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Original Research Article

The tranexamic acid: as chemical tourniquet during Ward-Mayo's operation

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ABSTRACT

Background: The intra-operative blood loss which required transfusion is one of the complications in Ward-Mayo's operation. The objective of this study was to evaluate its effectiveness to minimizes hemorrhage in Ward-Mayo's operation
Methods: It is a well-designed, Clinical, interventional, prospective, randomized control trial. In the department of obstetrics and gynecology, IPGMER-SSKM (PG) H, Kolkata, West Bengal, India. More than one-year study. After ethics approval, the total number of sixty-six cases will be selected with randomization for Ward-Mayo operation and allocated into two groups operated as - Gr-A (n = 33 cases) - by infiltrating locally tranexaminic acid, Gr-B (n = 33-controls) - application local conventional haemostatics.
Results: The outcome informs of primary and secondary assessed, analyzed, tabulated and statistically significant showed accordingly as per graph pad software. In Table 1 and 2. The results of individual group (Gr. A and Gr. B) in forms of pry and Sec. outcomes showed that there are better outcomes in all aspects with zero mortality Tranexamic group than controls.
Conclusions: This study concluded that the Tranexamic Acid can safely and effectively used by local infiltration during Ward-Mayo' operation. Like other department, this technique can be utilized in other vaginal procedure (ex-Episiotomy).

Keywords: Better outcomes, In Ward-Mayo, Local tranexamic acid infiltration

INTRODUCTION

The intra-operative blood loss which required transfusion is one of the complication in Ward-Mayo's operation, that minimized by application of different techniques like sharp dissection, electrocautery, self-retaining vaginal retractor, thrombin-soaked oxidized cellulose pack, hydro dissection and diluted vasoconstriction agents (ex:-vasopressin, adrenaline), but some of them having drawbacks like their toxicities and hydro dissection having impair blood supply, tissues defences and healing.[1-5] After aspiring from good results by local application of Tranexmic acid (TXA) in some other surgical units (ex: dental, ENT, orthopaedic) and also recommended by WHO (2017) [TXA should be administered at a fixed dose of 1 g in 10 ml (100 mg/ml) IV at 1 ml per minute (i.e., administered over 10 minutes), with a second dose of 1 g IV if bleeding continues after 30 minutes or if bleeding restarts within 24 hours of completing the first dose in PPH], it can be used by local infiltration during Ward-Mayo's operation to reduce intra-operative blood loss and transfusion.[6-9]

When it is used before making incision, it acts as chemical-tourniquet not only minimized blood loss but also facilitates the identification of cleavage planes with

easy separation and development in such age group of patients to reduce morbidity and mortality.

Nowadays this agent is being used vastly in different department as below

Vaginal bleeding

Tranexamic acid is used to treat heavy menstrual bleeding. When taken by mouth it both safely and effectively treats regularly occurring heavy menstrual bleeding and improves quality of life. Another study demonstrated that the dose does not need to be adjusted in females who are between ages 12 and 16.

Child birth

Tranexamic acid is used after delivery to reduce bleeding, often with oxytocin. Death due to postpartum bleeding was reduced in women receiving tranexamic acid.

Haematology

There is not enough evidence to support the routine use of tranexamic acid to prevent bleeding in people with blood cancers However, there are several trials that are currently assessing this use of tranexamic acid. For people with inherited bleeding disorders (e.g. von Willebrand's disease), tranexamic acid is often given It has also been recommended for people with acquired bleeding disorders (e.g., directly acting oral anticoagulants (DOACs) to treat serious bleeding, but it has some contraindications and side effects.

Contraindication

- Allergic to tranexamic acid
- History of seizures
- History of venous or arterial thromboembolism or active thromboembolic disease
- Severe kidney impairment due to accumulation of the medication, dose adjustment is required in mild or moderate kidney impairment.

Common side effects include

- Headache (50.4-60.4%)
- Backache (20.7-31.4%)
- Nasal sinus problem (25.4%)
- Abdominal pain (12-19.8%)
- Diarrhea (12.2%)
- Fatigue (5.2%)
- Anemia (5.6%).

METHODS

The tranexamic acid is antifibrinolytic family of medication having synthetic derivatives of amino acid derivatives lysine that exert its effects through reversible blockade of lysine binding site (4-5 receptor site) on plasminogenm (PLASMIN) molecules which prevent plasmin (antiplasmin) from binding to and degradation of fibrin and preserve the framework of fibrin matrix structure, directly inhibits the activity of plasmin with weak potency and it can block the active-site of urokinase plasminogen activator with high specificity among all the serine proteases, blocks binding of α2-antiplasmin and inhibits inflammatory reactions and compared with epsilon-aminocaproic acid (EACA), it is more potent by a factor of 10 and the half-life in adults is approximately 2.3 hours.

It is so called chemical-tourniquet considerably decreased blood loss and help in easy creation of surgical plane when injected tranexamic acid (2 gms = 20 ml) in under mentioning sites/spaces:

Both sides of paravasical spaces, cervical insertion, paracervical part of Mackenrodt and bladder pillers (may be 8 ml in each site).[10]

The results of individuals groups (Gr-A and Gr-B) in forms of primary and secondary outcomes in different s parameters are now tabulated, analyzed statistically significant established and showed in (Tables 1, 2), diagrams and different tools by using graph pad software.

Exclusion criteria

- Known hypersensitivity
- Subarachnoid haemorrhage
- Renal failure
- Haematuria.

RESULTS

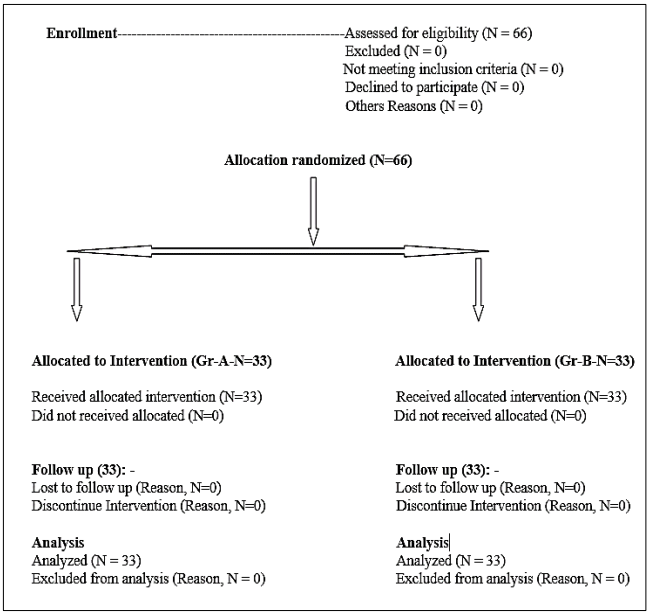

Figure 1: Consolidated standards of reporting trails (consort) statement.

Table 1: primary outcomes in the forms of following parameters of this study with conclusive statistically significant (p-value) accordingly.

Indicators	GR-A (N = 33)	GR-B (N = 33)	Conclusion
Organ damage/failure			
Ureter	1/32	8/25	p = 0.0268
Bladder	3/30 (stained urine)	12/21 (stained urine)	p = 0.0169
G.I.T.	1/32	9/24	p = 0.0129
Vessels	3/30	11/22	p = 0.0326
Blood loss			
Volume drain (operation)	*20, *5, *28.72.	*50, *8, *45.96	p < 0.0001
Drains (48 hours)	*150, *50,287.23	*300, *50, *287.23	p = 0.0378
Hb Drop	1, .05, .28	2, .05, .28	p < 0.0001
Mops wt (wet-dry)	400, 50, 287.23	800, 50, 287.23	p < 0.0001
Pcv drop	1.8, .01, .0574	2.7, .05, .28727	p < 0.0001
Transfusion required			
Blood	03/30 (01 unit)	12/21 (03 units)	p = 0.0169
F.F.P.	00/33	33/0 (≥ 1 unit)	p < 0.0001
Platelets	00/33	33/00 (≥ 1 unit)	p < 0.0001
Volume expanders	03/30	27/05	p < 0.0001
Hypotension/hypertension	05/28(BP increased)	25/08 (BP decreased)	p < 0.0001
Chest discomfort	2/31	15/18	p = 0.0005
I.T.U/C.C.U. care	00/33	08/25	p = 0.0048
Death	NIL	01	Not applicable

FET: Fisher's Exert Test, UTT: Unpaired-t-test, Mean SEM±SD.

Table 2: Secondary outcomes, in the forms of following parameters of this study with conclusive statistically significant (p-value) accordingly.

Indicators	Group A (n = 33) (cases)	Group B (n = 33) (controls)	p-value	Reference
Operation time	50.5±8.7 mins	76.3±9.4 mins	p < 0.0001	Unpaired-t-test
Angle hematoma	BUAL-Site-3 Incision-4	Clamps/tourniquet site-15 Incision-10	p = 0.0010	Fisher's Exert Test
Stitch line hematoma	10	36	p < 0.0001	Fisher's Exert Test
Approximation failure	11	34	p = 0.0002	Fisher's Exert Test
Stitch whole injury	14	30	p = 0.0099	Fisher's Exert Test
Cut through and avulsion	7	24	p = 0.0007	Fisher's Exert Test
Mobilization time	8, 2,11.49	18, 4, 22.98	p = 0.0288	UTT-TTP
Oral feeding time	10, 2, 11.49	20, 4, 22.98	p = 0.0288	UTT-TTP
Post-operative pain	Less and good satisfaction (30/3)	More and poor satisfaction (0/33)	p < 0.0001	Fisher's Exert Test
Analgesic needs and satisfaction	12, 2, 11.49	24, 4, 22.49	p = 0.0093	UTT-TTP
Febrile complication	5	20	p = 0.0022	Fisher's Exert Test
Wound healing, infection, pain and hardness, complication	6	23	p = 0.0010	Fisher's Exert Test
Re- admission	2	5	NA	NA
Hospital stay	7, 1, 5.74	14, 2, 11.49	P = 0.0026	UTT-TTP
Costs (sutures and medications)	≤ 3 sutures/case and less medications	≥ 5 sutures/case and more medications	NA	NA

FET: Fisher's Exert Test, UTT: Unpaired-t-test, Mean SEM±SD.

The results of individuals groups (Gr-A and Gr-B) in forms of primary and secondary outcomes in different s parameters are now tabulated, analyzed statistically significant established and showed in tables (Tables 1, 2), diagrams and different tools by using graph pad software (Figure 1).

Allocation done sequentially numbered opaque sealed enveloped (SNOSE), where sequence generated computerized random number generator and envelopes size, shape, weight confirmed equally having - Code-Gr-A (cases), Code-Gr-B (controls).

Aluminums foil inside envelopes was used to render envelops impermeable to light.

Envelops number in advanced, opened sequentially only after participants' name and other details written on appropriate envelops.

Envelops contains carbon papers which essential for audit trial.

Must registry entry of patients 'profile.

The primary outcomes in forms of organs failure or damages on ureters, bladder, GIT and vessels are statistically less in our study group compared to controls ($p = 0.0129$, $p = 0.0326$), estimated blood loss (EBL) (measured in form of drains, mops, Hb drops and PCV drops) are statistically less in our study group compared to controls ($p < 0.0001$, $p = 0.0378$), required transfusion in form of blood, FFP, platelets, volume expanders are statistically less in our study group compared to controls ($p < 0.0001$, $p = 0.0169$), cardiovascular and other complications (hypotension/ hypertension, chest discomfort, I.T.U/ C.C.U care) are statistically less in our study group compared to controls ($p < 0.0001$, $p = 0.0048$) without any mortality as per description from Table 1.

The secondary outcomes in forms of operation time ($p < 0.0001$), angle haematoma ($p = 0.0010$), stitch line haematoma ($p < 0.0001$), approximation failure ($p = 0.0002$), Stitch whole injury ($p = 0.0099$), cut through and avulsion ($p = 0.0007$), mobilisation time ($p = 0.0288$), oral feeding time ($p = 0.0288$), post-operative pain ($p < 0.0001$), analgesic needs and satisfaction ($p = 0.0093$), Febrile complication ($p = 0.0022$), wound healing, infection, pain and hardness, complication ($p = 0.0010$), re-admission, hospital stay ($p = 0.0026$) are statistically better in our study group compared to controls as per derived from (Table 2).

DISCUSSION

A systematic review (Cochrane reviewed) of randomized trials assessing the effects of tranexamic acid in patients undergoing surgery found that it reduced blood loss and the risk of receiving a blood trans-fusion along the risk of death (Ker 2012; Ker 2013). The CRASH-2 trial that involved 20,211 bleeding trauma patients found that early administration of tranexamic acid reduced the risk of death with no increase in thromoembolic effects. In the United States, FDA approved Tranexamic acid is used in dentistry in the form of a 5% mouth rinse after extractions or surgery in patients with prolonged bleeding time; e.g., from acquired or inherited disorders. It has also been recommended for people with acquired bleeding disorders (e.g., directly acting oral anticoagulants (DOACs)) to treat serious bleeding. The use of tranexamic acid, applied directly to the area that is bleeding or taken by mouth, appears useful to treat nose bleeding compared to packing the nose with cotton pled gets alone. Tranexamic acid is used to treat heavy menstrual bleeding. When taken by mouth it both safely and effectively treats regularly occurring heavy menstrual bleeding and improves quality of life. Tranexamic acid is used after delivery to reduce bleeding and death due to postpartum bleeding. In our study the primary outcomes informs of statistically significant less blood loss [volume drain (operation), drains (48 hours), Hb drop, mops wt (wet-dry), pcv drop], less transfusion required (blood, F.F.P., platelets, volume expanders), less chest discomfort, BP complications, organs damages and ITU/CCU care. The secondary outcomes statistically significant less in forms of operation time, angle hematoma, stitch line hematoma, approximation failure, stitch whole injury, cut through and avulsion, mobilization time, oral feeding time, post-operative pain analgesic needs and satisfaction, febrile complication, wounds (healing, infection, pain and hardness, complication), re-admission, hospital stay costs (sutures and medications).

Limitation of this study was on average; an additional 10 minutes of operating time was required for the uterine depletion procedure when combined with either an abdominal myomectomy.

The learning curve for ligation of the uterine arteries by the abdominal route might be longer for inexperienced surgeons.

If this uterine depletion procedure is to be routinely performed in myomectomy in the future, more surgical training will be required. It is single centre study, with small sample size required long follow-up required especially reproductive life in future not properly evaluated. Needs multicentre randomized controlled trials (RCT).

CONCLUSION

This step should be adopted as prophylactic ,integral and debut step by the surgeons specially in developing World where inadequate blood transfusion as this is a preliminarily more effective step for reducing blood loss , advocated and recommended its routine use as safe and convenient to other haemostatic methods not only in

this operation and must be incorporated in G&O training for enriched and taught surgeons other vaginal surgery.

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