Mechanical ventilation Haemoptysis Pulmonary contusion with impairment of ventilation	Nil.	FiO2 0.5 (HFNO) Age > 55yrs Flail segment Respiratory history Respiratory compromise (eg: ↑ WOB; ↑ RR; ↓ SpO2 ≥3 rib #s)	Multiple risk factors for poor outcome High risk clinical features and/or abnormal vital signs ≥3 rib fractures Significant injury load on imaging Vertebral/mediastinal injuries Need for ICC Need for positive pressure or mechanical ventilation	Age > 45yrs Respiratory history Respiratory compromise (↑ WOB; ↑ RR, ↓ SpO2 ≥3 rib #s) Flail segment Smoking history	Age >65yrs Frailty Smoking history Respiratory history Chronic opioid use ≥3 rib #s, bilateral injury or flail segment Respiratory compromise (↑ WOB; RR>30, SpO2<90%(RA) or <95%(O2), PaCO2 >45mmHg, poor cough/inspiratory effort)
Patient destination from ED	Ward or ICU. *High-risk* to Liverpool	ICU (*high-risk*) *or* trauma ward	Preferably HDU *High-risk* to Trauma Referral Centre	HDU	ICU (*high-risk*) *or* trauma ward	Ward or ICU. *High-risk* to St George	ICU or ward capable of managing HFNO.	ICU or trauma ward
Mandated consultations & reviews	Pain service ACBT Physiotherapy Aperients Consider Geriatrics	Pain service ACBT Physiotherapy Aperients Consider Geriatrics	Early mobilisation Pain service Physiotherapy Fluid restriction Aperients Consider Geriatrics	Early mobilisation Pain service Physiotherapy Fluid restriction Aperients	Early mobilisation Pain service Chest splints/support Incentive spirometry Physiotherapy Aperients Consider Geriatrics	Pain service Physiotherapy Incentive spirometry Consider Geriatrics	Pain service Physiotherapy & deep breathing exercises Early mobilisation Education Incentive spirometry Support/splint pillows Aperients	Pain service Physiotherapy Incentive spirometry Early mobilisation Cardiothoracic surgery Consider Geriatrics Aperients

Abbreviations:

ACBT: Active Cycle of Breathing Technique
HDU: High dependency unit
HFNO: High-Flow Nasal Oxygen
ICC: Intercostal catheter
ICU: Intensive care unit
NSAID: Non-Steroid Anti-Inflammatory Drugs
PCA: Patient-Controlled Analgesia
PTx: Pneumothorax
SC: subcutaneous

APPENDIX B - Serratus Anterior Plane Block Procedure

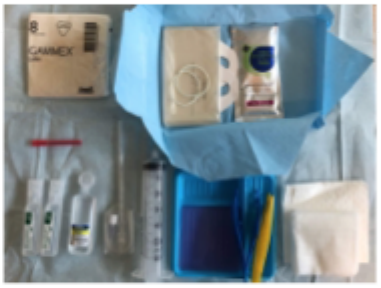
SERRATUS ANTERIOR PLANE BLOCK PROCEDURE

Background.

Any injury or procedure involving the chest wall, between the T2 and T9 dermatomes has the potential to be anaesthetised with a serratus anterior plane block (SAPB)[1].

Sensory blockade can be expected to last from approximately 30 minutes to 12 hours after injection[1]. Where block is effective, this can be followed by serratus plane catheter for ongoing regional anaesthesia should this be required. Coagulopathy is not a contraindication to performing a SAPB.

Equipment.



Ultrasound
Probe cover + sterile gel
Sterile gloves
2% chlorhexidine in 70% alcohol
Wound dressing kit plus drape
Syringe (50-60mL)
22G regional block needle
20mls 0.9% Saline
20mls 0.75% ropivacaine (150mg)
(alternate long acting local anaesthetic such as bupivacaine can be used based on local availability)

Local Anaesthetic Preparation.

The serratus anterior plane block, similar to the fascia iliaca block, is a high volume, low concentration technique. Combine Ropivacaine 0.75% with 0.9% saline to achieve a final volume of 40ml, creating a concentration of 0.375% as per instructions in Table 1. Note, a total dose of 3mg/kg is not to be exceeded.

Recommended concentration & dosing (based on ECI NSW FIB document) Ropivacaine 0.75% 10mL vials (x2) + 0.9% Saline 20mL vials (3.75 mg/mL)				
Concentration (mg/mL)	Weight (kg)	Vol (mL) given	Dose (mg) given	Dose (mg/kg) given
3.75	50	30	112.5	2.3
3.75	60	30	112.5	1.9
3.75	70	40	150	2.1
3.75	80	40	150	1.9
3.75	90	40	150	1.7
3.75	100	40	150	1.5

Table 1. Ropivacaine dosing instructions.

SAPB Procedure v2.0 29/06/2020

Skin Preparation.

Perform aseptic, no touch technique using a sterile drape, sterile gloves, probe cover, sterile US gel and 2% chlorhexidine in 70% ethanol. Donning a sterile gown, mask, and eye protection, are not required[2].

Patient Position.

In the patient with chest injuries, the procedure is usually performed with the patient in the semi-recumbent or supine position with the shoulder abducted and externally rotated.

The Technique.

A linear, high frequency ultrasound probe is placed at the mid-axillary line at the approximate level of the 5th rib and adjusted until the anterior edge of latissimus dorsi is clearly identified superior to serratus anterior (Fig. 1).

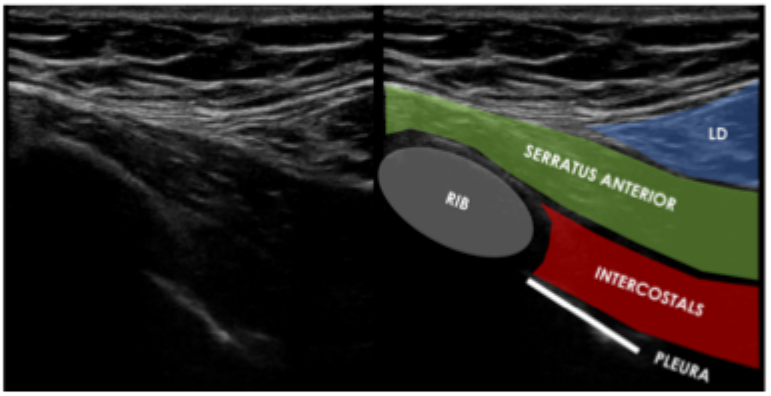


Figure 1. Serratus anterior muscle and surrounding anatomy.
LD = latissimus dorsi

Alternatively, the inferior tip of latissimus dorsi is palpated, and the linear array transducer, within the sterile probe sheath, is placed at this point in the mid-axillary line, here the latissimus dorsi is recognised as a striated triangular structure. Moving cranially, the serratus muscle can then be identified as a striated rectangular structure (Fig. 1).

The thoracodorsal artery can be used as an extra reference point to locate the plane superficial to the serratus muscle and the target for local anaesthetic infiltration
(Fig. 2).

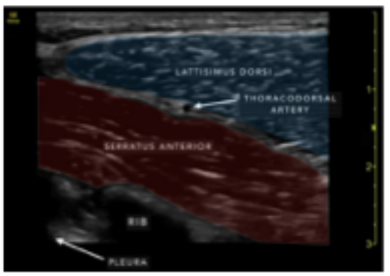


Figure 2. Location of thoracodorsal artery

Using an in-plane approach, the nerve block needle is inserted, and guided towards the target plane, always ensuring that the needle tip, needle shaft and pleura are visualised.

Following a haem-negative aspiration, slowly inject the local anaesthetic into the identified plane. If pain, or resistance occurs while injecting, stop and ensure your needle tip has not migrated.

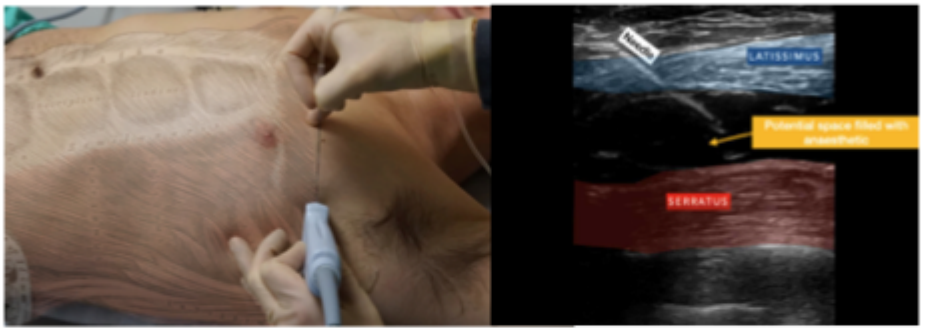


Figure 3. Needle insertion technique and resultant instillation of local anaesthetic into the superficial serratus plane.

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Additional online resources.

- Serratus Anterior Block online learning module (Northern Beaches Hospital)
- 5 Minute Sono - Serratus Anterior Block

APPENDIX C - The 4AT Rapid Clinical Test for Delirium

4AT

Assessment test for delirium & cognitive impairment

(label)

Patient name:

Date of birth:

Patient number:

Date: **Time:**

Tester:

		CIRCLE
[1] ALERTNESS *This includes patients who may be markedly drowsy (eg. difficult to rouse and/or obviously sleepy during assessment) or agitated/hyperactive. Observe the patient. If asleep, attempt to wake with speech or gentle touch on shoulder. Ask the patient to state their name and address to assist rating.*		
	Normal (fully alert, but not agitated, throughout assessment)	0
	Mild sleepiness for <10 seconds after waking, then normal	0
	Clearly abnormal	4
[2] AMT4 *Age, date of birth, place (name of the hospital or building), current year.*		
	No mistakes	0
	1 mistake	1
	2 or more mistakes/untestable	2
[3] ATTENTION *Ask the patient: "Please tell me the months of the year in backwards order, starting at December." To assist initial understanding one prompt of "what is the month before December?" is permitted.*		
Months of the year backwards	Achieves 7 months or more correctly	0
	Starts but scores <7 months / refuses to start	1
	Untestable (cannot start because unwell, drowsy, inattentive)	2
[4] ACUTE CHANGE OR FLUCTUATING COURSE *Evidence of significant change or fluctuation in: alertness, cognition, other mental function (eg. paranoia, hallucinations) arising over the last 2 weeks and still evident in last 24hrs*		
	No	0
	Yes	4

4 or above: possible delirium +/- cognitive impairment
1-3: possible cognitive impairment
0: delirium or severe cognitive impairment unlikely (but delirium still possible if [4] information incomplete)

4AT SCORE ☐

GUIDANCE NOTES Version 1.2. Information and download: **www.the4AT.com**

The 4AT is a screening instrument designed for rapid initial assessment of delirium and cognitive impairment. A score of 4 or more suggests delirium but is not diagnostic: more detailed assessment of mental status may be required to reach a diagnosis. A score of 1-3 suggests cognitive impairment and more detailed cognitive testing and informant history-taking are required. A score of 0 does not definitively exclude delirium or cognitive impairment: more detailed testing may be required depending on the clinical context. Items 1-3 are rated *solely on observation of the patient at the time of assessment*. Item 4 requires information from one or more source(s), eg. your own knowledge of the patient, other staff who know the patient (eg. ward nurses), GP letter, case notes, carers. The tester should take account of communication difficulties (hearing impairment, dysphasia, lack of common language) when carrying out the test and interpreting the score.

Alertness: Altered level of alertness is very likely to be delirium in general hospital settings. If the patient shows significant altered alertness during the bedside assessment, score 4 for this item. **AMT4 (Abbreviated Mental Test - 4):** This score can be extracted from items in the AMT10 if the latter is done immediately before. **Acute Change or Fluctuating Course:** Fluctuation can occur without delirium in some cases of dementia, but marked fluctuation usually indicates delirium. To help elicit any hallucinations and/or paranoid thoughts ask the patient questions such as, "Are you concerned about anything going on here?"; "Do you feel frightened by anything or anyone?"; "Have you been seeing or hearing anything unusual?"

APPENDIX D - EQ-5D-5L questionnaire

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

SELF-CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

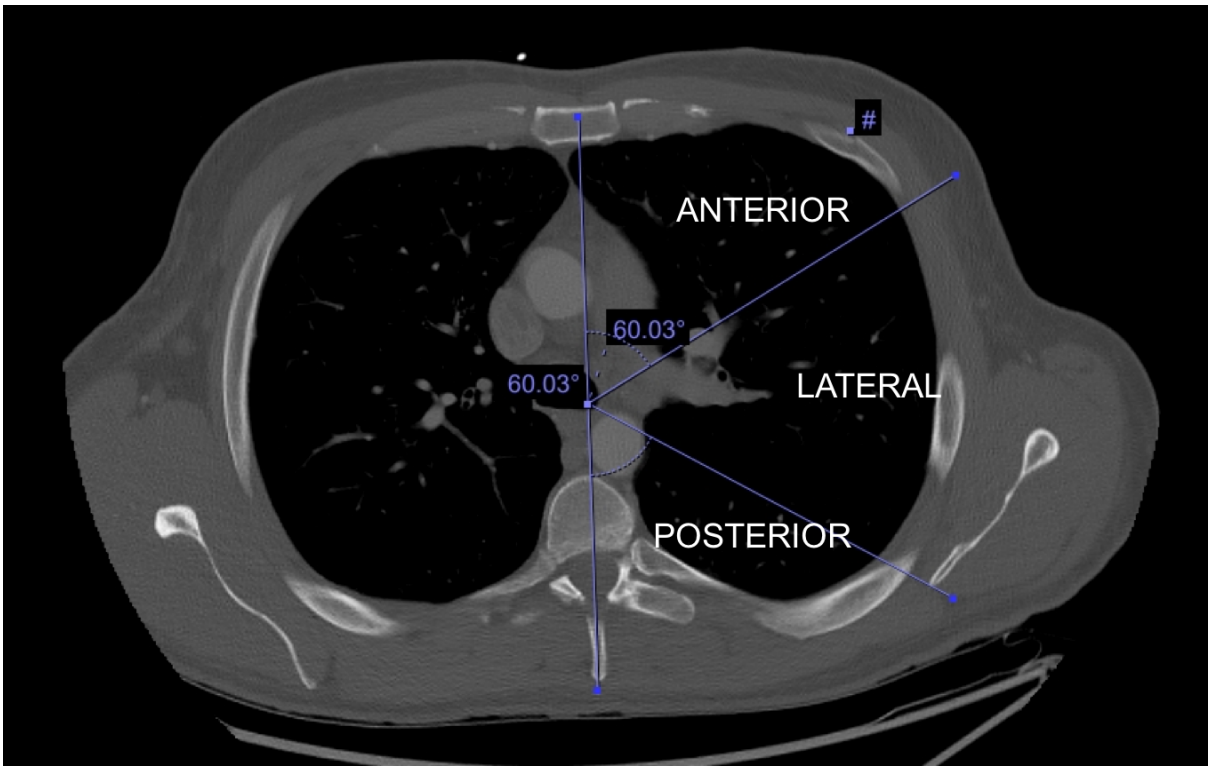
APPENDIX E - Rib fracture location within thoracic segments.

Patients who undergo CT imaging of the chest during their initial trauma evaluation will be entered into a subgroup analysis to determine the effectiveness of the SAPB relative to the segment of the thorax injured.

Procedure:

1. CT images will be accessed via EIR using NSW Health computers.
2. Axial thoracic CT images will be reviewed to identify the single location on the chest wall which best represents the majority of ribs injured.
3. A single CT slice representative of this injured region will be chosen with rib fractures labelled (*see image below*)
4. The chest will be divided into three equal 60 degree segments on the injured side (*see image below*)
5. Injuries will be designated as “anterior”, “lateral” or “posterior”

Sample image demonstrating a patient with “anterior” rib fractures.



APPENDIX F - SAPB Assessment Checklist.

SERRATUS ANTERIOR PLANE BLOCK

ASSESSMENT CHECKLIST

DATE: **CLINICIAN:** **SUPERVISING INVESTIGATOR:**

CONSENT	☐
PATIENT POSITIONING ADEQUATE	☐
EQUIPMENT SETUP (incl. ultrasound/probe cover)	☐
LOCAL ANAESTHETIC SAFELY PREPARED	☐
SURFACE ANATOMY DESCRIBED/IDENTIFIED	☐
SONOANATOMY IDENTIFIED	
RIB(s)	☐
PLEURA	☐
LATISSIMUS DORSI	☐
SERRATUS ANTERIOR	☐
THORACODORSAL ARTERY	☐
REAL-TIME IN-PLANE NEEDLE GUIDANCE SEEN	☐
ANAESTHETIC DELIVERED TO SERRATUS PLANE	☐

SUITABLE FOR INDEPENDENT SAPB / REQUIRES FURTHER SUPERVISION

PLEASE CIRCLE