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Role of tranexamic acid in reducing maternal mortality and need of surgical intervention in women with clinically diagnosed postpartum hemorrhage

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Abstract

Postpartum hemorrhage accounts for > 25% of deaths, an effective treatment for postpartum hemorrhage (PPH) would contribute importantly to the Millennium Development Goal of decreasing maternal mortality.

Objective: To observe whether the antifibrinolytic agent, tranexamic acid reduces maternal mortality, need of hysterectomy in women with diagnosed postpartum hemorrhage and to evaluate adverse drug reaction of tranexamic acid.

Materials and Method: This study was conducted at Department of OBG, Karnataka Institute of Medical Sciences(KIMS) Hubli during May 2010 to April 2011. Hundreds women who has been diagnosed PPH were included in the study**.** Patients were allocated into two groups:

Control group (fifty case**)** and **Study group (**fifty case**)**. To collect and quantify amount of collected blood, BRASS-V[-] drape was used. Numbers and cause of maternal mortality was evaluated. Surgical intervention or hysterectomy required for failed medical management, and maternal side effects caused by tranexamic acid were noted.

Results: Both groups are comparable with regards to, age, parity distribution, type of delivery, causes of PPH (p-value> 0.05). Mean blood loss in control group was 744±102ml while that in tranexamic acid group was 626±113ml this difference between the two groups was highly significant (p value<0.0001). Hence in terms of blood loss tranexamic acid group is more efficacious when compared to control group. There was no maternal mortality due to failure of treatment of post partum hemorrhage in both the groups. None of patients needed surgical intervention or hysterectomy for failed medical treatment of PPH. In two groups side effect like thrombosis is not seen either in control group or tranexamic acid group.

Conclusion: Tranexamic acid significantly reduced the blood loss and maternal morbidity and mortality in patients with post partum haemorrhage.

Keywords: Hysterectomy, Maternal mortality, BRASS-V[-] drape, Tranexamic acid, Blood loss

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Introduction

Each year nearly fourteen million mothers develop PPH. About 2% of them will die, with an average time from onset to death of about two-four hours. Systemic anti-fibrinolytic agents are widely used in surgery to prevent clot breakdown in order to minimize blood loss. This study will provide a reliable scientific basis for recommendations for the use of tranexamic acid in the treatment of postpartum hemorrhage.(1) If tranexamic acid decrease maternal mortality and maternal morbidity in women with PPH, it will be of considerable significance as global commitment to MDG of reducing maternal death by 3/4th by the year 2015, a commitment that requires a reduction of the maternal mortality ratio (MMR) by 5.5% each year. Because postpartum hemorrhage responsible for 1/4th of deaths, an effective treatment for postpartum hemorrhage would contribute importantly to the Millennium Development Goal of decreasing maternal mortality. Tranexamic acid might also reduce the need for hysterectomy, blood loss, decrease risk of anemia and avoid the need for blood transfusion transmitted infections.(2) The objective of study was to observe that tranexamic acid reduces mortality, hysterectomy and surgical interventions in women with clinically diagnosed postpartum hemorrhage and to evaluate adverse drug reaction of tranexamic acid.

Materials and Method

This is prospective, randomized placebo-controlled study carried out at Department of Obstetrics and Gynaecology, Karnataka Institute of Medical Sciences, Hubli from May 2010 to April 2011. Permission for the study was obtained from the College authorities prior to commencement.

Selection of patients: 100 women who delivered their babies at KIMS hospital or outside, with hospital admission following delivery. Who has been clinically diagnosed postpartum hemorrhage, satisfying inclusion and exclusion criteria, following vaginal delivery of a baby.

Inclusion criteria: Clinical diagnosis of PPH may be based on any of following

- Estimated blood loss after vaginal delivery of baby >500ml OR
- Estimated blood loss enough to compromise the hemodynamic status of the women.

Exclusion criteria:

- Severe medical and surgical complications involving the heart, liver, kidney, brain disease and blood disorders.
- Allergy to tranexamic acid
- History of thrombo-embolic disorders

Data Collection Method: Detailed history was taken and general physical and obstetrics examination was done.

Written and informed consent for participating in the trial. Patients were allocated into two groups:

Control group (50 case**)**: standard protocol for the treatment of PPH along with placebo (normal saline, 10ml) was given following diagnosis of PPH.

Study group (50 case**)**: tranexamic acid 1gm IV (if after 30 min bleeding continues, 1gm can be repeated) along with standard protocol for treatment of PPH was given following diagnosis of PPH.

Estimation of blood loss: BRASS-V˝ drape was used to collect blood and also to quantify amount of blood collected Fig. 1.

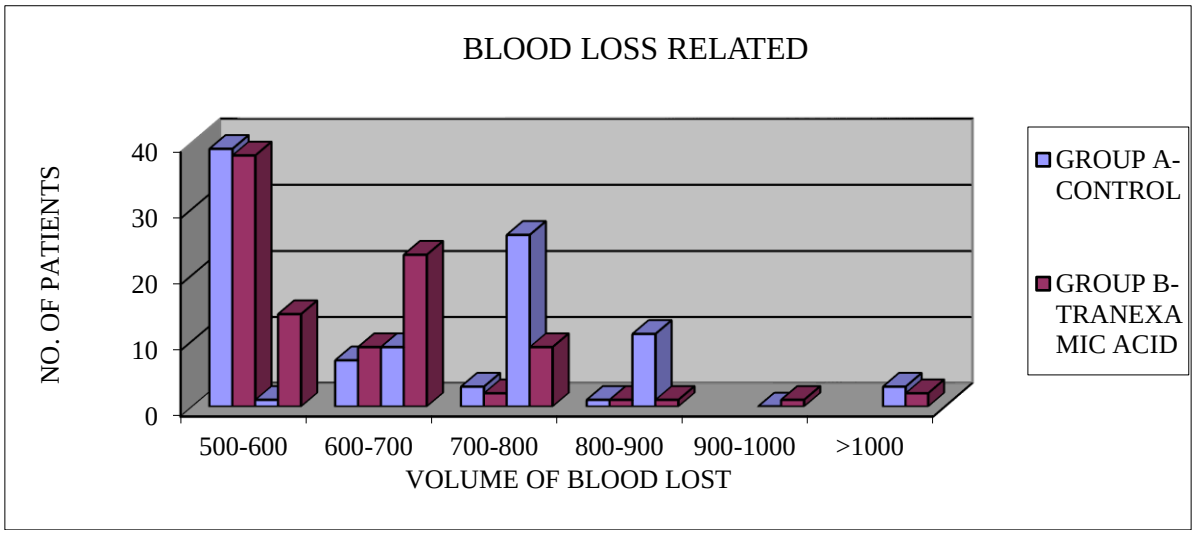
The drape has a calibrated and funneled collecting pouch, incorporated within a plastic sheet that is placed under the buttocks of the patient immediately after the delivery of baby. Clots were weighed separately. Blood soaked swabs were weighed, the known dry weight subtracted and the calculated volume added to that of drape (1gm=1ml)

- Maternal side effects caused by tranexamic acid like visual disturbance, chest pain, calf pain, in cordination was noted.
- Any surgical intervention or hysterectomy required for failed medical management was noted.
- Any maternal mortality and cause for it was evaluated.

Once enrolled all the subjects were followed up regularly and their obstetric outcome was carefully recorded using standard proforma as mentioned in the next section. The data and results so obtained were tabulated and analyzed using Microsoft excels spread sheet software of MS OFFICE 2007. The student –T test was used. The P-value was used for testing the statistical significance of the results obtained wherever applicable.

Results

Two groups under consideration are comparable with regard to age 24.04 yrs while in tranexamic acid group was 25.36 yrs. Both the groups are comparable with regards to, parity distribution, type of delivery, causes of PPH (p-value> 0.05). Mean blood loss in control group was 744±102ml while that in tranexamic acid group was 626±113ml this difference between the two groups was highly significant (p value<0.0001). Hence we can say that in terms of blood loss tranexamic acid group is more efficacious when compared to control group. For blood loss in both groups student test (t-5.44) is employ Fig. 2.



In both the groups there was no maternal mortality due to failure of treatment of post partum hemorrhage. In two groups, none of patients needed any surgical intervention or hysterectomy for failed medical treatment of PPH. Side effect like thrombosis is not seen in tranexamic acid group Table 1.

Table 1: Maternal mortality, need for surgical intervention or hysterectomy and side effects

		Control	Tranexamic acid
1.	Maternal Mortality	nil	nil
2	Hysterectomy	nil	nil
3	Thrombogenic side effects on mother or baby	+nt	nil

Discussion

In the present study, the mean blood loss in the two groups was 744±102ml in control group and 626±113ml in study group. This difference between the two groups is highly statistically (p-value, 0.0001) significant. Thus tranexamic acid is highly effective in reducing blood loss.

Similar study carried out by Ming-ying Gai,[3] in china showed that tranexamic acid significantly reduces bleeding from the time of placental delivery to 2 hrs postpartum in LSCS. P-value < 0.002. These results correlated well with present study.

Similar study, carried out by Yang H[4] in china showed similar results. Tranexamic acid significantly reduced blood loss after vaginal delivery. P-value <0.01. These results correlated well with study.

Similar study done by Gohel Mayur,[5] showed similar results. Tranexamic acid reduces blood loss significantly from the time of placental delivery to 2 hrs postpartum in LSCS. P-value < 0.003. These results correlated well with the study.

In the present study no maternal mortality occurred due to failure of medical treatment for PPH. Similar results were found in study done by Gohel[5] and co-workers (2007) and Ming-ying Gai[3] (2004). In this present study no patients required surgical intervention or hysterectomy for treatment of postpartum haemorrhage.

Study done by Anne-Sophie Ducloy-Bouthors et al at France[6] (2011). Hysterectomy or surgical uterine artery ligature was performed in two women in the control group and none in tranexamic acid group.

Table 2: Showing comparison of results of present study with others studies (control group)

Sl No	Parameters	Yang H et al[4] (2001)	Ming-ying Gai et al[3] (2004)	Gohel M et al[5] (2007)	Anne-sophie D et al[6] (2011)	Present Study
1	Blood loss	314.8ml	439.36±191.48 ml	472.79±43.54	-	744±102ml
2	Maternal mortality	Nil	Nil	Nil	-	Nil
3	Any surgical intervention or Hysterectomy	-	-	Nil	2	Nil

Table 3: Showing comparison of results of present study with others studies(tranexamic acid group)

Sl No.	Parameters	Yang H et al[4] (2001)	Ming-ying Gai et al[3] (2004)	Gohel M et al[5] (2007)	Anne-sophie D et al[6] (2011)	Present Study
1	Blood loss	243.3ml	359.29±152.02ml	374.92±51.46 ml	-	626±113ml
2	Maternal mortality	Nil	Nil	Nil	-	Nil
3	Any surgical intervention or hysterectomy	Nil	Nil	Nil	Nil	Nil

Conclusion

Tranexamic acid significantly reduced the amount of blood loss and maternal morbidity and mortality in patients with post-partum haemorrhage. These encouraging data strongly supports the need for large double-blind study to investigate the potential of tranexamic acid to reduce maternal morbidity and mortality worldwide.

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