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EFFECTIVITY OF INTRAVENOUS TRANEXAMIC ACID IN ADDITION TO OXYTOCIN ON BLOOD LOSS DURING AND AFTER CAESAREAN DELIVERY"- A RCT

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ABSTRACT

Introduction: "The Reasons behind Mothers' Deaths" Maternal mortality linked to postpartum hemorrhage (PPH) increased dramatically between 2000 and 2002, from one incidence in 1997–1999 to ten instances in the most recent triennial. 2, 830 women perish per day from complications associated with pregnancy or delivery, according to WHO statistics. In 2015, there were an estimated 303000 maternal deaths worldwide, with PPH contributing to around 25% of these deaths.

Aims: In order to minimize maternal mortality and morbidity from blood loss during cesarean birth, it is important to investigate the effectiveness of intravenous tranexamic acid administration in minimizing blood loss during and after the procedure.

Methods: From January 2021 to June 2022, 100 women scheduled for elective cesarean birth at the Department of Obstetrics & Gynecology, Burdwan Medical College and Hospital, participated in a prospective, randomized, placebo-controlled trial. The study group, consisting of 50 participants, was administered 1 gram of intravenous tranexamic acid dissolved in a 20 milliliters solution of 5% Dextrose. The control group, also consisting of 50 participants, got an intravenous placebo, which was a 30 milliliters solution of 5% Dextrose. Tranexamic acid and a placebo were administered intravenously for a duration of 5 minutes, specifically 20 minutes prior to the initiation of spinal anaesthesia. Following delivery, 500 milliliters of normal saline were mixed with 10 units of oxytocin for each patient. Over the

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course of 20 to 30 minutes, an intravenous injection of oxytocin was given. Ten more oxytocin units were added to the intravenous fluid infusion that followed. Furthermore, for a full twelve hours following surgery, each patient received fifteen units of oxytocin, five of which were given to each intravenous fluid bottle for three consecutive bottles. The amount of blood lost during the procedure, the amount lost in the two hours after delivery, the total amount lost during the entire operation (including intra-operative and post-operative losses), and the difference in packed cell volume (PCV) values before and after the procedure were the main variables evaluated.

Results: When compared to the control group, the study group showed substantially reduced amounts of intraoperative and postpartum blood loss. The trial group lost just 512.31 ± 60.16 mL and 65.94 ± 8.04 ml during the surgery and after delivery, compared to the control group's 731.42 ± 80.27 mL and 114.46 ± 15.65 mL, respectively. In all situations, these differences were statistically significant ($P < 0.001$), suggesting a substantial difference between the two groups. In comparison to the control group, the study group showed a significantly smaller difference in Packed Cell Volume values between the preoperative and postoperative phases (1.13 ± 0.48 versus 3.75 ± 1.16; $P <0.001$). In both groups, the average Apgar scores were comparable at 1 minute (6.56 ± 1.51 vs 6.37 ± 1.43, P=0.509) and 5 minutes (8.59 ± 0.99 vs 8.42 ± 1.17, P=0.243).

Conclusion: Tranexamic acid lowers blood loss during and after lower segment caesarean sections considerably, without adversely affecting the health of the mother or the infant.

Keywords: Caesarean Delivery, Intravenous Tranexamic Acid, Oxytocin, Blood Loss, Effectiveness and Randomized Controlled Trial (RCT)

INTRODUCTION

Postpartum hemorrhage (PPH) is a major cause of maternal death; the number of instances increased from one in 1997–1999 to ten in the most recent three-year period[1], according to the research "Why Mothers Die" (2000–2002).According to WHO figures [2], 830 women die per day from problems connected to pregnancy or childbirth. Global estimates for maternal mortality in 2015 indicated that over 303,000 deaths occurred, with postpartum hemorrhage (PPH) contributing to over 25% of these deaths. Maternal mortality has dropped dramatically in wealthy nations, but in Sub-Saharan Africa, it is still shockingly high at more than 1000 deaths per 100,000 live births. In India, the MMR (mother mortality ratio) dropped from 113 in 2016–18 to 103 in 2017–19. The data shown is in line with the MMR special bulletin that the Registrar General of India released on March 14, 2022. Maternal mortality is quite high in seven Indian states. Rajasthan, Uttar Pradesh, Madhya Pradesh, Chhattisgarh, Bihar, Odisha, and Assam are among the states. A rate of 130 or more maternal deaths per 100,000 live births is referred described as a "very high" maternal mortality ratio (MMR). West Bengal, Punjab, and Uttarakhand have high MMRs. This translates to a 100–130 death rate per 100,000 live births for mothers. With 71–100 maternal deaths per 100,000 live births, Haryana and Karnataka have relatively low rates of maternal mortality.

Obstetric hemorrhage is the major cause of maternal mortality globally. Approximately 1-2% of the 14 million mothers who suffer from postpartum hemorrhage each year pass away from it, usually in less than two hours after the hemorrhage begins. [3].

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Postpartum hemorrhage (PPH) is defined as blood loss after a vaginal birth that is more than 500 milliliters and more than 1000 milliliters after a cesarean delivery for quantitative reasons. On the other hand, clinically speaking, it is any bleeding into or out of the vaginal tract following childbirth and to the end of the puerperium that negatively impacts the mother's overall health and is characterized by a drop in blood pressure and an accelerated pulse rate. A more accurate description of PPH has been offered by the American College of Obstetrics and Gynecology, which states that it is defined as a 10% or more fall in hematocrit levels or the need for a blood transfusion. [4]

MATERIALS AND METHODS

STUDY AREA: The study was carried out in the Dept. Of Obstetrics and Gynaecology, BURDWAN MEDICAL COLLEGE AND HOSPITAL.

STUDY POPULATION:

Patients admitted in labour ward of BURDWAN MEDICAL COLLEGE AND HOSPITAL for delivery.

STUDY DESIGN:

This clinical study is placebo-controlled and randomized. A random number table is used to divide the patients equally into two groups. First, 50 patients get 1g (10 ml) of intravenous tranexamic acid dissolved in 20 ml of 5% Dextrose solution. This group is referred to as the study group. Fifty patients make up the second group, also known as the control group, and they are given a placebo in the form of 30 milliliters of 5% Dextrose solution.

TIME FRAME:

The time frame for this investigation was from January 2021 to June 2022.

INCLUSION CRITERIA:

1) Women in their twenties to forties who are carrying a single baby to term (37 weeks or more along) without any known medical complications.
2) Patient giving written informed consent.

EXCLUSION CRITERIA:

i. Pregnancy complications such as pre-eclampsia, polyhydramnios, multiple pregnancy, and macrosomia.

ii. Abnormal placenta conditions, such as placenta praevia and placental abruption.

iii. Severe medical and surgical complications affecting the heart, liver, or kidney, brain diseases, blood abnormalities, clotting disorders, and severe anaemia.

iv. Previous occurance of thromboembolic diseases

v. Tranexamic acid hypersensitivity

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RESULT

Table 01. Distribution of mean with all parameters

	GROUP			
	Case	Control		
	Mean ± Std. Deviation	Mean ± Std. Deviation	p Value	Significance
Age (years)	23.21 ± 3.12	23.54 ± 3.74	0.551	Not Significant
Weight(kg)	64.61 ± 5.26	64.57 ± 6.07	0.826	Not Significant
Height(meter)	1.42 ± 0.11	1.51 ± 0.13	0.894	Not Significant

Table 02. Association between Gravida, parity and Pre-OP Pallor

		GROUP		Total	p Value	Significance
		Case	Control			
Gravida	1	22(44)	21(42)	43(43)	0.896	Not Significant
	2	23(46)	25(50)	48(48)		
	3	5(10)	4(8)	9(18)		
Total		50(100)	50(100)	100(100)		
Parity	0	25(50)	27(54)	52(52)	0.861	Not Significant
	1	22(44)	21(42)	43(43)		
	2	3(6)	2(4)	5(5)		
Total		50(100)	50(100)	100(100)		
Pre-OP Pallor	ABSENT	28(56)	24(48)	52(52)	0.907	Not Significant
	PRESENT	22(44)	26(52)	48(48)		
Total		50(100)	50(100)	100(100)		

Table 03. Distribution of patients based on pre-operative vitals, based on pre op haematological parameter and all blood volume inml

		Group			
		Case	Control		
		Mean ± Std. Deviation	Mean ± Std. Deviation	p Value	Significance
based on pre-operative vitals	Pulse Pre-Operative (min)	81.41 ± 7.05	81.53 ± 7.13	0.967	Not Significant
	Systolic Blood pressure(SBP) Pre operative [mmHg]	114.16 ± 6.22	114.34 ± 6.28	0.908	Not Significant

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	Diastolic Blood Pressure(DBP) Pre operative [mmHg]	74.8 ± 4.46	74.5 ± 4.67	0.853	Not Significant
based on pre op haematological parameter	Respiratory Rate Preoperative(RR)	13.83 ± 1.48	13.76 ± 1.44	0.799	Not Significant
	PreopHaemoglobin (gm%)	10.16 ± 1.23	10.22 ± 1.19	0.776	Not Significant
	Pre op Packed Cell Volume (PCV)(%)	35.11 ± 3.27	35.09 ± 3.21	0.817	Not Significant
	Pre op Total RBC (million cells/cc)	4.08 ± 0.41	3.99 ± 0.37	0.607	Not Significant
	Pre op Platelet Count (lakh/cc)	2.05 ± 0.57	2.01 ± 0.49	0.992	Not Significant
	Pre op Bleeding Time (BT)[minute]	3.14 ± 0.82	3.19 ± 0.86	0.924	Not Significant
	Pre op Clotting Time(CT)[minute]	9.82 ± 1.12	9.79 ± 1.18	0.908	Not Significant
All blood volume in ml	Blood in Suction	103.44 ± 24.13	232.51 ± 35.28	<0.001	Significant
	Blood in Mops + sheets	412.62 ± 51.49	501.09 ± 72.44	<0.001	Significant
	Total Intra Operative Blood loss	512.31 ± 60.16	731.42 ± 80.27	<0.001	Significant
	Post-Operative Blood loss	65.94 ± 8.04	114.46 ± 15.65	<0.001	Significant
	Total Blood Loss Intra + Post-Operative	577.12 ± 62.84	846.17 ± 100.33	<0.001	Significant

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Table 04: Distribution of patients based on APGAR scores of newborn:

	Group			
	Case	Control		
	Mean ± Std. Deviation	Mean ± Std. Deviation	p Value	Significance
APGAR 1min	6.56 ± 1.51	6.37 ± 1.43	0.509	Not Significant
APGAR 5mins	8.59 ± 0.99	8.42 ± 1.17	0.243	Not Significant

Table 05. Post-operative distribution of pallor in the study and control groups

		Group		Total	p Value	Significance
		Case	Control			
Post OP Pallor	Absent	27(54)	12(24)	39(39)	0.002	Significant
	Present	23(46)	38(76)	61(61)		
Total		50(100)	50(100)	100(100)		

Table 06. Distribution of patient based on post-op haematological parameters (24 hours after closure of skin incision)

	Group		p Value	Significance
	Case	Control		
	Mean ± Sd.	Mean ± Sd.		
Post-Operative Hemoglobin	10.76 ± 1.21	8.99 ± 1.26	<0.001	Significant
Hemoglobin Difference PRE & POST OP	0.18 ± 0.11	1.32 ± 0.35	<0.001	Significant
Post-Operative Packed Cell Volume	34.52 ± 3.06	31.12 ± 3.11	<0.001	Significant
Packed cell volume difference pre &post op	1.13 ± 0.48	3.75 ±1.16	<0.001	Significant
Post-Operative Total RBC	3.75 ± 0.31	3.86 ± 0.34	0.557	Not Significant
Post-Operative Platelet Count	2.12 ± 0.49	2.08 ± 0.41	0.996	Not Significant
Post-Operative Bleeding Time	3.31 ± 0.65	3.12 ± 0.61	0.927	Not Significant
Post-Operative Clotting time	9.79 ± 0.83	9.81 ± 1.01	0.849	Not Significant

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The study group average age is 23.21 years, whereas the control group is 23.54 years. There is a 0.551 p-value. This implies that there isn't a significant age difference between the two groups.

Weight (kg)

The study group (case) weighs 64.61 kg on average, while the control group weighs 64.57 kg on average. The P value of.826 indicates that the weight differences between the two groups are not statistically significant.

Height (meter)

The average height of the study group is 1.42 metres, while the average height of the control group is 1.51 metres. The p-value is 0.894. This suggests that this confounding variable is evenly balanced between both groups. The disparity in height between these groups is not statistically significant.

There is no notable disparity in the number of first-time pregnant women (primigravida) and women who have been pregnant before (multigravida) in the two groups. The primary category consisted of primigravida, followed by 2nd gravida.

There is no substantial disparity in parity between the two groups. The majority of patients in both categories were nulliparous.

Pre-OP Pallor

The distribution of preoperative pallor in the two groups did not significantly differ, as the table above shows. Put differently, prior to the procedure, there was no significant difference between the two groups regarding the occurrence or lack of pallor. P has a value of 0.907.

The distribution of preoperative baseline vitals, including pulse, systolic blood pressure, diastolic blood pressure, and respiration rate, did not significantly differ between the two groups, as the table above shows. Put another way, the two groups were similar prior to the procedure. Every parameter has a p-value greater than 0.05.

The baseline characteristics of the two groups were similar, as the table above shows, suggesting that there was no discernible difference between them. There is a p-value greater than 0.05. Since p values are greater than 0.05, the statistics above do not indicate a significant difference in APGAR scores between the two groups.

The experimental group's average suction-collected blood volume was 103.44 ± 24.13 ml, whereas the control group's was 232.51 ± 35.28 ml. The P value, which is less than 0.001, indicates that the quantity of blood suction obtained by the two groups differs significantly. In the control group, the mean blood loss was 501.09 ± 72.44, whereas in the case group it was 412.62 ± 51.49. The amount of blood detected in mops and sheets in the control group increased statistically significantly, as indicated by the P value, which is less than 0.001. The case group's intraoperative blood loss was 512.31 ± 60.16, whereas the control group lost

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731.42 ± 80.27 units of blood. Blood loss in the control group was considerably greater, as shown by a P value of less than.001. With a p-value of less than 0.001, there is a statistically significant difference in post-operative blood loss and total blood loss (intra + post-operative blood loss) between the case and control groups. This implies that the control groups had much more blood loss.There is a significant difference between case and control group regarding post- op pallor as the p value is 0.002. Pallor was more in control group.

The postop hemoglobin difference between the two groups is statistically significant ($p < 0.001$).The two groups' post-operative PCV differs significantly (p value is less than 0.001). Differences of pre and after surgery hemoglobin and PCV between two groups are substantially greater in control group as p value is <0.001.

DISCUSSION

After placenta delivery, fibrin and fibrinogen rapidly degrade, while fibrin degradation products (FDP) and plasminogen activators spike as a result of the fibrinolytic system being activated. This stimulation may last for up to six to ten hours after giving delivery, which could result in increased bleeding[5].

Tranexamic acid has an antifibrinolytic effect by blocking plasminogen and plasmin molecules' lysine binding site, which stops them from adhering to the fibrin substrate. Tranexamic acid inhibits the conversion of plasminogen to plasmin via blocking the activity of plasminogen activators. It has been used to treat bleeding for a long time[6, 7]. This is the reason why, tranexamic acid is used in this study.

In this randomized, placebo-controlled trial, 100 patients were selected at random for an elective cesarean section using a random number table. The study group's fifty patients were split into two groups and given an IV injection of 1g of tranexamic acid (10ml) dissolved in 20ml of 5% Dextrose solution, whereas the 50 patients in the control group received an IV placebo (30ml of 5% Dextrose solution). The patient characteristics that were matched equally between the two groups included age, height, weight, gravida, parity, gestational age (at the time of LSCS), reason for caesarean section, pre-operative vitals, and haematological markers.

The result analysis shows that tranexamic acid significantly reduces bleeding in LSCS patients starting at placenta delivery and continuing for two hours postoperatively. Patients in the study group lost an average of 512.31 ±60.16 ml of blood during surgery, compared to 731.42 ± 80.27 ml in the control group ($p<0.001$; extremely significant). Patients in the study group lost an average of 65.94 ± 8.04 ml of blood two hours after surgery, compared to 114.46 ± 15.65 ml in the control group ($p<0.001$; extremely significant). During the intrapartum and postpartum phases—the two hours after placenta delivery and the point at which skin closure is complete—blood loss decreased. Combining the two findings, patients in the study group lost an average of 577.12 ± 62.84 ml of blood overall (intra-operative + post-operative blood loss), compared to 846.17 ± 100.33 ml for patients in the control group. As a result, blood loss was reduced by almost 32% ($p < 0.001$; extremely significant). In

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contrast to the patients in the tranexamic acid group, none of the four instances in the control group requiring an excessive oxytocin infusion required postpartum bleeding.

Leila Sekhavat, Afsar Tabatabaii, et al. [8] split 90 primipara individuals into two groups and performed cesarean sections on them as part of a prospective randomized trial. Their research showed that tranexamic acid significantly reduced the blood loss from the end of the cesarean section to two hours postpartum ($p = 0.000$). The tranexamic group's blood loss was 28.02 ± 5.53 mL, whereas the control group's was 37.12 ± 8.97 mL. These findings were similar to mine, although the previous study only included primipara patients, whereas the current study did not include parity-based inclusion criteria.

In their research, Movafegh et al.[9] demonstrated that 20 minutes before the skin incision during cesarean delivery, intravenous tranexamic acid administration at a dose of 10 mg/kg was able to reduce intraoperative and postoperative blood loss as well as the amount of oxytocin utilized during the surgery. Given that the patient demographics (mean age, weight, and duration of surgery) were similar across the two groups, the tranexamic acid group's mean blood loss for both intraoperative bleeding and hemorrhage was much lower than that of the control group (262.5±39.6 vs. 404.7±94.4 mL) and postoperative bleeding (67.1±6.5 vs. 141.0±33.9 mL; $p<0.001$). Oxytocin administration was significantly less in the tranexamic acid group compared with the control group (39±5.8 vs. 43±5.4 units; $p=0.001$). While the amount of tranexamic acid used in this trial was different from that used in the current study, these results were nonetheless in line with the current investigation.
The effectiveness of tranexamic acid in decreasing bleeding from placenta delivery to two hours postpartum is studied by Ming-ying Gai et al.[5] in China. While there was no decrease in post-placental delivery blood loss, the intervention did result in decreased bleeding two hours after surgery (42.75±40.45 ml in the study group vs. 73.98±77.09 ml in the control group, $p=0.001$). The fact that tranexamic acid was administered to the skin incision only ten minutes prior to it most certainly contributed to this. In this study, tranexamic acid is administered 20 minutes before to spinal anesthesia.

Results from K. Gungorduk's research [10] were comparable. The amount of tranexamic acid given (1 gm), irrespective of the patient's weight, was comparable to what we studied. Blood loss was recorded, with 499.9±206.4 ml in the tranexamic acid group and 600.7±215.7 ml in the control group ($p<0.001$). Furthermore, further uterotonic medicines were required by 14.5% of the placebo group and 8.5% of the tranexamic acid group of women, respectively. The results matched what I had discovered.

Tranexamic acid considerably decreased the amount of blood loss from the end of LSCS to two hours postpartum, according to a research by Gohel et al.[11] published in the Indian Journal of Obstetrics and Gynecology: 75.71 ml in the study group versus 133.03 ml in the control group ($p=0.001$). Additionally, it dramatically decreased the amount of blood lost from placenta delivery to two hours postpartum (372.71 ml in the study group compared to 469.70 ml in the control group; $p=0.003$).

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Two studies on effect of tranexamic acid in reducing blood loss after vaginal delivery by Yang HX Zheng SR,.[12] and Sentilhes L, Lasocki S, Ducloy AS et al.[13] showed significant decrease in occurrence of postpartum haemorrhage.

In the current study, following surgery, the pallor of the control group increased dramatically. Pallor was experienced by 23 participants in the study group as opposed to 38 in the control group. (p=0.002, extremely significant). The study group saw a substantial increase in pulse, with a mean of 85/min compared to 93/min in the control group (p<0.001). There was no discernible difference in the two groups' other parameters, such as respiratory rate, diastolic blood pressure, and systolic blood pressure (p value >0.05 for both parameters). In the study by Movafegh et al.[9] and Gai et al.[5] there was no significant increase in pulse as also the other post-operative vitals.

The two groups' post-operative hemoglobin levels varied greatly, with the study group's mean concentration being 10.76 gm% and the control group's being 8.99 gm% (p<0.001, Significant). The control group had a significantly higher difference in preoperative and postoperative hemoglobin values than the study group, with 0.18± 0.11 gm% in the study group compared to 1.32± 0.35 gm% in the control group (p<0.001; highly significant). Additionally, there was a significant difference in post-operative PCV levels between the two groups, with the study group having a PCV level of 34.52±3.06 compared to 31.12±3.11 in the control group (p value<0.001, significant). Additionally, the study group's pre- and post-operative Packed cell volume change was substantially less (1.13±.48) than the control group's (3.75±1.16).(significant, p-value<0.001). There was no significant difference found between the two groups for other measures such as bleeding time, clotting time, total RBC count, and platelet count (p value >0.05). These results were comparable in respect of post-operative haemoglobin change with the study by Movafegh, et al.[9] and Gai, et al.[5] but their study did not comment on change in packed cell volume post-operatively.

The trial group did not have a statistically greater incidence of tranexamic acid side effects, such as nausea, vomiting, or diarrhea. These outcomes matched those of earlier research.

Thrombosis occurs five to six times more frequently during pregnancy and puberty than it does in the general population. When giving the anticoagulant drug tranexamic acid, especially to the postpartum LSCS group, consideration should be given to the heightened risk of thrombosis. Not a single participant in our study shown any signs of thrombosis.

No thrombosis developed in any of the 67 instances of abruptio placenta treated with tranexamic acid, according to Svanberg and colleagues'[14] study. Thromboembolic incidents were not observed in any of the 3014 women (including 45 pregnant women) enrolled in Bekassy Z and Astedt A[15] trial; tranexamic acid was administered to reduce bleeding at cervix contraction. Similar results were found in studies by Movafegh , et al.[9], Gai , et al.[5], Gohel , et al.[16], Yang HX Zheng SR , et al.[12].

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All data demonstrated that tranexamic acid can be used safely without increasing the occurrence of thrombosis, but still need more cases to be observed for the occurrence of thrombosis.

One major worry was the safety of administering 1gm of tranexamic acid to a fetus while it was still in the womb. Consequently, a neonatologist carefully assessed the newborn outcome. The study group's mean APGAR scores at 1 and 5 minutes were 6.56 ± 1.51 and 8.59 ±.99, while the control group's were 6.37 ± 1.43 and 8.42 ± 1.17. Consequently, there was no discernible difference between the two groups' APGAR readings at 1 minute (p=0.509) or 5 minutes (p=0.243). Not a single baby needed to be admitted to the NICU. The findings were in line with other research [8, 11]. According to this research, giving tranexamic acid to a newborn 20 minutes before to spinal anesthesia appears to be a pretty safe practice.

CONCLUSION

Using tranexamic acid during and after a lower segment cesarean section can greatly minimize blood loss. Severe postpartum hemorrhage (defined as blood loss of 1000 ml or more) was not observed in the study population. Tranexamic acid did not show any statistically significant association with any of the most prevalent adverse medication reactions, such as diarrhea, clotting, or illness. Tranexamic acid was administered 20 minutes before to spinal anesthesia, and its administration had no influence on the APGAR score, which measures the health of the fetus. Transparent acid lowers bleeding during and after cesarean sections, which lessens the use for oxytocin. For those undergoing lower segment caesarean sections, tranexamic acid is a risk-free way to lessen hemorrhage after delivery.

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