# A clinical audit to assess the efficacy of the Coolsense® Pain Numbing Applicator for intravenous cannulation in children

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**Summary**

The Coolsense® device is a topical applicator that is used to anaesthetise the skin before a painful procedure. It is a handheld device with a temperature-controlled head that acts on application, without chemicals, to cool and anaesthetise the site of injection. This prospective observational audit of 100 children and adolescents aged six to 18 years studied the analgesic efficacy and patient and carer satisfaction rating of the device during intravenous cannulation and complications arising from its use. The audit demonstrated effective skin analgesia for intravenous cannulation in children and adolescents. Ninety-four percent of patients rated the pain during cannulation as less than or equal to three on a numerical pain rating scale of zero to ten. Patient and carer satisfaction with the device and cannulation success rates were high; 66% of patients and 82% of carers 'really liked' the device and 28% of patients and 12% of carers 'liked' it. Ninety-five percent of patients were cannulated on the first attempt. The incidence of complications using the device was low. The Coolsense device appears to be a useful tool that provides effective analgesia for intravenous cannulation in children with minimal complications. Comparative studies with topical local anaesthesia creams are warranted.

**Key Words:** child, adolescent, analgesia, intravenous, cannulation, device

## Introduction

The Coolsense® Pain Numbing Applicator (Coolsense Pty Ltd, Tel Aviv, Israel) (Figure 1) is a recently licenced Therapeutic Goods Administration, US Food and Drug Administration and European Commission approved topical skin numbing applicator that is used to anaesthetise the skin before needle penetration. It is a hand-held device with a head that is temperature-controlled by an electronic component. It acts upon application, without chemicals, to cool and anaesthetise the site of injection. Topical applications of cold materials such as oils, volatile agents, ice and, more recently, vapocoolant sprays, have been used historically for skin anaesthesia, but either control of their application has been difficult or results have been inconclusive[1,2].

The Coolsense device is easy to operate and has been used for many potentially painful skin procedures including skin pricks for blood glucose measurement in adult diabetic patients[3], immunisations and botulinum toxin injection[4]. Its clinical use in children has not previously been studied.

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Accepted for publication on November 29, 2016

Figure 1: The Coolsense® device.

Topical local anaesthetic creams such as eutectic mixture of local anaesthetic (EMLA) cream or amethocaine cream have been successfully used to anaesthetise the skin before painful skin procedures in children[5] but these require significant time before the local anaesthetic is effective and require staff to assess the site of injection and apply the cream and occlusive dressing. Topical creams also requires the operator to be successful within the area of application without the ability to immediately move to another site if unsuccessful. The Coolsense device has the advantage of taking less than 15 seconds to work, as well as allowing the operator to choose the best site for cannulation. Setup and application time for this device is short, making it useful in time-pressured situations such as emergencies or when children are anxious. As we had recently introduced the Coolsense device into our practice, we conducted an observational audit to investigate if the Coolsense device is an effective tool for providing skin anaesthesia to reduce pain during intravenous cannulation in children.

## Materials and methods

The audit was approved by the Royal Children's Hospital research ethics committee (HREC 34223B) and written consent was obtained from carers and assent from patients before inclusion in the study. The study was a prospective observational audit. One hundred patients aged six to 18 years undergoing intravenous cannulation for anaesthesia or the administration of contrast for magnetic resonance imaging (MRI) studies were recruited. Children and adolescents were cannulated by either anaesthesia staff or radiographers skilled in intravenous cannulation as per routine practice in our institution.

Children less than six years were excluded as they were unlikely to have the numerical competency to use the numerical pain rating scale (NRS). Children deemed by their carer as unable to rate pain using the NRS at the time of recruitment were also excluded.

The Coolsense device consists of two pieces: a base piece with metal rod and a cover with pre-filled alcohol disinfectant that can be replaced when empty (Figure 2). The device was retrieved from the operating theatre or MRI department freezer within 10 minutes of its intended use and the device checked to ensure that it was at an appropriate temperature. For this purpose the device has a colour indicator with a light that is either red (too warm for effective use), blue (too cold for safe use) or green (ideal temperature for use). The green light is indicated when the device is between approximately 0°C and -4°C.

A device placed in a freezer for 20–30 minutes would usually reach the desired temperature and a device out of the freezer for 20 minutes would usually be too warm for effective use.

It is important that the device is used at an appropriate temperature at the time of application and that it is stored in a freezer that limits the temperature to between 0 and -10°C. Industrial freezers would be unsuitable as retrieving the device would expose the user and patient to cold burn risk. The device colour indicator in this circumstance would be blue, indicating it is too cold for safe use.

Figure 2: The Coolsense® device in two sections showing the metal rod and replaceable cover.

The metal rod that resides in the replaceable cover of the device was checked prior to application on the skin to ensure there was a covering of the liquid alcohol solution. If the rod is dry, the liquid may have been exhausted or the sponge inlay needs to be soaked by depression of the top spring plunger. Using the device without the liquid film may precipitate a cold burn. The device was applied for approximately ten seconds, as per the manufacturer's instructions, to minimise cold stress to the skin. The patient was encouraged to notify the user at any time if they experienced discomfort during device application.

After following these recommended instructions for use, the treating practitioner performed venous cannulation.

For this study, the primary outcomes sought were pain scores using an NRS from zero to ten by both the patient and carer (if present), satisfaction scores by both patient and carer (if present), ease of cannulation, and success or failure

of cannulation. Secondary outcomes included complications sustained due to use of the device.

At the time of cannulation the patient and carer were separately asked to rate the pain score from zero to ten. The level of satisfaction as determined by the five-point Likert Scale (really liked it, liked it, neither liked nor disliked it, didn't like it, really didn't like it) and whether they would use the device again were assessed. Pain scores less than or equal to three and positive Likert scores by 80% of respondents were considered successful.

The practitioner inserting the intravenous cannula was asked about the ease of cannulation as determined by vein visibility and palpability before and after application of the device: easily visible and palpable, visible but not palpable, or poorly visible or palpable. The success or failure of the cannulation and the presence of complications, if any, were recorded. We specifically sought immediate or delayed pain, erythema, sustained blanching, urticaria and pruritus. In addition, the patient was asked if they had any comments about the procedure including skin irritation or discomfort.

Other data collected included demographics (age, weight and sex of the patient) as well as the site of cannulation and the gauge of the intravenous cannula used.

Descriptive statistics as percentages were used for most of the data. Paired variables were compared using chi-squared analysis (Stata 14, StataCorp LP for Windows). A *P* value of less than 0.05 was considered significant.

## Results

We recruited 100 patients; there was an equal distribution of males (50%) and females (50%), with a median age of 12 years (interquartile range, IQR = 6), and a median body weight of 45 kg (IQR = 26.5).

Twenty-eight percent of the children reported no pain with an NRS score of 0. Mild pain, as defined by an NRS score of 1 to 3, was reported by 66% of children, and moderate pain, with an NRS score of 4 to 6, was reported in 5% of children. Severe pain, with an NRS score of 7, was reported by one child (1%).

Fifty-three percent of the carers, usually the accompanying parent, observed that the procedure had been painless for their child with an NRS score of 0, while 44% felt that there had been mild pain, and 1% observed that cannulation had been moderately painful. Two carers (2%) reported observing severe pain. One carer was not present for the cannulation.

Satisfaction scores were recorded along a five-point Likert scale and 66% of patients 'really liked' the use of the device, 28% 'liked it' and 5% were ambivalent. One child (1%) did not like it, but we were unable to ascertain the reason for it.

Eighty-two percent of the carers 'really liked' the device, 12% 'liked it' and 4% were ambivalent. There were none who disliked it and one carer (1%) was not present for the cannulation.

Table 1

*Cannulation details*

| Cannulation practitioner | Successful at first attempt, n (%) | Unsuccessful at first attempt, n (%) |
|---|---|---|
| Anaesthesia consultant | 6 (6) | 0 (0) |
| Anaesthesia fellow | 4 (4) | 0 (0) |
| Anaesthesia registrar | 1 (1) | 1 (1) |
| Anaesthesia technician | 2 (2) | 0 (0) |
| Radiographer | 82 (82) | 4 (4) |
| Overall success at first attempt | 95 (95) | 5 (5) |
| **Appearance of vein after Coolsense application** | **Successful at first attempt, n (%)** | **Unsuccessful at first attempt, n (%)** |
| Easily visible and palpable | 80 (80) | 4 (4) |
| Visible not palpable | 9 (9) | 1 (1) |
| Poorly visible | 6 (6) | 0 (0) |
| **Size of cannula** | **Successful at first attempt, n (%)** | **Unsuccessful at first attempt, n (%)** |
| 24G | 35 (35) | 2 (2) |
| 22G | 60 (60) | 3 (3) |
| **Site of cannula** | **Successful at first attempt, n (%)** | **Unsuccessful at first attempt, n (%)** |
| Hand | 9 (9) | 1 (1) |
| Forearm | 10 (10) | 0 (0) |
| Cubital fossa | 76 (76) | 4 (4) |

Thirty-four percent of the children had previous cannulation with the Coolsense device being used. Of the 100 patients in this cohort, 97% said they would want the Coolsense used for subsequent cannulations. The other 3% who said they would not, had no documented reasons for their preference. Of note, all three had successful cannulations on the first attempt and two of the three had low (1–3) NRS scores.

The role of the cannulating practitioner, the number of patients cannulated at first attempt and the visibility of the vein after application of the Coolsense device are shown in Table 1.

After application of the device, no clinically significant change was observed in the visibility or palpability of the

Table 2

*Complications after application of Coolsense®*

| Complications | n (%) |
|---|---|
| Nil | 92 (92) |
| Delayed pain | 0 (0) |
| Erythema | 3 (3) |
| Raised welt | 0 (0) |
| Itching | 0 (0) |
| Transient blanching | 5 (5) |

vein. Of the five cases where cannulation was not successful on the first attempt, four were in cases where the vein was visible and palpable. In the remaining case, the vein was visible but not palpable. Four were successfully cannulated on the second attempt, and one on the third attempt. In all six patients where the vein was poorly visible, cannulation was successful on the first attempt. There were no complications in 92 cases (92%) (Table 2).

## Discussion

The Coolsense device resulted in effective analgesia for intravenous cannulation in children and adolescents. Ninety-four percent of patients rated their pain as less than or equal to three. These findings were encouraging given the difficulties or inconclusive success rates with topical cooling techniques previously studied[1,2]. The Coolsense device is easy to handle and this makes it more likely to be successful in providing skin analgesia for the relatively novice user.

Effective analgesia can also be achieved using topical local anaesthetic creams such as amethocaine or EMLA[5]. Proposed advantages of the Coolsense device over the topical creams include the marked reduction in time before effective analgesia is achieved (15 seconds versus 30–60 minutes), the labour required to identify a suitable vein and apply local anaesthesia cream and the cost saving from not needing to apply an occlusive dressing. Application of the cream is often performed by staff not involved with the cannulation who may place the cream in a suboptimal location, i.e. not over a vein. The Coolsense device has the added advantage that should the chosen vein(s) be unsuitable or the attempted cannulation unsuccessful, then the device can simply and immediately be applied to another site. With topical cream this is not an option unless an alternative site has had cream applied or more time (30–60 minutes) is available for another application. Removal of creams and dressings also has the disadvantage of potential discomfort and distress, in addition to oily skin making it difficult to secure cannulas. Some children are also sensitive to the creams and may develop skin complications such as erythema, oedema and itching[7].

Another advantage of the Coolsense device is its relatively low cost. The device can be used on multiple patients (the manufacturer recommends 100 uses before the replaceable alcohol-containing cover is exhausted). This compares favourably to the cost of topical local anaesthetic creams and occlusive dressings.

Patient satisfaction using the Coolsense device was high with the majority of Likert scores (94%) indicating that patients 'really liked' or 'liked' the device. All but three children would have the device again. This may be explained by the satisfactory analgesia that was achieved with the device. Another reason might be that the child was able to avoid having local anaesthesia cream applied. We suspect that wearing local anaesthesia cream may generate anxiety related to the anticipation of the cannulation to come. The instantaneous nature of the application of the Coolsense device at the time of cannulation may reduce this anxiety and improve satisfaction.

The majority of cannulations were performed by radiographers (82%) and the success rate was high for this study. This may reflect the skills of practitioners, both in radiology and anaesthesia, employed at a tertiary paediatric centre. However, as 95% of patients were cannulated at first attempt, this suggests that the device does not significantly compromise the ability to successfully insert a cannula. This compares favourably with another study in which the success rates for intravenous cannulation using local anaesthetic creams (amethocaine and EMLA) in a tertiary centre was 75 and 74 percent respectively. One of the potential problems with cooling the skin above the vein to be cannulated is the vasoconstriction that might occur. This was not an issue as the vein in most cases (84%) was easy to see and palpate after application of the device and no significant change in the visibility or palpability of the vein was seen after using Coolsense.

There were limitations of this observational audit and one was not having a control group to compare efficacy. As the standard of care for intravenous cannulation has been to attempt to anaesthetise the skin with local anaesthesia creams, a controlled trial comparing these techniques would be useful. Also our audit included children and adolescents who had previous experience with the device which may have introduced either a positive or negative bias on pain and satisfaction scores; patients who had previously experienced little or no pain may have anticipated good analgesia with the result that reported pain scores with repeat exposure may have been higher if their expectations were not met. On the other hand, pain scores may have been lower if their anticipation of pain with cannulation was reduced given their positive past experience.

Care must be exercised in interpreting the satisfaction scores in this study. If a child was anxious about cannulation, he or she may have been less likely to give a favourable Likert rating to the device. The scores by carers may also reflect their own experiences and potentially introduce bias to observations of their child's reaction.

Our study demonstrated a low incidence of complications with only erythema of the skin and transient blanching being reported. Nevertheless the device has the potential to cause morbidity related to cold burn if not used appropriately with attention to the recommended instructions for use[4].

## Conclusion

In conclusion, the Coolsense device appears to provide satisfactory analgesia for venous cannulation in children and adolescents in our institution. As currently the use of topical local anaesthetic cream is probably the most

commonly used strategy for anaesthetising the skin prior to inserting needles or cannulae in children, our audit supports a further randomised, controlled trial comparing these two strategies. Our findings may provide useful information for anaesthetists, proceduralists, and other staff performing venous cannulation who are looking to ensure that cannulation in conscious children is painless.

## Disclosures

The authors received no funding for this study and all authors had no conflict of interest.

The distributor of the Coolsense Device, Balance Medical Ltd, provided four of the devices for the purposes of this trial but had no input into the format or conduct of the study.

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