(54) Title of the Invention: A urinary catheter cleaning and fluid lock device and method of cleaning a urinary catheter and retaining a lock fluid

Abstract Title: A urinary catheter cleaning device using lock fluid

(57) The present disclosure provides a positive pressure urinary catheter cleaning and lock device 1 for the removal of biofilm and the destruction of micro-organisms from the lumen of an indwelling urinary catheter. One embodiment of the device comprises an elongate flexible tubular shaft 1 having a proximal and distal end. The device comprises a proximal stopper which may incorporate a transparent flask 2, tap body 4 and collar 3, an inflatable balloon 7, a distal exit hole 9, proximal exit holes 8, an inflation port 6 and a connector port 5 for a source of positive pressure and the lock solution. The flask 2, tap body 4 and collar 3 all have holes which may be aligned to provide an air exhaust outlet port, or the tap body may be rotated to occlude the exhaust port. In use, the device is inserted into a urinary catheter 12, the balloon is inflated to occlude the urinary catheter drainage holes 13, 14, lock fluid is introduced using positive pressure to fill the urinary catheter whilst the air holes are aligned to allow excess air to escape, and the air ports are then closed by rotating the tap.
Title: A Urinary Catheter Cleaning and Fluid Lock Device and Method of Cleaning a Urinary Catheter and Retaining a Lock Fluid

Background of the Invention:
There are many prior art examples of inventions to remove debris and clean the inside of urethral catheters. US patent 2005/0267421 describes a rod with a head to scoop and push debris into the bladder. US patent 4,227,533 describes a valve mechanism that closes the end of the catheter when flushing out debris and US patent 5,300,002 describes a catheter with an extra central lumen to be used for flushing the catheter. The problem with a rod is the flexibility needed and the risk of perforating a worn catheter. The problem with the valve mechanism is the fact that it did not flush the distal exit port of the catheter which is an area of significant debris build up. The problem with the extra lumen within the catheter is the increased surface area for biofilm growth which results in more encrustation.
Current research has shown that 43% of long term catheter patients experience some problems e.g. bypassing or infection and more that 50% experienced catheter blockage.
One of the main causes of catheter failure is blockage of the lumen by encrustation or blood. The encrustations develop due to bacteria producing a biofilm material which is invisible and represents cell growth and these cells produce a sticky glycocalyx material that sticks to the catheter wall and protects the bacteria from the effects of antibiotics. As the bacteria produce ammonia salts, crystals of a substance called struvite collect and calcium phosphate develops and these form around the eyehole exit areas and the central lumen of the catheter and result in the catheter bypassing or blocking completely. A blood clot that sticks to the glycocalyx will act as a floating flap valve allowing any flush solution to wash over itself, but then blocking the catheter as a suction force is applied to try to withdraw urine from the bladder by a bladder syringe.
The current method to deal with the problem of encrustation has been a catheter washout with a commercially prepared acidic solution containing citric acid or simple saline. The solution is flushed through the catheter using a bladder 50ml syringe. The studies to date have found no difference in complication rates from catheters washed out and those not washed out and a typical washout period over 3 months has been shown to cost £900.00. Clearly the washout is not removing the biofilm which has adhered to the wall of the catheter as the process of encrustation has continued to cause problems in those patients studied. The studies have also shown no advantage in using one solution over another when looking at bacteriuria, symptomatic urinary tract infection, catheter blockage and encrustation or catheter replacement and where a slight benefit was detected this was not confirmed by statistical tests and the conclusion was that no statistical difference between solutions used was found. When catheters are acutely blocked due to biofilm and encrustation build up, this often happens out of normal working hours and at weekends and results in visits to the emergency department from a resident in a nursing home, often by ambulance at a cost of £300 pounds per journey to hospital and then back home, before the medical time and equipment costs have been taken into consideration. A device to successfully maintain a patent, free flowing urinary catheter and prevent the development of intra-luminal biofilm would save a significant amount of money and medical and nursing time.
Lock fluids have been described in the prior art e.g US 6,958,049 by Stephen Ash who used a citrate salt solution to infuse into an intravascular catheter that would typically deliver intravenous fluids to a patient. Intravenous catheters are prone to develop infections due to the formation of biofilms and the catheter lock solutions have been found to reduce the incidence of these infections. A similar infection risk applies to the urinary catheter, but unlike the long central venous lines it is not possible to instil a lock fluid into the urinary catheter because the urinary catheter is large bore by comparison and the solution will drain directly into the bladder through large drainage eye holes at the catheters distal end.

Lock fluids containing agents like ethanol and citric acid have recently been shown to reduce infection rates in those patients with long term renal intravenous lines and feeding intravenous lines as these agents are soluble within a biofilm and destroy bacteria living in the biofilm matrix. The determining factors for bacterial kill are solubility of the agents in the biofilm and length of time in contact with the biofilm.

The rate of urinary catheter related urinary tract infection is high due to the inability to remove biofilm and destroy micro-organisms within the biofilm effectively within indwelling urinary catheters and these infections result in significant morbidity e.g pyelonephritis and a significant cost to health services worldwide. The widespread use of antibiotics has resulted in increased bacterial resistance and there is now an urgent need to look at ways to reduce urinary catheter related infections.

Researchers have been looking for a method to prevent biofilm and bacterial growth in indwelling urinary catheters for over 30 years and there are currently no research articles that identify clearly a product or device that maintains a clean, bacterial free indwelling urinary catheter when used in the long term.

Summary of Invention

The present invention proposes a positive pressure urinary catheter cleaning device, the device can remove urinary catheter biofilm and incorporates a urinary catheter fluid lock mechanism to lock a biocidal antibacterial solution inside an indwelling urinary catheter to destroy bacterial organisms within the biofilm matrix.
Advantages of the current invention:
The device locks a biocidal agent inside an indwelling urinary catheter
The lock fluid is small volume
The lock fluid will not irritate the patients bladder
The lock fluid will destroy micro-organisms inside the biofilm
The lock fluid can act along the whole inside lumen area of the indwelling urinary catheter
The device is preferably made of a soft medical grade plastic or silicone with no risk of perforating the urinary catheter.

The device allows the delivery of a positive pressure e.g. pulsed jet cleaning fluid, to be delivered to the distal regions of the urinary catheter and the distal catheter wall.

The device allows the delivery of many combinations of lock fluid and cleaning fluids to the inside of a urinary catheter e.g. ethanol and citric acid combinations.

Brief Description of Drawings
For a more complete explanation of the present invention and the technical advantages thereof, reference is now made to the following description and the accompanying drawings:

Fig 1 is the side view of the Urinary Catheter Cleaning and Lock Device with the lock balloon inflated

Fig 2 is a perspective view of the 3 component parts of the proximal stopper device.

Fig 3 is the side view of the Urinary Catheter Cleaning and Lock Device inserted into a standard Urinary Catheter with the lock balloon inflated.
4. Detailed Description of the Invention

Referring now to the drawings wherein the drawings are for illustration of the preferred embodiment of the present invention, Fig 1 illustrates the side view of the urinary catheter cleaning and lock device with the lock balloon inflated which comprises a flexible hollow tube 1, clear transparent flask 2, lock collar 3, body of locking tap 4 with tap handle 10, air exhaust ports B, C and D in the body of locking tap 4, the collar 3 and flask 2 respectively and aligned together, a lock balloon inflation port 6 and lock balloon 7, a lock solution connection port 5 and a series of lock solution exit ports 8 proximal to the locking balloon 7 and a distal exit port 9 distal to the locking balloon 7.

Fig 2 illustrates a perspective view of the component parts of the proximal catheter lock device showing the body of the locking tap 4 with entry port 15 for hollow tube 1, the tap handle 10 and the air exhaust port B, the collar 3 and air exhaust port C and the transparent flask 2 with air exhaust port D.

Fig 3 illustrates the urinary catheter cleaning and lock device inserted into a standard urinary catheter 12 and shows the proximal lock device with the locking tap 4, collar 3 and transparent flask 2 together with hollow tube 1 and with the lock balloon 7 inflated through inflation port 6 and occluding distal urinary catheter draining holes 13 and 14.

The urinary catheter may be a male or female catheter and although not illustrated the urinary catheter will be functioning in a patient and inserted into the patient's bladder.

A method of cleaning a urinary catheter will now be described in detail with reference to the component parts in Figures 1, 2 and 3. The urinary catheter cleaning and lock device 1 will be inserted into the urinary catheter as illustrated in Figure 3, but with the locking balloon 7 in the deflated position so as not to occlude the urinary catheter draining holes 13 and 14. With the proximal tap 4, collar 3 and flask 2 secure in the urinary catheter drainage port 16, the tap 4 is rotated 90 degrees on the collar 3 to close the air exhaust ports B, C and D. A positive pressure cleaning device typically a pulsed jet device delivering a cleaning solution under pressure is connected to connection port 5 to create a water tight seal. The pulsed jet will typically deliver 50 to 100ml of a cleaning solution at pressures typically from 10 psi to 150 psi and the cleaning fluid will be delivered to both the distal part of the urinary catheter through exit hole 9 and to the walls of the urinary catheter through exit holes 8 and will irrigate through the urinary catheter draining holes 13 and 14 and into the patient's bladder.

A method of locking a fluid into the urinary catheter will now be described in detail with reference to the component parts in Figures 1, 2 and 3.

The lock fluid may contain antibiotics, biocidal agents, detergents or enzymes in any combination. The urinary catheter cleaning and lock device 1 will be inserted into the urinary catheter 12 as illustrated in Fig 3. The proximal lock device is secured in the proximal draining port 16 of the urinary catheter 12. The proximal lock device will be in the open position with air exhaust ports B, C and D all aligned. The lock balloon 7 is inflated with air or fluid via the inflation port 6 and the lock balloon 7 occludes the urinary catheter draining holes 13 and 14. The lock solution is now added through port 5 and travels along hollow tube 1 to exit distally through exit port 9 and more proximally through exit ports 8. The lock solution fills the lumen of urinary catheter 12 and becomes visible in transparent flask 2 which may contain a marker to signal the lock fluid level. The proximal lock device tap handle 10 is now rotated clockwise or anticlockwise by 90 degrees.
which results in the displacement of air exhaust port B from air exhaust ports C and D and traps air and the lock fluid inside urinary catheter 12. The lock fluid is now sealed inside the urinary catheter 12.

This description of the various embodiments of the present invention is presented to illustrate the preferred embodiments. The materials used will be those that are used currently by specialist medical manufacturers and will be soft and yet provide structure and will be typical of those used for central venous cannulation e.g silicone or polyurethane. The internal diameters and lengths of the cleaning and lock device will vary with the sizes of current urinary catheters e.g 12F, 14F and 16F in both male and female sizes. The cleaning solution may be normal saline or a biocide and the lock solution may contain a biocide like ethanol or citric acid or combinations of these agents together with antibiotics or enzymes in a concentration determined by the length of time to penetrate and destroy various biofilms.
What we claim is:

1. A positive pressure cleaning and fluid lock device for removing biofilm and destroying micro-organisms inside urinary catheters and method thereof comprising:
   - An elongate flexible tubular shaft having a proximal and distal end with a fluid delivery lumen along the longitudinal axis;
   - An inflatable and deflatable balloon associated with the distal end of the flexible tubular shaft and associated with the external wall for occluding the draining holes in a urinary catheter;
   - A proximal stopper device to secure the flexible tubular shaft into the proximal draining port of a urinary catheter incorporating air exhaust ports and a rotatable tap that can open and close the air exhaust ports;
   - A proximal connector port adapted to connect a source of positive pressure to the proximal end of the elongate flexible tubular shaft;
   - A source of positive pressure.

2. The positive pressure cleaning and fluid lock device of claim 1 where the elongate flexible tubular shaft delivery lumen has an exit hole at the distal tip.

3. The positive pressure cleaning and fluid lock device of claim 2 where the elongate flexible tubular shaft has multiple exit holes disposed about the longitudinal axis of the flexible tubular shaft and disposed proximal to the balloon.

4. The positive pressure and fluid lock device of claim 1 where the inflatable and deflatable balloon is connected to a proximal inflation and deflation port through a duct in the wall of the flexible tubular shaft.

5. The positive pressure cleaning and fluid lock device of claim 4 wherein the balloon element is a continuous element positioned around substantially the entire outer surface of the distal region of the flexible tubular shaft.

6. The positive pressure cleaning and fluid lock device of claim 5 where the size and shape of the balloon is determined by the attachment points at the distal region and determines a shape that occludes the draining holes in a urinary catheter.

7. The positive pressure cleaning and fluid lock device of claim 1 where the proximal stopper device incorporates a transparent flask, a tap body and a collar.
8. The positive pressure cleaning and fluid lock device of claim 7 where the transparent flask inserts into and forms a water tight seal with the urinary catheter proximal draining port.

9. The positive pressure cleaning and fluid lock device of claim 8 where the transparent flask incorporates an air exhaust port.

10. The positive pressure cleaning and fluid lock device of claim 9 where the transparent flask incorporates a fluid level indicator.

11. The positive pressure cleaning and fluid lock device of claim 7 where the tap body contains an air exhaust port.

12. The positive pressure cleaning and fluid lock device of claim 7 where the collar contains an air exhaust port.

13. The positive pressure cleaning and fluid lock device of claims 11 and 12 where the tap body rotates inside the collar and opens and closes the air exhaust ports.

14. The positive pressure cleaning and fluid lock device of claim 1 where the proximal connector port forms a water tight seal with a source of positive pressure.

15. A method of destroying micro-organisms within an indwelling urinary catheter comprising the steps of:

a) providing a flexible tubular shaft having a proximal and distal ends and a fluid delivery lumen
b) inserting the flexible tubular shaft within the lumen of an indwelling urinary catheter
c) securing the flexible tubular shaft inside the urinary catheter proximal draining port
d) inflation of the distal balloon to occlude the urinary catheter draining holes
e) alignment of the air exhaust ports in transparent flask, tap body and collar
f) attachment of a source of lock fluid to the proximal connector port
g) a positive pressure application to the lock fluid source to fill the urinary catheter as indicated by a fluid level indicator in the transparent flask
h) closure of the air exhaust ports by rotating the tap body on the collar thus locking the lock fluid inside the urinary catheter.
16. A method of removal of biofilm within an indwelling urinary catheter comprising the steps of:
   a) completing the method steps of claim 15

   b) deflation of the distal balloon thus allowing free drainage of fluid through the urinary catheter draining holes.

   c) attaching a source of positive pressure to the proximal connector port.
Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

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<th>Category</th>
<th>Relevant to claims</th>
<th>Identity of document and passage or figure of particular relevance</th>
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<td>A</td>
<td>-</td>
<td>US 2005/267421 A1 (WING) See paragraphs 27-37 and figures 1 and 2 in particular</td>
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<td>A</td>
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<td>US 2009/178681 A1 (BRACKEN) See paragraphs 14-21 and figure 2 at least</td>
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<td>A</td>
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<td>WO 00/10385 A1 (ASH MEDICAL SYSTEMS, INC) See page 10, line 31, to page 13, line 19, and figure 1 in particular</td>
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<td>US 6090069 A (WALKER) See column 3, line 40, to column 4, line 4, and figures 7 and 8 in particular</td>
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Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKPC:

Worldwide search of patent documents classified in the following areas of the IPC:

A61B; A61M; B08B

The following online and other databases have been used in the preparation of this search report:

EPODOC, WPI

International Classification:

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