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An analysis of deep vein thrombosis in burn patients (part II): A randomized and controlled study of thrombo-prophylaxis with low molecular weight heparin[☆]

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ABSTRACT

Introduction: Morbidity and mortality from venous thrombo-embolism (VTE) remains a significant problem for trauma and medical patients and there are established guidelines for prophylaxis in these patients. However, the efficacy and safety of VTE prophylaxis in thermally injured patients continue to be elusive as it has never been studied in a prospective, randomized fashion. Selective use of VTE prophylaxis, for high risk patients, is practiced by some burn units even if objective evidence is lacking for majority of risk factors enunciated in burn patients. Differing demographics and wound management techniques are other confounding factors mandating more prospective studies to evaluate the need and role of chemoprophylaxis for deep vein thrombosis (DVT) prevention in burn patients. Ours is the first prospective, randomized, controlled study which seeks to identify risk factors for DVT in our patients, and evaluate the role of routine chemoprophylaxis and its complications.

Methods: The study design (sample size, inclusion/exclusion criteria, randomization, methodology and statistical methods) is detailed in part-1 of this two part manuscript.

Results: Doppler ultrasound (DUS) identified DVT in four out of 50 patients (8% incidence) forming the control group. DVT was not detected in any of the patients on prophylaxis (0% incidence). This difference was found to be statistically significant (p value—0.021). Patients with DVT had significantly higher %TBSA, prolonged immobility and a longer duration of stay as compared to patients without DVT in the control group. Only one patient on enoxaparin prophylaxis developed mild epistaxis which resolved spontaneously. Fifteen patients died during the study out of which two had DVT but none showed autopsy evidence of pulmonary embolism.

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Conclusion: With a moderate risk of developing DVT (8%) and a complication rate of only 2% with chemoprophylaxis, we feel that routine prophylaxis has the potential to decrease the incidence of VTE, without associated complications, in the moderate to high risk category.

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1. Introduction

Deep vein thrombosis (DVT) and venous thrombo-embolism (VTE) are fairly frequent complications seen in the trauma and surgical/medical patients. There is sufficient data to support the clinical benefit and cost-effectiveness of routine thromboprophylaxis in these patients [1-3] but similar data does not exist for the burn population. Moderate to high-risk groups for trauma and surgical/medical patients are categorized when there is an estimated DVT prevalence of 2-8% and 10-20% respectively, and DVT prophylaxis is recommended in these patients [4]. The reported incidence of DVT in burn patients ranges from 0.9% [5] to 53% [6] if no DVT prophylaxis is provided (Table 1, study part-1). This incidence reduces to 0.25% [7] and to 2.4% [8] if prophylactic measures are adopted but it may still be as high as 23% if predisposing co-morbid features are present [9] (Table 1). In a large retrospective study on 33,637 thermally injured patients, Pannucci et al. [10] reported an incidence of 0.61% for VTE but they could not comment on the status of DVT prophylaxis as they lacked relevant records. It is obvious from majority of previous studies that the risk of DVT in burn patients ranges between moderate to high. Thus, it is necessary to examine objectively the utility of chemoprophylaxis for DVT in burn patients. The need for a randomized, controlled trial (RCT) data which examines the effectiveness of chemoprophylaxis for VTE prevention after thermal injury has been expressed before [11,12].

It is well documented in trauma literature that complications from DVT chemoprophylaxis are not common [13-15] but much remains unknown regarding the real risks and benefits of thrombo-prophylaxis for the burn population. Fecher et al. reported no complications with routine DVT chemoprophylaxis with heparin in a large retrospective study on 4102 patients [7]. Similarly, Bushwitz et al. found no incidence of heparin induced thrombocytopenia in their retrospective study of 1111 burn patients, 600 of whom received heparin prophylaxis and the other 511 patients received enoxaparin [16]. They were, however, unable to identify the incidence of prophylaxis related bleeding from their study [16]. Still, for burn population many authors have advocated prophylactic treatment of 'high risk' patients only [5,17,18]. However, the risk factors for DVT in burn patients are also not clearly defined

barring the association with total body surface area burns (TBSA) and inhalation injury, through a large burn data repository of American Burn Association. These two risk factors were derived by multivariable logistic regression and a weighted risk scoring system [11]. Several other risk factors have been implicated by various studies but these associations have low objective evidence [4,5,7,9,10,17,19,20]. There is still a need in burn patients to address the risk factors for DVT and further evaluate the complications with routine chemoprophylaxis to better document the risk-benefit ratio.

Currently, there are no standardized guidelines for DVT prophylaxis in burn patients. Even large survey studies of burn units across USA and Canada fail to express a consensus on the routine use of chemoprophylaxis [21,22]. A survey study of 71 US burn centers [21] found 76% of the centers providing routine DVT prophylaxis whereas 24% of the centers did not provide any form of prophylaxis. Another survey of 16 Canadian burn centers [22] found 50% of the centers using routine prophylaxis and 25% using it only for the high risk groups. The remaining 25% did not use any form of prophylaxis.

Thus, we instituted the first randomized and controlled study to initiate addressing these controversies in a more objective manner; to identify risk factors for DVT in our burn population, to evaluate the role of low molecular weight heparin prophylaxis, and the complications associated with its routine use.

2. Materials and methods

The study design (sample size, inclusion/exclusion criteria, randomization, methodology and statistical methods) is detailed in part-1 of this two part manuscript.

3. Results

3.1. DVT incidence and demographics

The control and study groups were matched and comparable for all demographics, except BMI and %TBSA burns, which surprisingly were significantly higher in the study group (Table 2, study part-1). Four (eight percent) patients from control group (50 patients) developed DVT which was

Table 1 – Incidence of DVT in studies where DVT prophylaxis was used.

Study	No. of patients (n)	Diagnosis	DVT incidence	Prophylaxis (n)
Wahl and Brandt [8]	327	DUS (S)	2.4% (8)	Mechanical (3) & LMWH (3)
Wahl et al. [9]	30	DUS (R)	23% (7)	LMWH or mechanical (6)
Fecher et al. [7]	4102	DUS (S)	0.25% (10)	Routine heparin
Bushwitz et al. [16]	1111	DUS and venography	0.27% (3)	Routine heparin or LMWH

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