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Improved application of Lidocaine/Prilocaine cream in children. A randomized and prospectively controlled study of two application regimes

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Summary: Intravenous cannulation in children aged 6–12 years is less painful after a 90-min application of a Lidocaine/Prilocaine cream followed by a 30-min interval without cream, than cannulation immediately after a 60-min application.

Background: Sixty-min application of an eutectic mixture of 25 mg g^{-1} Lidocaine and 25 mg g^{-1} Prilocaine cream is widely used in both adults and children to alleviate pain related to intravenous cannulation. However, studies have shown that this is not the optimal procedure in adults. Inspired by the results from these studies, the aim of the present study was to find an improved application regime for children.

Methods: In this prospective, randomized, and single-blind study 60 Caucasian children, aged 6–12 years, presenting for an i.v. cannulation were included. The children were allocated to either a 60-min application of anaesthetic cream followed by i.v. cannulation (Group A) or to a 90-min application followed by an interval of 30 min before cannulation (Group B). No sedatives or analgesics were given. The children scored their pain by a faces scale with four faces.

Results: The i.v. cannulations in Group B were less painful than the cannulations in Group A (Mann–Whitney test, $P = 0.01$). There was no difference between the two groups as regards problems when performing the cannulations.

Conclusion: I.v. cannulation after application of anaesthetic cream for 90 min followed by a 30-min interval is less painful than the widely used 60-min application directly followed by cannulation.

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Key words: Anaesthetics; child; intravenous; lidocaine; local; pain scale; prilocaine.

APPLICATION of an eutectic mixture of Lidocaine 25 mg g^{-1} and Prilocaine 25 mg g^{-1} (anaesthetic cream) is used to relieve pain by intravenous cannulation and other painful procedures of the skin. The manufacturer recommends an application time of 60 min for both adults and children. However, studies in adults have shown that a 60-min application of anaesthetic cream is not the optimal application time for alleviation of the pain (1). Two clinical studies in adults regarding the effect of anaesthetic cream showed that only 64% and 65%, respectively, of the patients had acceptable analgesia by needle insertion after a 60-min application of the cream (2, 3). A better pain alleviation was obtained by using an application time of 90 min followed by an interval of 30 min before the cannulation. Furthermore, the pain threshold depth to needle insertion was increased by increasing the application time from 60 to 90 min, and further increased by a 30-min interval before needle insertion (1).

Anaesthetic cream is more frequently used in children than in adults in order to reduce pain by i.v. cannulation (4–6). Since results and conclusions from studies in adults have been transferred in clinical practice to children of all ages (7), we speculated on what would be the most appropriate application time for anaesthetic cream in children (8).

The aim of the present study was to evaluate whether a 90-min application of anaesthetic cream followed by an interval of 30 min without anaesthetic cream before cannulation is more effective than the often used 60-min application time in terms of reducing i.v. cannulation pain in children aged 6–12 years.

Materials and methods

The study was approved by the Regional Scientific Ethics Committee and the Danish Health Authorities,

and fulfils the Helsinki II Declaration. Before inclusion the parents gave oral and written informed consent, and the children verbally accepted participation in the study.

Study design

The study was randomized, prospective, and observer blinded (as a double-blind design with placebo cream was considered unethical). Sixty children, aged 6–12 years, scheduled for an i.v. cannulation before anaesthesia for an operation or diagnostic procedure (minor surgery, CT scan, MR scan, or renography) were included. To be included the children had to be able to speak and understand Danish, be of Caucasian origin, be ASA (American Society of Anaesthesiologists physical status) I–II, and had to demonstrate an appropriate understanding of the Visual Range Scale used. Children were excluded if allergic to local anaesthetics, if the application times were not respected, or if the occlusive dressing had significantly loosened on both hands. No sedatives or analgesics should be given before the cannulation.

Three of the authors (the three nurse anaesthetists) included the patients, informed the children and their parents, and tested the children's understanding of the Visual Range Scale. All children were told: 'When the magic cream is applied for 1 h, it may only hurt a little. We wanted to find out if it is less painful when the cream is on the skin another half an hour. It is a secret to me how long the cream has been on the skin, and you must not tell me when I cannulate'. The children received the same information orally and on paper written in a language understandable to the children. The nurse anaesthetist explained the four faces pain scale, pointing out that the first face showed a girl or boy afraid of being cannulated but having no pain (see Fig. 1). After having explained the meaning of the different faces, all children were asked questions like: 'which face would you choose for pain caused by a mosquito bite or falling on a road' to test the children's understanding of the faces pain scale. The nurse anaesthetists asked the children after the cannulation to score their pain caused by the needle insertion.

Fig. 1. The neutral 'no pain' faces scale used for pain scoring. Each of the four faces was assigned a rank from 0 to 3.

Anaesthetic cream and cannulation procedure

The anaesthetic cream used consists of an eutectic mixture of 25 mg g^{-1} Lidocaine and 25 mg g^{-1} Prilocaine (EMLA®, AstraZeneca AB, Södertälje, Sweden). The children were randomly allocated to either a 60-min application of anaesthetic cream, followed by i.v. cannulation (the standard procedure) (Group A), or a 90-min application of the anaesthetic cream followed by a 30-min interval without cream before cannulation (Group B). 2.5 g of the cream were applied on the back of each hand (10–16 cm^2) covered by an impermeable occlusive dressing (Tegaderm™, CE 3M, Health Care, Brookings, SD, USA). A parent at home or a nurse at the hospital applied the cream and the dressing. If the parents were considered able to follow instructions, it was carefully explained to them how and when the cream should be applied and at what time they should show up at the hospital. If the parents could or would not apply the cream, the ward nurse applied the cream.

After the 60- or 90-min application a nurse in the ward controlled the dressing. Then the dressing and the cream were removed, and the skin was wiped dry and encircled to be sure that the i.v. cannulation was performed in the anaesthetized area.

The i.v. cannulations were performed in the children's ward or in the day case surgery reception room as planned, but not in the operation theatre, in order to minimize the children's fear of the cannulation. As effective distraction is found to reduce the sensation of pain, the nurse anaesthetists, who were to cannulate, and the nurse from the ward if present during the cannulation, were informed just to comfort but not to distract the child in any way (4). The children were encouraged not to look at their hand while being cannulated. In all cases a parent was present, and in some cases also a nurse from the ward. The nurse anaesthetist, who performed the cannulation and asked about the pain, was blinded to the time of application and removal of the cream. These times were registered by the parents or ward nurse and collected by another nurse.

A 22-gauge (0.90 mm) catheter (Optiva2®, Johnson – Johnson Medical, Italy) was used in all children. An elastic band, less painful than the often used rubber tourniquet, was tightened around the arm to distend the veins before the cannulation. The plastic needle was fixed with a dressing designed for fixation of an i.v. needle, and the children were asked about the pain. The number of attempts of cannulation was recorded as l, 2, 3 tries, or impossible. Ability to see the vein was registered as easy, normal, or difficult.

Pain measurements

The children themselves scored their pain of the cannulation on a Visual Range Scale with four faces – a faces pain scale, starting with a neutral face (9, 10). Only the change of the mouth indicates the growing sadness because of pain (see Fig. 1). A neutral face meant 'no pain', a little more of a sad face 'a little pain', a sad face 'more pain', and a very sad face meant 'very much pain'.

To ensure that the pain scored was due to the insertion of the needle (and not to fear of the procedure) the nurse anaesthetist – just after the cannulation but before asking about the experienced pain – pointed out that the first neutral face showed a boy or a girl who feared a prick with a needle but did not actually feel any pain by the procedure. The children knew the faces from the information given when they were included in the study. The child was then asked to circle the face that showed how much pain he or she felt during the cannulation.

Adverse effects

Local skin reactions such as constriction, blanching, or erythema were not considered adverse reactions but predictable pharmacological effects of Lidocaine and Prilocaine due to vasoconstrictor and vasodilator properties (11, 12). The nurse who removed the anaesthetic cream assessed whether a rash, itching, or skin irritation was present or not.

Randomizing and blinding procedure

Randomization was performed using a computer-generated randomization list created by a person not otherwise involved in the study. The three nurse anaesthetists, who informed and included the children in the study, also performed the i.v. cannulations but were blinded to the application time.

Statistical analysis

The four faces were assigned a rank from 0 to 3. A clinically relevant difference was defined as one face. From our experience with anaesthetic cream we estimated that the 60-min group would comprise an equal number of children scoring 0, 1, 2, and 3. The necessary number of children to be included in the study was calculated based on the assumption that the pain scores in the 90-min group would be distributed as 50% scoring 0, 25% scoring 1, and 25% scoring 2. A power of 90% (1-β, $\beta = 10\%$) and a significance level of 0.05 ($2\alpha = 5\%$) were chosen. Based on these assumptions the number of children to be included was calculated to be 21 in each group. To compensate for children to be excluded 2×30 children were included in the study. The non-parametric Mann–Whitney rank-sum test (two-tailed) for unpaired data was used to evaluate the difference in pain scores between the two groups. Data are presented as median and range in the text. A P-value <0.05 was considered significant.

Results

Sixty children were included. None of the children being eligible declined to be enrolled in the study. Ten children were excluded. Three because of urgent operation or incorrect application time, two because the children were extremely afraid and incapable of co-operating, one because the cannulation was performed at the border of the analgesic area, two because of an erroneous inclusion (age out of the inclusion range), and for two children the pain scores were missing. Thus, 28 children were included in Group A and 22 in Group B.

Groups A and B were comparable as regards age (median 8 years 4 months and 8 years 6 months, respectively), number of planned vs. acute cannulations (24 vs. four in Group A, 18 vs. four in Group B), and gender (boys 15 and 14, respectively, and girls 13 and 8, respectively, in Group A and Group B). In Group A cannulations were carried out due to one renography, one CT scan and three MR scans. The rest of the children were scheduled for minor surgery. In Group B one child was cannulated due to a MR scan, and the rest due to minor surgery. The median value of the application time in Group A was 60 min (range 60–65 min), and the median value of the time from removal of the cream to the cannulation was 2 min (0–12 min). In Group B the corresponding values were 90 min (90–95 min), and the median time for the interval between removal of the cream and the cannulation was 33 min (26–50 min).

Pain scores

There was a statistically significant lower pain score in Group B than in Group A ($P = 0.01$). In Groups A ($n = 28$) and B ($n = 22$), respectively, 25% vs. 50% scored 'no pain', 36% vs. 45% scored 'a little pain', 32% vs. 5% scored 'more pain', and 7% vs. 0% scored 'very much pain', see Fig. 2. If we regard 'no pain' and 'a little pain' as acceptable levels of analgesia, 61% in Group A and 95% in Group B had acceptable analgesia.

Considering only the data of the children successfully cannulated at the first attempt, expecting less

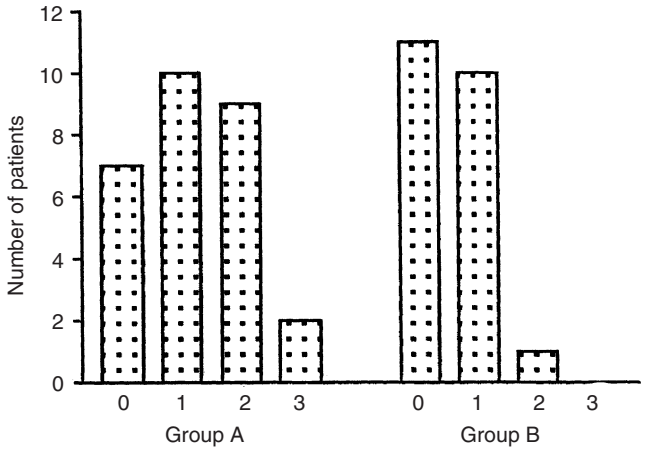

Fig. 2. Pain scores after intravenous cannulation in all patients in Groups A and B. Group A (n = 28): the anaesthetic cream was applied for 60 min, and cannulation was carried out immediately after removal of the cream. Group B (n = 22): the anaesthetic cream was applied for 90 min, and cannulation was carried out 30 min after removal of the cream. The children scored their pain by the neutral 'no pain' faces scale (see Fig. 1). Pain scores were compared by Mann–Whitney rank-sum test. There was a significant difference (P = 0.01) between groups.

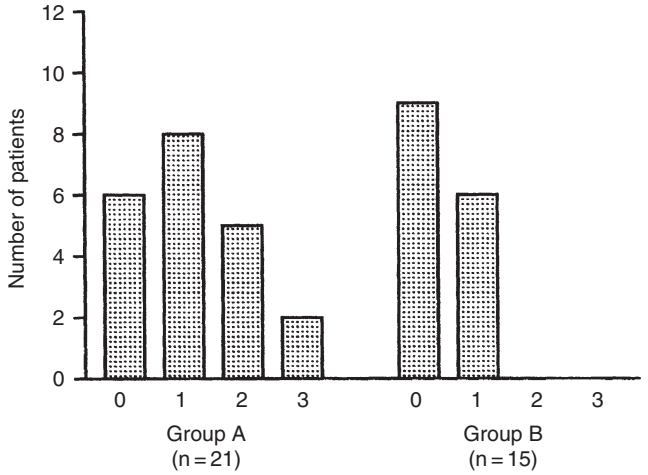

Fig. 3. Pain scores after successful intravenous cannulation at first attempt. Group A (n = 21): anaesthetic cream was applied for 60 min, and cannulation was carried out immediately after removal of the cream. Group B (n = 15): anaesthetic cream was applied for 90 min, and cannulation was carried out 30 min after removal of the cream. The children scored their pain by the neutral 'no pain' faces scale (see Fig. 1). Pain scores were compared by the Mann–Whitney rank-sum test. There was a significant difference (P = 0.02) between groups.

bias caused by anxiety or fear in this group of children, the corresponding scores in Groups A (n = 21) and B (n = 15), respectively, were 29% vs. 60%, 38% vs. 40%, 24% vs. 0%, and 9% vs. 0% ($P = 0.02$), see Fig. 3. Thus, 67% of the children successfully cannulated at first attempt in Group A expressed acceptable analgesia with a pain score of either 0 or 1 vs. 100% in Group B.

Difficulties of seeing the vein and problems with cannulation

The nurse anaesthetists, blinded to the application time, did not find any difference of the skin whether the anaesthetic cream was applied for 60 or 90 min. The ability to see the vein in Groups A and B, respectively, was scored as easy in 61% vs. 50%, normal in 18% vs. 23%, and difficult in 21% vs. 27%. The children were cannulated at the first attempt in 75% vs. 68%, at the second attempt in 7% vs. 27%, and at the third attempt (or impossible) in 18% vs. 5% of the cases. In Group A three children were difficult (third try) and two were impossible to cannulate. In all five children the vein was difficult to visualize. In Group B only one child was impossible to cannulate (no third try), and in this child the vein could not be seen.

Adverse effects

When anaesthetic cream was applied for 90 min, some itching was observed in two children and some rash in one child but the adverse effects disappeared before the cannulation. None with an application time of 60 min had any adverse effects.

Occlusive dressing

The occlusive dressing was applied correctly in most cases. In four cases the dressing had slightly loosened but the nurse in the ward, who reported all four cases, judged it to be of no importance.

Discussion

For years children have been promised painless i.v. cannulation when anaesthetic cream is applied on the skin before i.v. cannulation. Following the standard procedure of a 60-min application, however, some children clearly express a pain sensation during cannulation, even if the impression is that there is no component of fear. It has been shown that nurses underestimate children's pain (13). It is also known that although a child expresses the cannulation as painful, nurses would interpret this reaction of that child as less painful (14). Thus, it may be that the often used standard procedure of 60-min application of anaesthetic cream is not as effective as previously believed. As more efficient application regimes than the standard application have been elaborated in adults, these regimes might also be more effective in

children. Thus, the aim of the present study was to find an improved procedure for application of anaesthetic cream in children.

Duration of application

It is well known that the duration (1, 15, 16) and the site (17) of application of anaesthetic cream are important for a successful analgesic effect. Arendt-Nielsen and Bjerring carried out a study in adults (17), where 2.5 g of anaesthetic cream was applied under an impermeable occlusive dressing for 30, 60, 90, and 120 min on the forehead, right cheek, lower back, cubital fossa, and back of the right hand. Both the sensory and the pain thresholds were determined through laser stimuli, and cutaneous blood flow was measured. Different results were obtained in different skin areas, which were explained by differences in blood flow and differences in epidermal and dermal thickness. Two hours' application of anaesthetic cream was needed for total analgesia in the cubital fossa and on the hand, but 60 min was the best application time on the forehead. If the same dose of anaesthetic cream was applied for 120 min on the forehead, the analgesic effect had declined, probably because of a high blood flow in that area. In the cubital fossa and on the hand, the effect of the anaesthetic cream was delayed. A thick epidermis and a low blood flow could explain its long-lasting effect.

Interval between removal of cream and cannulation

In another study in adults, where 1.25 g of anaesthetic cream was applied on the dorsal side of the middle part of the forearm, optimal circumstances were obtained when the cream was left for 90 or 120 min (in contrast to 60 min) under an occlusive dressing (1). The effect of the duration of the interval between removal of the cream and the cannulation was examined. Intervals of 0, 30, 60, 90, and 120 min were used. Optimal pain reducing effect at a certain application time was achieved after an interval of 30 min, when the application time was 60 or 90 min. This effect was ascribed to continuous diffusion of the active substances in the cream to deeper skin layers.

Clinical studies in adults have shown that when anaesthetic cream was applied for 120 min, the analgesic effect did not increase after removal of the anaesthetic cream (1, 15), but a total sensory block was obtained (16). Such a loss of the sense of touch could be important, particularly in small children and in very frightened children, as they may not even feel the touch of the fingers and the needle before and during the cannulation.

Dose of cream

The back of the hand is probably a more sensitive and painful site for i.v. cannulation than the forearm, which was used in one study (1). In addition, inserting the needle perpendicularly to the skin, as used by Bjerring and Arendt-Nielsen, may be less painful than i.v. cannulation, and it has been found that i.v. cannulation on the hand is more painful than venepuncture in the cubital fossa (19). Thus, as a 'thick' layer (2.5 g) of anaesthetic cream is more effective than a 'thin' layer (0.5 g) in alleviating pain on the back of the hand (18), and we used 2.5 g, a higher dose than used by Bjerring Arendt-Nielsen in one of their studies (1).

Ease of cannulation

In a study comprising adults (11), where anaesthetic cream was applied on the ventral surface of the forearm, the maximum reduction in the cutaneous blood flow (to 62% of the initial value) was obtained after a 90-min application of the cream. Longer application times, however, increased the blood flow up to 150% of the initial value.

Also, the time period following the 90- or 120-min application of anaesthetic cream may be of importance not only for the analgesia, but also for reducing the potential problems of the i.v. cannulation. After removal of the cream a continued diffusion to the deeper skin layers and accumulation of the analgesics here may improve the conditions for cannulation, as Lidocaine and Prilocaine have a late dilating effect on blood vessels in contrast to an early vasoconstriction (11, 12). In the 30-min period after removal of the cream, the vasoconstrictive effect decreases, in addition to the increase in the analgesic effect (11). Theoretically the veins should be more visible in this period, however, comparing the scores of the visibility of the veins in the two groups in our study, no distinctive difference was found.

Pain measurement and the sensitivity of faces pain scale

Pain is difficult to measure in children. Cultural and psychological factors may influence the experience of pain (5, 14). Children of African origin were excluded due to prolonged absorption time of anaesthetic cream (20, 21). The need for analgesics or sedatives was an exclusion criterion as well, as the medicine may influence the scoring of pain (22). We did not register if any of the children had any previous experience with cannulation. However, all children were admitted because of the operation/examination in question, and none of the children had a chronic

disease with several procedures carried out. It was not our impression that previous experience was an important factor.

Because of the element of anxiety we may not reach the aim of a 'no pain' score for all children. Furthermore, the method of pain measurement is complicated and not straightforward. We wanted the children themselves to score their pain. Therefore only children of an age able to make a reliable measurement were included (9, 10). A faces pain scale (Fig. 1) with four faces, as described previously, was used (9, 10). This scale consists of a neutral face as a sign for 'no pain'. A smiling face as a symbol for 'no pain' may give a significant higher pain score than a neutral face (9, 10). If using a smiling faces scale with a neutral face in the middle of the scale, a child who is not feeling the i.v. cannulation painful but is unhappy and anxious by the procedure would tend to use the smiling faces scale wrongly to express feelings instead of pain. The result would be a false higher pain score for 'no pain'. Thus, although less sensitive, we used the four faces pain scale instead of a five faces pain scale, used in some other studies (9, 10), as a five faces pain scale might give an inappropriate greater probability of choosing the face in the middle. Some children gave an outburst, when the needle was inserted and still had a low pain score. The child's own explanation was, 'it didn't hurt, but I feared the cannulation'. When we only consider the cannulations carried out at the first attempt the difference between Groups A and B seems even more pronounced (Fig. 3). This strengthens our conclusion but also indicates that, in spite of our efforts to reduce the children's fear of the cannulation, the results are influenced by a certain 'fear factor', which can not be eliminated. A double-blind trial would have been preferable, but not possible, as the children and the parents would know the application time. A placebo cream in children would be ethically unacceptable (22).

Applicability in praxis

The 2-h procedure by which pain-free or nearly pain-free i.v. cannulation can be obtained is time consuming, but for i.v. cannulations in hospital before, e.g. planned operations or examinations, the procedure is useable without problems. However, in busy clinics and during emergencies this method is of less use and alternatives should be found.

Conclusion

We found that a 90-min application of the Lidocaine/Prilocaine cream, followed by removal of the cream and a 30-min interval before i.v. cannulation, was more effective in alleviating pain during i.v. cannulation than a 60-min application of the cream followed by cannulation.

The optimal interval between removal of the cream and cannulation at a given duration of application is still unknown in children. Due to variations in blood flow of the skin and thickness of the dermis and epidermis (17), future studies regarding this cream used in children should be standardized regarding age groups, application regimes, pain-generating procedures, and the localization of these procedures. Other lines for future research could focus on finding alternative drugs for this purpose.

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