NICE advice

SecurAcath for securing cerebrospinal fluid catheters

Medtech innovation briefing
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This advice should be read in conjunction with HTG440.

Summary

- The **technology** and indication described in this briefing is SecurAcath for securing cerebrospinal fluid drainage catheters. The device uses a small metal 'anchor' that sits below the skin and holds the catheter in place.
- The **innovative aspect** is that this is the only securement device available for cerebrospinal fluid catheters that aims to reduce the risk of accidental dislocation or removal of the catheter.
- The intended **place in therapy** would be as an alternative to current methods of securing cerebrospinal fluid catheters.
- The **main points from the evidence** summarised in this briefing are from 1 prospective observational study including a total of 29 children in secondary care. No complications relating to SecurAcath were reported.

- **Key uncertainties** are that the evidence is limited to 1 non-comparative study, which only examined the use of SecurAcath in children.
- The **cost** of SecurAcath is £200 for a box of 10 devices (excluding VAT), and the cost of standard care will vary depending on the alternative method of securement used. There is no published evidence on the resource consequences of adopting SecurAcath.
- NICE has also produced medical technologies guidance on this device for a different indication, SecurAcath for securing percutaneous catheters.

The technology

SecurAcath (Interrad Medical) is a securement device that uses an anchor below the skin to hold cerebrospinal fluid (CSF) drainage catheters in place. It comprises a base and a cover: the base contains 2 metal, blunt, flexible securement feet (which form the anchor) and 2 foldable arms; the cover holds the catheter shaft in place. The anchor sits just beneath the skin at the catheter insertion site. A YouTube video produced by the manufacturer illustrates the device's mechanism of action and mode of use.

SecurAcath is designed to remain in place for as long as the catheter needs to be secured, and does not need replacing. It is removed at the same time as the catheter by removing the cover from the anchor base, then removing the catheter. The anchor base can then either be cut lengthways and each half removed separately, or the base can be folded and the anchors removed. Local anaesthesia may be used before removal to reduce pain.

There are 6 versions of SecurAcath, used with 3, 4, 5, 6, 7 and 8 French (Fr) size (the unit of measurement for the outer diameter of a catheter) catheters. All sizes have the same functionality and the anchor base and anchor sizes are the same; only the channel diameter changes. Typically, catheters used for CSF drainage are 6 or 8 Fr.

SecurAcath can also be used to secure catheters for other purposes, such as for venous access. These indications are beyond the scope of this briefing.

Innovations

SecurAcath is designed to reduce the risk of accidentally moving the catheter. Accidental dislocation or removal of external CSF drainage may need emergency surgery to replace

the catheter.

SecurAcath can be lifted away to clean around the insertion site without detaching the catheter, which may allow for easier cleaning compared with adhesive securement devices.

Current NHS pathway

CSF drainage is done to treat hydrocephalus. Congenital and acquired hydrocephalus need prompt treatment to reduce pressure on the brain and avoid brain damage.

To diagnose hydrocephalus a lumbar puncture is done. This is where a sample of CSF is taken from the lower part of the spine and the pressure of the CSF sample is then checked. Removing some CSF in this way may also help improve symptoms. A spinal or lumbar drain may be done if a puncture does not improve the symptoms of hydrocephalus. This is carried out over a few days to see whether symptoms improve. The procedure is usually done using a local anaesthetic.

Longer-term treatments for hydrocephalus are shunt surgery or endoscopic third ventriculostomy (NHS Choices 2015). Alternatively, external ventricular drainage (EVD) can be used to temporarily drain CSF out of the body, away from the ventricles of the brain.

EVD allows the temporary drainage of CSF to relieve raised intracranial brain pressure. In this procedure a catheter is placed in the ventricle of the brain and connected to an external drainage system. Once the system is in place, the catheter can be secured with a suture or staple, or with adhesive devices, depending on local clinical practice. EVDs can stay in place for up to 3 weeks, but around 1 week is most common. SecurAcath provides an alternative method to secure the catheter for this drainage system.

Population, setting and intended user

SecurAcath would be used in secondary care settings in place of current securement methods for CSF drainage catheters. It can be used in people of all ages but is not suitable for people with an allergy to nickel.

Clinicians must be trained in placing and removing SecurAcath, as well as maintenance of the insertion site.

Costs

Technology costs

According to the manufacturer, the device can be purchased in boxes of 10 at a list price of £200, which amounts to £20 per device. The manufacturer provides training at no additional cost. SecurAcath devices cannot be reused, so the per-treatment (device only) cost amounts to £20 irrespective of how long the catheter remains in place (the dwell time).

Costs of standard care

Standard care can include sutures, staples and adhesive devices. The manufacturer has estimated, based on a US study of peripherally inserted central catheters (PICCs), that the equipment-only cost for applying sutures is £5, inclusive of suture, needle and removal kit (Interrad Medical et al. 2015). A review of studies comparing sutures with staples for treating cuts gives a range of equipment costs for stapling that are very similar to the equipment cost for suturing (Hogg and Carley et al. 2002). Surgery to insert the catheters to begin CSF drainage is done in a theatre setting and labour costs will depend on the professional that is involved.

Resource consequences

SecurAcath would be an additional cost compared with current securement methods, assuming that maintenance times and labour costs are similar. SecurAcath may be cost saving for longer dwell times because adhesive devices often need to be replaced, whereas 1 SecurAcath device is suitable for the entire dwell time.

According to the manufacturer, 23 NHS trusts currently use SecurAcath for a range of indications. The manufacturer is not aware of any NHS trusts currently using SecurAcath for CSF drainage catheters. No practical difficulties have been identified in using or adopting SecurAcath.

No published evidence on the resource consequences of adopting SecurAcath were identified. There may be differences in long-term resource use and costs between SecurAcath and standard care if its use were shown to result in differences in complication rates such as dislocation or infection.

Regulatory information

SecurAcath was originally CE marked as a class IIb device in 2010. The CE marking was renewed in 2015.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

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).

SecurAcath is not suitable for people with an allergy to nickel. It is contraindicated for people whose skin integrity is deemed unfavourable by the operator, for example because of chronic corticosteroid use, presence of cellulitis, or rashes at the prospective insertion site. People who have past irradiation of the site or the presence of known or suspected device-related infection, bacteraemia, or septicaemia are also contraindicated. SecurAcath may benefit people who are allergic to adhesives that may be used in the standard of care.

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 1 non-comparative study including 29 children.

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

Overall assessment of the evidence

The evidence on SecurAcath for CSF drainage was limited to 1 prospective study (Frassanito et al. 2016).

In order to improve the evidence base, additional studies including a comparative study of SecurAcath and alternative CSF drainage methods would be useful. This could include data on complication rates related to use of the device as well as catheter-related complications (such as dislocation) for SecurAcath compared with sutures, staples or adhesive securement devices. Studies investigating the use of SecurAcath should be adequately powered to identify differences in the effectiveness outcomes. Ideally, future studies of the device and its comparators would be in the form of randomised controlled trials in the NHS.

Table 1 Summary of the evidence

Frassanito et al. (2016)	
Study size, design and location	29 children (age 3 weeks to 16 years), prospective study, Italy
Intervention and comparator(s)	SecurAcath only; used to secure 25 ventricular catheters (1 patient had 2 catheters in the same procedure for bilateral brain abscess) and 5 lumbar drainages.
Key outcomes	Dwell time ranged from 1 to 4 weeks (median 22 days). No complications related to the use of the device were observed. There were no cases of dislocation, accidental removal, kinking or tearing of the catheter, skin erosion, or infection.
Strengths and limitations	Small sample size (power calculation was not provided) and there was no randomised comparator in the study.

Recent and ongoing studies

No ongoing or in-development trials 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.

One out of 3 of the specialist commentators was familiar with SecurAcath, but none had used it before.

Level of innovation

Two specialist commentators considered SecurAcath to be somewhat innovative, whereas the third commentator thought it to be a novel concept in the context of ventricular drainage. One of the commentators noted that a better estimate of the frequency of catheter displacement for CSF drainage would be useful in contextualising whether SecurAcath addresses an unmet need.

Potential patient impact

All 3 specialist commentators stated that the device has the potential to improve patient experience if it prevents dislodgement and reduces the frequency of catheter revision or replacement. The commentators also agreed that it has the potential to reduce infection risk and rates. One specialist said that SecurAcath could also reduce pain and distress, and avoid prolonged hospital stays.

Potential system impact

All 3 specialist commentators were of the opinion that user training would be necessary for SecurAcath. One explained that the additional cost of SecurAcath is considerable, and the other 2 noted that few patients ultimately need external drainage. One commentator noted that it is unclear how there would be repeat costs for adhesive securement devices in patients in whom SecurAcath was not used who have external ventricular drainage or a

lumbar drain.

One specialist stated that there is insufficient evidence to suggest that using SecurAcath would have an impact on the small number of patients having catheter placement to treat hydrocephalus. Two specialists stated that SecurAcath could be beneficial for these patients and reduce costs if it prevented repeat visits to theatre for catheter revision or reduced infection risk. Even in this case, 2 specialists agreed that the device would be more likely to generate savings if catheter displacement occurred in a large number of people needing CSF drainage.

General comments

One specialist commentator stated that the evidence is from a small sample, with no comparator to show whether accidental displacement is a common problem. A second specialist expressed a need to study whether SecurAcath affects external ventricular drainage infection rates or skin complications.

One specialist stated that it is difficult to quantify the number of accidental removals or dislocations of CSF drainage catheters; 2 specialists estimated that 5% to 10% of catheters will become displaced. One of the commentators also expressed concern that a catheter could still be accidentally removed with SecurAcath in place, and that the anchors of the device would cause extra problems because of skin tearing.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Andrew Brodbelt, consultant neurosurgeon, The Walton Centre NHS Foundation Trust. No conflicts of interest declared.
- Mr Timothy Jones, consultant neurosurgeon, St George's University Hospitals NHS Foundation Trust. No conflicts of interest declared.
- Dr Catherine McBain, consultant clinical oncologist, The Christie NHS Foundation Trust. No conflicts of interest declared.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre. 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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