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REVIEW

Publication bias may exist among prognostic accuracy studies of middle cerebral artery Doppler ultrasound

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Abstract

Objectives: The objective of this study was to assess if there is evidence of publication bias in prognostic accuracy studies of middle cerebral artery (MCA) or cerebroplacental ratio (CPR) for adverse perinatal outcome.

Study Design and Setting: We queried PubMed, EMBASE, the Cochrane Library, and ClinicalTrials.gov and searched abstract books of five perinatal conferences (1989−2017). We included prognostic accuracy studies on MCA and/or CPR. Highest reported accuracy estimates, sample size, study design, and conclusion positivity were extracted and compared.

Results: We included 127 full-text articles and 51 conference abstracts, 29 of which had not been reported as full-text article. In conference abstracts not reported in full, median negative predictive value was significantly lower compared to full-text articles (0.79 [interquartile range 0.67−0.97] vs. 0.95 [0.89−0.99]; $P < 0.001$). No significant difference was identified for positive predictive value (0.62 vs. 0.59; $P = 0.827$), sensitivity (0.67 vs. 0.71; $P = 0.159$), and specificity (0.86 vs. 0.86; $P = 0.632$). Study design differed significantly as well ($P = 0.030$), with fewer prospective studies in conference abstracts not reported in full compared to full-text articles (28% vs. 54%). We found no significant differences in sample size or conclusion positivity.

Conclusion: Possibly, a publication bias in previously published meta-analyses of MCA and CPR has led to overly generous estimates of prognostic performance.

Keywords: Cerebroplacental ratio; Doppler; Fetal growth restriction; Meta-analysis; Middle cerebral artery; Prognostic accuracy; Publication bias; Selective reporting; Systematic reviews

1. Introduction

Selective reporting of study findings is a potential threat to the validity of all systematic reviews, if the selection depends on the significance of hypothesis tests, the strength of effect estimates, or the level of test performance. Reports of studies that lead to a positive conclusion about the value of an intervention or a test may be more easily or sooner submitted by authors, or accepted by journals, than studies that fail to confirm the potential of such interventions or tests. Only relying on studies reported in scientific journals could then produce estimates that suffer from publication bias, typically leading to conclusions about effects that are too generous. Evidence of selective reporting of clinical trials has become abundant [1−5]. The existence of selective reporting practices has been less well documented in research on the performance of medical tests and markers, in particular on studies of diagnostic or prognostic accuracy [6]. Two previous studies showed that higher diagnostic accuracy was linked to faster publication [7,8].

Prognostic accuracy studies evaluate the ability of medical tests to predict disease or to identify patients likely to experience an adverse medical event among those who have disease. These studies typically present results in terms of sensitivity and specificity, the area-under-the-curve, or goodness-of-fit statistics, for example, from logistic regression.

Conflict of interest: None.

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What is new?

Key findings

- We found that data collected in prognostic accuracy studies of middle cerebral artery (MCA) Doppler ultrasound and cerebroplacental ratio (CPR) are not completely reported in full-text publications, with more than half of the included conference abstracts not reaching full-text publication.

What this adds to what was known?

- This represents a considerable waste of research. Importantly, we found differences in accuracy estimates, with a significantly lower negative predictive value in those studies that did not reach full-text publication compared to those that did reach full-text publications.

What is the implication and what should change now?

- A publication bias in previously published meta-analyses of MCA and CPR may have led to too generous estimates of their prognostic performance.

In the field of obstetrics, redistribution in the fetal circulation—or ''brain sparing''—is a potential measure of fetal hypoxemia. The existence of brain sparing can be tested by ultrasonographic Doppler measurement of the middle cerebral artery (MCA) or by calculating the cerebroplacental ratio (CPR), which is the ratio of the MCA and the umbilical artery [9]. Multiple recent meta-analyses concluded that both low MCA values and CPR values are associated with adverse perinatal outcomes [10−15]. The possible existence of publication bias was a concern raised by most authors of these meta-analyses, though not further investigated in most cases.

We aimed to assess if there is evidence of selective reporting of prognostic accuracy studies of MCA and CPR for adverse perinatal outcome. We did so by comparing study characteristics and accuracy estimates of studies only reported in conference abstracts and studies reported in full-text articles in scientific journals.

2. Methods

2.1. Search strategy and selection criteria

In this systematic review, we used a set of studies included in a recently published systematic review from our research group [13]; the search is described in full in Appendix 1. These studies had been identified through searches in PubMed, Embase, the Cochrane Library, and ClinicalTrials.gov. In the current analysis, we updated this search from inception to July 11, 2017 (C.A.V.H.-S. and M.A.d.B.) and identified all potentially eligible full-text articles and conference abstracts. In addition, all electronically available conference abstract books from 1989 to 2017 of the five largest perinatal conferences were scanned, including the Society for Maternal-Fetal Medicine (SMFM), the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG), the Society for Reproductive Investigation (SRI), the International Society for the Study of Hypertension in Pregnancy (ISSHP), and the British Maternal Fetal Medicine Society (BMFMS). The following search terms were each used to manually scan the pdf files or web sites of these conference abstract books (C.A.V.H.-S.): ''cerebral,'' ''MCA,'' ''cerebroplacental,'' ''CPR,'' ''brainsparing,'' ''brain sparing,'' ''Doppler,'' ''growth restriction,'' ''FGR,'' ''IUGR.''

For included conference abstracts for which a corresponding full-text article had not been identified through our database search, one investigator (C.A.V.H.-S.) additionally searched PubMed using the conference abstract's first and last authors' name, combined with (synonyms of) the tests under investigation to ensure that no full-text article was available. This latter search was updated in December 2018.

Studies (both published full-text articles and conference abstracts) were included if they reported on the association between brain sparing (measured by Doppler ultrasound of the MCA and/or the CPR) and a measure of compromise of fetal or neonatal well-being (such as perinatal death, 5-minute Apgar score, emergency delivery for fetal distress or neonatal intensive care unit admission). Excluded were studies including multiple pregnancies, or those including patients with known chromosomal or structural abnormalities. In case a study had been presented at multiple conferences, we used the conference abstract that was presented latest in our analysis.

We matched conference abstracts and full-text articles by comparing authors' names, dates of participant recruitment, and participant characteristics. Abstracts were considered to have reached full-text publication if the corresponding full-text article reported at least some of the presented prognostic accuracy data. If reported results were discrepant but clearly from the same study, the conference abstract was still considered to have reached full-text publication. The conference abstract was considered to not have reached full-text publication, if the conference abstract and full-text article corresponded to the same study, but the full-text article did not report on test accuracy or only reported on the accuracy of a test that was not presented in the conference abstract. If there was any doubt whether a conference abstract and full-text article matched, the case was discussed within the research team (C.A.V.H.-S., with D.A.K. and/or M.A.d.B.).

2.2. Data extraction

One author (C.A.V.H.-S.) extracted from each included study (both full-text articles and conference abstracts), the

first author, first author's country, year of publication, study design (prospective vs. retrospective vs. not reported) and sample size. In case a study was published in full, we also identified the journal and corresponding impact factor of that year (if available through Web of Knowledge), and the date of first publication. From each included study, we also extracted data on the index test (including Doppler index, threshold, and reference values) and targeted outcomes. We also extracted all available 2 × 2 tables and calculated sensitivity, specificity, positive predictive value, negative predictive value, and Youden's index (sensitivity plus specificity minus 1). For conference abstracts for which it was not possible to extract the 2 × 2 tables, we extracted reported accuracy estimates of sensitivity, specificity, positive predictive value, negative predictive value. Risk of bias and concerns about applicability were assessed with the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2) instrument [16] by one author (C.A.V.H.-S.). Finally, two authors (C.A.V.H.-S., 100%; D.A.K. and M.A.d.B., 50% each) independently classified the overall degree of positivity of the conclusion of the included conference abstracts and abstracts from full-text articles, according to the classification system developed by McGrath et al. [17]. For calibration purposes, the first 10 abstracts were scored by all three assessors and discussed in person. Disagreements were resolved through discussion.

2.3. Statistical analysis

This project primarily focused on the comparison of accuracy estimates between conference abstracts not reported in full and full-text articles. The latter group also included studies that had previously been reported as conference abstract, but ultimately reached full-text publication. We performed this dichotomization because we aimed to compare the results of studies that are available for inclusion in a meta-analysis (ie, full-text articles) with those that may not be available for inclusion (ie, conference abstract not reported in full).

Median accuracy estimates were compared using Mann-Whitney *U* test statistics. If a conference abstract or full-text article reported multiple 2 × 2 tables—for example, because multiple outcomes or thresholds were presented—the highest accuracy estimates were used in the analyses. In addition, we compared several study characteristics (sample size, study design, number of 2 × 2 tables, and abstract conclusion positivity) between conference abstracts not reported in full and full-text articles, using Mann-Whitney *U* test statistics and chi-square statistics. A *P*-value of <0.05 was considered statistically significant. Data were analyzed in SPSS version 22 (IBM, Armonk, NY).

3. Results

3.1. Selection of prognostic accuracy studies

We screened titles and abstracts of 3,286 results identified with our updated electronic search [13], and 78 annual proceedings from five different conferences (Fig. 1). This resulted in 552 potentially eligible full-text articles and 226 potentially eligible conference abstracts. Studies were most often excluded because accuracy estimates could not be extracted (94 full-text articles and 123 conference abstracts). References of the included studies are provided in Appendix 2. Overall, 127 published full-text articles (46,486 women) and 51 conference abstracts (25,194 women) could be included in our analysis. Of the 51 studies reported in conference abstracts, 20 had been reported in full in journal articles after presentation at the conference, whereas two conference abstracts had been reported in full in journal articles before presentation at the conference. Median time from conference presentation to publication was 17.0 months (interquartile range [IQR] 13.0−21.8).

3.2. Study characteristics

Fig. 2 shows that the number of conference abstracts and full-text articles concerning prognostic accuracy of brain-sparing has increased over the past 2 decades, with a steep rise over the past years. The 127 included full-text articles were published in 58 different journals, with the highest number in Ultrasound in Obstetrics & Gynecology (n = 29; 23%), followed by the American Journal of Obstetrics & Gynecology (n = 8; 6%), European Journal of Obstetrics & Gynecology and Reproductive Biology (n = 7; 6%), and Obstetrics & Gynecology (n = 5; 4%). The mean impact factor was 2.50 (standard deviation 1.37, range 0.38−5.65), which was available through Web of Knowledge for 77/127 journal articles.

Overall, the 51 included conference abstracts had been presented at eight different conferences. More than half of the abstracts had been presented at the ISUOG conference (n = 26; 51%), followed by the SMFM conference (n = 15; 29%), the World Congress of Perinatal Medicine (n = 4; 8%), the ISSHP conference (n = 2; 4%), the BMFMS conference (n = 2; 4%), the European Congress of Perinatal Medicine (n = 2; 4%), and one at the BMFMS and SRI conferences.

Overall results of the QUADAS-2 assessment are provided in Appendix 3. High or unknown risk of bias within at least one QUADAS-2 domain was detected in 121/127 published studies (95%) and in 51/51 (100%) conference abstracts. In the latter group, most items had been scored as unclear, probably as a consequence of word limits used in conference abstracts. Detailed results of each separate item of the QUADAS-2 risk of bias assessment can be found in Appendix 4.

3.3. Comparison between conference abstracts not reported in full and full-text articles

Overall, 29 of the 51 included conference abstracts had not reached full-text publication, which could be compared against the 127 full-text articles. Table 1 shows the

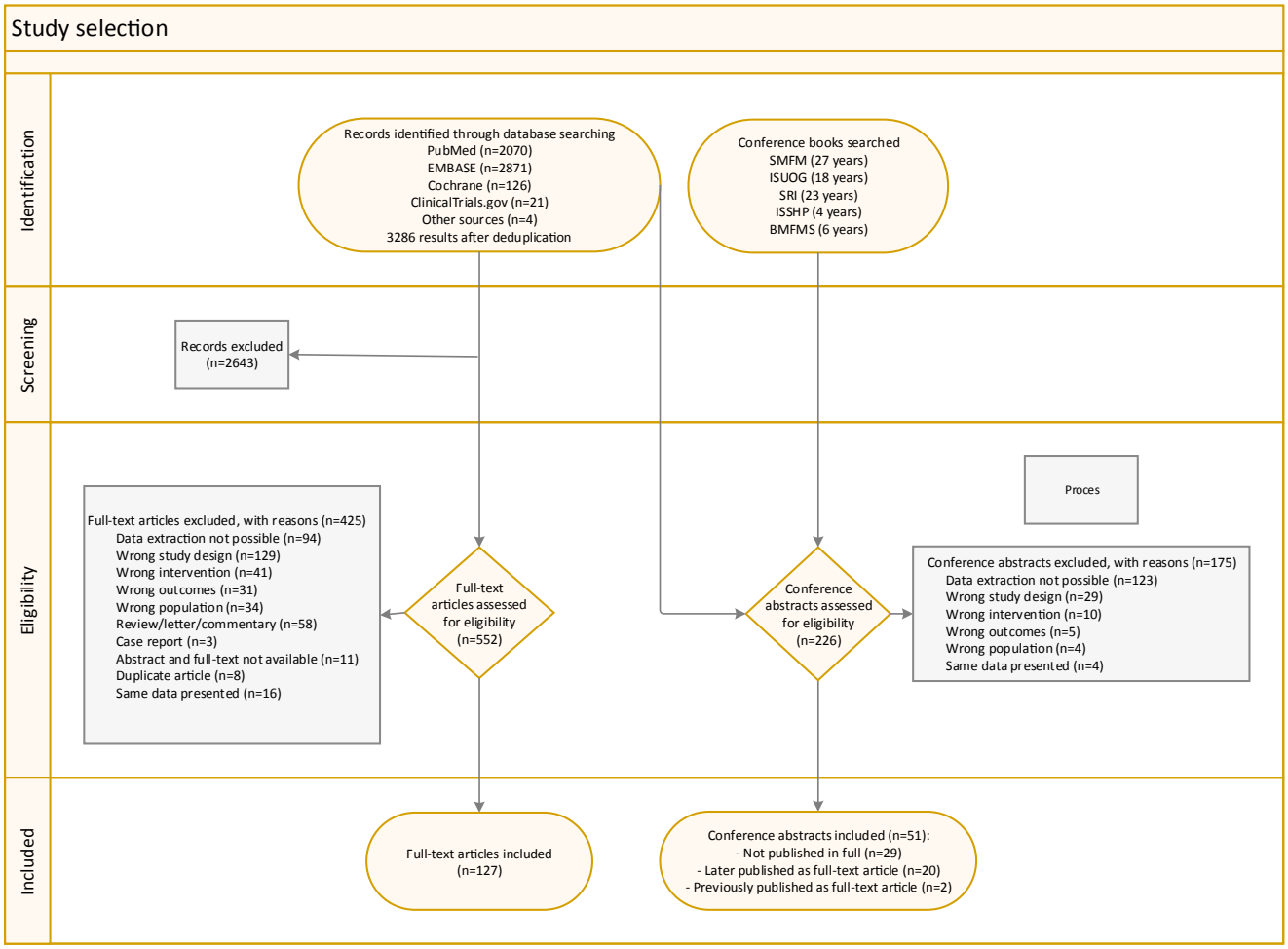

Fig. 1. Study selection.

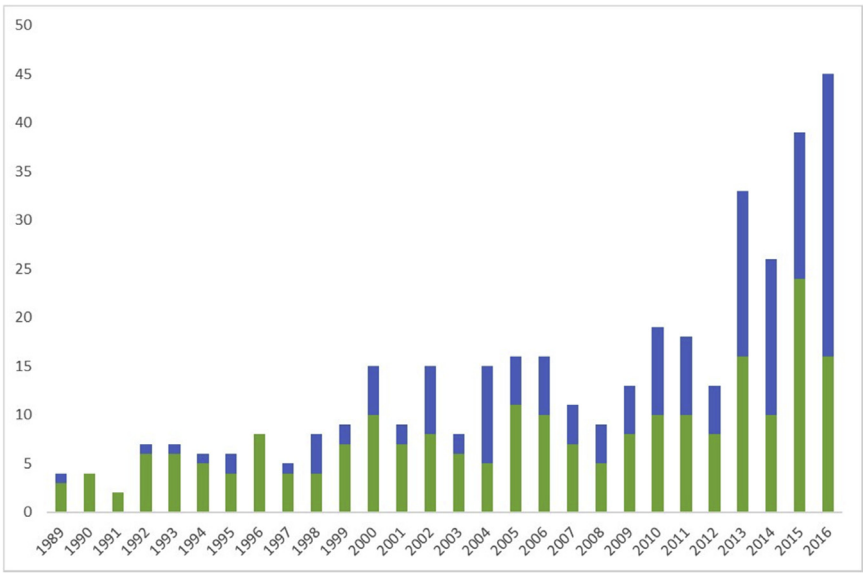

Fig. 2. Number of studies over time, including those of which data were not extractable and of which the same data were presented, reported in conference abstracts (blue, $n = 178$) and in full-text journal articles (green, $n = 237$). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

characteristics and accuracy estimates of these two groups of studies. The number of patients was similar, with a median of 101.5 (IQR 47.8−244.0) in the conference abstracts vs. a median of 100.0 (IQR 59.0−193.0) in the journal articles ($P = 0.889$). First author's country did not differ significantly, being non-European or non-North American in five conference abstracts (17%) and in 33 full-text articles (26%; $P = 0.322$). Study design however differed significantly ($P = 0.030$), with fewer prospective studies among conference abstracts not reported in full than among full-text articles (28% vs. 54%; $P = 0.030$). The median number of 2×2 tables reported in the conference abstracts was significantly lower compared to full-text articles: 1.0 (IQR 1.0−3.0) vs. 3.0 (IQR 2.0−5.0; $P = 0.002$).

Negative predictive value was significantly lower in conference abstracts not reported in full compared with full-text articles, with a median of 0.79 (IQR 0.67−0.97) vs. 0.95 (IQR 0.89−0.99; $P < 0.001$). No significant difference was identified for other accuracy estimates: positive predictive value (0.62 vs. 0.59; $P = 0.827$), sensitivity (0.67 vs. 0.71; $P = 0.159$), specificity (0.86 vs. 0.86; $P = 0.632$), and Youden's index (0.34 vs. 0.41; $P = 0.210$). Estimates of sensitivity and specificity extracted from conference abstracts not reported in full vs. full-text articles are visualized in Fig. 3. Conclusion positivity rates were similar among conference abstracts not published in full and abstracts of full-text articles: 76% vs. 79% were considered "positive," whereas 10% vs. 11% were considered "negative." The remainder were considered "neutral" or "not applicable."

In Appendix 5, a comparison of characteristics and accuracy estimates between the 29 conference abstracts not published in full, and 22 conference abstracts published as full-text article can be found.

4. Discussion

We found a steep increase over the recent years of reported studies on the prognostic accuracy of brain sparing assessment by MCA Doppler measurement and CPR calculation for adverse perinatal outcomes. These studies were reported as conference abstracts, in full-text articles, or both. More than half of the included conference abstracts did not reach full-text publication. Among conference abstracts not reported in full, we observed a significantly lower negative predictive value than in studies reported in full in journals. We also observed a significant difference in study design, with half as many prospective studies only presented at conferences compared to studies reported in full-text articles.

Some elements deserve consideration. First, although we showed significant differences between studies reported in full-text articles and those described in abstract, we do not claim there is a causal link between the magnitude of accuracy estimates and full-text publication. Such an analysis would require the consideration of multiple confounders, such as sample size and study design. Second, many reports of prognostic accuracy studies contained multiple accuracy estimates for MCA and CPR, for a range of perinatal outcomes and thresholds. In our analysis, we only focused on the highest reported accuracy estimates, assuming that these are the ones that mainly drive authors to pursue publication. This may not always be the case; other factors, such as resource constrictions, may hinder efforts to submit and publish a full-text study report. Another potential limitation is the fact that in some studies, MCA and CPR performance was not always presented as accuracy estimates. Because it was reported in 2×2 tables, any reader could calculate accuracy estimates. We acknowledge that these accuracy estimates may not have a similar effect on full-text publication as explicitly reported accuracy estimates do. We identified several studies that only reported that MCA or CPR had a low predictive value, while not providing actual accuracy measures. As these studies cannot be included in a meta-analysis, or in this review, this could have also caused a reporting bias. In addition, most of the data extraction was not performed in duplicate, which may have increased the chances of errors. The small number of later published conference abstracts limited an additional analysis of the effect of accuracy estimates on the time to publication. Finally, it cannot be excluded that some studies reported in conference abstracts may still get published in the future.

Previous assessments of conference abstracts in different fields of biomedical research showed publication rates similar to our findings [1,18−22]. In general, this represents a large amount of prognostic accuracy data collected, in a substantial number of study participants, for which findings were not fully reported. The failure to report a large proportion of studies in a full-text article represents a considerable waste of research [23]. This is even more worrying if studies with less positive results are less likely to reach publication than studies with positive results. This phenomenon has been well documented for drug trials and trials of therapeutic interventions. For studies of diagnostic and prognostic tests, there is less evidence of such reporting practices, although several reviews have shown that studies with higher accuracy estimates reach full-text publication sooner than those reporting lower estimates [7,8]. Previous evaluations of conference abstracts of test accuracy studies have not identified significant associations between reported accuracy estimates and full-text publication [19,21,22].

Our study showed that systematic reviewers of prognostic accuracy studies can include a considerable amount of unpublished material as part of gray literature, if they invest in additional efforts to identify conference abstracts. Still, conference abstracts are often difficult to identify as they are not always available through the large search engines, such as PubMed. Excluding these studies from a

Table 1. Comparison of characteristics and accuracy estimates between (1) conference abstracts not reported in full, and (2) full-text articles

Study characteristics and accuracy estimates	Conference abstracts not reported in full (n = 29)	Full-text articles (n = 127)	*P*-value
Sample size	101.5 (47.8–244.0)[a]	100.0 (59.0–193.0)	0.889
Country of first author not European or North American	5 (17%)	33 (26%)	0.322
Study design			*0.030*
Prospective	8 (28%)	69 (54%)	
Retrospective	11 (38%)	27 (21%)	
Not reported	10 (35%)	31 (24%)	
No. of 2 × 2 tables	1.0 (1.0–3.0)	3.0 (2.0–5.0)	*0.002*
Accuracy estimates			
Sensitivity	0.67 (0.32–0.88)	0.71 (0.53–0.89)	0.159
Specificity	0.86 (0.69–0.96)[a]	0.86 (0.67–0.94)	0.632
Positive PV	0.62 (0.33–0.72)[b]	0.59 (0.38–0.83)	0.827
Negative PV	0.79 (0.67–0.97)[b]	0.95 (0.89–0.99)	*<0.001*
Youden's index	0.34 (0.18–0.56)[c]	0.41 (0.25–0.62)	0.210
Degree of conclusion positivity			0.857
Positive	22 (76%)	100 (79%)	
Neutral/not applicable	4 (14%)	13 (10%)	
Negative	3 (10%)	14 (11%)	

Abbreviations: PV = predictive value.

Continuous variables are presented as median (IQR), and categorical variables as *n* (%). *P*-values calculated by Mann-Whitney *U* nonparametric test and chi-square test. Italic is statistically significant ($P < 0.05$).

[a] Unknown for 1 conference abstract.

[b] Unknown for 3 conference abstracts.

[c] Unknown for 2 conference abstracts.

systematic review, however, could potentially have led to an overestimation of test accuracy, as shown here, of the prognostic performance of MCA/CPR for adverse perinatal outcome, described in previous meta-analyses [10–15].

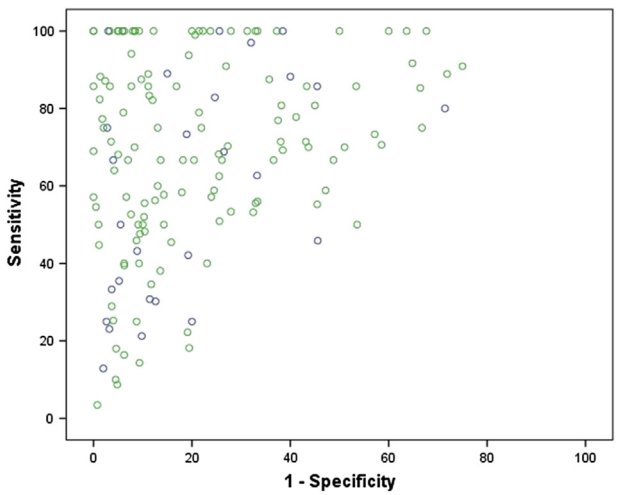

Fig. 3. Scatter plot of accuracy estimates reported in conference abstracts not reported in full (blue dots, n = 27), and studies reported in full-text articles (green dots, n = 127). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

We should not only consider the consequences of a failure to report, but also the likely causes. Potential factors could be sought for both on the side of the authors, who fail to submit or resubmit, and on the side of the journals that may be reluctant to accept some study reports for publication, although to date this has not been demonstrated [24]. A systematic review of survey studies [25] found that authors identified a lack of resources as the main reason of failure to publish.

Finally, we should consider interventions to arrive at more full, comprehensive and informative reporting of all studies performed. One element is the prospective registration of studies in trial registries. The declaration of Helsinki on the ethical principles for medical research involving human subjects [26] specifies that "researchers, authors, sponsors, editors, and publishers all have ethical obligations regarding the publication and dissemination of the results of research. Researchers also have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports." Full prospective registration would allow anyone to identify planned, ongoing, and completed studies, even if they are not (yet) reported in the scientific literature. So far, studies of prognostic and diagnostic accuracy are less well registered and documented compared to trials of therapeutic interventions [27]. Here, we can learn from efforts to improve the reporting of randomized trials,

such as ClinicalTrials.Gov and the AllTrials campaign, started by Ben Goldacre [28]. Researchers of prognostic and diagnostic accuracy studies should be encouraged, by their institutions and by funders, to register studies in trial registries so that they can be more easily identified [29].

5. Conclusion

We found that data collected in accuracy studies of MCA and CPR are often not completely reported in full-text publications, with probable differences in accuracy estimates between studies that did and did not reach full-text publication. This may have led to a publication bias in previously published meta-analyses of MCA and CPR, with too generous estimates of their prognostic performance. In general, these findings emphasize the need to include gray literature in meta-analyses if one wants to have a precise and representative estimate of the performance of a test or intervention. Future research could elucidate potential reasons for failure to publish and explore the effectiveness of possible solutions to arrive at a comprehensive set of reports of completed studies.

CRediT authorship contribution statement

Charlotte A. Vollgraff Heidweiller-Schreurs: Conceptualization, Formal analysis, Methodology, Project administration, Writing - original draft. **Daniël A. Korevaar:** Conceptualization, Methodology, Supervision, Writing - original draft. **Ben Willem J. Mol:** Writing - review & editing. **Caroline J. Bax:** Writing - review & editing. **Christianne J.M. de Groot:** Writing - review & editing. **Marjon A. de Boer:** Conceptualization, Supervision, Writing - review & editing. **Patrick M.M. Bossuyt:** Conceptualization, Methodology, Writing - review & editing.

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2019.07.016.

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