Clinical Study

The Use of Postoperative Restraints in Children after Cleft Lip or Cleft Palate Repair: A Preliminary Report

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Received 13 November 2012; Accepted 3 December 2012

Academic Editors: A. Ferri and İ. Özyazgan

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Purpose. This study examines whether the use of elbow restraints after cleft lip/palate repair has a relationship to postoperative complications. **Methods.** A comparative descriptive design was used to study a convenience sample of children undergoing repair of cleft lip/palate at Akron Children's Hospital with Institutional Review Board approval. The children were randomized into intervention or control groups with use of elbow restraints considered the intervention. The study consists of two arms; one examined children after cleft lip repair, the second examined children after cleft palate repair. Repairs were performed by a single surgeon. Data collected included age, comorbidities, patient discomfort measured by pain score, frequency and duration of pain medications, use of pacifier or finger/thumb sucking, and postoperative complications including disruption of the suture line. **Results.** With 47 post palate repair patients and 47 post cleft repair patients, there is no significant difference ($P > 0.05$) in the occurrence of postoperative complications. **Conclusions.** Study results provide prospective evidence to support postoperative observation of children by surgery staff and family following cleft lip or cleft palate repair without the use of elbow restraints. Clinicians should reevaluate the use of elbow restraints after cleft lip/palate repair based on the belief restraints prevent postoperative complications.

1. Introduction

The question of whether children require elbow restraints following cleft lip and palate repair is unresolved. The theory is that arm restraints prevent children from putting their fingers or objects into their mouth where they could disrupt the suture line. In a survey of plastic surgeons in the United Kingdom in 1993, 93% of plastic surgeons reported the use of arm restraints after repair [1]. Other reports also support the use of splints [2, 3].

In the United States, the use of arm restraints remains a part of the dogma. A survey of Cleft Palate Teams by Petersen [4] in 2008, showed 95% of respondents advocated postoperative arm restraints. A publication by Katzel et al. [5] in 2009, on current surgical practices in cleft care stated that 85% of cleft surgeons recommended the use of elbow restraints after surgery.

This approach has been generally accepted as good practice; however, Jiginni et al. [1] in 1993 found no statistically

significant difference between the use or nonuse of arm restraints in the development of postoperative complications. This is the only evidence-based evaluation in the medical literature. With family centered care practiced in the majority of pediatric hospitals parents should be given evidence-based medical results in order to be able to make informed decision on the use of restraints for their child postoperatively.

On this basis we conducted a prospective clinical trial to bridge the gap that still remains between practice and evidence based medicine in the use of arm restraints to prevent postoperative complications following cleft lip and palate repair.

2. Method

2.1. Participants. A comparative descriptive design was used to study a prospective sample of children undergoing repair of cleft lip/palate at our pediatric teaching hospital by a single surgeon. The study consisted of two arms. One arm examined

children after cleft lip repair; the second arm examined children after repair of cleft palate. All cleft lip patients had a Millard rotation advancement repair, and all cleft palate patients had an intravelar veloplasty repair. All parents of children under the age of 2 who were scheduled for repair of their cleft lip or cleft palate by the study author were invited to give consent to enter their child in the study. Children who required transfer to the critical care setting were excluded from the study. The study received IRB approval.

Because the use of arm restraints is thought to protect the incision from damage infants can cause by placing their fingers/thumb in or at their mouth, we included children whose parents reported them to be finger, thumb, or pacifier suckers in both the cleft lip and the cleft palate repair groups.

2.2. Instrument. The data collected included the child's age, gender, type of cleft repair (lip or palate), preoperative thumb, finger, or pacifier sucking, and the existence of any comorbidity. During hospitalization in the postoperative phase, antibiotic therapy, frequency of pain medications, premedication flacc pain scores, length of hospital stay in days, and an every four hour assessment of the operative site for excessive bleeding or indication of infection were recorded. Phone calls to the parents were made at one week postcleft lip or palate repair. Parents were asked to identify any disruption of the suture line such as a broken stitch or separation of the wound, excessive bleeding from the mouth or nose, signs of infection including redness, edema, drainage, or fever, and the child's discomfort reported as the average flacc pain score and frequency of pain medications at one week postoperatively. These questions were also asked of the parents at the followup office visit where standardized photographs were taken of the surgical site, and documentation of any disruption of the suture line was noted by the surgeon.

2.3. Procedure. Participants were divided into a control group, which used restraints, or into the intervention group, with no use of arm restraints. This assignment occurred as they entered the PACU following repair and after receiving parental consent. Assignment to the intervention or control group was alternated every other child. The study procedures were reviewed with parents/guardians in the postanesthesia care unit. This included the deviations from usual care which included the absence of arm restraints in the intervention group and a followup phone call to the home of all participants. Other than the use of restraints, each group received the same standard of care. After signing the consent, parents were given a copy of the study procedures and researchers' contact information. Data collection continued on the nursing care units with assessments of the surgical site recorded every four hours. Educational materials on the study protocol were presented to nursing staff and maintained on each unit to facilitate competency among nurse data collectors. A copy of the flacc pain scale (Merkel et al., 1997) [6] was reviewed with parents in the PACU and included in the home going instruction packet to parents. This aided parents in communicating a pain score assessment and use

of pain medications with the nurse during the one-week postoperative phone call. Assessment of the surgical site and any complications were noted by the surgeon and office staff at the postoperative office visit.

3. Results

A total of 47 children were enrolled in the cleft lip repair arm of the study, and 47 children were enrolled in the cleft palate repair group (Table 1). Twenty one of the children enrolled in the control group of the cleft lip repair arm had good ($n = 5$) to excellent ($n = 16$) postoperative healing of the surgical site. Twenty-six children enrolled in the intervention or no arm restraint group of the cleft lip repair arm demonstrated good ($n = 4$) to excellent ($n = 20$) repair. Families of 2 children in the intervention group did not return for followup evaluation.

The surgical outcome in cleft lip repair was initially evaluated by our surgical nurse and the surgeon. Postoperative photos at 6 months were then used as a final evaluation. Excellent results had no off set of the vermilion and no elevation of the lip on the cleft side. Good results had minor vermilion offset (<2 mm) and minimal (<2 mm) elevation of the lip on the cleft side.

In the palatal repair arm, 2 of 22 (9%) developed postoperative fistulae in the intervention group, and 2 of 25 children (8%) developed postoperative fistulae in the control group. Lehman [7] reported a fistula rate of 16.1% in 136 consecutive palate repairs. When examining the use of arm restraints after the repair of a child's cleft lip or cleft palate, the results show no significant difference in the occurrence of postoperative complications ($P > 0.05$).

The preoperative habit of finger, thumb, or pacifier sucking did not exclude a child from participating in the study. 79% of parents of children undergoing repair of their cleft lip reported the children placed their thumb/fingers in their mouths. 66% of the parents in the cleft palate repair group reported their children placed fingers, thumbs, or pacifiers in their mouths frequently (Table 1). The history of finger, thumb, or pacifier sucking did not add any significance to the results. In the intervention group, there was 1 fistula in the thumb sucking group and one in the nonthumb sucking group. In the control or arm restraint group both fistulas occurred in nonthumb sucking group (Table 1).

Our goal was to have two equal groups of patients (n) with equal numbers in both the control and intervention subgroups. This did not occur, but we believe that the numbers are adequate to make a strong statement regarding the use of postoperative splints.

4. Discussion

The literature does not answer the questions of whether the use of elbow restraints following the repair of the cleft lip/palate provides any evidence-based benefit. Our study which was a prospective study was stimulated by this long standing controversy to provide evidence-based information for surgeons, parents, and healthcare providers.

We also included patients who had a history of finger, thumb, or pacifier sucking.

TABLE 1: Demographics of patients.

Study group	Male	Female	Age in months	Use of pacifier or thumb	Type of cleft
Lip repair splints	61.9% ($n = 13$)	38.1% ($n = 8$)	M = 5.05 mo, SD = 4.22 mo	90.5% ($n = 19$)	CL-9 BCLP-3 UCLP-9
Lip repair no splints	61.5% ($n = 16$)	38.5% ($n = 10$)	M = 4.0 mo, SD = 2.36 mo	69.2% ($n = 18$)	CL-12 BCLP-3 UCLP-11
Palate repair splints	52% ($n = 13$)	48% ($n = 12$)	M = 11.76 mo, SD = 3.53 mo	60% ($n = 15$)	CP-14 BCLP-5 UCLP-6
Palate repair no splints	63.6% ($n = 14$)	36.4% ($n = 8$)	M = 13.86, SD = 4.05 mo	72.7% ($n = 16$)	CP-9 BCLP-14 UCLP-9

The traditional use of postoperative arm restraints following the repair of a child's cleft lip or cleft palate remains common. Two surveys of cleft surgeons by Jiginni [1] and Petersen [4] show continued support for the use of splints, and recent articles reinforce the postoperative use of arm splints. There is a cadre of other authors who have pointed out that they have had "no untoward effects" after abandoning the use of arm restraints [1, 8–10].

Two other publications add information to support not using restraints. Oxley [11] in 2001, in a small survey found that 53% of parents if given a choice would choose not to use restraints for their child postoperatively. Tokioka et al. [12] in 2009, observed no manipulating, scratching, or other harmful movements when eight infants were videotaped after repair of their cleft lip and/or palate without restraints.

Seventy-nine percent of parents of children undergoing lip repair and 66% of patients in the cleft palate repair group reported finger, thumb, or pacifier sucking. Because this is one of the major reasons surgeons advocate for splint use we felt this was important to include this subset of patients in our study. Interestingly, 3 of the 4 fistula occurred in the nonthumb sucking group.

The final results of our study showed there was no significant difference ($P > 0.05$) in the occurrence of postoperative complication in the group without elbow restraints. The question remains whether presenting restraint use after cleft repair with no evidence to support their use reflects adherence to the concept of family centered care [13].

5. Summary

We have presented a prospective study that demonstrates no statistical significant benefit to the use of arm restraints in children having cleft lip and palate surgery.

As healthcare professionals, we must provide evidence based information to parents, so that they can make informed decisions in the care of their child. We hope this study adds to the body of knowledge in the discussion of whether arm restraints are necessary after cleft lip/palate repair. We also believe a large multicenter study would enhance confirmation of our results.

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