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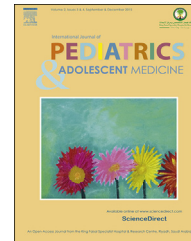


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ORIGINAL RESEARCH ARTICLE

The efficacy of the COMFORT score and pain management protocol in ventilated pediatric patients following cardiac surgery



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KEYWORDS

Pain management;
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Abstract *Background and objectives:* An optimal scoring system for pain assessment in pediatric intensive care is necessary to determine the efficacy of analgesics. We assess the COMFORT scale in postoperative ventilated children and study the effect of pain and sedation protocols on their outcomes.

Patients and methods: We included postoperative ventilated patients. The unit-based pain management protocol was used. The assessment of the COMFORT and FLACC scales was performed by 2-nurses at 2-h intervals on the day of surgery and at 4-h intervals during the first 2-postoperative days or until the patient was ex-tubated. The patients' outcomes were compared with age-matched and RACHS score matched patients prior to the application of the pain protocol.

Results: One-hundred-ten prospective patients were included. The mean age and weight was 24 months and 9.8 ± 8.4 kg, respectively. There was a weak, statistically significant correlation between the COMFORT and FLACC scales, with a range of ($r = 0.01-0.7$). The COMFORT scale demonstrated good internal consistency, with a Cronbach's alpha of 0.75. The mean ventilation days were 1.3 ± 3 , with a mean ICU and hospital stay of 5 ± 5 and 10 ± 9 days, respectively. The 110 patients were compared to 50 retrospective matching patients. The prospective group demonstrated statistically less ventilation days, ICU stay time and hospital stay time, with *P*-values of 0.0004, 0.001 and 0.0003, respectively.

Conclusion: The COMFORT scale is a valuable and reliable pain assessment tool for use in post-operative ventilated pediatric patients. The implementation of a pain and sedation protocol decreased the incidence of withdrawal and the duration of mechanical ventilation as well as ICU and hospital stays.

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1. Introduction

Many children experience moderate to severe pain following cardiac surgery [1]. In addition to pain and discomfort, stress is a well-recognized negative factor influencing the speed of recovery in children [2]. Repeated or long-term exposure to pain has negative consequences for children. These consequences include pain sensitivity alteration, neuroanatomical abnormalities, and emotional, behavioral and learning disabilities [3,4]. These factors warrant adequate sedation and pain relief for this vulnerable patient group [5].

Pain assessment in neonates, infants and children less than 3 years of age is a major challenge for health care professionals [6]. Younger children have physiological responses to small stimuli and cannot appropriately verbalize their pain intensity or location. Therefore, differentiating between sedation and analgesia is difficult in young children [7].

Children's self report of pain is regarded as the gold standard. However, infants and intubated children are unable to self-report their pain levels. Therefore, it is necessary to include behavioral and physiologic variables. An additional advantage of the COMFORT scale is that it accounts for these variables [8]. A study performed by van Dijk and colleagues [9] supported the use of the COMFORT 'behavior' scale to assess postoperative pain in neonates and infants.

Studies have shown that for the majority of ICU patients (critically ill adults), improved clinical outcomes are associated with a safe and effective strategy that ensures patient comfort while maintaining a light level of sedation [10,11]. The implementation of a sedation protocol has led to significant changes in sedation practices and improved patient outcomes [12].

Information is limited regarding pain management scoring systems in ventilated pediatric patients and the implementation of pain and sedation management protocols and their consequences on post-operative cardiac children managed in specialized cardiac surgical intensive care units (CSICU). We examined the use of the COMFORT score to assess postoperative pain and studied the effect of pain and sedation protocols on patients' outcomes.

2. Patients and methods

This was a non-randomized, prospective, observational study. We enrolled a sample of 110 patients (April 2013 to October 2013). The patients' ages ranged from 1 week to 13 years. Patients were intubated and mechanically ventilated and were admitted to the CSICU following cardiac surgery. Enrolment was stratified into 2 age groups (1 week–1 year and 1–14 years) to ensure the inclusion of both infants and

children. We excluded patients on extracorporeal membrane oxygenation (ECMO), and those receiving regular muscle relaxants.

Patients' demographic data and surgical procedures were collected. We grouped our patients based on their surgical complexity score because of the wide variety of cardiothoracic surgical procedures. Their score was assigned according to the RACHS (Risk Adjusted Congenital Heart Surgery) scoring system described previously [13]. This scoring system categorizes procedures based on the severity of their cardiac lesion and the complexity of cardiac repair (Appendix I).

We performed assessments using the FLACC (Face, Legs, Activity, Cry, Consolability) scale. FLACC was the pain assessment tool used in our CSICU prior to the application of the new COMFORT scale and pain management protocol.

Patients were enrolled when they met the study criteria and were assessed for 48-h after admission or until they were ex-tubated (whichever occurred first). Prior to scoring, patients were observed for 1–5 min at each time point. The regular assessment of the COMFORT and FLACC scales [6–8,14] (Appendix II) was performed by two trained pediatric critical care nurses. The scores were documented separately and simultaneously, in random order, at 2-h intervals on the day of surgery and at 4-h intervals during the first 2-postoperative days or until the patient was extubated. The scheduled surgery times were 1700, 1900, 2100, and 2300 h. The time points on the first and second post-operative days were 0400, 0800, 1200, 1600, 2000, and 2400 h. These time points were selected to avoid major confounding factors, such as hunger, administration of medication, and sleep.

As per the CSICU sedation and pain management protocol (Appendix III), patients were categorized into 3 groups based on the expected time of ex-tubation following their CSICU admission:

- Track I: patients who were extubated for less than 12-h.
- Track II: patients who were extubated between 12 and 72-h.
- Track III: patients who were extubated for longer than 72-h.

All doses and the frequency of administered sedatives and analgesics were performed according to each patient track and as defined in the unit protocol algorithm (Appendix III).

We pre-defined patient outcome as the duration of mechanical ventilation, developing opioid/sedation withdrawal, and CSICU and hospital stays. We also compared the patients' outcomes with age-matched and RACHS score-matched patients who underwent procedures prior to the application of the CSICU pain management protocol. From the 1st of January to the 31st of December 2012, 373

children underwent cardiac surgeries scored as RACHS II and III. Fifty age-matched patients were selected via systematic sampling. Prospective and retrospective patients were compared for the duration of mechanical ventilation, ICU and hospital stays. A comparison for withdrawal was not possible, as it was not documented for the retrospective patients.

The Institutional Review Board of the King Faisal Specialist Hospital and Research Centre reviewed and approved the study protocol. An information sheet was provided to the parents of enrolled subjects as required by the Institutional Review Board.

3. Results

A total of 110 patients were enrolled in the study. Sixty-two (56%) were infants and 48 (44%) were children. The mean age for all patients was 24 months, with a range of 0.1–156 months. Sixty-one (55%) patients were male and 49 (45%) patients were female, with a mean weight of 9.8 ± 8.4 kg. Patients were all admitted to CSICU intubated and ventilated following their cardiac surgery. All patients' demographics and surgical risk category details are reported in Table 1.

As per our unit protocol, all patients included in the study were receiving a fentanyl infusion and intravenous (IV) paracetamol until they were ex-tubated. The sedated patients (40%) received a combination of fentanyl and midazolam infusions. The starting doses of fentanyl and midazolam were 4 mcg/kg/hour and 100 mcg/kg/hour, respectively. Doses were titrated according to the patient's response based on their COMFORT scale score. The goal was a COMFORT score between 17 and 26. The majority of the patients (60%) followed the Track I pain management protocol. Their pain was completely controlled with fentanyl infusion and IV paracetamol until the time of extubation. Thirty-nine (36%) of the patients followed Track II and required a midazolam infusion and fentanyl to control their agitation until they were extubated, within 72-h of their

ICU admission. Only 5 (4%) of the patients followed Track III and required both fentanyl and a midazolam infusion with a titration of doses. This group remained ventilated more than 72-h from the time of their ICU admission (Fig. 1).

All patients included in the study were assessed by both the COMFORT and the FLACC pain scales. Spearman's Rho Correlation of the COMFORT and FLACC scores for all patients over the 48-h time period revealed a weak, but statistically significant, correlation at the majority of the time points. Positive correlations ranged between $r = 0.01$ and $r = 0.7$ and supported the concurrent validity of the pain scales (Fig. 2). The internal consistency of the COMFORT scale demonstrated a Cronbach's alpha of 0.75 (Fig. 3).

The 110 patients exhibited a mean days of mechanical ventilation of 1.3 ± 3 , with a range of 0.1–30 days. The mean ICU stay was 5 ± 5 days, with a range of 1–31 days. The mean hospital stay was 10.7 ± 9 days, with a range of 2–60 days. Three (2.7%) patients suffered from sedation/opioid withdrawal symptoms following the prolonged use of sedatives and opioids with higher dosages (Table 2).

The mean ventilation time (days) for the patients studied retrospectively was 3.1 ± 2.8 , with a range of 1–14 days. Their mean ICU stay was 8.5 ± 8.3 days, with a range of 1–35 days. The mean hospital stay was 25.6 ± 40 days, with a range of 2–159 days. A comparison of the 110 current patients with the 50 patients studied retrospectively yielded a statistically significant difference between both groups for ventilation days, ICU stay and hospital stay, with *P*-values of .0004, .001 and .0003, respectively (Table 3).

4. Discussion

Children undergoing cardiac surgery represent a special type of ICU patient. Many of them are infants and neonates requiring cardiopulmonary bypass and various invasive procedures. They are admitted to the ICU intubated and mechanically ventilated. These interventions result in significant pain and stress that must be well controlled to avoid negative consequences. The choice of an appropriate pain assessment tool is critical for this vulnerable group. Objective measures of distress in mechanically ventilated pediatric patients are increasingly available, but few have been evaluated [15]. We investigated the use of the COMFORT scale as a pain management assessment tool and demonstrated its reliability. In 2013, Dorfman and colleagues [15] conducted a systematic review to identify instruments that are appropriate for measuring the physiological and behavioral cues of pain, non-pain related distress, and the adequacy of analgesia and sedation in mechanically ventilated pediatric patients. They evaluated

Table 1 Patients' demographics and surgical risk category.

Variable	No. (%)
Age (month)	
Mean \pm SD	24 (31)
Range	0.1–156
Weight (kilogram)	
Mean \pm SD	9.8 (8.4)
Range	1.8–35.5
Gender	
Male	61 (55%)
Female	49 (45%)
RACHS	
RACHS I	7 (6%)
RACHS II	50 (45%)
RACHS III	46 (42%)
RACHS IV	5 (5%)
RACHS V	1 (1%)
RACHS VI	1 (1%)

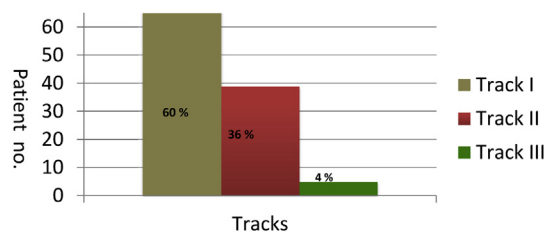


Figure 1 Patients' pain tracks.

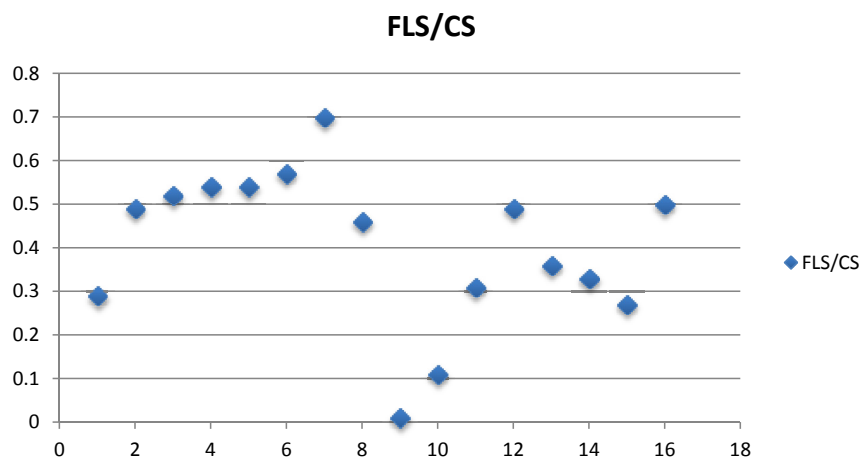


Figure 2 Spearman's Rho correlation of the COMFORT and FLACC variables.

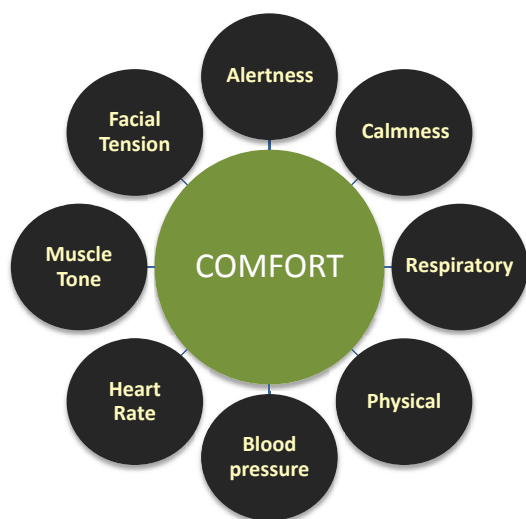


Figure 3 Cronbach's alpha internal consistency for the COMFORT scale.

Table 2 Patient Outcomes for 110 prospective patients.

Variable	Value
Ventilation days (Mean ± SD)	1.3 (3)
No.(%) of patients with withdrawal	3 (2.7%)
ICU stay (Mean ± SD) (d)	5 (5)
Hospital stay (Mean ± SD) (d)	10 (9)

these instruments according to their psychometric properties. Of the 15 instruments evaluated in their systematic review, the Comfort Scale demonstrated the greatest clinical utility [15]. When we tested the internal consistency of the COMFORT scale, it demonstrated a Cronbach's alpha of 0.75, suggesting its reliability as a pain assessment tool for ventilated children after cardiac surgery. Larson and colleagues [16] reported that the COMFORT scale was reliable and valid for assessing pain in children. Several additional studies have supported the validity of the

Table 3 Comparison of prospective and retrospective patients' outcomes.

Variable	Prospective (N = 110)	Retrospective (N = 50)	P-value
Ventilation (Mean ± SD)	1.3 (3)	3.1 (2.8)	0.0004
ICU stay (Mean ± SD) (d)	5 (5)	8.5 (8.3)	0.001
Hospital stay (Mean ± SD) (d)	10 (9)	25.6 (40)	0.0003
No.(%) of patients with withdrawal	3 (2.7%)		

COMFORT scale as a sedation assessment tool for sedated and mechanically ventilated pediatric patients [7–9].

The use of analgesics and sedatives is important for pain and stress management in children following cardiac surgery. To achieve adequate pain and stress relief, an endpoint or sedation goal should be established and regularly redefined for each patient via regular assessment. Sedation protocols have demonstrated effectiveness in improving ICU sedation practices [10,17]. We used a pain management protocol and titrated doses of opiates based on a goal COMFORT scale assessment score of 17–25. This value was suggested by Jacobi and colleagues [18]. They emphasized that analgesics and sedatives must be carefully titrated for the individual to avoid the consequences of under-sedation and over-sedation.

There is an increasing body of evidence suggesting that protocol-based strategies reduce the variation and cost of intensive care medicine. They also improve the morbidity and mortality of critically ill patients [19]. Analgesia and sedation are areas where considerable variations exist among practitioners [20,21]. We examined the effect of a pain management protocol on our patients' outcomes and demonstrated a reduction in ventilation time (20%) and reduced ICU (35%) and hospital (15%) stays compared to a retrospective matching group of patients. Our findings were consistent with a report by Brattebo et al [10], which demonstrated that a sedation protocol and scoring system

reduced the mean ventilator times from 7.4 to 5.3 days (28%) and the mean length of stay from 9.3 to 8.3 days (11%).

Opioid tolerance and withdrawal occur frequently in critically ill children. Opioid withdrawal is a major complication of prolonged opiate use in the ICU. We reported the incidence of withdrawal in our patients following our pain management protocol. The incidence of withdrawal in our patient group was 3%, lower than previously reported. Researchers have reported that opioid withdrawal occurs in 57%–60% of PICU patients [22–24]. Multiple reports have discussed the complications and prolonged hospitalizations that result from opioid tolerance following a critical illness [25,26].

5. Conclusions

The COMFORT scale is a valuable and reliable pain assessment tool for use in postoperative ventilated pediatric patients. It possesses internal consistency and is a reliable pain assessment tool for use in ventilated patients following cardiac surgery. Pain management protocols in the CSICU have significantly improved patient outcomes, as demonstrated by a reduction in the ventilation time and reduced ICU and hospital stays.

Conflict of interest

None.

Appendix A. Supplementary data

Supplementary data related to this article can be found online at <http://dx.doi.org/10.1016/j.ijpam.2015.11.001>.

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