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Original Article

Spinal Tuberculosis: Role of Tranexamic Acid in Managing Perioperative Blood Loss

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Abstract

Background: Management of spinal tuberculosis, the most common form of osteoarticular tuberculosis, consists of medical and surgical modalities. Surgical decompression and fixation of the spine are a high demanding procedure, complicated in presence of excessive intraoperative bleeding resulting in increased morbidity and mortality. This study aimed to evaluate the safety and efficacy of tranexamic acid (TXA) in controlling blood loss and complications in transpedicular decompression and fixation of the tuberculous spine.

Materials and Methods: The present study was a prospective study of 50 patients aged 18–60 years with thoracolumbar spinal tuberculosis requiring surgical decompression, conducted in a tertiary care institute from 2014 to 2020. 25 patients each were randomized to receive either a bolus of 15 mg/kg IV of TXA after induction followed by a maintenance infusion of 2 mg/kg/h of TXA (Group A), or an equivalent volume of placebo, normal saline (Group B). The primary outcome was the blood loss intraoperatively and 48-h postoperative drain volume. Secondary outcomes were postoperative hemoglobin and haematocrit (HCT), the incidence of allogeneic blood transfusion.

Results: The mean intraoperative blood loss (130 ± 30 vs. 151 ± 51; $P > 0.05$) and mean postoperative drainage volume within 48 h (395 ± 34 vs. 561 ± 54; $P < 0.05$). The mean value of the post-operative hemoglobin (HB) in the control group was less by 5.94 g/L ($P < 0.05$). The mean post-operative HCT in Group A was 31.6 ± 3.5% and that in Group B was 29.8 ± 2.4%, the difference was statistically significant ($P < 0.05$). The mean injected volume of allogeneic red blood cells in Group A was about 440 ml less than that in Group B (420 ± 40 ml vs. 860 ± 80 ml; $P < 0.05$).

Conclusion: In this study, we suggest that the intravenous use of TXA during decompression and fixation of spinal tuberculosis has been an effective method in reducing intraoperative and post-operative blood loss, the volume of blood transfusions, and HB levels.

Keywords: Tranexamic acid, Spinal tuberculosis.

INTRODUCTION

Spinal tuberculosis, caused by infection of mycobacterium tuberculosis, is one of the commonest forms of osteoarticular tuberculosis.[1] It can cause severe neurological deficits, kyphotic deformities from vertebral collapse, and paraplegia, thus, representing a life-threatening and disabling condition.[2,3] Vertebral body collapse with the accumulation of pus within and around the spinal canal along with the formation of granulation tissue results in spinal cord compression which may present as paraparesis or paraplegia.

Treatment of osteoarticular tuberculosis consists of medical and surgical modalities. Antituberculosis chemotherapy remains the mainstay of treatment. However, surgery is indicated in patients with disabling back pain or progressive neurological deficit for relieving the compression of the spinal cord.[4] Current surgical methods include anterior

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debridement with anterior fusion followed by anterior or posterior instrumentation and posterior debridement with or without posterior fixation.[5] Single-stage decompression and fusion with bone grafting with instrumentation through the posterior approach for spinal tuberculosis have been reported by some surgeons to have good outcomes with the lower complication rates.[6,7]

Surgical decompression and fixation of the spine through the posterior approach needs expertise and is a high demanding procedure due to the complex anatomy of the spine, and vascular network around the cord, and the Batson plexus of venous anastomosis in the epidural space. The presence of a good bloodless operative field helps in achieving good complete decompression of the cord through the complex anatomical tissues. Hence, control of bleeding is of paramount importance.

Spine surgery gets complicated in the presence of excessive intraoperative bleeding resulting in increased morbidity and mortality.[8] The amount of blood loss depends on many factors including the extent of the surgical procedure, perioperative coagulation dysfunction, and achievement of surgical hemostasis. Nevertheless, topical and systemic pharmacological agents are evidently of additional merit. Judicious surgical hemostasis and procoagulant agents are complementary in managing perioperative hemorrhage.[9]

Tranexamic acid (TXA) is a synthetic lysine analog that was demonstrated to be more potent and superior to the previously used antifibrinolytic agent, epsilon-aminocaproic acid (EACA). TXA, a widely used hemostatic agent in the clinical setting, works through competitive inhibition of the lysine moieties on the structural proteins plasminogen, plasmin, and tissue plasminogen activator (tPA), thus preventing fibrinolysis. It diminishes the binding ability of plasminogen and tPA to fibrin, which inhibits the activation of plasminogen to plasmin. TXA can be administered through several routes—orally, topically, or intravenously — and has a 100% bioavailability. A 10 mg/kg intravenous administration of TXA has a half-life of approximately 80 min and reaches peak concentration within 1 h after administration.[10]

This study aimed to evaluate the safety and efficacy of TXA in controlling blood loss and complications in transpedicular decompression and fixation of the tuberculous spine.

MATERIALS AND METHODS

The present study was a prospective study, conducted in a tertiary care institute from 2016 to 2020 with prior approval from the institutional ethics committee. A total of 50 patients undergoing surgery for spinal tuberculosis in the department of orthopedics in our institute were selected for this study. All patients were informed of trial contents, methods, potential risks, and complications, and written valid informed consent was obtained from the patients. The 50 patients who met the above criteria were serially numbered from 1 to 50 as per chronology of presentation and 25 patients each were randomized into two groups, those that were administered pre-operative TXA (Group A) and a control group (Group B). Randomization was done using a random number table.

Inclusion Criteria

Patients with thoracolumbar spinal tuberculosis, between the ages of 18 and 60 years, with a confirmed diagnosis on histopathological reports requiring surgical intervention due to

1. Not improving with primary anti-tuberculous drugs for more than 6 weeks.
2. Progressive neuro deficit and static neuro deficit for more than 3 weeks
3. Dense paraplegia and bowel bladder involvement.

All patients had normal preoperative blood investigations, coagulation function, and double lower extremity venous ultrasound. Patients had a preoperative hemoglobin (HB) >10 g% and a hematocrit (HCT) >35%.

Exclusion Criteria

The following criteria were excluded from the study:

1. Cervical and lumbosacral tuberculosis
2. Patients with a previously operated spine
3. Patients having an allergy to TXA
4. Patients on anticoagulant therapy -aspirin, warfarin, and other anticoagulant drugs
5. Patients with severe renal insufficiency, renal pelvis or ureteral solid lesions, diabetes, and other diseases that may affect coagulation function;
6. Patients having increased bleeding time, clotting time, prothrombin time
7. Patients with previous history of deep vein thrombosis (DVT) or pulmonary embolism.

The patient's plain radiographs (anteroposterior [AP] and lateral views) were reviewed to locate the affected segments and number of affected vertebrae and to evaluate the kyphotic angle of the localized spinal deformity using the Cobb angle. Other investigations, including computed tomography (CT), magnetic resonance imaging (MRI), hematologic examination, and histopathologic examination, were also reviewed to confirm the diagnosis. All the patients received the standard tuberculous chemotherapy consisting of isoniazid 5 mg/kg/day, rifampicin 10 mg/kg/day, pyrazinamide 20 mg/kg/day, and ethambutol 15 mg/kg/day,

for at least 6 months, followed by a course of isoniazid, rifampicin, and ethambutol for 12 months.

Protocol

After hospital admission, patients were evaluated thoroughly history, examination, investigations including routine blood examination, coagulation function, liver and kidney function, electrocardiogram, chest X-ray, and lower extremity venous Doppler studies. Standard X-rays of the affected spine in AP and lateral views were taken. CT scan and MRI were done to assess the bony destruction, extent of the lesion, and abscess volumes.

All patients were operated under general anesthesia in the prone position on a radiolucent table with a specialized frame to create hyperextension of the spine, using shoulder and iliac gel pads, achieving postural reduction. The pre-operative antibiotics were given 30 min before incision. Intraoperative mean blood pressure is maintained at 85 mm Hg.

Patients of Group A were given an initial dose of 15 mg/kg tranexamic 10 min before surgical incision and a maintenance dose of 2 mg/kg/h until the end of surgery. Patients in Group B were given an intraoperative intravenous infusion of the isodose normal saline.

Patients were operated on using the posterior midline approach to the spine after confirming the affected level under fluoroscopic guidance. The posterior elements of the vertebrae two-level above and below the pathological vertebra. The dissection was carried laterally to the tips of transverse processes, maintaining meticulous hemostasis. Free hand technique for insertion of pedicle screws was used and their position was confirmed in both AP and lateral views using an image intensifier. Four pedicle screws were bilaterally implanted into adjacent vertebrae above and below the affected level vertebra.

The transpedicular anterior decompression was planned on the side of maximum compression. The pedicle screws on the other side were implanted and the rod fixed, to get a correction of kyphosis [Figure 1]. In the thoracic spine medial end of the rib and transverse process of the vertebra were removed for decompression. For the affected vertebra, hemilaminectomy or laminectomy was performed, and the pedicle was exposed. The nerve root was identified and traced to gain access to the spinal canal amid granulation tissue. The anterior abscess was completely drained. The granulation tissue was gently removed and sent for examination with Gram staining and Ziehl-Neelsen staining, histopathological examination, culture sensitivity, and Cartridge Based Nucleic Acid Amplification Test.

The structures compressing the spinal cord such as the necrotic disc, superior, and inferior endplate of vertebra were removed. The endplates were curreted and based on the defect of corpectomy, the cage with autograft was placed. The decompression was confirmed by direct visualization. Hemostasis was achieved using bipolar cautery, and cancellous bleeding was controlled with bone wax.

Pedicle screws on the side of decompression were placed. Rods were contoured and placed over the screws and provisionally held by tapered nuts. Acceptable correction of deformity and vertebral height was achieved under image intensifier control and inner nuts were tightened to maintain reduction. The rods were connected and fixed. The correction of kyphosis, cage placement was checked and confirmed fluoroscopically. Posterior elements were gently decorticated and prepared for fusion and cancellous graft harvested from the spinous process and the iliac crest was generously spread. The erector spinae muscle was closed in a watertight fashion. Suction drains were placed without negative suction. The wound was sutured in layers, and a sterile dressing was done. The mean intra-operative time was 2:30 h.

Postoperatively, patients were given intravenous antibiotics for 48 h and then switched over to oral antibiotics till suture removal. Intensive physiotherapy was started from the 1st post-operative day in the form of stretching and active, active-assisted, and passive range of movements. Calf pumping exercises were started 6 h post-surgery. Patients with good neurological recovery were gradually weaned off urinary catheter whereas those with complete paraplegia and without good recovery were taught clean intermittent self-catheterization. On the 2nd day, they were allowed to roll from side to side. They were made to sit up and mobilized on a wheelchair after applying the Knight-Taylor brace from the 4th post-operative day. Sutures were removed on the 12th day. Heavy activities were restricted up to 12 weeks after the operation.

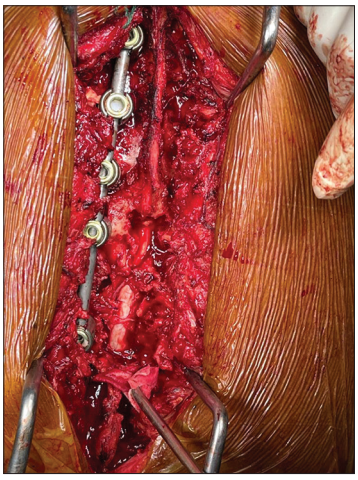

Figure 1: Intraoperative picture showing fixed pedicle screws and granulation tissue

Patients were followed up at monthly intervals with clinical and radiological assessment in the orthopedic outpatient clinic, with a mean follow-up of 24.01 months (range, 18–36 months). All patients were followed up in outpatient department at monthly intervals. At each follow-up, results were evaluated for neurological recovery, Doppler study to document DVT, functional recovery by ASIA score and radiological signs of healing and recovery, correction by sagittal angle, and index in documented. Radiological incorporation of bone graft documented. The complaints or complications were noted and treated.

RESULTS

The study was conducted in a tertiary care hospital after obtaining permission from the Institutional Ethics Committee. A total of 50 patients presenting to our tertiary care institute with thoracolumbar spinal tuberculosis requiring surgical decompression were included in the present study. The patients were divided into two groups, that is, Group A patients administered pre-operative TXA, and Group B – patients not administered TXA.

The demographic characteristic of the patients in both groups is as given in Table 1. The average age of the patients in Group A was 45.86 ± 7.35 years and of the patients in Group B was 47.8 ± 6.84 years in the range of 18–60 years. The difference in the mean ages of the two groups was not statistically significant ($P > 0.05$). In our study, the majority 30 (60 %) of the patients were females. There were 12 males and 13 females in Group A and 11 males and 14 females in Group B.

The mean intraoperative blood loss of patients in Group A was 130 ± 30 ml and that of patients in Group B was 151 ± 51 ml, the difference was not statistically significant. The mean post-operative drainage volume within 48 h in Group A was 395 ± 34 ml and that in Group B was 561 ± 54 ml. The difference between the mean post-operative drainage at 48 h was statistically significant ($P < 0.05$).

The mean value of the post-operative HB in the control group was less by 5.94 g/L ($P < 0.05$). The mean post-operative HCT in Group A was 31.6 ± 3.5% and that in Group B was 29.8 ± 2.4%, the difference was statistically significant ($P < 0.05$). Moreover, the mean of differences of HB and HCT between pre-operation and post-operation in Group A were lower than those in the control group, and the differences were statistically significant (28.6 ± 15.3 g/L vs. 32.8 ± 19.8 g/L; $P < 0.05$ and 8.5 ± 4.5% vs. 9.8 ± 5.9%; $P < 0.05$).

Transfusion triggers were found in five patients in the TXA group while 12 patients in the control group, and the difference was statistically significant ($P < 0.05$). The mean injected volume of allogeneic red blood cells in Group A was about 440 ml less than that in Group B (420 ± 40 ml vs. 860 ± 80 ml; $P < 0.05$). The mean injected volume of fresh frozen plasma in Group A was about 175 ml less than that in Group B (250 ± 25 ml vs. 425 ± 30 ml; $P < 0.05$).

Table 1: Demographics and baseline characteristics

	Group A (*n*=25)	Group B (*n*=25)	*P* value
Age(years) average	45.86	47.8	0.33
Male/Female	12/13	11/14	0.77
BMI	22.17	22.91	0.08
Pre-operative HB (g/dl)	13.25	13.08	0.69
Pre-operative HCT (%)	40.25	39.74	0.69

Table 2: Post-operative outcomes

	Group A	Group B	*P* value
Intraoperative Blood Loss (ml)	130±30	151±51	0.07
Post-operative 48 h drain (ml)	395±34	561±54	2.69E-17
Post-operative Hb (g/dl)	10.4±1.2	9.8±0.8	0.04
Post-operative HCT (%)	31.6±3.5	29.8±2.4	0.04

Post-operative DVT was found in no case of the TXA group while five cases in the control group, and the difference was statistically significant ($P < 0.05$). In addition, the fastigium of DVT rate appeared within 6 days after the operation. Post-operative pulmonary infection was found in one case of Group A while 2 cases in the Group B, and the difference was not statistically significant ($P > 0.05$) [Table 2].

DISCUSSION

Tuberculosis of the spine is the most common tuberculosis of bone and joint, accounting for 50% of the bone tuberculosis and 3–5% of all tuberculosis.[11,12] The underlying causes of malnourishment and immune status are the sole contributors of morbidity in tuberculous spondylodiscitis. The protein deficiency, vitamin, and micronutrients deficiency affect healing, coagulation process, granulation tissue, and healing of postoperative wound healing. In recent years, the morbidity of tuberculosis of the spine has been significantly increasing.[13] Tuberculosis of the spine is not typical and is associated with different degrees of anemia and hypoproteinemia at the early stage.[13] There are medical and surgical treatments for tuberculosis clinically. It is necessary for surgery at the early stage.[14] Different degrees of hemorrhage and post-operative complications were often associated with the process of surgery, so TXA and other hemostatic drugs are widely used.

TXA is a synthetic lysine analog that works by interfering with the fibrinolysis through the reversible binding and competitive inhibition of the lysine moieties on the structural proteins plasminogen, plasmin, and tPA.[15] It diminishes the binding ability of plasminogen and tPA to fibrin, which inhibits the activation of plasminogen to plasmin.[16] TXA can be administered through several routes — orally, topically, or intravenously — and has a 100% bioavailability. A 10 mg/kg intravenous administration of TXA has a half-life of approximately 80 min and reaches peak concentration within 1 h after administration. The dose-efficacy relationship of TXA remains a poorly understood area of research.[17] Therefore, the determination of a dosage regimen that retains its efficacy throughout the entirety of the perioperative period becomes even more important in complex surgical cases.[15] The elimination of TXA after a single-dose IV administration may take place over 2–3 h. Thus, complex spine procedures may necessitate a second bolus dose. Raksakietisak *et al.*[16] in their study evaluated 39 patients who received an initial bolus dose of 15 mg/kg bolus at the beginning of the procedure and an additional bolus 3 h later. The experimental group demonstrated less perioperative blood loss and decreased need for transfusions as compared to the control group.

In 1976, it was first reported that TXA was used in spinal tuberculosis surgery with good hemostatic effects.[18] Royston had started to use TXA for thoracic surgical procedures patients in 1995. He sprayed it in the thoracic cavity and got the satisfying result of hemostasis. In this study, we evaluated the efficacy of TXA in decreasing the amount of blood transfusion in surgery in patients with spinal tuberculosis surgery. It was consistent with the findings of Royston,[19] Wong *et al.*,[20] and Winter *et al.*[21]

Spinal surgery is often bloody. Blood transfusions are not uncommon. TXA decreased intraoperative blood loss in the study of intraoperative blood loss and transfusion requirements in adolescent idiopathic scoliosis patients undergoing posterior spinal fusion by a single surgeon.[22] Shi *et al.*[23] in their recently published randomized trial showed a 33.4% reduction in the intraoperative estimated blood loss and a 41% reduction in total blood loss when TXA was used intraoperatively for posterior lumbar surgery for spondylolisthesis.

The observations in our study are supportive of TXA reducing intraoperative blood loss. This reduces the need for hypotension during decompression of the spinal cord. It gives a clear operative field. Structure delineations are clear due to less blood in the operative field. The duration of surgery is also reduced. Time and dose of anesthetic agents and associated side effects of general anesthetics are also reduced. Hence, our study concludes that intravenous use of TXA is a safe and effective method for reducing intraoperative blood loss during tuberculosis spine decompression.

In our study, the blood loss within 48 h after surgery, HB, HCT, and their different values before and after operation were compared in patients receiving TXA with the control group. The results showed the TXA group had lesser blood loss during post-operative 48 h as compared with the control group.

TXA reduces the percentage of spinal surgery patients' blood transfusion need.[24] It reduces transfusion requirements to a higher degree than desmopressin[25] and proved to be equally effective as EACA in intraoperative hemorrhage reduction.[26] TXA was compared to aprotinin for blood loss control during spinal surgery and was found to be equally effective.[27] Our study also favors that antifibrinolytic agents, including TXA, could be valuable adjuncts to perioperative hemorrhage management. Evidence suggests that TXA reduces the need for transfusion.

The results of the study showed that intravenous TXA during surgery of spinal tuberculosis could reduce the risk of postoperative DVT. Lower extremity DVT and pulmonary embolism are a kind of common and dangerous complications for spine and orthopedic patients.[28] Its incidence is low but the consequences could be fatal. Hence, the emphasis is being laid on pre-operative and post-surgery ultrasound Doppler examination to monitor the occurrence during the hospital stay or follow-up visit of the lower extremities DVT.[28]

The attempt was made for statistical analysis on pulmonary infections and surgical site infections. The results showed that TXA could effectively lower the incidence of postoperative infections. It is well known that after spinal tuberculosis surgery, a variety of inflammatory mediators are released into the circulation and often result in a systemic inflammatory response. TXA has double effects of anti-inflammatory and hemostasis. Its possible mechanism is that: The TXA selectively reduced the production of extracorporeal circulation of active anti-inflammatory metabolite into the circulation. During a similar process, it enhances platelets to inhibit the leukocytic activation, adhesion, aggregation, and activation of endothelial cells, thereby reducing arachidonic acid metabolites and the release of inflammatory mediators, to reduce the occurrence of postoperative inflammatory reactions.

There are many limitations to this study. Due to the smaller sample size, the results cannot be generalized to larger

populations. It is necessary to expand the sample cases to study whether the TXA used in decompression of spinal tuberculosis can effectively reduce blood loss and the incidence of adverse reactions, thus improving the prognostic qualities.

CONCLUSION

In the present study, we suggest that the intravenous use of TXA during decompression and fixation of spinal tuberculosis is an effective method in reducing intraoperative and postoperative blood loss, the volume of blood transfusions, and HB levels. It does not affect the rate of postoperative DVT or surgical site infections. Post-operative complications associated with surgery are significantly found to be reduced.

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