Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	**Predictive monitoring for hypotension in high risk patients during surgery and in critical care**
Topic exploration report number:	TER222

Introduction and aims

Health Technology Wales researchers searched for evidence on predictive monitoring of hypotension in high risk patients during surgery and in critical care using the Acumen IQ sensor and Acumen Hypotension Prediction Index or similar technologies. This technology aims to predict intraoperative hypotension before it occurs, to provide more timely and detailed information that can guide treatment responses. This could lead to fewer postoperative complications, improved recovery, and reduced need for critical care.

Summary of evidence

Systematic reviews and economic evaluations:

No systematic reviews, economic evaluations, or other secondary evidence on the effectiveness of the technology were identified.

Primary studies:

The topic proposer provided several primary studies and an additional primary study was identified by the literature search.

For invasive monitoring, a study by Hatib et al. (2018) describes the development of a machine-learning algorithm and used a retrospective cohort of 1,334 patients with 25,461 episodes of hypotension and a prospective cohort of 204 patients with 1923 episodes of hypotension undergoing surgery or in critical care to validate the algorithm. They report that the algorithm predicted hypotension with a sensitivity of 92% and a specificity of 92% at five minutes before an event. Sensitivity and specificity reduced at 10 and 15 minutes before an event and were much reduced at over 17 minutes before an event. Another validation study by Davies et al. (2020) used a retrospective cohort of 255 patients undergoing major surgery and reported a sensitivity of 85.8% and a specificity of 85.8% at five minutes before an event, again reducing

at 15 minutes; the authors concluded that the algorithm outperformed other hemodynamic measures.

For non-invasive monitoring, a study by Maheshwari et al. (2020) examined whether the algorithm could be used via a finger cuff in a retrospective cohort of 320 patients undergoing non-cardiac surgery. At 5 minutes in advance, the sensitivity and specificity were both 86%, and as with invasive monitoring, diagnostic accuracy reduced as time to the hypotension event increased.

Two studies used randomised designs to examine whether use of the algorithm could reduce intraoperative hypotension. Schneck et al. (2019) randomised 49 patients to management with the algorithm or routine care as well as including a historic control of 50 patients. The intervention group had significantly fewer hypotensive events per hour than the control groups as well as a significantly reduced duration of hypotensive episodes. No significant differences were found on postoperative surveillance. Wijnberge et al. (2020) randomised 68 patients to either management with the algorithm or standard care and report that the intervention group had a significantly lower median difference in time-weighted average hypotension and time in hypotension. No serious adverse events resulting in 30-day mortality were recorded in the intervention group with two in the control arm. In total, there were 33 and 30 adverse events in the intervention and control groups, respectively.

Areas of uncertainty

There is some evidence from secondary literature on observational studies that intraoperative hypotension is associated with poorer outcomes in some populations. However, a key area of uncertainty is whether reduction in intraoperative hypotension by this intervention would lead to benefits by, for example, reducing adverse events, postoperative complications, and need for critical care. We identified one ongoing randomised trial using invasive monitoring but these outcomes are not reported to be included as primary or secondary outcomes in the trials registry.

We did not identify any relevant economic evidence that examines whether the additional cost of the technology provides value and no information on whether the technology would fit into standard care or adaptations to current processes would be needed. This could lead to additional costs beyond the costs of the technology.

At present randomised evidence is restricted to populations undergoing surgery that requires invasive monitoring, and it is unclear whether these results would be replicated for populations with non-invasive monitoring or in critical care. We identified one ongoing randomised trial which aims to replicate findings in lung surgery patients with non-invasive monitoring and has an estimated study completion date of December 2022.

Conclusions

The evidence identified suggests that algorithms can be successful in predicting intraoperative hypotension before it occurs in surgery and critical care. Randomised evidence from small scale studies suggest that this information can be effective in reducing intraoperative hypotension in patients undergoing surgery with invasive monitoring. However, there is currently not sufficient evidence to assess whether this would have benefits after surgery and whether these effects

would be replicated in patients undergoing surgery with non-invasive monitoring or in critical care.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant information or guidance from this source.
Health Technology Assessment Group	We did not identify any relevant information or guidance from this source.
Health Information and Quality Authority	We did not identify any relevant information or guidance from this source.
EUnetHTA	We did not identify any relevant information from this source.
UK guidelines and guidance	
SIGN	We did not identify any relevant information or guidance from this source.
NICE	We did not identify any relevant information or guidance from this source.
Secondary literature and economic evaluations	
Cochrane library	We did not identify any relevant secondary literature or economic evaluations from this source.
Medline	We did not identify any relevant secondary literature or economic evaluations from this source.
Primary studies	
Medline	• Maheshwari, K., Buddi, S., Jian, Z., Settels, J., Shimada, T., Cohen, B., Sessler, D. I., Hatib, F. (2020). Performance of the Hypotension Prediction Index with non-invasive arterial pressure waveforms in non-cardiac surgical patients. *Journal of Clinical Monitoring and Computing,* Online ahead of print. https://doi.org/10.1007/s10877-020-00463-5 The Medline search also identified each of the publications provided by the topic proposer.
Ongoing primary or secondary research	
PROSPERO database	We did not identify any ongoing systematic reviews or meta-analyses from this source.
Clinicaltrials.gov	• NCT03610165. The Role of Acumen Hypotension Prediction Index Software in Hypotension Management During Moderate to High-Risk Noncardiac Surgery: A Pilot Randomized Control Trial. Estimated study completion date: July 2020. https://clinicaltrials.gov/ct2/show/NCT03610165 • NCT04149314. PGDT With the "Hypotension Prediction Index" to Reduce the Number and Duration of Intraoperative Hypotension and the Incidence of Renal Failure in Patients Undergoing Lung Surgery. Estimated Study Completion Date: December 2022. https://clinicaltrials.gov/ct2/show/NCT04149314
Other	
Evidence provided by topic proposer	• Davies, S. J., Vistisen, S. T., Jian, Z., Hatib, F., Scheeren, T. (2020). Ability of an arterial waveform analysis-derived hypotension prediction index to predict future hypotensive events in surgical patients. *Anesthesia & Analgesia, 130,* 352-359. https://doi.org/10.1213/ane.0000000000004121 • Hatib, F., Jian, Z., Buddi, S., Lee, C., Settels, J., Sibert, K., Rinehart, J., Cannesson, M. (2018). Machine-learning algorithm to predict hypotension based on high-fidelity pressure waveform analysis. *Anesthesiology, 129,* 663-74. https://doi.org/10.1097/aln.0000000000002300

	• Schneck, E., Schulte, D., Habig, L., Ruhrmann, S., Edinger, F., Markmann, M., Habicher, M., Rickert, M., Koch, C., Sander, M. (2019). Hypotension Prediction Index based protocolized haemodynamic management reduces the incidence and duration of intraoperative hypotension in primary total hip arthroplasty: a single centre feasibility randomised blinded prospective interventional trial. *Journal of Clinical Monitoring and Computing,* OnlineFirst. https://doi.org/10.1007/s10877-019-00433-6 • Wijnberge, M., Geerts, B. F., Liselotte, H., Lemmers, N., Mulder, M. P., Berge, P., Schenk, P., Terwindt, L. E., Hollman, M. W., Vlaar, A. P., Veelo, D. P. (2020). Effect of a Machine Learning–Derived Early Warning System for Intraoperative Hypotension vs Standard Care on Depth and Duration of Intraoperative Hypotension During Elective Noncardiac Surgery: The HYPE Randomized Clinical Trial, *JAMA, 323*, 1052-1060. https://doi.org/10.1001/jama.2020.0592

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Concepts used:	**predictive monitoring, prediction, algorithm, hypotension, surgery, intraoperative, critical care**