

A MULTICENTRE RANDOMISED CONTROLLED TRIAL TO COMPARE CONTAMINATION RATES IN CONVENTIONAL MID-STREAM URINE SAMPLES WITH SAMPLES TAKEN USING A NOVEL COLLECTION DEVICE

Hypothesis / aims of study

The midstream urine sample is the standard non-invasive method of urine sampling in clinical practice. However, contamination of urine samples is inherent to the mid-stream sampling technique due, in part, to sampling from the non-sterile environment of the perineum. While mid-stream collection, should reduce the incidence of contamination due to expulsion of colonising bacteria within the urethra and perineum, previous studies have shown that the mid-stream urine sample collected in the conventional method is associated with high contamination rates (1). This is probably due to the inability of the patient to produce a correct specimen due to lack of proper instruction by staff or misunderstanding of instructions by the patient.

A novel urine collection system (Whiz UCD, JBOL Ltd., Oxford, UK) has been developed for urine sampling in women. The device automatically (i.e. independent of user intervention) collects a mid-stream sample by excluding the initial low flow portion of the urine stream.

The aim of the study was to determine if elimination of operator (that is the patient) dependent factors reduces contamination rates in urine samples collected by this new device.

Study design, materials and methods

Patients attending outpatients departments in four different hospitals who were required to provide urine sample for culture were asked to participate in the study.

Patients who agreed to take part in the study were randomised to two groups. Patients randomised to group I provided a mid-stream specimen of urine in a sample bottle by conventional method after instruction by nurses and the specimen was sent to the laboratory for microscopy and culture.

Patients randomised to group II were asked to provide a specimen by using the new urine collection device. Diagrams on the packaging provided instructions for use of the device.

Patients were also asked to fill a questionnaire to determine the incidence of spillage.

Unique trial numbers were used to identify trial specimens and the laboratory was blind to the collection method of the urine sample.

The urine was processed in the laboratory in the normal manner, which included microscopy and culture.

Urine culture was reported by the laboratories as the number of organisms per ml of urine.

Organism load of 100,000 organisms / ml of urine on culture was indicative of urinary tract infection.

Growth of less than 10,000 organisms / ml of urine indicated no urinary tract infection.

Organism load of 10,000 to 100,000 organisms / ml of urine was considered as equivocal growth.

Statistical tests consisted of Chi square and Wilcoxon / Mann Whitney tests.

The main outcome measure was contamination rates determined by growth of more than two species of organism (mixed growth) in a sample of urine.

Results

Total of 2839 patients were recruited to the trial.

2183 culture reports were obtained. The shortfall in the number of culture results compared with the total number of patients recruited was attributed to administrative errors in failing to log trial identification numbers on arrival to the laboratory or failure to place trial numbers on the sample bottles.

Table I shows urine culture results in 2183 reports obtained

Results	Total	GroupI (conventional)	GroupII(UCD)
No UTI (less than 10,000 organisms / ml)	1829(83.78%)	903(81.74%)	926(85.90%)
Equivocal growth (10,000 – 100,000 organisms / ml) of 1 – 2 species	37(1.69%)	19(1.72%)	18(1.67%)
*Equivocal growth (10,000 – 100,000 organisms / ml) of > 2 species	206(9.44%)	118(10.67%)	88(8.16%)
UTI (more than 100,000 organisms / ml) of 1 – 2 species	65(2.98%)	32(2.89%)	33(3.06%)
*Heavy mixed growth (more than 100,000 organisms / ml) of > 2 species	46(2.11%)	33(2.99%)	13(1.21%)
Total	2183(100%)	1105(100%)	1078(100%)

*Mixed growth i.e. growth of > 2 species of organisms = contamination

2603 questionnaires were obtained.

According to the patients replies the incidence of spillage was 45.46% in the conventional method and 27.48% in the UCD ($p < 0.005$).

Interpretation of results

The results show that standardisation of urine collection by use of the UCD significantly reduces the contamination rates which was 13.6% in the conventional method and 9.3% with the UCD ($p < 0.002$). Contamination rates were determined by adding the number of samples with equivocal growth of more than 2 species of organisms with the number of samples, which showed heavy mixed growth.

Concluding message

The use of the novel urine collection device (The Whiz UCD) helps in standardisation of mid-stream urine collection and removes operator dependence leading to significant reduction in contamination rates and the incidence of spillage during urine collection.

Reference

1. Outpatient urine culture: does urine collection technique matter? Arch Intern Med 160, 2537 - 2540

FUNDING: JBOL, Ltd, Oxford UK