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Perioperative pharmacological management of pain and anxiety in pediatric surgical patients: a randomized controlled trial

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ABSTRACT
Every year, millions of children in the US undergo outpatient surgery, and the great majority of them experience excruciating perioperative pain and anxiety. Behavioral preparation programs that focus on skill development and modeling, which are considered essential for optimal preparation, are no longer available to most children and families in the outpatient surgery setting. Additionally, what little preparation does occur is typically general rather than tailored to the unique characteristics of the child and family. Untreated anxiety and pain have a substantial impact on children's short- and long-term healing as well as their future interactions in the medical context. In order to fully evaluate the impact of distraction on preoperative anxiety, especially in pediatric patients, we conducted a randomised controlled experiment (RCT). This randomized controlled study (RCT) evaluates the safety and efficacy of pharmacological treatments for perioperative pain and anxiety in pediatric surgical patients. The study looks at how different drug regimens affect pain scores, anxiety levels, side effects, and recovery outcomes.

Keywords: *Perioperative pain, anxiety, pediatric patients, randomised controlled trial.*

1. INTRODUCTION

Pediatric patients may experience severe perioperative anxiety and anguish as a result of anesthesia and surgical treatments. High levels of preoperative anxiety are experienced by up to 64% of youngsters. The planned parental separation, unfamiliar surroundings, mask-wearing faces, alarm noises, and heightened parental worry before surgery may make pediatric patients feel threatened. This anxiety may be caused by the treatment itself or by their children's apprehension [1]. Postoperative pain, delirium, painkiller use, general anxiety, behavioral issues, and trouble sleeping can all be exacerbated by inadequate preoperative anxiety management. As a result, lowering children's anxiety prior to surgery can improve the entire perioperative experience, promote healing, and minimize pain following surgery. Furthermore, children are at risk of acquiring chronic pain, a debilitating and costly public health concern, and up to 30–40% experience moderate to severe postoperative discomfort. Untreated or poorly managed kid pain can negatively impact many facets of health-related quality of life in addition to disrupting typical developmental tasks. The elevated anxiety that people usually feel when getting ready for various medical procedures worries a lot of patients and medical professionals [13]. In addition to endangering patients' emotional and physical health, this widespread problem is linked to unfavorable outcomes like a higher need for anesthetic, a higher chance of surgical complications, and less than ideal rehabilitation [4]. A variety of behavioral and physiological signs indicate that anxiety in children undergoing medical procedures can manifest in numerous ways [15]. In more severe cases, young children may appear hypertonic, urinate unexpectedly, or attempt to run away from medical staff [2]. Young patients experience the most distress during the induction of anesthesia of any preoperative phase, as seen by their behavioral and physiological responses [14]. Anesthesiologists and surgeons face unique difficulties at this crucial juncture because of the obvious stress that both patients and parents are under. In addition to increased anxiety, a significant number of pediatric patients have made last-minute refusals, which is a sign of preoperative worry that complicates the anesthesia and surgical procedures [9]. Consequently, it's critical to recognize and treat children patients' preoperative anxiousness. Sedative medication has become a useful tool for lowering anxiety prior to surgery, facilitating a more seamless separation from loved ones, and easing discomfort throughout the induction procedure. However, it is important to understand that medicine efficacy is not guaranteed and that some young patients may refuse to take their meds [18]. Certain drugs may not always have the desired soothing effects, which might result in unanticipated side effects like irritability and disinhibition. Additional drawbacks associated with the use of sedative medications in pediatric patients include prescription costs, safety concerns

(like the potential for respiratory depression or airway blockage without close supervision), increased demands on nursing staff and additional supplies, and the potential for a delayed hospital discharge [6]. As a result, nonpharmacological treatments are becoming more and more popular [16]. Distraction is a non-pharmacological method that parents and medical professionals frequently use to help pediatric patients feel less anxious and in pain during medical procedures [8]. Juvenile patients' attention is diverted to pleasurable stimuli, which hinders the processing of painful feelings and reduces pain, suffering, and worry. Treatments for distraction can take many different forms, but they are generally classified as either active or passive [3]. Passive types include activities when the patient is exposed to outside stimuli, like watching a movie or listening to music [11]. Active distraction, on the other hand, involves active participation by young patients, frequently with adult supervision. Painting, toy play, and virtual reality are examples of activities that are classified as active diversion. Numerous entertaining strategies to lessen anxiety during medical procedures are provided by these activities.[10]

1.1 Research question

How well and safely can various pharmaceutical approaches, such as anxiolytics and multimodal analgesia, address perioperative pain and anxiety in pediatric surgical patients?

1.2 Objectives

- To assess how well multimodal analgesia works to lessen perioperative discomfort in children undergoing surgery.
- To assess the impact of anxiolytics on children's anxiety levels during surgery.

2. METHODOLOGY

Study design: This study was designed as a randomized, double-blind, placebo-controlled experiment to evaluate the safety and efficacy of pharmacological therapy for the management of perioperative pain and anxiety in pediatric surgery patients.

Participants: To provide a representative sample of the pediatric population, the trial recruited children between the ages of 2 and 12 who were having elective surgical operations.

2.1 Group allocation

- Group A (Control Group): A placebo was given in addition to standard care for comparison.
- Group B (Multimodal Analgesia Group): Acetaminophen, ibuprofen, and local anesthetics were administered in conjunction to treat pain.
- Group C (Multimodal Analgesia + Anxiolytics Group): To treat both pain and anxiety, they received the same multimodal analgesia as Group B together with an anxiolytic (such as midazolam).

To guarantee objective results, blinding was maintained for patients, parents, and doctors who administered and evaluated the data. For anesthetic, drug dosage, and monitoring, standardized procedures were used to minimize variation and guarantee uniformity among all groups.

Data collection: Preoperative, intraoperative, and postoperative data were gathered at various intervals to document dynamic shifts in pain and anxiety levels. With institutional review board permission and parental or guardian informed consent, the study complied with ethical guidelines. High internal validity is ensured by this meticulous approach, enabling trustworthy conclusions on the interventions' efficacy.

3. OUTCOME MEASURES

A number of scales are employed to measure it. A technique for measuring pain in younger children (those between the ages of two months and seven years) or in people who are unable to communicate their suffering is the Face, Legs, Activity, Cry, Consolability scale, or FLACC scale. The scale has a score range of 0–10, where 0 indicates no pain. The scale's five criteria each have a score of 0, 1, or 2. VAS for older children One instrument for measuring pain intensity is the Visual Analogue Scale (VAS). It is composed of a line, with no pain at one end and the most agonizing suffering at the other. Children's anxiety before surgery can be measured with the Modified Yale Preoperative Anxiety Scale (mYPAS). The m-YPAS scale is used to evaluate anxiety levels, and the patient indicates their level of pain by writing a point on the line. For evaluating children's anxiety before surgery, it is considered the "gold standard" [5]. Secondary outcomes included things like the frequency of side effects, recovery times after surgery, and patient and parent satisfaction with the therapies. Group C (multimodal analgesia plus anxiolytics) demonstrated the largest reductions in pain and anxiety scores when compared to Groups A (placebo) and B (multimodal analgesia only). The efficiency and safety of the therapies were demonstrated by the fact that all groups had very few side effects, although Group C had faster recovery times and higher satisfaction ratings. These findings suggest that managing pain and anxiety concurrently improves perioperative outcomes for pediatric patients.

3.1 Procedure

Participants were randomly assigned to one of three groups: A (placebo), B (multimodal analgesia), or C (multimodal

analgesia plus anxiolytics). Prior to surgery, baseline anxiety levels were assessed using the m-YPAS scale. Medication was administered 30 to 60 minutes before surgery, depending on group assignment. Standardized anesthetic protocols were followed during operation to ensure consistency. Following surgery, pain ratings were measured using the VAS for older children and the FLACC scale for younger children, and anxiety reassessments were performed at 2, 6, 12, and 24 hours [17]. Negative impacts, recovery times, and satisfaction levels were also documented. Prior to enrollment, parental consent was obtained, and all procedures adhered to ethical guidelines.

4. EXPECTED OUTCOME

According to the International Association for the Study of Pain, pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Everybody experiences pain differently. Pain was rephrased as "a mutually recognizable somatic experience that respects a person's apprehension of threat to their bodily or existential integrity" after the International Association for the Study of Pain (IASP) revised its definition.

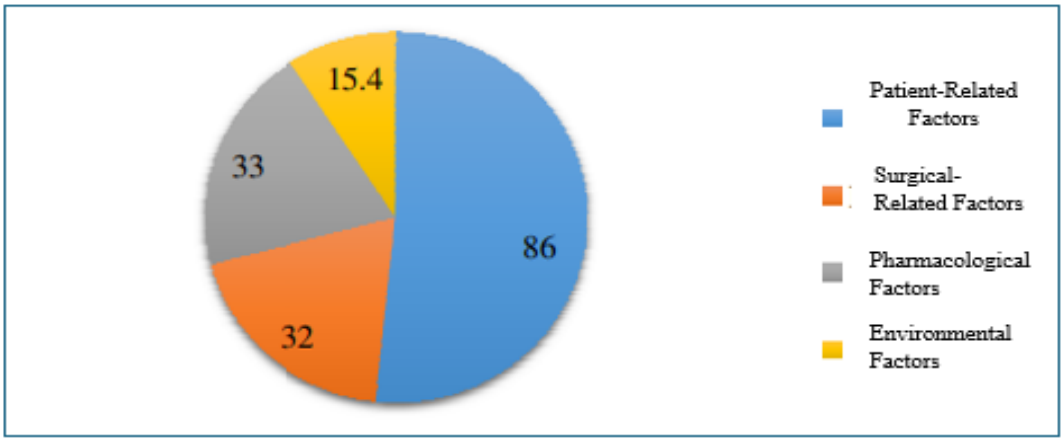

Figure 1: pediatric surgical patients

The concept of understanding the pain experienced by the patients has been noticeably increased for the past 20 years. But still patients are inadequately assessed and treated for their pain in spite of increased knowledge among the dental health care professionals.

Table 1: Participation profile

Variables	Number of respondents	Percentage
AGE		
21 to 30 years	**208**	**35**
31 to 40 years	**311**	**52**
Above 40 years	**75**	**13**
Total	**594**	**100**
GENDER		
Male	**278**	**47**
Female	**316**	**53**
Total	**594**	**100**
EDUCATIONAL QUALIFICATION		
Undergraduate	**312**	**52**
Post graduate	**271**	**46**
Doctoral	**11**	**2**
Total	**594**	**100**
MARITAL STATUS		
Married	**274**	**46**
Unmarried	**314**	**53**
Separated	**6**	**1**
Total	**594**	**100**

LEVEL OF EMPLOYMENT		
Lower Executive level	**245**	**41**
Middle Executive level	**201**	**34**
Upper Middle Executive level	**148**	**25**
Total	**594**	**100**
WORKING EXPERIENCE		
Below 3 Years	**121**	**20**
3 Years to 5 years	**177**	**30**
Above 5 years to 10 Years	**139**	**24**
Above 10 years	**157**	**26**
Total	**594**	**100**
ANNUAL INCOME		
Below Rs.2,00,000	**118**	**20**
Rs.2,00,001 to Rs.4,00,000	**161**	**27**
Rs.4,00,001 to Rs.5,00,000	**167**	**28**
Above Rs.5,00,000	**148**	**25**
Total	**594**	**100**
DISTANCE TO WORKPLACE		
Below 5 Kms	**64**	**11**
5 to 20 Kms	**217**	**37**
21 to 40 Kms	**197**	**33**
Above 40 Kms	**116**	**20**
Total	**594**	**100**

So, practicing painless dentistry is still a challenging task even though lots of technological advancements came into existence. There are numerous methods for reducing pain during administration of local anesthesia in dentistry, but the use of conventional technique is still considered a gold standard. The sight of needle and syringe itself increases the fear and anxiety for patients. Piercing the needle into the oral mucosa increases pain and creates a negative attitude towards the dentists as well as the dental procedure. For the successful dental treatment, adequate anesthesia plays an important role for reducing the pain during the treatment, thereby increasing the co-operation as well as a positive attitude towards the dental procedure. In order to reduce the fear of the needle, improve the patient's behavior during dental treatment and to enhance the patient co-operation, needleless anesthesia/needle-less Jet syringe for the administration of local anesthetic solution were introduced into the dental practice.

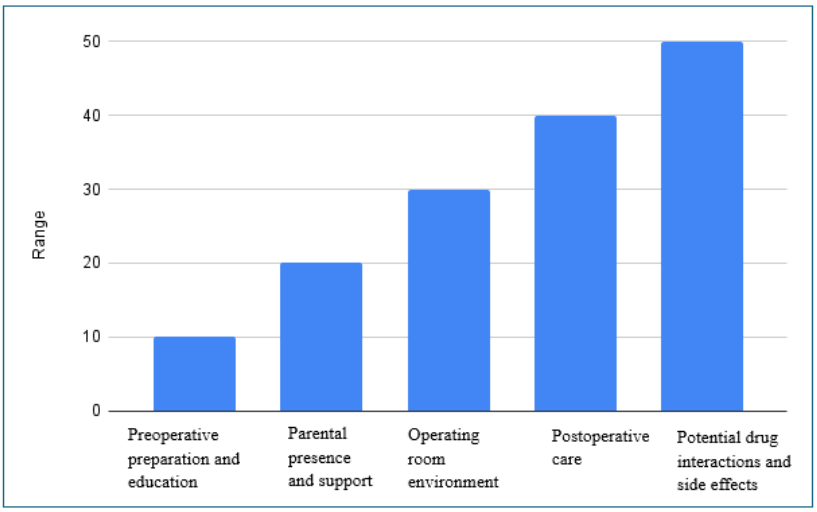

Figure 2: Factors Scale

The advantages of using jet injection are faster onset of action, fast delivery of drugs and absorption, less fear, less tissue damage etc. These jet injections are best suitable for the patients with needle phobia.

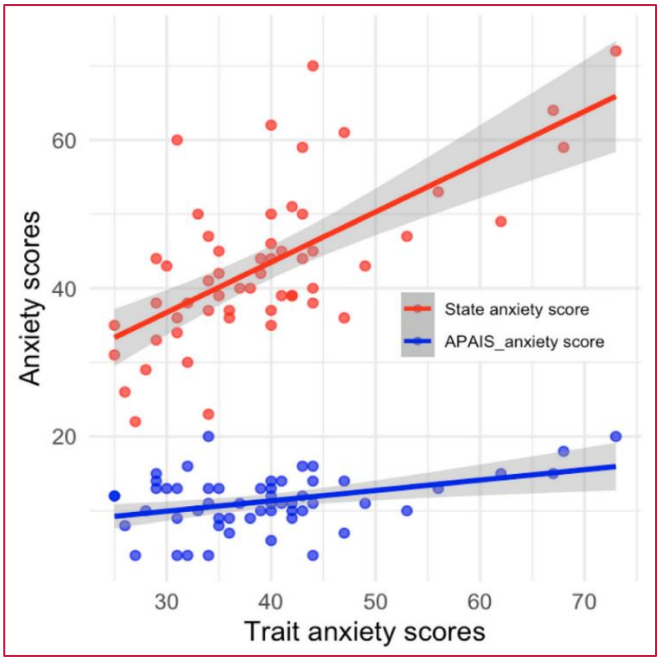

Figure 3: Scatter plot

The needleless jet injections such as were compared with traditional anesthesia for dental procedures in pediatric patients but there were no studies using "Comfort-In - Needle-Free Jet Injector System" for dental procedures in adult patients. Consequently, the current investigation was carried out to compare the anesthetic effectiveness of conventional anesthesia with needle-free anesthesia in patients with symptomatic irreversible pulpitis.

According to the current study's findings, individuals with symptomatic irreversible pulpitis responded similarly well to needle-free and traditional anesthesia procedures, and none of them needed more anesthesia. A topical anesthetic solution consisting of lidocaine HCl 2% and epinephrine 1:100,000 was employed.

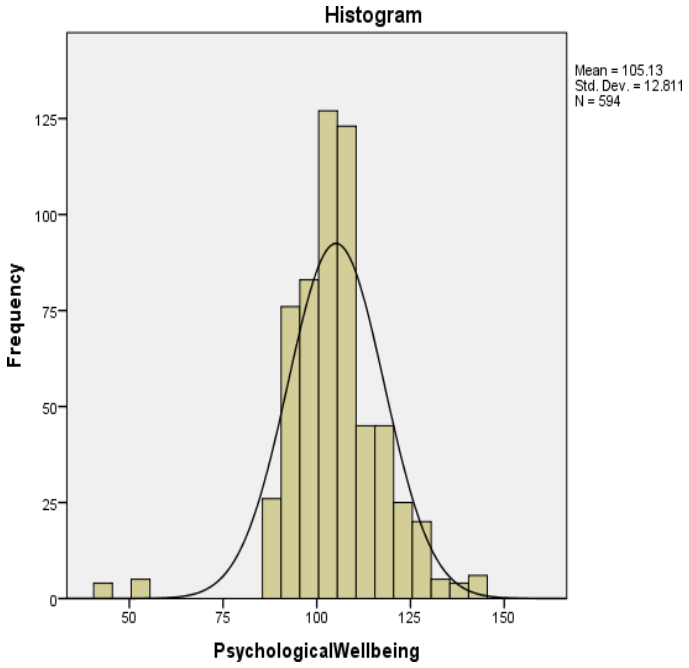

Figure 4: Frequency Histogram for Psychological Well-being

Both needle and pressure anesthesia techniques were compared and both the techniques were touted to have similar efficacy. 60% of patients required additional anesthesia following the use of Number - Needleless Anesthesia Delivery System. A need for additional anesthesia was reported during extraction after jet injection.

4.1 Future perspectives

Both parents' and children's surgical preparation should be affordable. In other words, parents should be able to attend the preparatory program on the weekends and in the evenings without having to miss work, and hospitals should have minimal operating expenditures related to the program staff [7]. Future preoperative education programs should be evidence-based rather than driven by personal prejudices and financial considerations. According to preliminary research, coping skills training and modeling (observation of desired abilities) were the most successful aspects of surgical preparation. Coping skills and modeling should be the main focuses of any future preparedness program for parents and children, as this view is firmly backed by recent research. Important details that parents would like to receive prior to the day of surgery should also be included. Future programs should also heavily emphasize pain treatment because most parents do not adequately address their children's suffering at home. This is extremely important since most surgeries are currently performed as outpatient procedures. According to a recent study, parents frequently have misunderstandings about the use of analgesics for their children. These misconceptions include worries about the negative effects of medications, worries that using analgesics could result in addiction, and the idea that analgesia is more effective when given seldom.[12] Parents' undertreatment of their children's postoperative pain has been connected to these views. Larger, multisite, longitudinal preliminary studies (lasting more than a year) are anticipated to reduce the incidence, severity, and effects of perioperative stress and postoperative pain in young children undergoing surgery. The approved proportions of gauge tension (both state and attribute), parental anxiety, uneasiness awareness, catastrophizing, torment nervousness, and apprehension about torment—all currently lacking in the writing—should be used in future research on the relationship between severe and ongoing postoperative pain. Regardless of the severity of the pain, information on the amounts of painkillers (both narcotic and nonopioid) should be gathered during a medical procedure, in the emergency room following a medical operation, and at home following discharge. Bigger, multisite, longitudinal preliminaries (enduring longer than a year) are expected to bring down the occurrence, force, and impacts of perioperative tension and postsurgical torment in youthful patients having a medical procedure. Future exploration on the connection among intense and constant postoperative torment ought to utilize approved proportions of gauge tension (both state and attribute), parental nervousness, uneasiness awareness, catastrophizing, torment nervousness, and apprehension about torment — which are all presently ailing in the writing. Data on the measurements of pain relieving (narcotic and nonopioid) drugs during a medical procedure, after medical procedure in the emergency clinic, and at home after release ought to be assembled notwithstanding torment seriousness levels.

5. CONCLUSION

This randomized controlled preliminary exhibits the viability and wellbeing of a thorough prescription procedure for overseeing perioperative torment and tension in pediatric patients. When contrasted with typical consideration or relief from discomfort alone, the blend of multimodal help with discomfort and anxiolytics really decreased agony and tension levels, accelerated recuperation, and worked on long haul and parental satisfaction. These findings demonstrate how important it is to manage discomfort and anxiety in pediatric perioperative treatment in order to optimize outcomes. Incorporating this combo method into clinical practice may improve children’s patients' overall surgical experience and long-term health. This study provides compelling evidence in support of the use of multimodal analgesia and anxiolytics to manage perioperative pain and anxiety in pediatric surgical patients, as opposed to standard care (placebo) and analgesia a lone, which were less effective, particularly in addressing perioperative anxiety. The findings also lend credence to the regular incorporation of anxiolytics and multimodal analgesia into perioperative regimens that are tailored to the individual requirements of each patient. Future research should look at long-term psychological and functional effects to further support these findings. This integrated strategy has the potential to raise the bar for pediatric surgical treatment and improve patient outcomes.

REFERENCES

[1] Ciccozzi A, Pizzi B, Vittori A, Piroli A, Marrocco G, Della Vecchia F, Cascella M, Petrucci E, Marinangeli F. The perioperative anesthetic management of the pediatric patient with special needs: An overview of literature. Children. 2022 Sep 21;9(10):1438.

[2] Kala T, Jayabal R. User perception about the library collections and services in Cherraan's College of Pharmacy, Coimbatore, Tamil Nadu. Indian Journal of Information Sources and Services. 2019;9(1):101-5. https://doi.org/10.51983/ijiss.2019.9.1.585

[3] Mathias EG, Pai MS, Kumar V, Narayanakurup D, Kulkarni M, Guddattu V, Bramhagen AC, Nayak BS, George A. Nonpharmacological interventions for managing postoperative pain and anxiety in children: a randomized controlled trial. Clinical and experimental pediatrics. 2024 Oct 31;67(12):677.

[4] Quezada Castro, M.D.P., Quezada Castro, G.A., Barturen Mondragón, E.M., Castro Arellano, M.D.P. and Gallo Aguila, C.I., 2023. Examining the widespread dissemination of fake news on Facebook: political instability and health panic.13(3), 1-15. https://doi.org/10.58346/JISIS.2023.I3.001

[5] Skovby P, Rask CU, Dall R, Aagaard H, Kronborg H. Face validity and inter-rater reliability of the Danish version of the modified Yale Preoperative Anxiety Scale. Dan Med J. 2014 Jun 23;61(6):A4853.

[6] Chow YW, Susilo W, Phillips JG, Baek J, Vlahu-Gjorgievska E. Video Games and Virtual Reality as Persuasive Technologies for Health Care: An Overview. J. Wirel. Mob. Networks Ubiquitous Comput. Dependable Appl.. 2017 Sep 1;8(3):18-35.

[7] Eerdekens M, Beuter C, Lefeber C, van den Anker J. The challenge of developing pain medications for children: therapeutic needs and future perspectives. Journal of pain research. 2019 May 23:1649-64.

[8] Vij P, Prashant PM. Predicting aquatic ecosystem health using machine learning algorithms. International Journal of Aquatic Research and Environmental Studies. 2024;4(S1):39-44. https://doi.org/10.70102/IJARES/V4S1/7

[9] Ramachandran S. Comparative Analysis of Antibiotic Use and Resistance Patterns in Hospitalized Patients. Clinical Journal for Medicine, Health and Pharmacy. 2023 Oct 9;1(1):73-82.

[10] Mustafa MS, Shafique MA, Zaidi SD, Qamber A, Rangwala BS, Ahmed A, Zaidi SM, Rangwala HS, Uddin MM, Ali M, Siddiq MA. Preoperative anxiety management in pediatric patients: a systemic review and meta-analysis of randomized controlled trials on the efficacy of distraction techniques. Frontiers in Pediatrics. 2024 Feb 19;12:1353508.

[11] Shimazu S. Maximizing Employee Satisfaction Through Wellness Initiatives. Global Perspectives in Management. 2023.1(1), 49-65.

[12] Li MM, Larche CL, Vickers K, Vigouroux M, Ingelmo PM, Hovey R, Ferland CE. Experience and management of the adverse effects of analgesics after surgery: A pediatric patient perspective. Journal of Patient Experience. 2022 Apr;9:23743735221092632.

[13] Hari Krishnan, Santhosh, Vijay, and Sabana Yasmin. Blockchain for Health Data Management. International Academic Journal of Science and Engineering. 2022;9(2):23–27. https://doi.org/10.9756/IAJSE/V9I2/IAJSE0910

[14] Beiranvand AD, Kordnoghabi R. Wise characteristics in religious thought in comparison to psychology theories of wisdom: a comparative study. International Academic Journal of Innovative Research. 2014;1(2):52-60.

[15] Frizzell KH, Cavanaugh PK, Herman MJ. Pediatric perioperative pain management. Orthopedic Clinics. 2017 Oct 1;48(4):467-80.

[16] Jalali Z, Shaemi A. The impact of nurses' empowerment and decision-making on the care quality of patients in healthcare reform plan. International Academic Journal of Organizational Behavior and Human Resource Management. 2015;2(1):60–66.

[17] Nilsson S, Finnström B, Kokinsky E. The FLACC behavioral scale for procedural pain assessment in children aged 5–16 years. Pediatric Anesthesia. 2008 Aug;18(8):767-74.

[18] Moghaddam AM, Aasi A, Hussein Fallah M. Psychology and Mental Health Promotion of Patients with Type 2 Diabetes. International Academic Journal of Humanities. 2017;4(2):161–166.