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Background and aims

A functioning vascular access (VA) is crucial to providing adequate haemodialysis (HD) and considered a critically important outcome by patients and healthcare professionals.

VALID aimed to validate a core outcome measure for VA function established via consensus among 918 health professionals and 237 patients and caregivers from 58 different countries^{1,2}.

Methods

- STARD guidelines for diagnostic accuracy studies (Figure 1)
- Prospective, multi-centre, multinational validation study (NCT03969225) assessing the feasibility, agreement, and accuracy of measuring VA function³.
- VA function defined as the need for interventions to enable and

Table 1 Baseline characteristics of study participants

Characteristic	Participants n=699
Age, years (mean [SD])	63 (16)
Male, n (%)	420 (60)
Female, n (%)	279 (40)
Ethnicity, n (%)	
- White	443 (63)
- Asian	158 (23)
- Indigenous	44 (6)
Body mass index, kg/m ² (mean [SD])	27 (7)
Vascular access type	
- AVF	514 (74)
- AVG	57 (8)
- CVC	135 (19)
Diabetes mellitus, n (%)	314 (45)
Cardiovascular disease, n (%)	263 (38)
- Cerebrovascular accidents	69 (10)
- Ischaemic heart disease	187 (27)
- Peripheral vascular disease	91 (13)
Dialysis duration, years (mean [SD])	4.2 (4.3)

maintain VA use for HD.

- Primary objective: to determine whether VA function can be measured accurately by clinical staff as part of routine clinical practice (Assessor 1) compared to the reference standard of documented VA procedures collected by a VA expert (Assessor 2) during 6 months of follow-up.
- Validity assessed by the sensitivity and specificity of the VA intervention data with sensitivity corresponding to the proportion of correctly identified interventions by Assessor 1 compared to Assessor 2.
- Secondary objectives: Feasibility (see Figure 1)

Figure 1 Study Design



Outcomes

Validity and Agreement:

Accuracy: 92% (95% confidence interval [CI] 91-94%) with high agreement (kappa=0.87) between Assessors 1 (n=15) and 2 (n=14). **Sensitivity** (Cluster-corrected) = 81% (95%Cl 75-85%) **Specificity** (Cluster-corrected) = 96% (95%CI 95-97%).

Feasibility:

Data collection time: 4 minutes (IQR 2-6min)/patient over 6 months Based on feasibility questionnaires and supported by qualitative interviews, the majority of assessors 1 and 2 agreed or strongly agreed that it was easy to collect the number (67%/83%), type (73%/92%) and date (80%/92%) of VA procedures and to report the outcome as part of routine clinical care (66%/75%). Catheter removals were considered the most challenging VA procedure to collect.

Conclusions

Measuring VA function using a standardised, patient-centred core outcome as part of routine care is feasible with moderate accuracy. Consistent reporting of this core outcome in clinical research will enhance research quality and relevance and help better inform HD care.

Results

Across 7 countries (Australia, Canada, France, Netherlands, Malaysia, the United Kingdom and Switzerland) and 10 centres, we recruited 699 adults on HD between December 2019 and December 2021.

Total of 359 VA interventions (rate=1.04 per patient-year). Most common interventions:

- 133 (37%) catheter-related procedures
- 131 (36%) fistulograms with/without angioplasty/stenting
- 43 (13%) surgical/endovascular arteriovenous access creation •
- 26 (7%) AV access revisions.

Baseline characteristics are shown in Table 1.

Funding bodies and collaborators



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References

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