ABSTRACT FORM ECAT SYMPOSIUM 15 – 16 SEPTEMBER 2022

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Title:

Biological Variation in haemostasis variables

Abstract:

Introduction
The diagnosis and monitoring of bleeding and thrombotic disorders depend on correct haemostatic laboratory measurements. Correctness of a measurement is defined by analytical performance, of which the targets are usually based on biological variation (BV). Many studies have reported BV of haemostasis variables, however, results are variable and not all fit for purpose, i.e. these data cannot be applied to determine analytical quality. Identifying good studies and thus obtaining reliable estimates is therefore needed for safe application of BV data.

Aims
The aims of the present study were to review published BV estimates for haemostasis variables and to deliver global within-subject (CV_I) and between-subject (CV_G) BV estimates by meta-analysis, selecting high-quality BV studies using the Data Critical Appraisal Checklist (BIVAC) criteria.

Material and Methods
BV studies for haemostasis variables were identified by a systematic literature search and all articles were reviewed and graded by the BV BIVAC. Four independent assessors reviewed the papers. Weighted estimates for CV_I and CV_G were obtained via a meta-analysis on all BV data derived from BIVAC-compliant studies (graded A-C) performed in healthy adults.

Results
In the 26 publications, BV data was reported for 35 different haemostasis variables. For 9 variables, only one publication was included in this study and a meta-analysis could thus not be performed. The majority of publications (74%) were graded as BIVAC C. The mean CV_I varied from 2.1 to 48.6% and the mean CV_G from 4.6 to 90.2%.

Conclusion
This study provides a systematic review and updated estimates of CV_I and CV_G (with 95% confidence intervals) for a wide range of haemostasis variables. These estimates are important when applying APS criteria for haemostasis tests used in the diagnostic work-up in bleeding- and thrombosis events and for risk estimation. Further expansion of high-quality BV studies is necessary to gain more knowledge of BV for different population groups and states of health.