

ORIGINAL ARTICLE

Clinical study of Evaluation of the Effect of Tranexamic Acid in Primary Cleft Palate Surgery in Children

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ABSTRACT

Aim : To evaluate tranexamic acid effect on quality of surgery.**Design:** Double-blind study, Prospective and randomized**Place & time of study:** June 2020 to may 2021 Allama iqbal memorial trust hospital Gujranwala.**Methods:** Two groups of candidates were made. The saline was administered to the control group whereas tranexamic acid was administered as 0.01g/kg in a bolus form, before surgical incision to tranexamic acid group. On a 10-point scale, grading of surgical field, primary hemorrhage and satisfaction of surgeon**Results:** As far as operating surgeon satisfaction is concerned, noteworthy improvement was witnessed and evaluation of surgery in case of control individuals group as compared to in case of test individual group in the tranexamic acid individuals group was estimated against the control members of group.**Conclusion:** tranexamic acid was given in dosage of 0.01g/kg of before surgical incision showed improved in a great way in surgical field during repairing of cleft palate operation.**Keywords:** tranexamic acid surgical field, pediatric, palatoplasty satisfaction, cleft palate

INTRODUCTION

One of the most common congenital pathology in children that needs surgical procedure for its correction is cleft palate. The loss of blood linked with this operation is not too much that need transfusion of blood⁵, but blood oozing during operation interact and disturbs the surgical process. There is more exudate likely from the nearby tissues because of scarring and repeated incidence due to infections. Tranexamic acid was proven to depict positive reviews in case of oral and maxillo facial surgical operations⁷ it mainly aimed at reduction of blood lost and making successful surgical operations. However, the role of tranexamic acid in case of cleft palate surgery related to children has not been analyzed.

The main aim of this case research, randomized study, and double-blind research was to do assessment of tranexamic acid effect with respect to surgical operation quality, satisfaction of surgeon and formation rate of primary hemorrhage in case of children that were operated for cleft palate.

METHODS

This case research got approval via ethical committee of hospital and then consent was taken via guardians of all children who were selected for surgery. All the candidates ranked physical status class I by Anesthesiologists, aging between 6 to 65 months. Candidates with a Group II cleft or III (Balakrishnan's classification) were also chosen. All the candidates having bleeding disorders, previous operation, heart disorders congenitally, hemoglobin less than 8 gm/dL or operatively, or respiratory infections were not included in case research. Two groups of candidates were made: a group of tranexamic acid (test) and second one is a control group. Candidates were not included if plan of surgical operation alters or if any alteration needed during anesthesia because of hemodynamic and movement or alterations. About consecutive seventy candidates were called for sake of palate primary surgical repair in this case research. All candidates were premeditated by aid of oral midazolam in dosage of 0.005 g/kg about thirty minutes given prior to surgical procedure. The inhalation induction of candidates was carried out via aid of 5%, sevoflurane at and placement of cannula intravenously was done in case of each

candidate. Intubation of candidates was done via aid of endotracheal tube at right-angled .15 minutes before making a surgical cut, the candidates in the test individuals group (40) were administered as a bolus 0.01g/kg dosage of tranexamic acid, and normal saline was administered to the candidates in control individuals group (42) as placebo. Adrenaline administration (1/400,000 with 0.5% lignocaine) was done in all selected candidates. Anesthesia maintenance was carried out via aid of 40% oxygen, 60% nitrous oxide and sevoflurane at 2.5% to 3% as end-tidal concentration. All candidates were administered anesthesia (moderate hypotensive) via aid of sevoflurane. The systolic blood pressure intraoperatively was kept around 20% below the blood pressure selected as baseline. The Intraoperatively analgesia was given via aid of fentanyl (2 lg/kg) intravenously. All operations were carried out via two surgeons, who were expert. This operation was carried out under loupe magnification with respect to standardized protocols that is palatoplasty two-flap via aid of levator sling myoplasty was carried out. Only operating surgeon per candidate evaluated the surgical field. The operating doctor was bound to do grading of field of surgical n scale of 10-points and to rank gratification level as well (good, average, or poor). Time taken by Surgery, quality of surgical field, transfusions of blood, and problems related to blood loss were all recorded. Moreover Primary hemorrhage as well as requirement for any intervention was also taken into account.

RESULTS

About Eighty two candidates were selected for case research. From control group, three candidates whereas, four candidates from test group were removed. The information like sex, weight and age were compared between members of both groups. No discrimination was found among groups member with respect to cleft grading. From evaluation point of view, the median grading of the surgical operation was 4 in case of control individual group and 3 in case of individuals belonging to test group. The operating surgeons documented level of satisfaction as satisfactory with the surgical field in 11 of 31 in cases related to control group, while operating surgeon satisfaction was ranked as good in case of 24 of 34 sites in case of test group members. One candidate of the control group showed the signs of minor bleeding 1 hour after surgery and was sent back to operating theater to overcome that complication; no mishaps were further witnessed as far as hemoglobin's levels were concerned, no

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noteworthy difference pre and postoperatively were noted. No noteworthy differences were seen as far as surgery duration concerned.

Table 1: Post and Preoperative demographic data

Parameter	Control Group (mean)	Test Group (mean)	P value
Age (months)	36	35	.78
Weight (kg)	10	11	.82
Cleft grade	3	3	.700
Pre operation Hb	10.1	10.4	.070
Post Operation Hb	9.6	9.9	.248
Grade of surgical field	3	3	.004

DISCUSSION

The final conclusion of this case research depict that a bolus of tranexamic acid in dosage of 0.01g/kg was given prior to surgical incision showed noteworthy results with respect to improvement in case of surgery by surgeons. The loss of blood in case of cleft operation varies from person to person. According to the case study via Adeyemo et al. a mean loss of blood estimated to be 95.8 6 144.9 mL (range, 2 to 800 mL) and in case of cleft palate and lip operation, blood transfusion resulted in 10% Improvements in surgical techniques and expertise. Moreover the instruments availability cause reduction of loss of blood and requirement for transfusions of blood. Although loss of blood linked with this surgical procedure is not serious as such that demands blood transfusion² but there is still blood oozing continuously during the entire operation. The oozing of blood is more likely to happen from the tissues surrounding incision because of repeated incisions and scarring and infections. In surgery, blood impacts badly to surgical quality. Infiltration via aid of adrenaline in surgery is a way to make surgery better in kids. Whereas, adrenaline absorption afterwards cause deleterious reactions hemodynamic ally¹ and positive effects lasting longer up to the expectations. Tranexamic acid is an cheap, safe medicine, but its importance in case of in cleft palate and lip surgery in children has not been estimated. Administration of tranexamic acid in case of pediatric surgery have depicted reduction in loss of blood⁹ along with nil evidence of harmful effects¹¹.

The tranexamic acid administration Intraoperatively was proved to be a productive way for conservation of blood in case of major operation like craniostylosis operation¹², pediatric cardiac operation¹⁵, and scoliosis operation¹⁴. However, its importance is still unclear in case of operations that result in less bleeding. Tranexamic acid when administered perioperatively as a single parenteral dosage depicted decrease in hemorrhage incidence after surgical tonsillectomy in a research in case of children¹¹, but other researches depicted no change in patients number who had experienced bleeding⁸. The administration of tranexamic acid did not decrease the incidence of bleeding during pediatric adenotonsillectomy⁶. Usually the loss of blood in case of cleft pate is minimal. Even in research that documented transfusion of 10%, two out of 10 transfusions were carried out for the reason of blood loss and the leftover transfusions were performed in order to overcome the condition of pre-existing anemia³. In case of our institution, the blood transfusion incidence witnessed about 1 in 500 and primary hemorrhage occurrence that require a need to return operating room is 1 out of 200 (personal communication). However, little amount of blood even can interact in field of surgery, especially when magnification used intraoperatively. The conclusion of present research depicted an improvement in the field of surgery but the doctors' satisfaction consequently increased with the surgery in a significant manner. The plasma half-life of tranexamic acid is 1.9 hours, and a injected bolus administration of 10 mg/kg helps in effective management of level of 5 mg/dL therapeutically⁴. Since the estimated time of operation was 2.5 hours approximately, we have given just a one bolus dosage. The significant shortcoming of present case research is

that the quantity of loss of blood was excluded from this this reseach, as it was impossible to estimate this parameter. The differences were witnessed in case of hemoglobin pre as well as postoperatively in case of either groups. There was no need of transfusions required. The conclusion of this case research depicted a great significant benefit of this acid. This cost friendly, inexpensive and safe medicine may be practiced in clinics and included in case of protocols required for cleft palate and lip repair in case of children.

CONCLUSION

The usage of tranexamic acid showed great betterment in surgery along with the doctor's satisfaction with respect to the surgical procedure.

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