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# Editor's Choice – Recommendations for Registry Data Collection for Revascularisations of Acute Limb Ischaemia: A Delphi Consensus from the International Consortium of Vascular Registries

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**WHAT THIS PAPER ADDS**

This international Delphi process has generated a core set of items to be captured by vascular quality registries that are specific for acute limb ischaemia (ALI) and supplement previous recommendations for chronic peripheral arterial occlusive disease. This core set can be used to standardise data collection for comparability across registries and thereby facilitate amalgamation of real world data, and comparisons between centres, regions, and countries. Ultimately, harmonised registries will provide a base for international collaboration to fill evidence gaps and contribute to improving the care of patients with ALI.

**Objective:** To develop a minimum core data set for evaluation of acute limb ischaemia (ALI) revascularisation treatment and outcomes that would enable collaboration among international registries.

**Methods:** A modified Delphi approach was used to achieve consensus among international multidisciplinary vascular specialists and registry members of the International Consortium of Vascular Registries (ICVR). Variables identified in the literature or suggested by the expert panel, and variables, including definitions, currently used in 15 countries in the ICVR, were assessed to define both a minimum core and an optimum data set to register ALI treatment. Clinical relevance and practicability were both assessed, and consensus was defined as $\geq$ 80% agreement among participants.

**Results:** Of 40 invited experts, 37 completed a preliminary survey and 31 completed the two subsequent Delphi rounds via internet exchange and face to face discussions. In total, 117 different items were generated from the various registry data forms, an extensive review of the literature, and additional suggestions from the experts, for potential inclusion in the data set. Ultimately, 35 items were recommended for inclusion in the minimum core data set, including 23 core items important for all registries, and an additional 12 more specific items for registries capable of capturing more detail. These 35 items supplement previous data elements recommended for registering chronic peripheral arterial occlusive disease treatment.

**Conclusion:** A modified Delphi study allowed 37 international vascular registry experts to achieve a consensus recommendation for a minimum core and an optimum data set for registries covering patients who undergo ALI revascularisation. Continued global harmonisation of registry infrastructure and definition of items allows international comparisons and global quality improvement. Furthermore, it can help to define and monitor standards of care and enable international research collaboration.

**Keywords:** Acute limb ischaemia, Consensus development, Delphi technique, Health services research, Registries
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## INTRODUCTION

Although more widespread antithrombotic treatment of atrial fibrillation (one of the most important causes) has led to a decreasing incidence of acute limb ischaemia (ALI), this limb and life threatening condition remains a great challenge for vascular surgeons and interventionists.[1] Like all emergency conditions, ALI is difficult to study. To date, the evidence base regarding open surgical vs. thrombolytic therapy is limited to a few outdated randomised controlled

[†] The full list of Acute Limb Ischaemia Collaborators is available in Appendix S1 (Supplementary Material).

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trials.[2] Thus there is a need to gather real world data on risk factors, treatment, and outcome at the time when novel pharmaceutical agents and interventional techniques have entered clinical practice. Patient registries can provide valuable contemporary data to address open questions. However, there is no consensus among national registries regarding which data elements are critical or how to categorise these to allow harmonisation.

International collaborations such as the International Consortium of Vascular Registries (ICVR; www.icvr-initiative.org) are intended to promote cross border research. The ICVR includes countries with vascular surgery registries such as the Vascular Quality Initiative (www.vqi.org) in the USA and the Vascunet collaboration of vascular registries from 20 countries in Europe and Australasia (www.vascunet.org).[3,4] The ICVR was established in 2014 with the goal of implementing a collaborative platform across registries to share data in order to improve the quality of vascular health care.[5] Contributions regarding abdominal aortic aneurysms,[6] carotid artery stenosis,[7] and recommendations on chronic peripheral arterial occlusive disease (PAOD) revascularisation registries were recently published by this collaboration.[8,9] In the current project, ICVR members applied a modified Delphi approach to achieve agreement on both a minimum core and optimum dataset for registries capturing risk factors, treatment patterns, and outcome for patients treated for ALI in addition to prior recommendations on chronic PAOD. The results of the current study aim to supplement the European Society for Vascular Surgery (ESVS) practical guidelines on ALI (to be published in 2020). Furthermore, the results of the current study aim to amplify prior recommendations on chronic PAOD. Registries already collecting patients with chronic PAOD can extend their scope by using the current recommendations.

## METHODS

The Delphi approach is widely accepted and used to gain consensus among a panel of experts,[10] and has previously been used in various specialties, including vascular medicine.[8,11–15] The registry data forms of all 14 registries participating in the ICVR were reviewed to identify relevant items for ALI needed to supplement current ICVR recommendations on registration of chronic PAOD revascularisations.[8] Additionally, a narrative literature review was conducted to identify potential additional items to record for ALI. Medline was searched for meta-analyses, systematic reviews, and guidelines, using a combination of keywords referring to ALI (acute limb ischaemia, acute limb ischaemia, acute arterial occlusion, acute leg ischaemia, acute leg ischaemia, ischaemic foot) and quality improvement measurement (registry, registries, outcome, end point, follow up, measures, performance measures, items). In addition, a grey literature search was performed: websites concerning ALI or indicators of outcome were searched by hand for guidelines, statements, and quality indicators. The search was restricted to the English language. No restriction regarding publication date was used. All ICVR experts were invited to evaluate the list of items identified during this process and to suggest additional items to be included in the Delphi process. All participants agreed to the scope of items identified through the above mentioned process. Members of the ICVR and members of the writing committees of the 2017 European Society of Cardiology Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the ESVS,[16] as well as the ESVS guidelines on ALI (to be published in 2020), were then invited to participate in web based, anonymised electronic questionnaires. Open source software (Limesurvey, Hamburg, Germany; www.limesurvey.org) was used to generate the questionnaires and there was no further quality control of the software by the authors. The participants could only submit one set of answers in each Delphi round. Following the preliminary survey and first round, a structured report, including distribution of the group responses using bar charts, as well as comments, was forwarded to the participants via email before they were invited to the next round. In the first round, each participant was asked to score each item in terms of clinical relevance, as well as practicability in clinical practice. Each item was scored for both parameters on a five point Likert scale, comprising "strongly agree", "agree", "neutral", "disagree", and "strongly disagree". Items received a consensus recommendation for the minimum dataset if at least 80% of the participants voted "strongly agree" or "agree" for clinical relevance and practicability. Items with $<$60% agreement for clinical relevance or practicability were eliminated from further consideration. In line with prior recommendations,[8] a set of minimum core data elements felt necessary for any registry (level 1) were defined, as well as an optimum set of additional data elements (level 2) recommended for registries capable of collecting more detailed information. In general, level 1 variables typically had simple options (e.g., yes, no), while level 2 variables had increasing specificity. For example, only a history of a peripheral aneurysm was recommended for level 1, while the specific location and diameter of a peripheral aneurysm were recommended for level 2 reporting (see Table 1). Level 1 data elements were judged sufficiently important to always be registered. The median time for the experts to answer a question in the modified Delphi process (duration between opening the questionnaire and saving the results) is displayed as median time in minutes, including interquartile range (IQR).

### *Statistical analysis*

The agreement of individual experts' answers in both Delphi rounds was tested using the Student *t* test and mean difference for the tendency of answering. Missing data due to non-participation in one round were not imputed. Statistical analyses were performed with software R version 3.3.2 (The R Foundation for Statistical Computing, Vienna, Austria).

## RESULTS

Of 40 experts invited, 37 (93%) accepted and completed the preliminary survey. The panel comprised vascular surgeons

**Table 1. Thirty-five items in five categories (risk factors, medication, clinical presentation, procedure details, outcome) to be recommended for acute limb ischaemia revascularisation registries**

| Item | Level 1 | Level 2/3 |
|---|---|---|
| *Risk factors* | | |
| History of malignancy | Yes/no | If yes: type of malignancy, type of treatment |
| History of atrial fibrillation or atrial flutter | Yes/no | If yes: paroxysmal vs. permanent |
| History of arterial embolisation | Yes/no | |
| History of peripheral aneurysm | Yes/no | If yes: location and diameter of peripheral aneurysm |
| History of stroke | Yes/no | |
| History of aortic aneurysm or dissection | Yes/no | |
| Prior revascularisation/ reconstruction of affected leg | Yes/no | Type of prior revascularisation/ reconstruction; if any: prior catheter based intervention |
| *Medication* | | |
| If any: type of anticoagulants at presentation | For example, vitamin K antagonists, direct oral anticoagulants, heparin | If any: name and dose of anticoagulants |
| Any recent stop or switch (change) of anticoagulants | –/– | Yes/no |
| *Clinical presentation* | | |
| Rutherford ischaemia classes | I, IIA, IIB, III | |
| Sensory deficit | Yes/no | |
| Motor deficit | Yes/no | |
| Upper vs. lower extremity | Arm/leg/both | |
| Aetiology or cause of acute limb ischaemia | –/– | Native artery thrombosis, embolus, acute native artery occlusion or thrombosis or embolus, thrombosed arterial aneurysm, occluded previous vascular reconstruction, other (e.g., popliteal entrapment syndrome) or unknown |
| Concomitant embolic focus | –/– | Coronary arteries, carotid or vertebral arteries, visceral arteries, renal arteries, other |
| Level/location of index occlusion | –/– | Upper/lower arm, aorto-iliac/ above the knee/below the knee |
| *Procedure* | | |
| Ischaemia duration: time from first symptom to procedure | In hours and minutes | |
| Type of treatment/procedure Including: open surgical thrombo-embolectomy, catheter directed thrombolysis, catheter guided thrombo-embolectomy | Multiple selection: best medical treatment only, primary amputation only, open surgical thrombo-embolectomy, catheter-directed thrombolysis, catheter guided thrombo-embolectomy | |
| Primary fasciotomy | Yes/no | |
| Intra-operative completion angiography | Yes/no | |
| *Outcome* | | |
| Rutherford ischaemia classes | –/– | I, IIA, IIB, III |
| Residual sensory deficit | –/– | Yes/no |
| Residual motor deficit | –/– | Yes/no |
| Compartment syndrome | Yes/no | If compartment syndrome: unplanned fasciotomy |
| Major bleeding or haemorrhage | Yes/no | |
| If any: intracranial haemorrhage | Yes/no | |
| Haemorrhage at access site | –/– | Yes/no |
| Infection at (surgical) access site | –/– | Yes/no |
| Acute kidney injury | Yes/no | |
| Multi-organ failure | –/– | Yes/no |
| If death: cause of death | –/– | Death related to acute limb ischaemia? |

and interventionists (both internal medicine specialists and radiologists), representing 15 countries and 36 institutions. In total, 76 items potentially useful to register ALI treatment were identified from the available literature, while another 79 items were already recommended for chronic PAOD in a prior study and, accordingly, excluded from this evaluation. Additionally, 41 complementary items were suggested by the expert panel during the preliminary survey. Ultimately, 117 items were included in the panel discussion (Table S1; see Supplementary Material). The final number of data elements was not defined prior to the Delphi rounds. The items were reviewed by the authors, and subsequently sorted into five main categories: risk factors, medication, clinical presentation, procedure details, and outcome.

Thirty-seven panel experts completed round 1 (median 22.6 min, IQR 18.0) and 31 of them also completed round 2 (median 7.7 min, IQR 3.7).

After the first Delphi round, 37 items reached the 80% consensus limit for clinical relevance. Of these, 23 items also reached the 80% consensus limit for practicability (excellent level of agreement) (Fig. 1) and one item failed to reach the 60% limit for practicability. Another 61 items failed to reach the 60% limit for clinical relevance. After a group discussion, 33 items were recommended after the first Delphi round and an additional 23 items with ambiguous results (between 60% and 80% limit of agreement) were forwarded to the second Delphi round.

After two Delphi rounds, two of 23 items with ambiguous results (from round 1) reached the 80% consensus limit for clinical relevance and practicability: "aetiology or cause of ALI" and "time from the first symptom to procedure" reached at least 80% consensus for clinical relevance and practicability. The remaining 21 items included into the second Delphi round failed to reach the 80% limit of agreement.

The Delphi process (Fig. 1) ultimately recommended 35 items (33 items from Delphi round 1 and two items from Delphi round 2) specific to ALI treatment for registry collection (with different levels of potential detail) (Table 1). It was also recommended that all registries create the response alternative "unknown", in order to differentiate omitted from unknown data, and not force users to choose an unclear option. However for simplicity, the "unknown" options for each variable have not been included in Table 1.

## DISCUSSION

In this modified Delphi study involving 37 international experts in multidisciplinary vascular care and registry based research, consensus to recommend 35 additional items specific to ALI treatment for registries was achieved. These items, specific for ALI, supplement prior recommendations on registering patients treated for chronic PAOD (79 items), and will help to harmonise international research using real world data.[8,17] It must be noted that in order to benefit from the current recommendations, registries should capture selected items of interest for ALI from prior recommendations on chronic PAOD. Important risk factors and outcomes such as amputations have not been included in the current ALI Delphi process but were already captured by prior recommendations.

Patients with ALI are known to be elderly, and they frequently suffer from multiple comorbidities. Of 45 different risk factors evaluated in this Delphi study, the expert panel selected seven items to supplement the minimum data set recommended for chronic PAOD. Interestingly, $>$ 10 different laboratory values were considered by the expert panel, but none reached the 60% consensus limit during the two Delphi rounds. As for medication, only treatment with any anticoagulation reached level 1. For example, the use of heparin in the emergency department was not included, despite the fact that this practice is associated with reduced risk of death and amputation.[18,19] The aetiology of ALI was considered clinically relevant but not practicable in $>$80%, and therefore set as a level 2 recommendation, owing to difficulty distinguishing between a non-classical embolism and thrombosis.

Despite changing environments and the widespread adoption of endovascular techniques, the treatment of this urgent condition in daily practice remains challenging. High amputation and mortality rates remain important consequences of ALI, emphasising the need for further research to improve and harmonise care.[20–23] To this end, treatment practices were included as an important component of this study. Ischaemic duration reached a high level of consensus and is a key factor for outcome, but to the authors' knowledge, is not yet included in any registry for ALI. This new indicator may help to reduce time delay and can be used for future quality improvement projects.

To ameliorate this situation and to reach consensus on the treatment of ALI, the ESVS has initiated a process of developing clinical practice guidelines for the treatment of ALI, to be published in early 2020.

This study has limitations. Firstly, the composition of the expert panel may have significantly affected the group discussion and subsequent consensus. As patients with ALI are treated by different medical specialties, there might be disagreement among the panel members on how to treat these patients which could affect the evaluation of items. To address this bias, the panel comprised experts from all medical specialties involving vascular surgery, internists, and radiology. Secondly, the point of including the patient's point of view is essential in modern patient centred medicine. According to that, items considering patient reported outcome measures (e.g., quality of life) were included in the Delphi process but failed to reach the required consensus limit (62% for clinical relevance, but only 38% for practicability in current registries). This result may be explained by the perceived difficulty, right or wrong, of involving patients who are frail and suffering an acute life threatening condition, in the decision making. Lastly, the recommendations of the current study can only reflect the group consensus among countries participating in the Delphi process. The VASCUNET collaboration and the ICVR should raise their efforts to involve more countries in the future.

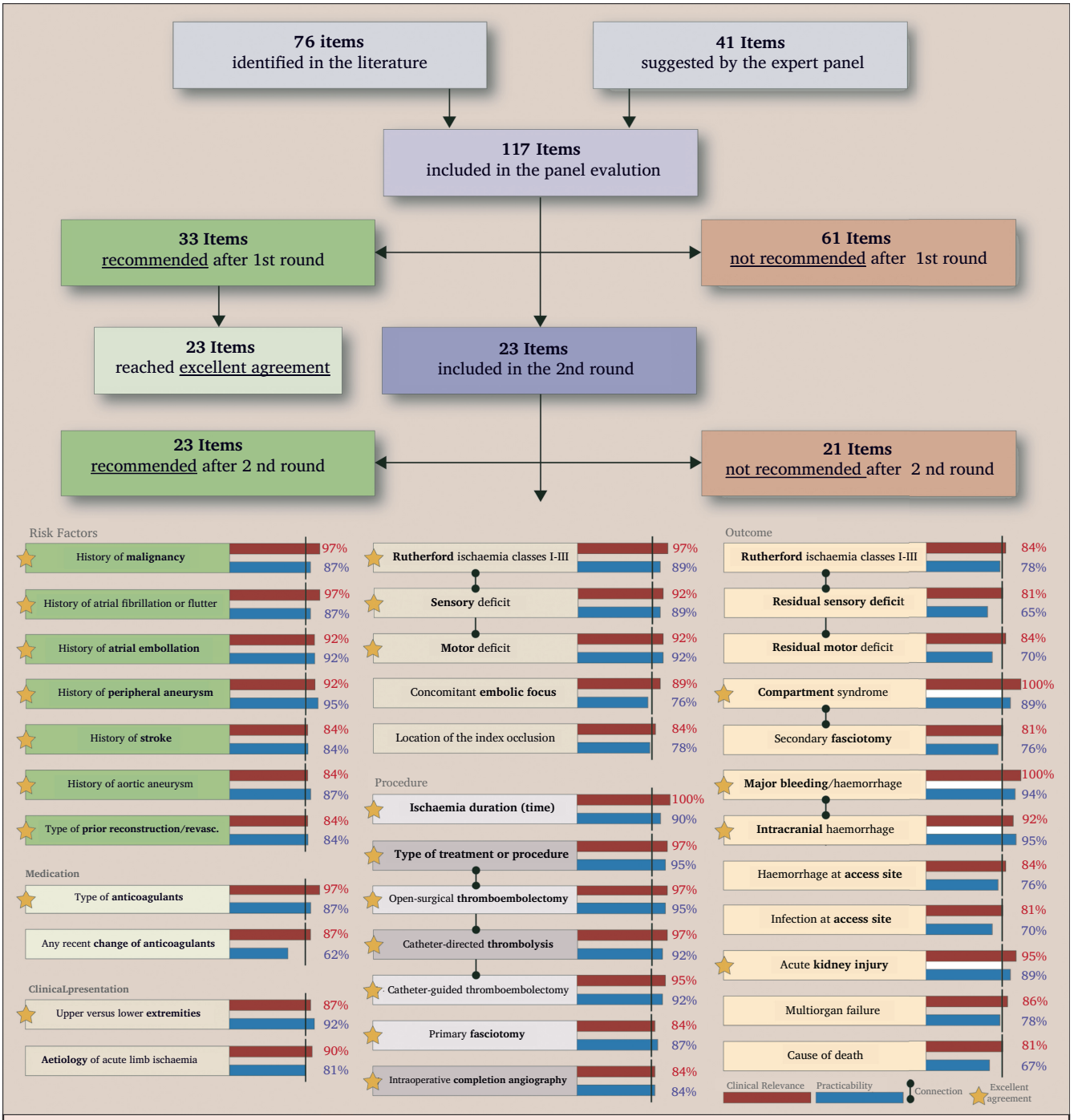


**Figure 1.** Flow chart of the modified Delphi expert consensus process. Of 117 items included in the panel evaluation, a total of 35 registry items were recommended for acute limb ischaemia revascularisation registries. The red bars illustrate the group results for clinical relevance. The blue bars represent the group results for practicability. Twenty-three items reached excellent levels of agreement for both clinical relevance and practicability (star).

Registry based quality improvement projects should in the future result in the collection of self reported patient data after treatment for emergency diseases such as ALI. This would also decrease the rapidly growing documentation burden and improve the practicability of quality improvement registries. There are a number of ways to integrate patient related outcome data into registries. The development of electronic health technology is a rapidly evolving field with easy to use applications that appears to enhance patient care.[24]

## CONCLUSIONS

This modified Delphi study among international vascular registry specialists achieved consensus on a minimum core and optimum dataset for registries evaluating ALI

revascularisation. It reduced the overall number of initial potential variables by nearly half. This core set of items has the potential to standardise data collection between existing and upcoming registries so that clinical data on ALI revascularisation can be merged and compared.

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## CONFLICT OF INTEREST

None.

## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2019.02.023.

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