Risk of venous thromboembolism and efficacy of thromboprophylaxis in hospitalized obese medical patients and in obese patients undergoing bariatric surgery


CRD summary
This review evaluated the efficacy and safety of venous thromboembolism (VTE) prophylaxis in hospitalised obese patients. The authors appropriately stated that the limited number and quality of studies comparing different methods of VTE prophylaxis precludes a definite conclusion about the most effective and safe method in these patients.

Authors' objectives
To review the efficacy of venous thromboembolism (VTE) prophylaxis in hospitalised obese medical patients and obese patients undergoing bariatric surgery.

Searching
MEDLINE (1976 to May 2006), Cochrane Database of Systematic Reviews (2005) and LILACS (1985 to 2005) were searched for studies in English, Portuguese, Spanish, Italian and French; the search terms were reported. The reference lists of retrieved studies were also checked.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), and cohort and case-control studies with at least 10 patients, were eligible for inclusion. Prospective, non-controlled studies were included.

Specific interventions included in the review
Studies evaluating the efficacy of low-dose unfractionated heparin (UFH), low molecular weight heparin and mechanical methods in VTE prophylaxis were eligible for inclusion. Various interventions and regimens were evaluated, including enoxaparin, nadroparin, low-dose UFH, continuous intravenous UFH, dalteparin and sequential compression devices (SCDs).

Participants included in the review
Studies of obese patients were eligible for inclusion. Surgical (general and bariatric) and medical patients were included. No further participant details were reported.

Outcomes assessed in the review
Inclusion criteria for the outcomes were not specifically stated. The outcomes included were incidence of VTE (pulmonary embolism and deep vein thrombosis) and haemorrhage (major and post-operative).

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Study quality was assessed on the basis of study design, randomisation, recruitment of consecutive patients, adequacy of follow-up, use of objective methods for the detection of VTE, blinded evaluation, precision or results, and applicability of the results to answer the clinical questions. The authors did not state how the validity assessment was performed.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative, with general surgical, bariatric surgery and medical patients being discussed separately.

How were differences between studies investigated?
Some differences between the studies were described in the text and tables.

Results of the review

Thirteen studies (n=10,313) were included in this review: 5 RCTs (n=6,488), 6 uncontrolled prospective studies (n=2,902) and 2 retrospective cohort studies (n=923).

Of the 2 studies in obese medical patients, one reported a non significant reduction in VTE with 40 mg/day enoxaparin, and the other a significant decrease in VTE with 5,000 IU/day dalteparin (relative risk 0.55, 95% confidence interval: 0.38, 0.80), compared with placebo.

One study evaluated several methods of prophylaxis in obese general surgical patients and reported a significantly higher incidence of deep vein thrombosis in the control group than in the study groups (37.3% compared with 26.9% for low-dose UFH and 11.9% for SCD), but this study was non-randomised and used a variety of detection methods.

In the 8 studies that investigated the use of a variety of regimens of VTE prophylaxis in bariatric patients, the incidence of VTE was low (range: 0 to 5.4%). One study reported a significantly lower incidence of deep vein thrombosis in patients taking 40 mg enoxaparin compared with 30 mg twice daily: 0.6% versus 5.4% (p<0.01).

Authors' conclusions
The limited number and quality of prospective studies comparing different methods of VTE prophylaxis in obese patients does not allow a definite conclusion about the most effective and safe VTE prophylactic method for obese patients.

CRD commentary
The research question was well-defined and the inclusion criteria were clear with regards to the study design, intervention and patient characteristics, but not outcomes. The authors searched three relevant databases and reference lists for studies reported in five languages, but it is still possible that studies in other languages might have been missed. There were no reported attempts to identify unpublished studies, which might also have increased the possibility that some relevant studies were not included in the review. The authors did not specify how the studies were selected, their validity assessed, and the data extracted, so it is not known whether any steps were taken to minimise bias or error in the review process. Although the authors stated that the validity of the studies was assessed, they only presented a level of evidence for each study in the review. In addition, few study details were provided to enable the reader to reliably determine the strength of the evidence presented. The decision to combine the studies in a narrative was appropriate given the clinical heterogeneity between the studies. The authors acknowledged some of the limitations of the review. These limitations, along with the apparent paucity of good-quality evidence, make the statement that they were unable to draw definite conclusions about the most effective and safe VTE prophylactic method, seem appropriate.

Implications of the review for practice and research
Practice: The authors recommended that obese medical patients be considered for pharmacological prophylaxis for VTE, and that enoxaparin (40 mg daily) and dalteparin (5,000 IU daily) should be considered as alternatives to low-dose UFH in acute medical illness. They also stated that prophylaxis must be employed in obese surgical patients once they have increased risk of VTE; SCD, low-dose UFH (5,000 or 7,500 IU daily), enoxaparin (30 or 40 mg daily or twice daily) and nadroparin (5,700 IU daily) should be considered.

Research: The authors stated that prospective, controlled trials to investigate ideal regimens of VTE prophylaxis in obese patients are highly warranted.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.