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Lidocaine 20% patch vs lidocaine 5% gel for topical anaesthesia of oral mucosa

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Background. Topical anaesthetics are important to provide pain control at dental injection.
Aim. The aim was to evaluate the effectiveness of the intraoral topical anaesthetics lidocaine 20% patch (DentiPatch™) and lidocaine 5% gel.
Design. The randomized unblinded cross-over study included 31 patients (ten boys, 21 girls) aged 13.5 ± 2.5 years. Application of lidocaine patch or gel was randomly used at first and second visit in the upper premolar region. Heart rate was measured before and at each needle insertion after 2.5, 5, and 15 min and at injection after 15 min. Discomfort and pain were expressed in visual analogue scales (VAS). Paired *t*-test and Mann–Whitney *U*-test were used for statistic analyses.
Results. Heart rate at buccal injection decreased more when the patch was used ($P = 0.0149$). Heart rate was lower at the second visit ($P = 0.0287$). Patients expressed less discomfort when the patch was used on both buccal ($P = 0.0150$) and palatal ($P = 0.0391$) site. Boys had lower heart rate and VAS pain scale ratings than girls.
Conclusions. Good pain control can reduce the patients' anxiety level – expressed in heart rate – at the second appointment. The patch and gel seem to provide similar pain reduction at needle stick and injection of local anaesthetics.

Introduction

New methods have been introduced to facilitate dental procedures, but administration of local anaesthetic is still necessary to perform pain control during several dental procedures. The thought and performance of local anaesthetic injection often provoke feelings of discomfort in the patient[1] and have been described as one of the most anxiety-provoking procedures in dentistry[2,3]. Topical anaesthetic gels are frequently used in dentistry in order to reduce or eliminate pain during the injection procedure[4]. A problem with conventional topical anaesthetic gels is their lack of bioadhesiveness to the oral mucosa. This leads to a movement of the topical anaesthetic away from the application site, making the topical anaesthetic effect inadequate[5]. Anaesthetic gel diluted in the mouth may also lead to an unpleasant taste and discomfort for the patient. By using a patch, which is adhesive to the oral mucosa, containing the topical anaesthetic, these problems may be decreased. Such a mucoadhesive anaesthetic patch containing lidocaine base, which is dispensed through a bio-adhesive matrix, was introduced for intraoral use in 1996 in the USA[6].

Previous studies have shown that the use of lidocaine patch for oral topical anaesthetics is efficient, safe, and reliable[5–7]. The lidocaine patch has successfully been used from the age of 3 years[8]. The efficacy of lidocaine 5% gel has previously been described[9,10].

The aim of the study was to evaluate the effectiveness of the two intraoral topical anaesthetics lidocaine 20% patch and lidocaine 5% gel using pulse oximeter and patients' subjective evaluation of pain and discomfort using a visual analogue scale (VAS), and to evaluate possible differences in heart rate at two consecutive treatments.

Materials and methods

Patients planned for orthodontic treatment including extractions of premolars bilaterally in the maxilla were invited to participate in the study. The participants had to be healthy, nonmedicating, and able to cooperate in the

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dental treatment situation and to complete a VAS scale. All participants and parents received written and verbal information about the study and gave their informed consent. Thirty-five patients were invited to participate in the study. Four patients did not want to participate due to fear of dental injection.

The same dentist performed all examinations and treatments. The study was performed in a quiet examination room. The dentist and the patient accompanied by one parent were the only persons present in the room during the study.

Topical anaesthetics was applied using either the 20% lidocaine patch DentiPatch™ (Noven Pharmaceuticals Inc, Miami, FL, USA) or lidocaine 5% gel (Apoteket AB, Stockholm, Sweden). Thirty-gauge short hypodermic needles (Milestone Scientific, Livingston, NJ, USA) were used for insertion and injection. For each application, 0.2 mL of lidocaine 5% gel was placed on a cotton roll. The Wand™ (Milestone Scientific, Livingston, NJ, USA) computerized standardized anaesthetic injection device was used for injection. A pulse oximeter (Nonin Medical Inc. Plymouth, MN, USA) was used to measure the heart rate before and at needle insertion and injection, as described in Fig. 1.

The first visit started with verbal information and a review of the current health status.

The patients' left ring finger was placed in the adult-size articulated finger clip sensor, which was attached to the pulse oximeter. The buccal mucosa of the first premolar in the maxilla was carefully dried, but not rubbed, with a cotton roll prior application of topical anaesthetic. The gel was applicated on a cotton roll that was pressed slightly to the oral mucosa. Application of lidocaine patch or lidocaine gel was randomly determined to be used at the first and second visit, respectively. Fifteen of the patients (12 girls, three boys) received lidocaine patch at the first visit. The heart rate was noted at application of the topical agent, before and at each needle insertion, and before and at injection of Xylocain® adrenalin (lidocaine 20 mg/mL, adrenaline 12.5 μg/mL) (AstraZeneca, Södertälje, Sweden). The topical anaesthetic effect on each application site was evaluated as the needle was inserted to the mucosa after lifting the edge of the patch or the cotton roll with gel. Insertion of the needle without injection of local anaesthesia was performed 1 mm into the buccal mucosa at the region of the apical part of the tooth during one second at 2.5, 5, and 15 min, respectively, counted from the time of application of lidocaine gel or lidocaine patch. The needle insertions were not allowed to reach any contact with bone. The patient was instructed to rate the pain from each needle insertion and injection and discomfort from the topical anaesthetics on a horizontal 100-mm VAS pain scale.

After the last insertion at 15 min, the lidocaine patch or lidocaine gel was removed from the mucosa and Xylocain® adrenalin was injected using the slow administration rate of The Wand™ during 20 s. Finally, 1.2 mL of the local anaesthetic solution was injected on the same place of the buccal mucosa. The topical anaesthetic was applied on the palatal mucosa 5 min after the first insertion, as described in Fig. 1. The palatal side was only evaluated before and at injection 15 min after palatal application of topical anaesthetic gel or patch. No needle insertion was performed on the palatal side during the first 15 min because that possibly could have interfered with the evaluation of the needle sticks on the buccal application site.

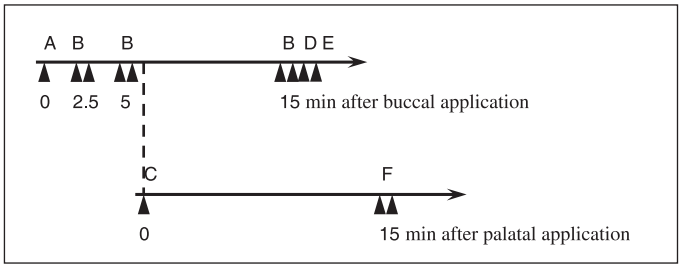
When the described injections had been performed, the patients answered questions regarding taste and experienced discomfort (described on a horizontal 100-mm VAS discomfort scale, and with a yes/no answer) during the entire study, as described in Table 1.

Statistical methods

The paired and unpaired *t*-test was used for comparison of mean values. The Mann–Whitney *U*-test was used for comparison between groups of patients.

Results

Thirty-one patients (ten boys, 21 girls) with a mean age of 13.5 ± 2.5 (range 10.3–18.8) years fulfilled the study. None of the patients asked for water or experienced any gag reflex during the time of the study. Both topical anaesthetics stayed well in place. Only minor sliding of the



▲ Registration of heart rate frequency.
A Application of lidocaine gel or patch to buccal mucosa of the first premolar.
B Insertion of needle to 1 mm depth in buccal mucosa.
C Application of the same topical anesthetic to palatal mucosa of the same first premolar.
D Injection of lidocaine (20 mg/mL Adrenaline (12.5 μg/mL) (Xylocain® adrenalin) during 20 s in buccal mucosa.
E Injection of 1.2 mL Xylocain® adrenalin in buccal mucosa.
F Injection of 0.8 mL Xylocain® adrenalin in palatal mucosa.

Fig. 1. Time schedule for the study.

Table 1. Questions answered by the patients regarding buccal and palatal application site during the study.

1.	How painful was the needle stick at 2.5 min?*†
2.	How painful was the needle stick at 5 min?*†
3.	How painful was the needle stick at 15 min?*†
4.	How painful was the injection?*
5.	What is your experience of the topical anaesthetic?‡
6.	How did the topical anaesthetic taste? Very good/Good/No taste/Bad/Very bad
7.	Did you feel any discomfort or irritation where topical anaesthetic was placed? No/Yes

*Answered only regarding buccal application site.
†Answered on a 100-mm visual analogue scale (VAS) pain scale between the extremes 'No pain' and 'Worst possible pain'.
‡Answered on a 100-mm VAS discomfort scale between the extremes 'No discomfort' and 'Worst possible discomfort'.

patch and the gel could be noticed. Neither the patch nor the gel slid away from the injection site.

Heart rate

The mean heart rate during the study was 82 ± 15 b.p.m. There was no significant difference regarding heart rate between gel and patch at any of the 11 measurements. The mean heart rate during the study is shown in Table 2. A decreased pulse was found at buccal injection when gel or patch was used, at buccal insertion at 15 min, and at palatal injection when gel was used.

There was a significantly ($P = 0.0149$) more pronounced percentage decrease in heart rate between the measurement immediately before and at buccal injection after 15 min – when the lidocaine patch was used (–19 ± 33%) as compared to when the gel was used (–4.1 ± 8.7%). At all other interventions, the differences regarding changed heart rate between the gel and patch were not significant.

The mean time between the two visits was 19.3 ± 11.0 (4–56) days. The mean heart rate frequencies at the different measurements at the two visits are shown in Table 3. There was a lower mean heart rate during the second visit (79 ± 14 b.p.m.) as compared to the first visit (84 ± 15 b.p.m.) ($P = 0.0264$).

Pain

VAS pain rating at insertion of needle and injection in buccal mucosa is shown in Fig. 2. No significant difference between patch and gel was found regarding subjective pain expression according to the VAS pain rating scale at the different measurements. A decreased VAS pain rating was found between 2, 5, and 15 min after application of the lidocaine patch ($P = 0.0487$).

Table 2. Mean heart rate before and at insertion/injection (n = 31).

Measurement	Time from application of gel or patch (min)	Gel	Change at intervention after gel	Patch	Change at intervention after patch	Gel vs patch
		Pulse (mean ± SD)	Paired t-test (P-value)	Pulse (mean ± SD)	Paired t-test (P-value)	Paired t-test (P-value)
At application	0	82 ± 15		80 ± 16		0.2384
Before needle insertion	2.5	83 ± 17		84 ± 17		0.7537
		}	0.2540	}	0.5620	
At needle insertion	2.5	85 ± 14		85 ± 18		0.8692
Before needle insertion	5	81 ± 14		81 ± 15		0.7326
		}	0.0772	}	0.8404	
At needle insertion	5	79 ± 14		81 ± 15		0.6014
Before needle insertion	15	83 ± 13		82 ± 17		0.7222
		}	0.0459*	}	0.1049	
At needle insertion	15	80 ± 13		80 ± 15		0.5433
Before buccal injection	15	83 ± 14		81 ± 16		0.3397
		}	0.0439*	}	0.0038*	
At buccal injection	15	79 ± 13		74 ± 13		0.0554
Before palatal injection	15	88 ± 16		84 ± 17		0.1121
		}	0.0057**	}	0.0658	
At palatal injection	15	79 ± 10		80 ± 14		0.5387
All 11 measurements	0–15	82 ± 14		81 ± 16		0.4366

*Significant difference at the 5% level.
**Significant difference at the 1% level. SD, standard deviation.

Table 3. Mean heart rate (pulse) in the 31 patients at the first and second visit, respectively.

Measure	Time from application of gel or patch (min)	Pulse at first visit (mean ± SD)	Pulse at second visit (mean ± SD)	Paired t-test (P-value)
At application	0	84 ± 16	77 ± 14	0.0264*
Before needle insertion	2.5	86 ± 18	80 ± 16	0.0029**
At needle insertion	2.5	87 ± 16	82 ± 15	0.0088**
Before needle insertion	5	81 ± 14	80 ± 15	0.4298
At needle insertion	5	82 ± 15	78 ± 13	0.0312*
Before needle insertion	15	85 ± 16	80 ± 13	0.0450*
At needle insertion	15	83 ± 15	78 ± 13	0.0098**
Before buccal injection	15	85 ± 16	80 ± 14	0.0069**
At buccal injection	15	79 ± 11	74 ± 14	0.0601
Before palatal injection	15	88 ± 17	85 ± 17	0.2390
At palatal injection	15	83 ± 13	77 ± 11	0.0287*

*Significant difference at the 5% level.
**Significant difference at the 1% level. SD, standard deviation.

No such change of VAS pain rating over time was found for the gel.

Discomfort

The mean VAS discomfort rating was 6.0 ± 10.2 for the gel and 1.7 ± 2.5 for the patch on the buccal application site and 7.7 ± 9.9 for the gel and 3.7 ± 6.7 for the patch. The lidocaine patch resulted in significantly less discomfort as compared to the gel both at buccal (P = 0.0150) and at palatal (P = 0.0391) application site, when evaluated by the patients in the 0–100 mm VAS discomfort rating scale – ranging from 'no discomfort' to 'worst possible discomfort' – after 15 min application of the topical anaesthetic.

Three patients described specific discomfort or irritation from lidocaine patch. One female patient expressed a feeling of pressure from the patch site. Another female patient had a shooting feeling on the applications site. One other female patient had a blister at the

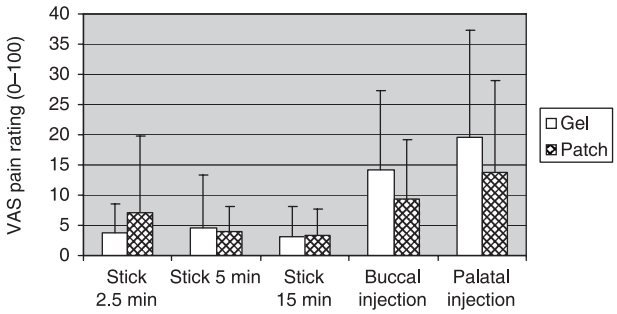


Fig. 2. Mean value and standard deviation of visual Analogue scale (VAS) pain rating at insertion (stick) and injection in buccal mucosa at different times after application of topical anaesthetic gel or patch in 31 patients. On the 100-mm VAS pain scale, 0 represents 'no pain', and 100 represents 'worst possible pain'.

application site the day after the treatment and felt like the flakes from the mucous membrane were loosened. Regarding the palatal side one male patient expressed discomfort from the patch and had difficulties to swallow while the patch was in place.

The patients' subjective evaluation of taste from gel and patch is shown in Table 4.

Sex

The mean age was 13.6 ± 2.6 years for the girls and 13.3 ± 2.5 years for the boys. The mean heart rate during the study was 84 ± 13 and 77 ± 17 b.p.m. for the girls and the boys, respectively. The difference between the mean values for the sexes was significant at the 5% level ($P = 0.0463$). Regarding the different measurements, the difference between the sexes was significant before application of topical anaesthetic ($P = 0.0428$) and at the insertion 5 min after application of the patch (0.0196) and after palatal injection ($P = 0.0283$).

The mean VAS pain rating during the study was also higher for the girls ($P = 0.0011$). The difference was significant at insertion of the needle after 2.5 ($P = 0.0180$) and 15 min ($P = 0.0088$), and at palatal injection ($P = 0.0015$), when lidocaine gel was used as topical anaesthetic. When lidocaine patch was used, the difference between the sexes – regarding the mean VAS pain rating – was significant at buccal insertion at 2.5 ($P = 0.0365$) and 15 min ($P = 0.0404$) and at buccal injection ($P = 0.0404$) and palatal injection ($P = 0.0387$).

Table 4. Distribution of taste expression from the topical anaesthetics used on buccal and palatal mucosa, respectively, during 15 min ($n = 31$).

	Buccal		Palatal	
Taste	**Gel**	**Patch**	**Gel**	**Patch**
Very good	1 (3%)	–	–	–
Good	5 (16%)	7 (23%)	3 (10%)	7 (23%)
No taste	16 (52%)	18 (58%)	16 (52%)	17 (55%)
Bad	8 (26%)	6 (19%)	10 (32%)	7 (23%)
Very bad	1 (3%)	–	2 (6%)	–

Discussion

Measurement of pain is complicated as it is experienced on an individual level[11], and is dependent of several physiological and psychological factors. This makes pain difficult to evaluate in an objective way. The self-reported pain from the patient is anyhow considered the most reliable evaluation[12]. Verbal indicators and observed motor-responses have previously been used as indicators of pain in smaller children[7]. In this study, we decided to use the change of heart rate and the VAS scale as indicators of pain and discomfort, as we found them useful and objective in the present patient group, and as they previously have been shown to be reliable indicators of a patient's response to pain[7,12].

Several studies have compared the efficacy of the lidocaine patch as compared to placebo[5,6] and other topical anaesthetics[13]. The 20% lidocaine patch is found to give a more profound and deep anaesthetic effect than the 10% patch. Therefore, the 20% patch was considered a good choice. Lidocaine 5% gel is one of the most commonly used topical anaesthetics in dentistry[4]. No previously presented study has compared the efficacy of the 20% lidocaine patch and the 5% lidocaine gel for topical anaesthesia at dental injection.

We decided to use The Wand (Milestone Scientific Inc.) – a computerized local anaesthesia device – to make the injection procedure so standardized as possible particularly regarding the standardized injection speed. We used the 30-gauge short hypodermic needle as it is

commonly used for first injection with The Wand to minimize pain and discomfort, and has been used in similar studies previously[14]. Although authors of previous studies have suggested that a larger dimension of the needle should be used for studies of topical anaesthetic effect[6], we find it preferable – for the paediatric dentist with ambition to minimize pain and discomfort for the patient – to choose the smaller needle size for injections.

Some authors have also suggested that the evaluation of a topical anaesthetic should include needle contact with the periosteum[6,15]. That is not a technique for injection when striving to attain a pain-free injection. Since topical anaesthetics is known to have hardly any value in reducing discomfort or pain in deep tissue[13], that is not a technique to be recommended. The injection should preferably be performed in such a way, that the first injection of the anaesthetic liquid should be given in the superficial mucosa, where the topical anaesthetic effect is expected to be present. Thereafter, a low-speed continuous injection during very slow penetration of the needle to deeper tissue will allow the anaesthetic effect to precede the needle, and thereby minimize the risk for pain and discomfort during the injection procedure[16,17]. The discomfort and pain from contact with the periosteum is thereby not expected to be influenced by the topical anaesthetic, but by the injection technique. Therefore, we did not evaluate periosteum contact in this study.

The use of each patient as his/her own control helps support the findings since the variability in a patient's response to pain is noticeable.

An increased heart rate has been shown to be a reliable physiologic response to painful stimuli[18]. After 15 min application time the patch showed a more pronounced decrease (and percentage decrease) in heart rate than the gel at the buccal injection, indicating that the 20% lidocaine patch is more effective when in place for 15 min on the buccal injection site. This is in accordance with another report[6], where the application time and concentration of the lidocaine patch are correlated to the penetration depth and duration of the topical anaesthetic effect. They also found that the application time for the transoral lidocaine patch should be 5–15 min to achieve maximum analgesic effect, as supported by the results in this study. The significant decrease found for the gel but not for the patch at insertion at 15 min indicates that the gel may be more efficient in the superficial part of the mucosa than the patch. The patch may, on the other hand, be more efficient in deeper levels, as indicated by the more pronounced percentage decrease as compared to the gel at buccal injection. The gel seems to be better than the patch to provide anaesthetic effect in palatal mucosa, as shown by the significant decrease in pulse at palatal injection after application of gel, but not after application of patch. This latter may be a result of the sometimes occurring wavy structure of palatal mucosa, making the gel adhere better to the mucosa than the plane surface of the patch.

In this study, there were discrepancies between the pain-related evaluations where the VAS pain scale indicated a preference for the patch, while the changes regarding heart rate (Table 2) indicated a preference for the gel except at buccal injection. As pain is considered a subjective experience, and as the relatively small heart rate changes in this study can be influenced by, for example, psychological factors, the VAS pain scale could be preferred as the more reliable indicator of pain measurement. On the other hand, the heart rate is an objective value (which in research often is related to less bias factors) in contrast to the obviously subjective VAS scale.

The lower heart rate found at the second visit is in contrast to the study by Martin *et al.*[19], who found that the second injections were more painful than first injections. A possible explanation for the difference between the studies is that this study was performed with smaller needle size and with a new technique using a computerized delivery system that made the patient feel the needle more comfortable and less painful than when the old-fashion syringe technique with larger needle size was used. A good pain control will reduce the patient's anxiety level and make the patient feel less stress at the following dental visit, as shown by the decreased heart rate at the second visit in our study.

The VAS has previously been used in several studies, sometimes in combination with another pain rating score[14] or a faces pain scale[20]. We

preferred to use a VAS as it is found to be reliable and easy to use[7,12].

The mean value on the VAS pain scale for the lidocaine gel and the lidocaine patch was almost similar at the insertions at 2.5, 5, and 15 min after application of the topical anaesthetics, indicating that an application time of 2.5 min may be enough to achieve topical anaesthetic effect from either patch or gel in the surface layer of the buccal mucosa.

We found no significant differences regarding VAS pain rating at either buccal or palatal injection between the lidocaine patch and the 5% lidocaine gel. Wu and Julliard[8] and Kreider *et al.*[7] did not find any significant difference regarding the self-reported pain between 20% benzocaine gel and 20% lidocaine patch, but when Sounds, Eyes, Motor (SEM) scale for measurement of pain was used, the benzocaine gel had greater scores, indicating that the patch reduced pain more efficiently than the benzocaine gel. Other evaluation methods for pain rating – such as the SEM scale[21] – may give further information of whether the lidocaine gel or patch, used in this study, is the best pain-reducing topical anaesthetic.

There was less discomfort for the patient on both buccal and palatal mucosa after 15 min application time when the patch was used as compared to the 5% lidocaine gel. A contributing factor to why the patch was experienced as more comfortable for the patients in this study is probably that the dimension of the patch is more adapted to the application area as compared to the cotton roll used. Even if three patients in this study experienced specific irritation from the patch, this did not influence the significantly lower rating of discomfort for the patch in the study group. Although the patch is considered safe and effective[6], mucosal irritations were found in this study only when the 20% lidocaine patch was used. We therefore suggest that the 5% lidocaine gel should be preferred before the 20% lidocaine patch when patients with immunodeficiency or allergy are treated.

Another reason for discomfort may have been the taste perception. Even if the taste for the gel was not significantly worse than for the patch, the discomfort rating might have been influenced by the subjective impression of the examiner that the topical anaesthetic patch often remained better in place. This in turn may have resulted in less unpleasant taste from the anaesthetic patch than from the gel.

The presence of more extreme evaluations regarding the taste of the gel may indicate that the gel has a more distinct taste that is either accepted or not by the patient. Especially on the palatal side, negative perception of taste from the gel was present in several patients. Our findings regarding the patients' experience of discomfort are in accordance with Wu and Julliard,[8] who found that 20% lidocaine patch was preferred by 77% of 3- to 10-year-old children, when compared to 20% benzocaine gel.

Our findings regarding higher heart rate and VAS pain rating for the girls are in correspondence with several other reports, showing that girls report higher levels of dental anxiety and pain than boys[2,22,23]. The reason for different pain perception between sexes has not been clearly understood, but potential mechanisms have been suggested, such as: experiential (learning about pain), biological (hormones, contact with pathological agents), and psychological mechanisms (attitudes towards pain)[24,25].

From the measured change in heart rate we find it reasonable to suggest that the lidocaine gel needs 5 min and the lidocaine patch needs 15 min until a decrease of the heart rate is reached. Regarding the VAS pain scale, the lidocaine gel showed a relatively stable level already after 2.5 min, while the lidocaine patch had a continuous decrease during the study. This is in accordance with a previous study by Hersh *et al.*[6] that also showed a continuous decrease during the first 15 min according to the VAS pain scale after application of the DentiPatch™. The manufacturer suggests that the DentiPatch™ should not be used during more than 15 min. The DentiPatch™ obviously seems to need more time than the 5% lidocaine gel to be effective.

A topical anaesthetic that stays in place and prevents unpleasant taste is preferable for both patient and dentist. The subjective experience of the dentist in this study was that it would be easier to use the topical anaesthetic patch if it was smaller in size and had a better adherence to the oral mucosa than the

evaluated DentiPatch™. This is in accordance with Sticker *et al.*, who found the DentiPatch not recommendable because of poor adherence and the extra time necessary to apply and retain the device[26].

Many aspects of and methods for pain measurement – such as behavioural and psychological/projective measures – have not been used in this study, and several factors influencing the pain perception – such as developmental factors, previous pain experience, and parental attitudes – are difficult to measure and evaluate[12]. This study included both physiological (heart rate) and psychological/descriptive (VAS) methods, but not behavioural or psychological/projective measures.

Conclusion

The 5% lidocaine gel may provide a better superficial anaesthesia of oral mucosa after 15 min application. The heart rate was significantly more decreased at buccal injection when the patch was used as compared to the gel. At palatal injection, a significantly decreased pulse was found for the gel but not for the patch. There were no significant differences regarding the VAS pain ratings between patch and gel. A good pain control can reduce the patients' anxiety level at following dental appointments. The patients experienced less subjective discomfort during the application time when the patch was used as compared to the gel. The patch and gel seem to have similar efficacy regarding pain reduction at insertion and injection of local anaesthetics.

What this paper adds

- A transoral delivery system for topical anaesthesia (20% lidocaine patch) reduces pain and discomfort as efficiently as lidocaine 5% gel during the injection procedure.
- A good pain control during dental procedures decreases the patient's anxiety level at next dental visit.

Why this paper is important to paediatric dentists

- Effective topical anaesthetics are useful to reduce pain. Paediatric dentists can minimize the risk for their patients to develop anxiety and dental fear by using effective topical anaesthetics.

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