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Research Article

# Randomized controlled comparative trial between low dose dexmedetomidine sedation and that of fentanyl in children after surgical procedures in surgical Pediatric Intensive Care Unit

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**KEYWORDS**

Dexmedetomidine;
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Sedation

**Abstract** *Background:* Children undergoing different surgical procedures and requiring postoperative ventilation need intense analgesia and sedation. This was done using opioids and benzodiazepines with their common side effects as respiratory depression and prolonged sedation.
*Aim of the study:* To study the efficacy of sedation and time taken form stopping the infusion to extubation using low dose of dexmedetomidine compared with fentanyl sedation in post-operative Pediatric surgical Intensive Care Unit (PICU).
*Patients and Methods:* A randomized double-blind study involving 50 children undergoing different surgical procedures was performed. The patients were equally divided into two groups, each including 25 patients. One group sedated with fentanyl at 1 μg/kg/h (Fen Group) and the other group sedated with dexmedetomidine at 0.3 μg/kg/h (Dex Group) for 18 h post-operatively with intermittent rescue fentanyl 0.5 μg/kg bolus in the 2 groups as required during endotracheal suctioning. The depth of sedation was assessed using the Ramsay sedation score, the tracheal suctioning score and pediatric intensive care unit sedation score. The time taken from discontinuation of infusion till extubation was recorded.
*Results:* All sedation scores in the fentanyl and dexmedetomidine groups were comparable. Hemodynamic parameters were comparable between the two groups. Average time (in minutes) required for extubation after stopping the infusions was 136.2 (±54.2 SD) in the Dex group compared with 341.4 (±125.4 SD) in the Fen group. The difference in mean time for extubation was statistically significant. Conclusions: Low dose dexmedetomidine provides adequate sedation for mechanically ventilated children and also early extubation as compared with fentanyl.


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## 1. Introduction

Pediatric patients in surgical ICU (SICU) require sedation and analgesia, especially if mechanically ventilated, where frequent suctioning is required. Opioids and benzodiazepines are commonly used in Surgical ICU to provide optimum sedation and prevent accidental extubation, in spite of their common side effects e.g. respiratory depression and delayed arousal after the end of the infusion [1].

Dexmedetomidine provides sedation with analgesia through its hypnotic effect and similarity to natural sleep. Central Nervous System (CNS) stimulation of parasympathetic outflow and inhibition of sympathetic outflow from the locus coeruleus in the brain stem plays an important role in sedation and anxiolysis [2]. There are dose dependant bradycardia and hypotension, with doses higher than 0.4 μg/kg [3].

The wide margin of safety of the drug is attributed to its limited respiratory depression effects, with high levels of sedation [4,5].

Dexmedetomidine, alpha2 adrenoceptor agonist, has been used in pediatrics for sedation during variety of clinical situations as non-invasive radiology procedures. Dexmedetomidine has minimal respiratory depressant effects, which makes it the drug of choice as an adjuvant drug for analgesia and sedation in pediatric ICU. It has also a role in preventing postanesthesia emergence delirium and shivering. The loading dose ranges from 0.5 to 1 μg/kg over 10 min followed by infusion dose of 0.2–5 μg/kg/h [6].

Infusion of Dexmedetomidine makes the patients sedated and easily arousable with hypnosis similar to natural Non-rapid Eye Movement (NREM) sleep [2].

Omitting the loading dose and minimizing the infusion doses to less than 0.4 μg/kg may avoid the occurrence of hypotension and bradycardia [3].

The alpha2 adrenergic agonist, dexmedetomidine, is used in children to produce sedation during radiological procedures, to produce controlled hypotension to decrease intra-operative blood loss and to produce sedation during mechanical ventilation in ICU [7].

Dexmedetomidine infusion at 0.3 μg/kg/h is an effective and well tolerated drug for both mechanically ventilated and spontaneously breathing pediatric patients after cardiac correction surgery. Hypotension and bradycardia were observed with increasing the doses but return back to normal shortly after discontinuation of the infusion [8].

Dexmedetomidine is having good analgesic effects in the postoperative period, reducing morphine requirements by up to 50%, with no adverse effects on respiratory rate, oxygen saturation, arterial partial carbon dioxide tension and arterial pH [9].

The use of different types of opioids via variable roots is associated with dose dependent respiratory depression [10].

Dexmedetomidine, when compared with other sedatives, has both sedative and analgesic effects, reduces agitation and delirium, and has no respiratory depression and minimal cardiovascular effects [11].

It declines noradrenergic output from the locus coeruleus and allows increase in firing of inhibitory neuron (GABA). Centrally acting alpha2 adrenergic agonists also activate central sympatholytic effects, leading to decrease in heart rate and blood pressure. Primary analgesic effects and the increase of opioid-induced analgesia result from the stimulation of alpha2 adrenergic receptor in the dorsal horn of the spinal cord and decrease of substance P release [11,12].

## 2. Aim of the study

In this study we compare the efficacy of sedation and time required for extubation for mechanically ventilated children during low dose dexmedetomidine infusion in surgical PICU with that of fentanyl.

## 3. Patients and methods

This study was performed in Abo-Elreesh teaching hospital and surgical PICU from September 2013 till December 2014, on 50 children, aged 1–10 years, ASA I&II. After approval from the ethical committee, informed consents were taken from the parents of 50 children to share in this randomized double blinded study. The children were equally divided into 2 groups 25 each, and randomization was done by the closed envelop method. One group sedated with fentanyl at 1 μg/kg/h (Fen Group) and the other group sedated with dexmedetomidine at 0.3 μg/kg/h (Dex Group) for 18 h post-operatively.

Inclusion criteria were pediatric patient's age group 1–10 years scheduled for abdominal surgery in whom overnight ventilation was anticipated (e.g. huge Hirrsprung's disease, intestinal resection and diaphragmatic hernia with mechanical compression of the lungs).

Exclusion criteria include patients younger than 1 year, emergency surgeries, patients with severe liver dysfunction, because there is precaution to use Dexmedetomidine in hepatic patients and patients requiring ventilation more than 24 h, to allow us to stop the sedation infusion after 18 h and record the time for extubation.

Preoperative sedation was given to all the patients with intramuscular midazolam 0.1 mg/kg and atropine 0.02 mg/kg.

Induction of anesthesia was done with propofol 3 mg/kg intravenously, after fixation of an intravenous cannula, followed by atracurium 0.5 mg/kg to facilitate endotracheal intubation and fentanyl 2 μg/kg. Anesthesia was maintained with sevoflurane 1 MAC and atracurium at intervals of 20 min.

At arrival to the SICU immediately either dexmedetomidine infusion at a dose of 0.3 μg/kg/h (Dex group) or fentanyl 1 μg/kg/h (Fen group) was started by an anesthesiologist, who is not involved in the study and unaware of the infused drugs [3,13].

The study observer was not aware of the infusion drugs given to the patients of both groups. The infusion was maintained to the next day and then stopped (see Fig. 1).

The sedation scores such as Ramsay sedation score (RSS), tracheal suctioning score (TSS), Pediatric Intensive Care Unit (PICU) sedation score, and hemodynamic parameters were monitored hourly and recorded at 1, 4, 10, 18 and 24 h respectively [14,15].