Healthcare Improvement Scotland | SHTG Advice on health technologies

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Innovative Medical Technology Overview:

Airglove for supporting vasodilation in patients where cannulation is difficult

Key points

- For some patients receiving systemic anti-cancer therapies, cannulation may be difficult. In such instances, warming the arm aids vasodilation and facilitates cannulation.
- There is no standard practice for inducing vasodilation and often patients' arms are immersed in warm water. This leads to inconsistency for patients, and may carry risk of burning and infection.
- Airglove is an alternative that can be used to heat the arm consistently using warm air.
- The evidence base for the effectiveness of Airglove consists of two oncology service audits, one NICE MedTech Innovation Briefing and one unpublished trial in healthy individuals.
- Data from two Airglove (n=148) and two warm water heating audits (n=465) showed that Airglove may produce more first time cannulations than warm water heating (mean 85% Standard Deviation 3.9 vs mean 72% SD 8.5).
- The costs associated with the purchase of the Airglove unit and consumables may be offset by resource efficiencies in nurse time spent heating patients' arms depending on current practice of oncology unit.

Technology

Airglove is an air warming system used to support vasodilation and improve access to the veins for the delivery of, via cannulation, medicines such as Systemic Anti-Cancer Therapies (SACT).

The Airglove technology, developed by Green Cross Medico Ltd, consists of a multi-use heating unit and tube containing a heat outlet, and single-patient use disposable double-walled polythene 'gloves'. The system gently heats the patient's lower arm as it forces warm air through a double walled polythene glove, with a choice of three temperature settings (31.5 ^{o}C, 35.5 ^{o}C or 38.5 ^{o}C) depending if a patient's skin type is thin, normal or thick. Heating time is automatically set to 3 minutes, but can be extended to 6, after which the system is automatically switched off. The warmed blood dilates the patient's veins in their arm which allows for easier cannula insertion.

The Airglove is an approved CE marked, Class I (low risk), medical device.

Innovative aspect

The Airglove is the only device specifically designed to aid vasodilation in patients where cannulation is difficult.

Patient group

Airglove was designed for patients who are receiving SACT whose veins are often damaged, collapsed and hidden. This can make cannulation, and delivery of treatment, difficult. Heating the arm increases the temperature of circulating blood and causes vasodilation which aids cannulation in these patients.

Airglove is intended to be used in settings where regular venous access is needed by healthcare professionals, and minimal training will be required prior to use. Although it is more likely to be used in specialities, such as oncology, that encounter patients with hard-to-access veins, it can be used in any clinical setting which requires venepuncture[1].

Current practice: comparators and use in pathway of care

There is no guidance from the Scottish Intercollegiate Guidelines Network (SIGN) or from the National Institute for Health and Care Excellence (NICE) on how to cannulate people presenting with hard-to-access veins[1]. Currently, if a patient presents with veins which are difficult to cannulate, practitioners immerse the patient's arm in a bucket of warm water or use microwavable heat pads to encourage vasodilation. There is no standardisation of time or temperature used. After using these techniques, cannulation is not always successful and patients may be sent home without treatment and asked to present the following day. This has an impact on patient well-being, productivity, appointment times and treatment schedules. In addition, it is difficult to regulate temperatures when warming a patient's arm in this way, and the technique may carry the risk of burning and infection.

Product performance: published data

No trials on the use of Airglove have been published, and there are no records of ongoing trials.

Product performance: local data

Two service evaluations[2,3], one NICE Medtech Innovation Briefing (MIB)[1], and details from one unpublished trial[4] were identified as relevant for this IMTO.

The most recent service evaluation[2] of the Airglove was undertaken in 2019 at the Beatson West of Scotland Cancer Centre. Seventy oncology day-patients consented to the evaluation over a one month period, with 68 patients included in the final report and two missing data. The methodology for recruitment, inclusion and exclusion criteria, was not described. All patients were assessed for level of complexity of cannulation using the validated 'Deciding on Intravenous Access/Venous Assessment Tool', which categorises complexity as either 'routine', 'difficult', or 'expert' cannulation. Fifty-five patients received 1 minute of heating from the Airglove (manufacturer's recommendation is 3 minutes) and heating using Airglove was deemed not necessary in 13 patients. The complexity of the 55 patients who received heating was 14 'routine', 38 'difficult' and three 'expert' cannulations.

Of the 55 patients who received heating from Airglove, 45 were cannulised on first attempt (82%). The complexity of the 10 patients who had a failed first attempt cannulation after heating comprised one 'routine', seven 'difficult' and two 'expert' cannulations. All participants who had a failed cannulation at first attempt were successfully cannulated with further attempts: second attempt (n=6, complexity not described), third attempt (n=3, 'difficult' complexity) and fourth attempt (n=1, 'expert' complexity).

Two previous audits at the Beatson West of Scotland Cancer Centre examined rates of cannulation on first attempt using the comparator method of warm water heating. One audit (n=422) had a first attempt success rate after warm water heating of 78%; the second audit (n=43) had a first attempt success rate after warm water heating of 66%.

The other service evaluation[3] of the Airglove was carried out in an oncology ward in NHS Maidstone and Tunbridge Wells between October and November 2017. Eighty patients, identified by oncology nurses as having known difficulties in cannulation, were included in the evaluation. The report noted that patients were randomly selected, but the selection process was not described. All 80 patients received 3 minutes of heating from the Airglove and 70 were cannulated successfully after just one heat treatment (87.5%). Of the 10 who had a failed first attempt, two had a second failed attempt and one had three failed attempts. There were no data on the other seven patients who had a failed first attempt. Reasons for failed cannulation were veins not being visible, palpable, or being thread-like.

The NICE MIB[1] considered the technology to be innovative and estimated the target population as 20% of patients requiring venous access. The MIB was based on evidence from the NHS Maidstone and Tunbridge Wells service evaluation. A number of potential benefits associated

with using the system were highlighted including: improved patient satisfaction and experience of care, improved successful cannulation rates and reduced time spent on getting venous access. One patient organisation (Chronic Lymphocytic Leukaemia Support Association (CLLSA)) noted that in addition to being time consuming, current cannulation methods for patients with hard-to-access veins were not standardised with regards to the risks to patients, timing or temperature.

One additional unpublished Airglove study[4] had a sample size of n=34 healthy adults. The study compared 3 minutes of lower arm Airglove heating to 3 minutes of warm water heating and reported statistically significantly more vasodilation upon ultrasound scanning (p<0.05).

Safety

In the service evaluation from NHS Maidstone and Tunbridge Wells, two adverse events were reported but no details recorded. The Beatson West of Scotland Cancer Centre evaluation reported that a "few" patients found the Airglove to be tight and painful but no more information was provided.

Economic and cost considerations

The Airglove unit costs £795 and each single patient polythene glove costs £0.80. The manufacturer states that Airglove generates a saving of £2.01 per patient. This estimate is based on an assumption that 75% of SACT patients will be difficult to cannulate and, in the absence of Airglove, will have two unsuccessful cannulation attempts and a third successful cannulation attempt at a consumable cost of £1.45 per attempt. The manufacturers applied this £2.01 per patient saving across Scotland and calculated a saving of £94,536 per oncology unit over a three year period with an outlay of £41,415 for the Airglove and gloves. Over the 29 oncology units in Scotland this would equate to a saving of £913,848 per year. This was based on the assumption that all 29 units had the same capacity and ran 300 cycles of SACT per week. The manufacturers also assumed that Airglove would facilitate cannulation on first attempt 100% of the time.

There are a number of uncertainties with this approach. It ignores current practice of warm water heating which produces a comparable, albeit slightly lower, success rate of first time cannulation. Consumable cost per cannulation in Scotland is £0.40 (based on standard peripheral venous catheter costs for NHSScotland). Expert advice indicates that the average number of SACT cycles per unit in Scotland is approximately 120 per week. The number of difficult to cannulate patients from the Beatson clinic audits has been around 66%, however 75% were heated.

The Scottish Health Technologies Group (SHTG) undertook an analysis to estimate the budget impact and cost implications of using Airglove. The differences in the amount of consumables used and nurse time spent on cannulation when using the Airglove versus warm water heating were estimated and presented separately. The potential costs arising from the use of Airglove were calculated for the following four scenarios:

1. Airglove heating in 100% of patients receiving SACT.

2. Airglove heating restricted to patients deemed as difficult or expert complexity of cannulisation (66% of patients as assessed by the VAT tool based on data from Beatson West of Scotland Cancer Centre report).
3. Airglove heating in a middling scenario of 33% of patients.
4. Airglove heating in patients deemed as expert complexity (4% of patients as assessed by the VAT tool based on data from Beatson West of Scotland Cancer Centre trial).

There was inconsistency in the literature in the amount of time nurses spent heating a patient's arm using warm water. This may have been due to some nurses including the time taken to prepare warm water and clean up after immersion. Estimates ranged from 3-12 minutes. Therefore time costings for 3 minutes, 6 minutes and 12 minutes were presented.

Based on the mean results from trial data it was assumed that the Airglove would facilitate a successful cannulation on first attempt 85% of the time. The remaining 15% of successful cannulations were spread over a second (9%) and third attempt (6%). This was compared to a 78% success rate of cannulation on first attempt using warm water, taken from the largest and most detailed warm water heating audit.

The following assumptions were made with respect to parameters in the consumables model (Table 1):

- An estimation of 180,960 cycles of SACT in Scotland per annum, based on 120 cycles per week for each of the 29 oncology units.
- Total capital cost of £46,110 for the purchase of two Airglove heating units for each oncology ward in Scotland (total of 58 units).
- Consumables cost of £0.80 for each patient receiving heating by Airglove.
- Consumables cost of £0.40 for each cannulation attempt.

The following assumptions were made with respect to parameters in the costing of nurse's time (Table 2):

- Cannulation time of 3 minutes per attempt, to be added to either 3 minutes of Airglove heating, and 3, 6 and 12 minutes of warm water heating.
- Cannulation would be carried out by a band 5 nurse at midpoint of their salary grade.

Table 1: Costs of implementing Airglove and consumables in Scotland compared with warm water heating

Consumables and set up cost	Scenario 1 (100% utilisation)	Scenario 2 (66% utilisation)	Scenario 3 (33% utilisation)	Scenario 4 (4% utilisation)
Airglove	£294,930	£209,620	£128,221	£56,774
Water heating	£91,064	£59,842	£30,051	£3,903
Additional cost year 1*	£203,866	£149,778	£98,170	£52,871
Additional cost year 2, 3*	£157,756	£103,668	£52,060	£6,761

*Note: Additional cost is difference between Airglove consumables and warm water heating consumables. Year 1 cost £46,110 higher as this includes cost of purchasing two Airglove heating units per oncology ward

Table 2: Cost of nursing time using Airglove in Scotland compared with warm water heating

Nursing costs*	Scenario 1 (100% utilisation)	Scenario 2 (66% utilisation)	Scenario 3 (33% utilisation)	Scenario 4 (4% utilisation)
Airglove	£389,443	£255,920	£128,516	£16,690
12 min water heating	£1,010,195	£663,842	£333,364	£43,294
6 min water heating	£606,117	£398,305	£200,019	£25,976
3 min water heating	£404,078	£265,537	£133,346	£17,318

*Note: nurses' time costs vary between Airglove and warm water heating at 3 minutes due to differences in probability of first, second and third time cannulation rates.

The analysis using Scottish specific data suggests that on a financial level Airglove will be cost inducing. If the 66% utilisation rate is used, as this is the rate of difficult cannulations, then it will cost £149,778 to implement in the first year and then £103,668 for consumable costs for the next two years. The Airglove needs replaced every three years so this cycle of costings would repeat.

When resource efficiencies in nursing time are considered these costings may be offset. However there is inconsistency in how long warm water heating is carried out for, with reports ranging from 3-12 minutes. If 6 minutes is considered, at the 66% utilisation rate, then this could generate a time resource efficiency of £142,385 per annum.

In summary, the cost analysis demonstrates that purchase cost of the Airglove unit and consumables may be offset by resource efficiencies generated in nurses' time. This offset should be treated with caution as efficiencies are dependent on the nurse not doing anything during the Airglove or warm water heating. There is a high level of uncertainty around this assumption of 'dead time', particularly in the case of warm water heating due to the uncertainty if time estimates included heating of water and cleaning up. Time for additional processes of setting up the Airglove and waiting for it to heat up were also not included in this analysis but were reported as challenges in the Beatson West of Scotland Cancer Centre evaluation.

Clinician and patient experience, and other considerations

The NHS Maidstone and Tunbridge Wells service evaluation[3] reported that nurses thought that Airglove was easier to use than warm water heating, they could control the temperature effectively and that "several" patients found Airglove to be more comfortable than warm water heating.

The Beatson West of Scotland Cancer Centre evaluation[2] reported that the polythene gloves broke easily and were difficult to re-use on the same patient. Some nurses felt the Airglove was more effective and dilated veins well but expressed challenges in relation to time required for the Airglove to heat up, set-up time between patients and re-application in a high turn-over

oncology unit. The report stated that a “few” patients found the Airglove to be tight and painful.

The Airglove manufacturer provided records of testimonials from clinical staff in oncology units and radiographers, all of which were positive.

Airglove use has also been trialled in a nuclear medicine and PET scan unit in a hospital in NHS Greater Glasgow and Clyde. Heating was deemed necessary in a significantly lower number of patients compared to the oncology units: 3.5% over a 3-week period. SHTG queried the difference in utilisation rate with the manager of the PET scan unit. It was explained that the difference in percentage of patients needing heating was likely due to people presenting for a scan at earlier stages in their disease and not having damage to their veins from SACT.

Conclusions

The Airglove is the only device specifically designed to aid vasodilation in patients where cannulation is difficult. Currently there is no standard of practice to vasodilate veins of patients in an oncology unit. Audit results suggest that it is well liked by health practitioners due to the convenience and effectiveness in vasodilation.

In two local service evaluations, use of Airglove led to a comparable but slightly higher rate of first-attempt cannulation compared with warm water heating. It is important to note that the warm water heating comparison data were from separate audits and comparisons should be interpreted with caution.

Results of a cost analysis showed that the capital and consumable costs of Airglove will be cost inducing but these costs may be offset by resource efficiencies in nursing time. Assumed resource efficiencies should be treated with caution due to the nature of ‘dead time’ during heating — where nurses are not freed up to carry out other tasks — and the uncertainties around estimation of relative heating times between Airglove and comparator techniques.

References

1. The National Institute for Health and Care Excellence. Airglove air warming system for venous access. Medtech Innovation Briefing. 2018 Available from: https://www.nice.org.uk/advice/mib151/resources/airglove-air-warming-system-for-venous-access-pdf-2285963511591877
2. The Beatson West of Scotland Cancer Centre, NHS Greater Glasgow & Clyde. Trial and audit of Airglove device with venous assessment tool prior to cannulation and commencement of systemic anti-cancer therapy. [Unpublished] 2019
3. Service evaluation of the Airglove Patient Warming Device, NHS Maidstone and Tunbridge Wells [online]. 2017 Available from: http://www.greencrossmedico.com/wp-content/uploads/2018/01/Patient-Evaluation-Final-Report-030118-1.pdf
4. Report for GCM – summary of final trial results GCU & participant satisfaction surveys. Cruz et al. (Green Cross Medico Ltd. Personal communications, 23 June 2019)

What is an Innovative Medical Technology Overview (IMTO)

An IMTO is a high-level, light-touch summary of the evidence surrounding an innovative technology. An IMTO seeks to offer an early indication of the strengths and weaknesses of the technology, with a view to contributing to local decision-making by NHS health professionals, managers and procurement colleagues.

IMTOs do not contain recommendations. IMTOs should be considered alongside existing guidance applicable to NHSScotland.

All new and innovative technologies need to have been registered on the NHSScotland Health Innovation Assessment Portal (HIAP).