NICE advice

Acumen IQ sensor for predicting hypotension risk

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Acumen IQ sensor with Acumen hypotension prediction index (HPI) software. It uses a machine-learning algorithm to predict the risk of a hypotensive event and provides information to help identify the cause.
- The **innovative aspects** are that the technology is claimed to predict hypotension up to 15 minutes before an event.
- The intended **place in therapy** would be to predict the chance of a hypotensive event happening during surgical and non-surgical cases in which an arterial line for blood pressure monitoring is recommended.
- The **main points from the evidence** summarised in this briefing are from 6 studies (including 3 randomised controlled trials) of 878 adults in intensive care or needing high-risk surgery. They show that Acumen IQ with Acumen HPI software is effective in predicting hypotensive events.

- **Key uncertainties** around the evidence or technology are that there is limited evidence for people in intensive care and limited evidence on patient outcomes.
- The **cost** of Acumen IQ sensor is £400 per unit (excluding VAT) and the HemoSphere monitor costs £27,470 (excluding VAT). There is currently no evidence to suggest that this technology is cost saving.

The technology

The Acumen IQ Sensor with Acumen hypotension prediction index (HPI) software (Edwards Lifesciences Ltd) is designed to predict the chance of an individual having a hypotensive event in surgical and non-surgical settings. A hypotensive event is defined as mean arterial pressure (MAP) of less than 65 mmHg, that exceeds a cumulative length of 15 minutes. The sensor attaches to any existing radial arterial line and is used to automatically calculate key parameters every 20 seconds. The parameters include HPI, contractility (systolic slope; dP/dt), afterload (dynamic arterial elastance), cardiac output, pulse rate, stroke volume, stroke volume variation, MAP, cardiac index, pulse pressure variation and systemic vascular resistance.

The Acumen IQ sensor uses Acumen HPI software on the HemoSphere advanced monitoring system. The Acumen HPI software uses a machine-learning based algorithm to detect the instability that causes potential hypotensive events, using predictive features from the arterial pressure waveform. The algorithm defines hypotension as MAP below 65 mmHg for at least 1 minute. The algorithm output is an index value called the HPI parameter, which ranges from 0 to 100. The higher the HPI parameter value, the higher the chance of an individual trending towards a hypotensive event. If the HPI parameter value exceeds 85 for 2 consecutive 20-second updates, or reaches 100 at any time, the HPI high alert popup will appear on the monitor. The Acumen HPI software (through its secondary screen) gives information on additional advanced haemodynamic pressure and flow parameters so clinicians can investigate the potential root cause of the hypotensive event. These include measures of stroke volume variation, left ventricular contractility and dynamic arterial elastance.

The HemoSphere monitor can be used with other non-invasive sensors to measure additional parameters, including haemodynamic status and peripheral or cerebral saturation. The monitor has a touch screen and can switch between different parameter measurement screens.

Innovations

The company states that the Acumen HPI software is the first technology of its kind in this area. It is unique because it is based on waveform analysis to give information on the chance of a hypotensive event. The company claims that this algorithm, developed by machine learning using data from over 59,000 hypotensive events and over 144,000 non-hypotensive events, predicts hypotension up to 15 minutes before an event. The company states that earlier detection of hypotension may reduce the risk of complications after hypotensive events, such as cardiac injury or acute kidney injury. This could reduce hospital length of stay and unplanned readmissions.

Current care pathway

Blood pressure is routinely monitored using a non-invasive blood pressure monitor which would alert the clinician when an individual becomes hypotensive. Arterial lines, normally situated in the radial artery, can also allow the continuous monitoring of the systemic arterial pressure (providing readings around every 5 to 15 minutes) and are generally used for the those who are critically ill.

- NICE's guideline on acutely ill adults in hospital: recognising and responding to deterioration recommends that adults in acute hospital settings should have physiological observations recorded at the time of their admission or initial assessment. After admission, these physiological measurements should be monitored regularly with predetermined response criteria to changes to identify deteriorating physiological status or risk of deterioration.
- The National Early Warning Score 2 (NEWS2) system gives aggregated scores to physiological measurements, already recorded in routine practice, when patients present to, or are being monitored in hospital. This includes routine monitoring of systolic blood pressure.
- The Royal College of Anaesthetists Guidelines for the Provision of Anaesthesia Services for Intraoperative Care recommends that an appropriate automatic non-invasive blood pressure device is used during anaesthesia, with a set recording interval, and should be used until the person has fully recovered from the anaesthetic.

Population, setting and intended user

The technology would be used for surgical cases (both cardiac and non-cardiac) in which an arterial line is recommended. It would be used in tertiary or secondary care by healthcare practitioners who are trained in monitoring physiological measurements. In an operating theatre, this would be an anaesthetist.

Costs

Technology costs

Acumen IQ sensor costs £400 per sensor (excluding VAT). The sensors are single use. The price per sensor decreases if more are purchased.

A HemoSphere monitor costs £27,470 per device (excluding VAT). The price per device decreases if more are purchased. Maintenance costs are part of the HemoSphere capital contract. This capital contract is in addition to the cost of the monitor. The useful lifespan of the monitor is 5 to 7 years. The monitor can be activated for HPI capability when a minimum of 10 Acumen IQ sensors are purchased.

Costs of standard care

An invasive blood pressure transducer costs around £13 to £24 (excluding VAT) and the cost of the monitor is around £10,000 to £23,000 per unit (excluding VAT).

Resource consequences

Acumen IQ sensor is currently used in clinical trials at 2 NHS trusts and routinely used in 1 NHS hospital. The company claims that using the Acumen IQ sensor with Acumen HPI software could be cost saving because of fewer hypotensive events and improved fluid management, leading to a reduction in adverse outcomes such as acute kidney injury and cardiac injury. This may lead to cost savings from reduced intensive care length of stay. It also could reduce overall length of stay, the need for further treatment or unplanned admissions. There is no published evidence to support these claims. The HemoSphere monitor can also be used for monitoring additional parameters that could prevent the use of multiple monitors in the operating room. However, experts state that additional monitors would still be needed in addition to the HemoSphere monitor. Training is provided by the

company and is included with the price of the monitoring platform and sensors. Training includes proctoring, in-person training, virtual training and on-site procedural support.

Regulatory information

Acumen IQ sensor is a CE-marked class IIa medical device. The HemoSphere monitor is a CE-marked class IIb 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.

No equality issues were identified.

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

There are 6 studies summarised in this briefing. This includes 3 randomised controlled trials, 1 prospective study and 2 retrospective studies. A total of 878 people are included in these studies.

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

Overall assessment of the evidence

The studies were in relevant populations, including those having major surgery with intra-arterial blood pressure measurement. However, there was limited evidence on using the device in intensive care. There was also limited published evidence relating to reduced hospital stay, need for further treatment or unplanned readmissions. One study was partially done in the UK, but other studies were done in the US or Europe which limits generalisability to the NHS. The evidence shown is on different versions of the monitor and sensor. The company states that the EV1000 monitor is the previous generation of monitoring platform and that the HemoSphere monitor has an improved interface and can have additional sensors attached. The FloTrac sensor is a different brand name that has subsequently been updated to the Acumen IQ sensor. It measures the same parameters as the Acumen IQ sensor, with the addition of hypotension prediction index (HPI), contractility and afterload. One study included in this evidence summary showed no changes to the incidence of hypotensive events. The company states that this is a result of the protocol design and the authors for this study note that over half of the hypotension alerts in the intervention groups were not treated.

Davies et al. (2020)

Study size, design and location

Retrospective study of 255 people who had major surgery at 2 centres in the UK and the Netherlands.

Intervention and comparator

EV1000 monitoring system with HPI software.

Key outcomes

This study included people having major surgery (major abdominal, vascular, or off-pump coronary artery bypass surgery) who had arterial cannulation for blood pressure and or cardiac output measuring. This included 78 women and 177 men with a mean age of 68 years. Of the 255 people in the study, 221 (86.7%) had 1 or more hypotensive events (defined as a mean arterial pressure [MAP] of less than 65 mmHg for more than 1 minute). The HPI software predicted hypotension with a sensitivity and specificity of 85.8% (95%

confidence interval [CI], 85.8% to 85.9%) and 85.8% (95% CI, 85.8% to 85.9%) respectively, 5 minutes before a hypotensive event. At 10 minutes before a hypotensive event, the sensitivity and specificity were 81.7% (95% CI, 81.6% to 81.8%) and 81.7% (95% CI, 81.6% to 81.8%). At 15 minutes before a hypotensive event the sensitivity and specificity were 80.6% (95% CI, 80.5% to 80.7%) and 80.6% (95% CI, 80.5% to 80.7%).

Strengths and limitations

Because this study was retrospective, there was no data available on the treatment of hypotensive events. Some of the clinicians involved in the study had access to the HPI software at the time of the surgery and so could have treated hypotensive events before they happened. The study used an EV1000 monitor. It is not clear what device was used to measure invasive blood pressure.

Hatib et al. (2018)

Study size, design and location

Prospective study of 204 adults having surgery with invasive arterial pressure recordings in the US.

Intervention and comparator

FloTrac algorithm analysis of collected data.

Key outcomes

The algorithm was developed using a retrospective training cohort of 1,334 records of those in intensive care or having surgery. External validation was then done using the software in people having surgery. The study showed that the software predicted arterial hypotension with a sensitivity and specificity of 88% and 87% 15 minutes before a hypotensive event, respectively. It had sensitivity and specificity of 89% and 90% 10 minutes before, and 92% and 92% 5 minutes before.

Strengths and limitations

This study used intensive care and surgical cases to train the algorithm, but only used

surgical cases for the external validation. The study used a FloTrac algorithm. This study was funded by the company.

Schneck et al. (2019)

Study size, design and location

Single-centre randomised blinded prospective study of 49 people having total hip arthroscopies with retrospective analysis of a further 50 people in Germany.

Intervention and comparator

EV1000 HPI monitoring system with FloTrac IQ sensor compared with routine anaesthetic care.

Key outcomes

There were 3 groups included in this study, 1 using the HPI software (n=25), a control group of routine anaesthetic care (n=24) and a historic control group (n=50). The study showed that significantly fewer people in the HPI group had at least 1 episode of hypotension during anaesthesia ($p<0.001$). The HPI group had significantly reduced relative duration of hypotensive episodes (minutes below MAP 65 mmHg in percent of total anaesthesia time) compared with both control groups ($p<0.001$).

Strengths and limitations

This feasibility study was underpowered to prove the outcome benefits of HPI use, as stated by the authors. This study was funded by the company.

Wijnberge et al. (2020)

Study size, design and location

Randomised control trial in 68 people needing noncardiac surgery under general anaesthesia in the Netherlands.

Intervention and comparator

FloTrac IQ sensor and HemoSphere monitor with HPI software or standard anaesthetic care.

Key outcomes

People were randomly assigned to have either the intervention (n=34) or standard care control (n=34), with 60 people (88%) completing the trial. The median time of hypotension per person was 8 minutes in the intervention group compared with 32.7 minutes in the control group. The median difference was 16.7 minutes (95% CI, 7.7 to 31.0 minutes; p<0.001).

Strengths and limitations

Because this was a preliminary single-centre randomised controlled trial the samples size was small. The study was unblinded. It only included people who needed invasive blood pressure monitoring, who were generally more severely ill and were at higher risk of hypotension than the general population. This study was funded by the company.

Maheshwari et al. (2020)

Study size, design and location

Pilot randomised controlled trial of 214 adults having moderate- or high-risk noncardiac surgery with invasive arterial pressure monitoring in the US.

Intervention and comparator

FloTrac IQ sensor and EV1000 monitoring system with HPI software with the HPI outputs only being unblinded to the clinicians in the intervention group.

Key outcomes

The HPI and advanced haemodynamic information was recorded in both groups but only available to the intervention group. The time-weighted MAP less than 65 mmHg was the same in the intervention and comparator groups (0.14, p=0.757). In the intervention group, more than half of all the alerts did not lead to interventions. However, when clinicians did

intervene, hypotension was reduced by 57%.

Strengths and limitations

This pilot randomised controlled trial included a large number of people, with 80% power for detecting about 20% relative reduction in the mean of the area under the curve MAP less than 65 mmHg. However, the study excluded those with certain cardiac conditions and half of the alerts were not followed by treatment. The study was done in the US and so may not be generalisable to the NHS. The study was funded by the company.

Shin et al. (2020)

Study size, design and location

Retrospective cohort feasibility study of 37 people having a cardiac procedure with invasive blood pressure monitoring in the US.

Intervention and comparator

Acumen IQ sensor with EV1000 monitor and HPI software.

Key outcomes

The study collected continuous waveform data from the EV1000 monitor for analysis at the end of the surgical procedure. The anaesthetic care team were blinded to the monitor outputs. The area under the curve, sensitivity, and specificity 5 minutes before a hypotensive event was 0.90 (95% CI, 0.853 to 0.949), 84% (95% CI, 77.7 to 90.5), and 84% (95% CI, 70.9 to 96.8), respectively. At 10 minutes before the event the area under the curve, sensitivity, and specificity was 0.83 (95% CI, 0.750 to 0.905), 79% (95% CI, 69.8 to 88.1), and 74% (95% CI, 58.8 to 89.6), respectively. At 15 minutes before the hypotensive event the area under the curve, sensitivity, and specificity was 0.83 (95% CI, 0.746 to 0.911), 79% (95% CI, 68.4 to 89.0), and 74% (95% CI, 58.8 to 89.6), respectively.

Strengths and limitations

This study was single-armed and retrospective. It was limited by having a small sample size, in which the procedural characteristics varied because multiple types of coronary

procedures were included.

Sustainability

The Acumen IQ sensor is single use and the HemoSphere monitor is reclaimed after the life of the contract. There is no published evidence to support these claims.

Recent and ongoing studies

- Hypotension prediction index for blood pressure management (HPI). ClinicalTrials.gov identifier: NCT03610165. Status: active, not recruiting. Indication: intraoperative hypotension. Devices: Acumen HPI-enabled EV1000 screen; control. Last updated: May 2021. Country: US.
- Hypotension prediction index study (HPI study). ClinicalTrials.gov identifier: NCT03805217. Status: active, not recruiting. Indication: hypotension. Devices: EV1000A clinical platform with Acumen HPI feature software. Last updated: August 2020. Country: US.
- The Predict H Trial. ClinicalTrials.gov identifier: NCT04301102. Status: recruiting. Indication: intraoperative hypotension. Devices: Hemosphere platform together with the FloTrac Acumen IQ sensor; Hemosphere platform together with the FloTrac sensor. Last updated: March 2021. Country: Spain.
- The "Hypotension Prediction Index" in Patients Undergoing Lung Surgery. ClinicalTrials.gov identifier: NCT04149314. Status: not yet recruiting. Indication: hypotension; haemodynamic instability; renal failure; myocardial injury; anaesthesia. Devices: HPI-based haemodynamic optimisation algorithm. Last updated: November 2019. Country: Germany.
- Influence of the "hypotension probability index" on intraoperative and postoperative hypotension in ENT- and OM-surgery. ClinicalTrials.gov identifier: NCT04151264. Status: not yet recruiting. Indication: hypotension; ear nose and throat disease; acute kidney injury; anaesthesia. Devices: HPI. Last updated: November 2019. Country: Germany.

- Changing doctors' behaviour in the treatment of low blood pressure. Trial identifier: ISRCTN17085700. Status: ongoing, recruiting. Indication: patients due to have elective major abdominal, orthopaedic, head and neck or vascular surgery. Devices: HPI. Last updated: March 2021. Country: UK.
- HPI index with goal-directed haemodynamic treatment in predicting hypotension in general anesthesia patients. ClinicalTrials.gov identifier: NCT04803903. Status: recruiting. Indication: hypotension during surgery. Devices: Flotrac Sensor with EV1000 incorporating the HPI algorithm. Last updated: March 2021. Country: Greece.
- Continuously iterative perioperative holistic evaluation of risk and hypotension prediction index (CIPHER-HPI). ClinicalTrials.gov identifier: NCT04807036. Status: not yet recruiting. Indication: surgery complications. Devices: HPI. Last updated: March 2021. Country: UK.
- Hemodynamic impact on critical care patients with lung damage secondary to COVID-19. ClinicalTrials.gov identifier: NCT04556864. Status: not yet recruiting. Indication: COVID-19; haemodynamic instability, human acute respiratory distress syndrome. Devices: HemoSphere/EV1000 platform with Acumen IQ sensor. Last updated: September 2020. Country: Spain.
- Prediction of hemodynamic instability in patients admitted to the intensive care unit: a prospective, nonrandomised, noninterventional study for clinical data collection. Trial identifier: NTR7349. Status: recruiting. Indication: Hypotension; patients in intensive care. Devices: HPI; Clearsight system and FloTrac system. Last updated: none given. Country: The Netherlands.

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.

There were 2 out of 3 experts who were familiar with or had used this technology before.

Level of innovation

Two experts thought that the Acumen hypotension prediction index (HPI) technology is

innovative because it uses machine learning. All experts stated that this device could mean that hypotension can be predicted and could allow for preventative treatment. However, one expert stated that it is unknown if actions on the alert will affect patient outcomes. All experts stated that this device would be used in addition to standard care. One expert further stated that the device needs to show that it increases safety before it is widely used.

Potential patient impact

Two experts stated that this device would be used for those at moderate-to-high risk when having major surgery. One expert further included those having high-risk surgery, those admitted to intensive care and those who are critically ill, including pre-hospital care and emergency room settings. One expert also included any person in intensive care with an invasive arterial line for a haemodynamic purpose. One expert stated that the benefit of the technology is the reduction in hypotension. However, they stated that this would only be beneficial if the cause of the hypotension is addressed. They also expressed uncertainties around whether a reduction in hypotension translates into improved patient outcomes. One expert stated that the potential benefits would depend on whether the device affects clinical behaviour and whether there are unexpected consequences of taking preventative measures. One expert stated that the technology could lead to improved outcomes, fewer hospital visits, fewer long-term complications, more appropriate use of existing resources and shorter lengths of stay.

Potential system impact

Two experts stated that there would be high equipment costs, which could be greater than standard care. One expert felt that the capital costs and the cost of the transducers is greater than the potential costs saved. This is because the evidence on outcome benefits is not proven. However, another expert felt that fewer complications, reduced length of stay (resulting in an increase in surgery capacity) and better allocation of post-operative high-care beds would lead to cost savings. One expert said that it will be difficult to show cost savings because the targeted measure is only one of the factors influencing cost. They also added that there could be additional costs associated with additional interventions triggered by device use. All experts stated that training would be needed to use the device. One expert further stated that there is a need for training on understanding the additional parameters displayed by the monitor.

General comments

One expert stated that there is a theoretical potential to overtreat hypotension because there is a false positive rate with the technology, but this is unlikely to have a clinical impact. Another expert also stated that caution is needed in using the HPI value as a physiological variable, rather than a predictive index. This could lead to inappropriate treatment being given and could cause unintended harm. One expert felt that the studies were more proof of concept and that separate evidence and consideration is needed for perioperative and intensive care management. One expert thought that there were uncertainties about whether actions taken because of using the technology would improve outcomes and whether the device was capable at reacting to extremes of physiology.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Alain Vuylsteke, consultant in anaesthesia and intensive care, Royal Papworth Hospital. Did not declare any interests.
- Professor Monty Mythen, professor of anaesthesia and critical care, University College London. Professor Mythen is a paid consultant for Edwards Lifesciences.
- Dr Simon James Davies, consultant anaesthetist, York Teaching Hospitals NHS Foundation Trust. Dr Davies is a paid consultant for Edwards Lifesciences.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings 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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