A novel midstream urine-collection device reduces contamination rates in urine cultures amongst women

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OBJECTIVE

To evaluate a novel urine-collection device (UCD) that automatically collects a midstream urine (MSU) sample, and compare contamination rates to those of the conventional MSU sampling method, as the contamination of urine samples for microbiological analysis in women leads to diagnostic ambiguity and unnecessary costs, and may result in part from an incorrect collection procedure.

PATIENTS AND METHODS

In all, 2823 women from four centres, most from antenatal clinics, were randomized to two urine-collection methods: conventional MSU collection and collection with a novel MSU UCD (the Whiz®, JBOL Ltd, Oxford, UK). Semi-quantitative growth and user acceptability were compared between the collection methods.

RESULTS

MSU samples collected with the UCD had significantly fewer mixed growth samples (9% vs 14%, $P = 0.001$; 36% relative reduction), significantly fewer heavy mixed growth samples (1.2% vs 3.0%, $P = 0.004$; 60% relative reduction) and required significantly fewer re-tests (11% vs 16%, $P = 0.002$; 31% relative reduction). There were more samples with clinically insignificant growth than the conventional MSU group (86% vs 82%, $P = 0.005$). Those using the UCD preferred it to the conventional method (67.5%) and experienced significantly less spillage during sample collection (27% vs 46%, $P = 0.001$; relative reduction 41%).

CONCLUSION

The UCD reduced contamination rates in urine samples and improved the predictive value of the urine culture in a manner acceptable to patients and staff.

KEYWORDS

clean-catch, mid-stream, preterm labour, urine contamination, urine collection

INTRODUCTION

UTIs and symptoms mimicking UTI are common in women. The diagnosis of UTI is based on urine sampling and testing with reagent sticks and/or laboratory culture, both of which require a high-quality specimen free of perineal, fecal or vaginal contaminating organisms and inflammatory cells [1]. The interpretation of the urine culture uses semiquantitative methods, including the number of colony-forming units per unit volume, the number of species of organism cultured and the identification of species as likely pathogenic organisms. Urine can be sampled by suprapubic puncture, catheter insertion or midstream urine (MSU) collection. Inherent in catheter insertion and MSU sampling is possible contamination by perineal, vaginal, fecal or skin flora. While suprapubic aspirate is free of contaminating organisms, the procedure is invasive and limited to a few specific clinical situations. MSU sampling is the commonest method, but has a high inherent contamination rate, defined by mixed-growth cultures and growth of nonpathogenic commensals [2]. Contamination rates as high as 30% have been reported [2]. Such contamination obscures interpretation of the urine culture and may mask underlying bacteriuria. The importance of reducing contamination levels in MSU samples is not limited to possible cost savings to health services. The threshold for treating bacteriuria is lower in some clinical settings, including pregnancy, dialysis and those who are immunocompromised, where bacteriuria may lead to complications, e.g. premature labour, or may indicate subclinical infections with slow-growing organisms [3].

To standardize the method of collecting a MSU sample, to remove dependence on patients to produce an adequate specimen, to simplify the compliance required from patients and the need for time-consuming instruction by clinical staff, a novel urine collection device (UCD) was developed for urine sampling in women. The device automatically (i.e. independent of user intervention) collects a MSU sample by excluding the initial low-flow portion of the urinary stream and with no interruption of urine flow, consistent with British Standard Operating Procedure for urine testing [4]. We conducted a clinical trial to investigate whether the novel UCD reduced contamination rates when compared with conventional MSU sampling methods, and to establish patient preference.

PATIENTS AND METHODS

The MSU collection devices (Whiz® UCD, JBOL Ltd, Oxford, UK) were donated by the supplier. Conventional MSU samples were collected using methods and supplies usually available in the participating centres.

Women attending outpatient clinics in four different centres, and who were required to provide a urine sample for microbiological analysis, were asked to participate in the trial. Most women were recruited from antenatal clinics (85%), with a minority from general practice (15%). The indication for urine testing was recorded. Women at each centre

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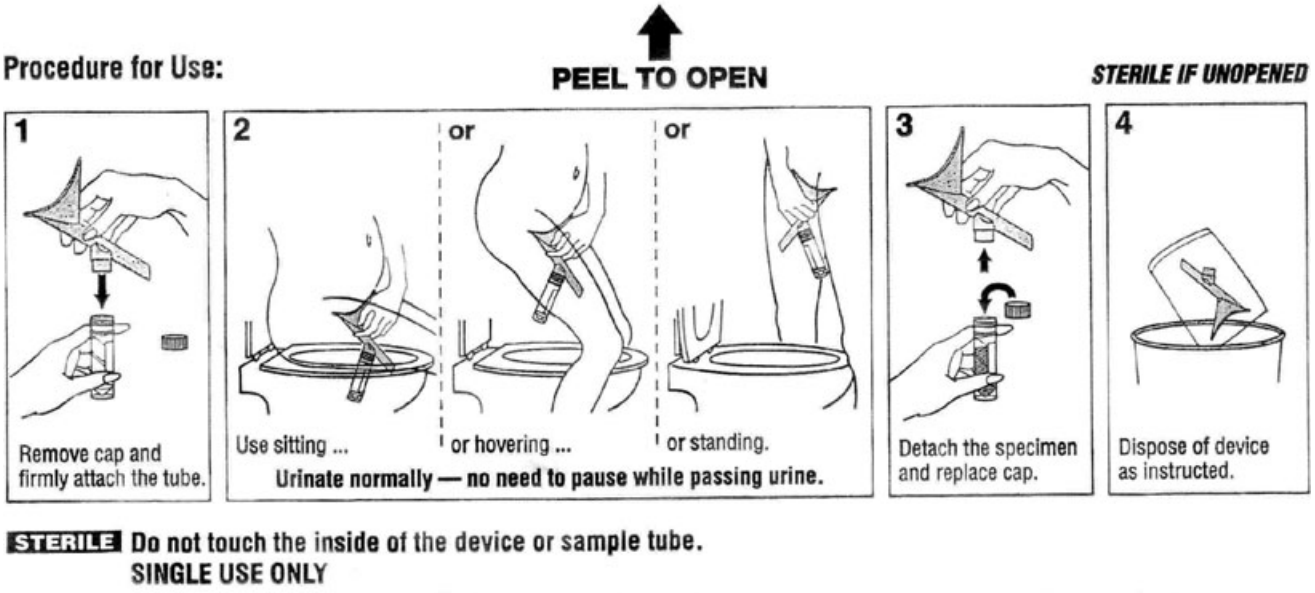
FIG. 1. Diagrammatic representation of the UCD and instructions for use.



were randomized into two equal test groups using serially numbered sealed envelopes. Individual samples and the group sample method were further identified by unique serial numbers, and thus laboratory staff were unaware of the collection method for each sample when reading the culture plates.

The practice of collecting conventional MSU samples (group 1) was according the usual procedure of instruction in each particular setting, and this varied among the centres. Not all centres advised patients on perimeatal cleansing or labial separation for conventional MSU sample collection.

In group 2 (UCD), patients were given the pack including the device, and asked to read the instructions provided on the side of the box (Fig. 1) and give a sample. No cleansing procedures or labial separation were advised.

To determine the patient response to the UCD and gauge opinions on the conventional methods, patients were asked to complete a questionnaire after giving a sample. Questionnaires provided details of age, posture during urine sampling, reason for the urine test, spillage during sample collection and preference for MSU collection technique. In addition, ease of use of the device and conventional method was scored using a numeric scale (1 to 10). The UCD user questionnaire contained an extra question, 'Have you ever given a urine sample before?' to enable a comparative evaluation amongst UCD users only between their use of the UCD and their previous conventional methods of collection. Patients using the UCD were asked to indicate whether they had given a conventional urine sample in the past. At the end of the trial the acceptability of the UCD to clinical staff was assessed by an interview and questionnaire to the clinical staff involved with the trial. In all, 2823 participants were recruited from four different centres and randomized to either conventional MSU collection (1420) or collection with the UCD (1403).

The results were assessed statistically using Pearson chi-squared tests to compare the percentages, and Mann–Whitney/Wilcoxon tests where outcomes were in ordered categories. ANOVA or logistic regression methods were used to investigate potential confounding factors.

RESULTS

The age distribution of the subjects was: <20 years, 4.3%; 20–35, 72.1%); 36–49, 21.2%; 50–64, 1.7%; ≥65, 0.69%; the mean (SD) age was 31 (8.1) years, using midpoints for the age categories, with most patients in both trial groups aged 20–35 years (72.1%). There was no difference in the age groupings of the different arms of the trial (data not shown). Of the 2823 samples collected for culture, the results of 641 (315 conventional and 326 UCD samples) were lost to the study through labelling errors and sample processing errors. This loss of laboratory data did not introduce a bias towards one or other method (chi-square 0.446, one degree of freedom, $P = 0.504$).

Microbiological culture results were obtained on 2182 urine specimens; Table 1 shows how the laboratory results were interpreted clinically, and Table 2 the results of semiquantitative culture, the relative reduction or increase between the arms of the trial and statistical values. In the study as a whole, 13.3% of samples required a re-test (see Table 1 for the criteria). However, samples collected with the UCD were significantly less likely to require re-testing than the conventional MSU samples (UCD 11%, conventional 16%, $P = 0.002$; relative reduction 31%). The reason for the test, posture during sampling and the centre at which the sample was taken had no effect on the significance of the results shown in Table 2 (Pearson chi-square $P = 0.004$, 0.364 and 0.916, respectively).

User acceptability data showed that half the respondents experienced little difficulty in collecting the urine sample with either method (score 1 or 2 from 10 on the numerical scale). There was no significant difference in ease-of-use scores between the methods of collection (Wilcoxon/Mann–

TABLE 1 Interpretation of and clinical response for semiquantitative MSU culture

Growth, CFU/mL	N different organisms	Clinical interpretation	Action
<10 000	Any number	Not significant	No further action if asymptomatic
10 000–100 000	1–2	Equivocal growth Possible early infection or contamination	Retest
10 000–100 000	>2	Equivocal growth. Probable contamination	Retest
>100 000	>2	Heavy mixed growth. Frankly contaminated	Retest
>100 000	1–2	Significant growth indicating UTI	Treat if clinically indicated

CFU, colony-forming units.

TABLE 2 Semi-quantitative culture results of 2182 urine specimens randomised to conventional MSU and UCD collection; chi square, P = 0.012

Culture result	Total, n (%)	Conventional	UCD	Change, % (95% CI)	Relative change, %
No significant growth	1829 (83.8)	902 (81.6)	927 (86.7)	4.4 (–1.4 to 7.5)	+5.16
Equivocal single species	33 (1.51)	17 (1.54)	16 (1.49)	0.05 (–1.0 to 1.1)	–3.25
Equivocal mixed growth	211 (9.67)	122 (11.0)	89 (8.26)	2.78 (0.3 to 5.3)	–33.66
Heavy mixed growth	46 (2.11)	33 (2.99)	13 (1.21)	1.78 (0.6 to 3.0)	–59.63
UTI	63 (2.89)	31 (2.81)	32 (2.97)	0.16 (–1.6 to 1.2)	+5.69
Total	2182 (100)	1105 (100)	1077 (100)		

Whitney test, $P = 0.1286$). Users of the UCD had significantly less spillage during collection (27% vs 46%, $P < 0.001$; relative reduction 41%); 67.5% of UCD users preferred the UCD to the conventional methods (95% CI 65.0–70.1%). UTIs were positively identified in 3.0% of patients in the UCD group and 2.8% of patients in the conventional MSU group, although the difference was not statistically significant ($P = 0.8$; 6% relative increase). All patients in the UCD group had, at some time in the past, provided urine specimens using the conventional MSU method; 62% of patients in both groups produced a sample while seated, 34% while squatting, and 4% while standing. Use of the UCD did not influence the posture adopted.

Acceptance of the device by clinical staff was assessed through interview, and all 12 interviewed indicated a preference for the UCD, citing time-saving and improved hygiene as the main reasons for their preference.

The indication for MSU testing in all patients from the hospital antenatal clinics (85% of patients) was 'routine antenatal screening'. Indications for specimens collected in general practice (15% of patients) were 'UTI' in 1% of all patients, 'other' in 8%, and 'routine' in the remaining 6%.

Both groups in all centres, except the GP surgeries, use dipstick testing, and did this by pouring a small portion of the urine sample collected onto the dipstick, rather than dipping in the sample, and the remaining urine in the collection bottle was sent to the laboratory.

The practice of collecting conventional MSU samples (group 1) varied among centres; instructions to patients on collection varied. At United Hospital Trust (Mid Ulster Hospital) patients were instructed to catch the middle part of the urine flow but they were not instructed on cleaning or separating the labia. At the John Radcliffe Women's Centre all patients in group 1 were given a sterile pack containing a gauze and cotton wool to facilitate cleaning of the peri-meatal area, and were instructed by staff on how to collect a MSU, which included separating the labia and to urinate into the toilet, then to stop, then to collect a sample and finish voiding into the toilet. It was reported by staff at the John Radcliffe centre that several of these peri-meatal cleaning packs were thrown away unused, nor could staff verify that the instructions for giving an MSU, i.e. separating the labia, were carried out while in the privacy of the sample areas. At Stoke Mandeville Hospital, those in group 1 were given a specially designed sterilized pack which contained cotton wool to facilitate cleaning the peri-meatal area and a small cup for urine collection, and users were instructed by staff on how to collect the MSU sample, which included separating the labia and to void into the toilet, then to stop, then to collect a sample and finish voiding into the toilet. The sample collected was then transferred to a universal sample bottle. At Royal Hampshire County Hospital group-1 patients were asked to give an MSU; some of the GP surgeries instructed on separating the labia and the need to give an MSU, but others did not. No further instructions were given.

All centres for group 2 were given the packet containing the Whiz UCD, which contained the instructions and device, and no further instructions were given. At Stoke Mandeville women were instructed to read the instructions and make sure the device was held against the perineum, i.e. not used as a funnel.

DISCUSSION

The ability of clinicians to accurately diagnose a UTI is impaired by high rates of contamination, particularly in samples obtained from women [2], children [5], the elderly [6] and in general practice [7]. In addition, clinical situations in which low levels of bacteriuria may be clinically significant, e.g.

in antenatal and urogynaecological patients, are complicated by bacterial contamination of samples. This may lead to a delay in the diagnosis of a urinary infection, with consequent adverse outcomes for the patient (e.g. pre-term labour) and consequent morbidity, mortality and healthcare costs.

The reasons for high levels of contamination in women include anatomical factors (proximity of urethral meatus to vulva and covering by labia [8]) and compliance factors in collecting the sample. Most samples in clinical practice are collected unsupervised, and while careful instruction to patients on technique may be beneficial in reducing contamination, this may be difficult to achieve in busy clinical environments and may equally have an undesired negative effect on contamination rates [9]. Physical constraints (e.g. old age, pregnancy) and urinary pathology (e.g. stress incontinence) may further limit compliance and good technique.

The collection of a MSU sample requires understanding and implementation by the patient, with little opportunity for intervention by clinical staff. It has been found that conventional MSU sampling with additional cleansing procedures does not significantly alter culture outcome or levels of contamination [2,10]. This is attributed at least in part to the lack of supervision in sample collection. For this reason, we hypothesized that removing the need for patient intervention, and standardization of MSU sample collection, might reduce contamination levels. The UCD used is not simply a funnel, but incorporates a flow-sensitive sampling channel and diverter that, using urodynamic principles, excludes the initial low-flow portion of the urinary stream, thus discarding the contaminated early stream volume, and automatically collects the midstream volume without interrupting the stream. The British Standard Operating Procedure for MSU testing states that 'the first part of voided urine is discarded and without interrupting the flow, approximately 10 mL is collected into a sterile container' [4]. The new device is also used with no need for cleansing or separating the labia.

The present data show that urine samples collected with the UCD had significantly lower contamination levels than conventional MSU samples. Use of the UCD resulted in a reduction in mixed-growth samples and consequently more samples with no significant growth. The lower levels of contamination resulted in fewer re-tests required for these patients and improved the predictive value of the urine culture, i.e. more true-negative and fewer false-positive results. Taken together, the quality of urine sampling was significantly improved.

A urine culture is a frequently requested investigation; the present data suggest that up to 15% of urine cultures collected by conventional MSU sampling cannot be interpreted clinically. This finding is similar to that of Valenstein and Meier [11], who found that a median 18% of outpatient urine cultures were contaminated. Furthermore, as sample collection is a fraction of the cost of the administrative, staffing and laboratory costs of the urine culture, we assert that a significant portion of the microbiology budget for urine culture is consumed by samples with little clinical worth. A greater accuracy in diagnosis of urinary symptoms, including those that require exclusion of a urinary infection, will positively affect patient care and is likely to improve outcomes for patients, and reduce wastage of laboratory and clinical resources. The trend towards detecting many UTIs using the UCD, while not statistically significant in the present study of asymptomatic patients, suggests further study on different patient groups, e.g. those who have symptoms suggestive of UTI.

The present data indicate that the UCD is both easy to use and more acceptable to the patients providing the samples. Reasons for this may include the reduction of spillage during collection, removal of the need to 'aim' or control the urine stream, and improved hygiene of sample collection. Clinical staff supervising the use of the UCD preferred it to conventional MSU sampling because they thought it reduced the time taken to collect and process samples. They also considered that the UCD improved hygiene for staff, because it removed the need to transfer the sample from a collection pot to a sample container.

This study was limited to women predominantly aged 20–35 years. Further studies are required to establish the possible benefit of the UCD in other populations, particularly men, children and the elderly, or where there are high rates of sample contamination and possibly lower rates of proper compliance with the MSU technique.

The trial samples were identified to the laboratory database by a unique trial identification number, to ensure that laboratory staff were unaware of the sample method. Several samples were excluded because of an administrative error while attaching labels to some of the specimens. This mislabelling affected both groups equally and was not a source of bias to the primary outcomes of the study.

In conclusion, we show that the rate of contamination of urine specimens can be reduced by using an automatic midstream UCD with no need for perimeatal cleansing or labial separation, and that such a device is more acceptable to patients and staff than conventional MSU sampling. Use of this UCD should be considered for collecting all MSU samples in women, where the specimen is to be used for bacterial culture. This may be particularly important during pregnancy, where UTI may result in serious complications, including premature delivery and its associated morbidity [12]. Further studies are needed in other clinical settings in which urine culture poses a diagnostic difficulty or leads to additional complications.

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CONFLICT OF INTEREST

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Abbreviations: **MSU**, midstream urine; **UCD**, urine-collection device.