98

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A CLINICAL EVALUATION OF A SENSOR TO DETECT BLOCKAGE DUE TO CRYSTALLINE BIOFILM FORMATION ON INDWELLING URINARY CATHETERS

Hypothesis / aims of study

Urinary catheter encrustation and blockage is believed to affect up to 50% of long term urinary catheter users (1). This is a potentially serious problem that impacts on patient morbidity and health care costs. Blockage stems from infection with urease-producing bacteria, particularly *Proteus mirabilis*. Urease causes an increase in urine pH, crystals of calcium and magnesium phosphate are deposited, and, when combined with bacterial biofilm, block the flow of urine down the catheter (2). There is no reliable way of predicting when blockage may occur, resulting in unnecessary or emergency catheter changes.

An early warning sensor has been developed to predict catheter blockage due to urease-producing bacteria. An earlier prototype was clinically assessed to establish proof of principle (3), and, following further development, a market-ready prototype has now been produced. The aim of this pilot study was to evaluate the performance and acceptability of this prototype in clinical use. The aims were to gauge the longevity of the encrustation sensor; gather user and healthcare professional (HCP)/carer feedback on the clinical relevance and usability; gauge sensitivity and specificity of the sensor; and to observe the time interval between sensor indication and catheter blockage.

The sensor is housed in a small, clear PVC connector positioned between the catheter and drainage bag or valve, where it is easily visible but not intrusive. It is designed to change colour from yellow to blue-black when catheter blockage is imminent. It is a Class 1 device manufactured by MBI (Wales) Ltd under license from Cardiff University.

Study design, materials and methods

The study was a pilot prospective observational study to record outcomes from 10 'blockers' and 2 'non-blockers'. Inclusion criteria were long term suprapubic or urethral catheter use (6 months minimum) and a plan to continue usage for a further 3 months. The 'blockers' were required to have a history of catheter blockage (patient records). Participants on antibiotic prophylaxis were included.

Informed consent was obtained and participants commenced the study on the date of a catheter change. Two sterile sensors were fitted in series between the catheter and the bag (Fig 1i). The sensor nearest the catheter, (A), was left in situ for the duration of the catheter life; the sensor nearest the bag, (B), was changed when the catheter bag was changed (weekly). The colour of the sensors was recorded weekly by the participant or carer (against a colour chart), and the pH of the urine recorded by the research nurse. This process was repeated until either the catheter blocked and was changed or a scheduled change took place. Urine samples and catheters were sent immediately to the BioMed laboratories for bacterial analysis.

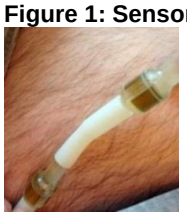
HCPs/carers attending to the catheter changes and participants were asked to complete a short questionnaire on the functionality and acceptability of the sensor. Participants were also asked to complete the Psychosocial Impact of Assistive Devices Scale (PIADS).

Results

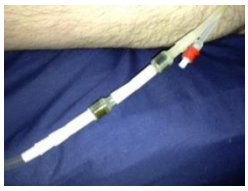
Two 'non-blockers' (01, 05) completed the study. Fifteen 'blockers' consented, 3 did not start; three (10, 11, 17) withdrew early; nine (02, 03, 07, 08, 09, 13, 14, 15, 16) completed the study (i.e. to catheter change). Of the 12 'blockers' who started three (08, 13, 15) were on prophylactic antibiotics and nine were on a regime of regular catheter changes (mean 5.4 weeks).

The two 'non-blockers' had scheduled catheter changes at 54 and 70 days respectively. *Pr mirabilis* was not present and both sensors (A & B) remained yellow throughout. An average urine pH of 6.4 (range 6.1 - 6.8) and 5.5 (range 5.1 – 6.0) respectively were recorded. Both participants had high levels of bacteriuria (10^6 – 10^8).

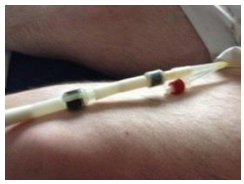
Figure 1: Sensors A & B in situ



i Sensors A & B yellow on insertion



ii Sensor A has turned blue-black; Sensor B is mid-way between yellow and blue-black



iii Sensors A & B have turned blue-black

Of the 'blockers' four (02, 08, 11, 17) had *Pr mirabilis* and only one (02) went to catheter blockage; 08 had a planned catheter change after 50 days and 11 and 17 both withdrew from the study early. In all four, the sensor changed from yellow to blue-black. Participants 13 and 15 also went to catheter blockage; in both there was evidence of the urease-producing bacteria Morganella or Providencia, and the sensor in both cases changed from yellow to blue-black. One participant (03) had her catheter changed as it was 'by-passing' but no urease-producing bacteria were present and the sensor did not change colour. Participants 07, 08, 14 and 16 went to planned catheter change, no urease-producing bacteria were identified; the sensor remained yellow throughout for participants 07, 09 and 16, and changed blue-black for participant 14. Participant 10 withdrew early and there was no evidence of urease-producing bacteria or sensor colour change.

Catheter blockage occurred after 25, 22 and 23 days for participants, 02, 13 and 15, respectively. Both sensors (A & B) went blue-black after 3-5 days and Sensor A remained blue-black throughout; Sensor B changed from yellow to blue-black within 24 - 48 hours after each sensor change. Participants 07, 08, 14 and 16 had planned catheter change between 42 and 53 days. Sensor A turned blue-black after 2-5 days in participants 08 and 14 and Sensor B changed within 24 - 48 hours after sensor change. All participants had high levels of bacteriuria (10^5 – 10^8).

Participants thought the sensor was a good idea and would recommend it to other catheter users. Fewer thought it would make them less anxious. Several expressed concern that the time between the sensor changing colour and catheter change/blockage could be several weeks. Many found the additional length caused by having 2 sensors in series (for purpose of the study only) was a nuisance and this factor contributed to at least one early withdrawal. The results of the PIADS were +0.45 for Competence, +0.42 for Adaptability and +0.30 for Self-esteem.
All thought the appearance of the sensor was acceptable and would be discreet if one sensor only was in place. Opinion was divided as to whether they thought it would be a good indicator, although the majority would recommend it if the time between the sensor changing colour and blockage was shorter. The colour change was deemed easy to identify by most carers and users, and those that commented said that the instructions for use were good.

Interpretation of results

Despite the history of catheter blockage, only one third of 'blockers' were infected with *Pr. mirabilis* although several had presence of other urease-producing bacteria. When measured by presence of urease-producing bacteria and colour change, the sensitivity of the sensor was 0.86 and specificity 0.75. When measured by pH and colour change, the sensitivity was 0.86 and specificity 1.00. However, while the sensor accurately detects change in pH, the link between urine becoming alkaline and catheter blockage appears not to be as well correlated as was anticipated.

Concluding message

If the sensor can be made to respond closer to the time of catheter blockage, it could be a useful clinical indicator.

References

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Disclosures

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