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Original Research Article

Efficacy of Low Molecular Weight Heparin Vs Dabigatran in the Prophylaxis against Venous Thromboembolism in High Risk Surgical Patients

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Conflict of interest: Nil

Abstract:

Introduction: After any major general surgery, venous thromboembolism (VTE) can happen. In this population, venous thromboembolism is thought to occur between 0.2% and 0.3% of the time. The best outcomes are obtained when mechanical and pharmaceutical techniques are combined. The last ten years have seen the development of new protocols for the early detection of DVT in patients at high risk, as well as the discovery of more effective newer oral anticoagulants, which has led us to consider the efficacy of newer oral anticoagulants Therapy alone from the day of diagnosis in prevention of DVT.

Objectives:

1. To compare efficacy of New Oral Anticoagulants (Dabigatran) vs Low Molecular Weight Heparin (LMWH) in the Prophylaxis against Venous Thromboembolism (VTE) among High risk surgical patients.
2. To compare the risk of bleeding in patients receiving DABIGATRAN and LMWH as Prophylaxis against VTE.

Methods: This study is a Prospective Open Labeled Randomized Control Trial in Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry. Patients more than 18 years admitted in surgery and ortho ward were included as per caprini score. Those who were Age<18years, Any recent head injury, Pregnant women, Severe burns, Severe renal insufficiency patient, Cancer patients admitted for Palliation, Severely ill patients with multiple co-morbidities, Bleeding diathesis were excluded from the study. The sample was taken based on the case flow during the study period, with minimum of 20-30 patients in both the group were planned to take, finally 25 in each group was taken as per convenient sampling technique. The participants were randomized and one group received Low molecular weight Heparin and the other group received oral Dabigatran. Universal sampling technique was used. Grey scale & Doppler USG were used to confirm DVTs.

Results: Mean age of group1 is 52.20 and group2 is 53.20. According to statistics, there is no age difference between the two groups. P value is 0.69.There are 17 girls and 8 males in group 1. 16 women and 9 men make up group 2.In terms of sex, there are no statistical differences between the two groups.(P=0.765).Height, weight, pulse rate, diastolic blood pressure, urea, creatinine, clotting time, prothrombin time, APTT, haemoglobin, bleeding time, and Caprini score did not differ between the two groups. The mean systolic blood pressure in groups 1 and 2 is 130.96 and 135.20, respectively, and there is a statistically significant difference between the two groups' blood pressures (P=0.008).

Conclusion: Hence, the two groups of low molecular weight heparin and dagabran are comparable in terms of all the factors, it can be concluded that dagabran is not less effective than low molecular weight heparin.

Keywords: Venous Thromboembolism, Dabigatran, Prothrombin Time.

Introduction

Following any extensive general surgery, venous thromboembolism (VTE) can develop. The most frequent definite cause of mortality in hospitalised patients is recognised as pulmonary embolism. In

comparison to general surgical operations and lower limb surgeries among orthopaedic departments, colorectal surgical procedures carry a greater risk of deep venous thrombosis (DVT) and pulmonary embolism (PE). In this demographic, venous thromboembolism is thought to occur between 0.2% and 0.3% of the time. [1] The majority of legally required quality efforts regard VTE prevention as a patient safety strategy. Mechanical techniques (graduated compression stockings and intermittent pneumatic compression devices) and pharmaceutical medications are used in the prevention of VTE. The best outcomes are obtained when mechanical and pharmaceutical techniques are combined. Based on patient risk factors, disease-related risk factors, and procedure-related risk factors, patients having surgery should be categorised according to their risk of VTE. Based on the composite risk profile, the form of prophylaxis should be proportionate with the risk of VTE.

The development of thrombosis inside the deep veins of the pelvis or lower limbs is known as deep vein thrombosis (DVT). Injury to the vessel endothelium slows blood flow, which increases the risk of blood clot formation, lowers venous blood flow, and, in extreme situations, can result in pulmonary embolism (PE) when thrombi travel from the deep veins to the lung through the vasculature [2].

Early detection of DVT and subsequent appropriate therapy with anticoagulants are crucial from a therapeutic standpoint since PE can be fatal in some situations. Early diagnosis is clinically difficult due to the lack of specificity in the clinical signs of DVT, which can even be asymptomatic. Newer oral anticoagulants with greater efficacy have also been discovered during the past ten years, which has led us to consider the efficacy of NEWER ORAL anticoagulant therapy alone from the day of diagnosis in preventing DVT. These developments have led to the development of new protocols for the early detection of DVT in patients at high risk.

Aims and Objectives:

- To Compare efficacy of New Oral Anticoagulants (Dabigatran) vs Low Molecular Weight Heparin (LMWH) in the Prophylaxis against Venous Thromboembolism (VTE)among High-risk surgical patients.
- To compare the risk of bleeding in patients receiving DABIGATRAN and LMWH as Prophylaxis against VTE.

Material and Methods

This study is a Prospective Open Labeled Randomized Control Trial in Sri Venkateshwaraa Medical College Hospital and Research Centre, Puducherry. Patients more than 18 years admitted in surgery and ortho ward were included as per caprini score. Any recent head injury. Pregnant women, severe burns, Patient who refused to give written consent, severe renal insufficiency patient, Cancer patients admitted for Palliation, Severely ill patients with multiple co-morbidities, Bleeding diathesis were excluded. The participants were randomized and one group received Low molecular weight Heparin and the other group received oral Dabigatran. Universal sampling technique was used. Grey scale &Doppler USG were used to confirm DVTs**.** A written consent for willingness to participate in the study was taken. Based on the case flow during the study period, with minimum of 20-30 patients in both the group.

At the time of admission medical history, age, gender, pre hospital interval, vital signs, abdominal signs and drug history and co-morbidities was recorded. After randomization patients received LMWH OR DABIGATRAN. Patients were evaluated daily for the clinical evidence of VTE and suspected patients have undergone duplex/CTPA scan.

Asymptomatic patients had duplex scan done at the time of discharge. At Discharge all patients were educated on symptoms of VTE and Bleeding and will be asked to review immediately in the occurrence of any of the above. A repeat duplex Doppler & grey scale USG was done during the patient's first visit in patients without VTE during index admission. All patient were asked to follow up at 3months from the date of inclusion and will have a repeat duplex scan in patients without VTE during index admission or 1st review. All patients were reviewed every day and during every visit for bleeding.

Patient who do not follow up were contacted over the phone and history of any VTE was evaluated and included. Patients were educated about the study and only those patients consenting to participate in the study were included.

Results:

The table -1 shows the distribution of study participants as per their general characteristics. From our study it had been found that the mean age of our study participants in group 1 is52.20 and group 2 is 53.20. With regarding to the height of the study participants in both the groups there no much difference among both the groups.

While the mean weight distribution among the study participants in the group1 is 66.52 and group 2 is 59.44. There found to be a statistically difference between the study participants among the two groups with regarding to their weight.

Table 1: Distribution of study participants as per general characteristics

Characteristics	Group I	Group II		
	Mean± S.D	Mean± S.D	t	p
Age	52.2±9.2	53.2±8.53	0.398	0.692
Gender	25	25	0.089	0.765
Height	1.65±0.065	1.53±0.05	0.156	0.87
Weight	66.52±12.65	59.44±7.69	23	0.02

The table -2 depicts the distribution of study participants as per their vitals. From our study it is evident that the mean pulse rate among the participants of group1 is 75.52 and group 2 is 76.2. With regarding to the systolic Blood pressure the mean systolic BP among group1 found to be 130.96 and group 2 is 135.2. It is found to be statistically significant among the two groups. But when comparing the diastolic blood pressure between the two groups, they do not differ statistically with respect to diastolic blood pressure.

Table 2: Distribution of study participants as per their vitals

Vitals	Group I	Group II		
	Mean± S.D	Mean± S.D	t	p
Pulse Rate	75.52±5.037	76.2±5.627	0.45	0.65
Systolic Blood Pressure	130.96±5.74	135.2±4.96	2.71	0.008
Diastolic Blood Pressure	82.88±4.833	83.12±5.449	0.165	0.87

The table-3 shows the distribution of study participants as per their blood investigations. All the patients were subjected for the same blood investigations. From the table it is evident that there is no much mean differences among the study participants of both the groups. And also found to be they are not statistically significant.

Table 3: Distribution of study participants as per their blood investigations

	Mean±S.D	Mean ± S.D	t	p
Urea	27.96 ±6.26	27.32±6.57	0.35	0.726
Creatinine	0.95±0.34	0.98±0.35	0.363	0.718
Random Blood Sugar	142.92±36.81	142.72±32.22	0.02	0.98
Platelets	2.85±1.01	2.95±0.93	0.362	0.719
Prothrombin Time	1.1±0.144	1.1±	0	1
APTT	42.04±4.93	42.76±5.02	0.511	0.612
Bleeding Time	2.64±6.75	2.68±0.8	0.181	0.85
Clotting Time	3.96±0.84	5.16±5.85	1.014	0.316

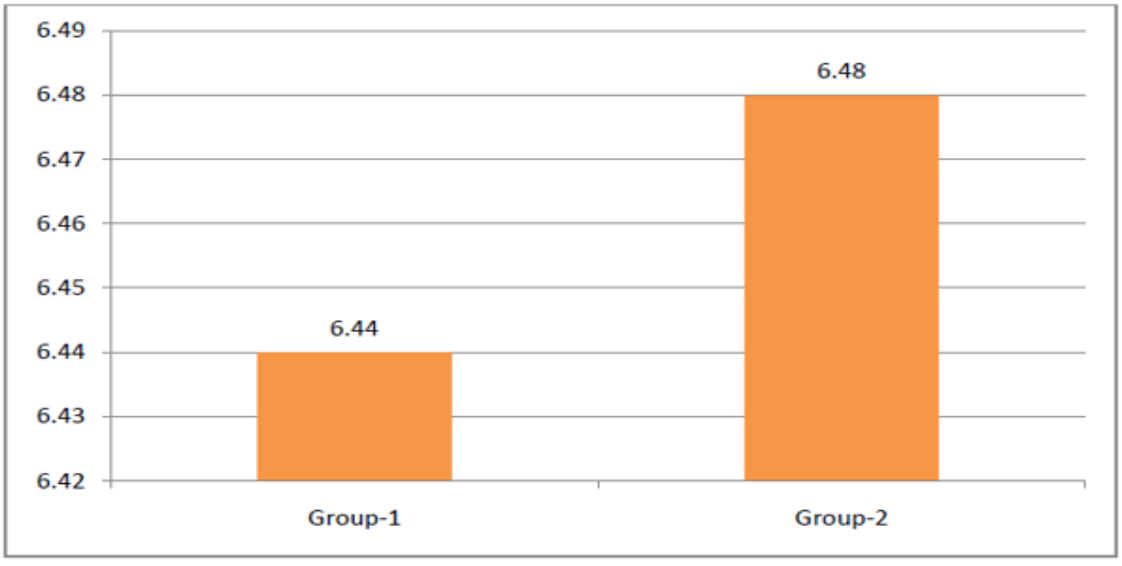

Figure 1: Capirini score among study participants

The above picture shows the comparison between the mean capirini score between the study participants of two groups. The mean score among the group1 is 6.44 and group 2 is 6.48.

Discussion

The current study is a randomised controlled trial with 50 patients, 25 patients in each group. The study includes SVMCH&RC patients who are

hospitalised to the departments of general surgery and orthopaedics and who, according to the Caprini score, have a high risk of developing VTE. Patients were given either LMWH OR DABIGATRAN following randomization.

The mean age of Group1 is 52.20, whereas group2's is 53.20. Statistics show no age differences between the two groups. There are 17 girls and 8 males in group 1.16 females and 9 males make up group 2. In terms of sex, there are no statistical differences between the two groups. Group 1's average height is 1.65, whereas group 2's is 1.53. The two groups do not differ statistically with respect to height. Similar results also seen in the study done by Wurnig et al [3]. In the study conducted by Li hao et al [4] found out that similar to our study results that the mean age of study participants is 52.48 years and 72% were men The mean weights of groups 1 and 2 are 66.52 and 59.44, respectively, and there is a statistically significant difference between the weights of the two groups (P=0.02). The two groups' mean pulse rates, 75.52 in group 1 and 76.20 in group 2, do not statistically differ from one another. The mean systolic blood pressure in groups 1 and 2 is 130.96 and 135.20, respectively, and there is a statistically significant difference between the two groups' blood pressures. The mean diastolic blood pressure in groups 1 and 2 is 82.88 and 83.12, respectively, and there is no statistically significant difference between the two groups in this regard. Similarly, in the study done by David et al [5], there is statistical difference in the blood pressure among their study participants. All the study participants were subjected for the same blood investigations such as serum urea, creatinine, Random blood sugar, Prothrombin time, APTT, bleeding time and clotting time. But form our study it had been found out that there is no much mean differences in the blood investigation among the study participants of both the groups. And also found to be they are not statistically significant. Similarly in the study done by Agarwal et al [6] found out that there is no much significance among the blood investigation values among their study participants.

According to the research done by Wurnig et al [3]., switching from LMWH to Dabigatran is both safe and effective in avoiding VTE. Similar to our study, Dawid et al [5].'s research found no significant difference between subcutaneous and oral thromboprophylaxis in terms of safety. In their study, Agarwal et al [6]. Discovered that 96.6% of individuals who did not receive prophylaxis experienced DVT.

Conclusion

The research was carried out among hospital surgical patients who had been admitted. Age, sex, height, weight, systolic, diastolic, pulse rate, blood sugar, urea, creatinine, platelets, prothrombin time, APTT, bleeding time, clotting time, haemoglobin, and caprini score did not substantially differ between the two groups. DVT disappeared during a follow-up scan without medical intervention and did not spread locally. None of the individuals experienced a pulmonary embolism that was clinically obvious. Therefore, it is clearly evident from the study that Dabigatran is not inferior to LMWH and that it can be used for prophylaxis so as to prevent the need for pointless injections. So, we conclude that Oral anticoagulants work just as well as low molecular weight Heparin.

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