ORIGINAL RESEARCH

Auto-controlled Syringe vs Insulin Syringe for Palatal Injections in Children: A Randomized Crossover Trial

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Abstract

Aim: This study aims to evaluate and compare the efficacy of auto-control syringe (ACS) and insulin syringe (IS) for palatal local anesthesia administration in children.

Materials and methods: The study was a double-blind, randomized, and crossover trial, comprising 80 children requiring palatal anesthesia bilaterally (total 160 injections). Palatal anesthesia on one side was delivered with ACS in one appointment and contralaterally with IS in the second appointment. One-week washout period was given between first and second appointments. Each child acted as his own control. Each injection technique subjective and objective pain scores were measured twice (during needle prick and during actual deposition of local anesthesia). Subjective and objective evaluation of pain was measured with Wong-Baker FACES pain rating scale (WB-FPS) and the face, leg, activity, cry, and consolability scale (FLACC), respectively. After concluding second appointment, child was asked about their preference between both ACS and IS. Statistical evaluation was performed using Chi-square test.

Results: Child reported less pain score for needle prick with IS as opposed to ACS (p value = 0.000416). There was no significant difference between dentist-reported pain scores between any group for both needle prick and local anesthesia administration. There is no significant difference between child reported pain score during administration of local anesthesia between two groups. Irrespective of pain scores, most of the children (96.5%) preferred IS.

Conclusion: For palatal local anesthesia administration in children, both IS and auto-controlled syringe have similar efficacy.

Clinical significance: Insulin syringe can serve as an economical alternative to the expensive auto-controlled syringe for palatal injections in children.

Keywords: Auto-controlled syringe, Children, Insulin syringe, Local anesthesia, Pain, Palate.

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Introduction

Dental fear in children can be due to combination of subjective, objective, and imaginary reasons.[1] Local anesthesia is the most feared dental procedure among children. Dental fear and anxiety are the most important factors that can result in avoidance of treatment.[2,3] Palatal anesthesia is considered to be the most painful among intraoral injections, yet they are very important for achieving complete anesthesia for successful invasive procedures on maxillary teeth.[4]

Pain due to needle prick in the palatal region can be mitigated with many methods, such as, topical anesthetic usage,[5,6] application of pressure to the palatal injection site,[7] precooling injection site,[8–10] application of vibration,[11–13] application of low-level laser,[14] and thin needle,[15] etc.

Pain during local anesthesia administration in palatal region can be reduced by following methods, such as, injecting local anesthesia solution at a slow-controlled constant flowrate,[16,17] administration of modified buffered local anesthetic solution,[18] and warming local anesthesia.[19]

Few studies recommended that buccal administration (without palatal administration) of articaine alone can induce palatal anesthesia.[20] Articaine has better diffusion property than lignocaine. Buccal infiltration alone is sufficient for diffusion into palatal tissue and bone; thereby, palatal anesthesia is achieved without the need for extra palatal injection.[20]

Pain during palatal anesthesia can be managed at two stages: pain during needle insertion and pain due to actual deposition of anesthesia. *Injection site preparation*: precooling is clinically feasible chairside method and can be accomplished with many methods, such as, ice application or by using ice or refrigerant spray (endo ice).[9,21,22] One study in adults reported that precooling with refrigerant spray caused adverse effects, such as, palatal necrosis so its use should be limited.[23] Pressure application to the palatal injection site can be accomplished with cotton bud.[7]

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Pressure application with iced cotton bud is also found to be effective.[24] *Topical anesthetic for palatal application in children*: 8% lignocaine, 20% benzocaine, EMLA, and cetacaine all are proved to be efficacious for palatal topical anesthesia in children.[6,25–27] Waiting for sufficient time before the actual insertion of needle prick also is important in reducing needle insertion pain.[28,29] Longer wait time after topical anesthesia can reduce only the needle prick pain but not the pain due to local anesthesia administration in palate.[28]

Computer-controlled Local Anesthesia Delivery

Computer-controlled local anesthesia delivery (CCLAD) is one of the most notable advances in the field of dental anesthesia. This device allows controlled delivery of anesthesia into the tissues with a slow, constant, continuous flow rate taking into account the density and resistance of target tissue. Flow rate is adjusted according to the resistance of tissue by the microprocessor in the device. Computer-controlled local anesthesia delivery is also called as auto-controlled syringe system (ACS) or comfort control syringe (CCS). Computer-controlled local anesthesia delivery is proved to be effective in both children and adults. In children, most of the studies reported increased comfort with CCLAD when compared to traditional syringe for all the injection procedures, such as, supraperiosteal, palatal, and blocks.[30–40]

Insulin Syringe

Insulin syringe is very easily available and is very economical. The main advantage of insulin syringe (IS) is its needle diameter and its barrel size. There is limited literature available on insulin syringe usage in dentistry. Few studies report the advantages of insulin syringe over conventional syringe.[41,42]

So far no study has compared CCLAD with insulin syringe for dental injections in children. In the current study, we aim to evaluate and compare CCLAD and insulin syringe especially for palatal anesthesia administration in children.

Materials and Methods

This study was a randomized, double-blind, crossover trial. Children aged 8–12 years, who were undergoing dental treatment in department of pedodontics, Malla Reddy Institute of Dental Sciences Hyderabad, Telangana, India, were screened for inclusion and exclusion criteria over a period of 10 months (March–December 2019). A convenience sample of 92 healthy children (age range 8–12 years) who required bilateral palatal anesthesia (maxillary extractions of primary molars) was recruited for the study. Children with medically compromising conditions, mental retardation, and definitely negative frank behavior were excluded from the study. Clear communication was made with the parent regarding procedure, equipment, advantages, and possible side effects. Informed consent from parents and assent from children was taken before the start of study. Study was approved by Institutional Ethical Committee. Out of total 92 children, 12 children were late for second appointment, and treatment was delivered to them at a later stage but their data were excluded from the study. Only 80 children (40 in each group) were subjected to data analysis.

The children were not given any premedication or conscious sedation, which can alter the response elicited by patient during local anesthesia administration. We followed split mouth design, where all children received both the syringes. Lag period between two appointments was one week. Random allocation was performed and 40 children were allotted to each group (www.randomiser.com). Forty children (22 males, 18 females) received ACS in the first and IS in the subsequent appointment and remaining 40 children (25 males, 15 females) received IS in the first and ACS in the subsequent appointments. Randomization and allocation was conducted by one operator. Pain scoring was carried out by another operator who was blind to treatment interventions. After the conclusion of both appointments, preference of child in-between two injections (ACS or IS) was recorded.

Palatal mucosa was dried with cotton pellets, topical anesthesia (*Precaine© B*) 20% benzocaine gel application was done before palatal injection prick (with either ACS or IS), and 2% lignocaine (1:120,000 epinephrine) solution was administered. ACS (smartJECT® KMG) was performed with 30 gauge short needle (Septoject) (Fig. 1). Insulin syringe used was BD Glide™ (31-gauge). Palatal administration was done in a slow manner for insulin syringe. Administration was self-controlled in ACS.

Tell-show-do (demonstration of ACS) was also performed on cotton sponge to demonstrate and decrease the anxiety of child. Both objective and subjective evaluations were done by second operator. Subjective evaluation of pain was done twice for each injection technique (during needle prick and during administration). Wong-baker faces pain scale was shown to the child and child was asked to express the pain in terms of faces after conclusion of appointment. Score can range from 0 to 5 (0-no hurt; 1-hurts little bit; 2-hurts little more; 3-hurts even more; 4-hurts whole lot; 5-hurts worst). Objective pain was also evaluated twice (during needle prick and during administration) using FLACC (Face, Legs, Activity, Cry, and Consolability) for both ACS and IS. Each measure was given a score ranging from 0 to 2, so total score of each measure can range between 0 and 10. Pain-related behavior was evaluated basing on total score of FLACC (0 = relaxed and comfortable, 1–3 = mild discomfort; 4–6 = moderate pain; 7–10 = severe discomfort/pain). Both the scales were explained clearly to the child before the procedure. As all the children in our study were above 6 years, there was no problem for communication of pain.

After recording the pain scores, extraction procedure was carried out and standard post extraction instructions were explained to both parent and child, and analgesic medication (Ibuprofen) was prescribed based on body weight.

All the data were recorded and coded in excel and sent for statistical analysis using SPSS software. Statistician is also blind

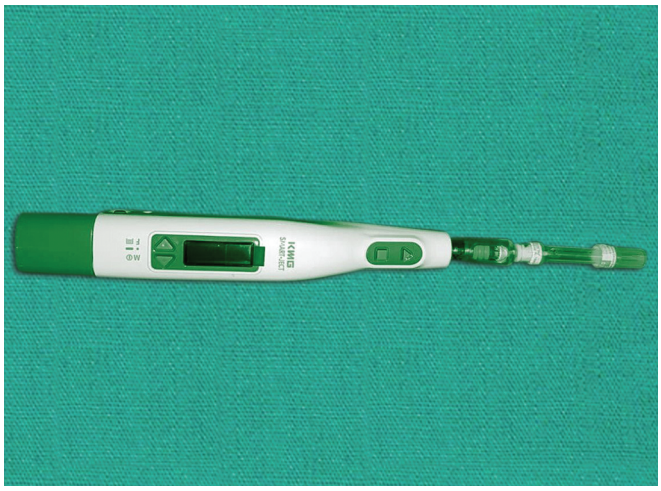

Fig. 1: ACS smartJECT®

to treatment groups. Chi-square test was performed to evaluate association between qualitative variables.

Results

Eighty children (47 boys and 33 girls) with an age range of 8–12 years (mean age of 9.54 ± 1.10) were subjected to two palatal injections bilaterally with a lag of one week for second injection from the first injection (ACS, IS). Total 160 palatal injections were administered to 80 children. Objective and subjective rating was given for each injection during needle insertion and anesthesia administration. No adverse effects were reported.

Subjective Evaluation of Pain (Pain Perception)

Child reported pain during needle prick and local anesthesia administration is evaluated with both ACS and IS with the use of Wong-baker faces pain scale (WB-FPS). Most of the self-reported scores of pain in both ACS and IS group is from mild (hurts little) to moderate (Hurts little more) in both prick and during administration. Severe pain is not reported in any group. Percentage of children reporting moderate pain (hurts even more category) is more in ACS-prick group (30%) when compared to IS-prick group (7.50%). Needle prick with ACS category is reported to be more painful than IS category and the difference is significant statistically ($p = 0.000416$) (Table 1).

Percentage of children reporting moderate pain (hurts even more category) is more in ACS-administration group (23.75%) than in IS-administration group (11.25%), but the difference is not significant statistically ($p = 0.5080$) (Table 1).

Objective Evaluation of Pain (Pain Reaction)

FLACC data show that most of the children exhibited a score (1–3), which belongs to mild discomfort in both ACS and IS groups. Dentist reported higher discomfort associated with ACS-prick (8.75%) when compared to IS-prick (1.25%); same is true for local anesthesia administration (ACS-administration 10% > IS-administration 2.50%) but the difference is not significant statistically. Slightly more number of children exhibiting higher FLACC score of (4–6) is reported in ACS (both prick and administration) when compared to IS group but the difference is not significant statistically. There is no significant difference in the dentist-reported pain scoring for ACS and IS both during needle prick and during administration of local anesthesia (Table 2).

Preference of Child (ACS or IS)

After the conclusion of second appointment, children belonging to both the groups were asked regarding the preference of injection between ACS and IS. Seventy-seven among 80 children (96.25%) preferred IS over ACS.

Discussion

FLACC scale and WB-FPS were used to evaluate the subjective and objective pain ratings. Children in the particular age group of 8–12 years were selected, as much younger children cannot effectively communicate pain rating. Definitely negative behavior-rated children were excluded from this study, as the child will not effectively cooperate for the procedures.

Pain Reaction

Pain reaction (FLACC) shows that the higher mean FLACC score of 3.08 ± 0.49 for ACS_{prick} when compared to 2.90 ± 0.58 for IS_{prick} but the difference is not significant. Similarly higher mean FLACC score of 3.08 ± 0.49 is reported for ACS_{admin} when compared to 2.90 ± 0.58 for IS_{admin} but the difference is not significant. Intergroup comparison reports that IS_{prick} has lowest mean pain reaction and ACS_{prick} has highest mean pain reaction. Results of this study suggest that there is no significant differences in dentist-reported (FLACC) pain score (objective), i.e., pain reaction between needle prick pain in both ACS and insulin syringe groups. No significant difference is noted in the FLACC score between two groups (ACS and insulin syringe groups) during palatal local anesthesia administration. Both the ACS and insulin syringe groups were comfortable and dentist-reported pain scores were under tolerable limits. This is contradictory to other studies where traditional syringe was used instead of insulin syringe and compared to CCLAD.[30,39,43] In these studies by Feda et al., Al amoudi et al., and klien et al., objective pain was evaluated using SEM (sound, eye, and motor) scale. Results of these previous studies reported increased comfort with CCLAD for palatal injections when compared to traditional syringes. These studies also were conducted on similar age group children (7–10 years). In these studies, only administration or deposition of local anesthesia is evaluated. Measure of needle prick pain is not carried out. In both these studies even for traditional syringe, needle gauge used is 30, which might have caused the difference in the pain reaction compared to the current study. Traditional syringe barrel

Table 1: WB-FPS self-reported (child) pain with auto-control syringe and insulin syringe

	No hurt	*Hurts little (%)*	*Hurts little more (%)*	*Hurts even more (%)*	*Chi-square*	*p value*	
ACS_{prick}	0	7 (8.75)	49 (61.25)	24 (30)	15.5704	0.000416	The result is significant at $p < 0.05$
IS_{prick}	0	17 (21.25)	57 (71.25)	6 (7.50)			
ACS_{admin}	0	5 (6.25)	56 (70)	19 (23.75)	5.9594	0.050809	The result is not significant at $p < 0.05$.
IS_{admin}	0	11 (13.75)	60 (75)	9 (11.25)			

Table 2: FLACC dentist-reported pain score with auto-control syringe and insulin syringe

	Relaxed and comfortable (%)	*Mild discomfort (%)*	*Moderate pain (%)*	*Severe pain*	*Chi-square*	*p value*	
ACS_{prick}	1 (1.25%)	72 (90%)	7 (8.75%)	0	5.6081	0.060564	The result is not significant at $p < 0.05$
IS_{prick}	3 (3.75%)	76 (95%)	1 (1.25%)	0			
ACS_{admin}	1 (1.25%)	71 (88.75%)	8 (10%)	0	4.7096	0.094913	The result is not significant at $p < 0.05$.
IS_{admin}	3 (3.75%)	75 (93.75%)	2 (2.50%)	0			

Table 3: Mean pain score with auto-control syringe and insulin syringe

		(WB-FPS)	*FLACC*
	n	*Mean ± SD*	*Mean ± SD*
ACS_{prick}	80	4.425 ± 1.17	3.08 ± 0.49
IS_{prick}	80	3.725 ± 1.04	2.90 ± 0.58
ACS_{admin}	80	4.375 ± 1.05	3.08 ± 0.49
IS_{admin}	80	3.95 ± 1	2.91 ± 0.59

is wider so if luer lock system is not present, the needle hub might get disconnected from syringe barrel. Insulin syringe advantage is due to its narrow barrel, which is proportional with the needle gauge, and barrel and syringe are fused together, so there is no dislodgment. One study compared pain reaction scores (SEM scale) and reported lower SEM scores for 30 gauge insulin syringe in comparison to 26 gauge traditional syringe (Tables 1 and 3).[42]

Pain Perception

WB-FPS (Wong-baker faces pain scale) is used to measure the self-reported pain perception of child after each procedure. Lowest mean WB-FPS scores were recorded for IS_{prick} 3.725 ± 1.04 and highest mean WB-FPS scores were recorded in ACS_{admin} group, and the difference is significant. Intragroup comparison in the mean WB-FPS scores between ACS_{admin} and ACS_{prick} and also between IS_{admin} and IS_{prick} reported no significant difference. Child-reported pain score for needle prick pain is lower for insulin syringe group when compared to ACS group and the difference is found to be significant statistically. There is no difference in the child-reported pain score between both the groups during local anesthesia administration. The difference in the needle prick pain between ACS and insulin syringe might be also due to needle gauge (ACS-30 gauge; insulin syringe-31 gauge). Results of this study are contradictory to the other studies, where pain perception scores were lower with CCLAD when compared to traditional syringes.[30,39] Few other studies reported no significant difference in the pain perception scores between CCLAD and traditional syringes.[43–45] In the study by Asarch et al. and Versloot et al., along with palatal other injection techniques, such as, inferior alveolar nerve block, buccal infiltrations were also taken into consideration, and pain scoring used was visual analog scale (VAS).[44] In these studies, younger-aged children were recruited to the study, so communication of pain perception will be limited with younger-age groups. In the study by Kour et al., pain perception recorded was significantly lower scores with insulin syringe when compared to traditional syringe (Tables 2 and 3).[42]

Despite the advantage of CCLAD, such as, delivery of local anesthetic solution in a slow and controlled manner, which is comfortable for the subjects, the notable disadvantages are its high cost, need to use cartridge system, need to use special needles, and bulkiness of device.

Few advantages of insulin syringe include the following: It is very economical, easily available, and easy to use. Child often associates size with pain, so child easily accepts insulin syringe as compared to bulky ACS (CCLAD), and also if the child is uncooperative and exhibits disruptive behavior in the middle of procedure, retraction of insulin syringe is easy as compared to bulky ACS. Insulin syringe can be easily hidden in the palm of hand, which is not the case for ACS. Disadvantages of insulin syringe are the following: it cannot be used for nerve blocks as length of needle is not sufficient.

Limitations of the Study

Sample size was only 80 in our study. Future studies with increased sample size with subgrouping based on age will increase the accuracy of results.

Conclusion

Palatal anesthesia administration is comfortable with both CCALD or insulin syringe. There is no significant difference between both the groups. Insulin syringe provides better comfort for palatal prick. Visually child preferred insulin syringe over CCLAD. Insulin syringe provides an economical alternative to CCLAD for palatal anesthesia administration in children.

Author Contributions

Manuscript was prepared by the collaborative work of all the authors.

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