Anaesthetic safety of the Macintosh® oral laryngeal spray device

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Keywords: Macintosh® oral laryngeal spray, local anaesthetic toxicity, anaesthesia

Abstract

Primary hypothesis: A single, maximal hand squeeze of the Macintosh® laryngeal spray atomiser bulb may deliver a toxic dose of local anaesthetic to the oral mucosa of small infants.

Method: Two anaesthetists, A and B, completed 10 single maximal bulb squeezes per individual Macintosh® atomiser (five for each anaesthetist). Seven atomisers in daily use at a children's hospital were tested. Spray volumes were compared between devices and individual anaesthetists, using a repeated measures analysis of variance model.

Results: The mean volume ± standard deviation of 2% lignocaine spray delivered per single maximal squeeze of the seven Macintosh® atomiser bulbs by anaesthetists, A and B, was 0.54 ± 0.7 ml, and 0.31 ± 0.4 ml, respectively. The range was 0.025-2 ml. This is equivalent to 10.8 mg ± 14 mg and 6.2 mg ± 8 mg of lignocaine, respectively. The difference between the two anaesthetists was statistically significant (p-value < 0.0001) and ranged from a maximum of 1.0 ml to a minimum of 0.05 ml.

Conclusion: There is a difference in the amount of local anaesthetic delivered when two anaesthetists use a single maximal squeeze of the Macintosh® spray atomiser bulb from the seven Macintosh® spray devices tested. The dose delivered was not dependent upon the user. In order to prevent a toxic dose being administered, it is recommended that the plastic chamber of the atomiser is filled with a safe dose of local anaesthetic calculated for each child, particularly small infants, before the upper airway is sprayed.

℗ Peer reviewed. (Submitted: 2013-01-14. Accepted: 2013-04-16.) © SASA

South Afr J Anaesth Analg 2013;19(4):212-215

Introduction

Topical anaesthesia may be indicated in certain clinical situations in paediatric anaesthesia. A variety of methods, including the Macintosh® laryngeal spray atomiser, are available to provide topical anaesthesia. At our institution, it was noted that not all of the Macintosh® laryngeal spray apparatus delivered the same predictable volume of local anaesthetic with each squeeze of the atomiser bulb.

Three concerns were addressed in this study. Firstly, is there a difference in the amount of local anaesthetic delivered when two anaesthetists use a single maximal squeeze of the atomiser bulb? Secondly, with any individual Macintosh® spray device, does a single maximal hand squeeze of the atomiser bulb deliver a consistent volume of local anaesthetic? Thirdly, with a single, maximal hand squeeze of the Macintosh® laryngeal spray atomiser bulb, would it be possible to administer a toxic dose of local anaesthetic to the oral mucosa of small infants?

Method

Seven Macintosh® laryngeal spray atomisers, ready for daily use and located in their respective operating rooms (numbered 1-7) at one hospital were individually and sequentially tested by both investigators. After filling the 2 ml plastic chamber with lignocaine 2%, the atomiser bulb was gently and repeatedly squeezed until the local anaesthetic was advanced to the tip of the distal limb of the Macintosh® spray. Care was taken not to expel any solution from the distal limb. The amount of local anaesthetic

expelled with a single maximal bulb hand squeeze was then collected in a 2-ml syringe with the nozzle capped off. The volume expelled was then measured, agreed upon by both anaesthetic investigators, A and B, and then recorded. The maximal hand squeeze sequence was repeated five times with each of the seven Macintosh® spray apparatus by both anaesthetists. Thus, 10 single maximal bulb squeeze readings per individual Macintosh® atomiser (five for each anaesthetist) were recorded and statistically analysed.

Statistical method

Spray volumes were compared between devices and anaesthetist using a repeated measures analysis of variance (ANOVA) model. Factors were included in the model to adjust for variance owing to device, anaesthetist, squeeze repetition and the interaction between the device and the anaesthetist. When the ANOVA model indicated statistically significant differences because of the model factors, pairwise comparisons were made among the factors using Student's t-test with Tukey's correction for multiple comparisons. A p-value of less than 0.05 was considered to be statistically significant. Logarithmic transformation was used to maintain the normality of the ANOVA model residuals. Spray volumes are presented as mean ± standard deviation.

Results

The volume of 2% lignocaine spray delivered per single maximal squeeze from the seven Macintosh® atomiser bulbs by an anaesthetist with glove size 8 and 6.5 was 0.54 ± 0.7 ml, and 0.31 ± 0.4 ml, respectively. This is equivalent to 10.8 mg ± 14 mg, and 6.2 mg ± 8mg of lignocaine, respectively. The difference between the two anaesthetists was statistically significant (p-value < 0.0001) and ranged from a maximum of 1 ml to a minimum of 0.05 ml.

A statistically significant difference in spray volume was found among the Macintosh® devices (p-value < 0.0001), and was not dependent upon the user (interaction term, p-value < 0.12). Pairwise comparisons among the devices indicated that the devices delivered different volumes from one another, with the exception of devices in operating rooms 3 and 6, which were not statistically significantly different from each other (p-value < 0.7). The potentially important clinical implications were differences in volumes, ranging from a minimum of 0.02 ml to 1.49 ml.

Delivered spray volumes were consistent among the five spray measurements, within each user and device (p-value < 0.52). Average volumes for each device and user are shown in Table I.

Discussion

This simple descriptive bench study highlights the potential dangers of the Macintosh® laryngeal atomiser spray which is widely used in paediatric anaesthesia, particularly in the developing world. As far as we are aware, no previous study has investigated how much local anaesthetic spray is delivered by a single hand squeeze of the Macintosh® atomiser spray by anaesthetists with different body morphology. In our study, anaesthetist A was male and one-metre-eighty-centimetres tall and weighed 82 kg, while anaesthetist B was female and one metre-sixty-centimetres tall and weighed 54 kg. This study does not show that hand size determines squeeze strength, as no attempt was made to measure grip strength in the two anaesthetists.

Plasma pharmacokinetic studies in children have shown rapid absorption of local anaesthetic agents from the mucosa of the upper and lower airway.[1-4] The safe dose for lignocaine, topically applied to the oral mucosa and airway in children older than three years of age is 5-7 mg/kg, provided it does not exceed an upper limit of 175 mg/m^2, and is gradually delivered over a minimum period of 15 minutes.[3] If more lignocaine is required, then it should be administered in small incremental doses, up to a maximum of 8.5 mg/kg, administered over at least 45 minutes.[3] Whittet et al showed that local anaesthetic is absorbed faster with a dry oral mucosa in children who are younger than two years of age, particularly when glycopyrolate or atropine have been administered.[2] The dose of topical lignocaine should be reduced in these circumstances.

The wide variation of administered local anaesthetic dose that was recorded in this study can be accounted for by the different user and the individual atomiser. The large difference in the measurement of a single squeeze of the atomiser bulb of the Macintosh® spray that was delivered by each individual is potentially hazardous. One atomiser (in operating room 2) delivered 2.02 ml ± 0.6 ml, and 1.0 ml ± 0.5 ml, when squeezed by anaesthetists A and B, respectively. This equates to 44 mg ± 1.33 mg, and

Table I: Millilitres delivered per single squeeze of the atomiser bulb (mean ± standard deviation) delivered by anaesthetist A and B, using the Macintosh® spray from the seven operating rooms

Operating rooms	1	2	3	4	5	6	7
A	0.9 ± 0.1	2.02 ± 0.08	0.12 ± 0.04	0.28 ± 0.2	0.38 ± 0.04	0.1 ± 0	0.025 ± 0
B	0.66 ± 0.9	1 ± 0	0.07 ± 0.03	0.14 ± 0.5	0.24 ± 0.05	0.05 ± 0	0.025 ± 0

A: first anaesthetist, B: second anaesthetist

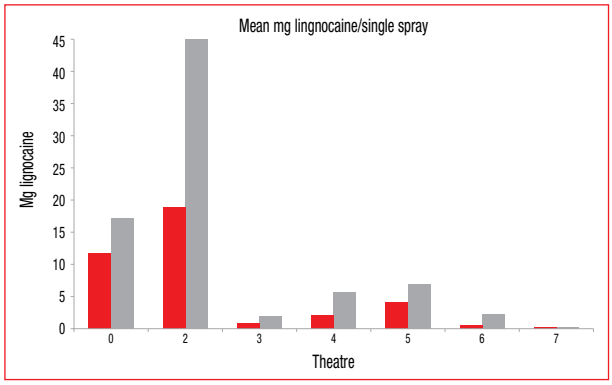

Figure 1: Mean local anaesthetic dose per single hand squeeze by anaesthetist A and B from each Macintosh® spray from each of the seven operating rooms

20 mg ± 10 mg, 2% lignocaine, respectively. The Macintosh® spray from operating room 2 in our study was found to be a dangerous outlier (Figure 1). This amount, inadvertently delivered to the oral mucosa of a 3-5 kg child for example, is well above what is considered to be a maximum safe dose of lignocaine in children (5 mg/kg), and is potentially life-threatening.[1] On closer inspection, the plastic chamber of the Macintosh® atomiser spray from operating room 2 revealed a small hairline crack in the plastic chamber, which probably influenced the amount of lignocaine that could be expelled from the chamber with one squeeze of the atomiser bulb.

The exact dose delivered is very relevant in the clinical setting. We have shown that factors that affect the volume of the local anaesthetic delivered include the squeeze of the atomiser bulb by an individual anaesthetist, as well as the individual atomiser. There was very little variability between the two anaesthetists for five of the measurements, indicating that the devices were consistent. The compliance of the rubber bulb may also vary with age and use, and thus impact on delivery. Other factors that may have contributed to the variability of the delivered dose include different-sized plastic chambers on the atomiser, different sizes and lengths in the proximal and distal tubing that connects to the atomiser, as well as the integrity of this tubing and that of the plastic chamber of the atomiser. To simulate clinical conditions as much as possible, no special inspection or extra cleaning was performed before testing was carried out on the seven Macintosh® laryngeal spray devices. Each device was tested sequentially by anaesthetist A and B, and we do not believe that user fatigue was a factor in this study.

Furthermore, in the clinical setting, invariably more than one squeeze is used. Extrapolating from the results of our study, and by adhering to the accepted safe limits of topical lignocaine in children, it can be seen that any child weighing 6 kg or less would be at risk of toxicity if more than one squeeze was used, or from even a single squeeze from the faulty Macintosh® spray (in operating room 2). The results of this study prompted withdrawal of the faulty atomiser. Regular checks of the remaining Macintosh® atomiser apparatus have been instituted.

Inflammation of the oral mucosa may increase the absorption of local anaesthetic. Markedly elevated plasma lignocaine levels have been described in an adult with oral candidiasis after receiving topical lignocaine.[5] Detectable plasma levels of lignocaine 0.2 µg/ml have been described in patients following a bone marrow transplant, where 2% lidocaine was used as a mouthwash to help relieve the pain of oral mucositis. By contrast, plasma local anaesthetic levels were not detectable in control patients.[6] Mucosal inflammation, following recent upper respiratory tract infections in children, may also increase absorption and potentially increase plasma levels, but this has not been studied. In the developing world, the prevalence of mucosal inflammation may be as high as 13-39% in children with human immunodeficiency virus/acquired immune deficiency syndrome, oral candidiasis and other oral lesions.[7,8] These children may be at additional risk.

These findings are of particular importance to anaesthetists practising in the developing world, where the use of topical anaesthesia is still widely used. Muscle relaxants to facilitate intubation are often unavailable in many rural medical facilities. Topical anaesthesia is used to facilitate intubation and obtund the coughing reflex. Unfortunately, Macintosh® sprays have a limited lifespan in these often austere environments and eventually break. They are invariably repaired in-house with bulbs, plastic chambers, or replacement tubing that was not originally designed for the device. Inadequate attention to recalibration follows.

Limitations of this study include non-blinding of the measurements. In clinical practice, the amount of drug drawn up in a syringe is checked by one or more clinicians or nurses before administration. The aim was to simulate the clinical setting as far as possible. The second limitation was that the volume of lignocaine was not measured with a micro pipette. Again, in keeping with adherence to the clinical setting, it was considered that since the submarking of each 2-to 3-ml syringe was 0.1 ml, the readings would, at most, be inaccurate at a level of 0.05 ml. These 2- to 3-ml syringes are used daily by most paediatric anaesthetists.

Conclusion

The three concerns that were addressed in this study have been answered. There is a difference in the amount of local anaesthetic delivered by different anaesthetists. For each Macintosh® spray device tested, the dose delivered by a single maximal hand squeeze of the atomiser bulb was variable and was not dependent upon the user. A single, maximal hand squeeze of the Macintosh® laryngeal spray atomiser bulb can deliver a toxic dose of local anaesthetic.

Therefore, Macintosh® laryngeal sprays should be used with caution in children. Quality assurance in the operating room requires that anaesthetists check and calibrate the used equipment on a regular basis to ensure safety. In view of the variability in the volume of lignocaine delivered by individual Macintosh® sprays and different anaesthetists, it would be prudent to fill the plastic chamber of the atomiser with a safe dose of local anaesthetic calculated for each child, particularly small infants, before spraying the upper airway. This guideline is equally applicable to any other device used for topical anaesthesia in children.

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