NICE advice

ViewSite Brain Access System (VBAS) for the surgical management of deep brain lesions

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the ViewSite Brain Access System (VBAS). It is used to access and visualise the surgical field during brain surgery.
- The **innovative aspects** are that it is made from transparent plastic to help visualise the surrounding tissue. It has an elliptical shape which is designed to distribute brain tissue evenly and help minimise surgical brain injury. It comes in different sizes to meet surgical needs and is compatible with most surgical arms.
- The intended **place in therapy** would be as an alternative to conventional self-retaining spatula-based brain retractor systems or other tubular retractors used during minimally invasive brain surgery for deep brain lesions.

- The **main points from the evidence** summarised in this briefing are from 6 studies including 1 systematic review and meta-analysis, 2 systematic reviews, 2 retrospective observational studies and 1 prospective observational study. The evidence includes a total of 224 patients undergoing brain surgery (aged between 15 months and 86 years). They show that VBAS appears to be safe and efficacious for managing deep brain lesions.
- **Key uncertainties** around the evidence or technology are that the primary evidence base consists mainly of single-centre retrospective observational studies with small sample sizes. There are no head-to-head comparative studies with self-retaining spatula-based brain retractor systems or other tubular retractors, no evidence from an NHS setting and there is limited evidence in children.
- **Experts advised** that the technology is relatively established but not yet widely used across the NHS. Experts agreed that the technology has the potential to reduce brain injury from retraction. This can lead to earlier recovery and reduced complications when used for deep-seated brain lesions by surgeons experienced in the use of the retractor. No major issues or barriers to adoption were noted by the experts.
- The **cost** of VBAS is £410 per unit for a single-use sterile packed system (excluding VAT). The costs of reusable self-retaining spatula-based brain retractors are between £8,000 and £14,000.

The technology

The ViewSite Brain Access System (VBAS; Vycor Medical) is a transparent tubular brain retractor system designed to access and visualise the surgical field during microneurosurgical techniques. It consists of an introducer and a working channel port, secured by a spring-controlled latch. VBAS is available in a range of device lengths (3 cm, 5 cm and 7 cm) and diameters (6 mm, 12 mm, 17 mm, 21 mm and 28 mm), and is compatible with most standard surgical arms and neuronavigational systems.

Innovations

The device is designed to give clear access and a visible working channel during brain surgery, while distributing brain tissue evenly. The company claims that compared with conventional self-retaining spatula-based brain retractor systems, VBAS has the potential to minimise tissue damage. It claims that this can lead to reduced operating times, shorter

intensive care unit (ICU) stays, and shorter postoperative hospital stays. The company claims that using VBAS may lead to lower morbidity and mortality and may allow operations on otherwise inoperable or difficult to reach brain locations.

Current care pathway

Brain retraction is important during brain surgery because it allows the surgeon to secure surgical space and access deep areas in the brain and skull base. It can be done using different types of retractor systems. The type of retractor used depends on the surgical approach, the size of the lesion and where it is located, and the preference of the surgeon. The most used brain retractors are self-retaining retractor systems with moveable arms and attachable blades (brain spatulas). These are made from malleable stainless steel or silicone rubber and have been associated with surgical brain injuries. The extent of surgical brain injury is influenced by several factors including the duration of retraction, the distribution of pressure applied and the structure of the brain tissue at the retraction site. Tubular brain retractors, such as the VBAS, have been designed to help reduce the number of brain retractor injuries. Other tubular retractor systems are available, including BrainPath (NICO) and METRx (Medtronic; indicated for use in spinal surgery rather than brain surgery).

No clinical guidelines on the use of brain retractors were identified.

Population, setting and intended user

VBAS is intended to be used to access and visualise the surgical field during brain surgery. It is approved for use in children and adults. The experts suggested that anatomy and deep-seated location would usually indicate when it should be used rather than specific histological diagnosis. VBAS would be commonly used for different types of deep-seated or intraventricular brain lesions or tumours (such as brain metastases, colloid cysts, and central neurocytomas) and intraventricular or intracerebral haemorrhage.

The technology would be used in secondary care by neurosurgeons during brain surgery.

Costs

Technology costs

The technology costs £410 per procedure (excluding VAT). This cost is for a single-use sterile packed system and is the same for all sizes of VBAS retractor. The company said that it includes the introducer, removable dilator and the navigation pointer holder adaptor.

Costs of standard care

The company states that self-retaining spatula-based brain retractors cost between £8,000 and £14,000. Standard retractor systems are re-sterilisable and reusable unlike tubular retractors which are single-use.

Resource consequences

The technology is currently being used in 12 UK neurosurgical hospitals (there are 31 neurosurgical sites in the UK).

The company said that adopting the technology may release resources through shorter operating times, reduced ICU stays and reduced postoperative hospital stays. There is no published evidence to support this claim. The company states that training on how to use the VBAS system, including appropriate preoperative sizing and correct and safe disposal, is included free of charge and provided for the whole clinical team.

The experts commented that no practical difficulties and no changes in facilities and infrastructure are associated with adopting the VBAS.

Regulatory information

The ViewSite Brain Access System is a CE-marked Class III medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and

others.

The ViewSite Brain Access System (VBAS) can be used for people with brain cancer. Cancer is recognised as a disability. The risk of getting a brain tumour increases with age. But some types of brain tumour are more common in children. Age and disability are protected characteristics 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 for medtech innovation briefings. 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

Six studies are summarised in this briefing. This comprises 1 systematic review and meta-analysis, 2 systematic reviews, 2 retrospective observational studies and 1 prospective observational study. This evidence includes a total of 224 people who had brain surgery using the ViewSite Brain Access System (VBAS).

Other published studies were identified including 3 small case series (Eichberg et al. 2020; Okasha et al. 2021 and Valarezo-Chuchuca et al. 2021) and a single patient case study (Hajtovic et al. 2021) but they have not been detailed further in this briefing.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

Evidence from systematic reviews suggests that VBAS may be safe and efficacious for use during surgery for deep-seated brain lesions. Outcomes reported included extent of resection and complication rates. Gross total resection (GTR) reported across the studies included in this briefing ranged from 27% to 72%, and total complication rate ranged from 2.8% to 35%. Evidence suggests that complication rates may be similar for the different tubular retractors. Comparison of GTR between different retractors has limitations

because it is a subjective measure and may differ in its definition between studies. The primary evidence for VBAS is limited in quality and mainly comes from single-centre retrospective observational studies with relatively small sample sizes. There is limited primary evidence comparing VBAS with conventional self-retaining spatula-based retractors or other tubular retractors. Although the evidence base includes people aged between 15 months and 86 years, most of the evidence comes from an adult population.

There is no evidence on VBAS from an NHS setting but the experts suggested that outcomes from non-UK studies are likely to be generalisable to the NHS.

Further evidence on the efficacy and safety of the technology in children would be helpful because their postoperative morbidity, mortality, prognosis and outcomes can differ from adults. Multicentre, prospective comparative studies or randomised controlled trials would be helpful in determining the comparative benefits of VBAS compared with conventional self-retaining spatula-based retractors and other tubular retractors. These studies would preferably be in an NHS setting and include outcomes that demonstrate potential reductions in resource use, such as reduced operating times, length of intensive care unit stay, and postoperative hospital stay.

Echeverry et al. (2020)

Study size, design and location

A systematic review of 3 tubular retractor systems in the management of deep brain lesions, including a total of 44 studies.

Intervention and comparator(s)

The systematic review included 3 different brain retractor systems: VBAS (12 studies), BrainPath (29 studies) and METRx (3 studies).

Key outcomes

A total of 426 procedures were done across all studies (289 for BrainPath, 106 for VBAS and 31 for METRx). Types of procedures included biopsy, tumour resection, haematoma evacuation, foreign body removal, and colloid cyst excisions. BrainPath had statistically significantly higher rates of GTR (80.2%) compared with VBAS (59.6%). VBAS had the highest rate of suboptimal tumour resection (STR; 40.4% compared with 19.7% for

BrainPath). Over 90% of haematoma evacuations were achieved in all attempts using VBAS. Rates of haematoma evacuation were statistically significantly higher with VBAS compared with BrainPath ($p<0.001$). The overall complication rate for all retractors was 7.7% and the overall mortality was 3.8%. There was no difference in complication rates ($p=0.627$) or mortality ($p=0.204$) among the 3 retractors.

Strengths and limitations

The search strategy appeared appropriate and included both database searches and other sources (company websites), but the date range of the searches was not reported. Reasons for excluding each study were reported. The review states that 4 reviewers critically appraised the studies, but it is unclear whether these reviewers were independent and blinded during the study selection and appraisal process. There was limited discussion on the level of evidence but the authors state that most of the studies included in the review were case–control or retrospective analyses. The study could not determine average lesion size for the retractors because parameters for this measure differed among studies.

Marenco-Hillembrand et al. (2020)

Study size, design and location

A systematic review and meta-analysis of 4 tubular retractor systems for resection of deep brain lesions in people aged 18 and over, including a total of 13 studies.

Intervention and comparator(s)

This systematic review included evidence on 4 different tubular retractors: VBAS (3 studies), BrainPath (6 studies), METRx (3 studies) and modified retractors (2 studies).

Key outcomes

The systematic review and meta-analysis included a total of 309 people who were operated on between 2008 and 2018. The pooled prevalence for GTR was 75% (95% confidence interval, 69% to 80%; $I^2 = 9\%$). The rates of GTR were similar between high-grade and low-grade gliomas ($p=0.45$). GTR was more likely to be achieved with metastases than gliomas ($p<0.006$ for high-grade and $p=0.002$ for low-grade gliomas). None of the retractors had better GTR rates ($p>0.05$). The pooled prevalence of

complications was 9% (95% confidence interval 6% to 14%; I^2 = 0%). A total of 21 people experienced postoperative complications, 13 of which were neurological. All but 3 neurological complications were transient and there were no postoperative central nervous system infections. The number of complications among the different types of retractors was similar.

Strengths and limitations

The study was a systematic review and meta-analysis and provides evidence on pooled GTR and postoperative complication rates. The evidence was reviewed by 2 independent investigators and disagreements were judged by a third reviewer. It used a defined inclusion and exclusion criteria and reasons for excluding studies were reported.

The systematic review included evidence on other tubular retractors and only 3 of the 13 studies were on VBAS. The studies only included data on adults so results may not be generalisable to children. The authors state that preoperative and postoperative lesion volumes, Karnofsky Performance Status, the presence of intraoperative neuromonitoring, and length of postoperative stay were under reported by the included studies.

Shapiro et al. (2020)

Study size, design and location

A systematic review on the use of VBAS for the management of deep brain lesions, including 12 studies.

Intervention and comparator(s)

VBAS, no comparator.

Key outcomes

Twelve publications (including a total of 106 patients aged between 15 months and 85 years) met the inclusion criteria. VBAS was most used for tumour resection (55 people), colloid cyst removal (13 people), foreign body removal (6 people) and haematoma evacuation (23 people). The overall complication rate associated with VBAS was 2.8%. Three people experienced short-term postoperative complications that resolved within 6 months (2 people had transient memory loss and 1 person had postoperative tract

damage). GTR was achieved in 63% of tumour resections, and subtotal resection was achieved in 37%. All cysts, foreign bodies, and hematomas were successfully removed.

Strengths and limitations

The review states that 4 reviewers critically appraised the studies, but it is unclear whether these reviewers were independent and blinded during the study selection and appraisal process. The authors state that most of the studies included in the systematic review were case–control or retrospective analyses and were not designed to assess adverse outcomes specific to VBAS or to provide direct comparisons between tubular retractor systems. Lesion volumes were not reported in all studies so average lesion size could not be calculated. The longest follow up for complication rates reported in the studies was around 6 months.

Eichberg et al. (2020)

Study size, design and location

A retrospective multicentre observational study including 113 people who had transcortical-transtubular resection of brain lesions using tubular retractors in the US.

Intervention and comparator(s)

VBAS (56 people) or BrainPath (57 people).

Key outcomes

A total of 113 people who were operated on between August 2013 and April 2019 from 3 centres were included. GTR was achieved in 71.7% of people (n=81), near total resection in 10.6% (n=12), maximal safe resection in 7.1% (n=8), and subtotal resection in 8.8% (n=10). The permanent complication rate was 4.4% (n=5). One person had a seizure within a week after surgery and no late seizures (after the 1-week follow up) were reported. Mean length of hospital stay after surgery was 4.1 days. Lesions resected using BrainPath were deeper than lesions resected with VBAS (4.8 cm [range 1.6 cm] compared with 3.9 cm [range 2.3 cm]; p=0.022). VBAS was more frequently used in cavernoma resection (p=0.015) and BrainPath was more frequently used in glioma (p=0.014) and metastatic tumour resections (p=0.013). There was no statistically significant difference in the extent of resection, rate of immediate complications or postoperative length of hospital stay

between the 2 retractors.

Strengths and limitations

The study included the largest number of people to date and included multiple centres and surgeons. The extent of resection was measured by a board-certified neurosurgeon who was blinded to the treatment.

The study was retrospective and non-randomised. Comparisons between the 2 retractors were not propensity score matched so heterogeneity in the study population may have prevented a true comparison of effectiveness. The study included adults aged 18 to 85 so results may not be generalisable to children. The study did not compare tubular retractors to conventional self-retaining spatula-based retractors.

Capitanio et al. (2020)

Study size, design and location

A prospective, single-centre observational study including 20 people who underwent surgery for large intraventricular deep-seated lesions, in Italy.

Intervention and comparator(s)

VBAS, no comparator.

Key outcomes

The study included 20 people who had ultrasound and MRI-navigated transcortical surgery using VBAS between January 2012 and December 2017. The age range was 15 to 71 years. Gross total removal was achieved in 70% of people (n=14). The mean duration of surgery was 225.9 plus or minus 59 minutes. No critical events, major bleedings or intraoperative deaths were reported. One person experienced a postoperative cerebrospinal fluid infection. Permanent neurological adverse effects were reported in 30% of people (n=6), including cognitive decline (n=3), memory deficits (n=2) and behavioural alterations (n=1). The mean Functional Independence Measure (FIM) score at last follow up was 105 (ranging from 65 to 124).

Strengths and limitations

The study was prospective and had an average follow up of 13 months (median of 8 months and a range of 6 to 30 months).

The study was non-comparative and reported experience from a single centre, with a relatively small sample size.

Shashivadhanan (2020)

Study size, design and location

A retrospective, single-centre, observational study including 22 people undergoing surgery for deep-seated subcortical supratentorial brain lesions with VBAS, in India.

Intervention and comparator(s)

VBAS. Outcomes were compared with a historical control group which shared a similar clinical profile. The control group was operated on using conventional retractor blades.

Key outcomes

The study included a total of 22 people who underwent surgery between April 2015 and July 2018. The lesion types included intracerebral haemorrhage (45%), colloid cyst (95%), high-grade glioma (27%), cystic tumours (9%) and metastasis (9%). Total excision was achieved in 27% of people and 90% excision was achieved in 45% of people. The overall complication rate was 13%. No retractor-induced infarction was reported with VBAS compared with 8% in the historical controls. Use of VBAS was also associated with a reduced need for steroids and cerebral decongestants after surgery. The ease of surgery and time taken were similar in both groups.

Strengths and limitations

The study involved a historical control group comparing VBAS with conventional retractor blades. However, no comparative statistical analyses were reported. There was very limited information on the demographics of the 2 groups. The study was retrospective in design, done at a single centre, and had a relatively small sample size.

Sustainability

The company did not make any claims around environmental sustainability benefits for VBAS.

Recent and ongoing studies

No ongoing or in-development trials were identified by NICE when searching key clinical trial registries.

Expert 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.

All 4 experts were familiar with the ViewSite Brain Access System (VBAS) tubular retractors and 3 had used the technology before.

Level of innovation

All experts felt that the technology is relatively established and no longer new, although it is not widely used across the NHS. One expert felt that the technology has the potential to replace standard care for deep brain lesions. Another expert said it could become an alternative first choice, depending on the specific nature of the lesion and its accessibility. The remaining 2 experts said that it would be used in addition to other technologies and minimally invasive approaches for deep brain lesions. Two of the experts noted that other tubular retractors like VBAS are available. Another noted VBAS's unique tapered design, transparent material and availability in a range of diameters and depths. The remaining expert said that the fully endoscopic approach is a competing procedure available to the NHS and felt that this was preferable for deep and difficult to access lesions. The fully endoscopic approach is a minimally invasive brain surgery done using endoscopic instruments through a working channel, under complete endoscopic visualisation. The expert noted that the working channel of endoscopes is smaller than most tubular retractors so has potential to cause less brain injury.

Potential patient impact

Potential patient benefits noted by the experts include reduced brain injury from retraction, earlier recovery, and reduced complications. The experts also noted that use of the technology may allow improved accessibility and visualisation of deep lesions during surgery in a minimally invasive way.

Potential system impact

Three of the experts felt the technology could lead to improved clinical outcomes which would benefit the system. These included shorter procedure times, shorter hospital stays, improved recovery time, avoiding procedure-related complications, improved extent of resection and improved clinical outcomes. One expert did not think the benefit to the healthcare system would be statistically significant compared with the current clinical pathway. Two experts noted that use of the technology involves an initial cost increase for the disposable retractor but felt that its use is likely to save costs overall when considering the impact on areas such as procedure time, clinical outcomes, recovery, and length of hospital stay. One expert was not sure about the cost impact of the technology.

Three experts said that no changes to current facilities would be needed to adopt the technology. Two experts said that training would be needed to ensure safe and efficient use of the technology, while 2 said that initial familiarisation with the system would be enough.

General comments

Two experts noted that the use of VBAS in the NHS has been increasing in recent years. Another said that they expect rapid uptake once it is widely available and known. Another noted that it is readily available in the UK and was aware of multiple centres around the world using it. Three experts were not aware of any issues that would prevent its adoption. One expert said that the only potential barrier to adoption would be hesitation around adopting new technology.

Three experts felt that no further evidence would be needed to adopt the technology. Another noted that randomised controlled trials (RCT) evidence can be difficult to collect because the choice of brain retractors and surgical approach is surgeon specific. The expert noted that although RCT evidence is not impossible, data from retrospective case

series may be more appropriate for this type of technology.

All experts noted that the technology would not be used in every hospital but in neurosurgical units only. One of the experts said that it would likely be available in large neurosurgical units that have large numbers of people needing surgery for brain tumours (between 10 and 20 units). Another said that all neurosurgical units in the UK should be able to use it.

Expert commentators

The following clinicians contributed to this briefing:

- Asim Sheikh, consultant neurosurgeon, Leeds Teaching Hospitals NHS Trust, did not declare any interests.
- Crispin Wigfield, consultant neurosurgeon, North Bristol NHS Trust, did not declare any interests.
- Dimitrios Paraskevopoulos, consultant neurosurgeon, clinical lead for neurosurgery, Barts Health NHS Trust, did not declare any interests.
- Mr Bassel Zebian, consultant paediatric and adult neurosurgeon, King's College Hospital NHS Foundation Trust, teaches an annual training course on endoscopy in neurosurgery in which the ViewSite Brain Access System tubular retractors are used. The retractors are provided free of charge by distributors.

Development of this briefing

This briefing was developed by NICE. 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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