Farco-fill Protect for indwelling urinary catheterisation

Medtech innovation briefing
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Summary

- The technology described in this briefing is Farco-fill Protect. It is a solution used to inflate Foley urinary catheter balloons.

- The innovative aspects are that Farco-fill Protect contains a broad-spectrum antimicrobial agent (triclosan) that aims to reduce the amount of bacteria in the urine and potentially reduce encrustation of the catheter.

- The intended place in therapy would be for use by any clinician responsible for inserting or changing an indwelling urinary catheter. Using Farco-fill Protect would not need any change to practice because it would simply replace the sterile water that is currently used to inflate catheter balloons.

- The main points from the evidence summarised in this briefing are from 1 randomised controlled trial, 1 before–after study and 1 case series including a total of 142 patients. There is some evidence to suggest that Farco-fill Protect may reduce the level of bacteria in the urine and decrease the frequency of premature catheter removal.

- Key uncertainties around the evidence or technology are the lack of comparative studies, whether the outcomes measured such as level of bacteria in the urine are of clinical importance, and if the use of Farco-fill Protect extended the patency of catheters or reduced the number of catheter-associated urinary tract infections. Triclosan has been banned by the US Food and Drug Administration from over-the-counter antiseptic washes because of lack of efficacy. This ban does not extend to antibacterial products used in healthcare settings.
The cost of Farco-fill Protect is £4.80 per 10-ml syringe (exclusive of VAT). The resource impact would be similar to standard care, but its use may lead to savings for the NHS through decreased risk of patients developing a blocked catheter.

The technology

Farco-fill Protect is a sterile solution that comes in a ready-to-use syringe. It is used to inflate urethral and suprapubic Foley catheter balloons, to hold the catheter in place. It contains 0.3% triclosan, a broad-spectrum antimicrobial agent, and is used in catheters that may remain in-situ for up to 4 weeks. There is a controlled release of triclosan from the solution in the balloon into the urine over time. The volume of solution needed depends on the type of catheter and balloon, but is normally between 5 ml and 10 ml. Farco-fill Protect is available as a single item or in packs of 10 and does not need refrigeration.

Innovations

Farco-fill Protect differs from catheter balloon solutions (often simply sterile water) in that it contains an antimicrobial agent, triclosan. This is designed to protect the outer surface of the catheter from bacterial colonisation and subsequent encrustation when in place over a long time.

Current NHS pathway

The NICE guideline on healthcare-associated infections recommends that indwelling urinary catheters should only be used after other methods of management have been considered, with patient need for catheterisation reviewed regularly. When there is a long-term need, the guideline recommends choosing a catheter based on the patient’s individual characteristics, and that catheter balloons should be inflated with 10 ml of sterile water in adults, and 3 ml to 5 ml in children. The risk of blockages, encrustations and catheter-associated infections should be minimised through patient-specific regimens, such as reviewing the frequency of planned catheter changes, increasing fluid intake and documenting catheter blockages. Bladder instillations or washouts should not be used to prevent catheter-associated infections. Prophylactic antibiotics should not be used routinely for catheter changes and only considered for patients who have a history of symptomatic urinary tract infection after catheter change, or who experience trauma during catheterisation. Using Farco-fill Protect would need minimal, if any, change in current clinical practice because it replaces sterile water, which is currently used to inflate Foley catheter balloons.

Long-term catheterisation (often defined as more than 28 days) is rarely free of complications. The most common complications are blockage and leakage; recurrent blockage occurs in 40% to 50% of
long-term catheters (Getliffe 2002). These complications can also occur in short-term catheterisation, especially in some patients with complex medical conditions. Biofilm formation on urinary bladder catheters from microbes such as *Proteus mirabilis*, *Escherichia coli* and *Klebsiella pneumoniae* are the main factors that contribute to encrustation, a common cause of catheter blockage.

**Population, setting and intended user**

Farco-fill Protect is intended for use in adults who need an indwelling Foley urinary catheter and have a history of their catheters becoming blocked because of encrustation. Farco-fill Protect could be used in primary, secondary or community care settings or in the home, and by clinicians trained in the appropriate catheterisation technique (usually specialist nurses or urologists). Healthcare professionals would not need any additional training to use Farco-fill Protect.

**Costs**

**Technology costs**

Each 10-ml syringe of Farco-fill Protect costs £4.80 (excluding VAT).

**Costs of standard care**

Given the diversity and complexity of the patient population using indwelling catheters there may be substantial variation in the associated costs. Furthermore, many clinicians prefer certain types of catheters based on clinical experience, patient assessment and materials that induce the least allergic response (Loveday 2014). Foley catheters available on the NHS supply chain range in price from around £0.30 to £21.42, depending on the technical specification, size and coating and associated consumables (NHS Supply Chain Catalogue, accessed September 2017). Many catheters come with a prefilled vial of sterile water.

**Resource consequences**

It is estimated there are around 450,000 people using long-term catheters in the UK (Prinjha 2013). Using Farco-fill Protect would increase initial costs compared with standard care (currently sterile water), but these may be offset if it were to reduce the incidence of catheter-related infection or other complications, or catheter change frequency. For patients with a history of catheter blockages, Farco-fill Protect may extend the wear time of the catheter and reduce the frequency of catheter changes and clinical interventions need to address blockages.
Regulatory information

Farco-fill Protect was CE marked as a class 1 sterile device in January 2014.

In 2016 the US Food and Drug Administration banned triclosan's use in soaps and hand washes because there was no evidence to show it was safe or effective for long-term daily use (FDA 2016). This ban does not apply to triclosan used in healthcare settings.

NICE is not aware of any CE-marked products which fulfil a similar function to Farco-fill Protect.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Farco-fill Protect is intended for use in adults only. Age is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 3 studies including a total of 142 patients. These comprise a case series (Holroyd 2017), a small prospective non-comparative study (Pannek and Vestweber 2011) and 1 randomised controlled trial (Sperling et al. 2014).

Table 1 summarises the clinical evidence as well as its strengths and limitations.
Overall assessment of the evidence

Published studies are limited in size, length of follow-up and measurement of clinically important outcomes.

More evidence is needed to determine the clinical effectiveness of Farco-fill Protect in terms of its reducing encrustation (and subsequently fewer catheter blockages, premature removals and complications). Ideally, this evidence would comprise sufficiently powered comparative studies with long follow-up, including patients with both suprapubic and urethral catheters.

Table 1 Summary of published evidence

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Holroyd (2017)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Study size, design and location</strong></td>
<td>3 patients (2 men and 1 woman; 1 with suprapubic and 2 with urethral indwelling catheters). Case series, UK.</td>
</tr>
<tr>
<td><strong>Intervention and comparator(s)</strong></td>
<td>Intervention was Farco-fill Protect (n=not stated). No comparator.</td>
</tr>
<tr>
<td><strong>Key outcomes</strong></td>
<td>Using Farco-fill Protect increased the length of time the catheter was able to stay in place from a few days up to 4 weeks. There was a reduction in the use and frequency of catheter maintenance solutions. All 3 patients reported less pain and discomfort during catheter changes.</td>
</tr>
<tr>
<td><strong>Strengths and limitations</strong></td>
<td>This was a non-comparative study with a small sample. The only outcomes were patient-reported experience.</td>
</tr>
<tr>
<td><strong>Pannek and Vestweber (2011)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Study size, design and location</strong></td>
<td>55 patients (46 men and 9 women; 67% with suprapubic and 33% transurethral catheters). Open-label prospective before-and-after study, 3 centres in Germany and Switzerland.</td>
</tr>
<tr>
<td><strong>Intervention and comparator(s)</strong></td>
<td>Intervention was Farco-fill Protect (n=not stated). No comparator.</td>
</tr>
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</table>
### Key outcomes

On average patients were followed-up for 41 days and catheters changed every 6 weeks, but it is unclear what effect Farco-fill Protect had on the patency of the catheters and how long they could remain in place. The incidence of high levels of bacteria in the urine (>105 bacteria/ml) fell from 71% to 46% with the introduction of Farco-fill Protect, and the proportion of patients with the presence of *Proteus mirabilis* decreased from 3.6% to 1.8%. However, there was an increase in the proportion of patients with the presence of *E. coli* (26% to 31%) and enterococci (3% to 15%). Visual assessment of catheter encrustation found that the proportion of patients with no catheter encrustation increased from 0% to 9%. The proportion of patients with minor encrustation increased from 66% to 73%, and the proportion of patients with moderate encrustation decreased from 27% to 22%.

### Strengths and limitations

The study included patients with both suprapubic and urethral catheters. However, it was non-randomised and had short follow-up. Moreover, the authors either consult or work for company.

### Sperling et al. (2014)

**Study size, design and location**

84 patients (58 men and 26 women; all with suprapubic catheters). Randomised, double-blind, multicentre, placebo-controlled study, Germany.

**Intervention and comparator(s)**

Intervention was Farco-fill Protect (n=43).
Comparator was placebo (n=41).

**Key outcomes**

Patients in the Farco-fill Protect arm had fewer premature catheter removals than patients in the placebo group (32% versus 11%). The groups did not differ in urinary diagnostics, pain when changing catheters, need for antibiotic therapy or level of encrustation.

**Strengths and limitations**

This was a randomised, double-blind study with patient-reported outcomes. It was stopped early because of logistical difficulties, and did not recruit enough patients to be properly powered. The study was funded by the company and the lead author is a company adviser. It is unclear how long patients were followed-up for or how long catheters remained patent in either group.
Recent and ongoing studies

No ongoing or in-development trials for Farco-fill Protect were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE’s view.

Three specialist commentator responses were received. One expert was familiar with and had used Farco-fill Protect as part of a case series.

Level of innovation

One commentator reported that Farco-fill Protect is the only product of its type. They considered it to be a relatively new product, having only been introduced to the NHS in November 2016.

One commentator thought that Farco-fill Protect is only a minor variation on what is currently available for patient use. Two commentators noted that silver-coated catheters are available that claim to reduce biofilm formation, but 1 noted that Farco-fill Protect differed in that it uses a special solution with a standard catheter.

Potential patient impact

The commentators identified various potential benefits, such as improved comfort and reduction in pain. Other benefits may include increased wear time of catheters and fewer catheter changes. One commentator noted that this would reduce the amount of contact with NHS staff and increase patient confidence in effectively managing bladder drainage. Improved quality of life and less patient distress were also cited as potential patient benefits. However, 1 specialist commentator noted that there has not yet been an adequate assessment of whether Farco-fill Protect decreases the number of catheter-associated urinary tract infections. All 3 commentators thought that the technology would be of most benefit to patients in community care or at home, who have complex health needs and need long-term catheterisation.
**Potential system impact**

All 3 commentators highlighted that using Farco-fill Protect could lead to less time spent on managing problematic catheters. This in turn would reduce demands on community nursing staff, through fewer catheter changes and visits to the emergency department for blockages. Two commentators felt that Farco-fill Protect had the potential to reduce costs; 1 considered that using for every catheter insertion could increase costs but these may be offset if its use reduced catheter-associated urinary tract infections. The commentator reiterated that there is currently no evidence for this. One commentator noted that there is potential for lower consumable costs with Farco-fill Protect, from less frequent catheter changes. None of the commentators indicated the need for any changes to facilities or infrastructure or any training to use Farco-fill Protect.

One commentator felt that there would be no resource impact from using Farco-fill Protect.

**General comments**

The specialist commentators noted that people with complex health conditions who need long-term catheterisation (urethral and suprapubic) would particularly benefit. One commentator stated that they had used Farco-fill Protect for 15 to 20 patients over 18 months and had not seen any adverse reactions. The commentator stated that they continue to recommend its use now that it is available on the NHS formulary. They noted that there are anecdotal patient reports of a cumulative improvement in clinical symptoms each time Farco-fill Protect was used.

Two commentators highlighted that the evidence on how catheter coatings affect infection and encrustation. One noted that catheter-associated urinary tract infection was a more clinically relevant measure than levels of bacteria in the urine. They added that a Cochrane review published in 2012 did not show a statistically significant advantage for antimicrobial-impregnated catheters. The review did not include catheters injected with Farco-fill Protect.

Two commentators reported that Farco-fill Protect would potentially be suitable for all patients needing long-term catheterisation, but ideally a cost–benefit analysis should be done. One felt that making people aware of Farco-fill Protect's proper use would be important. The commentators disagreed in terms of Farco-fill Protect's relationship to current practice: 2 commentators thought it could be used in addition to standard care (sterile water), whereas 1 felt it could replace standard care entirely. No issues with usability or practical aspects of Farco-fill Protect were highlighted; 1 commentator indicated that it was already being used in some NHS trusts and that data were being collected.
In terms of future research to address uncertainties, all commentators thought that a larger scale randomised controlled trial with follow-up of 1 to 6 months is needed, which should measure catheter-associated urinary tract infections and patient safety as outcomes.

Specialist commentators

The following clinicians contributed to this briefing:

- Ms Sharon Holroyd, lead continence nurse specialist, Calderdale and Huddersfield NHS Foundation Trust. Ms Holroyd received a payment of £150 from the Journal of Community Nursing for publishing case studies on the use of Farco-fill Protect.
- Mr Deepak Batura, consultant urologist, London North West Healthcare NHS Trust. No relevant conflicts of interest.
- Miss Vivienne Kirchin, consultant urologist, Sunderland Royal Hospital. No relevant conflicts of interest.

Development of this briefing

This briefing was developed by the NICE medical technology evaluation programme team. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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