European Journal of Obstetrics and Gynecology 286 (2023) 95–101

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.journals.elsevier.com/european-journal-of-obstetrics-and-gynecology-and-reproductive-biology

Full length article

Self-collected versus health-care professional taken swab for identification of vaginal-rectal colonisation with group B streptococcus in late pregnancy: a systematic review

Kenny Odubamowo [a], Maria Garcia [a], Francis Muriithi [a], Reuben Ogollah [b], Jane P Daniels [b], Kate F Walker [b,c,*]

[a] Department of Obstetrics and Gynaecology, Nottingham University Hospitals NHS Trust, Nottingham, UK
[b] Nottingham Clinical Trials Unit, University of Nottingham, UK
[c] Centre for Perinatal Research (CePR), University of Nottingham, UK

ARTICLE INFO

Keywords:
Group B streptococcus
Self-collected swab
Self-swab
Health-care professional swab
Colonisation
Pregnancy
Screening
Culture
Group B agalactiae
Third trimester

ABSTRACT

Background: Testing for group B streptococcus (GBS) requires a vaginal-rectal swab in late pregnancy.
Objective: A systematic review of the test accuracy of a self-collected swab compared with a health-care professional collected swab in the diagnosis of GBS colonisation.
Search strategy: The Cochrane Library (including the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects [DARE] and the Cochrane Central Register of Controlled Trials [CENTRAL]), EMBASE, MEDLINE and Trip were searched in May 2022.
Selection criteria: Randomised trials, test accuracy studies or diagnostic yield studies that compared the accuracy of a self-collected vaginal-rectal swab, compared to that taken by a health-care professional, for the detection of GBS colonisation in the third trimester.
Data collection and analysis: Two researchers independently screened, selected studies, extracted data and assessed study quality.
Main results: 10 studies, with 2578 women were included. Pooled sensitivity of self-collected swabs was 0.90 (95% confidence interval [CI] 0.81 to 0.95) and pooled specificity was 0.98 (95% CI 0.96 to 0.99).
Conclusion: This study provides reassuring evidence that self-collected swabs for maternal GBS colonisation are highly accurate relative to swabs collected by health-care professionals. Women requiring a swab for GBS colonisation can self-swab with appropriate instructions if they choose.
Funding: Personal fellowship from the University of Nottingham for KFW.

Introduction

Streptococcus agalactiae, or group B streptococcus (GBS), is a leading neonatal pathogen [1]. It causes sepsis (60% of cases), meningitis (22%) and pneumonia (15%) in newborns. It is a gram-positive organism which constitutes part of the normal flora of the gut and vagina in 20% of pregnant women [2] and over half of them will transmit it to their baby during pregnancy or more commonly, labour. Most colonised babies remain well, but 1 in 1750 babies in the UK and Ireland develop early-onset GBS infection (EOGBS).

There is no international consensus on routine testing for GBS. The American College of Obstetricians and Gynaecologists (ACOG) recommends universal GBS testing between 36 and 37 weeks gestation and women that are positive for GBS colonisation are offered intrapartum antibiotics prophylaxis. Intrapartum antibiotic prophylaxis for GBS is also indicated in the context of GBS bacteriuria during the pregnancy or a history of previous GBS-infected newborn [3]. In the UK universal bacteriological testing is not recommended by the Royal College of Obstetricians and Gynaecologists (RCOG), intrapartum antibiotics prophylaxis is administered to women with clinical risk factors that place them at increased risk of having a baby with early-onset GBS infection (EOGBS) [4]. In the UK, a choice of testing or intrapartum antibiotic

* Corresponding author at: Centre for Perinatal Research (CePR), Academic Department of Obstetrics and Gynaecology, D Floor, East Block, Queen's Medical Centre, Nottingham NG7 2UK, UK.
E-mail address: kate.walker@nottingham.ac.uk (K.F. Walker).

https://doi.org/10.1016/j.ejogrb.2023.05.027
Received 13 March 2023; Received in revised form 19 May 2023; Accepted 20 May 2023
Available online 22 May 2023

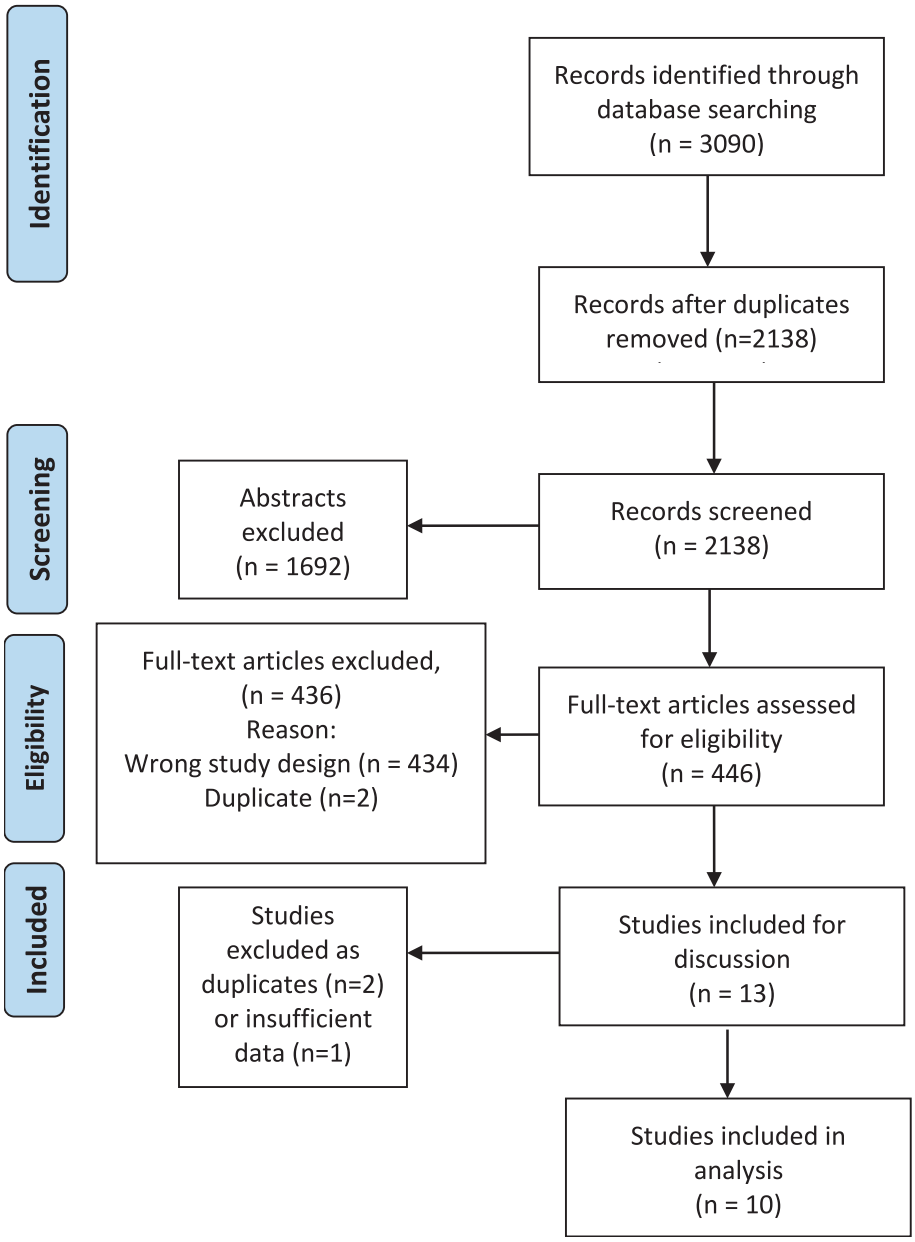

Fig. 1. PRISMA flow diagram.

prophylaxis is offered to women with colonisation in a previous pregnancy, otherwise testing specifically for GBS is not offered.

Both the RCOG and ACOG recommend that when testing is indicated for GBS colonisation, a swab should be taken from the lower vagina and the rectum. A single swab (vagina then rectum) or two different swabs can be used. The ACOG guideline states that women who receive training in collecting their own vaginal-rectal specimen can self-swab, and that the GBS detection is similar to the detection rates of specimens collected by health-care professional (HCP) [3]. The RCOG guideline states that the woman may self-swab if given appropriate instructions. A swab taken by a health-care professional is intrusive and potentially embarrassing for women and may lead some to decline testing for GBS. Swabbing by health-care professionals could be expected to have easier access to the vagina and anus, be able to collect a sufficient sample of mucosal fluid from both vagina and lower rectum and be less prone to accidental contamination.

There has been increased use of self-collected samples outside of obstetrics, for example self-collected samples for sexually transmitted infections in genitourinary medicine [5–7] and for COVID-19 [8]. Observational studies report that self-collected samples can provide the same yield as physician collected samples and one study found that they could provide a better yield [9].

Once a swab has been performed, what tests should be done? Broadly speaking there are two tests to use for GBS colonisation. Firstly, microbiological culture at 35–37 weeks' gestation, with a two-stage enrichment culture as the recommended method (ECM). [10] Alternatively, rapid tests have the potential to test women in labour on the maternity unit. The GeneXpert system (Cepheid) is the only currently available intrapartum test. The sensitivity and specificity of the rapid test were 86% (95% confidence interval 81% to 91%) and 89% (95% confidence interval 85% to 92%), respectively [11].

There are two ways in which microbiology labs can process vaginal-rectal swabs from pregnant women for GBS: 1) direct plating, 2) enriched culture medium (ECM).

The ECM test, a process which requires the swab to be placed into Lim broth and the broth to be sub-cultured onto solid medium after

Table 1
Study characteristics of the included studies.

Author	Authors description of study	Study design	Test method	Country	Setting	Number of women in study
Arya 2008	**Prospective cohort study** 600 pregnant women attending public and private antenatal clinics at the Unified Maternity Services, Cork, ROI were included. At 35–37 weeks of pregnancy, these women self-collected an ano-vaginal swab, and a health professional collected a second swab on same clinic visit.	Prospective single group diagnostic accuracy study	Direct plating on blood agar	Ireland	Two main teaching maternity hospitals in Cork from October 2003 to October 2004	600
Mercer 1995	Consenting women between 24- and 42-weeks' gestation were asked to collect vaginal and anorectal samples for group B streptococcus culture. Vaginal and anorectal samples were obtained by a trained obstetric nurse immediately after the patient collected specimens and before digital vaginal examination.	Prospective single group diagnostic accuracy study	Enriched culture medium, blood agar	USA	The outpatient obstetric clinic and the Maternal Fetal Assessment Unit of the Regional Medical Centre at Memphis. Period of study is not stated	251
Molnar 1997	Each consenting patient completed the survey and obtained her own GBS culture. Following this the physician collected their usual GBS-screening specimen.	Prospective single group diagnostic accuracy study	Not specified	Canada	Offices of five family physicians and eight obstetricians at Mount Sinai Hospital, Toronto - a tertiary care teaching hospital between 1st of November 1995 and 31st March 1996.	163
Nassie 2018	**Prospective study** Before vaginal examination was performed by the physician, and only after the patient took her own swab, an experienced physician took a second swab according to the CDC instructions. Both swabs were sent separately and anonymously to the microbiology laboratory	Prospective single group diagnostic accuracy study	Not specified	Israel	Not well described - University-affiliated, referral centre, from 2016 – 2017	139
Price 2006	**Randomised study** Consecutive patients presenting were randomly allocated to having vaginal-rectal swabs self-collected, and then collected by a clinician, or to having the swabs clinician-collected, and then self-collected	Prospective randomised diagnostic accuracy study	Enriched culture medium, Columbia Naladixic Acid agar	Canada	Maternity Centre of Hamilton (MCH) - between October 2003 and May 2005	330
Salvesen 1999	The women first took the test themselves instructed by a midwife followed by sample taken by a doctor	Prospective single group diagnostic accuracy study	Not specified	Norway	Regional Hospital in Trondheim	80
Seto 2019	**A randomised, prospective, crossover study** To reduce potential bias from a higher sensitivity of the first swab obtained, the women were randomized according to computer-generated random numbers into two groups in a 1:1 ratio. Group 1 had the first swab taken by the health-care workers first, followed by self-screening on the same day, whereas group 2 had self-screening first, followed by swabs taken by health-care workers on the same day.	Prospective, randomised, crossover study	Enriched culture medium, chromogenic agar	Hong Kong	The University of Hong Kong, Queen Mary Hospital, Hong Kong – Study conducted between May and October 2015	422
Spieker 1999	A volunteer sample of 240 pregnant self-collected then the physicians collected second specimens. Patient assigned to green team obtained a self-collected group B streptococcus specimen before their physicians whereas patient on the brown team had their physicians collect the group B streptococcus specimen first.	Prospective, single group, diagnostic accuracy study. Half of the women had a self-swab first, half of women had a health-care professional swab first (non-randomised)	Direct plating, blood agar	USA	The Family practice clinic at the Naval Hospital, Jacksonville Florida. Period of study is not stated	240
Torok 2000	Patients were assigned on an alternating basis to perform an anogenital culture swab before or after the physician performed a swab	Prospective, single group, diagnostic accuracy study	Enriched culture medium, blood agar	USA	Evans Army Community Hospital, Fort Carson, Colo. Family Practice Clinic. Period of study is not stated	250

(*continued on next page*)

Table 1 (*continued*)

Author	Authors description of study	Study design	Test method	Country	Setting	Number of women in study
Louis Dit Trieau 2009	**Prospective multicentric study** All women presenting for their 32–37th WG prenatal visit were offered the option to self-collect their vaginal swab which was then collected by a health professional.	Prospective, single group, diagnostic accuracy study)	Direct plating, blood agar	France	The study was conducted at the Bordeaux University Hospital maternity ward between November 10, 2007, and January 20, 2008	103

Table 2
QUADAS 2 tool assessment of methodology quality result.

Article	Risk of Bias				Applicability concerns		
	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Arya 2008	Unclear	Low	Low	Low	Low	Low	Low
Mercer 1998	Unclear	Unclear	Unclear	Low	Low	Low	Low
Molnar 1997	Unclear	Low	Low	Low	Low	Low	Low
Nassie 2018	Unclear	Low	Low	Low	Low	Low	Low
Price 2006	Low	Low	Low	Low	Low	Low	Low
Salvesen 1999	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Seto 2019	Low	Low	Low	Low	Low	Low	Low
Spieker 1999	Unclear	Low	Low	Low	Low	Low	High
Torok 2000	Unclear	Low	Low	Low	Low	Low	Low
Louis Dit Trieau 2009	Unclear	Unclear	Unclear	High	Low	Low	High

overnight incubation is recognised as the international 'gold standard' for detecting GBS. The test is highly sensitive, although maternal colonisation rates are influenced by the sites sampled and culture methods used. A UK study found that using ECM before plating onto selective agar identified 97% of the total positive rectovaginal swabs, whereas direct plating onto selective agar identified 75% [12].

Standardised and careful explanation of the procedure of vaginal-rectal self-swabbing to the pregnant woman could yield the same result as a sample collected by health-care professional. This may help to improve uptake of testing and free up health-care professionals' time. In this systematic review we aimed to determine diagnostic test accuracy of a self-collected versus a health-care professional swab for the detection of GBS colonisation in late pregnancy.

Methods

Study design

Systematic review

Review question

What is the diagnostic test accuracy of a self-collected versus a health-care professional taken swab for detection of GBS colonisation during late pregnancy?

Search strategy

This review was prospectively registered at PROSPERO (CRD42021233453) prior to any searches being performed and was conducted following the Cochrane Handbook for Diagnostic Accuracy Reviews, [13] and reported according to PRISMA guidelines.

The Cochrane Library (including the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects [DARE] and the Cochrane Central Register of Controlled Trials [CENTRAL]), EMBASE, MEDLINE and Trip were searched for relevant papers. The search was initially undertaken in January 2022 and updated in May 2022. The databases were searched using the relevant Medical Subject Headings (MeSH) terms, including all subheadings and synonyms, and this was combined with a keyword search. The search strategy is shown in Appendix S1. Search terms included, 'Pregnant woman', 'group B agalactiae', 'point -of-care testing', 'third trimester', 'late pregnancy', 'group B streptococcus', 'vaginal colonisation', 'genital colonisation', 'rectal colonisation', 'rectovaginal colonisation', 'health-care professional swab', 'self-swab' and 'testing'.

Study selection

Randomised trials, test accuracy studies or diagnostic yield studies that compared the accuracy of a self-collected vaginal-rectal swab (considered the index test), compared to that taken by a HCP (defined as the reference standard), for the detection of GBS colonisation in the third trimester of pregnancy, were eligible for inclusion.

Two reviewers (MG and KO) assessed for inclusion of all the potential studies identified using our search strategy. This process was facilitated using the Covidence software. Any disagreement was resolved by a 3rd reviewer (KFW). The selection process included a title and abstract review followed by a full text review.

Data extraction and quality assessment

A data extraction form was developed with input from all the reviewers. Two reviewers independently extracted data from the included studies (MG and KO). Discrepancies were resolved through discussion, and where necessary a 3rd reviewer was consulted for consensus (KFW). Where necessary, the authors of the included publication were consulted for any clarification.

Consensus data was entered into review manager software (RevMan) and checked for accuracy. We recorded the test used to detect GBS.

The QUADAS-2 tool was used for assessment of methodological quality. This tool consists of four key domains: patient selection, index test, reference standard and, flow and timing. Each domain was assessed in terms of risk of bias and the first three in terms of concerns regarding applicability. Signalling questions were included to assist in judgements about risk of bias.

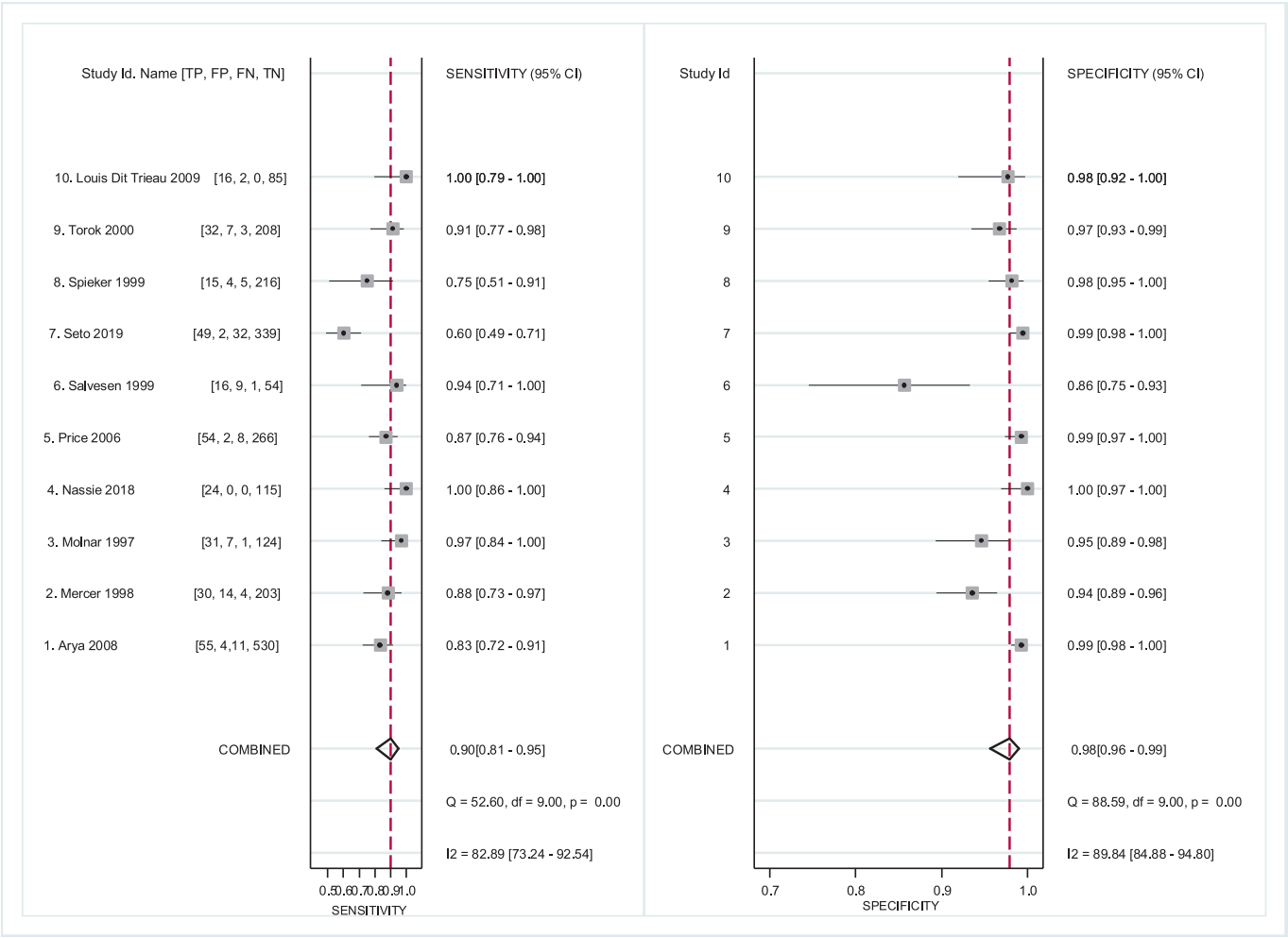

Fig. 2. Forest plot showing study-specific(box) and overall(diamond) point estimates and confidence intervals for each performance index pair. Also presented are the study-specific performance estimates: TP = True positive; FP = False positive; FN = False negative; TN = True negative. The combined pooled results are based on parameters estimated by the bivariate model.

Statistical analysis and data synthesis

For each included study, the estimated sensitivity and specificity along with the 95% confidence intervals (CIs) were presented in a forest plot.

Meta-analysis of sensitivity and specificity was performed using a bivariate mixed-effects model to preserve the 2-dimensional nature of the data while taking any correlation between them into account. The model estimated the mean logit sensitivity and specificity, with their standard errors and 95% CIs and estimates of the between-study variability (covariance) in logit sensitivity and specificity. Summary test accuracy measures (sensitivity, specificity, and likelihood ratios) were produced from this model by back-transformation. The estimated logit estimates of sensitivity and specificity and their respective variances were used to construct a hierarchical summary receiver operating characteristic curve (HSROC), with summary operating points for sensitivity and specificity on the curves and a 95% confidence contour ellipsoid. A graphical representation of the magnitude of heterogeneity was assessed by inspecting whether the confidence intervals on the forest plots overlap.

Analysis was performed using Stata Statistical Software: Release 17 [14] (with the *midas* and *metandi* modules for the bivariate mixed-effects regression).

Results

The study selected flow diagram is shown in Fig. 1. We identified 3090 studies in our search. 2138 remained after removal of duplicates. Following screening of titles and abstracts, 1692 studies were excluded. For the remaining 446 studies, full texts were examined against the inclusion criteria, of which, 13 studies met. Two of the 13 studies were excluded as duplicates, one was excluded due to inadequate data, leaving 10 studies which were included in the data synthesis. Papers were excluded for reasons such as inappropriate study design or lack of data.

Table 1 gives the study characteristics for the 10 included studies. Table 2 gives the results of the assessment of methodological quality. In seven of the included studies it was unclear how patients had been selected for the study.

All 10 studies provided sufficient data to construct a 2x2 table for the estimates of diagnostic accuracy and were included in the *meta*-analysis. The study-specific performance estimates, estimated sensitivity and specificity for each study and overall, along with the 95% confidence intervals (CIs) are presented in the forest plot in Fig. 2. Fig. 3 shows the resulting summary ROC curve, with summary operating points for sensitivity and specificity on the curves and a 95% confidence contour around these points. The area under the curve was 0.99 (CI, 0.97 to 0.99).

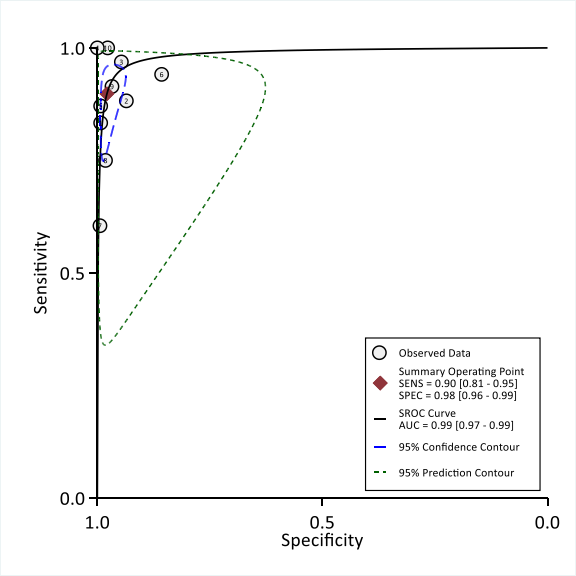

Fig. 3. Summary ROC curve with confidence and prediction regions around mean operating sensitivity and specificity point. Circles represent estimates of individual primary studies, and square indicates summary points of sensitivity and specificity. HSROC curve is plotted as curvilinear line passing through summary point. 95% confidence region and 95% prediction region are also provided.

Table 3
Summary estimates of Sensitivity, specificity, and DOR from the generalized linear random effects model.

Parameter	Estimate (95% CI)
Sensitivity	0.90 (0.81, 0.95)
Specificity	0.98 (0.96, 0.99)
Positive Likelihood Ratio	42.0 (21.0, 84.1)
Negative Likelihood Ratio	0.10 (0.06, 0.20)
Diagnostic Odds Ratio	403 (189, 863)

Synthesis of results

Table 3 presents the following estimates for the summary point produced from the bivariate mixed-effects regression model: sensitivity, specificity, diagnostic odds ratio, positive likelihood ratio and negative likelihood.

Discussion

Main findings

Self-collected swabs showed excellent sensitivity and specificity in diagnosing maternal GBS colonisation in late pregnancy and is an acceptable alternative to health professional collected swabs.

Strengths and limitations

This is the first systematic review to assess the diagnostic test accuracy of group B streptococcus (GBS) following a health-care professional swab compared with a self-collected swab in late pregnancy. The ten included studies were conducted in a wide variety of geographical locations improving generalisability of the results. We followed the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. The QUADAS-2 tool was used to assess risk of bias.

There was high level of heterogeneity between the studies. As only ten studies were included, we could not check for publication bias. Unfortunately only six of the included studies reported the culture method used.

We acknowledge that theoretically there is unlikely to be a difference in specificity between a self-swab and a health care professional swab other than through contamination of the swab by the individual. It is also possible that in a research setting, women would be better instructed and potentially more careful in performing a self-swab and therefore these results may not be born out in routine clinical practice.

Interpretation

Current national guidelines for bacteriological testing for GBS colonisation in pregnancy in the US (ACOG) and UK (RCOG) stipulate that a woman may self-swab if given appropriate instructions. The findings of this review provide reassurance that these guidelines are appropriate.

There has been increased use of self-collected samples outside of obstetrics, for example self-collected samples for sexually transmitted infections in genitourinary medicine [5–7]. There are conflicting results on acceptability of self-collected swabs with some studies demonstrating that pregnant women prefer self-swabbing for GBS [15–18] whereas a study performed in Hong Kong showed that there is preference for the doctor performing the swab collection [19].

This study provides reassuring evidence that self-collected swabs for maternal GBS colonisation have a similar diagnostic test accuracy to health-care professional swabs and health-care professionals should offer choice to women requiring a swab for GBS colonisation to allow for self-swab with appropriate instructions or a health-care professional collected swab.

There is conflicting evidence on the acceptability of self-swabbing in late pregnancy in the literature. It is important to address if self-swabbing is acceptable to women and if there are differences amongst women with different characteristics (e.g., maternal educational attainment, maternal age). There is some evidence to suggest that acceptability may differ by these factors [21].

Contribution to authorship

KFW designed the study. KO, FM and MG conducted the literature search, reviewed the literature and extracted the data. RO performed the statistical analysis. RO, FM, JD and KFW interpreted the data. KO, RO and KFW wrote the manuscript. JD revised the manuscript. All authors reviewed and approved the manuscript.

Funding statement

Personal fellowship from the University of Nottingham for KFW.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgement

None.

Details of ethical approval
Not applicable

References

[1] Lancefield RC. The Antigenic Complex of Streptococcus Haemolyticus: V. Anaphylaxis with the Type-Specific Substance. J Exp Med 1928;47(6):857–75.

[2] Seedat F, Taylor-Phillips S, Geppert J, Stinton C, Patterson J, Brown C, et al. Universal antenatal culture-based screening for maternal Group B Streptococcus (GBS) carriage to prevent early-onset GBS disease. Warwick Medical School 2016.
[3] Gynecologists ACoOa. Prevention of Group B Streptococcal Early-Onset Disease in Newborns. American College of Obstetricians and Gynecologists; 2020 February 2020. Contract No.: 797.
[4] Hughes RG, Brocklehurst P, Steer PJ, Heath P, BM S. Prevention of Early-onset Neonatal Group B Streptococcal Disease: Green-top Guideline No. 36. BJOG: Int J Obstet Gynaecol 2017;124(12):e280-e305.
[5] Richardson E, Sellors JW, Mackinnon S, Woodcox V, Howard M, Jang D, et al. Prevalence of Chlamydia trachomatis infections and specimen collection preference among women, using self-collected vaginal swabs in community settings. Sex Transm Dis 2003;30(12):880–5.
[6] Garland SM, Tabrizi SN. Diagnosis of sexually transmitted infections (STI) using self-collected non-invasive specimens. Sex Health 2004;1(2):121–6.
[7] Yancey MK, Armer T, Clark P, Duff P. Assessment of rapid identification tests for genital carriage of group B streptococci. Obstet Gynecol 1992;80(6):1038–47.
[8] Schuit E, Venekamp RP, Hooft L, Veldhuijzen IK, van den Bijllaardt W, Pas SD, et al. Diagnostic accuracy of covid-19 rapid antigen tests with unsupervised self-sampling in people with symptoms in the omicron period: cross sectional study. BMJ. 2022;378:e071215.
[9] Hicks P, Diaz-Perez MJ. Patient self-collection of group B streptococcal specimens during pregnancy. J Am Board Fam Med 2009;22(2):136–40.
[10] England PH. Detection of carriage of group B streptococci (Streptococcus agalactiae). 2015.
[11] Daniels J, Dixon EF, Gill A, Bishop J, D'Amico M, Ahmed K, et al. A rapid intrapartum test for group B Streptococcus to reduce antibiotic usage in mothers with risk factors: the GBS2 cluster RCT. Health Technol Assess 2022;26(12):1–82.
[12] Carreras-Abad C, Cochet M, Hall T, Ramkhelawon L, Khalil A, Peregrine E, et al. Developing a serocorrelate of protection against invasive group B streptococcus disease in pregnant women: a feasibility study. Health Technol Assess 2019;23(67):1–40.
[13] Deeks J, Bossuyt P, Leeflang M, Takwoingi Y, Flemyng E. Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. Cochrane; 2022 2022. Contract No.: 2.0.
[14] Stata Statistical Software. Release 17 ed: StataCorp LLC; 2019.
[15] Mercer BM, Taylor MC, Fricke JL, Baselski VS, Sibai BM. The accuracy and patient preference for self-collected group B Streptococcus cultures. Am J Obstet Gynecol 1995;173(4):1325–8.
[16] Price D, Shaw E, Howard M, Zazulak J, Waters H, Kaczorowski J. Self-sampling for group B streptococcus in women 35 to 37 weeks pregnant is accurate and acceptable: a randomized cross-over trial. J Obstet Gynaecol Can 2006;28(12):1083–8.
[17] Spieker MR, White DG, Quist BK. Self-collection of group B Streptococcus cultures in pregnant women. Mil Med 1999;164(7):471–4.
[18] Torok PG, Dunn JR. Self-collection of antepartum anogenital group B streptococcus cultures. J Am Board Fam Pract 2000;13(2):107–10.
[19] Seto MTY, Ko JKY, Cheung KW, To KKW, Hui PW, Lao TT, et al. The Accuracy of Self-Screening of Group B Streptococcus in Pregnant Women-A Randomized Crossover Study. J Obstet Gynaecol Can 2019;41(6):792–7.
[20] Price D, Shaw E, Howard M, Zazulak J, Waters H, Kaczorowski J. Self-sampling for group B streptococcus in women 35 to 37 weeks pregnant is accurate and acceptable: a randomized cross-over trial. J Obstet Gynaecol Canada 2006;28(12):1083–8.