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A Survey on Procedural Sedation and Analgesia for Pediatric Facial Laceration Repair in Korea

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Abstract

Background Most children with facial lacerations require sedation for primary sutures. However, sedation guidelines for invasive treatment are lacking. This study evaluated the current status of the sedation methods used for pediatric facial laceration repair in Korea.

Methods We surveyed one resident in each included plastic surgery training hospital using face-to-face interviews or e-mail correspondence. The health care center types (secondary or tertiary hospitals), sedation drug types, usage, and dosage, procedure sequence, monitoring methods, drug effects, adverse events, and operator and guardian satisfaction were investigated.

Results We included 45/67 hospitals (67%) that used a single drug, ketamine in 31 hospitals and chloral hydrate in 14 hospitals. All health care center used similar sedatives. The most used drug administered was 5 mg/kg intramuscular ketamine (10 hospitals; 32%). The most common chloral hydrate administration approach was oral 50 mg/kg (seven hospitals; 50%). Twenty-two hospitals (71%) using ketamine followed this sequence: administration of sedatives, local anesthesia, primary repair, and imaging work-up. The most common sequence used for chloral hydrate (eight hospitals; 57%) was local anesthesia, administration of sedatives, imaging work-up, and primary repair. All hospitals that used ketamine and seven (50%) of those using chloral hydrate monitored oxygen saturation. Median operator satisfaction differed significantly between ketamine and chloral hydrate (4.0 [interquartile range, 4.0–4.0] vs. 3.0 [interquartile range, 3.0–4.0]; $p < 0.001$).

Conclusion The hospitals used various procedural sedation methods for children with facial lacerations. Guidelines that consider the patient's condition and drug characteristics are needed for safe and effective sedation.

Keywords
- ketamine
- chloral hydrate
- hypnotics and sedatives
- pediatrics
- surveys and questionnaires

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Introduction

Pediatric facial lacerations are among the most common injuries encountered in emergency departments. Suturing is often performed under sedation, and this helps achieve an atraumatic, safe, and cooperative state. There are no statistics on pediatric sedation therapy for facial lacerations in Korea. However, according to the Healthcare Bigdata Hub of the Health Insurance Review and Assessment Service in Korea, 25,460 sutures for facial lacerations in children under the age of 5 and 72,309 claims for sedation management fees were reported in 2020,[1] indicating that sedation therapy was commonly applied for facial lacerations in children.

The Korean pediatric sedation guidelines, presented by The Korean Society of Pediatric Anesthesiologists in 2016, recommend the following depending on the expected sedation level: chloral hydrate for minimal sedation; chloral hydrate, midazolam, or nitrous oxide (N_2O) gas for moderate sedation; and midazolam, ketamine, or propofol for deep sedation.[2] However, there are no guidelines on determining the sedation level or drugs for invasive treatments such as suturing facial lacerations. The Korean Guidelines for Pediatric Procedural Sedation and Analgesia, formulated by the Korean Society of Emergency Medicine in 2012, recommend intramuscular (IM) or intravenous (IV) ketamine for simple sutures and IV ketamine for complicated laceration sutures as the first method of choice.[3] However, a pediatric sedation survey of university hospitals in Korea found that only 17% of the sedation treatments were performed by specialists, while most were performed by residents (42%) or interns (29%).[2] In the case of pediatric facial lacerations, plastic surgeons, who most commonly perform the required procedure, empirically implement sedation therapy. A comprehensive analysis of the current sedation therapy status in Korea is required to develop evidence-based guidelines suitable for domestic conditions to help achieve a more stable and effective sedation therapy.

Therefore, this study aimed to investigate the sedation therapy indications for suturing facial lacerations, drug types, usage, and dosage, monitoring methods, adverse events, and satisfaction level by surveying residents in plastic surgery training hospitals in Korea.

Methods

One resident at each plastic surgery training hospital in Korea completed a questionnaire through a face-to-face interview or e-mail correspondence between July and September 2018. The study protocol conformed to the ethical guidelines of the Declaration of Helsinki. The need to seek ethics approval was waived by the Daegu Fatima Hospital Institutional Review Board (IRB exemption No. DFE19ORI0047).

The primary end points included the status of sedative use and evaluation at the hospitals. The respondents' basic information, health care center (secondary or tertiary hospital), and the average number of weekly sedation cases for primary sutures were recorded. Sedation indications, sedative type, usage, dosage, re-administration, procedure sequence, induction time, sedation duration, sedation depth, monitoring, adverse events, and operator and guardian satisfaction were investigated. Sedation depth was based on the Ramsay Sedation Scale.[4] Guardian and operator satisfaction was evaluated on a 5-point Likert scale (1 = very unsatisfied, 2 = unsatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied). The pros and cons of the drugs used were investigated in a narrative form.

We analyzed the differences between secondary and tertiary hospitals and between ketamine and chloral hydrate use. Statistical analysis was performed using PSAW Statistics for Windows, Version 18.0 (SPSS Inc., Chicago, Illinois, United States). The Chi-square test was used to compare the proportions of usage of each sedative at the health care centers. The Kolmogorov-Smirnov test was used to assess the normality of the data distribution. Normally distributed continuous variables are presented as mean $\pm$ standard deviation and were assessed by the Student's *t*-test. Non-normally distributed continuous variables are presented as mean $\pm$ standard deviation and median (interquartile range), and were compared using the Mann-Whitney *U*-test. Categorical variables are presented as numbers (percentages) and were compared using the Chi-squared test or Fisher's exact test. The statistical significance was set at $p < 0.05$ for all analyses.

Results

Of the 67 plastic surgery training hospitals in Korea that were contacted, responses were obtained from 49 hospitals, resulting in a response rate of 73.1%. Among them, 31 (63.3%) hospitals used only ketamine, and 14 (28.6%) used only chloral hydrate for procedural sedation. Two hospitals used both, one used ketamine, chloral hydrate, and midazolam, and one used ketamine, chloral hydrate, midazolam, and diazepam. After excluding hospitals using two or more sedatives due to their small number and unclear answers as to the indications for each drug, 45 were included in the analysis (►**Fig. 1**).

Among the 45 hospitals included in the study, 27 (60%) were tertiary hospitals and 18 (40%) were secondary hospitals. Among tertiary hospitals, ketamine was used in 20 (74.1%) hospitals, and chloral hydrate in seven (25.9%) hospitals. Among secondary hospitals, ketamine was used in 11 (61.1%) and chloral hydrate in seven (38.9%) hospitals. There was no significant difference in the usage of sedatives between tertiary and secondary hospitals ($p = 0.357$; ►**Table 1**). The average number of weekly sedations for sutures was 20.5 ± 14.8 in tertiary hospitals using ketamine (median, 15.0 [interquartile range 10.6–26.1]) and 15.3 ± 10.4 in those using chloral hydrate (median, 12.8 [interquartile range 6.8–23.4]). The number of procedures using ketamine was higher (however, the difference was statistically insignificant) at both types of health care centers (tertiary hospitals, $p = 0.607$; secondary hospital, $p = 0.791$; ►**Table 1**).

The typical indications for sedation using ketamine included age under 72 months or body weight under 20 kg. The IM dose was 3 to 5 mg/kg at 23 hospitals (74%), and the IV dose was 1 to 2 mg/kg at eight hospitals (26%). The most

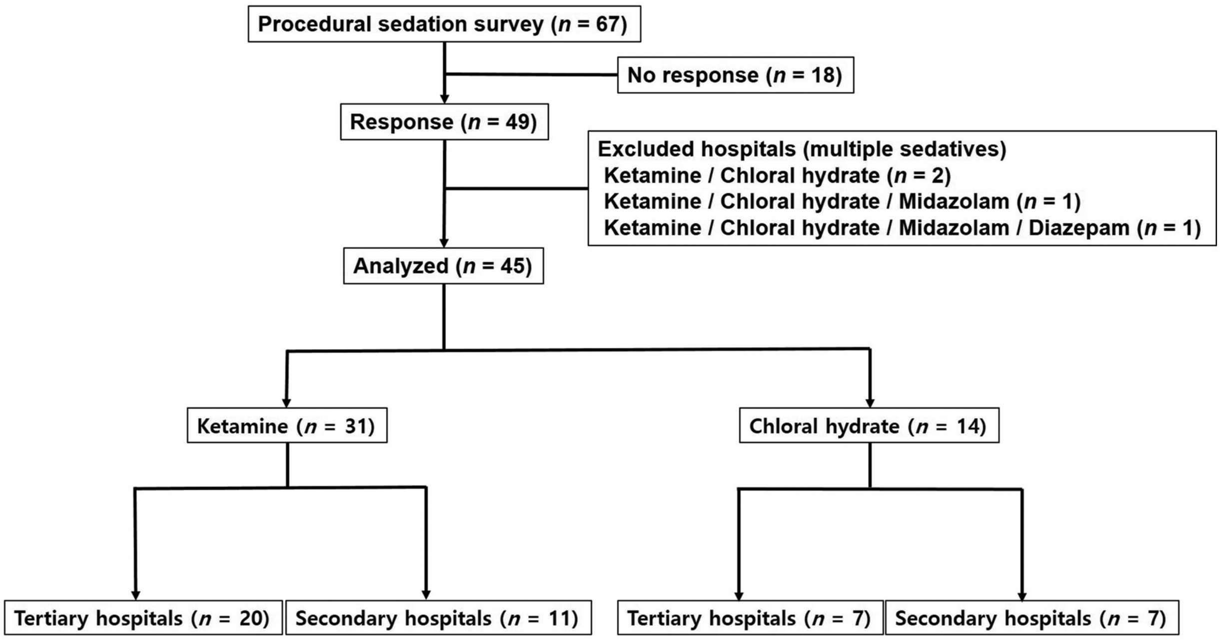

Fig. 1 Flow diagram of the study selection process. The *n* values pertain to the number of plastic surgery training hospitals.

Table 1 Drugs used for sedation and average number of sedation cases for primary sutures in tertiary and secondary hospitals

		Ketamine ($n = 31$)	Chloral hydrate ($n = 14$)	*p*-Value
Tertiary hospital	No. of hospitals	20[a]	7	
	No. of procedural sedation cases per week[b]			0.607
	Mean ± SD	20.5 ± 14.8	15.3 ± 10.4	
	Median (IQR)	15 (10.6–26.1)	12.8 (6.8–23.4)	
Secondary hospital	No. of hospitals	11	7	
	No. of procedural sedation cases per week[b]			0.791
	Mean ± SD	18.1 ± 12.0	15.7 ± 7.5	
	Median (IQR)	19.3 (7.9–26.1)	14.4 (12.1–21.3)	

Abbreviations: IQR, interquartile range; No., number; SD, standard deviation.
[a]Data not normally distributed.
[b]The mean values were compared using the Mann-Whitney *U*-test.

common procedure sequence was as follows: administration of sedatives, local anesthesia, repair of lacerations, and imaging work-up (13 hospitals, 42%). The local anesthesia was administered after sedation at all except two hospitals (29 hospitals, 94%). Of the eight hospitals that administered ketamine IV, four performed imaging work-ups before sedation, and four performed imaging work-ups after the sedation, local anesthesia, and suturing were completed. All hospitals using ketamine monitored oxygen saturation (SpO_2). Twenty-two hospitals (71%) only monitored oxygen saturation (►**Table 2**). The advantages as reported by the respondents included fast sedation induction, and the disadvantages included difficulties in securing an IV line to deliver IV sedation, short sedation duration, and adverse events such as nausea, vomiting, and desaturation.

The typical indications for chloral hydrate use included age under 36 months or body weight under 20 kg; oral administration was performed at all hospitals except one that used rectal administration. The dose varied from 50 to 100 mg/kg, but 50 mg/kg was the most commonly used dose (eight hospitals; 57%), followed by 80 mg/kg (three hospitals; 21%). When additional medication was required, one-third to half of the initial dose was re-administered at 12 hospitals (86%). The most common procedure sequence was as follows: local anesthesia, administration of sedatives, imaging work-up, and laceration repair (eight hospitals, 57%); at four hospitals (29%), local anesthesia was administered after sedation. Half of the hospitals (seven hospitals, 50%) did not perform any monitoring (►**Table 3**). The advantages reported by the respondents included few adverse events, while the disadvantages included long induction time, large variations in sedation induction time, and poor sedation effects.

The mean induction time for ketamine was significantly shorter than that for chloral hydrate (10.8 ± 7.6 vs.

Table 2 Ketamine usage status

	Ketamine ($n = 31$)	n (%)
Dosage and route of administration	5 mg/kg, intramuscular	10 (32)
	4 mg/kg, intramuscular	7 (23)
	3 mg/kg, intramuscular	6 (19)
	2 mg/kg, intravenous	5 (16)
	1.5 mg/kg, intravenous	2 (6)
	1 mg/kg, intravenous	1 (3)
Additional medications	1/2 of initial dose	11 (35)
	1/3 of initial dose	10 (32)
	No additional medication	2 (6)
	Same dose as the initial dose	1 (3)
	1/4 of initial dose	1 (3)
	Intravenous midazolam	1 (3)
	Declined to state	5 (16)
Procedure sequence	Administration of sedatives → Local anesthesia → Repair of laceration → Imaging work-up	13 (42)
	Administration of sedatives → Imaging work-up → Local anesthesia → Repair of laceration	9 (29)
	Imaging work-up → Administration of sedatives → Local anesthesia → Repair of laceration	7 (23)
	Imaging work-up → Local anesthesia → Administration of sedatives → Repair of laceration	1 (3)
	Local anesthesia → Administration of sedatives → Repair of laceration → Imaging work-up	1 (3)
Monitoring	Oxygen saturation	22 (71)
	Oxygen saturation + electrocardiogram	4 (13)
	Oxygen saturation + blood pressure	3 (10)
	Oxygen saturation + electrocardiogram + blood pressure	2 (6)

Table 3 Chloral hydrate usage status

	Chloral hydrate ($n = 14$)	n (%)
Dosage and route of administration	50 mg/kg, oral	7 (50)
	80 mg/kg, oral	3 (21)
	70 mg/kg, oral	2 (14)
	100 mg/kg, oral	1 (7)
	50 mg/kg, rectal	1 (7)
Additional medications	1/2 of initial dose	7 (50)
	1/3 of initial dose	5 (36)
	Same dose as the initial dose when defecating	1 (7)
	Declined to state	1 (7)
Procedure sequence	Local anesthesia → Administration of sedatives → Imaging work-up → Repair of laceration	8 (57)
	Administration of sedatives → Imaging work-up → Local anesthesia → Repair of laceration	3 (21)
	Imaging work-up → Local anesthesia → Administration of sedatives → Repair of laceration	2 (14)
	Imaging work-up → Administration of sedatives → Local anesthesia → Repair of laceration	1 (7)
Monitoring	Without monitoring	7 (50)
	Oxygen saturation	6 (43)
	Oxygen saturation + electrocardiogram	1 (7)

Table 4 Comparison of chloral hydrate and ketamine

	Ketamine ($n = 31$)	Chloral hydrate ($n = 14$)	p-Value
Induction time (min)	10.8 ± 7.6	38.0 ± 9.0	<0.001[a]
Sedation duration (min)	36.5 ± 19.1	40.0 ± 20.8	0.586
Re-administration rates (%)	10.8 ± 10.4	15.2 ± 11.1	0.204
Sedation depth[b]			
Mean ± SD	5.0 ± 0.3	4.5 ± 0.9	0.010
Median (IQR)	5.0 (5.0–5.0)	5.0 (4.3–5.0)	
Satisfaction (operator)[b]			
Mean ± SD	3.9 ± 0.3	3.1 ± 0.9	<0.001[a]
Median (IQR)	4.0 (4.0–4.0)	3.0 (3.0–4.0)	
Satisfaction (guardian)	3.4 ± 0.6	3.1 ± 0.8	0.125

Abbreviations: IQR, interquartile range; SD, standard deviation.
Note: Data are expressed as a mean ± standard deviation.
[a]Student's *t*-test or the Mann-Whitney *U*-test; $p < 0.05$ indicates a significant difference.
[b]The Mann-Whitney *U*-test, *p*-values, medians, and IQR are displayed.

38.0 ± 9.0 minutes; $p < 0.001$), while both had similar mean sedation durations (36.5 ± 19.1 and 40.0 ± 20.8, respectively; $p = 0.586$) and re-administration rates due to lack of sedation (10.8 ± 10.4% and 15.2 ± 11.1%, respectively; $p = 0.204$). The average sedation depth using the Ramsay Sedation Scale was 5.0 ± 0.3 (median, 5.0 [interquartile range, 5.0–5.0]) for ketamine and 4.5 ± 0.9 (median, 5.0 [interquartile range, 4.3–5.0]) for chloral hydrate. A Ramsay Sedation Scale score of 4 or higher was reached in both groups, indicating sedation level higher than sleep; ketamine was associated with significantly deeper sedation than chloral hydrate ($p = 0.010$). The operator's satisfaction rate for ketamine (3.9 ± 0.3; median, 4.0 [interquartile range, 4.0–4.0]) was significantly higher ($p < 0.001$) than that for chloral hydrate (3.1 ± 0.9; median, 3.0 [interquartile range, 3.0–4.0]), while the guardians reported similar satisfaction rates for the two drugs (3.4 ± 0.6 vs. 3.1 ± 0.8; $p = 0.125$; ►**Table 4**).

Discussion

Drugs commonly used for pediatric sedation in Korea include chloral hydrate, ketamine, and midazolam.[2] According to the results of a national and cross-sectional electronic survey conducted in the United States (US), midazolam, ketamine, and fentanyl were used as sedatives for pediatric lacerations,[5] In addition, according to an online, multinational, cross-sectional survey in Europe, midazolam, ketamine, and propofol were used in emergency departments for children.[6]

Chloral hydrate is one of the oldest sedatives still in use and is applied widely because of the high degree of familiarity with this drug and low cost.[7,8] However, it is associated with several disadvantages including difficulties during administration, delayed sedation, extended recovery time, considerable variations in sedation induction and maintenance time, no analgesic effect, and high sedation failure rate in children with a body weight of 15 kg or higher.[8,9] The 2016 "Children's Sedation Guidelines – Korean Guidelines" survey on sedative drugs conducted in 13 university hospitals in Korea found that chloral hydrate was the most commonly used sedative drug.[2] However, this study surveyed 49 plastic surgery training hospitals and showed that most of these hospitals used ketamine alone (31, 63%). The difference could be because this study focused on sedation for invasive procedures, while the "Children's Sedation Guidelines – Korean Guidelines" study included sedation for both examinations and procedures. Ketamine is a dissociative agent with analgesic effects, commonly used in painful procedures because of its rapid induction time and relatively predictable sedation effects.[10,11]

In 2011, Green et al suggested that 1.5 to 2.0 mg/kg IV and 4.0 to 5.0 mg/kg IM were the appropriate ketamine doses.[10] The 2016 Korean pediatric sedation guidelines recommend ketamine doses of 0.5 to 2.0 mg/kg IV or 4 to 5 mg/kg IM and chloral hydrate oral doses of 25 to 100 mg/kg.[2] A retrospective study suggested that an initial chloral hydrate dose of 48 ± 2 mg/kg used for procedural sedation was effective and had the least number of adverse events.[12] As per our study, and because IM administration is more likely to cause respiratory adverse events than IV administration, plastic surgery training hospitals in Korea administer IM ketamine at doses lower than those recommended in the guidelines.[11] However, as ketamine does not show dose-related adverse events in the standard dosing range, 4 to 5 mg/kg should be considered to obtain a consistent effect rather than a 3 mg/kg dose.[10] IV Ketamine and chloral hydrate were administered at doses close to the upper limit set in the current guidelines. As ketamine administered via the IV route has a shorter maintenance time than that administered via the IM route, it was administered via IV at close to the upper dose limit set in the guidelines. It was also clear that with reference to chloral hydrate, a deeper sedation level was required for surgical procedures than that for examinations.

In hospitals using ketamine, local anesthesia was administered after sedation in most hospitals because ketamine has an analgesic effect. Suturing was performed immediately after sedation in eight hospitals administering IV ketamine, and an imaging work-up was performed before sedation or after suturing; this was probably because the goal was to complete the suturing procedure while the short sedation period lasted.[13] Chloral hydrate is a pure sedative-hypnotic agent used mainly for painless procedures because it has no analgesic effect.[9] Sedation was performed after local anesthesia in ten hospitals (71%). In four hospitals (29%), sedation was performed before local anesthesia. One of these hospitals reported that many patients were observed to either wake up easily or to toss and turn after sedation. Local anesthesia after chloral hydrate sedation may affect the re-administration rate due to sedation failure; hence it appears necessary to perform procedural sedation after local anesthesia.

Hospitals using ketamine reported adverse events such as nausea and vomiting. A meta-analysis of 13,883 children reported several adverse events that occurred during procedural sedation[14] including vomiting (5.6%), agitation (1.8%), hypoxia (1.5%), apnea (0.7%), and laryngospasm (0.4%), with vomiting (8.1%) showing the highest incidence when ketamine was used.[11,14] A study from 2008 reported that the adverse events caused by chloral hydrate included vomiting (2–30%), paradoxical excitement (0–6%), and desaturation (0–4%).[15] Hospitals that used chloral hydrate in the present study listed shallow sedation depth and long sedation induction time as the disadvantages of this drug, but mentioned no adverse events. Half of the hospitals performing sedation with chloral hydrate performed no monitoring, making it difficult to identify adverse events related to desaturation. Chloral hydrate might cause respiratory depression and hypoxia; therefore, appropriate monitoring and management are required. Chloral hydrate is banned in Italy and France due to its carcinogenicity and genotoxicity,[16] and products containing chloral hydrate have not been produced in the US since 2012 because it has not been approved by the US Food and Drug Administration.[17,18] Additionally, ketamine is also used in combination with other drugs to increase their effects while reducing the side effects.[5,10] However, in most plastic surgery training hospitals in Korea, ketamine or chloral hydrate was mostly used as a standalone sedative agent. Therefore, it is important to find a safer sedation approach for pediatric laceration repair in Korea.

This was the first study to investigate the status of pediatric procedural sedation for facial laceration closure in Korea. In Korea, most facial lacerations in children requiring sedation are treated at plastic surgery training hospitals; therefore, our findings can be considered representative of the current situation in Korea. This was also the first study to specifically investigate the sedation drugs used, their administration and monitoring methods, and the procedure sequence with reference to pediatric facial laceration closure. The adverse events, advantages, disadvantages, and satisfaction levels experienced by the operator who performed the sedation and the guardians of the patients were also investigated. The study was limited by the dependence of the results on the respondents' memory and subjective judgment because of the survey method used. Furthermore, the guardians' satisfaction was rated from the operator's point of view, possibly causing bias.

This study found that various sedation methods were used in plastic surgery training hospitals in Korea, each with its own advantages and disadvantages. Standalone ketamine therapy was the most commonly used sedation approach for facial laceration closure in children. However, in the absence of standardized guidelines, we found differences among hospitals in usage, doses, re-administration doses, and monitoring. Furthermore, we found that at some hospitals, the drug characteristics were not considered in relation to the procedure sequence, resulting in reduced sedation effects or insufficient monitoring. Therefore, guidelines that consider the drug characteristics, operator treatment plans, and appropriate monitoring should be established to achieve ideal sedation for suturing facial lacerations in children.

Authors' Contributions

H.Y., Ha.P., and D.L. contributed toward conceptualization. D.L. and Y.L. did the data curation. H.Y., D.L., Y.L., Hy.P., and Ha. P. did the formal analysis and methodology. H.Y., Ha.P., D.L., and Y.L. did the project administration and wrote the original draft. H.Y. did the supervision. H.Y., F.L., Hy.P., and Ha.P. did the writing -review and editing. All the authors approved the final manuscript.

Ethical Approval

The study protocol followed the ethical guidelines of the Declaration of Helsinki. The need to seek ethics approval was waived by the Daegu Fatima Hospital Institutional Review Board (IRB exemption no. DFE19ORIO047).

Conflict of Interest

None declared.

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