Addition of graduated compression stockings to fondaparinux did not reduce risk for venous thromboembolism after hip surgery

Cohen AT, Skinner JA, Warwick D, Brenkel I. The use of graduated compression stockings in association with fondaparinux in surgery of the hip: a multicentre, multinational, randomised, open-label, parallel-group comparative study. J Bone Joint Surg Br. 2007;89-B:887-92.

Clinical impact ratings: Hospitalists $\star\star\star\star\star\star$ Hematol/Thrombo $\star\star\star\star\star\star$

QUESTION

In patients having hip surgery, does the combination of fondaparinux plus graduated compression stockings prevent venous thromboembolism better than fondaparinux alone?

METHODS

Design: Randomized controlled trial.

Allocation: Concealed.*

Blinding: Blinded (ultrasonographers).*

Follow-up period: 42 days.

Setting: Hospitals in the United Kingdom, Brazil, Hong Kong, and Spain.

Patients: 856 patients 18 to 99 years of age (mean age 65 y, 57% women) who were having surgery for total hip replacement (95%) or hip fracture (5%). Exclusion criteria included bilateral joint surgery, leg edema, peripheral vascular disease, and conditions that increase bleeding risk.

Intervention: Fondaparinux, 2.5 mg daily for 5 to 9 days (mean 7 d), plus continuous use of graduated compression stockings for 35 to 49 days (median 44 d) (n = 426), or fondaparinux, 2.5 mg daily for 5 to 9 days (mean 7 d) (n = 430).

Outcomes: Composite endpoint of sudden death or venous thromboembolism (symptomatic or asymptomatic, identified by duplex ultrasonography performed at the end of the study), bleeding, adverse events, and quality of life.

Patient follow-up: 93% (intention-to-treat analysis for efficacy†).

MAIN RESULTS

No patient had a fatal pulmonary embolism or sudden death. Groups did not differ for venous thromboembolism, minor bleeding, need for transfusion, or anemia (Table). Only 1 patient (in the fondaparinux-alone group) had an episode of major bleeding. Quality of life improved to a similar extent in both groups.

CONCLUSION

In patients having hip surgery, the combination of fondaparinux plus graduated compression stockings did not prevent venous thromboembolism better than fondaparinux alone.

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*See Glossary.

†For safety and quality-of-life outcomes, 4 patients in the fondaparinux-plus-stockings group who did not receive stockings were analyzed in the fondaparinux-alone group.

Fondaparinux plus graduated compression stockings vs fondaparinux alone to prevent venous thromboembolism (VTE) after hip surgery‡

Outcomes at 42 d	Fondaparinux plus stockings	Fondaparinux alone	RRR (95% CI)	NNT
VTE or sudden death	4.8%	5.5%	11% (-60 to 53)	Not significant
Asymptomatic proximal DVT	4.1%	4.8%	14% (-65 to 56)	Not significant
Minor bleeding	6.4%	7.1%	11% (-48 to 47)	Not significant
			RRI (CI)	NNH
Symptomatic VTE	1.0%	1.0%	1.3% (—72 to 267)	Not significant
Transfusion	36%	33%	8.7% (-10 to 32)	Not significant
Anemia	24%	20%	19% (—9 to 54)	Not significant

‡DVT = deep venous thrombosis; other abbreviations defined in Glossary. RRR, RRI, NNT, NNH, and CI calculated from data in article.

COMMENTARY

Mechanical means of prophylaxis for deep venous thrombosis, which include graduated compression stockings and intermittent pneumatic compression devices, are widely used in patients who have had surgery. Mechanical prophylaxis was originally proposed when trials assessing pharmacologic prophylaxis were in their infancy. Although pharmacologic prophylaxis has evolved as a highly effective strategy to prevent postoperative deep venous thrombosis, the use of mechanical prophylaxis persists. The effectiveness of adding this therapy to pharmacologic prophylaxis has not been well studied, although the added cost is significant: A recent report from the United Kingdom estimated that uniform implementation of graduated compression stockings in postsurgical patients would cost £19 million, which is only slightly less than the cost of pharmacologic prophylaxis (1).

The study by Cohen and colleagues is a welcome addition to the literature. This large, well-designed trial did not show a reduction in the rate of venous thromboembolism when an extended course of graduated compression stockings was added to a short course of fondaparinux in patients having hip surgery

One limitation of this trial is that the anticoagulant studied is not widely used for prevention of deep venous thrombosis, although the findings are likely to be applicable to patients who receive pharmacologic prophylaxis with other anticoagulants, such as low-molecularweight heparins. Another minor criticism is use of an "on-treatment' rather than an "intention-to-treat" analysis for safety and quality-of-life outcomes. However, these limitations do not detract from the study's

As the largest study of its kind, the trial by Cohen and colleagues should change clinical practice regarding the use of both mechanical and anticoagulant prophylaxis for deep venous thrombosis. It showed that graduated compression stockings are not required in patients who receive effective forms of pharmacologic prophylaxis after major orthopedic surgery. However, mechanical prophylaxis continues to play an important role in preventing deep venous thrombosis in patients at high risk for postoperative bleeding in whom anticoagulant therapy is precluded.

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Reference

1. National Institute for Health and Clinical Excellence. Venous Thromboembolism: Costing Report. Implementing NICE guidance. 2007. www.nice.org.uk/download.aspx?o=426959 (accessed on 2 November 2007).

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