NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

AnaConDa-S for sedation with volatile anaesthetics in intensive care

1 Technology

1.1 Description of the technology

The Anaesthetic Conserving Device-S (AnaConDa-S; Sedana Medical) is a volatile anaesthetic delivery system to give isoflurane or sevoflurane to people who are invasively ventilated, usually in an intensive care setting.

AnaConDa-S is a single-use device (replaced every 24 hours or when needed). The device can be inserted into either the breathing circuit of a ventilator between the endotracheal tube and Y piece, replacing the heat and moisture exchanger (standard placement) or in the inspiratory port of the ventilator (alternative placement). Liquid anaesthetic is injected through the anaesthetic agent line, into a porous rod in the AnaConDa-S device where the anaesthetic is vaporised. The vaporised anaesthetic is then inhaled by the patient with the inspiration flow from the ventilator. With continued breathing, the majority of anaesthetic agent that has not been absorbed by the lungs is exhaled and adsorbed by an active carbon filter in the device. On further inhalation, the anaesthetic is desorbed from the filter and transported back to the lungs, reducing the amount of anaesthetic agent wasted. The AnaConDa-S device also contains a bacterial and viral filter and a gas analyser port. This port is used to measure the exhalated anaesthetic concentration in minimal alveolar concentration (MAC value; a relative measure of the level of anaesthesia) or end-tidal concentration (Fet%). Side stream or mainstream gas monitors, which can measure concentrations of carbon dioxide and anaesthetic gases, must be used to continually monitor anaesthesia, these will need to be purchased separately if not already available.

AnaConDa-S can be used with almost any kind of ventilator, except high-frequency ventilators. It was launched in the UK in 2017 and is a newer version of the AnaConDa device (available in the UK since 2005), which is now only available on request in the UK. The AnaConDa-S has a lower dead space of 50 ml (compared with 100 ml in the original device) and works with tidal volumes as low as 90ml. The lower dead space allows AnaConDa-S to be used on smaller adults or children who have smaller minute or tidal ventilation.

1.2 Relevant diseases and conditions

The AnaConDa-S is intended for delivery of volatile anaesthetics as an alternative to IV sedatives for sedating people who are invasively ventilated in intensive care. The AnaConDa-S has a tidal volume working range of 200 ml to 800 ml when used in standard placement. Small tidal volume (90 ml) can be achieved when AnaConDa-S is used in the alternative placement. Volatile anaesthetics should not be used in people with a known history of malignant hyperthermia. Using volatile anaesthetics in pregnant women, especially in the first trimester, could have potential teratogenic or developmental effects on the unborn baby. The AnaConDa-S system could be used for people who need more rapid awakening for assessment; in people with difficult or limited IV access; or to manage sedation in cases when sedation is difficult despite using multiple sedative agents. Volatile anaesthetics can also be used to treat bronchospasm in mechanically ventilated people with severe acute asthma and in sedating mechanically ventilated people with acute respiratory distress syndrome (ARDS).

Most mechanically ventilated people receive sedatives to keep them comfortable and to facilitate treatment when in intensive care. A systematic review reported that there was a substantial incidence of sub-optimal sedation in people in intensive care unit (ICU) with a greater tendency toward over-sedation.

1.3 Current management

Adults who need sedation in intensive care are sedated using IV sedatives and analgesics, primarily propofol or midazolam with alfentanil or morphine. Children in intensive care usually have sedation with IV midazolam and morphine or fentanyl.

The Intensive Care Society's 2014 (update to be published in 2021) review of best practice for analgesia and sedation in ICU states that there was insufficient evidence to recommend a particular sedation regimen and that the type of sedation should be individualised to the patient's requirements and situation. However, it also notes that the current evidence supports modest benefits in outcomes with non-benzodiazepine based sedation versus benzodiazepines.

The guideline also states that there are difficulties in delivering and scavenging volatile anaesthetics. There are also concerns about fluoride accumulation (with sevoflurane use) and the dependency of ventilation. Delivery devices, such as AnaConDa-S, as well as scavenging systems, make using isoflurane and sevoflurane in intensive care safer for staff. Isoflurane has shown safe, effective sedation for up to 96 hours in small studies, with faster awakening than midazolam. Isoflurane has shown improved awakening to propofol. Isoflurane is also a potent bronchodilator and is valuable in treatment for status asthmaticus.

AnaConDa-S is for use by healthcare professionals, trained to use inhalational anaesthetic drugs and recognise and manage any adverse effects, in an intensive care setting. In the NHS this would likely be intensivists and intensive care nurses. Usually sedation parameters (such as Fet% and MAC) would be set by an intensivist and modified if needed by nurses. Administration of isoflurane and sevoflurane using AnaConDa-S should only be done in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function.

The following publications have been identified as relevant to this care pathway:

- BNF treatment summary on anaesthesia (general).
- BNF for Children treatment summary on anaesthesia (general).
- Sedation for patients in ICU. Intensive Care Society Guideline.
- Medication concentration in critical care areas. Intensive Care Society Guideline
- British guideline on the management of asthma. British Thoracic Society and Scottish Intercollegiate Guidelines Network
- Guidelines on the Management of Acute Respiratory Distress Syndrome (ARDS). The Faculty of Intensive Care Society and Intensive care Society, supported by British Thoracic Society.

1.4 Regulatory status

The AnaConDa-S received a CE mark in February 2017 as a class IIa device under the EU MDD 93/42/ECC.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Shorter, more predictable wake up time after ICU sedation and avoidance of slow sedative excretion and slow emergence from sedation
- Reliable, sustainable sedation efficacy (comprised of time to extubation, proportion of time within desired sedation level, titration ability)
- Potential reduction in markers of cardiac, liver, gut, kidneys and brain injury
- Effective sedation in patients with life-threatening bronchospasm and asthma
- Improved oxygenation through improved gas exchange
- Improved cognitive recovery/psychological outcomes (e.g. reduction in memories of hallucination, and long-term psychological morbidity)
- Improved maintenance of spontaneous breathing, resulting in preserved respiratory muscle function

- Reduced dose and less frequent use of opioid administration

The benefits to the healthcare system claimed by the company are:

- Shorter duration of mechanical ventilation and increased ventilator-free days
- reduced length of stay in the ICU and in hospital
- Reduced costs compared with IV sedation
- Reduction in staff time for daily IV sedation interruption and sedative administration.

The sustainability benefits claimed by the company are:

- Reduction in volatile anaesthetic use via the anaesthetic conserving function of AnaConDa-S.
- Replacement for the need of a 'wet circuit', its associated consumables and energy resource requirements.

2 Decision problem

Population	People who are invasively ventilated in intensive care using a mechanical ventilator but not a high frequency ventilator.
Intervention	AnaConDa-S AnaConDa (previous version)
Comparator(s)	IV sedatives Standard vaporiser
Outcomes	The outcome measures to consider include: • wake-up time after ICU sedation • cognitive recovery • sedation efficacy (time to extubating, proportion of time within desired sedation level and titration ability using the Richmond Agitation-Sedation Scale) • markers of cardiac injury, liver, gut, kidneys and brain for short-term operative sedation • sedation effectiveness in patients with life-threatening bronchospasm and asthma • oxygenation and inflammatory markers in patients with ARDS

	• psychological outcomes (e.g. memories of hallucination, and long-term psychological morbidity, PTSD) • Effectiveness of ventilation on people with bronchoconstriction • Reduction of additional bronchodilators • duration of mechanical ventilation/ increased ventilator-free days • length of stay in the ICU. • hospital length of stay/ hospital-free days. • Amount of volatile anaesthetic agent used • Staff exposure to volatile anaesthetic agents • Staff time in the ICU • Amount of opioid drug used • Device-related adverse events.
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• People with acute asthma that need to be mechanically ventilated. • People with acute respiratory distress syndrome that need to be mechanically ventilated • Children that need to be mechanically ventilated • Patients who need to have regular neurological wake up tests performed. • People who are intolerant to IV sedation (e.g people who misuse alcohol, people who misuse drugs, people on overdose, people with COVID-19) • People with hepatic and renal failure • People with super-refractory status epilepticus • People under prolonged sedation who need an IV sedation break (due to being at risk of developing tolerance, tachyphylaxis and/or propofol infusion syndrome)
Special considerations, including those related to equality	Volatile anaesthetics may not be suitable for pregnant women. Volatile anaesthesia may particularly benefit children for whom sedation is difficult. Volatile anaesthesia may benefit elderly people who are considered vulnerable to excess or insufficient sedation, due to their reduced ability to eliminate and excrete drugs, may benefit from this technology through sedation becoming more easily monitored and titrated. Pregnancy and age are protected characteristics under the 2010 Equalities Act.

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
	AnaConDa-S has been significantly reduced in the volume of the device compared to the original AnaConDa device. This allows it to be used in children and young people with small/minute tidal ventilation. Age is a protected characteristic under the Equality Act 2010.	
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Bronchial thermoplasty for severe asthma (2018) NICE interventional procedure guidance IPG635.
- Extracorporeal membrane oxygenation for severe acute respiratory failure in adults (2011) NICE interventional procedure guidance IPG391.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Academic Paediatrics Association of Great Britain and Ireland
- Anaesthetic Research Society
- Association for Paediatric Emergency Medicine
- Association of Anaesthetists
- Association of Anaesthetists of Great Britain & Ireland
- Association of Paediatric Anaesthetists of Great Britain and Ireland

- Neuro-Anaesthesia and Critical Care Society of Great Britain and Ireland
- Royal College of Anaesthetists
- Paediatric Intensive Care Society
- Royal College of Paediatrics and Child Health
- Intensive care society
- British Paediatric Respiratory Society

