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No Increase in Complications with Intravenous Tranexamic Acid Use in Vaginoplasty: A Retrospective Study

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Cover Letter

No Increase in Complications with Intravenous Tranexamic Acid Use in Vaginoplasty: A Retrospective Study

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Abstract (225 out of 250 words):

Background: Across surgical specialties tranexamic acid (TXA) is applied to reduce intraoperative and postoperative bleeding. Within plastic surgery, both topical and intravenous routes are used. The application of TXA has yet to be examined in vaginoplasties.

Methods: We performed a retrospective chart review of Mayo Clinic patients receiving penile inversion vaginoplasty from January 2017 through July 2021. Incidence of hematoma formation was assessed as the primary outcome. Secondary outcomes included perioperative hemoglobin, vaginoplasty complications, and possible TXA complications. These outcomes were compared between topical only (t-TXA), any intravenous (IV-TXA), and no TXA groups.

Results: Of the 124 vaginoplasties, 21 and 43 received t-TXA only and any IV-TXA, respectively. Only four patients developed a hematoma; two were from the no TXA, while two were from the any IV-TXA groups. There was no significant change in perioperative hemoglobin across groups. Analysis showed lower incidence of splayed urine stream (OR=0.499 [0.316-0.789], P=.003) and neovaginal stenosis (OR=0.435 [0.259-0.731], P=.002) within the any IV-TXA group and no increased incidence of other complications.

Conclusions: The use of either t- or IV-TXA in vaginoplasty cases did not result in an increased rate of complications. There was no significant reduction in hematoma formation or postoperative hemoglobin drop across groups. There was a significant decrease in splayed urine stream and neovaginal stenosis for any IV-TXA patients though clinical significance of this association remains unclear.

Background

As part of gender-affirming care, some transwomen may choose to pursue bottom surgery. The mainstay of this procedure includes orchiectomy, labioplasty, urethroplasty, and clitoroplasty.[1] Some patients may also desire creation of a vaginal canal. One approach is penile inversion to create the introitus and proximal canal, with possible grafting from donor sites, such as the scrotal skin or medial thigh, to achieve sufficient depth.[2] The creation of the canal is in an nonanatomic plane and there are risks of hematoma formation. In addition, shearing and moisture in the perineum region make the surgery prone to graft failure.[3, 4]

Effective intraoperative hemostasis is important in reducing ongoing blood loss. In addition to technical steps, another recent tool empirically applied to limit intraoperative and postoperative bleeding is tranexamic acid (TXA). TXA is an antifibrinolytic, which only carries formal FDA approval for procedural prophylaxis in hemophilia patients and treatment of menorrhagia.[5] Its use has been extrapolated to many surgical applications. Studies have shown the effective use of the intravenous-TXA (IV-TXA) formulations in reducing transfusion requirements and drain output in total joint arthroplasties.[6,7] Outside of orthopedics, TXA's usage has been examined within trauma,[8, 9] neurosurgery,[10] and obstetrics practice,[11] and gaining wide use in plastic surgery, among others with results suggesting or demonstrating the treatment's efficacy.

Within plastic surgery, TXA is also often administered topically. Amongst survey respondents within the American Society of Plastic Surgeons (ASPS), around 18% used TXA routinely in their practice, and of these surgeons nearly half gave TXA either topically alone or in combination with an IV bolus[MBL1].[12] Topical-TXA (t-TXA) in randomized controlled trials has been found to reduce operative blood loss as well as the need for blood transfusion, when compared with placebo or no TXA use.[13] Within reconstruction, t-TXA has demonstrated efficacy in reducing drain output in mastectomy[14] and reduction mammoplasty.[15] For those

utilizing the liposuction technique in mammoplasty reduction, the addition of t-TXA, as a component of Klein's solution, with IV-TXA administration decreased liposuction decanted volume and dermal bleeding during deepithelialization when compared to those without this local component.[16] Moreover, single as well as dual route administration of this agent has reduced intraoperative and postoperative blood loss or drainage in various aesthetic surgeries, though the clinical significance of this reduction remains unclear.

Although TXA's application is extended to vaginoplasties from the other specialty and plastic surgery reconstructive procedures, we are unaware of studies examining either routes or combined administration in vaginoplasties. Thus, we performed a retrospective review of vaginoplasty cases at our institution to characterize the route of TXA administration and to compare outcomes for these routes.

Methods

Patient Cohort

A retrospective chart review was performed for patients who underwent penile inversion vaginoplasty at Mayo Clinic from January 2017 through July 2021. Patients were excluded [MBL2]if they withdrew their Minnesota (MN) research authorization.

Institutional Practice

Over this time frame, three primary surgeons performed vaginoplasties. Additionally, TXA usage was not introduced into our practice until 2019. At our institution the t-TXA formulation usually includes 3 grams of TXA in 75 cc of saline, whereas IV-TXA is 1 gram IV bolus administered at the beginning of the case.

Data Collection

Patient demographic information and co-morbidities at the time of surgery were recorded including age; BMI; smoking status; and diagnosis of hypertension, COPD or

asthma, cardiovascular disease, and diabetes. Intraoperative use of TXA (topical and IV) was recorded.

To assess the efficacy of these interventions, the primary outcome, hematoma formation, was recorded as well as secondary outcomes of difference in hemoglobin (post-operative minus pre-operative), when available, and other surgical complications, such as graft loss, neovaginal stenosis, or dehiscence. Multiple complications were classified as minor or major depending on provider follow-up notes; descriptors such as *mild* or *moderate* warranted minor classification, whereas complications characterized as *substantial, severe,* or *functionally impairing* were classified as major[MBL3]. Additionally, possible adverse outcomes of TXA were recorded as well as the patient's final follow-up date.

Statistical Analysis

Patients were stratified into the following groups based on TXA usage and route: no TXA, t-TXA only, and any IV-TXA use (IV-TXA alone or both IV- and t-TXA). Statistical analysis was performed using Excel and SPSS v.26 software, Armonk, NY. Significance was assessed for parametric and non-parametric data using ANOVA and Kruskal-Wallis testing, respectively. The association between TXA use and complications was evaluated by univariate and multivariate analysis, and the odds ratio with 95% confidence interval and p values were calculated using COX regression or logistic regression as appropriate. All tests were two-sided, and a P-value of <0.05 was considered statistically significant.

This study was approved as exempt by the Mayo Clinic Institutional Review Board in Rochester, MN.

Results

Patient Cohort

A total of 124 vaginoplasties were reviewed, of which t-TXA alone, IV-TXA alone, and both t- and IV-TXA were used in 21 (16.9%), 2 (1.6%), and 41 (33.1%) cases,

respectively. Further, the cohort of any IV-TXA use included 43 patients. The remainder of patients (60, 48.4%) received no TXA formulation. Demographic data and comorbidities for these groups are shown in **Table 1**. Cohort characteristics were not significantly different except for the higher incidence of active smoking within the no TXA group, former smoking within the any IV-TXA use group, and COPD/asthma within the only t-TXA group. The average length of time to last postoperative follow-up was 34.0 weeks.

Hematoma Formation

Concerning the primary outcome, only four patients (3.2%) developed a hematoma, one of which was classified as major. The major hematoma formed in a patient who did not receive TXA. The other three hematomas were classified as minor. While one of these occurred within the no TXA group, the other two minor hematomas affected patients receiving both t- and IV-TXA.

The major hematoma was located at the neovaginal introitus, whereas the minor ones were identified along the labia and/or mons pubis. The major hematoma required return to the operating room for evacuation. Minor hematomas warranted observation, drainage, or aspiration in clinic.

Perioperative Hemoglobin

Preoperative and postoperative hemoglobin labs were available for 77 patients. Overall, the average difference in hemoglobin was a drop in 1.8 units. Among these patients, 15 received t-TXA alone (average difference = -1.2), 31 received IV-TXA (average difference = -1.9), and 31 did not receive TXA (average difference = -2.1). Comparison of these groups did not show these differences to be significant (P = 0.150).

Other Vaginoplasty Complications

Overall, only 18 (14.5%) vaginoplasty cases had no complications, though few patients (8, 6.5%) had major complications. The most common major complications included

wound dehiscence (2.4%) and infection (2.4%). Likewise, wound dehiscence (46.7%) and tissue necrosis (30.6%) were the most frequent minor complications. Additional complications not categorized by severity included granulation tissue, splayed urine stream, and neovaginal stenosis affecting of 76, 28, and 24 patients, respectively. Notably, no patients developed a fistula or an adverse thromboembolic event (VTE) from the TXA.

Across this population, on average patients were affected by 2.2 complications. This complication frequency was similar among the subgroups (shown in **Table 2**). While rates of various complications were similar across subgroups, analysis showed significantly lower incidence of splayed urine stream (OR=0.499 [0.316-0.789], P=.003) and neovaginal stenosis (OR=0.435 [0.259-0.731], P=.002) within the any IV-TXA group. Our findings are summarized in **Figure 1**. Additionally, several confounding factors were investigated using univariate and multivariate analysis, including the effect of smoking and the difference in surgeon's experience and skills over time, and we did not find any statistically significant difference and the significant effect of lower splayed urine and neovaginal stenosis remains.

Discussion:

Overall, there was no significant reduction in hematoma development between the any use of IV-TXA or only t-TXA groups. Additionally, neither group showed measurable improvement in this outcome when compared to no TXA use. Notably, patients receiving IV-TXA as part of their regimen were less likely to develop splayed urine stream and neovaginal stenosis after controlling for confounding factors such as surgeon experience and smoking history. Although efficacy of these interventions for the primary outcome was not found in this retrospective review, the results demonstrated no increased adverse events or complications with either TXA route in vaginoplasty, suggesting it is a safe agent to use in these procedures. As well, subjective assessment by the operating surgeon showed that the use of TXA provided a clearer and more hemostatic field; this permitted a more effective

dissection of the tissues. Our hypothesis is that the increased visualization of tissues and decrease in subclinical hematomas may have contributed to the differences in outcomes. The improved surgical efficacy may have resulted in the better alignment, less swelling, and less splayed urine streams and neovaginal stenosis.

We found hematomas complicated 3.2% of cases overall. This is consistent with other studies finding hematoma formation in 4-6% of vaginoplasties.[17] If untreated, hematomas can precipitate tissue necrosis, partial/total graft loss, and fistula formation.[3] These complications were seen in 32.3, 21.8, and 0% of cases in our retrospective analysis. Though we did not demonstrate efficacy of TXA in reducing hematoma formation in vaginoplasties, its effectiveness in other surgeries[6, 14, 15] suggests it may reduce hematomas or other intra- and postoperative bleeding that can have clinically significant sequelae. The significant decrease in splayed urinary stream and neovaginal stenosis in patients receiving any IV-TXA in our study suggests the clinical efficacy of this intervention, specifically with IV administration.

In this study, the average perioperative change in hemoglobin was not significant between groups with an overall average drop of 1.8 units. While volume status – with resuscitation dilution or insensible loss hemoconcentration – can impact the accuracy of this change, these measurements have been used in prior studies to validate TXA efficacy. Still, if not warranting transfusion, the clinical significance of a postoperative drop remains unclear. Thus, the absence of significant improvement in perioperative hemoglobin change in our results with TXA's application need not restrict practice and intervention recommendations for TXA in vaginoplasty.

Notably, no patients experienced VTE with TXA use. This complication has been a theoretical concern of IV-TXA; however, studies have not found an association between IV-TXA and VTE incidence.[18] The use of t-TXA has still been strongly considered given its similar efficacy to the IV formulation and potential mitigation of theoretical VTE risk and

other side effects through decreased systemic absorption.[19] Literature has shown an association with TXA usage and an increased frequency of seizures in the postoperative period.[20] When deciding on TXA use in vaginoplasty, this seizure association should be considered along with other predisposing patient factors.

Although this retrospective review included a large cohort of vaginoplasty cases, there was limited incidence of the primary outcome, making it challenging to find significance in TXA efficacy for either group. Likewise, not all patients received perioperative hemoglobin measurements, restricting assessment with this outcome as well. While other short- and long-term complications were tracked, multiple factors may contribute to their development, making a reduction in complication difficult to attribute to the benefits of TXA use.

Future studies would benefit from a randomized trial approach comparing the two routes of TXA, topical and IV. The assessment of drain output, blood transfusion requirements, and perioperative hemoglobins can serve as additional metrics in assessing the efficacy of the intervention, given the low incidence of hematoma formation in cases. Also, since TXA can provide benefit for intraoperative visualization, surgeons could score the difficulty of cases from a bleeding perspective. Further, as studies within other fields have suggested, the optimal administration timing and dosage for any TXA routes still need to be elucidated in future trials.

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Legends

Table 1. Cohort demographics and medical co-morbidities.

Table 2. Cohort post-operative complications of vaginoplasty.

Figure 1. Summary of findings.

Figure 1

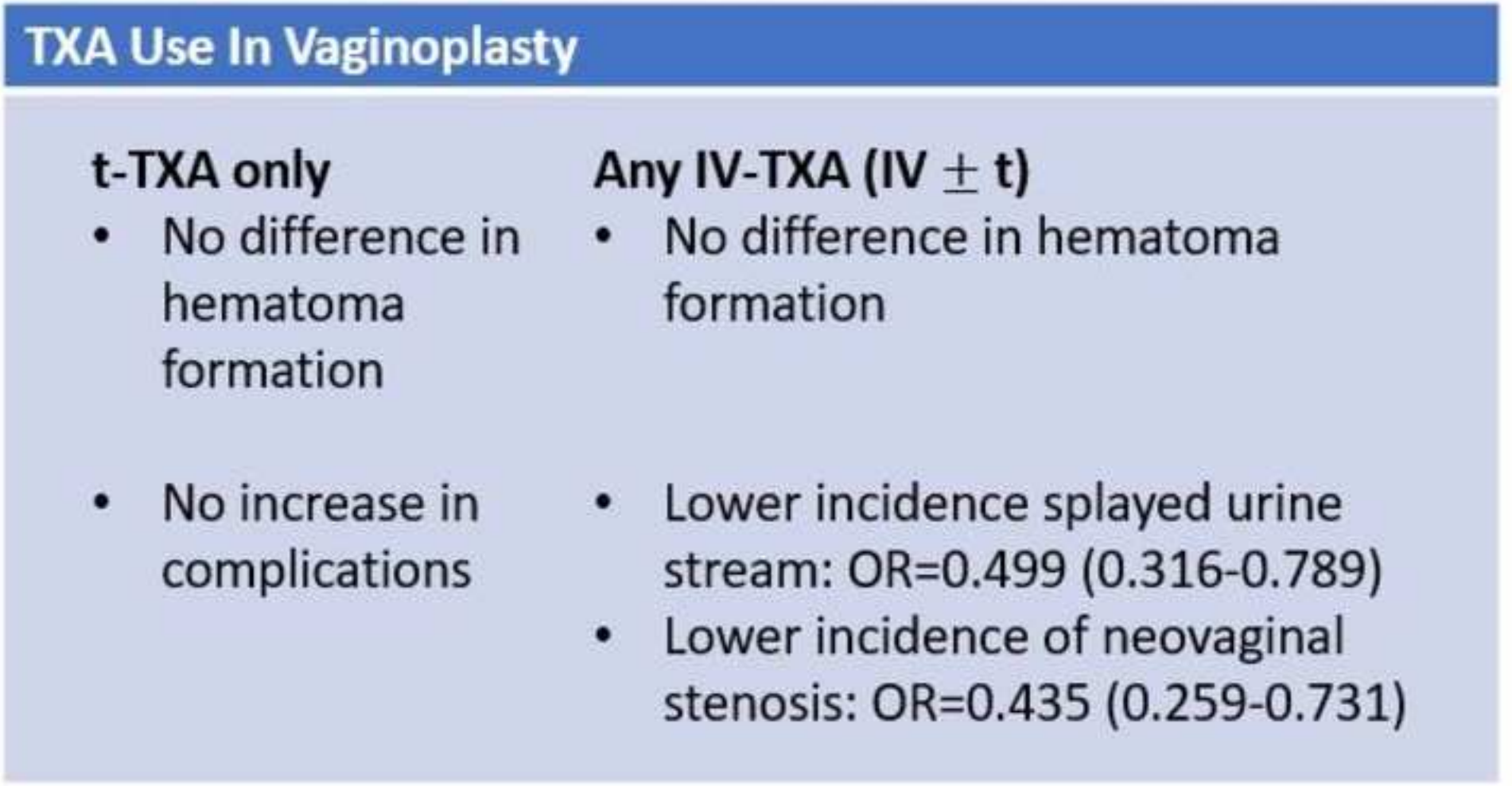

Table 1. Cohort demographics and medical co-morbidities.

	Only t-TXA N=21	Any use IV-TXA N=43	No TXA N=60	Total N=124	p-Value
Age, Median (IQR)	40.9 (25.0)	35.4 (17.0)	34.5 (19.9)	35.5 (20.8)	0.421
BMI, Median (IQR)	28.8 (7.8)	24.7 (6.8)	25.7 (8.7)	25.9 (7.7)	0.148
Smoking status, N (%)					
Active	1 (4.8)	3 (7.0)	17 (28.3)	21 (16.9)	0.0095**
Former	0 (0)	7 (16.3)	1 (1.7)	8 (6.5)	0.0131*
Hypertension, N (%)	4 (19.0)	3 (7.0)	6 (10.0)	13 (10.5)	0.333
COPD or Asthma, N (%)	6 (28.6)	2 (4.7)	7 (11.7)	15 (12.1)	0.023*
Cardiovascular disease, N (%)	2 (9.5)	1 (2.3)	1 (1.7)	4 (3.2)	0.199
Diabetes, N (%)	2 (9.5)	2 (4.7)	5 (8.3)	9 (7.3)	0.708

Table 2. Cohort post-operative complications of vaginoplasty.

	Only t-TXA N=21	Any use IV-TXA N=43	No TXA N=60	Total N=124	OR 95% CI p-Value
Hematomas, N (%) Minor Major	0 (0.0) 0 (0.0) 0 (0.0)	2 (4.7) 2 (4.7) 0 (0.0)	2 (3.3) 1 (1.7) 1 (1.7)	4 (3.2) 3 (2.4) 1 (0.8)	1.130 (0.403-1.170) 0.816
Infection, N (%) Minor Major	3 (14.3) 2 (9.5) 1 (4.8)	2 (4.7) 1 (2.3) 1 (2.3)	2 (3.3) 1 (1.7) 1 (1.7)	7 (5.6) 4 (3.2) 3 (2.4)	0.885 (0.380-2.060) 0.777
Tissue necrosis, N (%) Minor Major	4 (19.0) 4 (19.0) 0 (0.0)	12 (27.9) 11 (25.6) 1 (2.3)	24 (40.0) 23 (38.3) 1 (1.7)	40 (32.3) 38 (30.6) 2 (1.6)	1.091 (0.726-1.640) 0.675
Dehiscence, N (%) Minor Major	10 (47.6) 8 (38.1) 2 (9.5)	15 (34.9) 15 (34.9) 0 (0.0)	36 (60.0) 35 (58.3) 1 (1.7)	61 (49.2) 58 (46.7) 3 (2.4)	1.350 (0.892-2.043) 0.155
Graft loss, N (%) Partial Complete	5 (23.8) 5 (23.8) 0 (0.0)	9 (20.9) 9 (20.9) 0 (0.0)	13 (21.7) 11 (18.3) 2 (3.3)	27 (21.8) 25 (20.2) 2 (1.6)	0.815 (0.508-1.307) 0.396
Splayed urine stream, N (%)	5 (23.8)	4 (9.3)	19 (31.7)	28 (22.6)	0.499 (0.316-0.789) 0.003**
Neovaginal stenosis, N (%)	7 (33.3)	3 (7.0)	14 (23.3)	24 (19.4)	0.435 (0.259-0.731) 0.002**
Fistula, N (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	_
Granulation tissue, N (%)	13 (61.9)	28 (65.1)	35 (58.3)	76 (61.3)	0.685 (0.451-1.040) 0.076
Thromboembolic event, N (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	_
Complications, per patient	2.2	1.7	2.4	2.2	_
Patients without complications, N (%)	4 (19.0)	9 (20.9)	4 (10.0)	18 (14.5)	_
Patients without major complications, N (%)	19 (90.5)	42 (97.7)	56 (93.3)	116 (93.5)	_