INPLASY

Point of Care Ultrasound in the Emergency Department: An Umbrella Review of Systematic Reviews of Diagnostic Test Accuracy

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 September 2024 and was last updated on 27 September 2024.

INTRODUCTION

Review question / Objective The aim of this umbrella review is: i) to summarize the existing evidence for various specific Point-of-care ultrasound (POCUS) conditions, ii) to provide a grading of the reported pooled sensitivity and specificity of POCUS for these conditions in comparison to the respective reference standard, enabling clinicians to confidently use POCUS among adults or mixed population in emergency settings, and iii) to offer a qualitative synthesis where multiple DTA-SR exist for the same condition, ensuring that the best available evidence is accessible and clearly presented to guide clinical practice.

Rationale Emergency departments (EDs) worldwide face overcrowding, leading to longer wait times, patient discomfort, and diagnostic errors that contribute to increased hospital stays and mortality rates. Fast and accurate diagnostics are therefore essential. Point-of-care ultrasound (POCUS), performed at the bedside in real time, meets these needs by providing immediate imaging that facilitates rapid diagnosis and treatment. It reduces reliance on slower, resource-intensive imaging methods and enhances patient flow. Although many diagnostic test accuracy systematic reviews (DTA-SR) including MA have explored POCUS, diagnostic accuracy estimates often lack clear evidence ratings, and no comprehensive synthesis has yet integrated these findings.

Condition being studied Specific conditions, in particular diseases, in the ED settings that can be evaluated through a POCUS examination will be studied in this umbrella review. The conditions have to be investigated in a DTA-SR with MA. The conditions will be grouped as follows: i) cardiovascular, ii) ear/nose/throat, iii) eye, iv) further clinical assessment, v) gastrointestinal, vi) genitourinary, vii) intervention-related, vii) musculoskeletal/rheumatological, viii) neurological, ix) respiratory, x) trauma conditions, xi) other.

METHODS

Search strategy A systematic literature search will be performed on the databases Ovid (Medline) and Embase. The detailed search algorithm has been developed and validated in collaboration with an information specialist (Tanya Karrer, University of Bern) and content experts in POCUS (Beat Lehmann and Martin Müller).

Ovid MEDLINE(R) ALL
1 exp "sensitivity and specificity"/
2 false negative reactions/ or false positive reactions/
3 (sensitivity or specificity).ti,ab.
4 (predicitve adj value$1).ti,ab.
5 (likelihood adj ratio$1).ti,ab.
6 (false adj (negative$1 or positive$1)).ti,ab.
7 (randomized controlled trial or controlled clinical trial).pt.
8 double blind method/ or single blind method/
9 practice guideline.pt.
10 consensus development conference.pt.
11 random$.ti,ab.
12 random allocation/
13 (single blind$3 or double blind$3 or triple blind$3).ti,ab.
14 (review or review academic).pt.
15 meta analysis.pt.
16 (systematic adj review$).ti,ab.
17 or/1-14
18 17 and (15 or 16)
19 (pocus or (point*-of-care* adj3 (ultrasound* or ultra-sound* or sonograph*)) or ultrasound* or sonograph* or (focused cardiac ultras* or cardiac ultras* or ((transthoracic or trans-thoracic) and echocardiogra*) or tte)).ti,ab,kw.
20 exp "Sensitivity and Specificity"/ or sensitivity.tw. or specificity.tw. or ((pre-test or pretest) adj probability).tw. or post-test probability.tw. or predictive value$.tw. or likelihood ratio$.tw. or diagnos* test*1 accurac*.ti,ab,kw.
21 19 and 20
22 18 and 21

Embase
1 exp "Sensitivity and Specificity"/
2 false negative result/ or false positive result/
3 (sensitivity or specificity).ti,ab.
4 (predicitve adj value$1).ti,ab.
5 (likelihood adj ratio$1).ti,ab.
6 (false adj (negative$1 or positive$1)).ti,ab.
7 (randomized controlled trial* or controlled clinical trial* or rct).ti,ab.
8 double blind procedure/ or single blind procedure/
9 practice guideline.ti,ab.
10 random$.ti,ab.
11 randomization/
12 (single blind$3 or double blind$3 or triple blind$3).ti,ab.
13 or/1-12
14 meta-analys*.ti,ab,kw. or exp meta analysis/
15 (systematic adj review$).ti,ab,kw. or exp "systematic review"/
16 13 and (14 or 15)
17 (pocus or (point*-of-care* adj3 (ultrasound* or ultra-sound* or sonograph*)) or ultrasound* or sonograph* or (focused cardiac ultras* or cardiac ultras* or ((transthoracic or trans-thoracic) and echocardiogra*)) or tte).ti,ab,kw.
18 exp "Sensitivity and Specificity"/ or sensitivity.tw. or specificity.tw. or ((pre-test or pretest) adj probability).tw. or post-test probability.tw. or predictive value$.tw. or likelihood ratio$.tw. or diagnos* test*1 accurac*.ti,ab,kw.
19 17 and 18
20 19 and 16.

Participant or population Adult (16 years or older) or mixed populations (adults and children) with an emergency medicine relevant condition and/or acute intervention in which ultrasound was used as a diagnostic tool will be included. Studies on patients with chronic conditions without acute exacerbation, cancer diagnostics, and studies focusing on children will be excluded.

Intervention Any ultrasound examination with (potential) applicability as a POCUS examination in an acute care setting as the index text will be included. Only DTA-SR focusing on the use of conventional ultrasound (B-Mode, color doppler) and/or contrast enhanced ultrasound (CEUS) will be included. DTA-SR focusing on specialized ultrasound such as transvaginal, transrectal, or endosonographic ultrasound as well as elastography will be excluded.

Comparator DTA-SR have to compare the POCUS based index test to an accepted reference standard of the specific condition. If the authors of a DTA-SR combined different reference standards in a metanalytic approach, both reference standards will be considered accepted. If the authors stratify their meta-analytic approach only according to different reference standards, the most accepted reference standard will be determined by our research team and will be preferred for study reporting especially in the GRADE approach (see below).

Study designs to be included The review will include DTA-SRs that present a pooled sensitivity and specificity in a metaanalytic approach

addressing specific research questions related to the diagnostic accuracy of ultrasound examinations, particularly those applicable to POCUS in EDs.
A review has to fulfil the criteria suggested by Krnic Martinic et al. (2019) to be defined and included as an SR for the purpose of this umbrella review:
i. Specific research question
ii. A reproducible search strategy (naming of databases, naming of search platforms/engines, search date and complete search strategy)
iii. Reporting of inclusion and exclusion criteria
iv. Presentation of selection/screening methods
v. Critically appraisal and report of the quality/risk of bias of the included studies
vi. Information about data analysis and synthesis that allows the reproducibility of the results.
Additionally, at least two databases had to be searched.

Eligibility criteria DTA-SR will be included if the studied patient complaints/conditions address acute onset chief complaints/conditions or be related to an acute intervention (e.g., intubation) and conventional ultrasound (B-Mode, color doppler) or CEUS is used as a diagnostic tool with focus on the ED setting and compared to an accepted reference standard.
Studies will be excluded if i) there is a focus on children, ii) specialized ultrasound techniques (e.g., endosonogography) were evaluated, iii) there is a focus on ultrasound use in intensive care unit or perioperative care (non-ED focus), iv) there is a focus on the disease course of chronic diseases or diseases typically monitored in specialized clinics (e.g., inflammatory bowel diseases), and v) DTA-SR that focus on cancer screening, grading, and diagnostics.
Furthermore, if no pooled sensitivity or specificity is presented graphically or numerically with a 95% confidence interval or standard error the study will be also excluded.

Information sources Databases Ovid Medline and Embase.

Main outcome(s) Pooled sensitivity & specificity for the studied condition. We excluded studies that only provided narrative summaries without a meta-analytic approach and those where no pooled sensitivity, specificity with 95% confidence interval (CI) or standard error was presented either graphically or numerically, such as a summary receiver operating characteristic curve without a summary estimate due to high heterogeneity or only a pooled diagnostic odds ratio.

Additional outcome(s) None.

Data management The titles and abstracts will be independently assessed by four reviewers using a two-step approach. Initially, two reviewers will perform a sensitive screening, excluding: i) studies that are clearly not DTA-SR, ii) or those explicitly stating that they did not conduct a MA or did not reporting pooled sensitivity and specificity data, iii) studies on ultrasound in pediatric populations, iv) studies on prenatal ultrasound, v) endosonography studies, vi) reviews focused on cancer screening techniques, and vii) reviews addressing ultrasound for non-specific conditions/interventions, except for (e)FAST. Subsequently, the titles and abstracts of these reviews will further be evaluated by two senior emergency physicians for their applicability as a POCUS examination in an ED setting. The reviews deemed applicable will then be selected as the preliminary eligible publications for full-text evaluation. Any discrepancies between researcher screening decisions will be discussed, and, where no consensus is achieved, rectified by an ED and ultrasound expert. The full texts of the potentially eligible reviews will be obtained. Two reviewers will independently assess each full text for inclusion, resolving any discrepancies through discussion and, if necessary, involving a third researcher. Studies excluded during full-text review will be listed. Data extraction from the eligible articles will be independently performed by two reviewers, with discrepancies solved through discussion with a senior emergency physician: general study characteristics (first author, publication year, study design); the condition or disease being studied, categorized into a main group (cardiovascular, eye, ear/Nose/Throat, gastrointestinal, genitourinary, musculoskeletal/ rheumatological, neurological, respiratory, trauma, further), subgroup (e.g. aortic disease, endocarditis, venous thromboembolism, shock related), and detailed description of the condition (e.g. fluid responsiveness or pulmonary embolism); details on the index test and reference standard; information about funding, information to assess the risk of bias of the DTA-SR and a summary statement of the risk of bias of the included studies; and DTA measures, including the selected (see Data synthesis) pooled sensitivity and specificity with 95% confidence interval (CI) or standard error (SE) and a summary statement about all reported diagnostic accuracies. For each condition, the number of studies and participants in each study for the DTA measure, prevalence of the condition, and information for GRADE for sensitivity/specificity will be extracted. If a study conducted a subgroup analysis, these DTA will be as well extracted. When a study presented different index tests to evaluate the conditions, all the tests with their information will be extracted.

Quality assessment / Risk of bias analysis To assess the methodological quality of the included DTA-SR, we adapted the AMSTAR-2 checklist for quality assessment for SR to take into account the DTA character of the included SR. Included articles will be independently categorized by two reviewers as "critically low", "low", "moderate", or "high" quality based on the identified critical and non-critical weaknesses (see Other relevant information). Discrepancies in the final rating will be resolved through discussion, with a third researcher involved only if consensus cannot be reached. The risk of bias of the primary studies including the potential impact of risk of bias on the results of the presented pooled measured will also be evaluated with the adapted AMSTAR-2 checklist (items 12 and 13).

The quality of evidence for each specific condition and for each pooled diagnostic accuracy measure, i.e., pooled sensitivity and specificity, as described in Data synthesis, will be independently assessed by two reviewers using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. With GRADE, the following domains will be assessed: the i) risk of bias, ii) indirectness, iii) inconsistency and iv) imprecision (detailed explanation in the next paragraph). As the impact of publication bias in DTA-SR is not well understood and the evaluation as well as the reporting of publication bias in DTA-SR is not adequate, publication bias assessment was only used indirectly for downgrading of the evidence through risk of bias evaluation (adapted Amstar-2 tool).

Detailed explanation on how the grading will be performed: The pooled sensitivity and specificity, along with their 95% confidence intervals, will initially be rated as high-quality evidence. The evidence will be downgraded (to moderate, low, or very low) based on the following GRADE criteria: Risk of bias: If the AMSTAR-2 rating is moderate or low, the evidence will be downgraded. A critically low rating will automatically result in downgrading. Inconsistency: If high heterogeneity is observed in the results of the DTA studies, the evidence will be downgraded. This will be assessed through visual inspection of the forest plot, the I^2 statistic, and the Chi^2 test. Lack of data for assessing inconsistency will also lead to downgrading. Indirectness: Evidence will be downgraded if the studies are not directly applicable to the umbrella review's research question, such as when studies are conducted in specialized settings or require extensive experience for interpretation. Imprecision: Evidence will be downgraded if the confidence interval of the pooled measure is wide (greater than 0.10) or includes clinically relevant thresholds for diagnostic accuracy (below 0.70).

Strategy of data synthesis The included DTA-SR will be grouped according to the conditions studied (one DTA-SR could be listed several times if multiple conditions were studied), see above. Each main group will be further subdivided into subgroups and/or followed by the detailed specific condition, mostly the suspected disease/condition. Each DTA-SR that fulfils our inclusion criteria will be summarized for each examined condition with the following framework: clinical context, index test(s), reference standard, included study characteristics, methodological quality (of the DTA-SR), diagnostic accuracy, quality of evidence, conclusion of study authors. Multiple fact sheets may exist for one specific condition if there are multiple (overlapping/not overlapping) DTA-SR with MA on that specific condition. For each condition, a narrative synthesis will be conducted based on all fact sheets for that condition, integrating all available DTA-SRs for the specific condition. As there is anticipated overlap in the included studies, a meta-analytic approach for this umbrella review is waived. For each fact sheet, one pair of pooled sensitivity and specificity will be selected, graded (see: quality assessment) and shown in a forest plot with other DTA-SR for that condition. If multiple pooled pairs of sensitivities and specificities are presented on a fact sheet, the pair that will be used for grading is identified in a hierarchical evaluation process: 1.) DTA-SR that most focused on ED/POCUS, 2.) multi-organ POCUS was preferred over single organ US for complex conditions such as pulmonary embolism, 3.) the largest number of included studies. If this pair is not unique, all pairs with the highest sensitivity and/or specificity with the narrowest confidence interval will be graded. The following definitions will be used to describe/group a sensitivity respectively a specificity: very high > 90%, high 80%-90%, moderate 70%-80%, low 50%-70%, very low < 50%.

Subgroup analysis None planned.

Sensitivity analysis None planned.

Language restriction English.

Country(ies) involved Switzerland.

Other relevant information Adapted Amstar-2 rating tool

Only adapted icons are listed. Not assessed criteria are shown in brackets. An asterixis indicates a critical domain. Additionally, we classified domains 2 and 15 as non-critical.

1. Did the research questions and inclusion criteria for the review include PICO components?

Population, Index test (Intervention), Reference standard (Comparator), and Outcome are considered.
(3. Did the authors explain study design selection for inclusion?)
4.* Did the authors use a comprehensive literature search strategy? Partial Yes: Searched at least 2 databases, provided keywords and/or search strategy, justified publication restrictions. Yes: Searched bibliographies, conducted search within 24 months of completion of the review, and consulted experts. (searched trial/study registries, searched for grey literature)
8. Did authors describe included studies in detail? Partial Yes: Described populations, index test (interventions), reference standard (comparators), outcomes, and research designs. Yes: Also included study settings and follow-up timeframes.
9.* Did authors use a satisfactory technique to assess risk of bias (RoB)? Partial Yes: Assessed RoB from patient selection, index test, reference standard, (confounding and selection bias). Yes: Also assessed timing (methods for exposures, outcomes, and flow).
11.* If meta-analysis was performed, did authors use appropriate methods for statistical combination of results? Justified combining the data in a meta-analysis and used appropriate weighted technique to combine study results, adjusting for heterogeneity. (Combined data using weighted techniques and reported separate summary estimates for RCTs and NRSI).
12 If meta-analysis was performed, did authors assess RoB impact on results? Included only low RoB DTA studies (RCTs) or analyses for RoB impact.
13.* Did authors account for RoB in interpreting results? Included only low RoB DTA studies (RCTs) or discussed RoB impact if moderate or high RoB studies were included.

Keywords POCUS; Point-of-care ultrasound; diagnostic test accuracy; sonography; sensitivity; specificity; echocardiography; ultrasound; emergency medicine.

Contributions of each author

Author 1 - Claudio Schneider. Protocol development, data collection, data analysis, supervision, writing – original draft
Author 2 - Nico Frei. Protocol development, data collection, data analysis, writing – original draft
Author 3 - Antoine Fernandez. Protocol development, data collection, data analysis,
Author 4 - Catherine Frei. Data collection
Author 5 - Katharina Wahedi. Data collection
Author 6 - Carole Elodie Aubert. Supervision
Author 7 - Beat Lehmann. Conceptualization, supervision
Author 8 - Martin Müller. Conceptualization, supervision, protocol writing
All: writing- review and editing