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The feasibility and acceptability of self-testing for proteinuria during pregnancy: A mixed methods approach

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ABSTRACT

Objective: To investigate feasibility and acceptability of self-testing for proteinuria during pregnancy.
Study design: Mixed methods approach which included: an accuracy study where pregnant women (n = 100) and healthcare professionals (n = 96) tested seven synthetic protein samples and completed a questionnaire, a feasibility study where pregnant women who were self-monitoring their blood pressure were asked to self-test for proteinuria (n = 30), and an online questionnaire about women's experiences of self-testing (n = 200).
Main outcome measures: Sensitivity and specificity of testing and questionnaire results.
Results: There were no significant differences in the accuracy of synthetic sample testing by pregnant women (sensitivity 0.81 (95% confidence intervals (CI) 0.78–0.85), specificity 0.93 (95% CI 0.91–0.95)) and healthcare professionals: (sensitivity 0.83 (95% CI 0.79–0.86), specificity 0.92 (95% CI 0.90–0.94)). Automated readers had significantly better sensitivity (0.94 (0.91–0.97) ($p \leq .001$ in each case), but worse specificity 0.78 (0.69–0.85). Similar results were gained using self-tested urine samples compared to staff-testing using a reference standard of laboratory urine protein-creatinine ratio (uPCR). Women who completed the online survey with experience of self-testing (n = 39, 20%) generally found it easy, and with support from healthcare professionals felt it improved involvement in their care and reduced anxiety.
Conclusions: Self-testing for proteinuria by pregnant women had similar accuracy to healthcare professional testing and was acceptable to both groups. Self-testing of urine combined with self-monitoring of blood pressure could provide a useful adjunct to clinic-based surveillance for the detection of pre-eclampsia. Such novel strategies warrant further research.

1. Introduction

Apart from blood pressure measurement, urinalysis for protein is the most commonly performed antenatal screening test and is central to pre-eclampsia diagnosis [1]. The development of proteinuria in a hypertensive pregnancy is an important feature of multi-organ involvement [2]. Urine testing is routinely carried out by midwives, obstetricians or family physicians at antenatal visits [1]. Urinalysis reagent strips (dipsticks) are widely commercially available, inexpensive, convenient, and provide a rapid result [4]. Such testing strips are examined with automated readers or by visual inspection, the latter still commonplace out of hospital settings, where automated readers are seldom available. If positive results are found, then further testing, using spot urine protein: creatinine ratio (uPCR) or 24-h sample analysis, is undertaken [5].

Confidential enquiries into maternal deaths in the United Kingdom report that women can develop pre-eclampsia between antenatal visits; and reiterate the importance of blood pressure and proteinuria testing at every opportunity [6,7]. Urine self-testing in pregnancy is widely acceptable for confirming a pregnancy through urinary beta-hcg assays [8,9], but few data on the accuracy of self-testing for proteinuria in the pregnant population exist [4]. An Australian study, comparing urinary protein self-testing by 212 women in clinic, to re-testing by a single nurse, found that self-testing was practical and easily implemented, but did not include an independent reference standard [10]. Several other studies describe providing pregnant women with urine dipsticks to

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periodically check for protein alongside self-monitoring blood pressure, but have not formally evaluated test performance [11–13].

The aim of this study was to assess the accuracy of self-testing for proteinuria during pregnancy compared to healthcare professionals (HCPs) or automated testing with a laboratory reference standard and to explore feasibility and acceptability in a UK context.

2. Methods

This was a mixed methods study combining test accuracy studies and questionnaires. There were four parts comprising: 1) test accuracy study for 'proteinuria' (using synthetic samples to provide a range of protein levels) comparing assessment by pregnant women, HCPs and an automated reader to a laboratory reference standard; 2) self-testing of urine by pregnant women compared to testing by HCPs and a laboratory reference standard; 3) a questionnaire to participating women and HCPs and 4) an online questionnaire aiming to understand women's experience of self-testing and opinions on its future use.

2.1. Test accuracy of urinary protein testing

Up to 50 pregnant women of any gestation and 50 HCPs from antenatal maternity services were selected on a convenience basis from hospital sites in Oxfordshire (John Radcliffe and Horton Hospitals, Ox) and London (St Thomas' Hospital, STH) between November 2015 and April 2016. Following written informed consent, participants were provided with simple instructions for protein testing, synthetic protein samples and standard dipstick reagent strips (a visually read enzymatic test) (ALBUSTIX reagent strips, SIEMENS, Surrey UK). Protein solutions were prepared using bovine serum albumin (Sigma-Aldrich, Dorset, UK) in 150 mmol/L sodium chloride (Fresenius Kabi Ltd, Cheshire, UK). Sodium azide was added at a concentration of 100 mg/L as a bacteriostat. Stock solutions were produced at protein concentrations equivalent to seven different dipstick readings between 'negative' and '3 + ' ($\geq$ 500 mg/dL). The level of protein in the samples was confirmed by repeated testing by urinary protein-creatinine ratio, (uPCR) (Supplementary Table 1). Samples were tested by participating women and HCPs using visual determination as well as using an automated reader (Clinitek Status + Analyzer, SIEMENS, Surrey, UK) by the research team. Researchers and participants were masked to the level of protein in each sample until recruitment and testing was complete. Samples were re-tested following the study to confirm that storage and testing had not resulted in contamination. Ethical approval was obtained from the Northern Ireland Research Ethics Committee (15/NI/0157/HSC REC-B).

2.2. Self and healthcare professional proteinuria testing compared to a PCR reference standard

Thirty women, participating in a pilot study of blood pressure self-monitoring in higher-risk pregnancy, attending antenatal care in Oxfordshire additionally tested their urine for protein. (National Institute for Health Research (NIHR) Central Research Network (CRN) Portfolio number: 14151) They used a standard testing strip for proteinuria (as above) and retained the sample, which was subsequently (same day) tested by the midwife and then sent for laboratory analysis (uPCR). Equivalent categories for testing were 0–14 mg/dL (negative), 15–30 mg/dL (trace), > 30 mg/dl (1 + or more). Ethical approval was obtained from Oxford South Central Research Ethics Committee (12/SC/0625 REC-B).

2.3. Questionnaire

Participants in the synthetic sample testing study above completed a short questionnaire about the potential for self-testing during pregnancy, included three closed statements and an open question asking for comments (Supplementary Fig. 1).

2.4. Online survey

An online survey (March 2106) collected information on women's views and experiences of self-testing, including multiple-choice questions and a free text section for women to comment on the idea of self-testing. A link to the survey was posted on the 'Action on Pre-eclampsia' (APEC) Facebook Forum, a UK charity and patient support group. Ethical approval was obtained from St Georges Research Ethics Committee (SGREC16/0005).

2.5. Statistical analysis

Data were analysed using Excel and R. Descriptive statistics were compiled from the questionnaire and survey results for questions with categorical answers. For proteinuria dipstick accuracy results, the errors of the dipstick readings were grouped into five categories (-2, -1, 0, $+1$, $+2$), representing the difference between the reading from the woman, the HCP and the automated reader respectively compared to the uPCR reference standard. (e.g. $+1$ error where the woman's reading was one category above that of the uPCR). Each participant's test performance (pregnant woman, HCP, automated reader) was calculated across all seven samples and a mean calculated per participant to obtain sensitivity and specificity for each participant. In the case of missing data for an individual, the sensitivity and specificity were calculated using the available samples. In order to compare sensitivity and specificity per group, mean sensitivity and specificity were calculated, using a threshold for a positive result of 1 + proteinuria (as errors across this threshold were considered clinically important) [3]. False positive and false negative rates were calculated and a logistic regression model was used to compare the difference between the three groups (pregnant woman, HCP, automated reader). All data were included.

2.6. Questionnaire analysis

Free text responses in the questionnaire and online survey were analysed using a thematic approach. The qualitative data was read multiple times by researchers (KT, LB and PM) and analysed using the 'one sheet of paper' (OSOP) method [15]. Themes were examined across the whole dataset and in the context of individual responses.

3. Results

3.1. Test accuracy study

A total of 100 pregnant women and 96 HCPs performed dipstick urine testing on the seven synthetic protein samples (Supplementary Fig. 2 Produced using STARD reporting guidelines [14]). Of the pregnant women approached, 100 of 105 (95%) agreed to participate. Participating women had a mean gestation of 31 weeks (range 9–41 weeks), with 21 (21%) having had raised blood pressure during their pregnancy. There were small numbers of missing data (three missed samples). The HCPs who participated included 54 (56%) midwives, 21 (22%) midwife support workers and 21 (22%) doctors.

Overall, the number and type of errors from pregnant women and HCPs were similar (Table 1; Fig. 1). There were a similar proportion of errors of potential clinical importance (Supplementary Fig. 2) (i.e. those around 1 + threshold (Table 1) between pregnant women (10% false negatives and 2% false positives) and HCPs (10% false negatives and 4% false positives) when compared to laboratory reference standards whereas the automated reader had fewer false negatives (4%) but more false positives (10%).

There was no statistically significant differences between pregnant women and HCPs in sensitivity, specificity ($p = .45$ for both), positive

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