SSC Subcommittee Project/Collaborative Project

Standardized reporting and analysis for diagnostic studies in venous thromboembolism

Subcommittee:

Predictive and Diagnostic Variables in Thrombotic Disease

Person responsible (Principal Investigator):

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Description abstract

Over the past decades, the diagnostic management of venous thromboembolism (VTE) has gone through a great change. An abundance of studies has been published, evaluating ever-improving diagnostic algorithms and tests. However, as reporting of diagnostic studies has been shown to be often incomplete, correct interpretation and appraisal of study results, as well as incorporation in future analyses, and repeatability may be hampered.[1,2] To improve the quality of reporting in diagnostic accuracy studies, the Standards for Reporting Diagnostic Accuracy (STARD) statement has previously been developed and published.[3] However, several VTE-specific reporting elements are not covered by STARD. In addition, VTE diagnostic studies require specific statistical analyses, as a considerable amount of studies include the use of a diagnostic algorithm instead of a single diagnostic test. Moreover, most studies do not have a cross-sectional design, but are rather management studies in which a clinical follow-up for the occurrence of VTE events is the reference standard in those in whom VTE is ruled out at baseline. The aim of the present project is to evaluate reporting and statistical analysis of recent diagnostic VTE studies in a systematic review, and subsequently propose recommendations for standardized reporting and analysis for diagnostic studies in the field of VTE.

Design and methodology

1. Systematic review of reported variables and statistical analysis in diagnostic VTE studies

The first step includes a systematic review to evaluate completeness of reporting and statistical analysis in recent diagnostic studies in the field of VTE. The findings of the systematic review will be used in the development of a novel guidance on standardized reporting and statistical analysis in VTE studies.

A systematic search of the literature was conducted in MEDLINE and Embase from January 1st, 2005 until August, 1st, combining terms for 'diagnosis', 'deep vein thrombosis', and 'pulmonary embolism'. Diagnostic management studies including adult patients with suspected deep vein thrombosis or pulmonary embolism were eligible. Patients in whom VTE was excluded at baseline had to be followed for the occurrence of VTE events. Cross-sectional diagnostic accuracy studies were excluded. Titles, abstracts, and subsequently full-text articles were screened by two independent authors. Data extraction will be performed independently in duplicate using standardized forms, including reporting of study and patient characteristics, study outcomes, follow-up duration, and handling of losses to follow-up/protocol violations. In addition, time-to-event data of the patients with VTE during follow-up will be requested from the corresponding authors.

2. Draft guidance essential reporting items and analysis

Based on the findings of the systematic review, a preliminary list with essential reported items and analysis strategies will be developed. A consensus meeting will be planned with the members of the SSC working group to establish (and extend if needed) the first draft of the list with essential reporting items and preferred analysis strategy.

3. Delphi survey with thrombosis experts

An online modified Delphi survey with international thrombosis experts will be conducted to establish the final guidance recommendations. Participants will be selected via the INVENT-VTE network, the SSC on Predictive and Diagnostic variables co-chair members, as well as from the studies included in the systematic review. An invitation will be sent by email, followed by a reminder email after 2 weeks. Proposed items to be included in the guidance statement will be presented and participants will be able to indicate whether they agree with the separate items on a 4-point Likert scale (ranging from strongly disagree to strongly agree). In addition, participants will be able to comment on the separate items with free text, as well as propose novel items that may be included. A second survey will be held to reach consensus on the final guidance statement. Consensus will be defined as at least 75% agreement for each of the items.[4] In case consensus has not been reached, the SSC working group will make the final decision.

4. Preparation of the final guidance statement

The final SSC guidance statement will be based on the results of the Delphi questionnaire.

Expected timeline

Project stage/set up: February 2020 (systematic review started)

Launch: March 2022

Duration: 36 months

Finalization/analysis: February 2023

Reporting: July 2023

Expected outcomes

The results of the systematic review on completeness of reporting will be published as a separate manuscript, as well as the results of the Delphi questionnaire. The final guidance statement will be submitted as an SCC Communication at the *Journal of Thrombosis and Haemostasis.*

Description of project set/up and management, needed infrastructure and resources:

We will set-up a team of 6 to 10 members in total. Thus far, Noémie Kraaijpoel (The Netherlands), Tobias Tritschler (Switzerland), Grégoire Le Gal (Canada), Marc Righini (Switzerland), Helia Robert-Ebadi (Switzerland), Kerstin de Wit (Canada) have agreed to participate. In addition, we will invite several other members from different backgrounds.

References

1 Glasziou P, Altman DG, Bossuyt P, *et al.* Reducing waste from incomplete or unusable reports of biomedical research. Lancet. 2014; **383**: 267–76.

2 Smidt N, Rutjes AWS, van der Windt DAWM, *et al.* The quality of diagnostic accuracy studies since the STARD statement: Has it improved? *Neurology* 2006; **67**: 792–7.

3 Bossuyt PM, Reitsma JB, Bruns DE, *et al.* STARD 2015: An updated list of essential items for reporting diagnostic accuracy studies. Clin. Chem. 2015; **61**: 1446–52.

4 Diamond IR, Grant RC, Feldman BM, *et al.* Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. *J Clin Epidemiol* 2014; **67**: 401–9.