International Journal of Pediatric Otorhinolaryngology 77 (2013) 1139–1142

Contents lists available at SciVerse ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Topical application of tranexamic acid after adenoidectomy: A double-blind, prospective, randomized, controlled study

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ARTICLE INFO

Article history:
Received 28 February 2013
Received in revised form 9 April 2013
Accepted 12 April 2013
Available online 10 May 2013

Keywords:
Adenoidectomy
Hemorrhage
Antifibrinolytics
Tranexamic acid

ABSTRACT

Objective: Is to evaluate the efficacy of tranexamic acid when applied locally in children after primary isolated adenoidectomy with respect to intra-operative blood loss and post-operative bleeding.
Study design: Prospective, double-blind, randomized, controlled trial.
Setting: Otolaryngology department, Tanta University and Tiba Hospitals, Egypt.
Patients and methods: Over three years, 400 children underwent primary isolated adenoidectomy followed by topical application of tranexamic acid (tranexamic acid group, 200 children) or saline (Placebo group, 200 children) with at least two weeks' follow up. Intra-operative blood loss and post-operative hemorrhage were monitored.
Results: Both groups were almost equivalent in age and gender. The frequency of primary post-adenoidectomy hemorrhage as well as the rate of postnasal packing and blood transfusion required to manage severe bleeding were higher in placebo group. The volume of blood loss during surgery showed significant reduction in tranexamic acid group.
Conclusion: Topical application of tranexamic acid after adenoidectomy led to a significant reduction in blood loss during surgery and decreasing in the rate of post-operative bleeding as well as the need for postnasal packing and blood transfusion.

1. Introduction

Adenoidectomy is an effective, safe and commonly performed surgical procedure in the field of otolaryngology. However, diffuse microvascular post-adenoidectomy bleeding remains a common problem. When it occurs, the experience is frightening, uncomfortable for the patient, worrisome for the surgeon, and can even be life threatening [1,2]. The incidence of post-adenoidectomy bleeding is reported to range from less than 1% to as high an 8% [3]. It is usually classified as primary (<24 h postoperatively) and secondary (>24 h, usually 5–10 days postoperatively) [4].

Systemic use of antifibrinolytics reduces intra-operative and post-operative bleeding following some surgical procedures [5]. Tranexamic acid (TA) is an antifirinolytic agent that may be administered orally or by i.v. injection. Recently, some investigators have used TA topically aiming to reduce intra-operative and post-operative blood loss [6]. To our knowledge, no one tried it topically after adenoidectomy. This study aimed to investigate the effect of topical application of TA on intra-operative blood loss and the frequency of post-operative bleeding after primary isolated adenoidectomy in children.

2. Patients and methods

Over a period of 3 years, with institutional ethics committee approval, all children scheduled for primary isolated adenoidectomy at Otolaryngology department, Tanta University hospital and Tiba private hospital (Tanta, Egypt), were scrutinized for eligibility enrolment. Adenoidectomy was indicated in children with recurrent purulent therapy-resistant rhinorrhoea, recurrent otitis media with or without effusion (after failed aeration tube insertion), dental malocclusion, sleep disturbances, or development of nasal speech. Exclusion criteria included children who had revision adenoidectomy, combined procedure (adenotonsillectomy), hemoglobin level <9.0 g/dL, bleeding diathesis (e.g. hemophilia or thrombocytopenia), renal or hepatic impairment, known allergy to TA, recent (<7 days before surgery) intake of anti-platelets (e.g. Aspirin, non-steroidal anti-inflammatory drugs) or Heparin administration within 48 h of operation.

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http://dx.doi.org/10.1016/j.ijporl.2013.04.021

Four hundred children met the requirements for inclusion, and informed consent was obtained from the parents. The children were randomly allocated into one of the two groups. Tranexamic acid group included 200 children who received 1000 mg of TA diluted in 10 mL normal saline. Placebo (PL) group included 200 children who received 10 mL normal saline as placebo.

Anesthesia was induced and maintained by 1.5% halothane (*v*/*v*) in a mixture of oxygen. After removal of the adenoid using Beckman's Curette by the same surgeon, the solution was locally poured into the nasopharynx via the nose using endoscopic guided trans nasal catheter or transoraly, with the patient's neck extended to avoid losing the solution, and left in place together with anchored gauze for 5 min followed by a continuous low grade suction of the nasopharynx for another 5 min. Total amount of the suctioned mixture of blood and solution was monitored in graduated pediatric vacuum flasks, and the intra-operative blood loss was calculated after subtracting 10 mL. The study was carried out as a prospective randomized double-blind investigation. Randomization was carried out with random-number tables. The solutions were prepared by one of the co-authors in two identical bottles and delivered to the operating theater. Topical tranexamic acid is available in ampoule form (''Kapron'', Amoun Pharmaceutical Co., SAE, Cairo, Egypt). Neither the surgeon, nor the anesthetist or the scrub nurse knew the composition of the solution administered.

Hemoglobin level (Hb), hematocrit concentration (Hct), platelets count and partial thromboplastin time (PTT) were measured before the operation and post-operatively when the child arrived at the ward. The children who did not present with complications within 8 h of surgery were discharged from hospital for service follow-up. The follow-up was carried out daily via phone for at least two weeks. New returns were scheduled in case of complications that needed an interference. Post-operative bleeding was considered if the patient experienced a continuous transnasal dripping of fresh blood and/or an active postnasal blood film not responding to frequent sniffing, in a trial to clean the nasopharynx, for at least 15 min. The frequency of post-operative bleeding that occurred during the initial admission or during the follow-up period (either required a return to the theater or was managed conservatively) was reported and compared in-between the surgical groups.

3. Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences version 11.0 software program (SPSS Inc., Chicago, IL, USA). Data were expressed as mean ± SD or percentage. Parametric tests such as *t* test were applied for data that followed a normal distribution. Nonparametric tests such as Mann–Whitney *U* test and χ^2 test were applied for data that did not follow a normal distribution. *p* values less than 0.05 were considered significant.

4. Results

The youngest patient of TA group was 6 months old, and the oldest was 14 years old (median, 5 years; mean, 5.6 years; SD, 2.5 years); 65.5% of the children were male. The youngest child of PL group was 1.2 years old, and the oldest was 13.6 years old (median, 4 years; mean, 4.9 years; SD, 1.8 years); 59.5% of the patients were male. Statistically, there was no significant difference with respect to age and gender in-between the surgical groups.

Primary hemorrhage was reported in 5 children of TA group (2.5%; 60% were male). Of these children, 4 cases were managed conservatively by removing the blood clot in the nasopharynx using a blind-end wide-bore trans nasal catheter, followed by local application of trans nasal decongestant drops. Only one case had required nasopharyngeal packing for 12 h. None of the children who experienced primary hemorrhage had required blood transfusion (Hb level was above 9 g/dL). No secondary hemorrhage was reported in this group.

In PL group, primary hemorrhage was noted in 12 patients (6%; 67% were male), of whom 8 children were managed conservatively without a need for blood transfusion, and in 4 patients the bleeding was so severe to require nasopharyngeal packing. Two of the latter cases had required blood transfusion (Hb level was less than 9 g/dL). Only one case in PL group had reported secondary hemorrhage 7 days after surgery and was managed conservatively using parentral broad spectrum antibiotic, transnasal decongestant drops and systemic TA.

In a total of 17 children who experienced primary hemorrhage, the frequency was higher in PL group than TA group without a statistically significant difference ($p = 0.3$). Of these cases, the youngest child was 2.1 years old and the oldest was 11.3 years old (mean, 7.3 years; median, 3 years; SD, 0.5 years) with no significant difference in-between the surgical groups ($p = 0.4$).

The mean time of primary hemorrhage episodes was 79 min in TA group and 65 min in PL group. The latest episode of bleeding occurred 21 h (TA group) and 18 h (PL group) after surgery. This difference did not record a statistically significant value ($p > 0.05$). Massive bleeding indicated packing of the nasopharynx was higher in PL group (4 cases) than TA group (1 case) with statistically significant difference ($p = 0.03$).

Pre and post-operative hemoglobin concentrations, hematocrit concentrations, platelets counts and partial thromboplastin times were not significantly different between the two groups. However, intra-operative blood loss was more in PL group than TA group with statistically significant difference as depicted in Table 1. Detailed coagulation studies were performed for the patients who required nasopharyngeal packing with or without blood transfusion and did not reveal deficiencies in coagulation factors such as factors VIII, IX or XIII in both groups.

5. Discussion

Primary hemorrhage is the most common and potentially life-threatening complication after adenoidectomy because of the possible risks of aspirations, laryngospasm, and invisible swallowing of blood with a consequent collapse of blood circulation. Secondary hemorrhage occurs rarely and is observed mainly within the first 10 postoperative days [4]. Like any surgical procedure, an amount of tissue might be exposed to injury after adenoidectomy. This may release enzymes, such as tissue plasminogen activators which convert plasminogen to plasmin,

Table 1
Intra-operative blood loss and pre and post-operative hematological profiles.

Parameter[a]	Tranexamic acid[b]	Placebo[b]	*p* value
Intra-operative blood loss (mL)	19 ± 2.5	26 ± 4.3	0.03
Hemoglobin (g/dL)			
Pre-operative	12 ± 1.3	12 ± 2.1	0.33
Post-operative	11 ± 0.7	10 ± 1.3	0.37
Hematocrit value (%)			
Pre-operative	35 ± 2.7	34 ± 4.3	0.43
Post-operative	33 ± 2.1	30 ± 3.4	0.35
Platelets count (10^3/Cmm)			
Pre-operative	198 ± 70	196 ± 74	0.34
Post-operative	196 ± 68	192 ± 69	0.34
Partial thromboplastin time (s)			
Pre-operative	25.7 ± 7.3	26.4 ± 6.4	0.55
Post-operative	25.3 ± 4.2	25.7 ± 2.7	0.53

[a] The values are presented as the mean ± the standard deviation.
[b] 200 patients in each group.