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ORIGINAL SCIENTIFIC ARTICLE

# Self-induced soft-tissue injuries following dental anesthesia in children with and without intellectual disability. A prospective study

S. Bagattoni[1] · G. D'Alessandro[1] · M. R. Gatto[1] · G. Piana[1]

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## Abstract

**Purpose** Self-induced soft-tissue injuries (SSI) are reported as local anesthesia complications, particularly in children. The purpose of the study was to evaluate the frequency of SSI following dental anesthesia in children with and without intellectual disability.

**Methods** 241 children receiving dental treatments with local anesthesia were divided into 2 groups: A, children without intellectual disability (159 individuals, 299 injections); B, children with intellectual disability (82 individuals, 165 injections). Each group was divided into subgroups according to age, injection technique and dental treatment. Two days after the dental procedure, a phone survey was conducted to determine the presence of SSI.

**Results** The frequency of SSI in group B was 19%, with no differences in relation to gender and age. In group A the frequency of SSI was significantly lower (9%; $p=0.002$; Chi-square test); the children in the ≤ 6 years-old subgroup experienced a higher frequency of SSI ($p=0.002$). The lower arch was at major risk of SSI in both groups ($p=0.002$). According to a multilevel approach group ($p=0.001$) and injection technique ($p=0.0001$) significantly influenced SSI; no influence of dental treatment is evidenced.

**Conclusions** SSI are common complications of local anesthesia in young children and individuals with intellectual disability.

**Keywords** Dental anesthesia · Soft-tissue injury · Lip biting

## Introduction

The absence of pain during dental treatment enhances a positive attitude for future visits and reduces dental fear and anxiety in the pediatric dental patient. An adequate local anesthesia allows dental care to proceed safely in a pain-free setting and promote a positive relationship between the dentist and the child (AAPD 2016). However, the injection of local anesthetics represents a fear-inducing procedure and the patient often associates the needle to a painful experience (McLenon and Rogers 2018). An accurate technique of local anesthesia administration, with the aid of topical anesthesia, is an important consideration in pediatric behavior guidance. In addition, techniques such as the use of age-appropriate nonthreatening terminology, distraction, topical anesthetics and nitrous oxide/oxygen analgesia/anxiolysis help the patient to have a positive experience during the injection (AAPD 2016).

The duration of the soft-tissue anesthesia is greater than the pulpal anesthesia and the effect persists for hours after the injection (Hersh et al. 1995). Self-induced soft-tissue injuries (SSI) following accidental biting or chewing of the lip, the tongue or the cheek are reported as complications of the administration of local anesthesia, especially in pediatric special needs patients (Malamed 2013). Because no pain is felt, a child may bite the soft-tissues out of curiosity associated with the unfamiliar numbness sensation or inadvertently during postoperative eating or sleeping. These injuries commonly present with localized swelling, edema and pain. Most of these lesions are self-limiting and heal without complications, however, the swelling may produce anxiety in the parents. Furthermore, it is likely that the child

✉ S. Bagattoni
simone.bagattoni@gmail.com

[1] Department of Biomedical and NeuroMotor Sciences (DiBiNeM), Unit of Dental Care for Special Needs Patients and Paediatric Dentistry, University of Bologna, Via San Vitale 59, 40125 Bologna, Italy

may develop a negative dental attitude for the future visits due to the memory of this unpleasant experience.

An extensive review of the literature revealed sparse case reports or case series on this topic (Chi et al. 2008; Bendgude et al 2011; Vempaty and Robbins 2017). Just one prospective study (College et al. 2000) investigated the incidence of SSI: the 13% of the individuals included into the study (age 2–18 years-old) experienced SSI following unilateral or bilateral inferior alveolar nerve block (IANB).

Given the lack of data in the scientific literature, the purpose of this study was to evaluate and compare the frequency of SSI following the dental anesthesia administration in a pediatric population with and without intellectual disability.

## Material and methods

The investigators were three dental specialists in Pediatric Dentistry and Special Needs Dentistry.

This prospective study was conducted on outpatients attending the Unit of Special Needs Dentistry and Pediatric Dentistry, Department of Biomedical and Neuromotor Sciences, University of Bologna, Italy. Children with special health care needs were referred from the Pediatric Units of St. Orsola-Malpighi Polyclinic, Department of Medical and Surgical Sciences, University of Bologna, Italy. Any child admitted for any dental treatments requiring local anesthesia from January 2016 to 2018 was eligible for the participation in the study. The inclusion criteria were: primary or mixed dentition, Italian-speaking child and caregivers, just one injection performed in the same appointment. Individuals in permanent dentition were excluded. The written informed consent for participation and publication was obtained from the parents/legal guardians of each individual in full accordance with the ethical principles of the Helsinki Declaration.

### Sample sizes

We estimated the proportion of SSI for children with intellectual disability from that obtained in non-collaborating children in College et al. (2000) (equal to 21%) because of the lacking of previous study on disabled population; we estimated proportion of SSI for children without intellectual disability from the same study (College et al. 2000) (equal to 10%: maximum frequency value of SSI obtained in a pilot survey performed by College et al. 2000). We performed the sample size calculation basing on these estimated proportions, at an α level of 0.05 with a power of 80%: the number of units in each group was at least 169. As for healthy subjects we included 159 children; as for subjects with intellectual disability only 82 children were recruited because of the attendance during the two years of follow-up.

### Individuals/injections

During the data collection period, 249 individuals met the inclusion criteria. Eight of these were excluded because the caregivers could not be reached by phone during the next days. A total of 241 individuals were included in the study. A total of 464 dental injections were administered and scheduled according to the formulated treatment plan.

According to the medical diagnosis, the sample was divided into 2 groups: group A, children without intellectual disability (159 individuals, 299 injections); group B, children with intellectual disability (82 individuals, 165 injections). Children in group B were affected by Down syndrome (46) or medical conditions (e.g. Fetal Alcohol Syndrome, Noonan Syndrome, congenital brain defects, infections during pregnancy or infancy, preterm birth) associated with intellectual disability (34). Demographic characteristics of group A and B are shown in Tables 1 and 2.

### Procedure

Before the injection, a topical anesthetic spray with 15% lidocaine (Septodont, France) was applied with a cotton roll for at least 1 min on the dried mucosa. Mepivacaine 2% with 1:100,000 epinephrine (Septodont, France) was used for the IANB, articaine 4% with 1:100,000 epinephrine (Molteni Dental, Italy) for both maxillary and mandibular infiltrations. The injection was slow (approximately 1 mL per minute) using an aspirating syringe. The amount of anesthetic solution used was based on the weight of the child. Each child was unaware of the injection procedure and never

**Table 1** Demographic characteristics of group A and distribution of the injections according to the gender and the age

| Gender | *n* (%) | Min age (years) | Median age (years) | Max age (years) | ≤ 6 years-old *n* (%) | > 6 years-old *n* (%) |
|---|---|---|---|---|---|---|
| M | 92 (58) | 3 | 8 | 12 | 34 (37) | 58 (63) |
| Injection | 173 (58) | | | | 80 (46) | 93 (54) |
| F | 67 (42) | 3 | 8 | 13 | 26 (39) | 41 (61) |
| Injection | 126 (42) | | | | 62 (49) | 64 (51) |
| Total | 159 | 3 | 8 | 13 | 60 (38) | 99 (62) |
| Injection | 299 | | | | 142 (47) | 157 (53) |

**Table 2** Demographic characteristics of group B and distribution of the injections according to the gender and the age

| Gender | *n* (%) | Min age (years) | Median age (years) | Max age (years) | ≤6 years-old *n* (%) | >6 years-old *n* (%) |
|---|---|---|---|---|---|---|
| M | 44 (53) | 5 | 8 | 13 | 14 (32) | 30 (68) |
| Injection | 92 (56) | | | | 38 (41) | 54 (59) |
| F | 38 (47) | 4 | 9 | 12 | 15 (39) | 23 (61) |
| Injection | 73 (44) | | | | 29 (40) | 44 (60) |
| Total | 82 | 5 | 8 | 13 | 29 (35) | 53 (65) |
| Injection | 165 | | | | 67 (41) | 98 (59) |

saw the syringe or the needle; positive verbal reinforces and behavior guidance techniques were used. Ninety-five children were treated with the aid of nitrous oxide/oxygen analgesia/anxiolysis.

At the end of the dental procedure, three pictures of SSI (one of the tongue, one of the upper lip and one of the lower lip) were shown to the caregivers by the operator to stress the importance of a careful observation of the child during the numbness period and to describe the typical localization and the clinical features (redness and/or swelling of the lip, cheek or tongue) of these lesions. The pictures were given to parents as a guide to identify the SSI at home. Verbal instructions were given to the caregivers and to the child following the same checklist for each patient (eg, do not bite or suck the lips and the cheeks, to eat ice-cream, do not ingest hot foods or beverages) and a cotton roll was given to the child to bite.

Two days after the dental procedure, the same operator contacted the caregivers by a phone-call to ask if they could identify any soft tissue injury similar to those in the pictures. After 3 failed phone-calls on 3 consecutive days, if the caregiver did not recall, the individual was excluded from the study. During the phone-call, if pain and swelling were present, the application of a topical solution with chlorhexidine 0.20% was suggested to the parents. In case of persistent signs and symptoms for more than a week, the caregivers were invited to refer the child for a clinical examination.

If the same individual received more than one dental treatment with local anesthesia during the period of observation, the data collection was repeated for each injection.

### Statistical analysis

The unit of statistical analysis was the injection.

Descriptive statistical analyses were first performed. Each group was divided into subgroups according to the age (≤6 years-old; >6 years-old) (Tables 1, 2), the injection technique (maxillary infiltration, mandibular infiltration, IANB) and dental treatment (restorative/endodontic treatment, extraction, both during the same appointment). Chi-square test was used to verify the presence/absence of statistically significant differences between genders, groups (A vs B) and subgroups (≤6 years-old vs >6 years-old, among injection techniques and among dental treatments).

A multilevel approach (mixed effect model) was carried out given that more than one injection per child was performed: group, technique and dental care were considered fixed effects, age and gender random effects. The level of significance was set at $p < 0.05$. SPSS for Windows (23.0, SPSS Inc, Chicago, IL, USA) was used.

## Results

### Group A: children without intellectual disability

A total of 28 SSI (9%) were reported, without any significant difference between genders ($p = 0.601$) (Table 3). One of the children with SSI was referred for a clinical examination and a pediatric formulation of ibuprofen was prescribed to control pain.

**Table 3** Frequency of SSI according to gender and age in group A and B

| | *SSI n (%)* | *p* |
|---|---|---|
| *Group A* | | |
| Gender | | |
| Males (*n*. 173) | 18 (10) | 0.601 |
| Females (*n*.126) | 10 (8) | |
| Age | | |
| ≤6 years-old (142) | 21 (15) | 0.002* |
| >6 years-old (157) | 7 (4) | |
| *Group B* | | |
| Gender | | |
| Males (*n*. 92) | 17 (18) | 0.738 |
| Females (*n*. 73) | 15 (21) | |
| Age | | |
| ≤6 years-old (*n*. 67) | 16 (24) | 0.228 |
| >6 years-old (*n*. 98) | 16 (16) | |

*n* number of injections

*Significant difference (Chi-square test)

The frequency of SSI was 15% in the ≤ 6 years-old subgroup and 4% in the > 6 years-old subgroup. The difference between the subgroups was statistically significant ($p = 0.002$) (Table 3).

According to the injection technique, the highest frequency of SSI occurred with IANB (12 SSI: 15%), followed by mandibular infiltration (14 SSI: 13%); two children (2%) (a 3 years-old male and a 4 years-old female) reported a SSI following a maxillary buccal infiltration. The difference among the subgroups was statistically significant ($p = 0.002$; Chi-square test); the difference between IANB and mandibular infiltration was not statistically significant ($p = 0.919$; Chi-square test).

According to dental treatments, the highest frequency of SSI occurred with restorative/endodontic treatments (24 SSI: 12%), followed by extractions (1 SSI: 2%) and both therapies (3 SSI: 5%). The difference among the subgroups was not statistically significant ($p = 0.093$; Chi-square test).

### Group B

A total of 32 SSI (19%) were reported, without any significant difference between genders ($p = 0.738$) (Table 3). Two children were referred for a clinical examination and a pediatric formulation of ibuprofen was prescribed to control pain.

The frequency of SSI was 24% in the ≤ 6 years-old subgroup and 16% in the > 6 years-old subgroup. The difference between the subgroups was not statistically significant ($p = 0.228$) (Table 3).

According to the injection technique, the highest frequency of SSI occurred following the IANB (35%); infiltration anesthesia was followed by SSI with a frequency of 19% in the lower arch and 9% in the upper arch. The difference among the subgroups was statistically significant ($p < 0.001$; Chi-square test). The difference between the IANB and the mandibular infiltration was not statistically significant ($p = 0.817$; Chi-square test).

According to dental treatments, the highest frequency of SSI occurred with restorative/endodontic treatments (17 SSI: 18%), followed by extractions (10 SSI: 28%) and both therapies (5 SSI: 15%). The difference among the subgroups was not statistically significant ($p = 0.337$; Chi-square test).

### Group A vs Group B

Regarding the frequency of SSI, the difference between the two groups (A:9% vs B:19%) was statistically significant ($p = 0.002$; Chi-square test).

According to a multilevel approach, only group and injection technique significantly influenced SSI (Table 4). SSI were less frequent in group A than group B ($p = 0.001$) and following maxillary infiltration than IANB ($p = 0.0001$).

## Discussion

This prospective study showed that SSI are possible and not-rare complications of the administration of dental anesthetics in both pediatric and special needs patients.

The frequency of SSI was 9% in children without intellectual disability. There was an overall higher frequency of SSI in the ≤ 6 years-old subgroup (15%) than in the > 6 years-old subgroup (5%), regardless of the injection technique. Similarly, College et al. (2000) reported the highest frequency of SSI following unilateral or bilateral IANB in the youngest age groups (18% in children < 4 years-old, 16% in children 4–7 years-old, 13% in children 8–11 years-old, and 7% in children > 12 years-old). In the same study, there were no statistically significant correlations between the prevalence of soft tissue trauma and anesthetic type, amount, and additional sites of injection. Odabaş et al. (2012) reported a large scratch injury on the right side of the chin in a 4-year-old male child following IANB and a scratch injury on the ala of the nose in a 5-year-old child following a maxillary infiltration.

At the end of the dental treatment, a careful supervision of the child was always suggested to the caregivers. However, the strong recommendations and the awareness of the risk of injuries were not sufficient to prevent SSI in all patients. This may be explained by the greater difficulty in explaining to a young child how to cope with the numbness

**Table 4** Multilevel analysis: influence of group, therapy and technique on SSI

| Fixed effect | Coefficient | Standard error | *t* | *p* | 95% CI | |
|---|---|---|---|---|---|---|
| | | | | | Inferior | Superior |
| Intercept | 0.272 | 0.047 | 5.785 | 0.0001 | 0.180 | 0.365 |
| Group A vs B | −0.105 | 0.032 | −3.299 | 0.001 | −0.167 | −0.042 |
| Maxillary infiltration vs IANB | −0.190 | 0.037 | −5.136 | 0.0001 | −0.263 | −0.188 |
| Mandibular infiltration vs IANB | −0.074 | 0.039 | −1.894 | 0.059 | −0.150 | 0.003 |
| Restorative/endodontic treatment vs both | 0.031 | 0.040 | 0.785 | 0.433 | −0.047 | 0.109 |
| Extraction vs both | 0.017 | 0.051 | 0.329 | 0.742 | −0.083 | 0.117 |

sensation of the lips, the cheeks and the tongue. The ability of the child to successfully cope with the soft-tissue numbness may increase with age, resulting in a decrease of accidental lip and cheek biting. Furthermore, while the soft tissues are still numb, significant trauma from involuntary bites may occur during the way back home, especially if the child is accompanied by just one caregiver. All the lesions were self-limiting without requiring the prescription of systemic antibiotics.

The dental injections administered in the lower jaw were at greater risk of SSI, regardless of the anesthetic technique used (buccal infiltration vs IANB). The buccal infiltration for the anesthesia of the lower primary molars causes the mental nerve block, resulting in a prolonged numbness sensation over the lower lip and the chin. Despite the area of altered sensation is smaller compared to the IANB, it may be sufficient to favor SSI.

In children with intellectual disability, the frequency of SSI was significantly higher (19%). The intellectual disability resulted a predisposing factor, regardless of the age. The highest frequency of SSI (35%) was reported following the IANB. Even if there was not a statistically significant difference from the buccal infiltration, this data appears of clinical relevance.

From the clinician's perspective, all efforts to reduce the duration of the soft-tissue anesthesia should be made. Long-acting local anesthetics, as bupivacaine, are not recommended either for children or patient with intellectual disability, as the prolonged effect of the anesthesia increases the risk of SSI (AAPD 2016; Malamed 2013).

When treating the lower jaw, the IANB produces a profound anesthesia and makes it possible to treat multiple teeth during the same appointment. However, the IANB includes as a disadvantage, especially for young children and individuals with intellectual disability, a prolonged anesthesia of both the lower lip and the tongue (Oulis et al. 1996). There is a misconception that a local anesthetic without a vasoconstrictor, such as plain 3% mepivacaine, for the IANB provides a shorter duration of the soft-tissue anesthesia than one with a vasoconstrictor. A recent study (Elbay et al. 2016) demonstrated that the mean duration of the soft-tissue anesthesia was 139.68 min for 3% mepivacaine and 149.10 min for 2% lidocaine-epinephrine, without a clinically significant difference. The same study showed that the anesthetic solution used had no effect on the frequency of postoperative complications, including SSI. Similarly, Odabas et al. (2012) reported no statically significant difference in the accidental lip and/or cheek injury between articaine with epinephrine and plain mepivacaine. Hersh et al. (1995) found that the onset of the soft-tissue numbness and the numbness duration were "quite similar" when comparing plain 3% mepivacaine and 2% lidocaine with epinephrine. In conclusion, the use of plain 3% mepivacaine does not provide any benefit with respect to the prevention of SSI, but the higher concentration of local anesthetic in the 3% mepivacaine solution and the absence of vasoconstrictor make it easier to reach the maximum recommended dosage (Saraghi et al. 2015). The use of vasoconstrictors is recommended in children to decrease the risk of systemic toxicity of the local anesthetic agents by slowing the absorption from the site of injection (Kühnisch et al. 2017). The vasoconstrictor provides additional local hemostasis and prolongs the analgesic effect (Haas 2002).

When restoring a single tooth, the periodontal ligament (PDL) anesthesia using a computer-controlled delivery system may be used in young children or individuals with intellectual disability to avoid an extensive soft-tissue anesthesia. The PDL injection has been reported effective as local infiltration when used during restorations and root canal treatments of primary mandibular posterior teeth (Chenchugopal et al. 2017); however, local infiltration resulted more effective than PDL when used during extraction procedures (Odabaş et al. 2012).

Another option to reduce the duration of the soft-tissue anesthesia is the administration of phentolamine mesylate, a nonselective alpha-adrenergic-blocking agent (Daubländer et al. 2017). In 2008 an injectable form of phentolamine mesylate (OraVerse™) was approved by the Food and Drug Administration granted (FDA 2008) for the reversal of the soft-tissue anesthesia resulting from the intraoral injection of an anesthetic solution containing a vasoconstrictor. Phentolamine mesylate is administered at the same site and with the same technique used for the anesthetic agent. A randomized controlled trial (Tavares et al. 2008) conducted on pediatric patients showed a median recovery time to normal lip sensation for phentolamine mesylate patients of 60 min, compared to 135 min for the sham group, with a 75 min reduction of residual soft-tissue anesthesia for both maxillary and mandibular arches.

To date, the use of phentolamine mesylate is not recommended in children younger than 6 years-old or weighing less than 15 kg but it may be particularly indicated for older children with intellectual disability to reduce the risk of SSI at the end of the dental procedure.

The major limitation of the present study may be considered the absence of a clinical examiner to assess the presence/absence of the adverse event SSI. The soft-tissue evaluation was made by the caregivers due to the impossibility of carrying out a control visit to each participant during the days following the dental procedure. It is possible that by providing in advance the description and the photos of SSI, parents were sensitized to the expected outcomes, resulting in a higher incidence of reported injuries. Another limitation was the absence of information regarding supervision: we did not investigate if the children were supervised by the caregivers for the whole duration of local anesthesia or if the children returned to school. Multiple variables were

examined but power calculation was based only on the frequency of SSI derived from a previous study (College et al. 2000). However, the post-hoc power derived from the comparison of SSI between group A and group B was equal to 87%. Being that SSI may be considered a rare event when stratification by type of injection and dental treatment is performed, further analysis on greater samples need aiming to support the clinical choice.

## Conclusion

Giving the results of the present study, every possible effort should be made to reduce the risk of SSI when treating children. It is important to inform the caregivers that a close supervision is strictly recommended for the whole duration of the local anesthesia to prevent the child from biting lips, cheeks, and tongue. When treating young children or individuals with intellectual disability, it may be recommended the presence of at least two caregivers, to carefully monitor the child during the way back home.

### Compliance with ethical standard

**Conflict of interest** The authors declare no conflict of interest.

**Ethical approval** The local Ethics Committee of the Bologna University Hospital Authority St. Orsola-Malpighi Polyclinic (Bologna, Italy) approved this study (PG. N 0019293). The Informed consent was obtained from the parents of the children.

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