REGIONAL ANAESTHESIA WITH AXILLARY/MUSCULOCUTANEOUS BLOCK COMPARED TO INTRAVENOUS SEDATION FOR FISTULA INTERVENTION

Study number:

ABOUT THE TRIAL

- The study aims to assess the efficacy of regional anaesthesia with axillary and musculocutaneous nerve blocks compared to intravenous sedation for endovascular treatments of fistulas in interventional radiology.
- Participants will be anaesthetised with intravenous sedation or regional nerve block, based on the choice of the primary interventionist based on current treatment guidelines.
- Pain levels will be monitored during the procedure and assessed post procedure.
- Procedure time, adverse events or complications will also be recorded for correlation and analysis.
- Ultimately, it is hoped that this will help reduce pain and anxiety for all patients undergoing interventional radiology procedures in the future.

CONSENT

- ❏ I give my consent for information about myself relating to the subject matter above to appear in the journal and associated publications or presentations at professional medical conferences.
- ❏ Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers. The information will be published **without my name** attached and the investigators will make every attempt to ensure my anonymity.
- ❏ The information may be published in the journal, which is distributed worldwide. The journal goes mainly to doctors but is seen by many non-doctors, including journalists and scientific journal websites.
- ❏ I can revoke my consent at any time before publication without prejudice to my relationship with the Interventional Radiology Department, Liverpool Hospital, but once the information has been committed to publication (“gone to press”) it will not be possible to revoke the consent.
- ❏ I understand that if I have any questions relating to my participation in this research, I may contact ross.copping@health.nsw.gov.au
- ❏ I acknowledge receipt of a copy of this consent form.

Complaints may be directed to the South-western Sydney Local Health District Human Research Ethics Committee by emailing **SWSLHD-ethics@health.nsw.gov.au.**

Participant

Signature: Print name: Date:

1. PATIENT DEMOGRAPHICS

Age		Sex	☒M ☒F
DOB		MRN	
ASA score:	☒I ☒II ☒III ☒IV ☒V ☒VI		
ECOG score:	☒0 ☒1 ☒2 ☒3 ☒4 ☒5		
ESRF cause			

2. PROCEDURE INFORMATION

Procedure date	
Indication	
Procedure	☒plasty ☒drug coated balloon ☒stenting ☒trawling ☒thrombectomy/thrombosuction ☒diagnostic, no intervention
Site of treatment	☒arterial inflow ☒anastomotic ☒juxta-anastomotic (<2 cm from anastomosis) ☒swing segment/venous outflow ☒central
%/length of stenosis	
Analgesia	☒SEDATION ☒AXILLARY BLOCK

3. FISTULA DETAILS

Fistula type	☒radiocephalic ☒brachiocephalic ☒brachiobasilic ☒AVG/PTFE ☒other, please specify_____
Side	☒right ☒left
Fistula age	
Last fistuloplasty	

4. PRE PROCEDURE PATIENT QUESTIONNAIRE

Please rate your pain by ticking the number that best describes your pain right now (pre procedure).

1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○

No pain at all — Worst pain imaginable

4. INTRAPROCEDURAL PATIENT MONITORING

PROCEDURE START TIME: FINISH TIME: TOTAL PROCEDURE TIME:

TIME	PAIN SCORE (0-10)	MEDICATIONS GIVEN	DETAILS (inc type of intervention)
Baseline (0)			
Puncture			
Pre intervention 1			
WITH intervention 1			
Pre intervention 2			
WITH intervention 2			
Pre intervention 3			
WITH intervention 3			
Pre intervention 4			
WITH intervention 4			
Pre intervention 5			
WITH intervention 5			
Pre intervention 6			
WITH intervention 6			
Pre intervention 7			
WITH intervention 7			
Pre intervention 8			
WITH intervention 8			
Haemostasis/closure			
On leaving dept			

5. POST PROCEDURE PATIENT QUESTIONNAIRE

Please tick the number that best describes your pain right now (post procedure).

1 2 3 4 5 6 7 8 9 10

○ ○ ○ ○ ○ ○ ○ ○ ○ ○

No pain at all — Worst pain imaginable

Please tick the number that best describes your worst level pain during the procedure.

1 2 3 4 5 6 7 8 9 10

No pain at all Worst pain imaginable

Please tick the number that best describes your <u>average level of pain</u> during the procedure.

1 2 3 4 5 6 7 8 9 10

No pain at all Worst pain imaginable

Based on your experience today, how willing would you be to undergo the procedure again with this form of analgesia or sedation?

1 2 3 4 5 6 7 8 9 10

Not willing at all Very willing

Did you experience any other unexpected symptoms or side-effects? _____

	Worst possible				Low		Mod erate		High		Highest possible
Overall satisfaction with care	0	1	2	3	4	5	6	7	8	9	10
Satisfaction with the procedure	0	1	2	3	4	5	6	7	8	9	10
Satisfaction with pain relief	0	1	2	3	4	5	6	7	8	9	10

Additional post procedure medication required

Phone consult follow-up next day

? pain at site ? any pain for dialysis
? return to normal sensation
? any residual neurology e.g. paresthesia

6. POST PROCEDURE <u>PROCEDURALIST</u> QUESTIONNAIRE

Was the procedure completed in the expected time frame? ☒yes ☒no

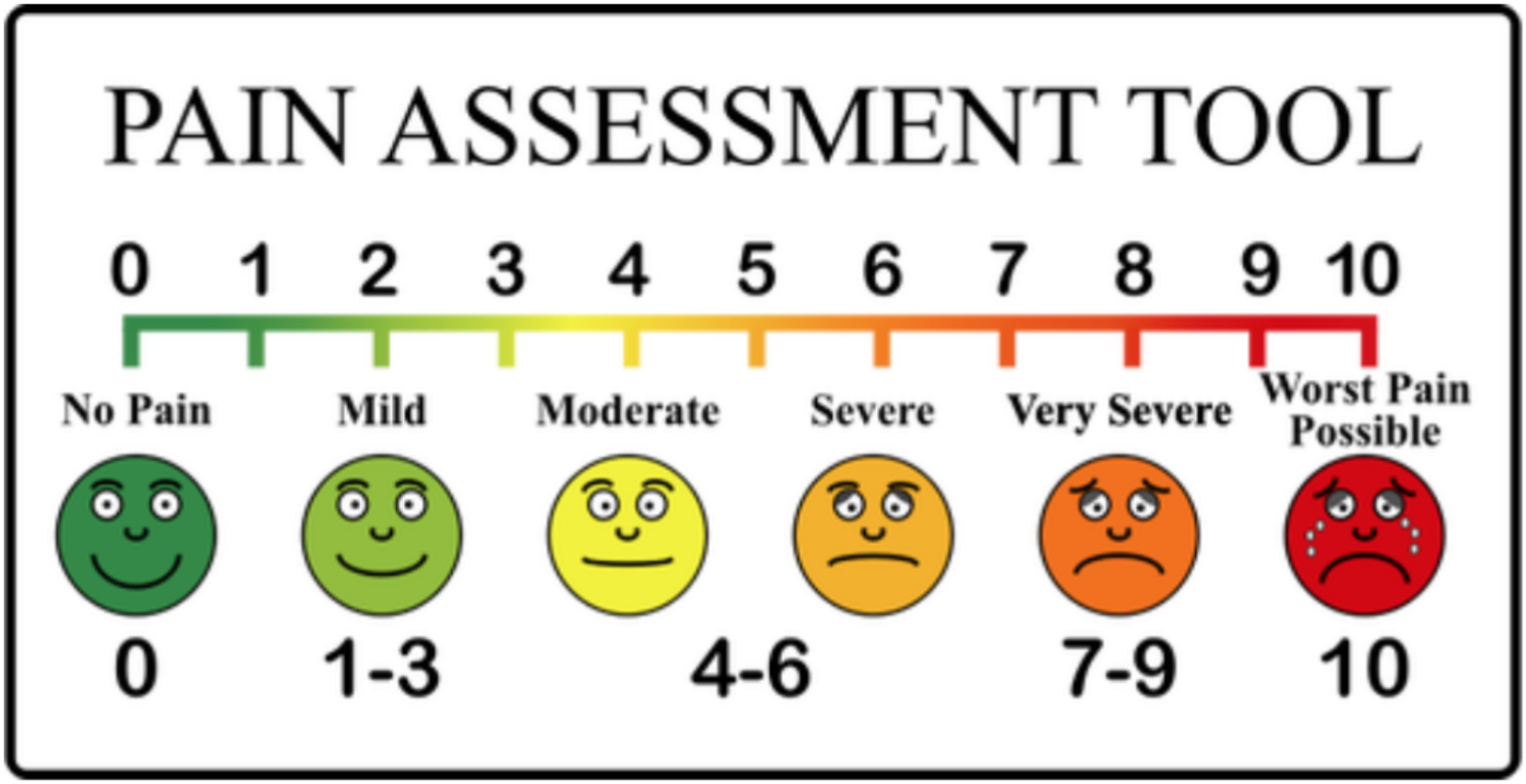
Was there any procedural complication or adverse event? (see Clavien Dindo classification)
☒uncomplicated ☒minor complication ☒major complication ☒unsuccessful

If there was a complication or adverse event, please specify:_____

Was the patient comfortable throughout the procedure? ☒yes ☒no ☒mostly yes ☒mostly not

Was the analgesia effective for the procedure? ☒yes ☒no ☒mostly yes ☒mostly not

PAIN ASSESSMENT TOOL



NSW GOVERNMENT Health
South Western Sydney Local Health District

ASA score

I. Healthy patient
II. Mild systemic disease with no functional limitation
III. Severe systemic disease with definite functional limitation
IV. Severe systemic disease that is constant threat to life
V. Moribund patient unlikely to survive 24h with or without operation

ECOG score

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in *Am J Clin Oncol*: Oken MM, Creech RH, and Tormey DC *et al. (1982)* Toxicity and response criteria of the eastern cooperative oncology group *Am J Clin Oncol* 5 *649–655.*