Intravenous Thiamylal and Local Anesthetic Infiltration for Pediatric Facial Repair Procedures Performed in Emergency Departments

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Thiamylal is widely used for procedural sedation in emergency departments (ED); however, there are limited safety data for doses of thiamylal >5 mg/kg in children. We investigated whether intravenous thiamylal in combination with local anesthetics is safe and effective for pediatric procedural sedation in the ED and to identify the association between increasing doses thiamylal and adverse events. Between July 2004 and June 2008, 227 children who underwent procedural sedation met the inclusion criteria, including 105 males (46.3%) and 122 females (53.7%). Facial laceration was the most common indication for procedural sedation. All children received an intravenous injection of thiamylal, with a loading dose of 5 mg/kg. Eighty-one children (35.7%) received a supplemental dose of 2.5 mg/kg thiamylal because of inadequate sedation. Of these, 27 (11.9%) received a second supplemental dose of 2.5 mg/kg because of inadequate sedation. Sixty-six patients (29.1%) experienced 75 mild and self-resolving adverse events, and most of which (15/75; 20%) were drowsiness. Four (1.8%) patients experienced oxygen saturation below 96%, which was related to the supplemental dose of thiamylal ($p = 0.002$). No children suffered from any lasting or potentially serious complications. Our results indicate that intravenous thiamylal in combination with local anesthetic infiltration is a well tolerated for therapeutic procedures in the ED. Thiamylal offers rapid onset of sedation without compromising the patient's cardiorespiratory function during pediatric procedural sedation.

Key Words: emergency department, pediatric, procedural sedation, thiamylal
(*Kaohsiung J Med Sci* 2010;26:192–9)

Received: Jul 30, 2009 Accepted: Oct 7, 2009
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It is common to perform painful but essential procedures such as wound cleaning, closure of superficial lacerations, incision of abscesses, nail bed repair and extraction of foreign bodies for frightened children in the emergency department (ED). Successful treatment not only requires cooperation from the child and

parents, but also relies on appropriate pain relief to reduce discomfort [1,2]. Most children requiring procedural sedation for therapeutic procedures might not cooperate with the treatment solely with local anesthetic administration. To avoid using general anesthesia and unacceptable delays of initiating treatment when children undergo therapeutic procedures, pediatric procedural sedation and local anesthesia provide an alternate method to allow patients to tolerate unpleasant procedures and preserve cardiorespiratory function.

Local anesthetic infiltration can provide excellent analgesic effects on cooperative children. However, for most injured young children who do not realize the benefit of local anesthesia and who suffer from anxiety and tissue damage-induced pain, they need moderate to deep sedation for the therapeutic procedures. Agents such as propofol [3,4], ketamine [5,6], and midazolam [7] are normally used for procedural sedations. Because of the different pharmacologic mechanisms of each drug, there are no criteria to use one drug rather than another for therapeutic sedation. Barbiturates, which suppress the transmission of excitatory neurotransmitter and enhance the transmission of inhibitory neurotransmitters, have been used as monotherapy for procedural sedation [8–10]. They produce minimal respiratory and cardiovascular depression. Replacing the sulfur atom with oxygen at the C2 position of barbiturate acid has resulted in the development of short-acting barbiturates such as sodium thiopental and thiamylal, which have been used successfully as the sole anesthetic for computed tomography/magnetic resonance imaging of children [11,12].

In the ED, short-acting barbiturates are often used as the sedative agent in combine with a muscle relaxant for rapid intubation [13–16]. Indeed, many studies have demonstrated the safety and effectiveness of thiamylal in the induction of anesthesia. However, there are limited data in children regarding the induction of deep sedation and the incidence of adverse events associated with the use of thiamylal in the ED.

In this study, we used thiamylal, a short-acting barbiturate that is structurally similar to but slightly more potent than thiopental, as an adjuvant to local anesthetic infiltration for therapeutic procedures. The objectives of this study were to investigate the effect of thiamylal for pediatric sedation in the ED and to identify the association between dose of thiamylal and incidence of adverse events.

Materials and Methods

We conducted a 5-year retrospective observational study of the use of thiamylal for procedural sedation in the ED of a large suburban general hospital. This study was approved by the Institutional Review Board of Kaohsiung Medical University Hospital. The medical records of 400 patients were reviewed for this study if they met all of the following criteria: (1) American Society of Anesthesiologists physical status of I or II; (2) age between 2 and 7 years old; (3) preoperative fasting for more than 6 hours; and (4) undergoing brief sedation with various doses of thiamylal for a painful procedure between July 2004 to June 2008. Patients were excluded if they had significant head injuries (unconscious, vomiting, or mentally obtunded) or wound requiring formal surgical exploration or other injuries requiring admission for further care. Patients with known history of a recent episode of bronchiolitis or bronchial asthma were also excluded.

The adequacy of sedation was assessed using a 7-point scale developed and validated at the Children's Hospital of Wisconsin [17] (range, 0–6; 0 = unresponsive to painful stimuli; 1 = aroused, but not to consciousness, with painful stimuli; 2 = aroused to consciousness slowly with sustained painful stimuli; 3 = aroused to consciousness with moderate tactile or loud verbal stimuli; 4 = drowsy, eyes open or closed, but easily aroused to consciousness with verbal stimuli; 5 = spontaneously awakes without a stimulus; 6 = anxious, agitated or in pain). In the ED, children planned for therapeutic painful procedures in a strange environment do not cooperate with a sedation score of 4. Thus, adequate sedation was defined as a sedation score of 0–3 and unacceptable sedation was defined as a score of 4–6. The patient was considered to have recovered from sedation when his/her vital signs became stable and consciousness became clear, and when extremity motility was restored.

Overall, 227 children received an intravenous bolus of 5 mg/kg thiamylal, which was followed by local infiltration of 1.5% lidocaine (≤ 3 mg/kg) [18] when the child lost eyelash reflex. Patients were divided into three groups [Group S, patients received an intravenous bolus of 5 mg/kg thiamylal at a regular rate of 0.5–1.0 mL/sec; Group O, patients received a supplemental dose of 2.5 mg/kg thiamylal when sedation was considered inadequate (sedation score

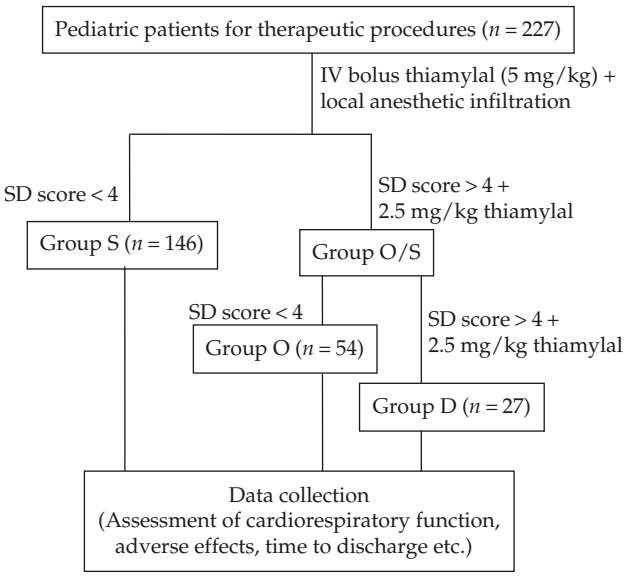

Figure. *Experimental setting. Patients were grouped according to the number of doses of intravenous thiamylal required for procedural sedation.*

≥4); Group D, patients received a second supplemental doses of 2.5 mg/kg thiamylal when sedation was again considered inadequate (sedation score ≥ 4)] (Figure). An anesthesiologist was consulted when needed. The ED surgeon was accompanied with staff with basic training in anesthesiology and advanced pediatric life support to monitor the patient's vital signs when procedural sedation was performed in this setting. Vital signs, including blood pressure, electrocardiogram, and pulse oximetry, were routinely monitored throughout the procedure.

Data including demographic characteristics, wound type, thiamylal dose, duration of therapeutic procedures, time to discharge, and adverse events were collected. Time to discharge was defined as the time from the injection of thiamylal to the patient discharge. Adverse events including O_2 desaturation < 96% with assisted airway maintenance, hypoxia [oxygen saturation (SaO_2) < 90%], apnea (breath holding > 20 sec), laryngospasm, bronchospasm, cardiovascular instability, and emergence delirium were considered serious while nausea, vomiting, and cough, for example, were considered mild.

Statistical analysis

Demographic data, wound type, thiamylal dose, time to complete the therapeutic procedure, time to discharge, and adverse events were compared between the groups using two-sample *t* tests for continuous variables and χ^2 tests for categorical variables or Fisher's exact tests for small sample sizes. We performed univariate analysis to identify significant factors affecting time to discharge and adverse events. The time to discharge was compared between Groups O and D using unpaired Student's *t* test. Results were considered statistically significant at $p < 0.05$.

Results

During the 5-year period, 227 patients underwent procedural sedation and met the inclusion criteria, including 105 males (46.3%) and 122 females (53.7%). As summarized in Table 1, face laceration was the most common indication for sedation. All children received an intravenous injection of thiamylal, with a loading dose of 5 mg/kg. Of the patients, 81 children (35.7%) received a supplemental dose of 2.5 mg/kg because of inadequate sedation and, of these, 27 (11.9%) received a second supplemental dose of 2.5 mg/kg because of inadequate sedation.

There were no serious adverse events such as laryngospasm or cardiorespiratory depression. Four episodes of SaO_2 below 96% were recorded; the lowest SaO_2 was 93% (Group S *vs.* Group O *vs.* Group D; $p = 0.002$). However, all episodes were transient and recovered to > 96% under assisted airway maintenance by trained medical staff. All four episodes occurred in the children receiving supplemental doses of thiamylal (Group O, $n = 1$; Group D, $n = 3$). None of the children required admission to hospital as a result of these events. Mild adverse events were recorded in 26 (11.5%) patients while in the ED, and in 49 (21.6%) patients after discharge (Table 2). Sixty-six patients (29.1%) experienced 75 mild and self-resolving adverse effects, and most of which (15/75; 20%) were drowsiness.

Of the 146 patients in Group S, three (2.1%) developed nausea, one (0.7%) developed urticaria, three (2.1%) vomited, four (2.7%) coughed, three (2.1%) mentioned pain at the injection site, and four (2.7%) exhibited mild agitation. Among the 54 patients in the Group O, only one (1.9%) coughed and two (3.7%) exhibited mild agitation. A 6-year-old female experienced a visual hallucination. The child told her parents she saw something blurred coming out of the wall. Both she and her parents were not distressed by the hallucination, and it seemed to resolve quickly.

Table 1. Patient demographic characteristics and wound distribution ($n = 227$)*

	Group S ($n = 146$)	Group O ($n = 54$)	Group D ($n = 27$)
Age (yr)	3.87 ± 1.34	4.37 ± 1.77	4.41 ± 1.55
Sex, female:male	82:64	23:31	17:10
Weight (kg)	15.92 ± 2.94	17.20 ± 4.31	17.22 ± 3.81
Wound type, lacerations	146	54	27
Chin	22 (15.1)	9 (16.7)	2 (7.4)
Eyebrow	3 (2.1)	7 (13.0)	4 (14.8)
Eyelid	13 (8.9)	2 (3.7)	1 (3.7)
Face	28 (19.2)	5 (9.3)	3 (11.1)
Forehead	44 (30.1)	22 (40.7)	14 (51.9)
Hand	0	1 (1.9)	0
Head	19 (13.1)	5 (9.3)	2 (7.4)
Lip	13 (8.9)	1 (1.9)	1 (3.7)
Nose	4 (2.7)	2 (3.7)	0

*Data presented as mean ± standard deviation, *n*, or *n* (%). Group S = 5 mg/kg thiamylal; Group O = 5 mg/kg thiamylal plus one supplemental dose of 2.5 mg/kg thiamylal; Group D = 5 mg/kg thiamylal plus two supplemental doses of 2.5 mg/kg thiamylal; F = female; M = male.

Table 2. Treatment-emergent adverse events observed in the emergency department and at home*

	Group S ($n = 146$)		Group O ($n = 54$)		Group D ($n = 27$)		*p*
	ED	Home	ED	Home	ED	Home	
Circulatory depression	0	0	0	0	0	0	1.000
Respiratory depression							
Mild ($SaO_2 < 96\%$)	0	0	1	0	3	0	0.002†
Severe ($SaO_2 < 90\%$)	0	0	0	0	0	0	1.000
Emergence delirium	0	0	0	0	0	0	1.000
Pain at injection site	3 (2.1)	0	0	0	0	0	0.704
Skin rashes	0	5 (3.4)	0	1 (1.9)	0	0	0.569
Urticaria	1 (0.7)	1 (0.7)	0	0	0	1 (3.7)	0.433
Nausea	3 (2.1)	1 (0.7)	0	0	0	0	0.743
Vomiting	3 (2.1)	4 (2.7)	0	1 (1.9)	0	1 (3.7)	0.887
Drowsiness	0	6 (4.1)	0	6 (11.1)	0	3 (11.1)	0.156
Hallucinations	0	0	1 (1.9)	0	0	0	0.352
Agitation	4 (2.7)	5 (3.4)	2 (3.7)	1 (1.9)	1 (3.7)	1 (3.7)	0.950
Cough	4 (2.7)	0	1 (1.9)	1 (1.9)	3 (11.1)	0	0.151
Others	0	9 (6.2)	0	1 (1.9)	0	1 (3.7)	0.477
Total	18 (12.3)	31 (21.2)	4 (7.4)	11 (20.4)	4 (14.8)	7 (25.9)	0.707

*Data presented as *n* or *n* (%); †Fisher's exact test. Group S = 5 mg/kg thiamylal; Group O = 5 mg/kg thiamylal plus one supplemental dose of 2.5 mg/kg thiamylal; Group D = 5 mg/kg thiamylal plus two supplemental doses of 2.5 mg/kg thiamylal; ED = emergency department; SaO_2 = oxygen saturation.

The average duration of the procedure was 5.38 ± 1.37 minutes for Group S, 6.35 ± 2.04 minutes for group O, and 9.96 ± 2.90 minutes for Group D. All of the children were discharged home and the mean time to discharge was 40.01 ± 8.41 minutes for Group S, 55.22 ± 13.54 minutes for Group O, and 63.89 ± 17.37 minutes for group D (Table 3). There was a significant positive correlation between time to discharge and

Table 3. Duration of therapeutic procedures and time to discharge from the emergency department*

	Group S ($n=146$)	Group O ($n=54$)	Group D ($n=27$)	p
Therapeutic procedure (min)	5.38 ± 1.37	6.35 ± 2.04	9.96 ± 2.90	< 0.001‡
Time to discharge (min)				
< 30	1 (0.7)	0	0	1.000
30–40	82 (56.2)	11 (20.4)	4 (14.8)	0.002
41–50	51 (34.9)	10 (18.5)	3 (11.1)	0.048
51–60	8 (5.5)	17 (31.5)	6 (22.2)	< 0.001†
61–90	4 (2.7)	16 (29.6)	13 (48.1)	< 0.001†
> 90	0	0	1 (3.7)	0.120
Average time spent (min)	40.01 ± 8.41	55.22 ± 13.54	63.89 ± 17.37	< 0.001‡/ 0.029§

*Data presented as mean ± standard deviation, n or n (%).†χ^2 test; ‡one-way analysis of variance; §unpaired Student's t test between Group O and Group D; Group S = 5 mg/kg thiamylal; Group O = 5 mg/kg thiamylal plus one supplemental dose of 2.5 mg/kg thiamylal; Group D = 5 mg/kg thiamylal plus two supplemental doses of 2.5 mg/kg thiamylal.

increase in thiamylal dose (Group S *vs*. Group O *vs*. Group D: $p < 0.001$; Group O *vs*. Group D: $p = 0.029$).

Discussion

In this study, we retrospectively reviewed the data for children sent to our ED, mostly to treat facial lacerations needing immediate therapeutic procedures. An intravenous injection of 5 mg/kg thiamylal for procedural sedation was insufficient for 35.2% (81/230) of the children. A supplemental dose (2.5 mg/kg) was given in 23.5% of patients (i.e. Group O) and a second supplemental dose was given in 11.7% of patients (i.e. Group D) to achieve deep sedation. With adequate cardiorespiratory monitoring and provision of airway support, as needed, by experts, there were no cases of circulatory or severe respiratory depression during the therapeutic procedures, although four patients (1.7%) experienced O_2 desaturation < 96%. No delirium occurred on recovery from sedation either at the ED or at home. Our study indicated that intravenous thiamylal was well tolerated and an effective procedural sedation for minor pediatric procedures performed in the ED. Furthermore, our study also demonstrated the absence of severe adverse events, although supplemental doses of thiamylal were needed to achieve adequate sedation. Unsurprisingly, the time to discharge from the ED was significantly longer in patients given repeated doses of thiamylal ($p < 0.001$).

Scared children suffering from pain, distress, and anxiety are often unable to calm down in a strange environment, even if they are accompanied by their parents. Local analgesia either by a topical anesthetic or local anesthetic infiltration usually provides sufficient analgesia for facial laceration repair. Once an intravenous line is placed, sedative agents such as midazolam, propofol, thiopental, or ketamine can be used to sedate uncooperative children. However, propofol causes pain at the injection site and suppresses cardiorespiratory function, and ketamine can induce delirium on recovery, which restrict the use of these agents in the ED. Parenteral midazolam is a good option for either diagnostic or therapeutic procedures. However, as compared with barbiturates, its slower onset, prolonged duration, rate of failure to achieve sedation, and potential risk of respiratory suppression limit the use of midazolam for short, but painful, therapeutic procedures [19]. Babl et al [20] reported that high concentrations of nitrous oxide [(N_2O) 70%] are safe for children undergoing procedural sedation and analgesia. However, routine administration of N_2O to children in the ED is not recommended because it is detrimental to medical personnel after long-term exposure. This study revealed that thiamylal provided rapid onset, steady cardiorespiratory function, and few adverse effects. In addition, local anesthetic infiltration appears to provide favorable peri-operative and post-operative analgesia. Our results demonstrate that intravenous thiamylal in combination with local anesthetic infiltration is well tolerated for therapeutic procedures and that thiamylal is effective for pediatric procedural sedation. Our findings also confirm that

thiamylal offers an alternate to the conventionally used sedative agents for therapeutic procedures in the ED.

One limitation of this study is that an intravenous access line was needed in all children before the therapeutic procedures could be started. Therefore, we excluded children in whom intravenous access could not be prepared because of technical difficulties in inserting the access line or because the behavior of the child prevented insertion of the access line. Some children with facial laceration resisted intravenous access via the forearm or the dorsal hand, even though local EMLA (Eutectic Mixture of Lidocaine and Prilocaine) cream was used. In such situations, intramuscular ketamine was indicated [21]. However, the increased salivation and delirium on recovery from anesthesia associated with ketamine is bothersome. Montes and Bohn [22] reported that the inconvenience associated with obtaining intravenous access in children was eliminated by inhaled sevoflurane. However, air pollution of the working environment by volatile anesthetics and N_2O remains a barrier to their use. In addition, it is inappropriate to use volatile anesthetics and N_2O in a busy ED in which air-conditioning might not be efficient and waste gas scavengers might be inadequate because medical personnel exposed to sevoflurane or N_2O may show impaired judgment and alertness [23,24].

Injured children in the ED, a unique and strange environment, suffer from wound pain in addition to varying degrees of anxiety and distress. Thus, the provision of analgesia by local anesthetic infiltration alone, without procedural sedation, is generally insufficient. Intravenous administration of thiamylal can induce moderate to deep sedation in children. This study revealed no harmful circulatory or severe respiratory suppression during the therapeutic procedures. Therefore, we conclude that intravenous thiamylal in combination with local anesthetic infiltration is a well tolerated modality for therapeutic procedures performed in the ED.

Acknowledgments

The authors would like to thank Dr Yun-Chi Fergus Huang for professional statistical assistance and Mr Richard H. Davis for reviewing and editing the manuscript for English grammar.

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以靜脈 Thiamylal 合併局部麻醉劑浸潤應用於急診小兒臉部修復處置之回溯性研究

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Thiamylal 是急診常用於處置過程鎮靜的用藥，惟其較高劑量（**> 5mg/kg**）用於兒童的安全性報告有限。本研究的目的為評估於急診使用 **thiamylal** 作為兒童輕至中度鎮靜劑的療效與其劑量增加和副作用出現的關連性。回朔性的蒐集由 **2004** 年 **7** 月至 **2008** 年 **6** 月的五年內，前往市郊一所教學綜合醫院急診處進行小型侵入性手術的 **227** 位病童的資料，本研究評估了靜脈投予 **thiamylal**，合併使用局部麻醉劑浸潤的安全性與有效性。**105**（**46%**）位男性與 **122**（**54%**）位女性病童中，臉部撕裂傷的侵入性手術處置為使用鎮靜劑的主因。所有的病童都先接受 **thiamylal 5mg/kg** 作為初始劑量，其中 **81**（**35.68%**）位因鎮靜作用不夠再接受了 **thiamylal 2.5 mg/kg** 的追加劑量；這 **81** 位中又有 **27**（**11.89%**）位仍因鎮靜作用不夠而再接受了一次 **thiamylal 2.5 mg/kg** 的追加劑量。結果顯示，**66**（**29.07%**）位病童出現了 **75** 項輕微且不需緊急處置或用藥的副作用；其中，困倦（**20%**）為最常出現的副作用。有 **4** 位病童曾出現血氧濃度低於 **96%** 且此與劑量追加有關（$p = 0.002$），但完全沒有病童出現嚴重的副作用，亦沒有病童出現嚴重的併發症。這些結果顯示了在急診給予需要侵入性治療的病童靜脈投予 **thiamylal** 且合併使用局部麻醉劑浸潤是安全的，**thiamylal** 提供了作用迅速與維持平穩心肺功能的優點。

關鍵詞：急診，小兒，處置過程鎮靜，**thiamylal**

（高雄醫誌 **2010;26:192–9**）

收文日期：**98** 年 **7** 月 **30** 日

接受刊載：**98** 年 **10** 月 **7** 日

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