

The outcome of DVT prophylaxis in patients with solid organ injury undergoing non operative management (NOM)

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Abstract

Background: Blunt abdominal traumatic injuries account for more than 80% of all trauma related hospital admissions.¹ Solid organ injuries are the most common injury pattern. Trauma patients are at risk of venous thrombo-embolism (VTE). More than 50% may develop thrombus in the lower limbs, which substantially increases the risk of pulmonary embolism (PE).² In trauma patients who survive 24 hours, pulmonary embolism is one of the commonest causes of death. Even with Enoxaparin, DVT can be detected in 15% of patients when screened with duplex ultrasonography.³ Non operative management (NOM) is the current standard of care for managing hemodynamically stable patients with isolated blunt solid organ injuries.³ The optimal time to initiate venous thromboembolism (VTE) chemoprophylaxis in blunt solid organ injury (BSOI) patients is debated. Early initiation of DVT prophylaxis

with low molecular weight heparin (<48 hours) reduce the thromboembolic complications.⁵ The aim of this study was to determine the safety of early initiation of chemical VTE prophylaxis in patients with isolated solid organ injuries who undergo an initial trial of NOM.

Methods: It was a prospective interventional study. 37 hemodynamically stable patients aged >18years with blunt abdominal trauma and solid organ injury were enrolled. Patients with AAST grade 1 & 2 injury eligible for nonoperative management (NOM) were enrolled and given LMW Heparin VTE prophylaxis. The usefulness of early LMW Heparin initiation and its safety in NOM patients of blunt solid organ injuries were evaluated.

Results: Most of the patients with trauma and injuries were aged between 40-70 years of age and predominantly males. Most common injured solid organs in blunt trauma were liver followed by spleen and kidney. Frequency of grade 2 solid organ injuries were greater than that of other

AAST grade injuries. Among the presented patients, most common cause of blunt abdominal trauma was RTA followed by fall from height and physical assault. Duration of the hospital stay was positively correlated to grade of the injury sustained. Out of the enrolled patients 2 of them developed venous thromboembolism (VTE) and one patient was shifted to operative management due to loss of hemodynamic stability.

Conclusion: Early initiation of anticoagulants in patients with blunt trauma abdomen with solid organ injury (Grades I to III) who are hemodynamically stable, seems to be safe and very effective in reducing the risk of venous thromboembolism without increasing the risk of adverse outcomes such as bleeding manifestations, failure of non-operative management and mortality.

Keywords: VTE, DVT, BSOI

Introduction

One of the most prevalent causes of preventable trauma-related fatalities is abdominal trauma. Because to urbanization and industrialization, its frequency is growing. More so for the working population, greater use of equipment and road traffic accidents have led to considerable morbidity and death. Blunt abdominal traumatic injuries account for more than 80% of all trauma related hospital admissions. Solid organ injuries are the most common injury pattern. Trauma patients are at risk of venous thrombo-embolism (VTE). More than 50% may develop thrombus in the lower limbs, which substantially increases the risk of pulmonary embolism (PE). In trauma patients who survive 24 hours, pulmonary embolism is one of the commonest causes of death. Even with Enoxaparin, DVT can be detected in 15% of patients when screened with duplex ultrasonography. Non operative management (NOM) is the current standard of

care for managing hemodynamically stable patients with isolated blunt solid organ injuries.

Patients who don't require surgical intervention are handled by NOM (Non-Operative Management) (Non-Operative Management). In such patients VTE (Venous Thromboembolism) which includes DVT (Deep Vein Thrombosis) & PE (Pulmonary Embolism) are feared consequences related to extended immobility in such individuals. Hence prophylaxis against VTE should be begun in such individuals. The time of commencement of prophylaxis is not uniform to all the patients. Early commencement of prophylaxis may lead to bleeding from injuries of Abdominal trauma and delay in initiation may lead to complications. Hence the time of start is a subject of dispute.

It was also shown by earlier studies that the proportion of patients undergoing non operative management who develop hemodynamic instability after the initiation of anticoagulants is not statistically significant. However, the clinicians in India are apprehensive about the initiation of anticoagulants in such patients, fearing that the patient might develop hemodynamic instability. Only a few studies conducted in India, looked at the effects of anticoagulants in patients undergoing non-operative management; and their results have been conflicting. With the previous literature in consideration, we hypothesized that early initiation (within 48hrs of trauma) of VTE prophylaxis is beneficial in patients with blunt abdominal trauma undergoing NOM.

Materials and methods

It was an open label, prospective interventional Study conducted in Department of General Surgery, ESIC MC PGIMSR, Rajajinagar, Bengaluru. Patient enrollment was done from March 2021 to August 2022. The study was conducted as per ICH-GCP guidelines and Declaration of

Helsinki. The study commenced after obtaining ethical clearance from the Institutional Ethics Committee.

Patients above the age of 18 years irrespective of the gender were the study subjects. Hemodynamically stable patients with sustained abdominal solid organ injury were included in the study. Exclusion criteria were hemodynamically unstable patients with solid organ injuries; patient not willing to give informed consent; previously diagnosed thromboembolism; patients who were on thromboprophylaxis for various conditions; solid organ injury who also had head injury.

Patients with history of blunt trauma abdomen were included in the study. After doing the initial management, and stabilization, routine investigations like Complete hemogram, Liver function test, Renal function test, Coagulation profile, D-dimer and serology were done. CECT

Abdomen and Pelvis was done and assessed for the severity of trauma using American Association for the Surgery of Trauma (AAST) grading. Patients having Grade I and II abdominal injury excluding thoracic injury or head injury who were hemodynamically stable were given LMW Heparin 40mg subcutaneous, once daily for 5 days as VTE prophylaxis (<48 hours) after an initial DVT scan to rule out existing DVT. Dosing schedule and timing of the first dose was noted and a repeat DVT scan was done after 1 week.

The primary objective of the study was to determine, how useful is early initiation of Low Molecular Weight Heparin in isolated blunt solid organ injuries who undergo initial trial of NOM. The secondary endpoint was to determine safety of early initiation of chemical venous thromboembolism (VTE) prophylaxis among patients undergoing NOM of blunt solid organ injuries.

NOM is defined as not performing any surgery or angio-embolization in patients having solid organ injury in the first 4 hours after hospital admission. NOM was performed.

Only in hemodynamically stable patients. The standard care for NOM consists of continuous monitoring of vital signs in the intermediate care or intensive care unit, clinical re-evaluation every 6 to 8 hours and checking serial hemoglobin levels every 6 to 8 hours. Failure of NOM is defined as the need for operative intervention in patients who received early (< 48 h) VTE prophylaxis. Effectiveness is measured based on the number of patients having successful NOM.

Sample size was calculated based on previous study conducted by Norwood et al. In which it was observed that failure of NOM and occurrence of VTE complications were 9%. In the present study, considering expected proportion as 9% with margin of error as 8% and applying finite population correction with confidence level of 95% the minimum size was estimated to be 38.

Statistical analysis

All quantitative variables were analyzed and presented using descriptive statistics such as mean and standard deviation. Qualitative /categorical variables were presented using frequency and percentage.

Chi square test was used to find association between operative intervention and the outcomes like VTE complications length of hospital stay and mortality.

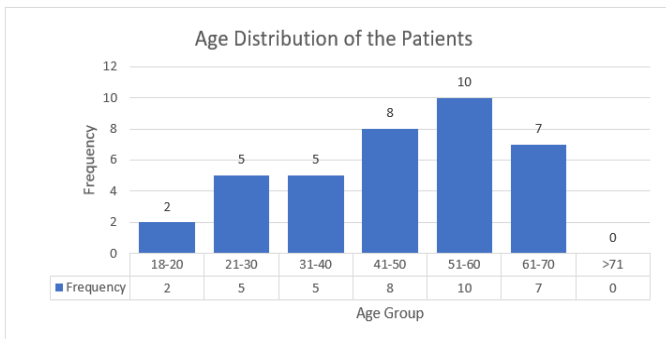
Results

This prospective analytical study was done on thirty-seven patients with blunt abdominal trauma with isolated solid organ injury who had presented to the outpatient department/casualty of ESIC MC & PGIMSR during the study period from March 2021 to August 2022.

Age Distribution

The oldest patient in our study group was 67 years old and the youngest one was 19 years old. In this study most of the patients [54.5%, n=22] were aged between 40 and 70 years. The mean age of patients included in our study was 46.03 with a standard deviation of 13.85.

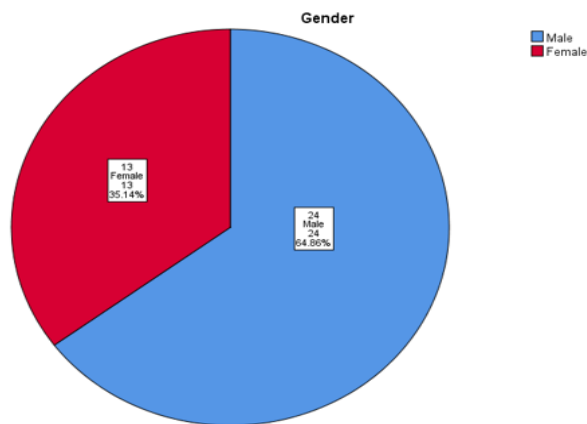
Age Group (years)	Frequency (n)	Percentage (%)
18-20	2	5.4
21-30	5	13.51
31-40	5	13.51
41-50	8	21.62
51-60	10	27
61-70	7	19
>71	0	0
Total	37	100



Gender distribution

Out of the thirty-seven patients included in our study, twenty-four were males and thirteen were females.

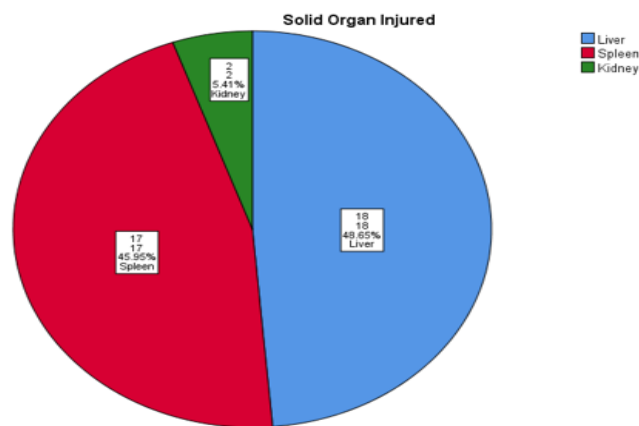
Gender	Frequency	Percent
Male	24	64.86
Female	13	35.14
Total	37	100



Frequency of Solid Organ Injury

The most common solid organ injured was liver (n=17, 45.9%) followed by spleen (n=15, 40.5%) and kidneys (n=3, 13.5%); diagnosed based on CECT abdomen and pelvis on admission

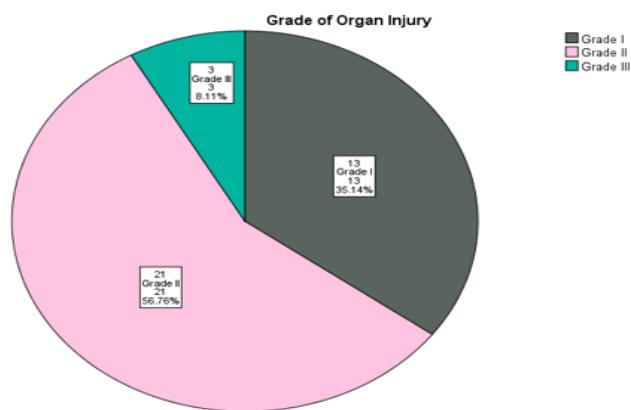
Organ Involvement	Frequency	Percent
Liver	17	45.9
Spleen	15	40.5
Kidney	5	13.5
Total	37	100.0



Frequency of Grades of Solid Organ Injury

Out of the 37 patients, 35.1% (n=13) had Grade I, 56.8% (n=21) had Grade II, and 8.1% (n=3) had Grade III solid organ injuries as per the AAST grading of solid organ injuries.

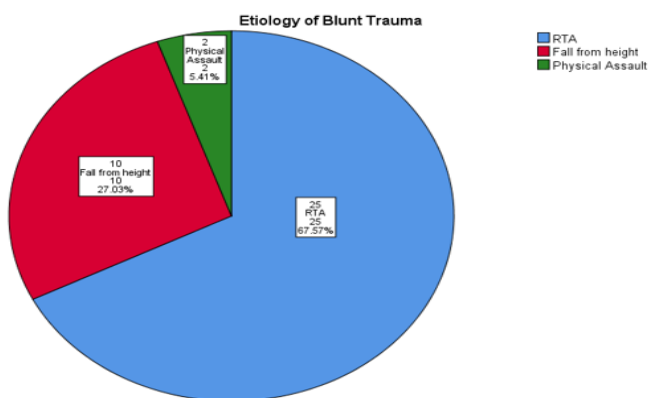
Grade of Injury	Frequency	Percent
Grade I	13	35.1
Grade II	21	56.8
Grade III	3	8.1
Total	37	100.0



Etiology of Blunt Abdominal Trauma

The most common etiological factor implicated in the causation of blunt abdominal trauma in our study cohort was road traffic accident followed by Fall from height and Physical assault.

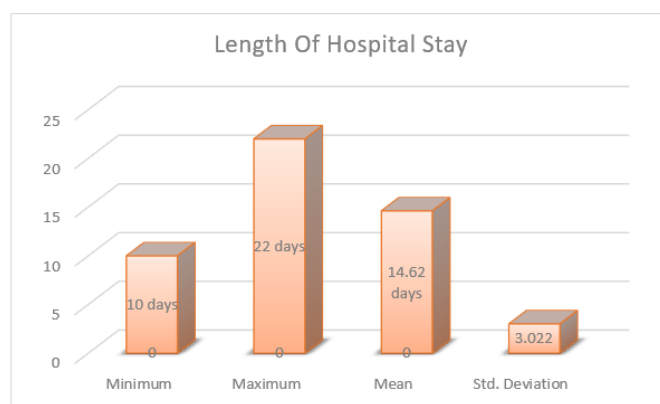
Etiology of trauma	Frequency	Percent
RTA	25	65.8
Fall from height	10	26.3
Physical Assault	2	5.3
Total	37	97.4



Length of Hospital Stay

The longest duration of hospital stay in our study group was 22 days and the shortest duration was 10 days. The mean length of hospital stay in our study cohort was 14.62 days with a standard deviation of 3.022. Also, a positive correlation was noted between the duration of hospital stay and the grade of sustained injury with hospital stay being significantly longer in patients with Grade II or Grade III injury as compared to a Grade I injury.

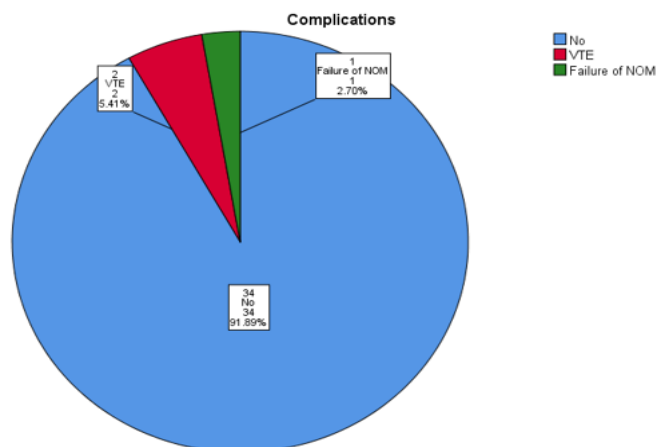
	Minimum (days)	Maximum (days)	Mean (days)	Std. Deviation
Length of Hospital Stay	10	22	14.62	3.022



Frequency of Complications

Only one patient (n=1, 2.7%) out of thirty-seven, had a failure of non-operative management. He was a 48-year-old male with a Grade III liver injury (as per AAST) who required emergency laparotomy due to the development of hemodynamic instability within four hours of diagnosis. Out of 37 patients two patients (n=2, 5.4%) showed evidence of lower limb deep vein thrombosis on repeat doppler which was done a week after the admission.

Complications	Frequency (n)	Percent (%)
No	34	89.5
VTE	2	5.3
Failure of NOM	1	2.6
Total	37	97.4



Discussion

Most of the traumatic injuries encountered in the surgical casualty are due to blunt trauma. If there is injury to the solid organs the mainstay of treatment now is non-operative management if the patient is hemodynamically stable. It is seen that venous thromboembolism is the third leading cause of death in patients with abdominal trauma with solid organ injury undergoing non-operative management. Non-operative management has become the mainstay of management with hemodynamically stable patients with solid organ injuries. It is defined as the absence of operative intervention or angioembolization within the first four hours of diagnosis of a solid organ injury based on cect findings in hemodynamically stable patients. It was shown by multiple studies in the past that approximately 15% of the patients undergoing non-operative management, who are on anticoagulants, will develop venous thromboembolism. So, the rate of venous thromboembolism in patients who are not on any

anticoagulants will be much higher (as traumatic injury is a pro-thrombotic state and hypercoagulability sets in within 12 hours of injury) leading to a higher rate of adverse outcomes.

During the study period a total of 37 consenting patients with blunt abdominal trauma with concomitant solid organ injury, fulfilling the inclusion and exclusion criteria were admitted for non-operative management. Out of 37 patients 35.1% (n=13) had grade i, 56.8% (n=21) had grade ii, and 8.1% (n=3) had grade iii solid organ injuries. Blunt trauma abdomen patients with multiple organ injuries, massive hemoperitoneum, hemodynamic instability, requiring operative intervention, concomitant head injury, death on admission/within 24 hours, or age less than 18 years were excluded from this study. The most common solid organ injured was liver (n=17, 45.9%) followed by spleen (n=15, 40.5%) and kidneys (n=3, 13.5%); diagnosed based on cect abdomen and pelvis on admission (grading as per aast classification). Most common mode of blunt abdominal trauma in our study group was road traffic accidents (n=25, 67.56%) followed by fall from height (n=10, 27.03%) and physical assault (n=2, 5.4%). The mean age of patients included in our study was 46.03 with a standard deviation of 13.85. Out of 37 patients, 24 were males and 13 were females. These results concurred with the results of previously conducted studies by peitzman ab et. Al. (2000), zarazur b.l. Et. Al. (2015) and norwood et. Al. (2001).

Only one patient (n=1, 2.7%) out of thirty-seven, had a failure of non-operative management. He was a 48-year-old male with a grade iii liver injury (as per aast) who required emergency laparotomy due to the development of hemodynamic instability within four hours of diagnosis. Out of 37 patients two patients (n=2, 5.4%) showed evidence of lower limb deep vein thrombosis on

repeat doppler which was done a week after admission. The average duration of hospital stay in our study group was 14±7 days. None of patients developed adverse outcomes such as pulmonary complications (However, no additional investigation was done to rule out pulmonary embolism due to the absence of clinical suspicion, additional risk of radiation exposure, and additional expense), mortality, need for surgery due to the development of hemodynamic instability after 24 hours of admission, need for blood transfusion, development of bleeding manifestations/deranged coagulation profile, etc.. These findings concurred with the previously conducted studies. A study done by Alejandro et. Al. (2003) on a similar cohort of patients had findings like our study. Out of the 94 patients who were subjected to early initiation of anticoagulants, the rate of adverse outcome in the form of failure of NOM was 6.1 %. Similarly in a study conducted by Tatsiana khatsilonskaya et.al. (2016), the failure of NOM in patients subjected to early initiation of anticoagulants was 1.3% (p=0.043) and the rate of venous thromboembolism was 2.1% (p=0.066).

	Our study (n=37)	Alejandro et. al. (2003) (n=94)	Tatsiana Khatsilonskaya et.al. (2016), (n=142)
Failure of NOM	1 (2.7%)	2 (4.5%)	3 (4.8%)
Incidence of venous thromboembolism	2 (5.4%)	3 (6.75%)	4 (6.1%)
Mortality	0 (0%)	0 (0%)	1 (1.6%)

Strengths & limitations

Strengths of this study was that it is one of the very few studies conducted in India which studied the safety and effectiveness of early initiation of anticoagulants in patients with blunt trauma abdomen having solid organ injuries.

Limitations of the study were, there was no control group, and the study was not randomized, and blinding could not be employed contributing to the bias. The study sample

size was relatively small, even small changes in outcomes by chance could change the results significantly.

Conclusion

The study findings suggest that early initiation of anticoagulants (Imwh) are safe and efficacious in preventing venous thromboembolism in patients with blunt trauma abdomen with isolated grade i to grade iii solid organ injuries, provided the patient is hemodynamically stable at the time of presentation. As this study had a small sample size, and lack of control arm, blinding and randomization; before drawing the conclusions further prospective studies with large sample size with proper randomization and control arm would provide more precise information.

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