

Supplementary Online Content

Frey TM, Florin TA, Caruso M, Zhang N, Zhang Y, Mittiga MR. Effect of intranasal ketamine vs fentanyl on pain reduction for extremity injuries in children: the PRIME randomized clinical trial. *JAMA Pediatr*. Published online December 28, 2018. doi:10.1001/jamapediatrics.2018.4582

eTable 1. University of Michigan Sedation Scale

eTable 2. Highest Achieved UMSS Score

eTable 3. Vital Signs

eTable 4. Rescue Analgesia

eFigure 1. Weight-Based Dose Administration Reference

eFigure 2. Visual Analog Scale

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. University of Michigan Sedation Scale

The University of Michigan Sedation Scale for Children	
UMSS^a	Clinical Features
0	Awake and alert
1	Minimally sedated; tired/sleepy, appropriate response to verbal conversation and/or sound
2	Moderately sedated; somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command
3	Deeply sedated; deep sleep, arousable only with significant physical stimulation
4	Unarousable

^a UMSS = University of Michigan Sedation Scale

eTable 2. Highest Achieved UMSS Score

Highest Achieved UMSS Score					
		Highest UMSS			
Treatment	Number of Patients	0	1	2	
Ketamine	44	23 (52%)	17 (39%)	4 (9%)	
Fentanyl	42	32 (76%)	9 (21%)	1 (2%)	

eTable 3. Vital Signs

Vital Signs		
Measures/Time	Ketamine (n=44)	Fentanyl (n=42)
HR, mean (SD), bpm		
T0	90.8 (15.2)	88.6 (14.8)
T15	90.1 (12.8)	84.4 (14.1)
T30	90.5 (12.8)	85.6 (13.5)
T60	85.1 (12.4)	82.9 (12.9)
RR, mean (SD), breaths/min		
T0	22.1 (6.6)	23.0 (7.4)
T15	23.1 (11.9)	22.3 (5.8)
T30	23.3 (8.7)	19.9 (5.7)
T60	21.8 (8.1)	19.7 (5.7)
SBP, mean (SD), mm Hg		
T0	126.5 (19.1)	128.9 (19.6)
T15	127.3 (18.0)	127.9 (19.3)
T30	126.3 (15.0)	123.4 (15.6)
T60	122.3 (14.9)	122.0 (15.1)
DBP, mean (SD), mm Hg		
T0	78.9 (13.6)	73.5 (12.9)
T15	76.1 (10.7)	73.4 (12.7)
T30	76.3 (10.3)	73.6 (11.2)
T60	70.8 (9.2)	70.6 (10.4)
O ² sat, mean (SD), %		
T0	99.8 (0.6)	99.6 (0.6)
T15	99.6 (0.7)	99.2 (0.9)
T30	99.5 (0.7)	99.4 (0.9)
T60	99.3 (0.9)	99.3 (0.9)
ETCO ₂ , mean (SD), mm Hg		
T0	36.6 (6.4)	38.0 (4.4)
T15	36.6 (5.2)	38.3 (4.2)
T30	38.6 (5.6)	40.4 (6.8)
T60	38.7 (4.2)	38.9 (5.4)

eTable 4. Rescue Analgesia

Rescue Analgesia		
Rescue Analgesic	Ketamine (n=44)	Fentanyl (n=42)
Ibuprofen	1	3
Fentanyl	1	3
Morphine	7	3
Ketamine	1	0
Toradol	1	0
Total (n, %)	11, 25%	9, 21%

eFigure 1. Weight-Based Dose Administration Reference

A Randomized Controlled Trial of Intranasal Sub-dissociative Dosing of Ketamine Compared to Intranasal Fentanyl for Treatment of Pain Associated with Acute Extremity Injuries in Children (PRIME - Pain Reduction with Intranasal Medications for Extremity injuries)

- 1) Determine corresponding volume to be administered (see table below)
- 2) MD orders PRIME study medication using Epic order set
 - “ED-PRIME, Intranasal Ketamine/Fentanyl Study for Orthopedic Evaluation”
 - Order volume to be administered that corresponds with dosing sheet in the envelope
- **DO NOT ADMINISTER OR WASTE MEDICATION UNTIL CONSENT OBTAINED
- 3) RN attaches atomizer to syringe, primes the atomizer with drug solution and discards the rest of the study drug down the sink with a witness.
 - If a full 2 mL is to be administered, prime the atomizer with 0.1 mL drug solution (overflow of 0.1 mL is provided in the study drug syringe)
- 4) CRC documents syringe number and volume to be administered
- 5) RN administers medication
 - Administer intranasally via mucosal atomizer.
 - For doses greater than 0.5 mL, give 0.5 mL per nostril at a time up to 4 times. (Please DO NOT deviate from this administration protocol – this is what was approved for the study.)
- 6) RN “wastes” appropriate amount in Pyxis (see table below)
- 7) RN documents administration in EPIC on MAR

Weight (kg)	Fentanyl OR Ketamine	Volume of Waste to Document in Pyxis
25 – 29	0.8 mL	1.2 mL
29.1 – 32	0.9 mL	1.1 mL
32.1 – 36	1 mL	1 mL
36.1 – 39	1.1 mL	0.9 mL
39.1 – 42	1.2 mL	0.8 mL
42.1 – 46	1.3 mL	0.7 mL
46.1 – 49	1.4 mL	0.6 mL
49.1 – 52	1.5 mL	0.5 mL
52.1 – 55	1.6 mL	0.4 mL
55.1 – 59	1.7 mL	0.3 mL
59.1 – 62	1.8 mL	0.2 mL
62.1 – 65	1.9 mL	0.1 mL
≥65.1	2 mL	N/A

Please circle the volume given on the table

PRIME Study ID # _____

eFigure 2. Visual Analog Scale

Visual Analog Scale

