

## BLOOD LOSS IN CLEFT PALATE SURGERY WITH AND WITHOUT INFILTRATION OF TRANEXAMIC ACID ALONG WITH LOCAL ANESTHETIC AND ADRENALINE

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### ABSTRACT

**Objective:** To assess the impact of local infiltration, both with and without tranexamic acid, on blood loss during cleft palate surgery.

**Methods:** A total of 60 patients of age 9 to 60 months having congenital cleft palate and planned for surgical repair in Patel hospital Karachi were included. In group I, TXA infiltration was performed. While in group II, infiltration was performed without TXA addition. After 10 minutes of infiltration surgical procedure started, repair was performed using Sommerlad's technique. Amount of intra-operative blood loss was noted.

**Results:** Mean age was  $12.6 \pm 2.5$  months in group TXA and  $12.4 \pm 2.3$  months in control group ( $p$ -value 0.7). 23 (76.7%) children in TXA group and 24 (80%) in control group presented with bilateral cleft ( $p$ -value 0.75). 21 (70%) children in TXA group and 20 (66.7%) in control group had complete cleft palate ( $p$ -value 0.78). Mean operative blood loss was  $58.6 \pm 12.7$  ml in TXA group and  $83.8 \pm 16.3$  ml in control group ( $p$ -value  $< 0.0001$ ).

**Conclusion:** TXA infiltration before surgery significantly reduces the blood loss during cleft palate repair surgery. This subsequently reduces the necessity for additional intra-operative haemostatic measures, and diminishes the requirement for post-operative blood transfusions.

**Keywords:** Cleft palate, Blood loss, Infiltration, Tranexamic acid.

### INTRODUCTION

Oral cleft is among the most prevalent birth defects globally, occurring either independently or as part of a syndrome. Orofacial cleft arises during the initial phases of development as a result of the inadequate or incorrect fusion of tissues.<sup>1</sup> Congenital cleft lip and/or palate (CLP, CL, CP) are classified as oral clefts. In many instances, it is influenced by a combination of genetic and external factors. External factors encompass malnutrition, hormonal disorders, medications, toxins, and biological triggers.<sup>2</sup> The global prevalence of CP according to recent meta-analysis is 0.33/1000 live births and that of CL is 0.3/1000 live births.<sup>3</sup>

Children with cleft lip and palate may experience significant challenges related to nutrition, speech, hearing, mental and social development. Additionally, these patients frequently encounter maxillary hypoplasia and oral respiration, leading to decreased saliva production and heightened periodontal issues, as well as oral disorders that negatively impact their quality of life.<sup>4</sup> Consequently, prompt and proactive intervention for

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these abnormalities via surgical procedures and specialized care can significantly contribute to minimizing certain disabilities.<sup>5</sup>

This anomaly is managed between the ages of 9 and 18 months, with several surgical methods used to divide the oral and nasal canals.<sup>6,7</sup> The potential for intraoperative blood loss increases as a result of the extended duration of the surgery. Furthermore, considering the age of pediatric patients, it is critical to manage and stabilize their hemodynamic parameters while reducing blood loss during surgery.<sup>7</sup> Several approaches, including controlled hypotension with sevoflurane, remifentanyl, or propofol-based anesthesia, as well as the administration of antifibrinolytic agents such as tranexamic acid (TXA), have been proposed to reduce blood loss and maintain the patient's hemodynamic stability.<sup>8,9</sup>

The application of tranexamic acid for the reduction of blood loss has enhanced outcomes, and its utilization has been embraced by plastic surgeons to minimize intraoperative bleeding.<sup>10</sup> In plastic surgery, the application of tranexamic acid has primarily been confined to craniomaxillofacial procedures,<sup>11</sup> while information regarding its effectiveness in managing blood loss during cleft palate surgeries remains scarce. The objective of the current study was to assess the impact of local infiltration, both with and without tranexamic acid, on blood loss during cleft palate surgery.

## Methods:

A total of 60 patients of age 9 to 60 months having congenital cleft palate and planned for surgical repair in Patel hospital Karachi were included. Children planned for redo cleft palate surgery, having traumatic cleft palate or those with coagulopathy were excluded. The study was performed from January-2024 to September 2024. Informed consent from patient's guardians was obtained.

All procedures were performed by single consultant surgeon under general anesthesia. In group I, TXA infiltration was performed. While in group II, infiltration was performed without TXA addition. The solution for group I was prepared using 15 ml normal saline, 4 ml adrenaline, 5 ml xylocaine and 5 ml (250 mg) TXA, making total 29 ml. While for group II, all the composition was same except TXA solution. Moreover for group II, 6 ml adrenaline was added to kidney tray for soaking gauze pieces during surgery. A 31 gauge needle was used to inject this solution in all tissue planes meant to be for incision. After 10 minutes of infiltration surgical procedure started, repair was performed using Sommerlad's technique. Amount of intra-operative blood loss was noted.

Data analysis was performed using SPSS v25. Independent sample t-test was applied to compared intra-operative blood loss, considering p-value  $\leq 0.05$  as significant difference.

## Results:

There was no significant difference in mean age, weight and gender between the groups. 23 (76.7%) children in TXA group and 24 (80%) in control group presented with bilateral cleft (p-value 0.75). 21 (70%) children in TXA group and 20 (66.7%) in control group had complete cleft palate, while 9 (30%) in TXA group and 10 (33.3%) in control group had incomplete palate (p-value 0.78) [Table 1].

Mean operative blood loss was  $58.6 \pm 12.7$  ml in TXA group and  $83.8 \pm 16.3$  ml in control group (p-value  $< 0.0001$ ) [Table 2].

**Table 1. Baseline Study Variables.**

	Group I (TXA, N=30)	Group II (Control, N=30)	P-value
Age (Months)	12.6 $\pm$ 2.5	12.4 $\pm$ 2.3	0.7
Weight (Kg)	9.1 $\pm$ 1.2	9.3 $\pm$ 1.1	0.50
<b>Gender</b>			
Male	18 (60%)	17 (56.7%)	0.79
Female	12 (40%)	13 (43.3%)	

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Type of cleft Palate			
Bilateral	23 (76.7%)	24 (80%)	0.75
Unilateral	07 (23.3%)	06 (20%)	
Complete	21 (70.0%)	20 (66.7%)	0.78
Incomplete	09 (30.0%)	10 (33.3%)	

**Table 2. Comparison of Intra-operative Blood Loss.**

	Group I (TXA, N=30)	Group II (Control, N=30)	P-value
Blood Loss (ml)	58.6±12.7	83.8±16.3	<0.0001

## DISCUSSION:

Blood loss is a critical parameter that must be prioritized in pediatric surgeries. The low circulatory volume observed in this patient limits the permissible loss, which can adversely affect the overall surgical outcome. Pediatric patients undergoing cleft palate surgeries with an average body weight of 10 kg have an overall circulatory volume of 800 ml, with a maximum allowable loss limited to 80 to 100 ml.<sup>9,12</sup> 50 to 100 milliliters of blood are often lost during a palatal repair, according to reports.<sup>13</sup> Even though this range seems to be within physiologically acceptable bounds, patients who are borderline anemic or have low body weight may experience a significant cardiovascular burden from it. Reducing the amount of blood lost not only helps to avoid these issues but also promotes better healing of the surgical sites overall.<sup>9</sup>

A range of strategies has been articulated in the existing literature to mitigate intraoperative volume loss. The strategies encompass the utilization of hypotensive agents such as clonidine, NTG infusion, dexmedetomidine infusion, and intravenous beta blocker administration. These agents have been noted to reduce blood loss and enhance the comfort of the operator by creating a bloodless field; however, their application is frequently limited to adult patients.<sup>14</sup>

Tranexamic acid is acknowledged as a very safe antifibrinolytic agent that effectively inhibits fibrinolysis. TXA has demonstrated a notable reduction in intraoperative blood loss when given one hour prior to surgery.<sup>15</sup> TXA plays a crucial role in hemostatic resuscitation in the setting of acute trauma life support. The medication is administered through intravenous infusion and is processed and excreted by the renal system. This has been established as safe for pediatric patients and individuals with renal compromise.<sup>16</sup>

In present study, we found significantly positive effect of TXA in reduction of blood loss, with a blood loss of 58.6±12.7 ml in TXA group and 83.8±16.3 ml in control group.

Khavidaki et al. in their study on evaluation of effect of IV TXA on post-operative blood loss reported mean blood loss of 11.73 ± 4.42 ml in TXA group and 17.36 ± 4.99 ml in control group.<sup>17</sup> This study reported blood loss was significantly less in comparison to our's and other studies.

Shafa et al. conducted a study to determine the ideal IV dose of TXA for preventing blood loss in cleft palate surgeries, the authors did not find any significant difference in blood loss amount among different doses of TXA, however mean blood loss was significantly higher in control group who did not received TXA.<sup>18</sup> In present study we used TXA for infiltration not IV.

In study from Pakistan reported that TXA infiltration prior to surgery significantly improves surgical field visualization during cleft palate repair.<sup>19</sup>

Intraoperative bleeding presents a significant challenge in numerous surgical procedures. It is linked to a notably high rate of mortality and morbidity, particularly in pediatric surgeries like cleft palate repair. Surgery is the main approach for treating cleft lip and cleft palate disorders. So administrating TXA before surgical repair can help to reduce bleeding and its associated morbidities significantly.

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## CONCLUSION:

TXA infiltration before surgery significantly reduces the blood loss during cleft palate repair surgery. This subsequently reduces the necessity for additional intra-operative haemostatic measures, and diminishes the requirement for post-operative blood transfusions.

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