

## Topical Tranexamic Acid Compared with Anterior Nasal Packing for Treatment of Anterior Epistaxis in Adults: A Randomized Controlled Trial

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### Abstract

**Background:** Epistaxis is one of the common complaints in the emergency department. Anterior Nasal Packing (ANP) a frequently performed procedure in the management of epistaxis has many complications. The topical application of Tranexamic Acid (TXA) was found beneficial for the treatment of anterior epistaxis. Objective of this study was to evaluate the role of topical tranexamic acid over anterior nasal pack in epistaxis management.

**Materials and methods:** The study was a randomized controlled trial to compare the effect of topical TXA with ANP for treatment of anterior epistaxis conducted in the Department of Otolaryngology-Head and Neck Surgery of Chittagong Medical College Hospital (CMCH) Chattogram for a period of two years from February 2020 to January 2022. All adult patients admitted with epistaxis was the study population. A total of 220 patients (110 in each group) aged from 18 years and above with both genders were included as per selection criteria. Patients were followed up to control of epistaxis, then at 24 hours and finally from 24 hours up to 1 week from procedure. Fourteen patients were lost during follow up, eight from TXA group and six from ANP group. So, a total of 206 patients, 102 from TXA and 104 from ANP group were analyzed.

**Results:** The mean age was  $43.36 \pm 13.54$  years in TXA group and  $45.07 \pm 12.27$  years in ANP group and was not statistically significant,  $p = 0.261$ . Number of male and female were 61 and 41 in TXA group and in ANP group were 52 and 52 ( $p=0.716$ ). Mean bleeding arrest time in TXA group were  $7.74 \pm 3.28$  minutes and in ANP group

$9.28 \pm 3.69$  minutes ( $p$  value 0.004). Rebleeding within 24 hours was found in 6 patients in TXA group and 16 patients in ANP group ( $p$  value 0.045 and risk coefficient 1.213). Overall treatment failure in TXA group was 11 and in ANP group was 30 ( $p$  value 0.0018). Mean length of hospital stay in TXA group was  $24.71 \pm 2.84$  hours and in ANP group was  $27.92 \pm 8.92$  hours ( $p$  value 0.000). Nasal Obstruction Symptom Evaluation (NOSE) score in TXA group was  $24.95 \pm 4.9$  and in ANP group was  $66.92 \pm 5.96$  ( $p$  value 0.000). Visual Analogue Scale (VAS) score in TXA group was  $3.74 \pm 0.9$  and in ANP group was  $6.21 \pm 1.08$  ( $p$  value 0.000).

**Conclusion:** Topical TXA may be considered an effective treatment option for the management of anterior nasal epistaxis with less chance of re-bleeding, less discomfort and less duration of hospital stay.

**Key words:** Anterior nasal packing; Epistaxis, Tranexamic acid.

### Introduction

Epistaxis is bleeding per nose, is a common problem which is rarely severe and seldom requires hospital admission. Up to 60% of population will have had at least one nose bleed by the age of 10 years.<sup>1</sup> Most episodes resolved spontaneously and can be managed at home by pinching the ala nasi. Currently a wide variety of management strategies are employed such as: local pressure, cauterization, application of topical vasoconstrictor substances, nasal packing or endoscopic control depending on personal physician preference.<sup>2,3</sup>

While effective, nasal packs typically remain in situ for at least 24 hours, which causes ongoing pain and an uncomfortable sensation of nasal obstruction and its removal is also painful. In addition to the pain, patients undergoing anterior nasal packing are admitted to hospital having a mean length of stay of 2 days and also associated with various complications. These warrants need for prophylactic antibiotics and need for analgesics.<sup>4</sup>

The plasma concentration of topically applied TXA has been shown to be approximately 90%

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Submitted on □ 31.08.2025

Accepted on □ : 06.12.2025

less than when the medication is administered intravenously.<sup>5</sup> Studies have compared the use of topical TXA and ANP for epistaxis management.<sup>6,7,8</sup> The findings of these studies suggest that there may be slight benefit to patients by using topical TXA. However, these studies had several limitations. This type of protocol is believed to be safe in otherwise healthy patients.<sup>5,9</sup> So, topical TXA can be used for epistaxis management. The purpose of the study was to evaluate the role of topical tranexamic acid over anterior nasal pack in epistaxis management.

### Materials and methods

This was a single center randomized controlled trial in the Department of Otolaryngology-Head & Neck Surgery of Chittagong Medical College Hospital (CMCH) Chattogram for a period of two years from February 2020 to January 2022. All the adult patients aged 18 years and above seeking treatment for epistaxis in our department were screened to select eligible participant during study period. Patients with known allergy to tranexamic acid, patients with trauma, shock, posterior epistaxis, chronic liver disease, renal disease, granulomatous diseases of nose, known bleeding disorder, pregnant woman, documented INR  $> 1.5$  were excluded from the study. A sample size of 110 subjects per group was included. After receiving institutional clearance (Memo No.CMC/PG/2019/654, Dated: 16/09/2020) patients were selected according to inclusion and exclusion criteria. Informed written consent was taken from participants. All adult patients with epistaxis were offered the simple first aid measures- digital pressure for atleast 10 minutes. If bleeding stopped, then they were excluded from this study. If epistaxis persists, then they were assessed for eligibility. After enrollment, the individuals were recruited by simple random method using envelope technique putting in a box as one of the two treatment arms. Equal number of envelope (i.e. 110 each) remained in the box. Then the study subjects received the corresponding treatment according to randomization. Patients with TXA group received the TXA 500 mg/5ml topically soaked in a 15-cm long cotton wool dental roll into the affected nostril/s which didn't create any pressure effect. Patients of the control group was given the ANP which was made of

sterile ribbon gauze impregnated with 2% lidocaine gel and topical antibiotic. After doing the procedure, the patients were checked as per SOP at intervals according to specific schedule in Case Record Form (CRF). Patient's outcome variables were bleeding arrest time, re-bleeding within 24 hours, rebleeding after 24 hours until 1 week, treatment failure, Nasal Obstruction Symptom Evaluation (NOSE) Score, Visual Analogue Scale (VAS) Score of pain, hospital stay. Statistical analysis of the results was obtained using SPSS version 23. The numerical data were expressed as mean with Standard Deviation (SD) and were compared by Student's t-test if the distribution is normal, otherwise Wilcoxon signed rank test was used. The categorical data were expressed as number and percentage and was compared by Chi-square test if data distribution was normal, otherwise Fisher's exact test was used. The 95% Confidence Interval (CI) was calculated for these values.

### Results

**Table I** Baseline characteristics of all 206 patients, 102 in Tranexamic Acid group and 104 in Anterior Nasal Packing group in this study

	Tranexamic Acid (n=102)	Anterior Nasal Packing (n=104)	p value
Age (Years)	43.36 $\pm$ 13.54	45.07 $\pm$ 12.27	0.261 <sup>α</sup>
Gender (M:F)	61:41	52:52	0.716 <sup>β</sup>
BMI	23.83 $\pm$ 1.86	23.56 $\pm$ 1.63	0.15 <sup>α</sup>
HTN (YES/NO)	40:62	39:65	0.912 <sup>γ</sup>
DM (YES/NO)	14:88	12:92	0.793 <sup>γ</sup>

Values are mean,  $\pm$  indicate standard deviation, <sup>α</sup> Wilcoxon signed ranks test, two sided p value, <sup>β</sup>Chi-square test, two sided p value, <sup>γ</sup>Fisher's exact test, two sided p value.

**Table II** Overall Clinical details of epistaxis management of all 206 patients, 102 in Tranexamic Acid group and 104 in Anterior Nasal Packing group in this study

Variables	Tranexamic Acid (n=102)	Anterior Nasal Pack (n=104)	p Value
Mean bleeding arrest time			
(Minutes)	7.74 $\pm$ 3.28	9.28 $\pm$ 3.69	0.004 <sup>α</sup>
$\leq$ 5 min	31(30.39%)	15(14.42%)	
6-10min	49(48.04%)	63(60.58%)	
11-15min	22(21.57%)	19(18.27%)	
>15min	0(%)	7(6.73%)	

Variables	Tranexamic Acid (n=102)	Anterior Nasal Pack (n=104)	p Value
Bleeding stoppage time (Minutes) median IQR (Minutes)	7 [5-10]	9[7-10]	0.004 <sup>b</sup>
Rebleeding within 24 hours (Yes:No)	Yes-6 No-96	Yes-16 No-88	0.045 <sup>e</sup>
Risk Coefficient			1.213
Rebleeding after 24 hours until 1 week (Yes:No)	Yes-5 No-91	Yes-14 No-74	0.03 <sup>e</sup>
Treatment failure (Yes:No)	Yes-11 No-91	Yes-30 No-74	0.0018 <sup>e</sup>
Hospital Stay in Hours	24.71±2.84	27.92±8.92	0.000 <sup>a</sup>
NOSE Score <sup>+</sup>	24.95±4.9	66.92±5.96	0.000 <sup>b</sup>
VAS Score <sup>Y</sup>	3.74±.9	6.21±1.08	0.000 <sup>b</sup>

Values are mean,  $\pm$  indicate standard deviation, <sup>a</sup>Wilcoxon signed ranks test, <sup>b</sup>two tailed paired sample student t-test, <sup>e</sup>two tailed Fisher's exact test, <sup>+</sup>Nasal Obstruction Symptom Evaluation Score, <sup>Y</sup>Visual Analogue Scale Score.

Table II shows overall clinical details of epistaxis management of all 206 patients in two groups in this study, 102 in TXA group and 104 in ANP group. Mean bleeding arrest time in TXA group were  $7.74\pm3.28$  minutes and in ANP group  $9.28\pm3.69$  minutes (p value = 0.004). Out of 102 patients in TXA group rebleeding within 24 hours was found in 6 patients and rest of 96 patients were found normal. In ANP group rebleeding was found within 24 hours in 16 patients and no rebleeding was found in 88 patients (p value = 0.045 and risk coefficient was 1.213).

Among 96 patients in TXA group that were found no rebleeding within 24 hours, 5 patients were found rebleeding after 24 hours until 1 week and rest of 91 patients were found normal. Out of 88 patients in ANP group that were found no rebleeding within 24 hours, 14 patients were found rebleeding from 24 hours until 1 week and rest of 74 patients were found normal (p value = 0.03). Overall treatment failure in TXA group was 11 and in ANP group was 30 (p value = 0.0018). Mean length of hospital stay in TXA group was  $24.71\pm2.84$  hours and in ANP group was  $27.92\pm8.92$  hours (p value = 0.000). Nasal Obstruction Symptom Evaluation (NOSE) Score in TXA group was  $24.95\pm4.9$  and in ANP group was  $66.92\pm5.96$  (p value = 0.000). Visual Analogue Scale Score (VAS Score) in TXA group was  $3.74\pm.9$  and in ANP group was  $6.21\pm1.08$  (p value = 0.000).

## Discussion

A total of 220 patients, 110 in each groupaged from 18 years and above with both genders were included in the study. Patients were followed up to control of epistaxis, then at 24 hours, from 24 hours upto 1 week from the procedure. Fourteen patients were lost during follow up, eight from TXA group and six from ANP group. So, a total of 206 patients, 102 from TXA and 104 from ANP group were analyzed.

In this study mean age of the case i.e. in TXA was  $43.36\pm13.54$  years and in control group i.e ANP was  $45.07\pm12.27$  years within a range of 18-60 years and male and female in TXA group were 61(59.8%) and 41(40.2%) and in ANP group it were 52(50%) and 52(50%) p value was not statistically significant.

In this study mean BMI, number of hypertensive and diabetic patients were compared between two groups. Pvalue was not statistically significant.

In this study, mean bleeding arrest time in TXA group were  $7.74\pm3.28$  minutes and in ANP group  $9.28\pm3.69$  minutes. This result is statistically highly significant (p = 0.004). In study conducted by Amini K, et al. and Zahed R, et al. there was similarities in bleeding cessation time for TXA with our study.<sup>8,10</sup> However, dissimilarities was found in a study conducted by Whitworth K et al.<sup>14</sup> However, their sample size was too small to show the real scenario.

In this study, in TXA group rebleeding within 24 hours was found in 6(5.88%) patients compared to 16(15.38%) patients in ANP group and rest of 96 patients and 88 patients were found normal respectively (p value = 0.045). In their study conducted by Zahed R et al. and Akkan S et al. was almost similar to our study.<sup>8,12</sup>

In present study, among 96 patients in TXA group that were found no rebleeding within 24 hours, 5(5.21%) patients were found rebleeding after 24 hours until 1 week. Out of 88 patients in ANP group that were found no rebleeding within 24 hours, 14(15.91%) patients were found rebleeding from 24 hours until 1 week (p value = 0.03). Similarities was found by Zahed R et al. and Amini K et al. and dissimilarities by Birmingham AR, et al.<sup>8,10,13</sup> However, McGarry GW described continued or rebleeding with packs in situ is observed in up to 40% cases.<sup>15</sup>

We found overall treatment failure in TXA group was 11(10.78%) and in ANP group was 30(28.85%)(p=0.0018). Similarities were found by Amini K et al., Essam Ali Abo El-Magd and Akkan S et al.<sup>10,11,12</sup> However, Traboulssi described a review article that concluded failure rate of ANP was 52%.<sup>16</sup>

In this study, mean length of hospital stay in TXA group was  $24.71 \pm 2.84$  hours and in ANP group was  $27.92 \pm 8.92$  hours (p=0.000) which is similar to study by Zahed R et al.<sup>8</sup> However, in study by Amini K et al. there was no time limit of hospitalization and they discharged patients after initial cessation of bleeding.<sup>10</sup> As per our institutional protocol we admitted both group of patients for at least 24 hours. However, Middleton, McGarry GW and many other studies supported to keep ANP for at least 24 hours which is similar to our study.<sup>4,15</sup>

In this study, NOSE Score in TXA group was  $24.95 \pm 4.9$  and in ANP group was  $66.92 \pm 5.96$  (p value =0.000).

In the study, VAS Score in TXA group was  $3.74 \pm 0.9$  and in ANP group was  $6.21 \pm 1.08$  (p value =0.000).

### Limitations

- Single centered study, it may lack the representation of the whole population.
- No true blinding was done.
- Did not classify nosebleeds in terms of severity because there is no universal severity scale for spontaneous anterior epistaxis.

### Conclusion

Our study demonstrated that faster bleeding cessation, less rebleeding cases, less pain and shorter length of hospital stay in patients treated with topical TXA compared with ANP.

### Recommendations

- We recommend that it may be more logical to manage anterior epistaxis with topical TXA, which is simple, safe, cheap, effective, readily available and comfortable, instead of the relatively uncomfortable ANP.
- Further multi centered studies are recommended.

### Acknowledgement

The authors express gratitude to the respondents.

### Contribution of authors

RAH-Acquisition of data, data analysis, drafting & final approval.

KKU-conception, design, data analysis, interpretation of data, critical revision & final approval.

SA-Data analysis, interpretation of data, critical revision & final approval.

ARN-acquisition of data, data analysis, drafting & final approval.

RC-Acquisition of data, data analysis, drafting & final approval.

MMA-Conception, design, interpretation of data, critical revision & final approval.

### Disclosure

All the authors declared no conflict of interest.

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