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Research Article

# The Efficacy of General Anesthesia with Sevoflurane for Pain Management in Neonates and Infants with Idiopathic Clubfoot Treated with Ponseti Technique and Percutaneous Achilles Tenotomy

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## ABSTRACT

**Background:** Idiopathic clubfoot deformity is a relatively common congenital pediatric foot deformity. A percutaneous Achilles tenotomy (PAT) is required to correct the equinus deformity as it is the most resistant component of clubfoot deformity. Although this procedure is mainly performed with local anesthesia, performing this procedure with general anesthesia has significant advantages. Aims: The purpose of this study was to compare the safety and efficacy of post-procedural pain management of PAT in the treatment of clubfoot with the Ponseti method when performed in a clinic setting with local anesthetic or under general anesthesia

**Methods:** This is a multicentric prospective observational evaluation on children less than one year of age with idiopathic clubfoot whom referred for Ponseti casting and PAT. This procedure was done in the control group with local anesthesia and in the intervention group with Sevoflurane mask 8% (MAC 2) and maintenance of anesthesia with Sevoflurane mask 4% (N2O/O2, 50%). The neonatal infant pain scale (NIPS), the amount of milk, and mood changes were evaluated as a criterion to measure the pain level.

**Results:** NIPS score in the intervention group was significantly lower than the control group. Children in the intervention group consume significantly more milk than the control group. Furthermore, 76% of children in the intervention group were classified as "calm," 24% as "relatively restless," and no child was classified as "severely restless." While in the control group, 54% of children were classified as "severely restless," and the remaining 46% as "relatively restless."

**Conclusion:** Our result showed that using general anesthesia to perform achillotomy in the treatment of clubfoot in children could be associated with less pain in these patients and without significant complications.

The authors declare no conflicts of interest.

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## Introduction

The Conservative method is considered a first-line treatment for idiopathic clubfoot deformity, a relatively common congenital pediatric foot deformity with a prevalence of one out of 1000 live births [1-3]. Ponseti introduced a comprehensive treatment method using serial casting in which most patients with idiopathic clubfoot deformity can obtain correction of their cavus, adduction, and heel varus deformities [4]. In addition, literature shows that this method has been associated with achieving satisfactory functional results in 89% of legs [5-7]. As a result of these positive results over the last two decades, many clinicians have accepted this method as the gold standard in the treatment of congenital clubfoot.

In approximately 72–91% of the patients, a percutaneous Achilles tenotomy (PAT) is required to correct the equinus deformity as it is the most resistant component of clubfoot deformity [7-8]. PAT is usually performed in a clinic setting using a local anesthetic while the child is awake. Over-injection of local anesthetic can obscure landmarks and make tendon localization more difficult. In addition, some infants (especially those older than three months) experience discomfort during tenotomy despite local anesthetic injection [9]. However, some orthopedic surgeons prefer to perform this procedure in the operating room under sedation [10] or general anesthesia [11]. The risk of complications, including bleeding from local vascular injury [12] and neurological complications [13], and the ability to completely remove the equinus are the two main concerns that lead some surgeons to prefer the operating room. Residual equinus is caused by the presence of the lateral soleus tendon or incomplete transection of the tendon [14]. Nevertheless, many complications of general anesthesia, including bradycardia and apnea, have been reported in the pediatric population, especially among infants [15].

The use of general anesthesia protocols to perform PAT in the Ponseti method is controversial. To our knowledge, only a few studies have discussed the effect of using sedation protocols in the Ponseti correction method. The purpose of this study was to compare the safety and efficacy of post-procedural pain management of PAT in the treatment of clubfoot with the Ponseti method when performed in a clinic setting with local anesthetic or under general anesthesia.

## Methods

### Ethical considerations

This study was approved by the Institutional Research Ethics Committee School of Medicine - Tehran University of Medical Sciences. Written informed consent was obtained as a routine from the patients' parents (as surrogate decision-makers).

### Study design

As tertiary referral centers, we conducted a multicentric prospective observational evaluation from March 2019 to August 2020 at Children's Medical Centre and Imam Khomeini Hospital. The population in this study were children less than one year of age with idiopathic clubfoot referred to and treated with the Ponseti method and PAT.

Patients with idiopathic clubfoot who were a candidate for Ponseti casting and PAT, with American Society of Anesthesiologists (ASA) I-II class and formula feeding, were included in the study. In addition, patients with other deformities associated with clubfoot, breastfeeding, a history of seizures, and patients for whom general anesthesia was not applicable for any reason were excluded from the study. Patients were randomly assigned to one of two intervention group or control group.

Patients in the control group were treated by the Ponseti casting and PAT with local anesthesia. Subcutaneous lidocaine hydrochloride was applied as local anesthesia with a maximum total dose of 1.5 mg/kg. Patients in the intervention group were treated with 5% dextrose per kg after induction of anesthesia with Sevoflurane mask 8% (MAC 2) and maintenance of anesthesia with Sevoflurane mask 4% (N2O/O2, 50%). The duration of fasting was 2 hours in the control group and 4 to 6 hours in the intervention group based on the age of the patients. In addition, in the intervention group, the patients were allowed to breastfeed 2 hours after the procedure. Ponseti casting and PAT were performed in 2 groups with the same technique.

### Outcome measurement

Patients' data, such as prior apnoeic events, medical risk factors, surgical and anesthesia-related complications, and demographic data, including age, sex, and weight, were recorded. In addition, Systolic and diastolic blood pressure and heart rate were assessed before, during, and after the procedure. The duration of the recovery stay was also measured. In addition, the neonatal infant pain scale (NIPS), the amount of milk consumption in the first 24 hours after the procedure, and mood changes were evaluated as a criterion to measure the pain level in patients. NIPS, which ranged from 0 to 7, was recorded in a pre-designed checklist at 1, 6, and 12 hours after the procedure. The NIPS score of less than 2, between 3 to 5, and more than five were defined as patients with mild, moderate, and severe pain, respectively.

### Statistical Analyses

All data were analyzed using SPSS software version 23 for Windows (IBM Inc, NY). Quantitative variables are expressed as mean ± SD, and qualitative variables are expressed as numbers and percentages. The Paired T-test, the Mann-Whitney test, and the repeated measures ANOVA were performed to compare quantitative variables. In addition, the Chi-square test was used for

qualitative variables. A P value less than 0.05 was considered statistically significant.

## Results

A total of 100 eligible patients were included in this study. Patients were randomly divided into two groups, the intervention group (50 children, 50%) and the control group (50 children, 50%). The intervention group comprised 18 females and 32 males with a mean age of 83.6±55.5 days, and the control group consisted of 19 females and 31 males with a mean age of 84.6±53.1 days. The average weight of children in the intervention group was 3310±266.7 grams, and the average weight in the control group was 3428±501.8 grams. The age distribution, weight distribution, and sex were similar in both groups (P = 0.95, P = 0.14, and P = 0.84, respectively).

No cases of decreased oxygen saturation and nausea and vomiting were reported in patients who underwent general anesthesia. Changes in blood pressure and heart rate during general anesthesia were less than 20% of the baseline value in most patients. Hemodynamic changes of more than 20% were recorded in 3 patients, of which only one patient needed treatment due to bradycardia.

Systolic and diastolic blood pressure before the Ponseti casting and PAT did not differ between the two groups, and heart rate was significantly lower in the control group (P = 0.007). Nevertheless, all three parameters measured in the intervention group were significantly lower than the control group during and after the procedure (Table 1).

Measuring and comparing the pain level between the two groups using NIPS criteria at 1, 6, and 12 hours after the procedure demonstrated that the score of the patients in the intervention group was significantly lower than the patients in the control group (Table 2).

The comparison of the amount of milk consumption in the first 24 hours after the procedure between the two groups shows that the children in the intervention group consume significantly more milk than the control group. Also, the comparison of children's mood changes after the procedure showed that 76% of children in the intervention group were classified as "calm," 24% as "relatively restless," and no child was classified as "severely restless." While in the control group, 54% of children were classified as "severely restless," and the remaining 46% as "relatively restless." The average duration of recovery stay was lower in the control group (Table 2).

**Table 1- Systolic and Diastolic Blood Pressure, and Heart Rate of Patients at Different Times**

| | | Intervention Group (N=50) | Control Group (N=50) | P value |
|---|---|---|---|---|
| SBP | Before | 103.1±3.5 | 103.5±2.70 | 0.10 |
| | During | 96.9±4.4 | 115.5±4.0 | 0.001 |
| | After | 101.4±3.3 | 108.9±2.50 | 0.001 |
| DBP | Before | 65.2±2.5 | 64.6±3.40 | 0.06 |
| | During | 62.0±3.0 | 75.8±3.20 | 0.001 |
| | After | 68.0±2.8 | 70.0±2.50 | 0.001 |
| HR | Before | 105.2±6.7 | 104.4±4.20 | 0.007 |
| | During | 124.3±10.8 | 137±5.80 | 0.001 |
| | After | 111±8.9 | 120±6.0 | 0.001 |

SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; HR: Heart Rate

**Table 2- Result of NIPS Scores, milk consumption, mood change and duration of recovery stay**

| | | Intervention Group (N=50) | Control Group (N=50) | P value |
|---|---|---|---|---|
| NIPS Scores | | | | |
| | 1 hour | 1.3±0.5 | 5.0±0.6 | 0.001 |
| | 6 hours | 0.9±0.5 | 3.6±0.7 | 0.001 |
| | 12 hours | 0.4±0.2 | 2.3±0.6 | 0.001 |
| Milk consumption (ml) | | 382.6±130.3 | 234.4±61.5 | 0.001 |
| Mood change | | | | 0.001 |
| | Calm | 38 (76%) | 0 (0%) | |
| | Relatively restless | 12 (24%) | 23 (46%) | |
| | Severely restless | 0 (0%) | 27 (54%) | |
| Duration of recovery stay | | 92.3±2.1 | 35.1±0.7 | 0.035 |

## Discussion

Clubfoot is a relatively common congenital deformity in pediatric orthopedics that can be successfully treated using conservative treatments. The Ponseti clubfoot treatment method is known as the gold standard treatment of this disease, during which correction of lower limb cavus, adduction, and varus deformities is achieved using

serial casting and manipulation [4]. The success of treatment in this method depends on strict adherence to Ponseti's protocol, including weekly casting and manipulation and long-term bracing with a derotational foot orthosis [10]. About 90% of patients treated with this method need PTA to correct equinus deformity [8]. This procedure is commonly performed on an outpatient basis in the setting clinic using local anesthetics and results in a painful experience being imposed on children in the early years of birth.

Studies have shown that children's memories of painful experiences can have long-term consequences for their response to subsequent painful events and their acceptance of following healthcare interventions [16]. Studies have also shown that inadequate analgesia for initial procedures in young children may reduce the effectiveness of adequate analgesia in subsequent procedures [17]. Therefore, appropriate pain management methods in children during therapeutic procedures are critical. This study aimed to evaluate the efficacy of procedural general anesthesia in pain management after the Ponseti casting and PAT in neonates and infants with idiopathic clubfoot.

In this randomized controlled trial, we demonstrate that the utility of general anesthesia protocols for PAT as an important, usually necessary step in Ponseti clubfoot management was associated with better pain management in children without significant complications. The measurement of hemodynamic parameters before, during, and after the procedure, as well as the use of the NIPS scoring system, the amount of milk consumption, and mood changes as criteria for evaluating pain in patients, showed that the use of general anesthesia to perform PAT leads to better pain management in children. In this study, three patients experienced more than 20% changes during general anesthesia, and one was treated for cardiac arrhythmia. No cases of decreased oxygen saturation, nausea, vomiting, apnea, or death were recorded in this study.

Ponseti initially used general anesthesia in this treatment, which was later replaced by local anesthesia because it felt safer [18]. Various risks associated with general anesthesia, such as mortality, aspiration, cardiac arrhythmia, cardiac arrest, and larynx spasm or bronchospasm caused by intubation, led to the avoidance of this procedure in those years. In the early years of his experience, Ponsetti witnessed a severe adverse reaction to general anesthesia in an infant undergoing tenotomy. This prompted him to develop a local anesthetic protocol. Morray et al. published an article in 2000 using data from the Pediatric Perioperative Cardiac Arrest (POCA) Registry, based on which cardiac arrest related to anesthesia had an incidence of 1.4±0.45 per 10,000 instances of anesthesia [19]. A pediatric perioperative morbidity rate of 7.5% was reported in a study on 24,165 anesthetics performed over 30 months in a pediatric teaching hospital, during which only one death was reported, and it was not anesthesia-related [20].

Parada et al. conducted a study on 137 children to review the safety of PAT procedures performed in the operating room under general anesthesia. This study showed that out of 182 tenotomies performed, no patient showed apnea or anesthesia-related complications. This study used sevoflurane with a mask or laryngeal airway mask to induce and maintain general anesthesia in patients. Drugs were strictly avoided. Patients received a weight-based dose of acetaminophen suppository after induction of general anesthesia. After tenotomy, a local anesthetic of 1 mL bupivacaine HCl with 1:200,000 epinephrine was injected [11]. The use of induced sedation using a mixture of oxygen/nitrous oxide (30:70) and its maintenance using isoflurane as a safe and alternative method for general anesthesia to perform PAT was introduced by Bor et al. [10]. To relieve pain in these patients, the surgical wound was infiltrated with 0.25% bupivacaine at the end of the operation. For most patients, a single acetaminophen suppository was sufficient for pain relief after the procedure. In this study, only one patient who needed a laryngeal mask was reported, but he recovered quickly after the operation. On the one hand, using a sevoflurane mask is associated with lower risks related to the process and the use of endotracheal intubation than general anesthesia. On the other hand, as shown in this study, it leads to a decrease in the amount of pain in children compared to the method of using local anesthesia.

The use of general anesthesia to perform PAT in this study was associated with more prolonged fasting than the local anesthetic method, which was associated with imposing distress on families and infants. Similarly, this issue has been reported in other studies so that when a retrospective examination was made, it was noticeable that all the families clearly remembered the time that the infant remained hungry [21]. Therefore, from this point of view, local anesthesia is more acceptable to families before the operation.

Moreover, the recovery duration in patients who underwent general anesthesia was significantly longer than in the control group. This issue resulted in more extended hospitalization of these patients, which can indirectly lead to an increase in treatment costs, the risk of hospital infections, as well as an increase in the occupancy rate of hospital beds. This issue, especially in centers where the number of referred patients is high, and the number of beds and conditions of the operating room cannot adequately respond to the volume of referrals, can be associated with the preference for the achillotomy method with local anesthesia.

This study has some considerable limitations. First, technical complications related to PAT were not studied in this study. Studies have shown that general anesthesia has no superiority over local anesthesia in reducing the

amount of these complications, including damage to local vessels and nerves [13, 21]. Second, due to the short follow-up period, the rate of incidence and negative results of incomplete achillotomy and recurrence could not be evaluated. Therefore, a study with a longer follow-up is needed to investigate the incidence of incomplete achillotomy as one of the potential complications of PAT using local anesthesia for comparison.

## Conclusion

Our result showed that using general anesthesia to perform achillotomy in the treatment of clubfoot in children can be associated with less pain in these patients. In addition, in this method (general anesthesia without intubation), the complications of general anesthesia are not imposed on the patients. However, the need for hospitalization and longer fasting time are disadvantages of using this method compared to local anesthesia. However, cost-effectiveness studies with long-term follow-up are needed to decide the proper strategy and appropriate for different settings.

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