

Eves J, Cai P, Latham R, et al. A randomised clinical trial of ultrasound guided cannulation of difficult fistulae for dialysis access. *The Journal of Vascular Access* Copyright © 2020 SAGE Publications
DOI: <https://doi.org/10.1177/1129729820954725>

Title:

A randomised clinical trial of ultrasound guided cannulation of difficult fistulae for dialysis access

Authors :

Joshua Eves¹, Paris Cai¹, Ross Latham¹, Clement Leung¹, Daniel Carradice¹, Ian Chetter¹, George Smith¹

1 - Academic Vascular Surgery Unit, Hull York Medical School

Corresponding Author:

George Smith

Academic Vascular Surgery Unit, Hull, HU3 2JZ, UK.

georgeedsmith@gmail.com

Declarations and completing interests: None

Funding: Internal funding from Academic vascular surgery unit, Hull York Medical School.

Ethical Approval: Full Health Research Authority Ethic Committee Approval

Guarantor: As corresponding Author

Contributorship:

Concept : GS. Planning and Staff training: JE, GS, CL. Patient recruitment and data collection: JE, GS. Data analysis: JE, GS, RL, DC. Drafting of manuscript: JE, GS, RL, DC, IC. Final approval of submission: All authors.

Acknowledgements: None

Abstract:

Background: Arteriovenous fistulae (AVF) are preferred for dialysis access but require accurate cannulation for effective dialysis. Evidence supports improvements in cannulation and complication rates using ultrasound guidance (USG) in cannulating other sites. This mixed methods, randomised controlled trial aimed to assess effects of USG during AVF cannulation.

Methods: Participants with difficult to cannulate AVF had each cannulation event randomised to USG or standard technique (no USG). The primary outcome was the incidence and number of additional needle passes. Secondary outcomes included: the incidence and number of additional skin punctures; time to achieve two needle cannulation; pain associated with cannulation; local complications. Qualitative outcomes were assessed using patient and staff questionnaires.

Results: 32 participants had 346 cannulation events randomised (170 to USG and 176 to standard cannulation). USG resulted in a significant reduction in additional needle passes (72 vs 99 $p=0.007$) and additional skin punctures (10 vs 25 $p=0.016$.) but prolonged time to cannulation ($p>0.001$). There was no difference in pain score ($p=0.705$) or complications between groups. Questionnaires demonstrated that USG cannulation is acceptable to patients and staff.

Conclusion: USG cannulation of AVF is more accurate and no more painful than non-image guided cannulation, but prolonged time to cannulation. Some of the excess time involved may be due to the trial being performed early in cannulating staff's learning curve with the USG technique. Further work to elucidate which patients gain most benefit from USG cannulation and the effect of USG on cannulation complications and AVF patency is warranted.

Background:

Autologous arteriovenous fistulae (AVF) are the gold-standard haemodialysis access, associated with reduced morbidity and mortality compared to other forms of dialysis access (1) With increasing AVF prevalence as well as aging and more obese populations in the developed world, increasing numbers of difficult-to-cannulate AVFs are being encountered in practice (1,2,3). AVFs that require multiple needling attempts may suffer more frequent complications which can require prolonged central catheter use or even cause AVF failure resulting in patient dissatisfaction, increased interventions and higher costs. (3,4,5).

There is good evidence that ultrasound guidance (USG) significantly increases successful cannulation rates in central venous (6,7) and peripheral vessel access (8,9). Additionally, there have been increasing reports of the use of US for difficult fistulae access (3,10,11). USG is currently recommended by the Canadian Association of Nephrology Nurses and Technologists' recommendations for the management of vascular access (12), with evidence that 'blind' cannulation results in suboptimal needle placement and potential AVF complications (13)

We hypothesised that USG cannulation of fistulae would improve accuracy of cannulation of AVFs, focusing on those deemed difficult to cannulate by a pre-existing clinical classification in our unit.

Objective:

To investigate whether USG cannulation improves cannulation accuracy, time to completion of two needle cannulation, and reduces complication rates in difficult fistulae.

Methods:

A prospective non-blinded randomised controlled trial was performed comparing the use of USG for the cannulation of difficult to access AVF compared to standard practice (non-USG). Full UK research ethics committee approval was obtained prior to study commencement and the protocol was prospectively registered with ClinicalTrials.gov - identifier: NCT01163981.

Many units stratify AVF according to the level difficulty of their needling to ensure that the most difficult fistulae are cannulated by the most experienced staff. Stratification criteria are based on a variety of factors including the maturity of the fistulae, history of complications or thrombosis, difficulty of palpation and patient anxiety. In our unit, AVF are regularly stratified according to

a “traffic light” system (Table 1) by the vascular access co-ordinator. This stratification ensures appropriate staff are available to cannulate each patient.

Patients were recruited from the current population receiving dialysis in a University Teaching Hospital dialysis unit. Inclusion criteria included: Patients over 18 years with a difficult to cannulate AVF (amber, red or black) (Table 1) who dialyse three times weekly via two needles; ability to provide informed consent. Exclusion criteria included: deviation from routine dialysis protocol; active or recent (within 2 weeks) AVF complications. Accurate AVF stratification was confirmed by the vascular access nurse specialist prior to recruitment. Depth of the AVF wall from the skin surface was measured at 4 points along the needled length of the fistula at the time of consent by a Ultrasound competent investigator.

Staff training was commenced 2 months prior to patient recruitment. A training package was developed by a senior vascular surgeon and two investigators trained in US guided cannulation for delivery to dialysis unit staff. Delivered training consisted of two theory sessions covering use of sonosite portable US machines, followed by two practical teaching sessions with low fidelity models (branched 2 vessel training block, *Blue phantom USA*) favouring the transverse imaging cannulation technique. Assessment of cannulation technique using models was then conducted, with each member of staff having to cannulate low-fidelity model vessels of 5mm diameter at 20mm depth accurately and independently at least three times before they were allowed to perform the task supervised on patients. Training in consenting dialysis patients was practised for cannulation of difficult AVF with US guidance under investigator supervision by each member of cannulation staff over four weeks prior to trial commencement.

Randomisation: Following informed written consent, participants had each dialysis cannulation event over the subsequent four weeks randomised to either the USG or standard (non-USG) technique. Both interventions were undertaken by an appropriately trained member of staff. A randomisation list was produced via an online generator (www.randomization.com) and placed in sequentially numbered sealed opaque envelopes. Envelopes were opened by investigators immediately prior to cannulation and neither cannulation staff nor the patients were aware of allocation prior to the cannulation event. Due to the nature of the intervention over a prolonged

period in an open plan unit, blinding was not possible. We were able to reduce confounding factors such as BMI, staff aptitude for a particular skill, patient tolerance and fistula characteristics by randomising cannulation events rather than patients.

Interventions: USG cannulation was performed using an aseptic transverse ultrasound technique with the Sonosite Edge II ultrasound system (Fujifilm Sonosite, Washington, USA). The HFL50X Sonosite straight probe was used with no preset, the use of simple ultrasound with a straight probe making the intervention generalisable to dialysis units around the globe. Sterile probe covers and gel were used for USG cannulations, and standard drape covers used for all procedures as per normal policy in our unit. The standard or control (non-USG) cannulations were performed using vision and palpation to guide the placement of needles. ‘Wet’ cannulation, using needles pre-flushed with normal saline is standard practice in our unit. Every cannulation event was observed and timed by one of two investigators to ensure accurate recording of outcomes and times. Time recording was started from the time of placing the probe on the fistula for USG cannulations and time of the fingers touching the fistula for control cannulations. Completed cannulation and stopping of timing was once blood ‘flash back’ was checked in both arterial and venous needles ready for dialysis. Ropeladder cannulation technique is used as standard practice in our unit.

Outcomes: Primary outcome was the incidence and number of additional needle passes required for successful needle placement. Additional needle passes were defined as needle pull back and change in direction of the needle following skin puncture, without withdrawal from the skin / additional skin punctures. This was chosen as there is some evidence that increased passes of the needle correlate with fistula complications (14).

Secondary outcomes assessed at each cannulation event included:

The incidence and number of additional skin punctures required, defined as full withdrawal of the needle from the skin necessitating further passage of the needle through the skin.

Time in seconds to achieve two needle cannulation, defined as the time from first skin puncture to successful flushing of the second needle.

Patient reported pain associated with cannulation, recorded on a 10cm visual analogue scale scored from 1 (no pain) to 10 (worst pain imaginable), as well as difficulty in cannulation as recorded by staff, scored from 1 (minimal difficulty) to 10 (extremely difficult.)

Local complications (e.g. bleeding, vessel and needle thrombosis) relating to the individual cannulation event were also recorded.

Patient Questionnaires: were completed by patients at recruitment, halfway through the trial period and at trial conclusion. Questions related to cannulation discomfort and anxiety prior to cannulation, measured on an ordinal scale from 'Not at all' to 'Extreme.' Additionally, questions related to overall fistula satisfaction and acceptability of USG to patients.

Staff questionnaires: were completed by staff responsible for cannulation of participants within the trial following trial completion. Question related to the perceptions of USG in AVF cannulation.

A convenience sample of 30-35 consenting patients each having 12 cannulations was used based upon the suitable patients dialysing in the unit at the time of the trial and investigator resources available to complete the study. Each visit was randomised to cannulation either using USG or standard practice.

Data analysis was performed using SPSS (version 22, IBM, New York, USA). Needle passes and skin puncture outcomes were analysed as binary outcomes (those requiring only 2 punctures or passes and those requiring additional punctures or passes). For pain and difficulty scores, we examined those above and below the mean. Pearson Chi-squared and Mann-Whitney U non-parametric tests were used to determine significance depending on the distribution of data. Levene's test was used to test homogeneity. A comparison of results between stratification of AVF was made to determine the relative benefits of USG with different levels of expected cannulation difficulty. Similarly, maximum and minimum fistula depth were averaged and split into two groups around the mean, for rating of the benefits of USG for fistula at greater depth.

Results

Patients: 48 of 185 screened patients on the dialysis unit were identified as dialysing with an AVF stratified as either 'amber,' 'red' and 'black'. Thirty seven patients met all eligibility criteria and were invited to participate in the study, and 32 patients subsequently consented to participate. One participant withdrew after 7 cannulations due to dissatisfaction with the ultrasound technique, and 3 participants were transferred to satellite dialysis units during the study period (figure 1), resulting in 346 cannulation events being randomised; 170 events to USG cannulation and 176 events to standard (non-USG) cannulation.

Baseline demographics were collected for patients, including age, BMI and co-morbidities at time of consent. These are reported alongside recent UK national audits for renal vascular access in Table 2 (15).

Overall Results are summarised in Table 3.

Primary Outcome

USG cannulation resulted in a significant reduction in the incidence of additional (72 vs 99)($p=0.007$) and absolute number (mean 2.74 vs 3.77)($p<0.001$) of needle passes (Table 3)

Secondary outcomes

USG cannulation resulted in a significant reduction in the incidence of additional (10 vs 25)($p=0.016$) and absolute number (mean 2.06 vs 2.17)($p=0.015$) of skin punctures.

USG cannulation resulted in a significant increase in the time to achieve two needle cannulation (median 190sec vs 118sec)($p<0.001$). Mean time to cannulation in the USG events is indicated in figure 2 and was seen to significantly improved by over a minute when comparing the first and last quartiles of the recruitment period ($p=0.013$).

Patient reported pain associated with cannulation was not significantly different between the USG cannulation and the standard (no USG) group. Lidocaine injections or topical anaesthetic creams were used as per patient preference as is normal on our unit. No changes to patients usual anaesthetic regime was made for either USG and non-USG cannulations and there was no significant difference in their use between events ($p=0.802$.)

There were no significant differences in local complications between the 2 groups (Table 3).

.Comparison of results between stratifications of AVF are shown in table 4, while results between fistula of different depths are shown in table 5. Results according to AVF stratification and fistula depth were post hoc exploratory analyses and were not predefined outcomes.

Patient questionnaires

There was no difference in levels of patient satisfaction with their fistula between baseline and trial exit ($p=0.98$), nor any difference in patient anxiety related to cannulation ($p=0.87$). 57% of recruited patients reported to experience 'A little bit' of discomfort. There was no difference in overall levels of discomfort reported by patients at baseline compared to trial exit or between US

guided and control cannulation events. There was no significant association between anxiety and reported discomfort in the recruited patients.

Staff questionnaire

Twenty two cannulating staff questionnaires were completed at the cessation of the trial. Greater USG cannulation experience was correlated with improved confidence in the technique though this did not reach significance ($p=0.059$). 25% of staff felt that US guided cannulation was neither slower nor faster than the conventional method while 50% maintained that the US method took longer.

Questionnaire data from nursing staff suggested that confidence increased with increased USG experience, and that staff with more USG experience were also noted to have a greater appetite for further training indicating that the technique was popular with staff. 85% of nurse respondents felt they would benefit from further cannulation experience. Those nurses with the highest levels of prior experience with non-image guided cannulation tended to report the least enthusiasm for further USG experience and additional training. Apart from training offered by trial investigators, none of the cannulating staff involved in the trial had significant prior USG cannulation training, while limited numbers of senior nurses were in the practice of using US for basic fistula assessment in the event of complications. Prior non-USG haemodialysis cannulation experience ranged from 6 months to 20 years.

Discussion

This prospective randomised trial of USG cannulation of difficult to cannulate fistulae has proven the feasibility of the technique for use in a busy tertiary outpatient haemodialysis unit. Previously, barriers to the use of ultrasound in dialysis access have included the requirement of skilled staff, logistical difficulties due to the high turnover of staff, time-pressured haemodialysis environment and cost (5) We have demonstrated the effectiveness of introducing a short training programme for cannulating staff and shown that use of USG cannulation did not impact on patient anxiety or discomfort. USG facilitated cannulation, reducing additional needle passes and skin punctures, though prolonged time taken for cannulation by approximately 60 seconds. It should be acknowledged that nurses were assisted by trial investigators in the setup of US including moving the US system and placing sterile probe covers prior to commencement of the timer. The small increase in time to set up dialysis did not interfere with the running of the unit

during this study and cannulation times improved significantly over the course of the trial (figure 2), implying that the nurses were likely to still be relatively early in their learning curves for USG cannulation. As such, further improvements in speed of use and other outcomes might be expected with increased experience as was seen by a reduction in USG cannulation time during the trial period as above.

Though numbers for analysis are small, an exploratory comparison of cannulations over the three grades of AVF included demonstrated that amber patients appeared to gain relatively limited benefit from use of ultrasound. Amber AVF showed a non-significant difference in the number of skin punctures or needle passes between US guided and control cannulations, whilst there was a marked increase in time taken (70 seconds longer). Benefits of US guidance were more pronounced in the more difficult red AVF showing highly significant reductions in needle passes and skin punctures with a much reduced disparity in time taken (only 10 seconds). The most difficult black fistulae might be expected to show the greatest level of benefit, though differences for accuracy were non-significant in this group and time to cannulation was significantly longer again (73 seconds longer on average). Explanations of this seemingly anomalous finding may be that some AVF were labelled as black solely due to being less than 3 months since old, and may in fact be readily palpable and easy to cannulate without imaging assistance. Equally, cannulation of black fistulae is reserved exclusively for those staff with the highest levels of experience so the standard cannulations of this group may be expected to be of the very highest standard.

Breakdown of results by relative depth of a fistula appear to reinforce the idea that US guided cannulation has greater benefit in those fistula which are expected to be more difficult to cannulate. There were significantly reduced needle passes and skin punctures in USG cannulation of deeper fistulae, as well as reduced differences in time to cannulation (table 5.)

Limitations

This trial was a pragmatic design demonstrating that US can be quite quickly implemented in a busy haemodialysis outpatient unit without major disruption to the day to day running of the unit. Randomisation of cannulation event rather than participants was used to reduce the risk of selection or performance bias, as well as confounding factors. However due to the nature of the intervention, it was impossible to blind patients to the use of US. The learning curve for US

guided cannulation may also have been underestimated prior to trial implementation and a measurable improvement in US performance seen during the trial would support this. It is conceivable that further training and experience may result in improved speed and other desirable outcomes. Further work could also elucidate whether familiarity with USG cannulation might allow cannulating staff to identify signs of fistula complications early, which could result in earlier intervention and improved fistula care or even survival.

Patient and cannulation numbers in this study were relatively small and insufficient to detect observable improvements in complication rates, concentrating instead on outcomes of accuracy as a surrogate marker of the risk of complications. As such, any future prospective studies may require a larger sample and longer follow-up in order to detect a reduction in complication rate or improved AVF patency. As USG becomes more widely practiced in dialysis centres, an important outcome measure for subsequent work will be cannulation site rotation. It is the belief of the investigators of this study that equipping nurses with ultrasound skills may give nurses confidence to cannulate additional areas of the AVF, helping reduce the practice of relative 'area' cannulation and thus further reducing AVF complications.

Conclusion

This trial demonstrated that US guided cannulation can be introduced to a busy dialysis unit, and showed a significant benefit in terms of accuracy of cannulation for more difficult to cannulate patients. While cannulation times were slightly prolonged, there were no significant changes in patient reported pain, or staff reported difficulty. It is possible that this trial was conducted early in the cannulating staff's learning curve as measurable and significant improvement in time to cannulation was seen, even over the short duration of this trial. Further analysis by AVF grading and fistula depth suggested that US guidance has greatest benefit in the most difficult patients.

References

- 1- Lok C and Foley R , Vascular Access Morbidity and Mortality: Trends of the Last Decade. Clin J Am Soc Nephrol 8:1213-1219,2013
- 2- Ward F, Faratro R, McQuillan RF. Ultrasound-Guided Cannulation of the Hemodialysis Arteriovenous Access. Seminars in Dialysis. 2017;30(4):319-25.
- 3- Kamata T, Tomita M, Iehara N. Ultrasound-guided cannulation of hemodialysis access. Renal Replacement Therapy. 2016;2(1):7.

- 4- Lee T, Barker J, Allon M. Needle infiltration of arteriovenous fistulae in hemodialysis: risk factors and consequences. *Am J Kidney Dis.* 2006;47.
- 5- Harwood LE, Wilson BM, Oudshoorn A. Improving vascular access outcomes: attributes of arteriovenous fistula cannulation success. *Clin Kidney J.* 2016;9(2):303-9.
- 6- Prabhu MV, Juneja D, Gopal PB, Sathyanarayanan M, Subhramanyam S, Gandhe S. Ultrasound-guided femoral dialysis access placement: a single-center randomized trial. *Clin J Am Soc Nephrol.* 2010;5.
- 7- Hind D, Calvert N, McWilliams R, Davidson A, Paisley S, Beverley C. Ultrasonic locating devices for central venous cannulation: meta-analysis. *BMJ.* 2003;327.
- 8- Roberts J, Manur R. Ultrasound-guided radial artery access by a non-ultrasound trained interventional cardiologist improved first-attempt success rates and shortened time for successful radial artery cannulation. *J Invasive Cardiol.* 2013;25.
- 9- Egan G, Healy D, O'Neill H, Clarke-Moloney M, Grace PA, Walsh SR. Ultrasound guidance for difficult peripheral venous access: systematic review and meta-analysis. *Emerg Med J.* 2013;30.
- 10- Patel RA, Stern AS, Brown M, Bhatti S. Bedside ultrasonography for arteriovenous fistula cannulation. *Semin Dial.* 2015;28.
- 11- Kumbar L, Soi V, Adams E, Brown Deacon C, Zidan M, Yee J. Coronal mode ultrasound guided hemodialysis cannulation: A pilot randomized comparison with standard cannulation technique. *Hemodial Int.* 2017.
- 12- Canadian Association of Nephrology Nurses and Technologists. Nursing recommendations for the management of vascular access in adult haemodialysis patients: 2015 update. *CANNT J.* 2015;24(supp1):1 –45
- 13- Marticorena R, Kumar L, Concepcion Bachynski j, Dacouris n, Ian Smith, and Donnelly S. Ultrasound evaluation of intraluminal needle position during hemodialysis: Incidental findings of cannulation complications.. *CANNT Journal April-June 2018.*)
- 14- Suri R, Larive B, Sherer S, Eggers P, Gassman J, James SH et al. Risk of vascular access complications with frequent hemodialysis. Suri RS et al. *J Am Soc Nephrol.* 2013 Feb;24(3):498-505
- 15- Hole B, Caskey F, Evans K, Fluck R, Kumwenda M, Steenkamp R, et al. UK Renal Registry 19th Annual Report: Chapter 12 Multisite Dialysis Access Audit in England, Northern Ireland and Wales in 2015 and 2014 PD One Year Follow-up: National and Centre-specific Analyses. *Nephron.* 2017;137 Suppl 1:269-96.