

Generalizability and variability in tranexamic acid dosage and efficacy in postpartum haemorrhage

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Abstract

Background

Tranexamic acid (TXA) effectively reduces postpartum haemorrhage (PPH), but the optimal dosage and conditions for maximizing clinical efficacy remain uncertain.

Aim

To synthesize current evidence on the efficacy of TXA in managing PPH.

Methods

A systematic review and meta-analysis of experimental and observational studies was conducted following PRISMA guidelines. PubMed, MEDLINE, Cochrane Library, Academic Search Complete, and CINAHL were searched. The primary outcome was total blood loss (TBL). Secondary variables included age, gestational age, TXA dose, administration route, bleeding risk, and clinical setting. Pooled standardized mean differences (SMDs) were estimated using a random-effects model, and subgroup analyses explored sources of heterogeneity.

Results

Sixty-three studies involving 7,029 participants were included, with over 80% classified as low risk for bleeding. TXA significantly reduced blood loss (SMD = -1.80, 95% CI: -2.06 to -1.53). Greater reductions were observed following cesarean delivery (SMD = -1.84, 95% CI: -2.11 to -1.57) than vaginal delivery (SMD = -1.09, 95% CI: -2.16 to -0.55). Considerable heterogeneity was partly explained by TXA dose, bleeding risk, delivery mode, and sample size. The largest effect was observed with a 10 mg/kg loading dose followed by a 1 mg/kg/h infusion (SMD = -2.46, 95% CI: -3.37 to -1.56). Studies from high-income countries and those enrolling more women at high risk of bleeding reported smaller treatment effects.

Conclusions

TXA effectively reduces blood loss in PPH. Treatment efficacy appears to vary by dosage regimen, bleeding risk, and mode of delivery, with the greatest benefit observed in cesarean deliveries and lower-risk populations.

Introduction

Obstetric haemorrhage remains a primary cause of maternal mortality, and more 100,000 deaths per annum are attributed to it [1]. Bleeding may occur before delivery due to placenta praevia or an abruption, during labour, or after delivery due to a ruptured uterus, uterine atony, coagulopathy, or cervix/vaginal trauma [2]. However, most cases of obstetrics haemorrhage arise shortly, following delivery [3]. According to the World Health Organisation (WHO) [4], postpartum haemorrhage (PPH) causes more than 100,000 maternal death annually worldwide, 60% of which occurs in developing countries. PPH is a common birth complication that typically affects 2–4% of vaginal deliveries and 6% of cesarean deliveries [5]. It is frequently linked to uterine atony [3]. Organ ischemic injury, respiratory disorders, anaemia, loss of fertility, and Sheehan syndrome, are some of the complications identified for PPH [6, 7]. This underscores the need for the most effective therapeutic options to be devised for the treatment of PPH.

PPH is often regarded as an emergency that requires immediate care [8]. The degree of the bleeding and the underlying reason both have a role in determining how PPH should be treated [3]. Although uterotonics are the standard of care for bleeding caused by uterine atony, alternatives, such as antifibrinolytics, may be required if the coagulation-fibrinolytic balance is altered [9]. A concomitant increase in fibrinolytic activity occurs when normal haemostatic changes such as strong myometrial contractions, increased activity of platelets, and coagulation are induced to reduce bleeding in the event of placental discharge, a surgical incision in the uterus, or rupture [10]. Although uterotonics strengthen myometrial contractions, antifibrinolytics namely tranexamic acid (TXA) may inhibit fibrinolysis [11].

Several randomized controlled trials (RCTs) have evaluated the effect of tranexamic acid (TXA) on the prevention [12–15] and treatment [16,17] of postpartum haemorrhage (PPH) following both caesarean and vaginal deliveries. While these studies generally suggest that TXA may reduce blood loss and improve PPH-related outcomes without major safety concerns, their findings vary with respect to study design, patient populations, treatment protocols, and reported outcomes. Furthermore, individual trials may be underpowered to adequately assess uncommon adverse events such as thromboembolism and seizures. Therefore, a systematic review and meta-analysis is warranted to synthesize the available evidence, increase statistical power, provide more precise estimates of efficacy and safety, and explore sources of heterogeneity across studies. Furthermore, there is moderate evidence in supports of the WHO's recommendation that TXA be administered with standard therapy within three hours following diagnosis of PPH [18]. However, the existing evidence is limited in areas pertaining to study generalizability and variations in dosage, timing of administration [19] and mode of delivery. The need for large-quality RCTs in the prevention and treatment of PPH was acknowledged in two previous systematic reviews of RCTs published in 2015 and 2017 [15, 20]. New RCTs regarding TXA's impact on PPH have emerged including [9, 21, 22]. Thus, it is pertinent that the available evidence is synthesized since clinical practice and policies require up-to-date evidence to ensure cost-effectiveness and efficiency [18]. Therefore, this review aims to synthesize up-to-date evidence on the generalizability and variability of TXA dosage and efficacy in postpartum haemorrhage

Methods

PECOT criteria

The population is pregnant and postpartum women. The exposure is TXA, irrespective of route of administration and dosage. For the RCT, the comparator was either a control group or placebo; for the case-controlled and cohort studies, the comparator was a control group while no comparator was involved for the pre-post quasi experiments. The primary outcome was total blood loss. The review covered the time between the inception of the oldest database and August 2023.

Systematic review team members

The primary reviewers HCO, DO and MN organized and coordinated this review process including the development of the research questions, screening of relevant articles, data extraction and analyses, and manuscript preparation. MN, GUI, CSE and TUN devised the search strategy for all the databases. The contents experts were TUN, CEN, JTE, NA and DNO. The retrieved articles were screened by HCO, EAM, MN, CEN and JTE. Data extraction was carried out by a trained research assistant. The extracted data was verified by all authors. Training of research assistant was undertaken by MN, CSE and DNO. Statistical analysis was performed by MN who is experienced in meta-analysis and statistical analysis.

Design, protocol and registration

This is a systematic review of randomized controlled trials investigating the efficacy of TXA for the prevention and treatment of PPH. This protocol was structured according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [23]. The protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO) [CRD42023454820].

Eligibility criteria

Inclusion criteria

Studies were included if they (1) peer-reviewed randomized controlled trials, quasi-experiments, case-controlled or cohort studies, (2) investigated the effect of TXA for the prevention and/or treatment of PPH (3) included pregnant women with postpartum bleeding due to vagina bleeding or elective CS, irrespective of the route of TXA administration (4) studies will be included irrespective of the publication date, language, setting, sample size and test statistics

Exclusion criteria

Studies that did not meet the inclusion criteria were excluded including case reports, review articles, editorials, and conference proceedings and studies with a mixed population of women with antenatal haemorrhage and PPH.

Outcomes and outcome Measures

The efficacy of TXA for the prevention of PPH was determined by the reduction in estimated blood loss, blood transfusion requirements, and maternal death. Secondary outcomes included gestational age, bleeding risk, mode of delivery, dose, setting, age amongst others.

Information Sources

Literature searches were carried out using Medline, PubMed, Cochrane Library, CINAHL, and Academic Search Complete. We searched the databases from their inception to date. Also, the reference list of identified systematic reviews were searched for eligible articles.

Search strategy development

We developed, tested, and refined the search strategy. Search terms were identified from the key concepts in the review model. All searches were executed using a range of terms from the medical subject categories and free search terms. A PubMed pilot search was carried out to ascertain the appropriateness of the search strings. The search terms were modified to fit the syntax and subject headings of the other databases namely Medline, Cochrane Library, CINAHL and Academic Search Complete. The search strings including index terms and keywords were combined using Boolean operators (OR and AND).

Data Management

The results of the literature searches were exported into EndNote 20 where de-duplication and abstract screening were carried out. Following the eligibility criteria, we performed title and abstract screening, and articles that met the inclusion criteria were downloaded. The flow of articles, both included and excluded, were arranged in EndNote 20 for the PRISMA flow chart generation.

Study selection and data extraction

The initial screening of titles and abstracts retrieved were carried out. The PRISMA diagram was used to demonstrate the flow of studies throughout the selection process, as well as the reasons behind exclusions. Relevant data were extracted from the included articles using a pre-designed extraction template.

Risk of bias

We undertook quality appraisal using the Cochrane risk-of-bias tool for randomized trials (RoB 2). It is the recommended tool to assess the risk of bias in randomized trials. This instrument covers seven domains (random sequence generation and allocation concealment for selection bias, blinding of participants and providers for performance bias, blinding of outcome assessor for detection bias, incomplete outcome data for attrition bias, selective outcome reporting for reporting bias, and other sources of bias [24]. It is judged thus: high quality (score 7–9), Scoring from 4–6: high risk of bias (4–6), and express some concern risk (Scoring from 0–3) [25].

Data synthesis

Study characteristics including doses, routes of administration, type of RCT, bleeding risk, gestation age, sample size, and country were summarised using an evidence table (Table 1). We carried out a random-effect meta-analysis with aid of the Comprehensive Meta-Analysis (CMA, version 4) software [26]. The standardized mean difference (SMD) was the effect index and reported together with its 95% confidence interval and *p*-value. We computed the mean and standard deviation for studies that summarized age using median and interquartile ranges using the McGrath calculator [27]. The average of the effect sizes in studies that reported two or more effect sizes (based on doses) from the same population were included as a sample in the meta-analysis [28]. We used a random-effect model to compute the pooled SMD as the true effect size in different studies is expected to be heterogeneous [28]. The model assumes that the studies in the meta-analysis are only a sample of all the possible studies that could be conducted on a particular subject [29], thus allowing statistical inference to be made on studies not included in the analysis [30]. The I^2 statistic was used to assess the heterogeneity of included studies [31]. Higher values indicate that total variability in effect size is accounted by higher heterogeneity and lower sampling error. In event of a substantial degree of heterogeneity, sub-group analyses were conducted to account for the responsible factors.

Table 1
Characteristics of the studies included in systematic review and meta-analysis and meta-analysis

Study ID	Country	Study design	Sample Size (Exposure vs control)	Age (y) (Exposure vs control)	Gestational age (wk)	Elective or emergent	Bleeding risk	Experimental intervention	Comparator intervention	Follow up duration
Abbas et al, 2019	Egypt	Double-blinded, single-centric, placebo-controlled	62 (31 vs 31)	30.6 ± 2.5 vs 30.7 ± 2.8	36.5 ± 0.8 vs 36.6 ± 0.6	Elective	High	1 g TXA IV just before skin incision	Saline just before skin incision	24 h pos
Abd Allah Ali et al. 2019	Egypt	Cohort	200 (100 vs 100)	27.81 ± 5.07 vs 28.32 ± 4.65	38.19 ± 0.7 vs 38.22 ± 1.1		NR	1 g TXA IV, 20 mins before CS	not reported	
Abdel-Aleem et al, 2013	Egypt	Open-label, single-centric	740 (373 vs 367)	26.34 ± 5.16 vs 26.62 ± 5.05	39.32 ± 1.15 vs 39.31 ± 1.17	Elective	Low	1 g TXA 10 min before incision	Standard treatment	24 h pos
Ahmed et al, 2015	Egypt	Open-label, single-centric	124 (62 vs 62)	28.6 ± 5.9 vs 26.9 ± 5.2	38.5 ± 0.7 vs 38.5 ± 0.6	Elective	Low	10 mg/kg TXA 5 min before incision	Standard treatment	1 wk pos
Ali et al. 2021	Egypt	prospective-randomized clinical trial study	92 (46 vs 46)	24.45 ± 5.78 vs 25.80 ± 6.44	NR	NR	Low	1 g TXA IV in 100ml of Ringers lactate solution	10 IU of oxytocin	NR
Bhavana et al, 2016	India	single-centric, placebo-controlled	200 (100 vs 100)	NR	NR	Elective	Low	1 g TXA before anaesthesia	20 mL of normal saline	48 h pos
Bouet et al. 2015	France	Quasi-experiment	159 (60 vs 99)	28 ± 5.7 vs 28 ± 4.7)	40 ± 1.4 vs 39.8 ± 1.8	NR	Low	4 g of TXA intravenously then 1 g hly for 6 h	Standard treatment	NR
Chandak et al. 2017	India	A randomized case controlled prospective study	100 (50 vs 50)	24.3 ± 2.6 vs 23.6 ± 2.5	NR	NR	NR	1 g TXA slowly IV, 20 mins before Skin incision	NR	NR
Chaudhary and Ulla, 2014	Pakistan	Randomised controlled trial	120 (60 vs 60)	23.56 ± 3.82 vs 24.18 ± 3.47	39 ± 2 vs 39 ± 2	NR	NR	1 g TXA, 10 min before incision	NR	2 h post-
Ducloy-Bouthors et al. 2022	USA	double-blind, placebo controlled, randomised, multicentre dose-ranging study	175 (57 vs 58 vs 60)	33.7 ± 5.5 vs 33.1 ± 5.8	37.8 ± 2.3 vs 38.0 ± 2.4	Elective	Both	0.5 g, 1 g TXA	Standard treatment	NR
El-Gaber et al, 2018	Egypt	Double-blinded, single-centric, placebo-controlled	500 (250 vs 250)	27.14 + 4.986 vs 26.77 ± 4.942	38.32 ± 1.124 vs 38.24 ± 1.26	Elective	Low	1 g TXA after birth	Normal saline 0.9%	24 h pos
El-Sttar et al, 2019	Egypt	Open-label, multicentric	150 (75 vs 75)	27.81 ± 5.07 vs 28.32 ± 4.65	38.19 ± 0.70 vs 38.22 ± 1.10	Elective	Low	1 g TXA 10 min before incision	Standard treatment	24 h pos
Fahmy et al, 2021	Egypt	Double-blinded, single-centric,	100 (50 vs 50)	27.60 ± 4.03 vs 26.88 ± 4.55	NR	Elective	Low	2 g TXA, with induction of anaesthesia	Placebo	24 h pos
NR: Not Reported										

Study ID	Country	Study design	Sample Size (Exposure vs control)	Age (y) (Exposure vs control)	Gestational age (wk)	Elective or emergent	Bleeding risk	Experimental intervention	Comparator intervention	Follow up duration
		placebo-controlled								
Gai et al, 2004	China	Open-label, multicentric	180 (91 vs 89)	29.71 ± 4.18 vs 29.75 ± 4.01	38.80 ± 1.11 vs 38.67 ± 1.03	Elective	Low	1 g TXA 10 min before incision	Standard treatment	2 h postpart
Ghosh et al, 2014	India	Double-blinded, multi-centric, Placebo-controlled	140 (70 vs 70)	25.94 ± 3.78 vs 26.04 ± 3.39	38.62 ± 0.78 vs 38.72 ± 0.67	Elective	Low	1 g TXA before skin incision	10 mL sterile water	24 h pos
Gobbur et al. 2014	India	Randomised controlled prospective study	100 (50 vs 50)	23.62 ± 3.43 vs 24.5 ± 3.98	NR		not reported	1 g TXA 20 mins before CS	Normal saline	
Goswami et al, 2013	India	Double-blinded, single-centric, placebo-controlled	90 (30 vs 30 vs 30)	23.6 ± 2.5 vs 24.3 ± 2.6	NR	Elective	Low	10 mg/kg and 20 mg/kg TXA, 20 min before incision	Distilled water in 5% dextrose	24 h pos
Gungorduk et al, 2011	Turkey	Double-blinded, single-centric, placebo-controlled	660 (330 vs 330)	26.3 ± 3.5 vs 26.6 ± 3.6	38.7 ± 0.6 vs 38.8 ± 0.6	Elective	Low	1 g TXA 10 min before incision	5% glucose	6 wk pos
Halder et al. 2013	India	Prospective randomised case-controlled study	100 (50 vs 50)	26.06 ± 2.51 vs 26.04 ± 2.50	NR	NR	NR	1 g TXA IV, 10 mins before CS	NR	NR
Halifa et al, 2021	Nigeria	Double-blinded, single-centric, placebo-controlled	154 (77 vs 77)	31.10 ± 4.28 vs 21.35 ± 4.97	NR	Both	Low	1 g TXA, 10 min before incision	Normal saline	24 h pos
Hemapriya et al, 2020	India	Open-label, single-centric	200 (100 vs 100)	not reported	NR	Elective	Low	10 mg/kg TXA 10 min before incision	Standard treatment	24 h pos
Ibrahim, 2019	Saudi Arabia	Double-blinded, single-centric, placebo-controlled	46 (23 vs 23)	32.3 ± 5.2 vs 30.6 ± 5.7	NR	Elective	High	10 mg/kg TXA over Normal saline 10 min after cord clamping and 10 mg/kg/h continued until skin closure	Normal saline	24 h pos
Ifunanya et al, 2019	Nigeria	Double-blinded, single-centric, placebo-controlled	168 (84 vs 84)	28.2 ± 5.2 vs 28.6 ± 5.4	38 ± 1.5 vs 38 ± 1.3	Both	High	1 g TXA 20 min before incision	20 mL of 0.9% normal saline	6 wk after discharg
Igboke et al. 2022	Nigeria	double-blind randomized placebo-controlled study	162 (78 vs 84)	27.95 ± 5.10 vs 29.95 ± 3.60	39.01 ± 1.38 vs 39.01 ± 1.33	Elective	Low	1 g TXA, IV 2 mins after birth	Placebo	2 h of de
Jafarbegloo et al, 2021	Iran	Double-blinded, single-	50 (25 vs 25)	30.48 ± 4.71 vs	38.24 ± 0.44 vs	Elective	Low	1 g TXA IV 10 min	Distilled water	42–72 h delivery
NR: Not Reported										

Study ID	Country	Study design	Sample Size (Exposure vs control)	Age (y) (Exposure vs control)	Gestational age (wk)	Elective or emergent	Bleeding risk	Experimental intervention	Comparator intervention	Follow up duration
		centric, placebo-controlled		31.46 ± 4.85	37.83 ± 1.76			before incision		
Kafayat et al, 2018	Pakistan	Open-label, single-centric	62 (31 vs 31)	28.13 ± 4.79 vs 27.38 ± 4.80	39.07 ± 1.07 vs 39.24 ± 1.26	Elective	Low	1 g TXA over 10 min at the time of skin incision	Standard treatment	2 h after
Kamel et al, 2018	Egypt	Open-label, single-centric	300 (150 vs 150)	29.39 ± 3.84 vs 29.82 ± 3.94	39.49 ± 1.01 vs 39.29 ± 1.01	Elective	Low	1 g TXA 20 min before incision	Standard treatment	NR
Lakshmi and Abraham, 2016	India	Open-label, single-centric	120 (60 vs 60)	26.77 ± 2.807 vs 26.82 ± 2.801	NR	Elective	Low	1 g TXA 20 min before incision	Standard treatment	24 h pos
Maged et al, 2015	Egypt	Single-blinded, single-centric, placebo-controlled	200 (100 vs 100)	24.9 ± 4.6 vs 25.3 ± 4.7	NR	Elective	Low	1 g TXA 15 min before incision	Placebo	4 wk after delivery
Malathi et al, 2016	India	Open-label, single-centric	200 (100 vs 100)	23.40 ± 3.06 vs 23.59 ± 3.56	NR	Elective	Low	10 mg/kg TXA 15–20 min before incision	Standard treatment	24 h pos
Mayur et al, 2007	India	Randomised case-controlled prospective study	100 (50 vs 50)	24.3 ± 3.65 vs 24.89 ± 3.99	38.85 ± 1.29 vs 38.64 ± 1.24		NR	1 g TXA IV, 20 mins before CS	Normal saline	
Milani et al, 2019	Iran	Double-blinded, single-centric, placebo-controlled	60 (30 vs 30)	29.33 ± 5.59 vs 31.2 ± 5.53	37.93 ± 0.69 vs 37.86 ± 0.80	Elective	Low	1 g TXA 15 min before incision	5% dextrose in water	Within 1 h post-op
Movafegh et al, 2011	Iran	Double-blinded, single-centric, placebo-controlled	100 (50 vs 50)	27.0 ± 3.4 vs 27.6 ± 4.1	38.9 ± 0.4 vs 39.0 ± 0.6	Elective	Low	10 mg/kg TXA 20 min before anesthesia	200 mL normal saline	24 h pos
Naeiji et al, 2021	Iran	Double-blinded, single-centric, placebo-controlled	200 (100 vs 100)	27.2 vs 27.9	38.7 vs 38.5	Elective	Low	1 g TXA, before incision	5% dextrose solution	6 h post-solution
Nargis and Dewan, 2020	Bangladesh	Double-blinded, single-centric, placebo-controlled	120 (60 vs 60)	25.34 ± 3.8 vs 25.68 ± 3.3	38.84 ± 1.28 vs 38.6 ± 1.67	Elective	Low	1 g TXA, immediately after delivery	Distilled water	24 h postoper
Obi et al, 2019	Nigeria	Double-blinded, multi-centric, Placebo-controlled	115 (57 vs 58)	29.5 ± 4.8 vs 28.2 ± 3.7	39.6 ± 1.5 vs 39.3 ± 1.4	Elective	Low	1 g TXA 20 min before incision	Distilled water	48 h pos
Ogunkua et al, 2022	United States	Double-blinded, single-centric, placebo-controlled	110 (55 vs 55)	29.8 ± 5.2 vs 28.7 ± 5.2	NR	Elective	Low	1 g TXA, 10 min before incision	Normal saline	24 h after deliver
NR: Not Reported										

Study ID	Country	Study design	Sample Size (Exposure vs control)	Age (y) (Exposure vs control)	Gestational age (wk)	Elective or emergent	Bleeding risk	Experimental intervention	Comparator intervention	Follow up duration
Oseni et al, 2021	Nigeria	Double-blinded, single-centric, placebo-controlled	244 (122 vs 122)	27.6 ± 4.6 vs 27.5 ± 4.6	39.2 ± 1.1 vs 39.4 ± 1.1	Emergent	Low	1 g TXA IV 5 min before incision	Normal saline	5 d post-
Poonia et al. 2012	India	Randomised case controlled study	100 (50 vs 50)	NR	between 38 weeks and 40 weeks	NR	NR	10 mg/kg TXA IV, 20 mins before CS	Normal saline	
Ramani and Nayak, 2014	India	Open-label, single-centric	120 (60 vs 60)	24.9 ± 3.9 vs 24.4 ± 3.7	not reported	Emergent	Low	1 g TXA 10 min before incision	Standard treatment	7 d post-
Rani et al. 2021	India	Open-label, placebo-controlled study	100 (50 vs 50)	25.0 ± 4.71 vs 25.88 ± 5.39	38.92 ± 1.38 vs 39.02 ± 1.42	Elective	Both	1 g TXA, 20 min before incision	5% glucose	2 h post-
Rashmi et al. 2010	India	Randomised case controlled study	100 (50 vs 50)	25.70 ± 3.70 vs 25.10 ± 4.73	37.85 ± 1.09 vs 37.80 ± 0.95		NR	1 g TXA IV, 30 mins before CS	Normal saline	
Ray et al, 2016	India	single-centric, placebo-controlled	100 (50 vs 50)	25.00 ± 4.71 vs 25.88 ± 5.39	38.92 ± 1.38 vs 39.02 ± 1.42	Elective	Low	1 g TXA 20 min before anaesthesia	5% dextrose solution	24 h pos
Rushulo et al. 2016	India	Prospective Randomised controlled study	60 (30 vs 30)	26.6 ± 5.0 vs 28.8 ± 4.7	NR	NR	NR	10mg/kg TXA, IV, 10 mins before skin incision	Normal saline	NR
Sanad et al, 2020	Egypt	Open-label, multicentric	74 (37 vs 37)	26.08 ± 3.53 vs 26.68 ± 3.05	38.95 ± 1.03 vs 38.73 ± 1.19	Elective	Low	1 g TXA, 10 min before incision	Standard treatment	4 h post-
Sekhavat et al. 2009	Iran	Prospective Randomised controlled study	90 (45 vs 45)	26.2 ± 4.7 vs 27.1 ± 4.1	38.8 ± 0.6 vs 38.7 ± 0.6	NR	NR	1 g TXA IV, 10 mins before CS	5% glucose	
Sentilhes et al, 2021	France	Double-blinded, single-centric, placebo-controlled	4431 (2086 vs 2067)	33.3 ± 5.3 vs 33.3 ± 5.3	39(38–40)	Both	Low	1 g TXA 3 min after birth	Placebo	3 mo aft delivery
Senturk et al, 2013	Turkey	single-centric, placebo-controlled	223 (101 vs 122)	30.20 ± 6.83 vs 29.22 ± 6.93	NR	Both	Low	1 g TXA 10 min before incision	5% dextrose solution	8 h post-
Shabir et al, 2019	Pakistan	Single-centric, placebo-controlled	100 (50 vs 50)	26.02 ± 4.69 vs 26.79 ± 5.39	37.95 ± 1.41 vs 38.97 ± 1.44	Elective	Low	1 g TXA, 20 min before anaesthesia	5% dextrose	24 h pos
Shady and Sallam, 2017	Egypt	Double-blinded, single-centric, placebo-controlled	120 (40 vs 40 vs 40)	29.6 ± 2.68 vs 29.5 ± 2.42	36.45 ± 0.9 vs 36.38 ± 0.87	Both	High	1 g TXA IV just before anaesthesia	Placebo	24 h pos
Shahid and Khan, 2013	Pakistan	Double-blinded, multi-centric, Placebo-controlled	74 (38 vs 36)	24.18 ± 3.93 vs 24.89 ± 4.16	38.32 ± 0.80 vs 38.47 ± 0.910	Elective	Low	1 g TXA 10 min before incision	Distilled water	3 d post-
NR: Not Reported										

Study ID	Country	Study design	Sample Size (Exposure vs control)	Age (y) (Exposure vs control)	Gestational age (wk)	Elective or emergent	Bleeding risk	Experimental intervention	Comparator intervention	Follow up duration
Shakur-Still et al. 2023	Zambia and Pakistan	Randomised controlled trial	120 (30 vs 30 vs 30)	31 ± 5 vs 32 ± 5	NR	Elective	Low	1 g IV, 1 g IM, 4 g oral TXA	No TXA	24 hours randomi:
Shalabi et al, 2020	Egypt	Double-blinded, multi-centric, placebo-controlled	200 (100 vs 100)	28.41 ± 4.63 vs 29.12 ± 5.54	38.54 ± 0.64 vs 38.76 ± 1.00	Elective	Low	1 g TXA, 10 min before incision	5% glucose	24 h postpart
Shalaby et al, 2022	Egypt	Double-blinded, single-centric, placebo-controlled	160 (80 vs 80)	28.9 ± 4.6 vs 28.5 ± 4.45	38.1 ± 1.1 vs 39.1 ± 1.1	Elective	High	1 g TXA, diluted in 20mL glucose 5% 15 min before surgery	30 mL of glucose 5%	48 h, re-examina done at 4 wk after discharg
Sharma et al, 2011	India	Open-label, single-centric	100 (50 vs 50)	25.63 ± 3.72 vs 25.88 ± 3.8	39.25 ± 0.99 vs 39.06 ± 1.12	Both	Low	1 g TXA 5 min before incision	Standard treatment	3 d post-
Soliman et al, 2021	Egypt	Open-label, single-centric	100 (50 vs 50)	21.46 ± 2.71 vs 21.46 ± 2.71	39.34 ± 0.47 vs 39.28 ± 0.45	Elective	Low	1 g TXA, 20 min before incision	Standard treatment	24 h pos
Sujata et al, 2016	India	Double-blinded, single-centric, placebo-controlled	60 (30 vs 30)	29.40 ± 4.16 vs 30.27 ± 4.31	NR	Both	High	10 mg/kg TXA 10 min before incision	Normal saline	48 h pos
Tabatabaie et al, 2021	Iran	Multi-centric, placebo-controlled	300 (100 vs 100 vs 100)	NR	NR	Elective	Low	10 mg/kg TXA 20 min before incision	Normal saline	24 h pos
Taj et al, 2014	Pakistan	single-centric, placebo-controlled	120 (60 vs 60)	23.56 ± 3.82 vs 24.18 ± 3.47	39 ± 2 vs 39 ± 2	Elective	Low	1 g TXA 20 min before incision	Standard treatment	2 h post-
Thavare and Patil, 2019	India	Open-label, single-centric	100 (50 vs 50)	NR	NR	not reported	Low	1 g TXA, 20 min before incision	Standard treatment	2 h postpart
Torky et al, 2021	Egypt	Double-blinded, multi-centric, Placebo-controlled	180 (60 vs 60 vs 60)	30.7 ± 4.66 vs 30.8 ± 4.37	NR	Elective	Low	1 g TXA, 20 min before incision	Normal saline	24 h pos
Xu et al, 2013	China	Double-blinded, multi-centric, Placebo-controlled	174 (88 vs 86)	26.7 ± 3.7 vs 27.1 ± 4.1	38.7 ± 1.0 vs 38.8 ± 1.1	Electiv NR: Not	Low	10 mg/kg TXA 20 min before anaesthesia	200 mL normal saline	24 h pos
Yehia et al, 2014	Egypt	Double-blinded, single-centric, placebo-controlled	212 (106 vs 106)	28.4 ± 4.9 vs 28.6 ± 4.7	39.1 ± 1.1 vs 39.0 ± 1.2	Elective	Low	1 g TXA with anaesthesia	Placebo	24 h pos
NR: Not Reported										

Meta-bias & meta-regression

Publication bias was examined by visual inspection of the funnel plot. Furthermore, a statistical approach using Egger's test was used to test the symmetry of the funnel plot. Non-significant test statistic shows funnel plot symmetry, which reflects no publication bias [32].

Confidence in cumulative evidence

The quality of evidence for the efficacy of TXA for the prevention and treatment of PPH was examined using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [33, 34]. The GRADE rates the quality of evidence into high, moderate, low, or very low, based on the confidence in the synthesized effect estimate. The overall confidence in the synthesized effect estimate is a summary of risk of bias, publication bias, imprecision, indirectness of evidence, and inconsistency of results.

Results

Review profile and study characteristics

We identified 648 records. After duplicate removal and title and abstract screening, and full-text screening, a total of 63 studies met the eligibility criteria and were included in the review (Fig. 1). Of the 63 studies, 57 (90.5%) were randomized controlled trial, 4 (6.3%) were randomized case-controlled prospective studies while one each was a cohort and pre-post quasi-experiment (Table 1). Eighteen each of the 63 studies were conducted in Egypt and India, seven studies were conducted in Iran, five each of the studies were conducted in Nigeria and Pakistan, while two each of the studies were carried out in Turkey and United States. About half of the study were doubled blinded randomised controlled trials. We include sixty-three studies in the meta-analysis, out of which sixty investigated the prophylactic efficacy of tranexamic acid for postpartum hemorrhage following cesarean section and three investigated the prophylactic efficacy of tranexamic acid for postpartum hemorrhage following vagina delivery. A total of 7029 participants were included in the study (Table 1). The mean ages for the exposed and control groups were 27.35 ± 2.60 years and 27.37 ± 2.6 years, respectively. The mean gestation ages for the exposed and control groups were 38.61 ± 0.71 weeks and 38.65 ± 0.68 weeks. Over 80% were at low risk of bleeding and received 1g of intravenous (IV) TXA, in line with the WHO [17] recommendations. Of the cesarean section studies, over 50% of the studies reported a follow-up period of 24 hours post-operation (Table 1).

Efficacy of tranexamic acid for post-partum hemorrhage

Of the 61 studies involved in the meta-analysis, 57 (93.4%) reported statistically significant reduction in volume of blood loss, with effect size (SMD) ranging from 0.395 (Mirghafourv et al. 2015) and -16.388 (Chaudhary and Ulla 2014). Overall, there was a statistically significant reduction in PPH in response to TXA (SMD = -1.800 (95% CI: 0.133 to -2.060). We observed a substantial degree of heterogeneity ($I^2 = 97.754$) (Fig. 2). Sub-group analysis revealed that TXA possesses better therapeutic effect for cesarean section [-1.840 (95% CI: -2.109 to -1.570), $I^2 = 97.821$], compared to vaginal delivery (-1.090 (0.547 to -2.162 , $I^2 = 97.821$) (Fig. 3a&3b).

Examining the putative influence of dose, mode of delivery, bleed risk status and sample size on the prophylactic efficacy of tranexamic acid for postpartum hemorrhage

Following the substantial degree of heterogeneity observed in our study, we conducted several sub-group analysis to explore the possible causes of the variation in reported study effects. Results showed that studies which employed a loading dose of 10mg/Kg followed by an infusion dose of 1 performed reported a larger aggregate effect estimate (SMD = -2.46 95% CI -3.37 to -1.56 ; $I^2 = 97.64\%$) than the overall pooled study effect (Fig. 4). The aggregate effect estimates for studies conducted in high-income countries (-0.264 95% CI -0.504 to -0.024 ; $I^2 = 61.83\%$) (Fig. 5), and (Fig. 6), those with a greater percentage of women with a high bleeding risk (SMD = -1.35 95% CI -2.28 to -0.42 ; $I^2 = 95.95\%$) (Fig. 7) reported a smaller aggregate effect estimates smaller than the overall pooled study effect. Result shows a greater a larger effect estimate size in studies with sample size greater than 100 (SMD = -1.57 95% CI -1.996 to -1.135 ; $I^2 = 89.87\%$) compared to the overall study effect (Fig. 7).

Discussion

The finding that TXA possesses a large therapeutic effect for PPH is suggestive of its role as an important antifibrinolytic agent for care of PPH. This is consistent with previous reviews [35–37]. According to Al-dardery et al. [35], the prophylactic use of TXA following vaginal delivery was associated with lower total blood loss, with a large effect to the tune of MD= -1.800 mL, 95% CI [0.133 to -2.060]. In Cheema et al. [36], TXA reduced the risk for blood loss > 1000 mL by 26% following cesarean section, with a pooled mean difference in total blood loss of 179.97mL in low risk group to 377.89 mL in high risk group, thus reducing the need for blood transfusion in both low- and high-risk patients. Furthermore, tranexamic acid is associated with a beneficial effect in the secondary outcomes, including a decline in hemoglobin levels. Our finding is consistent with the World Health Organisation recommendation of early use of intravenous tranexamic acid (TXA) within 3 hours of birth in addition to standard care for women with clinically diagnosed postpartum haemorrhage (PPH) following vaginal birth or caesarean section [18]. According to WHO [18], the administration of TXA should be considered as part of the standard PPH treatment package and it be administered as soon as possible after onset of bleeding and within 3 hours of birth. It further recommends that TXA for PPH treatment should not be initiated more than 3 hours after birth, and should be should be used in all cases of PPH, regardless of whether the bleeding is due to genital tract trauma or other causes [18]. While our study supports the WHO's recommendations, we argue that recommended flat 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 1g IV if bleeding continues after 30 minutes does not reflect the variation in the efficacy of TXA with respect to mode of variation. With our sub-group analysis showing a stronger efficacy of TXA for bleeding following caesarean section compared with bleeding following vaginal delivery, we argue that there is a need for dose adjustment as per the mode of delivery to further optimize its therapeutic efficacy whilst reducing the potential adverse effects. This is substantiated by the evidence from a sub-group analysis revealing a larger effect, 1.5 times the overall effect estimate, for patients treated with a dose of 10mg/kg followed by infusion dose of 1 mg.kg⁻¹.h⁻¹. Although one may argue that the WHO's recommendation provides a room for dose adjustment over the treatment period. However, the fact that treatment delay in use of TXA reduces TXA benefit indicative of the need for timeliness in dose optimization. TXA benefit appears to decrease by 10% for every 15-minute delay, with no benefit seen after 3 hours [18]. The best dose of tranexamic acid for this purpose remains unknown [38] However, doses larger than loading dose of 10 mg.kg⁻¹ followed by 1 mg.kg⁻¹.h⁻¹ do not provide additional hemostatic benefit [38].

The substantial degree of heterogeneity recorded in our study is indicative of clinical and methodological diversity including varying dose response with two clear divides namely the fixed dose of 1 g in 10 mL and the loading dose of 10mg/Kg followed by an infusion dose of 1 mg.kg-1.h-1, varying sample size with large studies possessing higher effect sizes compared to studies with small studies size less than 100, and bleeding risk; studies in which participants were of high bleeding risk reported pooled smaller effects (SMD=-1.35) smaller than the overall. Although this finding contradicts Cheema et al. [36], which reported greater benefits of TXA in women with higher bleeding risk compared to those with lesser bleeding risk. The disparity might stem from the fact that Cheema was limited to studying the prophylactic effects of TXA hemorrhage during cesarean section unlike ours that combined both vaginal delivery and cesarean section. Putting it together, our study might indicate that low risk group could benefit from TXA as much as the high-risk group. Also, study setting contributed to the substantial heterogeneity recorded in this study, with studies conducted in high income countries possessing small effect compared to the low- and middle-income counterpart. This could be due to the fact that in our study, only 15.1% of the included low- and middle-income countries studies were limited to women with a high risk of bleeding compared to 25% in studies conducted in high-income countries.

Strength and limitations

The study draws its strength from employing meta-analysis to answer the research question. However, the substantial degree of heterogeneity and publication bias constitute a weakness. Nonetheless, we employed-group analyses in an attempt to account for the possible causes of the substantial heterogeneity recorded in our study. The fact that the included studies were mainly of low and middle income origins constitute a limitation and might explain the publication as the propensity for publication bias is higher in low and middle income countries compared to high income countries [39, 40].

Conclusions

Tranexamic acid possesses a moderate to high efficacy for PPH. However, several factors including optimal dose vis-à-vis mode of delivery and bleeding risk status are yet to be established. In the meantime, a loading dose of 10mg/Kg followed by an infusion dose of 1 mg.kg-1.h-1 performed better than a fixed dose of 1 g in 10 mL (100 mg/mL) IV at 1 mL per minute.

Recommendations

We recommend that further dose-response multinational randomised controlled trials be undertaken to unravel the optimal dose of TXA for haemorrhage following both cesarean and vaginal delivery. Such studies should employ stratification to account for factors responsible for heterogeneity such as bleeding risk status, mode of delivery, study settings (low and middle income versus high-income income countries), amongst others. In the meantime, we recommend a loading dose of 10mg/Kg followed by an infusion dose of 1 mg.kg-1.h-1 might be more benefit particularly those with high bleeding risk compared to a fixed dose of 1 g in 10 mL (100 mg/mL) IV at 1 mL per minute (i.e., administered over 10 minutes). By implication, we recommend that bleed risk assessment be undertaken in all cases before the administration of TXA.

Declarations

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Figures

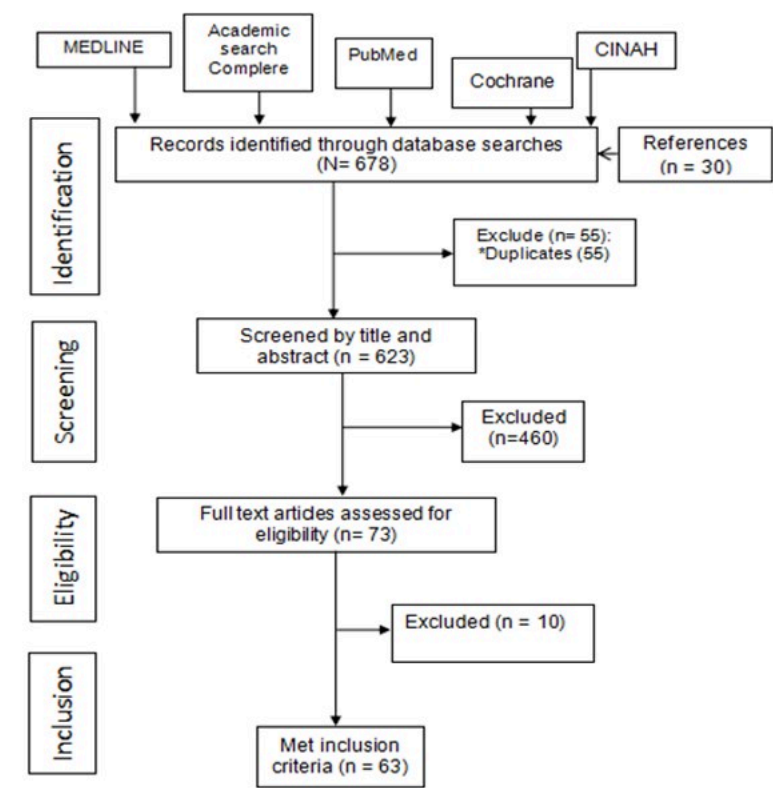


Figure 1

Figure 1. PRISMA flow diagram for systematic review and meta-analysis of prophylactic efficacy of tranexamic acid for postpartum haemorrhage (2004-2023)

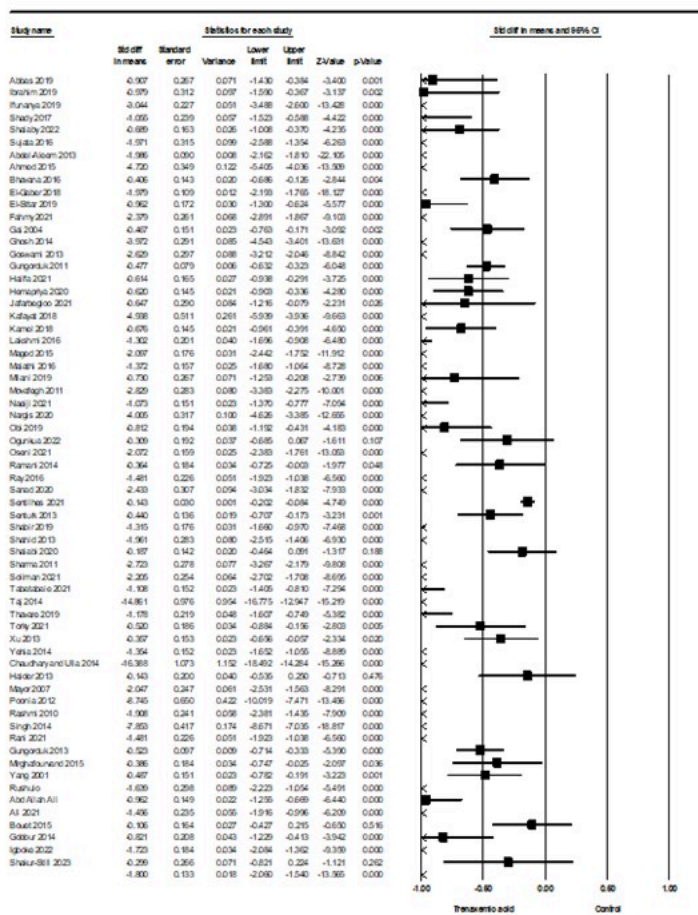


Figure 2

Figure 2: Forest plot displaying efficacy of Tranexamic acid for postpartum haemorrhage

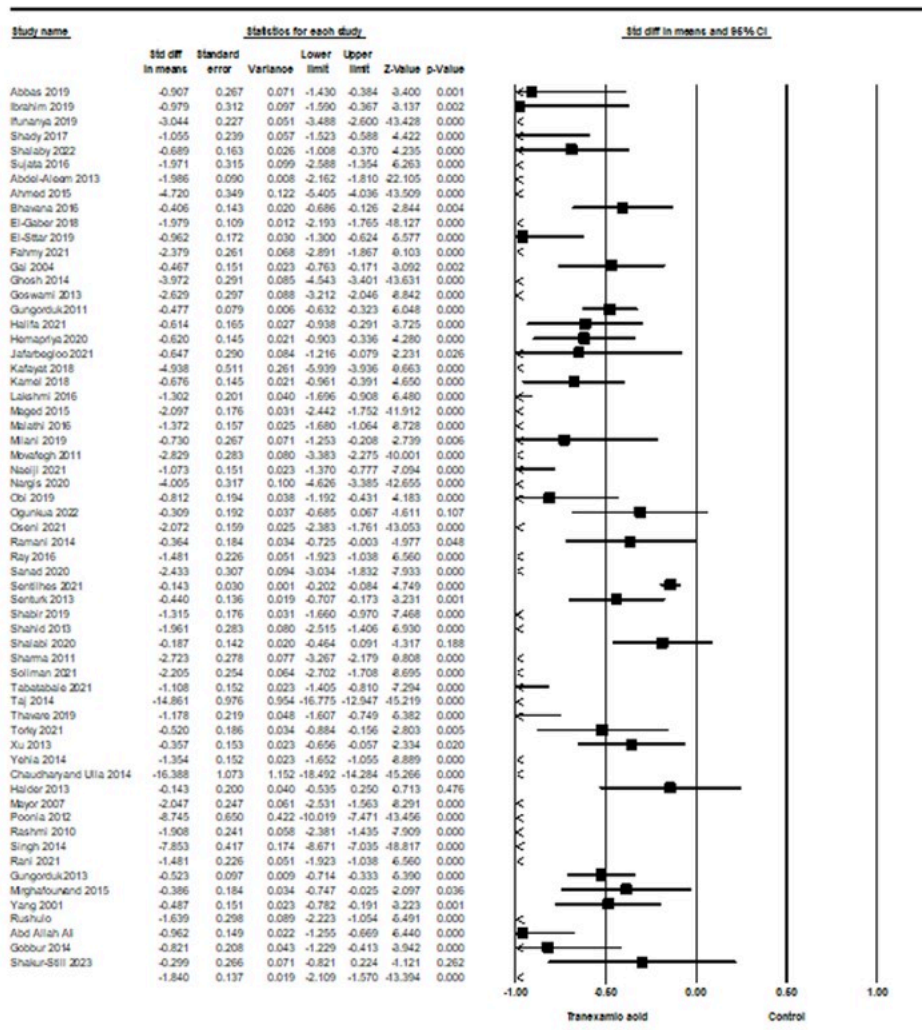


Figure 3

Figure 3a: Forest plot displaying sub-group analysis of the efficacy of Tranexamic acid for postpartum haemorrhage following cesarean section.

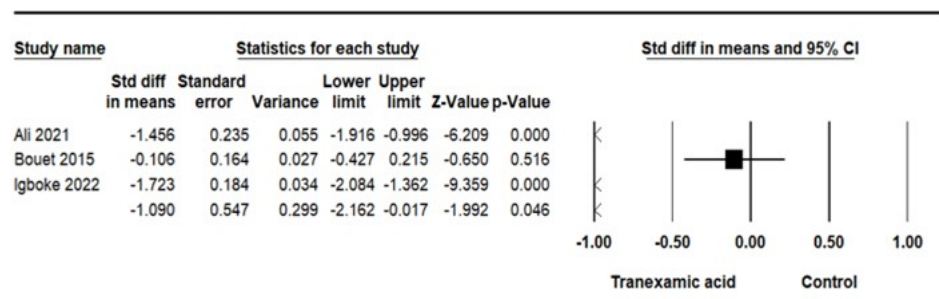


Figure 4

Figure 3b: Forest plot displaying sub-group analysis of the efficacy of Tranexamic acid for postpartum haemorrhage following vaginal delivery.

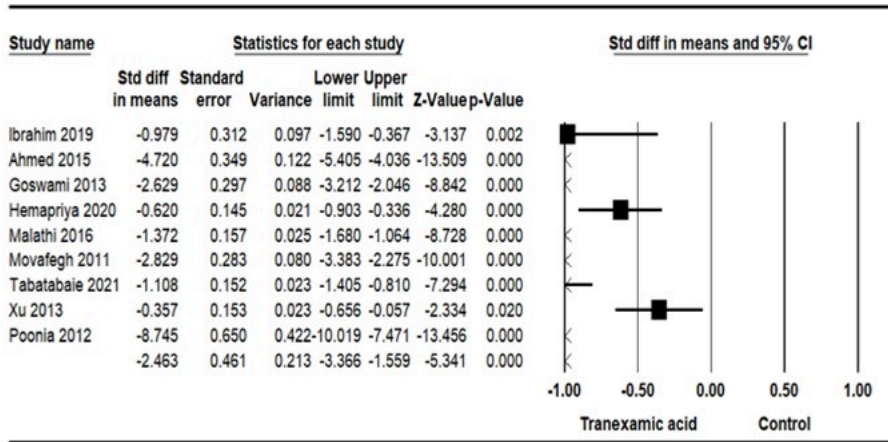


Figure 5

Figure 4: Forest plot displaying sub-group analysis of the efficacy of tranexamic acid for (dose of 10mg/kg) for postpartum haemorrhage ($I^2 = 97.64$)

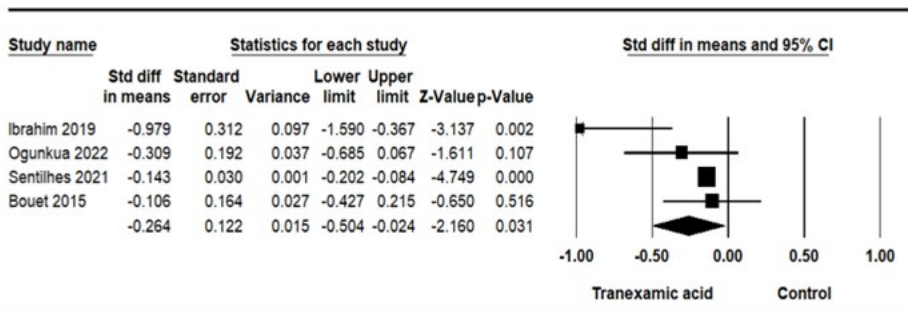


Figure 6

Figure 5: Forest plot displaying sub-group analysis of the efficacy of tranexamic acid for postpartum haemorrhage in high income countries ($I^2 = 61.38$)

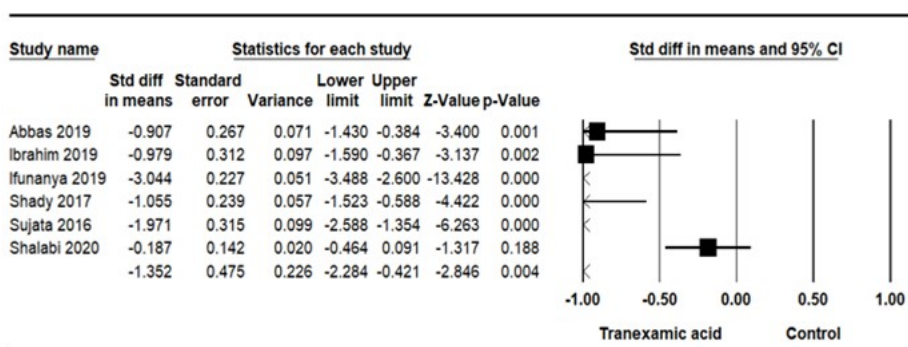


Figure 7

Figure 6: Forest plot displaying sub-group analysis of the efficacy of tranexamic acid for postpartum haemorrhage in studies with high bleeding risk ($I^2 = 95.95$)

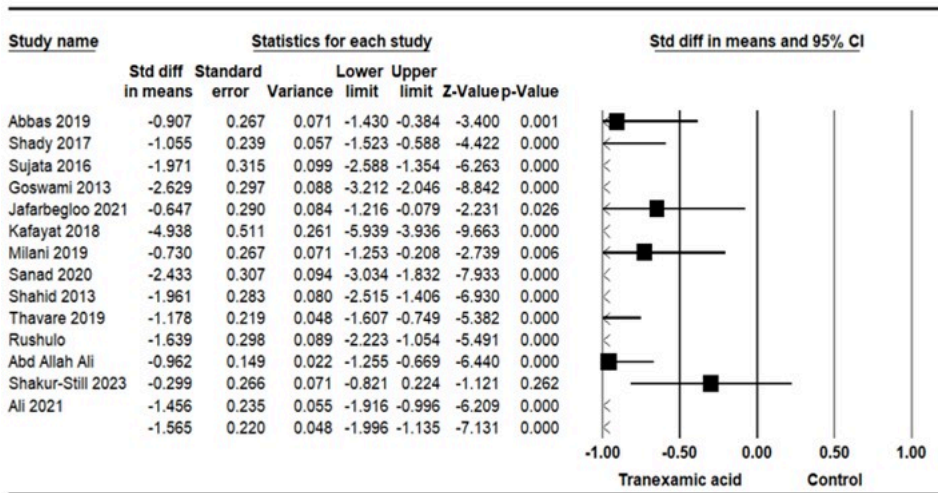


Figure 8

Figure 7: Forest plot displaying sub-group analysis of the efficacy of Tranexamic acid for postpartum haemorrhage as in the studies with sample size less than 100 ($I^2 = 89.87$)