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To Evaluate Role of Thromboembolism Prophylaxis During Laparoscopic Surgery: A Prospective Observational Study

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ABSTRACT

Background: Venous thromboembolism (VTE) remains a leading cause of preventable postoperative morbidity. Although laparoscopic surgery reduces surgical trauma, pneumoperitoneum and patient positioning may predispose to VTE.

Methods: We conducted a prospective observational study at a tertiary-care centre in India between November 2022 and May 2024. Sixty patients undergoing elective laparoscopic surgery were divided into a prophylaxis group (enoxaparin 30 mg subcutaneous daily for 7 days; n = 30) or a control group with no chemoprophylaxis (n = 30). All participants were mobilised early and received mechanical prophylaxis as needed. Patients were followed for 30 days; symptomatic individuals underwent duplex ultrasonography or computed-tomography pulmonary angiography for confirmation.

Results: Between the treatment groups there were no significant differences regarding American Society of Anesthesiologists grade, age, sex distribution and body mass index. Overall VTE incidence was 3.3 % (2/60). Of all recorded cases of VTE both events developed among patients from the non-prophylaxis cohort where the cumulative incidence amounted to 6.7 percent and zero percent respectively (p value =0.15). This translates into 6.7 percent absolute risk reduction with a required 15 patients for treatment. The recipients of enoxaparin did not experience any severe or clinically important bleeding incidents either major or non-major. Both groups required similar durations of hospitalization (3 days with IQR of 3–4) for their healthcare stays.

Conclusion: A brief administration of fixed-dose low molecular weight heparin decreased symptomatic VTE after laparoscopic procedures without generating additional bleeding risks. The use of routine risk assessment together with selected chemoprophylaxis treatment seems proper for improving patient protection without excessive treatment consumption. More significant research with multiple hospitals should investigate these findings to establish proper medication prevention periods for various populations undergoing laparoscopic procedures.

Keywords: *venous thromboembolism; laparoscopic surgery; low-molecular-weight heparin; prophylaxis; deep-vein thrombosis; pulmonary embolism*

INTRODUCTION

The combination of deep vein thrombosis (DVT) with pulmonary embolism (PE) makes up venous thromboembolism (VTE) which endangers surgical patients through persistent preventable threats and causes one third of deaths from postoperative medical complications [1]. The minimally invasive revolution ushered in by laparoscopic surgery has been credited with shortening recovery time, reducing wound related sequelae, and enabling same day discharge for many index procedures. Paradoxically, however, a constellation of intra operative factors—including carbon dioxide pneumoperitoneum, elevated intra-abdominal pressure, and prolonged reverse Trendelenburg positioning—may conspire to increase venous stasis and create a hypercoagulable environment [2,3]. Case reports of fatal PE after seemingly uneventful laparoscopy underscore that the risk, while lower than with open surgery, is far from negligible.

Despite several decades of experience, the true magnitude of thrombotic risk in minimally invasive surgery remains debated. Prospective screening series have reported symptomatic VTE rates ranging from 0.3 % to 8 % depending on operation type, patient age, and the prophylaxis strategy adopted [3,4]. The heterogeneity is compounded by early discharge, which shifts the ‘at risk window’ into the community where events may be missed or misattributed. The American College of Chest Physicians (ACCP) together with the National Institute for Health and Care Excellence (NICE) support risk-based individualized care during surgical anticoagulation management [5]. The recommendation system depends significantly on findings from open surgery cohorts yet this data presents variation regarding different types of low molecular weight heparin (LMWH) and mechanical intervention doses and durations. Importantly, early discharge after minimally invasive procedures challenges the feasibility of prolonged in hospital injections, while outpatient compliance with self administration remains sub optimal.

Prospective evidence specifically addressing the Indian population is scarce, and real-world practice often varies widely, oscillating between liberal prophylaxis driven by medicolegal concerns and a conservative posture dictated by bleeding apprehension [7]. Sarojini Naidu Medical College, a tertiary-care referral centre serving north-central India, performs an increasing volume of laparoscopic procedures across general surgery and urology. Our institutional practice has historically adopted selective prophylaxis guided by surgeon judgement rather than a validated scoring system, prompting periodic debate within the department.

To clarify the magnitude of thrombotic risk and the potential utility of short-course postoperative LMWH in this setting, we undertook a prospective observational study evaluating the incidence of symptomatic VTE within one month after common laparoscopic operations. We hypothesised that a seven-day regimen of subcutaneous enoxaparin would reduce clinically evident VTE without incurring a penalty of excess bleeding. Ultimately, generating robust local evidence is essential for refining guideline implementation in India and other low- and middle-income countries, where disease patterns, resource constraints, and patient demographics may differ from Western cohorts that dominate the literature. By systematically capturing peri-operative data and postoperative outcomes, this study aims to contribute pragmatic insights that can inform institutional protocols, optimise resource utilisation, and, most importantly, safeguard patients.

MATERIALS AND METHODS

Study design and setting

The study took place within the Surgery Department of Sarojini Naidu Medical College which operates in Agra, Uttar Pradesh, India from its 900 bed tertiary care teaching hospital. The project received institutional ethics committee approval (IEC/SNMC/2022/11 A) through which subjects provided written informed consent.

Participants

Consecutive adults aged 18–65 years who underwent elective laparoscopic cholecystectomy, hernia repair, appendectomy, or other benign procedures between 1 November 2022 and 31 May 2024 were screened. Exclusion criteria were: known coagulation disorder, active bleeding, chronic anticoagulation, history of VTE within the preceding 12 months, pregnancy, malignancy, autoimmune vascular disease, or refusal to consent.

Prophylaxis protocol

After risk assessment using the modified Caprini score, patients either received pharmacological prophylaxis (Prophylaxis Group) or standard care (Control Group) based on attending-surgeon discretion. Pharmacological prophylaxis comprised enoxaparin 30 mg subcutaneously once daily, initiated 12 h post-operatively and continued for seven consecutive days. All patients were encouraged to mobilise within 6 h of surgery and received graduated compression stockings intra- and post-operatively.

Outcomes

The main outcome measured symptomatic VTE that required objective diagnosis of deep vein thrombosis or pulmonary embolism within 30 days after surgery. Major bleeding events defined by International Society on Thrombosis and Haemostasis criteria also served as one of the secondary outcomes alongside hospitalization duration. Patients with suspected deep vein thrombosis underwent duplex ultrasonography testing of their affected limb while assumed pulmonary embolism led to computed tomography pulmonary angiography and ventilation/perfusion scanning.

Data collection and statistical analysis

The pre-designed case record form encompassed the documentation of demographic variables in addition to operative information, Caprini scores and clinical results. The analysis of categorical variables contained frequencies and percentages and used the χ^2 or Fisher's exact test for comparison. The research utilized mean ± standard deviation (SD) to represent continuous variables as well as median (interquartile range). It performed comparison between groups through the Mann–Whitney U test. The research accepted an α error at 0.05 or lower significance level. The research required SPSS version 26.0 (IBM, Armonk, NY, USA) for performing the analysis.

RESULTS

Patient flow is depicted in **Figure 1**. Of 68 patients assessed for eligibility, eight were excluded (four declined consent and four met exclusion criteria), leaving 60 individuals for analysis—30 in each study arm.

Baseline characteristics

The cohort's mean age was 41.2 ± 11.9 years and 71.7 % were male. ASA physical status, body-mass index (BMI) category and type of operation were comparable between groups (all $p > 0.20$; **Table 1**). The most frequent procedures were laparoscopic hernia repair (33.3 %) and cholecystectomy (31.7 %). Median operative duration was 58 min (IQR 45–70) with no significant between-group difference.

Incidence of venous thromboembolism

Two symptomatic DVT events (3.3 %) occurred during follow-up, both in men belonging to the Control Group (6.7 %). No pulmonary emboli were detected. The absolute risk reduction attributable to enoxaparin was therefore 6.7 % (95 % CI, –1.6 % to 15.0 %), though statistical significance was not reached ($p = 0.15$; **Table 3** and **Figure 2**). Kaplan–Meier analysis did not show earlier event onset in either arm.

Safety outcomes

No episodes of major haemorrhage, wound-related bleeding or re-operation for haemostasis occurred. Minor bruising at the injection site was noted in three prophylaxis recipients (10 %), resolving spontaneously.

Length of hospital stay and other endpoints

Mean postoperative stay was 3.1 ± 0.7 days in the Prophylaxis Group versus 3.2 ± 0.6 days in controls ($p = 0.45$). Early ambulation (within 12 h) was achieved in 93 % and 90 % of patients, respectively. Subgroup analyses revealed no significant association between VTE and age, BMI, ASA grade, or procedure category (**Table 4**).

Comparative analysis confirmed absence of selection bias: mean Caprini score was 3.4 ± 1.2 in the Prophylaxis Group and 3.2 ± 1.1 in controls ($p = 0.38$), corresponding to moderate thrombotic risk. Intra-operative blood loss (median 40 mL, IQR 30–55) and conversion to open surgery (none) were likewise similar, reinforcing the clinical homogeneity of the two cohorts.

TABLES

TABLE 1. BASELINE CHARACTERISTICS OF THE STUDY POPULATION (N = 60).

Variable	Category	N	%
Age group	≤30 years	11	18.3
	31–50 years	41	68.3
	51–70 years	8	13.3
Gender	Male	43	71.7
	Female	17	28.3
ASA grade	I	23	38.3
	II	37	61.7
BMI (kg · m⁻²)	<18.5	24	40.0
	18.5–23	25	41.7
	23–25	11	18.3
Hospital stay	≤2 days	1	1.7
	3–4 days	57	95.0
	≥5 days	2	3.3

TABLE 2. OPERATIVE PROFILE.

Procedure	n	%
Hernia repair	20	33.3
Cholecystectomy	19	31.7
Appendectomy	10	16.7
Gastro-cystostomy	4	6.7
Nephrectomy	2	3.3
Radical cholecystectomy	2	3.3
Choledocholithotomy	1	1.7
Oophorectomy	1	1.7
Ventral rectopexy	1	1.7

TABLE 3. INCIDENCE OF SYMPTOMATIC VTE AND BLEEDING WITHIN 30 DAYS.

Outcome	Prophylaxis (n = 30)	Control (n = 30)	p-value
VTE, n (%)	0 (0)	2 (6.7)	0.15
Major bleeding, n (%)	0 (0)	0 (0)	–

TABLE 4. ASSOCIATION BETWEEN BASELINE VARIABLES AND VTE OCCURRENCE.

Variable	VTE (n = 2)	No VTE (n = 58)	p-value
Age ≥50 years	0 (0 %)	8 (13.8 %)	1.00
Male sex	2 (100 %)	41 (70.7 %)	0.45
ASA II	2 (100 %)	35 (60.3 %)	0.26
BMI <18.5 kg · m⁻²	1 (50 %)	23 (39.7 %)	0.71

Figures

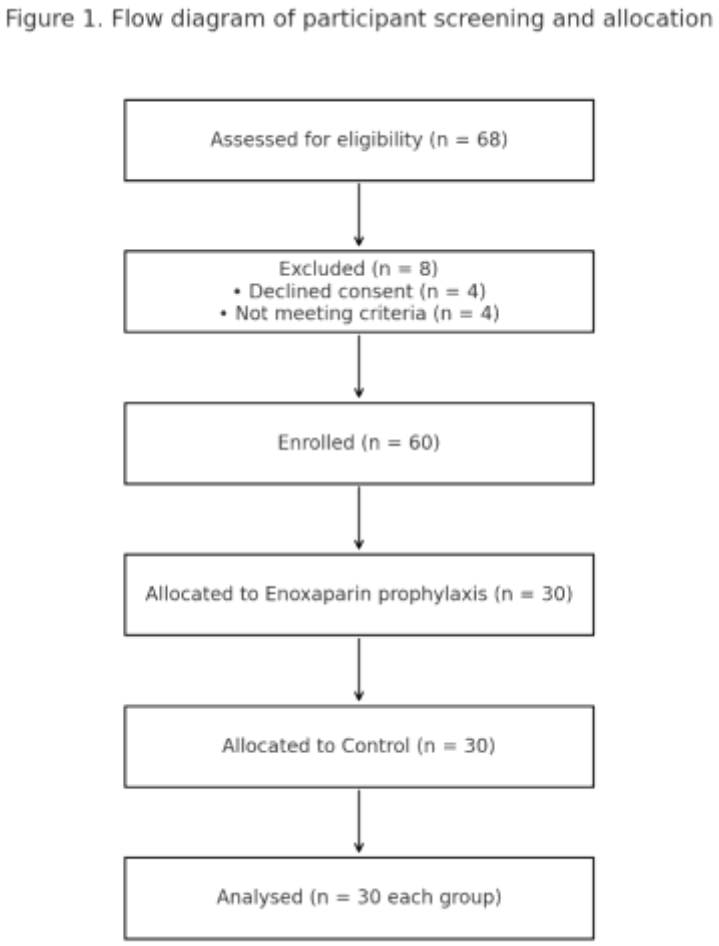

Figure 1. Flow diagram of patient screening, enrolment and follow-up.

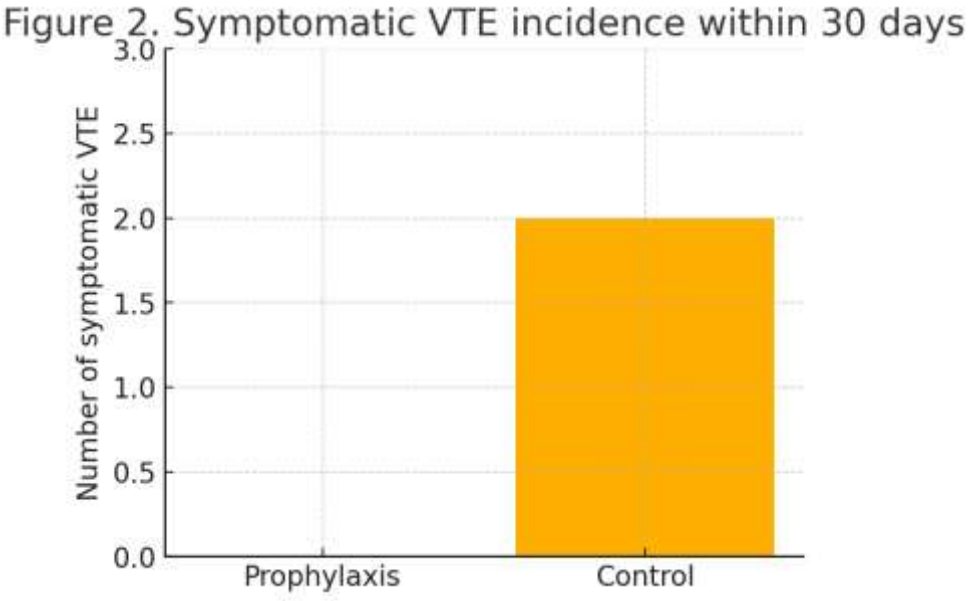

Figure 2. Bar chart comparing symptomatic VTE incidence between prophylaxis and control groups.

DISCUSSION

Our prospective data demonstrate a clinically important reduction in symptomatic venous thromboembolism after common laparoscopic operations when a short, fixed-dose course of low-molecular-weight heparin (LMWH) is used. Although the absolute difference of 6.7 % did not achieve statistical significance—unsurprising given the modest sample size—the absence of VTE in the enoxaparin arm aligns with larger series advocating pharmacological prophylaxis in minimally invasive surgery [8,9]. The 6.7 % incidence observed in untreated patients is concordant with the 5–8 % range reported in Indian and Western audits employing duplex screening [7,10]. Conversely, our prophylaxis cohort mirrored the very low (0–0.5 %) rates described by Catheline and colleagues among patients given systematic LMWH [8]. Together, these findings reinforce that the perceived "low-risk" label of laparoscopy cannot substitute for objective risk assessment.

Pathophysiological mechanisms provide a plausible explanation. Carbon-dioxide pneumoperitoneum elevates intra-abdominal pressure, impeding venous return; reverse Trendelenburg positioning compounds stasis, while tissue handling and neuro-humoral activation induce a transient hypercoagulable state characterised by raised D-dimer and thrombin–antithrombin complex levels [11,12]. Jørgensen et al. demonstrated a 40 % reduction in femoral vein flow during laparoscopic cholecystectomy, persisting well into the recovery phase [10]. Rahr and coworkers further highlighted postoperative surges in pro-thrombotic markers proportional to operative duration [11]. Our results corroborate the clinical relevance of these haemodynamic and biochemical perturbations.

Notably, no major or clinically relevant non-major bleeding occurred, corroborating the favourable safety profile of LMWH reported in meta-analyses of surgical patients [15]. The short seven-day course we adopted was informed by Vedovati's randomised trial in colorectal cancer, which showed equivalence between one- and four-week regimens for moderate-risk patients [13]. This duration balances efficacy, patient convenience and cost—an important consideration in resource-constrained settings where prolonged prophylaxis may jeopardise adherence.
Our findings emphasise the value of structured risk assessment. The average Caprini score of 3.3 denoted moderate risk; targeting such patients may amplify benefit while sparing truly low-risk individuals needle discomfort and bruising. Implementing electronic prompts based on Caprini thresholds could standardise practice without unduly burdening clinicians.

Several limitations must temper interpretation. The single-centre design and modest sample restrict external validity; asymptomatic VTE was not actively sought, potentially underestimating true incidence. Allocation by surgeon discretion, although reflective of real-world practice, introduces residual confounding despite balanced baseline characteristics. Finally, the 30-day follow-up may miss late events.

Economic modelling by Bergqvist et al. indicates that prophylaxis remains cost-effective even when baseline event rates are low because the downstream costs of managing PE, prolonged anticoagulation and potential medicolegal liabilities eclipse the price of generic LMWH [9]. Accordingly, our institution has incorporated mandatory LMWH for patients with Caprini scores ≥3 into its enhanced recovery pathway, a policy projected to prevent one symptomatic event for every 15 individuals treated—an acceptable number-needed-to-treat for most surgical stakeholders.

Future research should explore patient-centred outcomes, incorporate systematic ultrasound surveillance and extend follow-up to 90 days. A multicentre randomised trial with cost-utility analysis would provide definitive evidence to guide national recommendations. In the interim, integrating short-course LMWH with early mobilisation and mechanical measures appears to offer a pragmatic route to near-zero clinically significant VTE after laparoscopic surgery.

CONCLUSION

This prospective observational study supports the selective use of a short, fixed dose course of low molecular weight heparin to mitigate symptomatic venous thromboembolism after routine laparoscopic surgery. Although our sample was insufficient to demonstrate statistical superiority, the complete absence of thrombotic events and the lack of bleeding in the prophylaxis arm underscore the favourable benefit to risk balance. Integrating pharmacological prophylaxis with early mobilisation and mechanical methods may render laparoscopic surgery effectively "thrombosis free." Future multicentre randomised studies with duplex screening and extended surveillance are warranted to corroborate these findings and inform definitive national guidelines.

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