NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Evidence review

Bardex IC Foley catheter

CEP 06001

Verdict

- RECOMMENDED
- SIGNIFICANT POTENTIAL
- EVIDENCE INCONCLUSIVE
- NOT RECOMMENDED

Informing procurement – Encouraging innovation

Contents

Summary

The product

Bardex IC silver alloy coated hydrogel Foley catheter manufactured by Bard Medical US.

Field of use

Catheter associated urinary tract infections (CAUTIs) are the most common type of hospital acquired infection (HAI) and account for up to 40% of all HAI. Normally the urinary tract is sterile but catheters disturb the body's natural defences and bacteria can be introduced either intraluminally (along the bore of the catheter) or extraluminally (along the outer wall of the catheter).

There have been many initiatives to reduce this burden of infection, the most promising of which is the use of anti-infective catheters. This review concentrates on studies of one type, the Bardex IC silver alloy coated hydrogel Foley catheter manufactured by Bard.

Evidence reviewed

We reviewed the clinical and economic evidence on use of the Bardex IC catheter. Most studies indicated a reduction in the rate of CAUTI following introduction of the Bardex IC. However, the majority suffered from significant limitations, such as low patient numbers, use of historical baseline data, and absence of controls. In addition, there was no standard definition of CAUTI which could lead to the data being misinterpreted.

CEP's verdict – significant potential

Because of the way the studies were conducted, no firm conclusions can be drawn on the clinical and cost effectiveness of the product.

There is no evidence to suggest that there is any clinical disadvantage associated with the use of the Bardex IC catheter. There is however a significant body of evidence, including that available from early adopters in the NHS, which indicates that the product might be effective in reducing CAUTI in short-term catheterised patients.

CEP recommends that an independent randomised controlled study, including an economic evaluation, should be undertaken to fully assess the effectiveness of the Bardex IC catheter based on the rate of CAUTI. CEP also recommends that a standard definition of CAUTI should be agreed and used for all future studies.

Introduction

General information

Catheter-associated urinary tract infection (CAUTI) places a huge burden on healthcare providers. Exact figures vary with some authors claiming that up to 40% of all hospital acquired infections (HAIs) are due to CAUTI (1, 2, 3). However, Lai and Fontecchio (4) state that urinary tract infections are responsible for 40% of HAI with 80% of these being catheter associated infections. Other authors state that UTI accounts for 20% of all hospital acquired infections (5).

Routes and type of infection

Normally the urinary tract is sterile, closed and has natural defences against bacterial infection (6). Natural defences include epithelial cells that resist bacterial adherence in the urethra as well as the flushing mechanisms provided by the process of urination (5). Catheterisation can disturb or bypass the normal defence mechanisms in the urinary tract (7). Microorganisms can be introduced into the bladder and urinary tract at the time of catheter insertion either from the patients' commensal bacteria or from the healthcare worker inserting the catheter (5). In addition, microorganisms can enter the urinary tract when the catheter is *in situ* by either extraluminal or intraluminal routes. The most common route of infection is extraluminal, where the bacteria enter the urinary tract by migrating along the external surface of the catheter, usually from the perineum (1, 8). Intraluminal colonisation is caused by bacteria migrating along the internal surface of the catheter, usually from access to urine in the collecting bag when the tap is opened and subsequent migration within the collecting system and catheter to reach the bladder (1, 8).

Once the bacteria have entered the urinary tract they can colonise the area, cause infection, or remain as free floating planktonic bacteria without causing infection (6). In addition, bacteria can enter the urinary tract and form biofilms on the surface of the catheter (7, 9). Biofilms are the main source of pathogenic bacteria as they tend to be resistant to shear forces, phagocytosis and antimicrobial agents (10). There is also evidence that urease producing organisms, such as *Proteus mirabilis*, colonise catheters and release urease which triggers a complex cascade of biochemical changes (6). This can result in the precipitation of mineral deposits including crystalline magnesium ammonium phosphate and amorphous calcium phosphates that can eventually block the catheter (11).

Catheterisation issues

Catheterisation is a commonly used medical procedure which is, nevertheless, associated with a number of risks. It has been linked to increased risk of surgical site infection, an increased rate of infective complications (such as prostatitis, orchitis, epididymitis and perinephric, vesicular and urethral abscesses) and other complications such as trauma to the bladder, stricture formation, bladder calculi, encrustation, urethral perforation and neoplastic changes (6).

Catheters colonised with bacteria can also lead to further complications. CAUTI is quoted as the second most common cause of bacteraemia (1).

Figures for patients with catheter associated bacteriuria or CAUTI that develop a secondary bloodstream infections vary greatly. Johnson *et al* state that secondary bloodstream infections occur in fewer than the traditionally quoted 1 to 5% of patients with catheter associated bacteriuria (2). However, it is acknowledged that most bloodstream infections are caused by gram negative bacilli which have most likely originated in the catheter. Gentry and Cope (12) have cited that 8.5% of bacteraemia cases are attributable to catheter associated UTIs (12).

CAUTI also poses a significant financial burden to the healthcare system. Hospital acquired urinary tract infections are estimated to cost the UK National Health Service £124 million a year (3). With an estimated 80% of hospital acquired UTIs associated with an indwelling catheter, the cost of CAUTI to the NHS could be as much as £99 million per year (3), at an estimated cost per CAUTI episode of £1327 (13) mostly due to the increased time spent in inpatient care.

Risk factors

There are several well documented risk factors for CAUTI. These include malnutrition (1), an underlying chronic condition such as diabetes (1, 6), bacterial infection at other sites (1, 6), placement of the drainage tube above the level of the bladder, old age, lack of systemic antibiotics and poor catheter care (1,8, 6). However, the two main risk factors for the development of CAUTI are female gender and prolonged catheterisation (for longer than 6 days) which results in universal colonisation by day 30 and an obvious increase in the CAUTI rate (1, 8, 6).

Measures to reduce infection

There have been several methods used to reduce the rate of catheterisation and thereby the levels of CAUTI. These are summarised in the table below.

Table 1. Methods to reduce CAUTI

Initiative	Efficacy	Reference
Antiseptic in collection bag	No effect	1
Anti-infective irrigation of bladder	No benefit shown. An increase in organisms resistant to the anti-infective used has been observed	1
Anti infective lubricants at insertion	No effect	1
Anti reflux valves	No effect	7
Antiseptic / anti-infective / medicated coated catheters	Reduction shown by reducing adherence to catheter walls	1, 7, 14
Silver alloy coated catheters	Reduction shown	1, 4, 7
Antiseptic ointment around meatus	No effect	8
Sealed catheter tube junctions	Could be beneficial	8
Antibiotic prophylaxis	Should be avoided due to fears over the increase in antibiotic resistance	8
Silver oxide coated catheters*	Initially promising and showed reduction	1, 3
Correct catheter maintenance	No data	2

*Notes: * Withdrawn from sale after disappointing results in large scale study.*

Of all the methods discussed in the literature to reduce CAUTI, the most promising and studied has been silver alloy coated catheters. This review examines studies of one type of silver alloy coated catheters, the Bardex IC Foley catheter manufactured by CR Bard, New Jersey, USA.

Anti-infective catheters

Bacteria have been shown to colonise catheters and form biofilms on the surface of the catheter. Such biofilms have reduced susceptibility to antibiotics, and the prevention of biofilm formation is thus an important factor in the reduction of CAUTI.

There have been many initiatives to produce anti-infective catheters. These have been developed by coating the catheter surface with substances that prevent colonisation. The coatings used include hydrophilic substances, antibiotics, silver oxide and silver alloy. In addition, there are catheters coated or impregnated with antibiotics, although these are restricted in use. This is due to, as with all antibiotic use, an increased risk of antibiotic resistance, although this risk is currently theoretical. Silver oxide catheters have been withdrawn due to lack of reduction in the rate of CAUTI (1, 3).

The Bardex IC Foley catheter is coated with silver alloy and hydrogel, both of which appear to inhibit bacterial colonisation.

Silver has a broad spectrum activity against Gram negative and Gram positive organisms. Silver alloy-coated catheters, such as the Bardex IC, have been claimed to reduce biofilm formation by reducing bacterial adherence (15), although the evidence to support this claim is weak (16).

It is has also been claimed that the Bardex IC reduces colonisation by releasing silver ions into the urinary tract and catheter system (3). It should be noted that methods employed for the collection of clinical urine samples from catheterised patients often involve temporary clamping of the catheter, producing a column of urine within the lumen. In the case of a silver coated catheter, this might give rise to an increased concentration of silver ions in the clinical sample, inhibiting subsequent culture in the laboratory and therefore giving a misleading picture of the rate of colonisation (16).

Studies into the efficacy and cost-effectiveness of the Bardex IC Foley Catheter were researched using PubMed (www.ncbi.nlm.nih.gov./entrez/query.fcgi), www.highwire.org and NHS Economic Evaluation Database. Keywords such as ‘urinary catheters’, ‘silver coated catheters’, ‘Bard catheters’ and ‘Bardex catheters’ were used. In addition, only papers published since 1990 were included. The findings from the research are summarised below (Table 2).

Studies in this review were limited to papers covering the silver alloy coated catheters and, if possible, only to catheters manufactured by CR Bard. However, for completeness, several studies were included that appear to evaluate the same type of catheter as the Bardex IC Foley catheter but no details of manufacturer were included in the review. These are summarised separately (Table 3).

Studies in the economic literature review were limited to full economic evaluations, comparing two or more catheterisation options and considered both the costs and consequences of the interventions. The studies not included in the clinical evidence tables (Tables 2 and 3) are summarised in Table 4.

Review of the quality of published studies

In addition to published clinical studies, several papers review the quality of the studies and evaluate the published evidence that is supposed to support the use of silver coated catheters. Niël-Weisse *et al* (17) state they found fundamental problems with the studies reviewed and concluded that there was insufficient evidence to recommend the use of silver alloy catheters (17).

Brosnahan *et al* (18), in the *Cochrane Database of Systemic Reviews* conclude that results indicate a significantly reduced rate of bacteriuria when using silver coated catheters, however the methods used in the studies were flawed. The authors state that the methods of randomisation and blinding were unclear, different types of silver alloy coatings were used and that published trials are of poor quality and the evidence is not strong enough to support the use of silver alloy coated catheters (18).

Trautner *et al* (19) reviewed studies that were published within the period of a year. This paper reviewed studies on the pathogenesis of CAUTI, biofilm development and infection control measures. The authors of this paper state that using bacteriuria as a measure of infection is flawed and argue that for robust conclusions to be drawn about the efficacy of silver coated catheters a distinction has to be made between UTI and asymptomatic bacteriuria. In addition, this paper expresses concern that most authors of papers reviewed are extrapolating data from short term catheterisation and assume that the same can be applied to long term catheterisation (19).

Published studies are summarised in tables 2-4.

Limitations of studies reviewed

Although most studies show a reduction in the rate of CAUTI during the trial period, they do not have sufficient power to state definitively that Bardex IC Foley catheter reduces the rate of infection.

Most studies included only a very small population size, for example Verleyen *et al* (20) included thirty five males in their initial study. This study not only has a small population but also does not include patients that are at the greatest risk of infection, *ie* females. Although this study showed a reduced CAUTI rate, the patient group used was not sufficiently robust.

Another limitation is the lack of a suitable control. Nearly all studies use historical data as a 'control' which involves taking a baseline rate of CAUTI over a finite period. After this, the trial catheter is introduced and the rate of CAUTI reduction determined by comparison to the baseline rate. This was the most common method employed in the studies reviewed. This is not an ideal as natural fluctuations in the infection rate may have an effect on the apparent reduction in the rate of CAUTI.

Most studies reviewed did not give a definition of the criteria used to define 'catheter associated urinary tract infection'. This is a major limitation as it is sometimes unclear if they are investigating colonisation of the catheter or actual infection. Also it is not always clear what defines infection when associated with catheter use. Some papers do not always make it clear whether the study was looking at colonisation or CAUTI rates. This could lead to greater effect being observed than is real or a misleading dataset. Few of the studies declared which definition of 'CAUTI' they used. A robust, clinically workable definition must be devised to be certain of the effect of any intervention that is used to reduce the level of bacteriuria in catheterised patients.

Few studies were randomised; this is essential to ensure all patient groups and risk factors are covered. For example, if the control group has more female patients (the greatest risk factor for developing a CAUTI), and the trial catheter study has less females, then this could skew the infection rate and give a false impression of trial catheter's efficacy.

Some studies provided extrapolated data to demonstrate that there is a benefit of using silver coated catheters when undergoing long term catheterisation. Authors have stated that if a benefit is shown during short term catheterisation, then the same effect will be seen during long term catheterisation. There is currently no evidence to support this (21).

Finally, CR Bard funded some studies and/or was closely involved in the actual data collection. This could represent a conflict of interest and raise doubts about the robustness and independence of the trial.

Table 2. Summary of studies published

Ref.	Methods	Claims/Results	Study limitations	Notes
Lai and Fontecchio, 2002 (4)	Measured baseline rates in Jan 1996, introduced SCC in Oct 1996, re-measured baseline rate in Jan 1997. Measured in patient days	• 45% reduction in CAUTI (from 4.9 CAUTI/1000 patient days). • Also calculated to have 216 less CAUTI per year. • A CAUTI was estimated to cost $1,214 per episode • Estimated overall cost saving of $142,000 per year.	1. Not randomised, blinded controlled. 2. CAUTI rate after introduction of silver coated catheter is compared to historical data. 3. Used hospital days and not device days so reduction may not be truly attributable to catheter. 4. No demographic data or risk factors collected. 5. Personnel involved were not aware of the study 6. Two months data was used and extrapolated to cover year.	Recommend a large scale, double blind, placebo controlled study in all healthcare settings.
Gentry and Cope, 2005 (12)	Measured baseline catheterisation and CAUTI rate, introduced Bardex IC Foley catheter and re-measured baseline CAUTI rate.	• CAUTI rate reduced from 7.7% to 5.1% after introduction of Bardex IC Foley catheter (represents a 33.5% drop) • Study saved £2,654	1. Only a small scale study with a large scale study planned. 2. Only 4 CAUTI were observed in each period. 3. No statistical analysis done to determine if rates were statistically significant.	Definition of CAUTI used was 10,000 bacteria per mL of urine and one or more loin pain or suprapubic tenderness. pyuria (10,000 white blood cells/mL) and fever. Incorrect baseline rate reported (should be 7.3%)
Thomas *et al* (Reviewed in Davenport and Keeley. 2004[3])	Compared infection rate between patients using standard catheters and silver alloy coated catheters on general medical/surgical wards.	• Reduced risk of CAUTI from 32 to 20.4 CAUTI's per 1000 catheterised patients. • Reported a 33% reduction in secondary bacteraemia. • Reported a 42% lower incidence of multi-drug resistant organisms.	None given.	
Newton *et al*, 2002 (22)	Study was based on John M. Still Burn Centre, Doctors Hospital, Augusta, Georgia. Measured base rate from January 1998 to November 1999 where patients were admitted with latex catheters and CAUTI rate was determined. From Dec 2000 unit replaced latex with silver alloy coated catheters exclusively.	• Rate of UTI reduced from 7.2 per 1000 catheter days to 4.4 per 1000 catheter days. • Decreased hospital stay observed. • Decreased use of antibiotics observed.	Baseline rate not ideal as 17% of these patients had silver alloy coated catheters in place.	Definition of UTI was as established by the NNIS system of the Centre for Disease Control and Prevention.

Table 2. Summary of studies published contd.

Ref.	Methods	Claims/Results	Study limitations	Notes
Verleyan *et al*, 1999A (20)	Initial prospective and randomised study performed on patients undergoing radical prostatectomy. Patients received either Bardex IC Catheter (18 patients) or silicon catheter (17 patients).	• No significant difference in bacteriuria after 14 days catheterisation (50% of patients had bacteriuria with Bardex IC catheter vs 53.3% silicon catheter).	Only used small sample size and only included males in study. No data on fever or other symptoms of infection taken therefore data cannot be used to assess reduction in CAUTI.	Defined bacteriuria as 10^5 CFU/ mL
Verleyan *et al*, 1999B (20)	Second part of prospective and randomised study investigated 101 patients with latex catheter and 79 patients with Bardex IC catheter. Patients were randomised to receive either Bardex IC or latex catheter.	• Observed significantly delayed bacteriuria in patients with silver alloy coated catheter. • 35.4% of patients with silver alloy coated catheter were colonised whereas 59.4% of standard latex catheter were colonised. • By day five, 6.3% with Bardex IC catheter had bacteriuria compared with 11.9% with latex catheter. • If bacteriuria was observed, there was no significant difference between the relative amounts of microbial flora between the Bardex IC and latex catheter	Small sample size	Defined bacteriuria as 10^5 CFU/ mL
Bologna *et al*, 1999 (23)	Five hospitals took part in a blind prospective study. A baseline rate was taken prior to introduction of Bardex IC Foley catheter.	• Overall the unadjusted CAUTI rate reduced from 7.1 infections per 1000 patient days to 4.5 infections per 1000 patient days after introducing the Bardex Foley catheter. • Individually, only one of the five institutions in the study showed a statistically significant reduction. • Cost analysis at one hospital shows an average cost per UTI of $2471. The use of the Bardex IC foley catheter was estimated to reduce infection rate by 41 infections per year, this saving $98,021.	Authors state that a longer duration, randomised, double-blind, prospective controlled study is required for further statistical significance.	
Rupp *et al*, 2004 (24)	This was a two year prospective surveillance study in 10 patient care units. The Bardex IC catheter was introduced solely into the units and it's efficacy determined by comparing historical rates of UTI with rates during the period the Bardex IC catheter was in place.	• In 1999 there were 5.51 CAUTI per 1000 catheter days. In 2000 there were 5.40 CAUTI per 1000 catheter days. This decreased to 2.16 and 2.65 CAUTI per 1000 catheter days in 2001 and 2002 respectively. • Difference between 1999 and 2001/2002 was statistically significant. • Cost saving estimates range from $13,469 to $535,452 in 2001 and $5,811 to $484,070 in 2002 depending on cost model used to analyse data.	1. Study is retrospective. 2. No data on patient groups given.	Examines levels of resistance to silver, with all microorganisms tested remaining susceptible to silver. Implies a prospective, randomised, controlled trial is needed.
Seymour 2006 (25)	Baseline audit taken, then all standard catheters removed from wards and replaced with Bardex IC Foley catheter. Study based in an audit format.	• Highlighted use of many different catheter types which may not be needed and this could reduce costs. • Calculated to have cost avoidance of £9140. • Intervention of Bardex IC foley catheter saved 16.4 bed days.	1. Small specimen number which meant there was no statistical analysis performed. 2. Some CAUTIs may have been missed due to some symptoms not being documented.	This small scale study results in recommendation that the Bardex IC foley catheter is catheter of choice in their trust. Study also observed a higher than normal risk rate

Table 3. Summary of studies published with unknown manufacturer

Ref.	Methods	Claims/Results	Study limitations	Notes
Liedberg and Lundeberg 1990 (26)	Randomised study of 120 patients. A silver alloy coated catheter (60 subjects) was compared to a control of a Teflonised latex catheter (60 subjects).	• Statistically significant difference in incidence of catheter associated bacteriuria after 6 days catheterisation (6 patients with silver alloy coated catheter had bacteriuria compared to 22 in control group).	Small sample size. Study subjects were predominantly male.	
Liedberg *et al*, 1990 (27)	Randomised study of 90 patients. Three types of catheter were compared (30 subjects in each group), a silver alloy and hydrogel coated catheter and a hydrogel coated catheter.	• Significant difference in rate of bacteriuria between catheter coated with silver alloy and hydrogel and the non coated catheter (3 vs 15 patients with bacteriuria). • No significant difference in the rate of bacteriuria between silver alloy hydrogel catheter and standard hydrogel catheter. • No significant difference in the rate of bacteriuria between hydrogel and standard catheter. • Reduced rate of bacteriuria in subjects with silver alloy hydrogel coated catheter when compared to standard catheter after 5 days of catheterisation.	Small sample size. Study subjects were predominantly male.	
Thibon *et al*, 2000 (28)	Compared silicone Foley catheters to catheters coated with hydrogel and silver salts. Tested 199 patients (109 with silicone and 90 with coated catheter). Study was randomised, double-blind multi centre study	• 13 urinary tract infections were identified in patients with the silicone catheter and 9 in the patients with the coated catheter. • No significant differences observed between the two groups.	Possibly sample size was too small	This study used the same catheter as the two studies summarised above.

Table 4. Summary of economic studies published

Ref.	Methods	Claims/Results	Study limitations	Notes
Saint *et al* 2000 (29)	Decision-analytic model used to compare silver alloy coated catheters to standard non-coated urinary catheters, from a health care payer's perspective. Analysis is in the form of a cost-consequences analysis. Effectiveness measured as incidence of symptomatic UTI and costs included were catheter, urinalysis, urine and blood cultures, hospital care and antibiotic treatment	• 47% reduction in symptomatic UTI (from 30 to 16 cases/1000 patients). • 44% reduction in bacteremia (from 4.5 to 2.5 cases/1000 patients). • Average cost per case using silver coated catheter was $16.78 and $20.87 for the standard catheter, resulting in an estimated cost saving of $4.09 per case.	1. US based resource use. 2. Generalisability of results. 3. The model is based on 2-10 day hospitalised catheterisation. Cost savings may not result from shorter or longer term catheterisation.	NB. Cost-consequences analysis is a form of economic evaluation where output measures are presented alongside costs. Unknown manufacturer.
Plowman *et al*, 2001 (30)	Decision-analytic model used to compare silver alloy coated catheters to standard non-coated urinary catheters. Cost-benefit analysis (form of economic evaluation where consequences are valued in monetary terms, alongside costs)	• 17376 medical and 48784 surgical patients acquire a catheter related nosocomial related UTI (NUTI) resulting in additional 62553 bed days valued at £15 million for medical patients and 175621 bed days. • Silver alloy coated catheters reduced incidence of NUTI in medical and surgical catheterised patients. • Estimated additional cost of a silver coated catheter was £9. Based on the model, the estimated annual cost of routine use on all medical and surgical wards would cost £2,132,509 and £5,987,165 respectively. • 14.6% reduction in the incidence of UTI in medical patients and 11.4% reduction in surgical patients would cover the additional costs.	Validity of the model is dependent on the accuracy of the model structure and parameters, and quality of the data sources. This is partly addressed in the sensitivity analysis.	Study funded by PrevNiTech Ltd.
Karchmer *et al*, 2000 (31)	12 month randomised crossover trial comparing silver-coated and uncoated catheters, presented as a cost-consequences analysis. Effectiveness measured using rate of CAUTI. Total cost was based on the cost of catheterisation and related infection. A lower and higher estimate was presented	• Relative risk (RR) of CAUTI with silver coated catheters compared to uncoated was 0.68 per 100 catheters (95% CI, 0.54 – 0.86, P-value=0.001). • • RR or CAUTI with silver coated catheters compared to uncoated in intensive care units was 0.94 per 100 catheters (95% CI, 0.64 – 1.38, P-value=0.001). • Use of silver-coated catheters resulted in a catheter-related annual cost saving of between $14456 and $573293 depending on cost estimates used. • Cost savings were associated with reduction in cost of infections.	1. US based study. 2. Costs were not broken down beyond catheter and infection related costs so specific resource use associated with catheter use was not presented. 3. Catheter randomisation was used as unit of randomisation rather than individual patients, therefore bias due to patients moving between wards. 4. Does not distinguish between UTI and asymptomatic bacteriuria. 5. Although the study was run by randomising units, the data was analysed as if the patients were randomised.	All catheters manufactured by CR Bard Possible conflict of interest as study part funded by CR Bard CDC definitions used.

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