A Randomized Study to Compare Two Methods of Pain Management During Chest Tube Removal

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Introduction

- A review of the literature failed to identify published literature regarding an effective medication, single or in combination, that resulted in effective pain control during chest tube (CT) removal for adults or children.
- Retrospective chart review (2007) identified significant practice variation; eight different modalities for pain control during CT removal within the pediatric cardiovascular departments.
- Inconsistent pain management
  - -Results in undue pain for the pediatric patients, their family and staff
  - -Fails to meet quality standards for optimal pediatric care.

Study Purpose

- The purpose of this study is to identify a medication combination that will provide optimal patient comfort during the chest tube removal process in the pediatric post operative cardiac patient population.

Hypotheses

- Ketorolac Tromethamine (Toradol) and Midazolam Hydrochloride (Versed) administered intravenously prior to the removal of chest tubes will provide pain control with rating of 5 or below (on the OPS scale) during and immediately following the removal of chest tubes compared to Morphine Sulphate and Versed.
- Toradol and Versed administered intravenously prior to the removal of chest tubes will provide pain control with a rating of 3 or below (on the OPS scale) within 15 minutes of chest tube removal compared to Morphine Sulphate and Versed.
- Clinicians and parents will perceive that intravenous administration of Toradol and Versed will more effectively manage pediatric patients' pain experience during chest tube removal than intravenous Morphine Sulphate and Versed.

Study Sample

- Randomized sample of pediatric post-cardiothoracic surgery patients (N=27)
- Two Comparison Groups:
  - I. Toradol (0.5 mg/kg – 1 hour before the procedure & Versed (0.1 mg/kg (max dose of 6mg up to 5 years of age and 10 mg up to 12 years of age) - 5 minutes before procedure)
  - II. Morphine Sulphate (0.1 mg /kg –20 minutes before procedure) & Versed (0.1 mg/kg (max dose of 6mg up to 5 years of age and 10 mg up to 12 years of age – 5 minutes before procedure

Inclusion Criteria

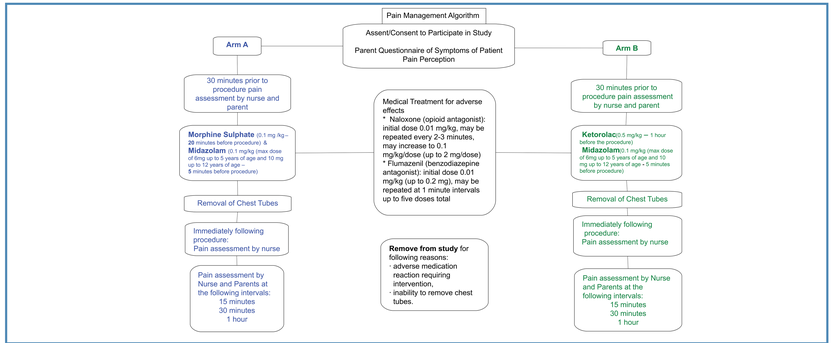
- Patients 2-18 years of age
- Transferred to the Cardiac Stepdown Unit post op cardiac surgery
- Had at least one chest tube in place
- Had normal kidney function
- Had an intravenous line
- Availability of Child Life Specialist at time of removal

Exclusion Criteria

- Known allergy to Versed, Toradol or Morphine Sulphate
- All transplant patients
- Fontan procedure, post op day 1
- Diagnosis of clotting disorder (i.e. ITP, thrombocytopenia)
- Diagnosis of renal disease
- Chest tube smaller than 15 French Blake Drain.

Study Design

- Experimental Design:
  - -Parents, patient, clinician (MD, NP) and researcher blinded to randomized treatment arm assigned to patient.
  - -Multiple Pain Assessments
    - -Pain assessed by the researcher at timed intervals using OPS pain scale
    - -Pain assessed by parents at timed intervals using FACES scale after removal
  - -Open ended question for clinician and parent to describe the patient's pain response



Pain Scales

Observational Pain Scale

Observation	Criteria	Score
Blood Pressure	< 10% Baseline > 20% Baseline B/P _____ > 30% Baseline	0 1 2
Crying	Not Crying Crying but responds to tender loving care (TLC) Crying and does not respond to TLC	0 1 2
Movement	None Calm Thrashing	0 1 2
Agitation	Patient asleep or calm Mild Hysterical	0 1 2
Verbal Evaluation	Patient asleep or states no pain Mild pain (cannot localize) Moderate pain (can localize) verbally or by pointing	0 1 2

Faces Scale

0	2	4	6	8	10
No Hurt	Hurts little bit	Hurts little more	Hurts even more	Hurts whole lot	Hurts worst

Outcomes

	Toradol (0.5 mg/kg) Versed (0.1 mg/kg) (N=14)	Morphine (0.1 mg/kg) Versed (0.1 mg/kg) (N=13)
Gender- male female (N=27)	10 (37.05%) 4 (14.6%)	9 (33.35%) 4 (14.6%)
Pain level during Procedure	4.43 (std. error =.56)	5.63 (std. error =.49)
Pain level after procedure*	1.64 (std. error =.55)	4.08 (std. error =.57)
Pain level 15 minutes after procedure	.94 (std. error =.45)	1.29 (std. error =.47)

**P= .04 when controlling for the number of Chest tubes and pre-procedure pain level*

Open Ended Question: Parent's Description of Patient Response

Toradol (0.5 mg/kg) & Versed (1 mg/kg)
- "His pain was better controlled this time…previous times he was really uncontrollable"
- He is usually very cranky with CT removal…he was talking and calm – This was the BEST ever"
- "YES- pain was controlled"

Morphine Sulphate (0.1 mg /kg) & Versed (1 mg/kg)
- "He is drowsy and not very interactive since the CT removal.
- "He was out of it for awhile"
- "He was acting drunk"
- "I don't think his pain was well controlled."

Clinician Description of Patient Response

Toradol (0.5 mg/kg) & Versed (1 mg/kg)
- "This was the least amount of pain EVER displayed"
- "Patient was interactive and playing right after the procedure"
- "He didn't even flinch when I removed the CT's"

Morphine Sulphate (0.1 mg /kg) & Versed (1 mg/kg)
- "Patient was staring off into space…"
- "Patient was acting drunk before the CT removal"
- "Patient was loopy, almost sedated for 20 minutes after procedure."

Results

Hypothesis #1 supported:
- Average pain score on OPS was less than 5 during the CT removal when patients received the intravenous combination of Toradol and Versed.
- Average pain score on OPS was greater than 5 during CT removal when patients received the intravenous combination of Morphine Sulphate and Versed.

Hypothesis #2 was NOT supported:
- Pain scores of patients in both groups were lower than 3 and there was not a statistically significant difference between the two groups on pain scores 15 minutes after the procedure.
- However, qualitative data suggest that the Toradol and Versed group was awake with low pain vs. the Morphine Sulphate and Versed group was sedated with low pain.

Hypothesis #3 is supported:
- When patients were administered Toradol and Versed, parents and clinicians described the patients as more alert and interactive after the procedure.
- When patients were administered Morphine Sulphate and Versed, parents and clinicians described the patients as being "drugged" and "loopy" after the procedure.
- In most cases, the parents stated they believed their child's pain was well managed when the patient received the combination of Toradol and Versed.

Discussion

- Although the combination of Toradol and Versed demonstrated lower pain scores during the procedure than the combination of Morphine Sulphate and Versed in this patient population, the difference in pain scores 15 minutes after the procedure was not statistically significant.
- The intravenous combination of Toradol and Versed provided the patients with lower pain scores after the procedure than when patients were administered Morphine and Versed.
  - -The difference in pain scores were both clinically and statistically significant.

Recommendations

- The combination of Toradol and Versed may be an effective premedication to decrease pain during chest tube removal in the pediatric cardiac postoperative surgical population.
- Further study of this medication combination for pain relief during chest tube removal in other pediatric patient populations is indicated.
- Disseminate results of this study to contribute to the body of evidence needed to change practice.

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