



## Comparison of Mean Blood Loss in Women Undergoing Cesarean Section Who Received Tranexamic Acid Preoperative Versus Those Didn't Receive It

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### ABSTRACT

**Background:** Postpartum hemorrhage (PPH) after cesarean sections is one of the major risk factors to maternal mortality and morbidity. Even though tranexamic acid (TXA) is now recommended for the PPH treatment, it is still not suggested to use it as a prophylactic intervention during delivery. The study aim is to evaluate the comparison of the effect of Tranexamic acid (TXA) versus control group in pregnant women undergoing Cesarean section. **Methods:** This Randomized controlled trial study was conducted at Labour room and operation theatre of KVSS Hospital during March-Oct 2022. One hundred pregnant women who had a cesarean-section participated in the study. Two-groups of women were formed: the study group had a slow IV-infusion of 2grams of tranexamic acid (20 ml volume) mixed in 50ml of normal saline solution 0.9% (70ml volume) under spinal anesthesia, while the control group receive normal saline. Blood volume, estimated blood loss, and preoperative and postoperative hemocrit were documented. **Results:** As compared to control group, mean blood loss in TXA group found significantly less during cesarean delivery and blood loss 2-hours from end of CS ( $p \leq 0.05$ ). This was reflected in the change of Hb and hematocrit values, which also showed highly significant statistical difference ( $p \leq 0.001$ ). **Conclusion:** Without causing any immediate risk to the woman or the newborn, tranexamic acid treatment during an elective cesarean section has been shown to be beneficial in minimizing blood loss, which sequentially reduces the risk of PPH.

### INTRODUCTION

Postpartum hemorrhage (PPH) characterize by heavy bleeding that occurs within 24 hours of child birth. It is a significant risk factor of mortality in postpartum women. Due to PPH about 68,500 deaths occur in a year and most sufferers belong to developing countries. Approximately 99% incidence has been reported in these countries. In 6% of births, patients with PPH suffer blood loss of more than 500 ml and in 1-2% 1000 ml. of blood loss occurs that represents a huge global health burden.<sup>1</sup> Unfortunately PPH is more common in low income countries. WHO describes PPH "Blood loss from birth canal in excess of 500 ml during first 24 hrs after delivery". Around one-fourth of maternal deaths globally are caused by postpartum hemorrhage, and more than 10% of those who survived might suffer with severe anemia.<sup>2</sup>

PPH is correlated with tachycardia, sweating, weakness and unstable hemodynamic may occur with 40% of blood loss. Most frequent complication of caesarian delivery is Post-partum hemorrhage (PPH) which is a life-threatening condition. According to recent data caesarian

delivery (CD) has increased to 25-30% in many developed countries.<sup>3</sup> Risk factors of PPH include older maternal age, multiple pregnancies, obesity, primipara, placental complications, macrosomic birth, assisted vaginal birth, III or IV degree perineal tears, A pre-term or post-term birth, a 12- to 24-hour labor period, the use of oxytocin infusion during labor, and polyhydramnios are all significant factors in cesarean sections.<sup>4</sup>

A significant proportion of births between 3% and 15% have estimated PPH, and around one in five of these hemorrhages worsen to the point where the mother's life or future fertility may be compromised putting her at risk for intensive care or blood transfusion surgery. The study indicated that, about 1/4<sup>th</sup> of all maternal deaths worldwide are caused by PPH.<sup>5</sup>

Tranexamic acid is potent antifibrinolytic agent. It has a potential to boost the efficiency of patient's haemostatic mechanism as well. Therefore, bleeding declines and fibrinolysis is inhibited. Tranexamic acid is a serine protease inhibitor.<sup>6</sup> It has been shown that using tranexamic acid as an antifibrinolytic medicine greatly

lowers mean blood loss and the requirement for blood transfusions in various kinds of non-obstetric operations.<sup>7</sup> The use of tranexamic acid in obstetric settings has been the subject of multiple published clinical trials,<sup>8,9</sup> but there is still lack of consensus on the management.

Fahmy NG et al. demonstrated that the average blood loss was significantly lesser in the intervention (TXA) group when compared with the control group  $416.1 \pm 89.9$  &  $688.6 \pm 134.7$  ( $P < 0.05$ ); respectively. Similar findings were observed for 24-hours post-operative mean Hb level  $11.6 \pm 0.7$  mg/dl vs.  $10.5 \pm 1.1$  mg/dl ( $P < 0.05$ ), and mean hematocrit level  $34.9 \pm 2.4$  vs.  $31.6 \pm 3.2$  ( $P < 0.05$ ).<sup>10</sup> Another study also evaluated the impact of tranexamic acid prior to a cesarean section on blood loss (ml) during as well as any adverse medication reactions. Mean blood loss of was relatively lower as observed in previous studies  $436.5 \pm 118.1$ , while the control group observed  $616.5 \pm 153.3$  ( $P < 0.05$ ) while only 4% women blood loss exceeding 500 ml, while 18% ( $P \leq 0.05$ ) had PPH. The post-operative hemoglobin change was  $0.49 \pm 0.12$  vs.  $0.59 \pm 0.16$  ( $P < 0.05$ ) in the tranexamic acid and control groups, respectively.<sup>11</sup>

This is a comparative study between groups of patients who managed preoperatively by tranexamic acid versus control group. The idea of this study to examine either Preoperative administration of tranexamic acid safely reduces blood loss in women undergoing cesarean delivery. Previously very few studies are available to rule out exactly the quantified effect of Tranexamic acid as antifibrinolytic agent use preoperatively in view of mean blood loss. This study results will provide the evidence of the usefulness of the drug as it is cheap, easily available drug and it can be useful in low resources population like our country.

## MATERIAL & METHODS

This Randomized controlled trial study was conducted at the Labour room and operation theatre of KVSS Hospital during March 2022- Oct 2022 after taking approval from institutional review ethical board. Inform consents were obtained from all women who met the selection criteria. women of age 18 - 45 year, Gestational age  $\geq 34$  weeks, Patients who will undergo cesarean section (elective/emergency), All parities, Booking status (Booked and un booked) Women Singleton pregnancy were included. Patients with history of Venous thrombosis, Epilepsy, Gestational Diabetes, Any known CV, CKD, CLD, Sickle cells disease, Severe hemorrhagic disease, Abnormally invasive placenta, Eclampsia, Multiple pregnancies, Administration of low molecular weight heparin or anti platelet drugs week before delivery were excluded. Primary investigations were done through proper antenatal checkups, hemoglobin Range  $> 8.0$  gm/dl were minimum benchmark. ultrasonography were performed.

Sample size (n) was estimated using "OpenEpi sample size calculator". Taking statistics of mean blood loss  $436.5 \pm 118.1$  ml in the TXA group in and  $616.5 \pm 153.3$  ml in the control group<sup>11</sup>, at confidence interval 95% and power of the test 80% minimum calculated sample size is 10 in each group but I will include at least 50 cases in each group.

A total of one hundred pregnant women were randomly allocated in 2 groups equally. In intervention group, pregnant women got 2grams of tranexamic acid (TXA) (20ml in volume) diluted in 50ml normal saline solution 0.9% (70ml volume) as slow IV infusion with induction of spinal anesthesia. With spinal anesthetic induction, pregnant women in the control group were given 20 ml of saline solution 0.9% diluted in 50 ml of normal saline 0.9% (70 ml in volume) and 10 IU of oxytocin were given to each group immediately following delivery.

Pre and post operative Hematocrit, blood volume and estimated blood loss were calculated using the following calculations "Estimated blood loss = estimated blood volume  $\times$  (pre-operative hematocrit - post-operative hematocrit)/pre-operative hematocrit" where estimated blood volume (mL) = weight (Kg)  $\times 85$ ". Post partum hemorrhage also reported blood loss exceed to 500 ml.<sup>7,12</sup>

The collected data was entered in computer software SPSS version 20. Descriptive statistics were determined in term of mean, standard deviation for quantitative variables Age, parity, Hemoglobin level, hematocrit level, RBC volume, BMI and blood loss. Frequency (%) for qualitative variables such as Socio economical status, booking status, C/section (elective/ emergency) and PPH. Mean blood loss in both groups were compared by using t-test. PPH in both groups were compared by using chi square test. Effect modifiers were controlled through stratification. Post-stratification t-test for mean blood loss and chi-square for PPH were applied. P-value less than 0.05 were considered significant.

## RESULTS

A total of 100 patients fulfilling selection criteria were included in the study and randomly divided into two groups; In table 1 descriptive statistics of study variables such as age, weight, height, BMI, and parity of both study groups and overall sample was stated in term of mean and standard deviation .Mean age of the patients in Tranexamic Acid group was  $27.34 \pm 4.57$  years, In Control group, Mean age of the patients was  $27.7 \pm 4.95$  years, In overall sample, mean age was  $27.52 \pm 4.74$  years. Mean BMI of the patients in Tranexamic Acid group was  $25.84 \pm 4.17$ , In Control group, Mean BMI of the patients was  $25.78 \pm 4.98$ . In overall sample, mean BMI was  $28.51 \pm 4.57$ .

In table 2 Distribution of study variables such as Socio economic status, booking status, and type of C/ Section of both study groups and overall sample was stated in term of frequency and percentages. Where 22(44%) belonged from lower class, 12(24%) were from middle class and 16(32%) study subjects were from upper class in Tranexamic Acid group and 13(26%) belonged from lower class, 11(22%) were from middle class and 26(52%) study subjects were from upper class in Control group. In Tranexamic Acid group, type of C/Section of 30(60%) subjects was elective and 20(40%) subjects had emergency C/ Section, while in control group 29(58%) subjects were underwent elective and 21(42%) subjects had emergency C/ Section. Distribution for booking status also stated.

In Figure 1 & 2 age group and parity status wise distributions presented. Most of the women were older

than 25 years in both of the study groups. Parity status showed that majority of women had 1-2 parity and small proportions of women status were primiparity.

In table 3 descriptive statistics of study outcome including pre and post delivery, and change in Hb level, Hematocrit level and blood loss (ml) of both study groups and overall sample was stated in term of mean and standard deviation.

Mean change in Hb level of the patients in Tranexamic Acid group was  $-0.73 \pm 0.58$  g/dl. In Control group, Mean change in Hb level of the patients was  $-1 \pm 0.85$  g/dl (P-value= 0.072). In overall sample, mean change in Hb level of the patients was  $-0.87 \pm 0.73$ .

Mean change in Hematocrit level of the patients in Tranexamic Acid group was  $-2.15 \pm 1.09$ . In Control group, Mean change in Hematocrit level of the patients was  $-2.27 \pm 1.05$  (P-value= 0.564). In overall sample, mean change in Hematocrit level of the patients was  $-2.21 \pm 1.07$ .

Mean blood loss of the patients in Tranexamic Acid group was  $353.08 \pm 152.07$ . In Control group, Mean blood

loss of the patients was  $386.89 \pm 198.44$  (0.341). In overall sample, mean blood loss of the patients was  $369.99 \pm 176.71$ .

Although the statistical significance not achieved but the findings showed that Tranexamic Acid group performed better than control group.

Distribution and comparison of PPH group-wise and overall was stated, In table 4, where 2(4%) study subjects had PPH in Tranexamic Acid group while 5(10%) subjects had PPH in Control group. More patients developed PPH in control group as compared to the treatment group.

In table 5 & 10 stratification for PPH in both groups with respect to all effect modifiers i.e age, parity, pre delivery Hb level, SES, type of C/Section and booking status had done, chi- square test was used to observe the significance kept p-value less than or equal to 0.05 as significant. In table 11-13 mean blood loss was compared with effect modifiers independent t- test was used to observe the significance kept p-value less than or equal to 0.05 as significant.

**Table 1**

*Descriptive Statistics of Study variables*

Study Variables	Total (n=100)	TXA Group (n=50)	Control Group (n=50)	P values
Age (in years)	27.52 $\pm$ 4.74	27.34 $\pm$ 4.57	27.7 $\pm$ 4.95	0.706
Weight (in kg)	67.24 $\pm$ 12.72	67.6 $\pm$ 13.31	66.88 $\pm$ 12.22	0.779
Height (in feet)	5.31 $\pm$ 0.21	5.31 $\pm$ 0.2	5.31 $\pm$ 0.22	1.000
BMI (kg/m <sup>2</sup> )	25.81 $\pm$ 4.57	25.84 $\pm$ 4.17	25.78 $\pm$ 4.98	0.948
Parity	2.32 $\pm$ 2.26	2.4 $\pm$ 2.66	2.24 $\pm$ 1.79	0.725
<b>Age Groups</b>				
25 or less	40(40%)	19(38%)	21(42%)	0.683
More than 25	60(60%)	31(62%)	29(58%)	
<b>Parity</b>				
Primiparity	18(18%)	9(18%)	9(18%)	0.974
1-2	51(51%)	26(52%)	25(50%)	
More than 2	31(31%)	15(30%)	16(32%)	
<b>Socio Economic Status</b>				
Lower Class	35(35%)	22(44%)	13(26%)	0.094
Middle Class	23(23%)	12(24%)	11(22%)	
Upper Class	42(42%)	16(32%)	26(52%)	
<b>Booking Status</b>				
Un-booked	3(3%)	1(2%)	2(4%)	0.558
Booked	97(97%)	49(98%)	48(96%)	
<b>Type of C/Section</b>				
Elective	59(59%)	30(60%)	29(58%)	0.839
Emergency	41(41%)	20(40%)	21(42%)	

"Independent t-test applied. Chi-Square test applied; P-value<0.05"

**Table 2**

*Descriptive statistics and Comparison of Study Outcomes*

Study Outcomes	Total (n=100)	TXA Group (n=50)	Control Group (n=50)	P values
Pre Delivery Hb level(g/dl)	10.86 $\pm$ 1.01	10.93 $\pm$ 0.98	10.79 $\pm$ 1.05	0.493
Post Delivery Hb level(g/dl)	9.99 $\pm$ 1.03	10.2 $\pm$ 0.91	9.79 $\pm$ 1.11	0.049
Change in HB level(g/dl)	-0.87 $\pm$ 0.73	-0.73 $\pm$ 0.58	-1 $\pm$ 0.85	0.072
Pre Delivery Hematocrit Level	33.22 $\pm$ 3	33.45 $\pm$ 3.01	32.99 $\pm$ 2.99	0.449
Post Delivery Hematocrit Level	31.01 $\pm$ 2.74	31.3 $\pm$ 2.64	30.72 $\pm$ 2.85	0.293
Change in Hematocrit level	-2.21 $\pm$ 1.07	-2.15 $\pm$ 1.09	-2.27 $\pm$ 1.05	0.564
Blood Lose (ml)	369.9 $\pm$ 176.7	353.1 $\pm$ 152.1	386.9 $\pm$ 198.4	0.341

"Independent t-test applied; P-value<0.05"

**Table 3**

*Comparison of PPH between groups with respect to associated factors*

Study Variables	PPH	Study Group		Total	P values
		Tranexamic Acid Group	Control Group		
<b>PPH</b>	No	48(96%)	45(90%)	93(93%)	0.240
	Yes	2(4%)	5(10%)	7(7%)	
<b>Age Groups</b>					
</=25 years	No	19(100%)	20(95.2%)	39(97.5%)	1.000
	Yes	0(0%)	1(4.8%)	1(2.5%)	
>25 years	No	29(93.5%)	25(86.2%)	54(90%)	0.417

	Yes	2(6.5%)	4(13.8%)	6(10%)	
<b>Parity</b>					
Primiparaus	No	9(100%)	9(100%)	18(100%)	-
1-2	No	24(92.3%)	24(96%)	48(94.1%)	1.000
	Yes	2(7.7%)	1(4%)	3(5.9%)	
> 2	No	15(100%)	12(75%)	27(87.1%)	0.101
	Yes	0(0%)	4(25%)	4(12.9%)	
<b>Socio Economic Status</b>					
Lower Class	No	21(95.5%)	13(100%)	34(97.1%)	0.435
	Yes	1(4.5%)	0(0%)	1(2.9%)	
Middle Class	No	12(100%)	9(81.8%)	21(91.3%)	0.122
	Yes	0(0%)	2(18.2%)	2(8.7%)	
Upper Class	No	15(93.8%)	23(88.5%)	38(90.5%)	0.571
	Yes	1(6.3%)	3(11.5%)	4(9.5%)	
<b>Booking Status</b>					
Un-booked	No	1(100%)	2(100%)	3(100%)	-
Booked	No	47(95.9%)	43(89.6%)	90(92.8%)	0.240
	Yes	2(4.1%)	5(10.4%)	7(7.2%)	
<b>Type of C/Section</b>					
Elective	No	29(96.7%)	28(96.6%)	57(96.6%)	0.981
	Yes	1(3.3%)	1(3.4%)	2(3.4%)	
Emergency	No	19(95%)	17(81%)	36(87.8%)	0.169
	Yes	1(5%)	4(19%)	5(12.2%)	
<b>Pre-Delivery Hb level</b>					
11 or less	No	29(100%)	27(87.1%)	56(93.3%)	0.045
	Yes	0(0%)	4(12.9%)	4(6.7%)	
>11	No	19(90.5%)	18(94.7%)	37(92.5%)	0.609
	Yes	2(9.5%)	1(5.3%)	3(7.5%)	

“Chi-Square test applied; P-value<0.05”

**Table 4**

*Stratification for mean Blood lose in both groups with respect to Effect modifiers*

Effect modifiers	TXA Group		Control Group		P-values
	N	Mean+/-SD	N	Mean+/-SD	
<b>Age group</b>					
25 or less	19	333.4+/-131.9	21	352.6+/-129.5	0.645
> 25	31	365.1+/-164.1	29	411.7+/-235.4	0.375
<b>Parity</b>					
Primipera	9	337.489+/-153.0	9	425.9+/-47.1	0.117
2-Jan	26	366.1+/-166.7	25	339.8+/-189.7	0.6
more than 2	15	339.8+/-131.4	16	438.5+/-249.8	0.183
<b>Pre delivery Hb level</b>					
11 or less	29	325.5+/-120.8	31	405.6+/-232.6	0.103
>11	21	391.1+/-183.3	19	356.3+/-124.1	0.49
<b>Booking Status</b>					
Un-booked	1	426.2+/-00	2	294.8+/-261.7	0.752
Booked	49	351.6+/-153.3	48	390.7+/-198.0	0.279
<b>Socio Economic Status</b>					
Lower Class	22	343.3+/-146.6	13	344.7+/-117.4	0.976
Middle Class	12	371.583+/-143.7	11	467.3+/-313.8	0.35
Upper Class	16	352.6+/-172.9	26	373.9+/-165.0	0.393
<b>Type of Section</b>					
Elective	30	344.73+/-146.7	29	330.6+/-135.2	0.702
Emergency	20	365.6+/-162.8	21	464.6+/-244.8	0.137

“Independent t-test applied; P-value<0.05. “

## DISCUSSION

Tranexamic acid, discovered by “Utako Okomoto” in the 1950, it blocks plasminogen's lysine binding site, restricting the lysis of clots. Its action starts within 5 to 15 minutes and lasts up to 3-hours. Oral tranexamic acid emerged as an antifibrinolytic drug in the early 1990s. Its intravenously use was approved in 2010 by the US FDA to decrease blood loss during surgery. Research demonstrates that intraoperative administration, particularly in trauma and transplant procedures, reduces the requirement for blood transfusions.<sup>13</sup>

This study represents the clinical situation of low-income populations such as Pakistan and settings with low resources for women, with low pre-operative hemoglobin levels, un-booked antenatal care, and low educational

status. Most PPH-affected women have low-risk pregnancies and no visible risk factors. It is crucial to prevent PPH and potential blood loss by using prohemostatic agents like Tranexamic acid (TXA) and AMTSL. Placental delivery can release coagulant factors and rapidly degrade fibrinogen and fibrin due to vascular injury, highlighting the need for effective treatment.<sup>14</sup> Extensive tissue damage following CS delivery exacerbates fibrinolysis, a process that can continue for several hours after pregnancy delivery. Pharmacokinetic studies indicate that the period of hyperfibrinolysis, which lasts for around 8 hours following surgery, can be covered by therapeutic levels. This is because Tranexamic acid effectively lowers mean blood loss within the 2-hours post delivery. According to earlier research, the TXA group's



blood loss after surgery ranged from 262-499 mL, while the control groups' mean blood loss was between 329 and 710 mL.<sup>15, 16</sup>

It is widely believed that post-partum blood loss and the drop in hemoglobin post delivery can be estimated to approximate the change in hemoglobin. Such as, Hemoglobin changes have been utilized by researchers to verify indirect or visible approaches for estimating blood loss.<sup>17</sup> On the other hand, the data currently available suggest that postpartum hemoglobin and pre-partum hemoglobin changes are not well predicted by postpartum blood loss. Despite the fact that there was a significant relationship between blood loss and hemoglobin outcomes, the results of other studies have been confirmed by the findings of an insignificant level of association.<sup>7, 17</sup>

The research demonstrated that there were variations in the two groups' hemoglobin and hematocrit levels as well as in the amount of blood loss. Just 4% of patients in the trial arm experienced higher bleeding, compared to 10% of subjects in the control arm who lost more than 500 milliliters of blood. There aren't many studies that are comparable to this one. This study finding is comparable to previous researches.<sup>14, 18</sup>

Blood loss measured from placental birth till the completion of operation was significantly reduced, according to a study by Lakshmi A et al. mean blood loss was reported 347.2ml in TXA group vs. 517.7ml in control group ( $P < 0.01$ ). An additional criterion under investigation was the proportion of hemoglobin drop before and after surgical procedures, as well as the total number of participants experiencing a hemoglobin drop of more than 10%. Hemoglobin dropped observed in 9.3% patients in TXA group and 39% in control group subjects ( $P < 0.01$ ). The mother and the newborn did not experience any acute post-operative challenging circumstances. Significantly less blood loss during LSCS reported because of TXA. Adverse effects were not associated with the use of TXA. TXA is hence safe and useful for use in patients underwent LSCS.<sup>14</sup>

Although there is substantial evidence to support the intra-operative utilization of tranexamic acid, there is a modest higher risk of development of thromboembolic that may offset the advantages of using less blood. In trauma patients with severe bleeding, a single dosage of 1g of tranexamic acid should be followed by an 8-hour infusion, according to a multicenter trial conducted exclusively in low and moderate income countries. The primary outcome of the research was an examination of the overall death rates, which showed a decrease to 14.5% among patients receiving tranexamic acid compared to 16% in the control group. Additionally, a significant decrease in bleeding related mortality was seen (4.9% vs. 5.7%).<sup>19</sup>

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For women who have undergone caesarean sections, the use of IV TXA is strongly recommended in order to minimize blood loss and the need for blood transfusions, according to a Meta analysis of eighteen RCTs conducted by Franchini et al. there have been few researches reported TXA related side effects, such as thrombotic events or intra-operative hypotension.<sup>20</sup>

The results further support the suggestion that criteria of PPH in the future extend beyond blood loss. The difficulties in quantifying blood loss are widely acknowledged, and after the majority of deliveries, the precise amount of blood loss is undetermined. While it's important to monitor the woman's general health closely during the postpartum phase, busy settings with limited resources may not always routinely implement frequent vital sign measurement. In this vein, studies are being conducted to clarify the function of shock index as a supplementary PPH indicator.<sup>11</sup>

The Hb levels before and after procedure differed significantly ( $P < 0.05$ ). In the study by Abdel Aleem et al. found a noteworthy decrease in the mean blood loss within the first two hours following procedure.<sup>21</sup> It was also noted in another trial that tranexamic acid decreased the requirement for further uterotonics and may be safely administered prior to LSCS.<sup>22</sup> Similar findings reported by theSenturk et al., where patients had given 20ml of tranexamic acid diluted with 20ml of 5% dextrose. Which result in significant reduction in blood loss in intervention arm compared to the control arm.<sup>23</sup> Yehia and colleagues examined the need for iron replacement following operation. The study arm saw reduced vaginal bleeding during the first six hours following surgery. The trial arm's PPH incidence was 31% lower than that of the control arm, which was 63% higher.<sup>24</sup> Another meta-analysis that assessed the effectiveness of tranexamic acid revealed a significant difference in blood loss, Hb levels, and need for blood transfusions.<sup>25</sup> There were no major drug related adverse effects were observed in the majority of the researches.

## CONCLUSION

In order to prevent bleeding during elective and emergency LSCS, tranexamic acid is a safe prophylactic drugs. After the caesarean section, tranexamic acid did not considerably reduce blood loss; however, it did greatly reduce blood loss during the LSCS. No adverse effects or complications, such as thrombosis, were associated to its use. Women having LSCS can safely and successfully reduce blood loss using TXA. In people undergoing LSCS, TXA can therefore be utilized safely and successfully.

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