



Best evidence topic

Enoxaparin venous thromboembolism prophylaxis in bariatric surgery: A best evidence topic

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H I G H L I G H T S

- Evidence regarding enoxaparin VTE prophylaxis for post-op bariatric patients is limited.
- Evidence suggests that prolonged treatment for 10 days post-discharge reduces VTE incidence.
- Pre-operative enoxaparin 1 hour before surgery may be associated with a higher rate of major bleed.
- A dosage of 40 mg enoxaparin BD instead of 30 mg BD reduces VTE risk but increases bleeding risk.
- After discharge, a lower dosage of enoxaparin 50 mg OD is as effective at VTE prophylaxis as 90 mg OD.

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A best evidence topic in surgery was written according to a structured protocol. The question addressed was: which is the best regimen of enoxaparin thromboprophylaxis for patients undergoing bariatric surgery? One hundred and twenty-five papers were identified using the reported literature search, of which four represented the best evidence to answer the clinical question. The authors, country and date of publication, patient groups, relevant outcomes and results of these papers were tabulated. All four studies are non-randomized cohort studies examining venous thromboembolism rates and major postoperative bleeding following varying regimens of Enoxaparin thromboprophylaxis. There is no level 1 evidence which significantly favors any particular thromboprophylaxis regimen. There is some evidence that extended duration of treatment of ten days after discharge significantly reduces the incidence of VTE compared to in-hospital treatment only, and that a higher incidence of post-operative bleeding occurs with a regimen that includes a pre-operative dose of Enoxaparin. With regard to dosage, for in-hospital treatment the higher dosage of 40 mg twice daily as opposed to 30 mg seems to significantly reduce the incidence of VTE without significantly affecting bleeding rate.

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1. Introduction

Major risk factors for venous thromboembolism (VTE) include obesity and surgery. The incidence of VTE, presenting as deep vein thrombosis (DVT) or pulmonary embolism (PE), after bariatric surgery has been reported at between 0.5 and 2% [1–3]. There is at present no consensus as to which prophylactic regimen is best for bariatric surgery patients in the peri-operative period, and practice

varies substantially between centers. This subject is pertinent as bariatric surgery remains the best treatment for obesity and related co-morbidities [4], and as the global population becomes increasingly obese the demand for such surgery is likely to increase.

Many different formularies of LMWH exist. Enoxaparin is a commonly used form, and its use in thromboprophylaxis in peri-operative bariatric patients is examined and analyzed in this paper. In order to provide a robust and easily-accessible summary of the evidence regarding this matter, a best evidence topic (Best BET) was constructed according to a structured protocol. A Best BET is a reproducible and validated way of collecting and assessing the best available evidence to answer a clinical question, especially useful where evidence is of limited quality [5].

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2. Clinical scenario

Another surgeon has recently joined your department, and argues that the pharmacological regimen of Enoxaparin for VTE prophylaxis that he is accustomed to using for his bariatric cases is superior to that which is currently standard in your department. You resolve to check the literature to determine which thromboprophylaxis regimen for patients undergoing bariatric surgery is optimal.

3. Three-part question

What is the optimum dosing regimen of enoxaparin for peri-operative VTE prophylaxis in patients undergoing laparoscopic bariatric surgery?

4. Search strategy

A standardized literature search was performed on both the Medline and EMBASE databases (Medline 1946 to January 2015, EMBASE 1974 to January 2015 using OVID interface). The search terms were as follows: (Bariatric Surgery) AND (VTE OR thromboembolism) AND (Enoxaparin). These keywords were searched in subject headings, in title and in abstract. There were no restrictions on language, publication type or publication year applied to the search. In addition, reference lists of selected papers were searched. The search was current as of 11th April 2015.

5. Search outcome

125 papers were found on the EMBASE database. No additional papers were found on the Medline database. Two investigators independently selected the best available evidence for analysis in this review: they were in agreement. Thirty-three papers were excluded as they were reviews or editorials which did not contribute original data. Thirty irrelevant papers were excluded. Studies that analyzed VTE events after non-bariatric surgery were excluded: this accounted for 13 papers. Papers using methods of VTE prophylaxis other than enoxaparin and/or weight-adjusted enoxaparin were excluded (19 in total). Seven studies that looked into the effectiveness of anticoagulation by measuring anti-factor Xa cofactor levels were excluded. One paper looking at VTE after robotic bariatric surgery was excluded. Fifteen observational single-arm case series, one case study and two comparative trials studies with small patient numbers were excluded as deemed not to be the best available evidence.

The best evidence to answer this question consists of four comparative studies analyzing two or more non-weight adjusted doses of enoxaparin for VTE prophylaxis in patients undergoing bariatric surgery [6–9] (see Table 1). In these studies venous thromboembolism was defined as symptomatic proximal lower limbs (popliteal or more proximal) deep vein thrombosis or pulmonary embolism, confirmed with imaging. The definition of a major bleed was one resulting in a significant haemoglobin drop or that required a post op transfusion or surgical/radiological intervention.

6. Discussion

Obesity is a risk factor for VTE [1–3]. The American College of Chest Physicians has stated that all bariatric patients are classed as having moderate to high risk of VTE and therefore recommend pharmacological thromboprophylaxis [10]. This recommendation is largely based on examining the relative risk of obese patients undergoing other types of surgery. Data from the 2009 Longitudinal

Assessment of Bariatric Surgery suggests that VTE risk increases with weight [2]. A review of 19 studies in 2012, however, found little benefit from weight adjusted dosing regimens and an increased bleeding risk [11]. As a result, only non-weight adjusted regimens have been considered here.

Current VTE prophylaxis for patients post-bariatric surgery varies greatly depending on surgeon preference. This stems from the fact that there is currently no level I evidence to provide guidance on the type, duration or dose of bariatric thromboprophylaxis. Considering enoxaparin non-weight adjusted thromboprophylaxis alone, the dosage, duration, frequency and relation of administration to timing of surgery may all vary, which gives a great number of different possible regimens. The best regime would prevent peri-operative venous thromboembolic events without increasing the likelihood of major bleeding events.

Marie et al. [6] compared 50 mg with 90 mg once daily post-operative enoxaparin for 30 days post-surgery. Patients were assigned to different groups according to anesthetist choice. This is likely to have introduced bias to the groups, since anesthetists may have taken into consideration the risk factor profile of the each patient for VTE and bleeding when deciding on enoxaparin dosage. Patients with previous thromboembolic disease were excluded from the study and there were few patients with BMI>60 in the study, so results may not be generalizable to these groups of patients. Marie et al. found no difference in VTE or bleeding rates between their two groups.

Raftopoulos et al. [7] compared two groups with enoxaparin regimes that differed in two respects: group A had one dose of 30 mg enoxaparin 1 h prior to surgery, whereas group B had no pre-operative dose; and group A stopped chemoprophylaxis on discharge from hospital whereas group B had 40 mg enoxaparin once daily for 10 days post discharge. Scholten et al. [8] compared two post-operative regimens of enoxaparin, 30 mg versus 40 mg twice daily, until patients fully ambulatory or discharged. In both of these studies, the two patient groups were consecutive cohorts of the same surgeon, reflecting a change in practice over time. Clearly, other factors are likely also to have changed with time: for example, operative technique changed between the Raftopoulos groups. These changes may be confounding variables, also affecting VTE and bleeding rates. Raftopoulos et al. found that the group without a pre-operative dose of enoxaparin but with an extended post-operative course had decreased rates of VTE as well as decreased rate of major bleed. Scholten et al. concluded that the higher dosage of enoxaparin (40 mg twice daily) was superior in preventing VTE without conferring a higher bleeding risk.

Hamad et al. [9] retrospectively compared the VTE and bleeding outcomes at five centers each using a different Enoxaparin regime. This was a descriptive study, in which no comparative statistical analysis was undertaken (perhaps because of low incidence of primary outcomes). The authors observe, however, that in their large group (668 patients) all VTE events occurred after cessation of VTE prophylaxis, thus concluding that a longer duration of therapy is advisable. This finding is supported by data from the Bariatric Outcomes Longitudinal Database, which revealed that 73% of VTE occurred following discharge from hospital [1].

The first conclusion that can be drawn from this study is that a prolonged duration of prophylaxis, when compared to stopping chemoprophylaxis on discharge, seems to significantly reduce the incidence of VTE [7]. This corresponds to the evidence that prolonged VTE prophylaxis is beneficial in patients that have undergone surgery for abdominal or pelvic malignancy, for whom treatment for 28-days postoperatively is a NICE recommendation [12]. Post-discharge VTE prophylaxis seems likely to become more widespread for patients post-bariatric surgery, especially as hospital stays become shorter. The length of post discharge prophylaxis

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