

Effect of local anesthesia on postoperative pain and hemostasis after dental rehabilitation under general anesthesia in pediatric patients: a randomized control trial

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Background: This study aimed to investigate the effect of local anesthesia (LA) on postoperative pain and hemostasis after dental rehabilitation under general anesthesia (DRGA) in pediatric patients.

Methods: A total of 43 patients, aged 3-7 years and rated ASA I or II, who had a definitely negative rating on Frankel's behavior rating scale, were included in this two-arm, parallel-design, single-blinded, randomized, controlled study. The patients were allocated equally into two main groups receiving both restorative treatments and tooth extractions. Two pain scales and one bleeding scale were used. In Group A, the treatment was done with LA, and in Group B, the treatment was done without LA.

Results: The statistical analysis revealed no significant differences in the pain scores between the groups. It also revealed significant differences in the bleeding scores between the groups but no significant differences in the duration of bleeding.

Conclusion: Within the limitations of this study, the use of LA in pediatric dental patients undergoing DRGA had no effects on postoperative pain reduction or bleeding duration after teeth extraction. We also observed that the use of LA had an impact on the reduction in the bleeding scores in pediatric dental patients undergoing DRGA.

Keywords: General Anesthesia; Hemostasis; Local Anesthesia; Postoperative Pain.

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INTRODUCTION

Tooth decay is a common disease in children that affects the primary and permanent teeth, causing pain and discomfort, and consequently affecting school performance [1]. Pediatric dentistry offers two approaches to behavior management, non-pharmacological and pharmacological (including sedation and general anesthesia (GA), to provide suitable dental treatment to young patients. Some children are highly anxious, are of pre-cooperative ages, or have medical, mental, or physical impairments, and can only be treated under GA. Dental rehabilitation under general anesthesia (DRGA) has several drawbacks, such as high expenses, the necessity for specialized training, the requirement of an anesthesia team, and the likelihood of experiencing postoperative complications like pain, discomfort, and nausea [2,3].

The use of local anesthesia (LA), according to some authors, is considered a pain-controlling method in children undergoing DRGA [4]. In addition, some authors claim that LA reduces the bleeding through vasocon-

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striction in children undergoing DRGA. Some authors avoid using LA due to potential complications, such as breaking of needles, prolonged anesthesia, facial nerve paralysis, soft tissue injury, and pain on injection [5].

The American Academy of Pediatric Dentistry guidelines reported that "there may be enhanced sedative effects when the highest recommended doses of LA drugs are used in combination with other sedatives or opioids" [6].

According to Al-Bahlani et al. (2001) [7], LA in DRGA reduced postoperative bleeding; however, its use was associated with significant postoperative distress [7].

While using LA during DRGA may be a topic of debate, it is crucial to prioritize postoperative pain management and ensure proper hemostasis for the well-being of patients.

Postoperatively, it is crucial to achieve hemostasis when the patient wakes up from GA. This is important to minimize the risk of foreign body aspiration or suffocation when the throat pack is removed, and the patient is moved to the recovery room.

There is a lack of research on how LA impacts both postoperative pain and hemostasis after DRGA in pediatric patients, despite the numerous studies in the literature on its effects on each separately [8]. Our study aimed to investigate the effects of LA on postoperative pain and hemostasis after DRGA in pediatric patients.

METHODS

1. Study population

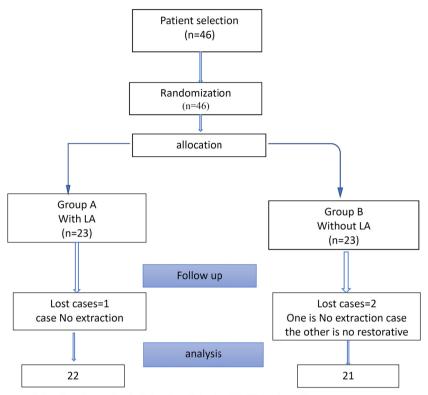
Our hospital is a government tertiary referral center that handles many DRGA cases every year. In 2019, 112 patients, aged 3–15 years, underwent DRGA procedures. Among these, 48 patients with an average age of 7 years, required restorative treatment for their primary teeth.

The success rate of LA in reducing postoperative pain in children undergoing DRGA was assumed to be 50%. Using the Steven K. Thompson formula, with an alpha level of 5%, a beta level of 20% (power equals 80%), and an effect size of 0.4, the required sample size was calculated to be 18 individuals for each leading study group, with 36 in total. The sample size was increased to 46 individuals to compensate for the dropout of participants. The sample size calculation was performed using Minitab 19.2.0 / October 2, 2019.

Forty-six patients, aged 3-7 years, were included in this two-arm, parallel-design, single-blinded, randomized, controlled study. The enrollment of participants took place between March 2020 and March 2022. The participants were selected by a consecutive clinical convenience sampling of children receiving DRGA. This study followed the Consolidated Standards of Reporting Trials statement (Fig. 1) [9]. The 46 patients enrolled in this study were divided into two groups based on whether they received LA prior to their dental treatment. The first group, Group A, consisted of 23 patients who received LA before their dental treatment, while the second group, Group B, consisted of 23 patients who did not receive LA before their dental treatment. The data from three patients were excluded from the analysis: one patient from Group A who did not require teeth extraction, and two patients from Group B, one of whom did not require teeth extraction and the other who did not require restorative treatment. The procedures adhered to the ethical standards of the Ministry of Health Research Ethics Committee [Moh/RECl2020144]. As per these guidelines, the patients were entitled to privacy, and written informed consent was acquired from a parent or guardian on the day of the scheduled procedure. The procedures were conducted following the guidelines outlined in the Declaration of Helsinki. This clinical trial was registered with ISRCTN registry [ISRCTN18557910].

All patients preoperatively underwent blood tests including CBC, PT, PTT, and INR to ensure a healthy coagulation status.

Patients who received treatment were scheduled for recall visits every 3–6 months based on their caries risk assessment using the International Association of Pediatric Dentistry Caries Risk Assessment and Care Pathways [10].



LA = Local anesthesia lidocaine 2% with 1:80000 adrenaline

Fig. 1. Flow chart indicating enrollment, treatment, follow-up, and analysis of study participants, according to the CONSORT guidelines. CONSORT, consolidated standards of reporting trials; n, sample size.

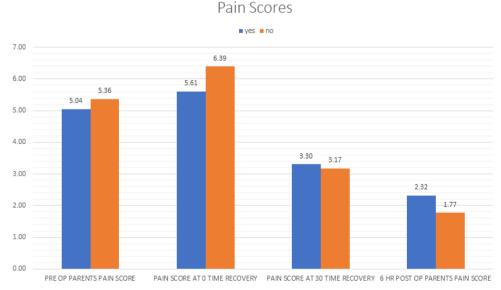


Fig. 2. Pain scores according to local anesthesia. The graph shows the mean values for Group A (blue color) and Group B (orange color) for the four different pain score scales.

2. Inclusion criteria

For the study, all cases required restoring at least two primary molars with vital pulp therapy and stainless-steel crowns and extracting two other primary molars. The participants were in good health, rated as I or II by the American Society of Anesthesiologists (ASA) [11], and had a definitely negative rating on Frankel's behavior rating scale [12].

3. Exclusion criteria

Patients who were outside of the predetermined age range were not eligible. Patients who required treatment or extraction of permanent teeth and those with medical, mental, or physical impairments. Additionally, patients who only needed restorative treatment without extraction, or vice versa, were excluded.

4. Study groups

Forty-six patients were divided into two main groups according to LA use: Group A (n = 23) patients received LA before starting the dental treatment and Group B (n = 23) patients did not receive LA before starting the dental treatment.

5. Randomization technique

This study randomly assigned 46 boys and girls, to either Group A or Group B. The assignment was done before the start of the study, with numbers from 1 to 46 randomly assigned on sealed envelopes, that were only opened at the time of the procedure.

6. Evaluation criteria

In total, each patient underwent four pain evaluations. The first evaluation was done preoperatively by the child's parent or caregiver using the Universal Pain Assessment Tool (UPAT). The UPAT tool used in this study was the Wong-Baker Faces Pain Rating Scale [13], which consisted of six faces, each corresponding to a number on a scale from 0 (no pain) to 10 (worst possible pain), as shown in Appendix 1.

In the recovery room, a trained pediatric dental resident recorded two scores at 0 and 30 min using the FLACC behavior scale (Appendix 2) [14]. This scale measures a child's reaction in five categories: face, legs, activity, crying, and consolability, and scores ranging from 0 to 2 are given for each category.

The last evaluation was conducted by the parent or caregiver using the UPAT. The scores were obtained over

the phone 6 h postoperatively, as patients are typically discharged 2-3 h post-surgery.

For the bleeding scores, the readings were obtained immediately after the extraction of the first tooth by the same unblinded pediatric dentist for all the patients to avoid bias. This was done using the Boezaart Surgical Field Grading Scale (Appendix 3) [15], which consists of six different grading stages for bleeding, starting from 0 (no bleeding) to 5 (severe bleeding).

The Post-Anesthesia Care Unit (PACU) nurses, pediatric dental residents, and parents or caregivers were blinded to whether the child had received LA.

7. Protocols for the administration of LA and GA

The anesthesia administered during the procedure followed a standard regimen that adhered to the Ministry of Health's protocol. It involved a nasal induction using sevoflurane, oxygen, and nitrous oxide. Additionally, the patients were given fentanyl (0.5 to 1.0 μ g per kg) and atracurium (0.5 μ g per kg) as induction medications. The anesthesia team only provided additional pain medication (narcotics) if necessary; however, no such intervention was required. Following the procedure, a PACU nurse administered paracetamol suppositories to all patients.

The duration of the procedure did not exceed the duration of soft tissue anesthesia for lidocaine, which is 90–200 min (Coté et al. (2019), AAPD LA guideline) [16].

Group A patients received 2% w/v lidocaine with 1:80000 epinephrine after a throat pack placement. Approximately one-third of the 1.8 mL LA cartridge was used per quadrant and the dose did not exceed 4.4 mg/kg. Multirooted teeth received buccal (mesial and distal) infiltrations to reduce LA failure bias [17], while single-rooted teeth, if the treatment was needed, received distobuccal infiltrations [17].

8. Protocol for hemorrhage score and hemostasis

After teeth extractions, the pediatric dentist evaluated the bleeding at the site, including the volume and rate. The dentist covered the extraction site with absorbent

Demographic data		Grou	ıp A	Gro	Group B		
		Mean \pm SD	Range	Mean \pm SD	Range		
Age		4.8 ± 1.29	3-7	4.79 ± 1.11	3-7		
	P-Value*		0.93	39			
		Male N (%)	female N (%)	Male N (%)	female N (%)		
sex		10 (45.5%)	12 (54.5%)	12 (57.1%)	9 (42.9%)		
	P-Value*	8.0	348	0.	476		

Table 1. Demographic characteristics of the study population

*P > 0.05 indicates no significant difference. N, number; SD, standard deviation.

Table 2. Summary statistics for study variables

Variables	Group) (A)	Group (B)		
ValidDies	Mean	SD	Mean	SD	
Operation time in min	32.96	5.28	30.74	10.73	
Number of posterior teeth treated	4.00	1.48	3.43	1.31	
Number of posterior teeth extracted	2.65	1.50	3.00	1.35	
Bleeding duration in min	4.38	1.88	5.09	2.29	
Bleeding score	2.05	0.59	2.41	0.50	
Pre-op parent's pain score	5.04	3.04	5.36	3.46	
Pain score at 0 time recovery	5.61	3.03	6.39	2.50	
Pain score at 30 time recovery	3.30	3.07	3.17	2.98	
6 hr post-op parent's pain score	2.32	2.36	1.77	1.93	
	n	%	n	%	
LA	22.00	51.00	21.00	49.00	

LA, local anesthesia; n, number; SD, standard deviation.

gauze and monitored it every minute to ensure proper hemostasis. No case of postoperative bleeding was recorded.

9. Dental rehabilitation regimen

The dental treatments were performed in a specific order for each quadrant: first, sealants, followed by glass ionomer restorations, composite resin restorations, pulpotomies, pulpectomies, and finally, stainless-steel posterior crowns. The extractions were saved for the end of the treatment to make it easier for measuring the bleeding score and duration. After completing the dental treatment and GA care, the patients were escorted to the PACU. All patients were discharged with a prescription of paracetamol as painkillers, starting 8 h postoperatively.

10. Statistical analysis

The T-test was employed to measure the differences in the bleeding and pain scores related to LA use. The F-test was employed to measure the differences in pain scores across different times. The study variables were summarized using descriptive statistics (mean and standard deviation) in SPSS 26 software (IBM Corp., Armonk, NY, USA). Repeated Measures were used to calculate the difference in the pain scores (UPAT and FLACC) across different times. A P-value less than 0.05 was considered statistically significant, with a confidence interval of 95% and a margin of error of 5%.

RESULTS

Out of the 46 children included in the study, the data from three patients were not analyzed. This was because, in one case, the minimum number of teeth requiring restorative treatment was not met, and in two cases, the minimum number of teeth requiring extraction was not reached. Therefore, the final sample for the study included 43 children (Fig. 1) who were equally distributed between two groups: Group A, who received LA, and Group B, who did not receive LA. Table 1 displays the demographic data for this study (mean value of age: Table 3. Pain scores across time

Pain scores	Group	(A)	Group (B)		
Faill Scoles	F test	P-value	F test	P-value	
Pre-op parents' pain score	127.9 	0.0001	194.73		
Pain score at 0 time recovery				0.0001	
Pain score at 30 time recovery				0.0001	
6 hr post-op parents pain score					
**P-value < 0.05					

'P-value < 0.05

Table 4. Bleeding according to LA groups (A and B)

LA	Grou	ир А	Grou	up B	t-test	P-value
Blooding duration in min	Mean	SD	Mean	SD	-1.108	0.274
Bleeding duration in min	4.38	1.884	5.09	2.287	-1.108	0.274
Pleading soore	Mean	SD	Mean	SD	-2.166	0.036
Bleeding score	2.05	0.590	2.41	0.503	-2.100	0.030

LA, local anesthesia; SD, standard deviation.

Group A = 4.8 ± 1.29 , Group B = 4.79 ± 1.11 (P = 0.939); sex distribution: Group A, females 54.5% and males 45.5% (P = 0.848) and Group B: females 42.9% and males 57.1% (P = 0.476). Table 2 shows the procedure time in minutes; there was no significant difference between the two groups; the mean value for Group A = 32.96 min and Group B = 30.74 min. (P = 0.381). The number of teeth treated and extracted did not vary significantly between the two groups. Group A had an average of 4.00 ± 1.48 teeth treated, while Group B had an average of 3.4 3 \pm 1.31 teeth treated. Similarly, Group A had an average of 2.65 ± 1.50 teeth extracted, and Group B had an average of 3.00 ± 1.35 teeth extracted. Both the differences were not statistically significant (P > 0.05).

1. Assessment of pain

Group A and Group B had no significant differences in the pain scores throughout the different stages of the study. The average UPAT scores before surgery were 5.04 \pm 3.04 for Group A and 5.36 \pm 3.46 for Group B, with no significant difference between the two groups (P =0.74). After surgery, Group A had an immediate postoperative mean FLACC score of 5.61 ± 3.03 , while Group B had a score of 6.39 ± 2.50 ; however, the difference was not significant (P = 0.34). Thirty minutes after surgery, Group A had a mean FLACC score of 3.30 ± 3.07 and Group B had a score of 3.17 ± 2.98 , with no significant difference (P = 0.88). Finally, the postoperative mean UPAT scores were 2.32 \pm 2.36 for Group A and 1.77 \pm 1.93 for Group B (P = 0.41) (Fig. 2).

Table 3 shows a noticeable variation in the pain scores between different time intervals, with a P-value of 0.0001, and illustrates that the average pain score decreases as time passes after the procedure for both Groups A and B.

2. Assessment of the bleeding score and hemostasis

According to Table 4, there was no significant difference in the bleeding duration, with Group A and Group B having a duration of 4.38 ± 1.884 and $5.09 \pm$ 2.287 min (P = 0.274), respectively. However, there was a significant difference in the bleeding scores; Group A and Group B had a bleeding score of 2.05 ± 0.590 and 2.41 ± 0.503 (P = 0.036), respectively. The mean bleeding score for Group A was significantly lower than that of Group B.

DISCUSSION

The administration of LA during DRGA is a topic of debate, and there is no conclusive evidence regarding its potential advantages [8]. Therefore, we conducted a study to assess the impact of LA on postoperative pain and hemostasis in children who have undergone DRGA,

excluding medical factors that could affect hemostasis. The study focused on healthy children who could express their pain effectively [18].

We followed the American Academy of Pediatric Dentistry's recommendations for our anesthesia protocol, which included using 2% w/v lidocaine with 1:80000 epinephrine [3]. Notably, this solution is widely used in the Ministry of Health. We found no significant differences between the two groups regarding the number of teeth treated or extracted and the procedure time, eliminating any possible bias related to these factors.

In this study, all children underwent nasal intubation to allow the pediatric dentist to examine their dental occlusion and have sufficient working space. An oropharyngeal pack was also inserted to safeguard their airway against foreign objects.

Each patient had four pain scores recorded: one preoperatively and three postoperatively in different timeframes. Blinded treatment allocation observers recorded all the four pain scales to avoid bias. The UPAT Wong-Baker Faces Pain Rating Scale was used because it is reliable, valid, and easy for patients and their parents/caregivers to understand [19]. The FLACC scale is reliable and valid for assessing the postoperative recovery stage pain in children and adolescents above 1 year with cognitive impairment [14,20]. Lastly, the Boezaart Surgical Field Grading scale is valid and reliable for recording the bleeding score in the surgical field [15]. Researchers have investigated the use of LA during DRGA for patients requiring only dental extractions [21, 22]. According to McWilliams et al. (2007), LA can be a useful supplement to GA. However, it should be noted that the positive results in this study may have been influenced by the oral administration of paracetamol (20 mg/kg) and ibuprofen (5 mg/kg) as preoperative pain medications for children [23]. Similarly, Sammons et al. (2007) found that intraligamental administration of lignocaine (lidocaine) can provide initial pain relief after recovery but doesn't significantly reduce the pain within the first hour after surgery [24]. Anand et al. (2003) also found that intraligamental anesthesia may be effective for pain management after extracting permanent molars under GA, although the results were not statistically significant [4]. It is possible that the positive results of LA observed in the study conducted by Anand et al. (2003) were influenced by certain factors, such as the age group (with a mean age of 11.3 years), the type of teeth that were extracted (permanent molars), and the type of anesthesia used (0.5% bupivacaine with 1:200,000 epinephrine).

According to our study, there was no significant difference in the pain scores between the two groups. However, we observed a significant difference in the bleeding scores between the two groups, although there was no significant difference in the bleeding duration. Our findings align with those of Leong et al. (2007) [25], which suggest that the administration of LA during the procedure does not impact the postoperative pain, discomfort, or anxiety experienced by young children who undergo extractions under GA.

Our results also concur with those of Moness and Hammuda (2019) [26], who found that administering LA to children during DRGA did not impact their postoperative pain levels. However, it is worth noting that their study utilized 3% plain mepivacaine hydrochloride. In our results, we observed significant differences in the bleeding scores based on the administration of LA, which may be attributed to the use of LA with vasoconstrictors. However, we did not observe any effect on the duration of bleeding. Based on this finding, we recommend using LA with a vasoconstrictor when extracting multiple teeth or performing a full mouth clearance in DRGA. This approach reduces the risk of foreign body aspiration or suffocation while removing the throat pack and transferring the patient to the recovery room.

Our findings on the bleeding scores were similar to those of Al-Bahlani et al. (2001) [7], who also used the same LA agent, 2% lidocaine with 1:80000 epinephrine. They found that using LA helped reduce postoperative bleeding.

McWilliams et al. (2007) [23] reported that using LA decreased the bleeding duration, which contradicts our

findings. However, the use of absorbable hemostatic packs and the lack of a precise bleeding score scale in their study may explain the difference.

There were three main limitations to our study. First, the follow-up period may have needed to be longer to establish the overall effect of LA. Second, the study was conducted during the COVID-19 pandemic, which resulted in several lock-down periods that significantly impacted the initial projected time for the study. Third, the operator was not blinded regarding the bleeding scores and duration of recording.

This study's confounders, age and gender, unlikely affected the results, as the sample size was small. Furthermore, the randomization of confounders between the study groups and their even distribution within each category helped to minimize any potential impact on the results.

Based on our study of 43 children, we found that using LA in pediatric dental patients undergoing DRGA does not reduce postoperative pain or the duration of bleeding after teeth extraction. We also observed the use of LA reduced the bleeding scores in pediatric dental patients undergoing DRGA. However, it's important to note that our study had certain limitations.

The following are essential points for pediatric dentists to consider:

- This is one of the first studies to explore the effect of LA on both postoperative pain and hemostasis.
- This study revealed that using LA in pediatric dental patients undergoing DRGA had no effect on postoperative pain reduction.
- This study revealed that using LA in pediatric dental patients undergoing DRGA affected the bleeding scores without any effect on the bleeding duration.

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AUTHOR CONTRIBUTIONS

Amal R Batarseh: Conceptualization, Data curation, Investigation, Methodology, Validation, Visualization, Writing - original draft, Writing - review & editing. **ACKNOWLEDGMENTS:** We are grateful to the nursing, anesthetic, and pediatric dentistry teams in Al Bashir hospital day case personnel for their help and cooperation in the study. We also thank the patients and their parents for their agreement to participate in our study.

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CONSENT FORM FOR PARTICIPATION AND PUBLICATION: Written informed consent was acquired from a parent or guardian on the day of the scheduled procedure.

DATA AVAILABILITY: The study was registered in the ISRCTN reference. The results are available at https://doi.org/10.1186/ISRCTN18557910. The datasets generated and/or analyzed during this study are available from the corresponding author upon reasonable request.

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Appendix 1. Preoperative universal pain assessment tool Wong-Baker FACES® Pain Rating Scale $\mathbf{)}$ •)• \odot \bigcirc





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Appendix	2.	FLACC	(Face,	Leg,	Activity,	Cry,	and	Consolability)
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Behaviors	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to the constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs were drawn up
Activity	Lying quietly, normal position moves easily	Squirming, shifting, back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams, sobs, frequent complaints
Consolability	Content, relaxed	Reassured by touching, hugging obeying talked to, distractible	Difficult to console or comfort

Adopted from Merkel Sandra, et al. Pediatric nursing. 23. 293-7. Lippincott Williams & Wilkins.

Appendix 3. Boezaart surgical field grading scale

0	No bleeding
1	Slight bleeding (no suctioning required)
2	Slight bleeding (occasionally suctioning required)
3	Slight bleeding (frequent suctioning required; bleeding threatens surgical field a few seconds after suctioning)
4	Moderate bleeding (frequent suctioning required; bleeding threatens surgical field directly after suctioning)
5	Severe bleeding (constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery not possible).

Adopted from Boezaart AP et al. Can J Anaesth. 1995 May; 42(5 Pt 1):373-6. With springer's permission.