ESTIMATION AND COMPARISON OF INTRA OPERATIVE BLOOD LOSS IN PATIENTS WITH AND WITHOUT VENOUS THROMBOEMBOLISM PROPHYLAXIS

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ABSTRACT

Objective: To estimate and compare intraoperative blood loss in surgical patients with and without deep vein thrombosis (DVT) prophylaxis using unfractionated heparin

Study Design: Clinical Trial

Place and Duration: Surgery Department of Fauji Foundation Hospital and Physiology Department Foundation University Medical College from October 2011 to August 2012

Patients and Methodology: Patients were selected by non probability purposive sampling. Patients fulfilling the inclusion criteria were divided into 2 groups 25 each on the basis of order of presentation at Fauji Foundation Hospital until cohort numbers were reached. Group I received no heparin whereas group II received heparin. Written informed consent was taken from the patient after explaining the procedure of the study. Coagulation profile was done for both groups before the planned surgery. Heparin in a dose of 5000 units was administered subcutaneously to group II on the morning of the planned surgery and it was stopped 24 hours post operatively. Blood loss was estimated in both groups by weighing cotton swabs pre and post operatively. Data was analyzed by SPSS version 17.

Results: Demographic data and surgical procedure time between the two groups did not differ. Blood loss between the two groups did not show any statistically significant difference.

Conclusion: DVT prophylaxis using unfractionated heparin did not lead to any significant overt blood loss when compared with those without it.

Keywords: Venous Thromboprophylaxis, Heparin, Intra operative, Blood loss.

INTRODUCTION

Venous thromboembolism (VTE) is one of the common consequences of hospitalization, especially in surgical patients and is associated with considerable morbidity, mortality and costs. Over the past fifty years several clinical trials have been conducted to demonstrate effectiveness of thromboprophylaxis in reducing the rate of deep vein thrombosis, thrombosis, pulmonary embolism and fatal pulmonary embolism by more than 60%[1]. Venous thromboembolism (VTE) risk is high among hospital patients and most of these at-risk patients are not protected with adequate prophylaxis according to data from the international ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting) study[2] . Several guidelines have been published for prevention of VTE amongst which American College of Chest Physicians (ACCP) guidelines are commonly considered and used. These guidelines recommend routine use of thromboprophylaxis in the form of low molecular weight heparin, low dose heparin or fondaparinux in patients undergoing major surgery e.g. orthopedic and where duration of surgery is more than 30 minutes[3]. Low molecular weight heparin (LMWH) has been shown to be safe, effective and cheaper thromboprophylactic option for most of the hospitalized patients[4].

Despite of available guidelines, their successful implementation remains far from optimal. One of the major barriers to the use of suitable thromboprophylaxis includes the belief

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of treating doctors that antithrombotic pharmacological modalities would increase the risk of bleeding[5]. Pakistani literature reveals comparable beliefs, where low molecular weight heparins are considered safe drugs but apparently the bleeding complications are regarded to be more and risk of VTE less when compared to western literature[6].

According to available evidence, though bleeding complications requiring a change in care occur less than 3% of the time[7] yet, irregular practice to prescribe thromboprophylaxis due to possible threat of bleeding was also recorded in a survey carried out at five tertiary care teaching hospitals of Pakistan including the hospital where current study took place[8]. This survey led to the question of measuring and comparing intraoperative blood loss in patients with and without VTE prophylaxis undergoing major surgical procedure using commonly used pharmacological prophylactic option. This would help in weighing risk and benefit of thromboprophylaxis. This study was planned with an objective to estimate and compare intraoperative blood loss without and with VTE prophylaxis using low dose unfractionated heparin in patients undergoing modified radical mastectomy

PATIENTS AND METHODS

This study was planned and carried out with collaboration of department of surgery at Fauji Foundation Hospital and department of Physiology at Foundation University Medical College from October 2011 to August 2012. Ethical approval was taken from college ethical review committee.

Patients were enrolled through non probability purposive sampling technique for this comparative study. Valid informed consent was taken after explaining the purpose of study since preoperative VTE prophylaxis is not a routine at Fauji Foundation Hospital. A total of 50 females, undergoing Modified Radical Mastectomy with known normal coagulation profile participated in the study. Patients with known bleeding disorder or liver disease, obesity (BMI > 30) anti platelet therapy or anemia were excluded from the study. Patients were divided into two groups of 25 each. Group I was the control group and group II was the interventional/treatment group.

Age, weight, height and relevant history of each patient full filling the inclusion criteria were recorded in patients' proforma. Routine investigations and coagulation profile was done for both groups before the planned surgery. A total of two low doses of unfractionated Heparin 5000 units were administered subcutaneously to Group II. First, one hour before the planned surgery and second in the evening after surgery. Group I did not receive any prophylaxis. All surgeries were done under general anesthesia. The operating surgeon and the operation theatre assistants were unaware of the grouping category of the patient however the anesthetist was informed before surgery. Same surgeon performed surgery on all patients. Duration of surgery was noted. Blood loss estimation in both groups was done immediately by weighing cotton swabs pre and post operatively using electronic scale. Though 1 ml blood weighs 1.06 mg yet for the sake of simplicity 1 ml blood was considered to be equal to 1 mg in this study. No

Table-1: Average difference of age, weight, duration of study and blood loss in patients of two study groups.

Parameter	Control group I n=25	Study group II n=25	*p* value
Age (yrs)	57.5 ± 10 SD	56.2 ± 9.2 SD	0.7
Weight (kg)	65.1 ± 8.8 SD	66.8 ± 10.1 SD	0.6
Duration of surgery (min)	86 ± 11.3 SD	83 ± 11.4 SD	0.79
Blood loss (ml)	529 ± 204 SD	554 ± 256 SD	0.24

$p < 0.05$ was considered significant

blood transfusion was required in any of the patients. Patients were also monitored clinically for DVT, if there was a suspicion then a duplex scan was requested. Data were subjected to SPSS version 17. Means and standard deviations of variables like age, weight, duration of surgery and blood loss were calculated. Blood loss in the two groups was compared using independent sample t-test. Blood loss in group II was considered significant if its difference reached statistically significant with p value of < 0.05 at 95% confidence interval.

DATA ANALYSIS AND RESULTS

The following were ranges of age (33-79 yrs SD 11.19) , weight (47-92 kgs SD 9.2), duration of surgery (60-110 min SD 10.9) and blood loss (204-1051 ml SD 236.19) in group I and II whereas average values for both groups are shown in table and figure.

In a total of 4 patients from both groups there was a suscipicion of DVT. In these patients a duplex scan was advised which confirmed DVT in one patient who belonged to control group.

DISCUSSION

Venous thromboembolism continues to be one of the most common preventable causes of death in hospitalized patients. Evidence suggests that various pharmacological and non pharmacological prophylactic approaches can prevent VTE in at-risk hospitalized patients. For example, pharmacological prophylaxis reduces the risk of pulmonary embolism by 75% in general surgical patients and by 57% in medical patients. Non pharmacological prophylaxis using compression stockings and intermittent pneumatic compression is also proposed method either alone or in combination with pharmacological prophylaxis[9]. Despite increasing evidence supporting the use of thrombo-prophylaxis, its practice remains underused even in hospitalized at risk patients as indicated by data collected from worldwide including Pakistan, through ENDORSE study[2]. VTE prophylaxis is not routinely followed by all health practitioners at our hospital, it is over specialists own values and preferences which differ among experts. A survey about knowledge, attitude and practices of medical personnel regarding VTE prophylaxis was carried out

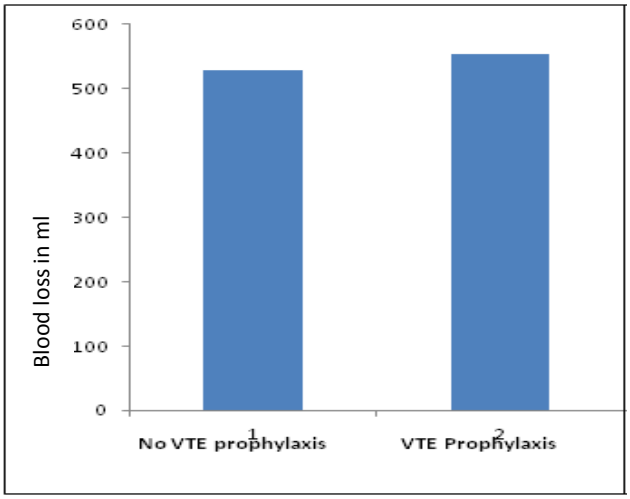

Figure-1: Average intraoperative blood loss in both study groups.

before conducting the current study. Significant number of doctors reflected that bleeding risk of VTE prophylaxis outweighs the benefits and also that DVT was less common in Asian population[8]. After approval from ethical committee current study was completed in six months. Low dose heparin was used as prophylactic agent in this study due to its safety and cost effectiveness. Same major surgical procedure was selected for both groups with expected duration of surgery at least more than 30 minutes to justify prophylaxis. Although this protocol is in accordance with 8th ACCP guidelines for venous thrombo-prophylaxis (Moderate VTE risk), prophylaxis should have been continued till the time of discharge but due to specialists concern and ethical reasons only 2 doses of heparin were considered appropriate. There is good evidence available that appropriately used thrombo-prophylaxis has a desirable risk/benefit ratio and is cost-effective[3]. Surgeon, theatre assistants and principle investigator were blinded of the grouping category of patients.

Results of this study showed no significant difference in blood loss in both groups which is

consistent with available data from meta analyses and placebo-controlled, blinded, randomized clinical trials which show little or no increase in clinically important bleeding with prophylactic doses of low-dose unfractionated heparin, low molecular weight heparin, (LMWH), or a vitamin K antagonist[10-12]. Another recent study also emphasized the importance of VTE prophylaxis in spinal surgery where no complications from prophylaxis occurred[13].

There is general belief that thromboembolic disease is uncommon in Asia and the Asian aversion to post-mortem examination have added to lack of awareness of a condition that is a common cause of preventable hospital deaths in the west. One of the patients from the control group developed DVT which was diagnosed on doppler scan. This suggests that venous thromboembolism unlike common belief is not a rarity in Asian population[14,15]. Another explanation could be hypercoagulability induced by breast cancer, which has been shown to increase the incidence of thromboembolic complications, where in a series of 91 patients who underwent modified radical mastectomy, 5% developed DVT and 2% pulmonary embolism, with one death within 30 days of surgery despite the use of compression stockings[16].

Routine use of thromboprophylaxis is recommended in surgical patients who are >40 years of age or patients undergoing major surgical procedures. In comparison with no prophylaxis, both subcutaneous, low-dose unfractionated heparin (LDUH) and low-molecular-weight heparin (LMWH) have been shown to lower the risk of VTE in these patients by more than 60%[17]. Majority of patients in the current study were above fifty years of age.

The sample size of the our study was small however current study was an effort to weigh bleeding risk and benefit of VTE prophylaxis at our set up where standard available guidelines are sparsely followed leaving VTE under diagnosed. We recommend grading of at risk patients according to standard guidelines and initiate prophylaxis to improve patient outcomes and reduce hospital costs.

CONCLUSION

No difference in intra operative blood loss was found in patients with or without VTE prophylaxis using low dose unfractionated heparin. VTE prophylaxis may be incorporated in surgical patients undergoing modified radical mastectomy to be on the safe side.

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