

PROTOCOL TITLE

Sedation vs Axillary or Brachial plexus block in Interventional Radiology (SABIR)

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STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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1. SUMMARY

1.1 Synopsis

Study Title	Sedation vs Axillary Brachial plexus block in Interventional Radiology (SABIR)
Aims/Objectives	<p>Aim: To improve the quality of care in interventional radiology (IR) by determining the optimal form of anaesthesia for fistula interventions whilst optimising resources for Liverpool Hospital and SWS LHD.</p> <p>Primary: to assess the efficacy and safety of regional anaesthesia for fistuloplasty in IR compared to conscious IV sedation.</p> <p>Secondary: to assess proceduralist and patient satisfaction with regional anaesthesia compared to conscious IV sedation.</p>
Study design	Prospective observational cohort study.
Planned sample size	50 patients.
Inclusion criteria	Patients undergoing endovascular fistula intervention in interventional radiology at Liverpool Hospital who are over 18 years of age and able to provide valid consent.
Exclusion criteria	Patients with documented allergy or anaphylaxis to contrast, pregnancy or patients who opt out or refuse enrolment.
Study procedures	Patients will be anaesthetised with regional (axillary nerve or brachial plexus) block or conscious intravenous sedation (midazolam + fentanyl). They will be closely monitored during the procedure (just prior to and during each intervention) as well as surveyed pre and post procedure to determine levels of pain and satisfaction. Procedure time, adverse symptoms, complications and perception of overall experience will also be recorded for correlation and analysis.
Analysis considerations	Pain scores will be recorded on a likert scale (0 to 10) and then summarised using mean, standard deviation, and IQR. Comparison between study groups will be made with 2 sample T-test with 95% confidence interval. Categorical variables will be recorded as counts and percentages and comparisons between study groups will be made using chi-square or Fisher's exact test. Calculated P-values will be two tailed with $P < 0.05$ indicating statistical significance.
Study duration	Data collection 6 months. Expected study duration 12 to 18 months.

1.2 Study investigators

Coordinating Principal Investigator:

Name: Dr Ross Copping

Position: Interventional Radiology consultant

Institution: Interventional Radiology, Liverpool Hospital

Investigator:

Name: Dr Louise Wei

Position: Diagnostic and Interventional Radiology registrar

Institution: Interventional Radiology, Liverpool Hospital

1.3 Funding

No funding has been requested nor is required for this project. All investigators are contributing their support willingly and voluntarily in their own time.

Department funded interpreters can be utilised if required to avoid burdening the public hospital interpreters service system, but ideally consent will be obtained for the research project and procedure at the same time.

1.4 Statistical analysis

Biostatistician Joseph Descaller was consulted for the trial.

Responses will be recorded according to a likert scale (0 to 10) for pain and anxiety prior to the procedure, intra procedurally and post procedure and compared between the two study groups. Mean, median and standard deviations will be calculated from these responses. The 2 sample T-test with 95% confidence interval will be employed from the data collected. The expected variation between the two study groups would be greater than 1.5 to in order to infer a significant difference.

2. BACKGROUND AND RATIONALE

Many patients with end-stage renal failure rely on their fistulas to be able to access lifesaving dialysis on a regular basis. The natural history of these fistulas necessitates ongoing maintenance in the form of fistuloplasty, which can be an invasive and uncomfortable procedure. Typically, this procedure would be done with the use of either conscious intravenous sedation or regional (axillary nerve or brachial plexus) block. The choice of anaesthesia for fistuloplasty in the interventional radiology department is a balance between patient safety, proceduralist skill and resource allocation including staffing.

Conscious intravenous sedation with midazolam and fentanyl is the most common form of analgesia used for more invasive IR procedures such as fistuloplasty, predominantly for historical reasons, however can carry significant drawbacks. In the fistuloplasty population, due to their underlying renal failure and other comorbidities, they are often at higher risk of narcotisation and respiratory depression with IV sedation [1]. Lack of staffing and inappropriate patient fasting prior to sedation often lead to procedural delays. Furthermore, the use of IV sedation is resource intensive, requiring dedicated nursing staff to deliver sedation and provide additional monitoring during and after the procedure, and a longer period of observation post procedure.

Regional anaesthesia with axillary or brachial plexus block is a safe and effective form of procedural analgesia that has already been used for upper limb surgeries in the orthopaedic and vascular spheres [2,3]. It involves the injection of xylocaine and bupivacaine around the nerve under ultrasound guidance to provide temporary complete anaesthesia. As there is no requirement for systemic administration of medication, patients undergoing axillary block are at minimal risk of overdosing or prolonged effect of sedation [1,4]. For the same reason, axillary block can be safely offered to a wider range of medically fragile patients who may not be suitable for IV sedation [1]. Other benefits include the preservation of scarce resources such as nursing staff as it does not require additional monitoring for the duration of the procedure.

The use of axillary blocks as procedural analgesia in fistuloplasties is offered at many centres including Liverpool Hospital, however its benefits over IV sedation have not been formally validated in the literature. Currently, factors influencing the choice of procedural analgesia include proceduralist expertise/experience, patients factors and resources including nursing staff availability. Anecdotally, patients undergoing axillary block report more complete analgesic effect and no side effects. For these reasons we aim to investigate the safety and efficacy of axillary block for fistuloplasty procedures in interventional radiology to formally validate our clinical experience.

3. STUDY AIMS/OBJECTIVES

Aim:

To improve the quality of care in interventional radiology (IR) by determining the optimal form of anaesthesia for fistula interventions whilst optimising resources for Liverpool Hospital and SWS LHD.

Primary objectives:

To assess the efficacy and safety of regional anaesthesia for fistuloplasty in IR compared to conscious IV sedation.

Secondary objectives:

To assess proceduralist and patient satisfaction with regional anaesthesia compared to conscious IV sedation.

Hypotheses:

We hypothesise, based on anecdotal experience, preliminary data and evidence in the literature in other clinical settings, that regional anaesthesia (axillary or brachial plexus block) is safer and more effective than intravenous sedation for anaesthesia/pain relief during fistula interventions. We also propose that this will lead to improved proceduralist and patient satisfaction and reduced burden on resources.

4. PARTICIPATING SITES

Liverpool Hospital.

5. STUDY DESIGN

Prospective observational (non-randomised) study comparing the efficacy and safety of regional anaesthesia (axillary or brachial plexus block) and conscious IV sedation for fistuloplasty procedures in interventional radiology.

Some proceduralists only perform fistuloplasty under sedation while others only perform with regional block. This provides 2 inherent inbuilt treatment arms based on current practise that we aim to compare (observational). In the vast majority of cases, the decision for sedation vs block is made automatically based on proceduralist

expertise, staffing availability and patient factors which removes the potential bias in choosing for each case.

Following filtration through the inclusion and exclusion criteria and informed consent, patients will be enrolled into the study. Levels of pain will be recorded and compared between the two groups. Patient and proceduralist satisfaction will also be assessed.

5.1 Study Type

Prospective observational comparing 2 treatment arms.

5.2 Expected Study Duration

Data collection for the study will be carried out over 6 months. During this time, it is expected that 50 patients will be enrolled in the study.

5.3 Data Source and Population

Clinical anecdotal evidence from within the Liverpool Hospital Interventional Radiology Department shows markedly improved levels of pain relief/anaesthesia with regional anaesthesia in the form of axillary or brachial plexus block in addition to strong patient preference. Comparatively, intravenous sedation does not offer the same degree of pain relief and is associated with a number of risks.

The expected duration of this study is 6 months with expected recruitment to include 50 participants subject to inclusion and exclusion criteria. This study will recruit from a single site; namely the Liverpool Hospital Interventional Radiology Department.

Consent, enrolment and participation in patient experience questionnaires (PEQ) for this study will be offered in a culturally appropriate format. PEQs will be offered to cater for a culturally and linguistically diverse participant cohort. The use of standardised graphics accepted in the literature for pain scores and patient satisfaction surveys will be utilised for a culturally and linguistically diverse participant cohort. Hospital interpreters may be used at the time of procedural consent. Interventionalists and nursing staff of English, Arabic, Vietnamese and Chinese background are available in the department to facilitate communication where needed. The patients will be assessed through standardised questionnaires pre and post procedure in addition to monitoring levels of analgesia just prior to and during each intervention within the procedure (e.g. for each angioplasty or stent). The pre procedure questionnaire will be performed at the time of procedural consent and the post procedure will be performed one hour post procedure (prior to discharge from Interventional Radiology). A proceduralist questionnaire will also be conducted post procedure. The questionnaires/data collection sheets have been attached as appendix 2. The procedure time, any adverse events or complications will also be recorded for correlation and analysis. If the patient withdraws consent, their involvement in the study will be terminated immediately and this will be clearly communicated at the time of consent and outlined in the participants information sheet. Any factors contributing to premature termination can be analysed.

5.4 Recruitment and Screening

All patients undergoing endovascular fistula intervention in the Liverpool Hospital Interventional Radiology Department will be offered participation in the study. Participation in the study will not affect any other aspects of their treatment or care. Patients will receive regional block or intravenous sedation regardless of their involvement in the trial; participation will just allow us to measure the outcomes.

Women of childbearing age will be screened for pregnancy by nursing staff on the day of procedure, as with all angiographic procedures, although it should be noted that pregnancy is physiologically not compatible with end-stage renal failure requiring haemodialysis. Urine pregnancy tests are performed whenever there is doubt about pregnancy status.

Patients can opt out of the trial at any time. Patients will be given a standardised questionnaire before and after the procedure to assess their experience and assisted by nursing staff where needed. Their levels of pain/analgesia will also be assessed just prior to and during each intervention during the procedure by nursing staff.

5.5 Inclusion Criteria

All patients undergoing endovascular fistula intervention in the Liverpool Hospital Interventional Radiology Department will be offered participation in the study. Both regional anaesthesia and intravenous sedation are used routinely for all of these procedures. Patients must confirm they are not pregnant or breastfeeding at the time of procedure. Patients must be over 18 years of age and have capacity to provide consent. Written informed voluntary consent will be obtained at the time of procedural consent. Interventionalists, radiographers and nursing staff of English, Arabic, Vietnamese and Chinese background are available in the department to facilitate communication where needed.

5.6 Exclusion Criteria

The research project will be discussed with the patients at the time of consent. It will be clearly explained that they may opt out of the study or deny/withdraw consent at any stage. Patients unable to provide informed, voluntary, competent consent will be excluded. Any patient with allergy or prior adverse reaction to iodinated contrast, xylocaine/bupivacaine or midazolam/fentanyl will not be given these medications. Patients who are pregnant or breastfeeding will be excluded.

5.7 Consent Process

Capacity to provide research and procedural consent will be clinically assessed on admission to the interventional radiology department. The patient will be approached by a doctor who is part of the project team. A medical interpreter will be used if required at the time of consent if the patient is of non-english speaking background (i.e. trial consent will be obtained at the time of procedural consent), as long as there is sufficient levels of communication to facilitate the questionnaire and any necessary communication for the remainder of the procedure. Interventionalists and nursing staff of English, Arabic, Vietnamese and Chinese background are available in the department to facilitate communication where needed.

Regional anaesthesia (axillary or brachial plexus block) and intravenous sedation will be discussed with the patient, as per standard practise, and information will be provided to the patient where requested. The patient will be informed about the role of the research, the use of anaesthesia in clinical practise (including risks, benefits and alternatives), what they can expect if they agree to participate (including any potential risks, rights and responsibilities). They will be reassured that they are able to withdraw/revoke consent at any point without penalty. A participant information sheet (PIS) will be provided to the patient during discussion. The patient will have until the commencement time of their procedure to decide if they would like to participate, which is at least 1 hour but may be up to 24 hours. If the patient is agreeable to participate in the study at this point, informed written consent will be obtained.

It will be ensured that consent is informed, voluntary and competent in accordance with *National Statement Chapters 2.2.9, 4.3*.

5.8 Study Procedures

Regional anaesthesia with axillary block is already used regularly in clinical practice at Liverpool Hospital and has been used in the Interventional Radiology Department for fistuloplasty procedures. Anecdotal evidence from reported patient and clinical experiences has shown positive feedback from patients in terms of procedural analgesia and we aim to formally validate its use for Interventional Radiology endovascular fistula procedures through this research.

All patients undergoing endovascular fistula intervention in the Interventional Radiology department at Liverpool Hospital will be offered participation in this study. Patients will be enrolled into the study after informed consent has been completed and patient has met all of the inclusion and none of the exclusion criteria. Women of childbearing age will be screened by nursing staff for possible pregnancy as per routine for all interventional radiological procedures. If any concern or doubt is present, urine pregnancy tests are available within the department.

Patients will be assigned to either the IV sedation with midazolam and fentanyl group or the regional anaesthesia with axillary block group pending proceduralist preference and resource availability.

The patients will be assessed through standardised questionnaires pre and post procedure in addition to monitoring levels of analgesia at defined points during the procedure (pre and during each fistula intervention). Pain will be assessed using a 0-10 scale. The pre procedure questionnaire will be performed at the time of procedural consent which includes the same 0-10 pain scale as a baseline, and the post procedure will be performed one hour post procedure just prior to discharge home. A proceduralist questionnaire will also be conducted. The questionnaires/data collection sheets have been attached as appendix 2. The procedure time, any adverse events or complications will also be recorded for correlation and analysis. If the patient withdraws consent, their data will be removed and excluded from the study, and this will be clearly communicated at the time of consent and outlined in the participants information sheet. Statistical analysis will be performed by the investigators using microsoft excel and SPSS in discussion with a biostatistician. Continuous variables will be summarised using mean (standard deviation) or median (interquartile range) where appropriate and comparison between the study groups will be made using the student T test or the Mann-Whitney U test. Categorical variables will be recorded as counts and percentages and comparisons between the study groups will be made using chi-square or Fisher's exact test. Calculated P-values will be two tailed with P90% and non-inferiority limit (d) 20%.

5.9 Randomisation

Not randomised.

Some proceduralists only perform fistuloplasty under sedation while others only perform with regional block. This provides 2 inherent inbuilt treatment arms based on current practise that we aim to compare (observational). In the vast majority of cases, the decision for sedation vs block is made automatically based on proceduralist expertise, staffing availability and patient factors which removes the potential bias in choosing for each case.

5.10 Data Linkage

Not applicable.

1. 6. TISSUE COLLECTION/BIOBANKING

Not applicable.

7. ETHICAL CONSIDERATIONS

7.1 Study Procedure Benefits

Regional anaesthesia with axillary nerve block has long been used as procedural anaesthesia for upper limb surgical procedures since the 1950's, allowing these procedures to be done without the risks involved with a general anaesthetic [5]. The technique for axillary nerve block has been refined in the intervening decades and is now routinely practiced with ultrasound guidance by a skilled practitioner such as an Interventional Radiologist rather than using surface anatomical landmarks, allowing it to be performed more accurately and more safely [5]. Whilst in the surgical theatre setting, these blocks are performed by a dedicated anaesthetist, in the Interventional Radiology setting, due to overlapping skillset, it can be performed by the proceduralist and thus does not require additional anaesthetic staff. It is currently offered as one of the possible options for procedural anaesthesia for fistula intervention in the Interventional Radiology Department at Liverpool Hospital.

It has been proposed that the use of regional axillary nerve block can avoid issues related to overdosing of analgesia and sedatives in comparison to the standard proceduralist controlled intravenous sedation/analgesia [1,4]. This is especially beneficial as patients with fistulas are at inherently higher risk of over sedation with intravenous sedation due to their profound renal failure. Furthermore axillary block is an opioid sparing procedure and reduced the use of restricted schedule 8 medications [4].

Other benefits of a nerve block include longer acting analgesia rather than the short acting fentanyl traditionally used in IV sedation [1]. An effectively delivered nerve block using xylocaine and bupivacaine can provide up to 8 hours of good analgesia using only a small volume of medication, and limit the analgesic effect to only the targeted body part [6, 7]. As medication is delivered perineurally in the subcutaneous tissue rather than systemically via the intravenous route, there is extremely little risk of systemic side effects such as over sedation or respiratory depression [4]. In addition, patients undergoing axillary block do not require a dedicated sedation nurse for additional monitoring during the procedure. This reduces the burden on resources requires for these sometimes lengthy procedures and should translate to optimisation of resources in the interventional radiology department, Liverpool Hospital and SWS LHD while improving overall patient comfort and care.

Thus far, our experience with axillary and brachial plexus blocks has been supportive of these benefits, which has been reflected in proceduralist, nursing and patient feedback. By obtaining data regarding the efficacy and safety of regional anaesthesia with axillary block compared to intravenous sedation for fistuloplasty, we hope to be able to verify these benefits and encourage its uptake to improve patient care.

7.2 Study Procedure Risks

Risks in this study include over-analgesia, under-analgesia, inadvertent nerve or artery injury, and prolonged numbness post procedure.

Over-analgesia:

The risk of over analgesia is mitigated by several factors. Primarily, the method of delivery of analgesia in axillary block is via infiltration of the subcutaneous tissue surrounding the nerve, rather than intravenous systemic delivery. Because of this the

risk of over analgesia and sedation is extremely minimal [4]. The patient will be continuously monitored by the proceduralist and nursing staff, in addition to assessment of pain and sedation just prior to and during fistula intervention. If over-analgesia, sedation or other adverse side effects are encountered the study will be aborted to ensure the safety of the patient. Previously, patients have been escalated to procedural sedation which involves opioid and other sedative agents which carry a higher risk of over-sedation and respiratory depression.

Under-analgesia

There is also a possibility of under-analgesia in participants receiving axillary block or intravenous sedation. Incomplete nerve block or inadequate titration of intravenous sedation can both lead to under-analgesia, although inherently more likely when giving aliquots of sedation; as conscious IV sedation is titrated to the patient's experience, dosing is given in response to the patient's pain rather than prophylactically/preventatively. Patients' pain levels will be monitored regularly throughout the procedure. If at any stage of the study patient reports under-analgesia, more analgesia may be considered within safe therapeutic limits or the procedure may be terminated or another form of analgesia administered immediately where necessary.

Inadvertent nerve or arterial injury

Inadvertent nerve or arterial injury with needle can occur during the administration of analgesia during axillary nerve block. This is mitigated by the use of ultrasound for image guidance when performing axillary block to ensure it is delivered safely and effectively. Furthermore, the needle used is a small 22-gauge needle, minimising the likelihood of serious harm.

Prolonged numbness post procedure

The duration of numbness post regional block depends on the agents used and its ratio; with xylocaine having a maximum effect duration of up to 2 hours and bupivacaine up to 8 hours [6]. Although the numbing effect is self-limiting, mindfulness will be exercised during patient allocation as patients will already poor mobility may be more prone to falls during this time period. Patients will be monitored post procedurally for 1 hour to ensure return of function, and if for discharge home, will be discharged with carer.

All patients in the study will be closely monitored by appropriately trained proceduralists and nursing staff. Inservices will be conducted where necessary to ensure adequate training for safe monitoring of procedural sedation and education provided on the research project.

Given the on-label use of these formulary medications, all the procedures for the detection, management, evaluation and reporting adverse events/drug reactions are already in place at Liverpool hospital.

Please see section 10 for early termination protocol.

Please see section 8 for adverse event reporting.

Please see section 7.3 for the privacy protection protocol.

All efforts will be made to ensure participant privacy and confidentiality is respected (please see section 7.3).

7.3 Confidentiality and Privacy

All data will be stored on two password-protected computers in the Liverpool interventional radiology department, locked in the doctor's office. All patient data will

be de-identified and anonymised in order to protect patient privacy. Anonymised data will be coded using a randomly assigned study number and stored separately to the data collection sheet. The separate file will link the key MRN data information and the file will be password protected. Specific patient details or identifiers such as name or ethnicity will not be required for the purposes of this study and will not be used or accessed. Confidentiality will be maintained by limiting access to only a few investigators involved in the project. Hard copy information will be destroyed once stored electronically and all data will be disposed of at the end of the standard retention period (15 years for clinical trial as stipulated by NSW requirements). All information in publication will not be identified by individual cases.

Collected data will be stored securely for the protection of patients' confidentiality. All data will be de-identified minimising the risk of confidentiality breach. All aggregated data will be stored on a SWSLHD network drive only accessible to research investigators listed.

7.4 Data Storage and Record Retention

All data will be stored on two password-protected computers in the Liverpool interventional radiology department, locked in the doctor's office and only authorised personnel will have access to the office which requires key and swipe card access and log in credentials would be required to access the computer. The computer is non-portable, no laptop devices will be used. All hard copy forms will be securely stored in the locked filing cabinet in the interventional radiology office and destroyed once stored electronically. The data will only be accessible to investigators involved in the study. Electronic data will be backed-up to protect against data loss. Patients' details will be anonymised from the data collection sheet. Data security is based on the SWS LHD network security as it will be on a SWS LHD network drive in accordance with the institution's data management protocol. The data will be stored for a minimum of 5 years and disposed of at the end of the standard retention period (15 years for clinical trial as stipulated by NSW requirements).

8. SAFETY REPORTING

CLINICAL TRIALS ADVERSE EVENT REPORTING

The use of regional anaesthesia and intravenous sedation will be reported in accordance with standard of practice in Liverpool hospital. Xylocaine, bupivacaine, midazolam and fentanyl will be used safely in accordance to TGA and hospital guidelines in a controlled environment and monitoring for adverse events will be reported in accordance to departmental and hospital policy. The NHMRC standards for safety reporting have been read and will be adhered to for the duration of the study. Additionally processes for the management of patient safety will be governed by ICH GCP guidelines and local policy and procedures.

Guidance will be actively sought if there are any concerns via the Clinical Trials Support Manager on 02 8738 8306.

9. DATA SAFETY AND MONITORING BOARD (CLINICAL TRIALS ONLY)

The Interventional radiology data and safety monitoring board (DSMB) will oversee the trial, meeting biannually to assess the safety and efficacy in each study group. The DSMB is composed of two senior interventional radiologists, one diagnostic radiologist, one clinical nurse educator and two senior radiographers. All members of the DSMB are independent, not involved with the study and do not have any conflict of interest. Measures will be in place to minimize any perceived conflict of interest.

The DMSB will operate under the rules of an approved charter that will be written and reviewed at the organizational DSMB meetings. At this time, each data element that the DSMB needs to assess will be clearly defined.

Both forms of analgesia/anaesthesia are already performed routinely in clinical practise with well established safety profile and low complication rate. Nonetheless, both arms of the study will be closely monitored for any safety issues or adverse outcomes.

10. EARLY TERMINATION

Regional anaesthesia and intravenous sedation are both already used regularly in clinical practise in the interventional radiology department. There have been no unexpected issues or concerns with safety. In addition, these forms of anaesthesia are used safely in other departments and other hospitals. Nonetheless, data (including adverse) will be collected and regularly reviewed for quality assurance, and the study would be terminated in the unlikely event that there were any concerns for patient safety.

11. BLINDING AND UNBLINDING

No blinding or randomisation.

12. CONFLICT OF INTEREST

There are no conflicts of interest. No sponsorship has been requested nor required. The investigators do not stand to benefit financially or otherwise from the outcomes of the study.

13. FUNDING

Nil financial disclosures.

No funding has been requested nor is required for this project. All investigators are contributing their support willingly and voluntarily in their own time.

14. RESEARCH OUTCOMES

There is no intention to return results or feedback to research participants on completion of the study unless required for safety reporting. Research outcomes will however inform future clinical practice. Potential uses of this de-identified data at the end of the project include publication to share insights gained from this study. The data collected covers a variety of patient experience endpoints and can hence provide various qualitative insights on the role of anaesthesia in interventional radiology procedures.

We will aim to publish the research in a peer reviewed journal. We can also use the results to guide best practice in our department, potentially using regional anaesthesia (regional blocks) in more circumstances where clinically appropriate. The data will be archived on two password-protected computers in the interventional radiology department and deleted at the end of the standard retention period. There are no plans to perform secondary analysis on the data at this stage. There are no plans to share the data in the future. There are no contractual, obligations or other agreements with any sponsors/funders/other parties that would influence publication or sharing of the data.

15. REFERENCES

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