

FONDAPARINUX IS AN EFFECTIVE ANTICOAGULANT FOR THE PREVENTION OF VENOUS THROMBOEMBOLISM IN OLDER ACUTE MEDICAL PATIENTS

Background

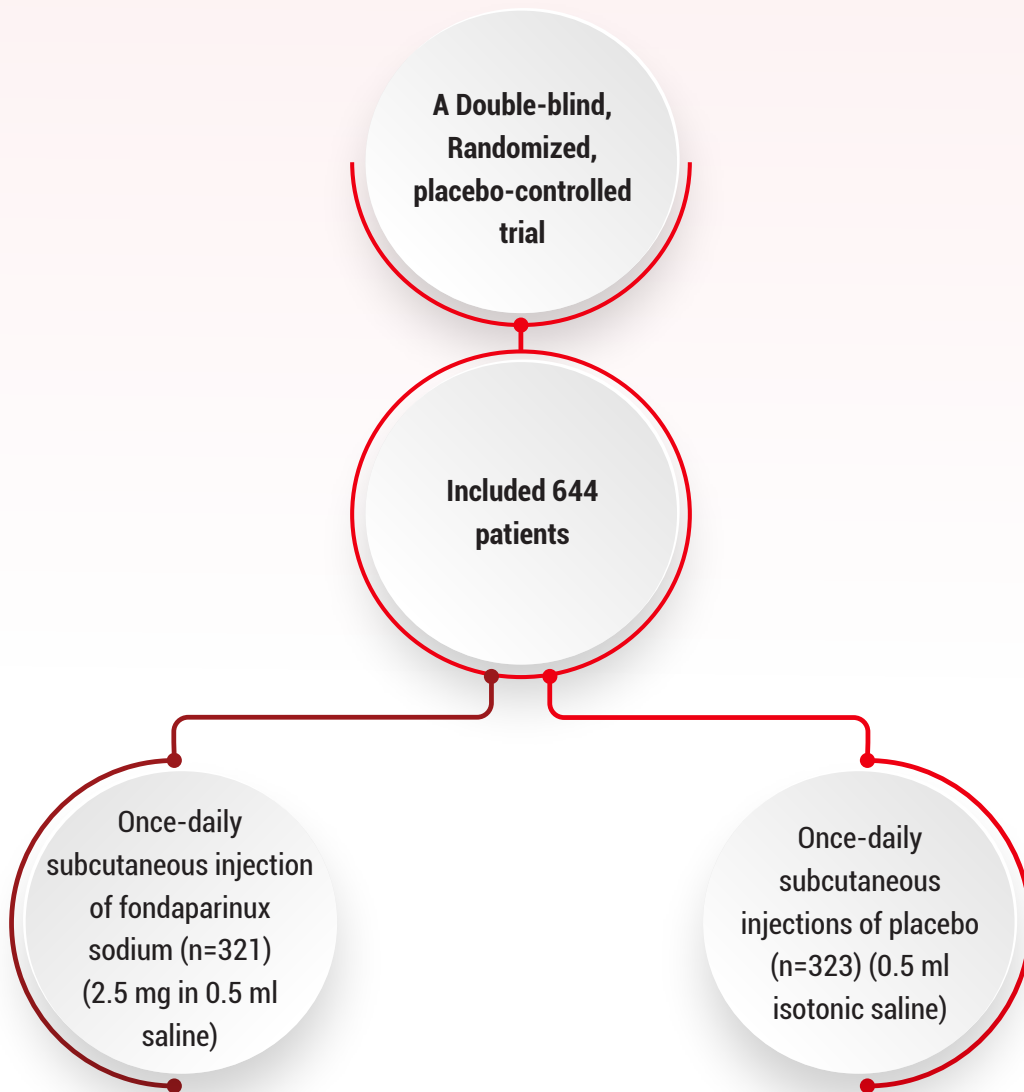
- ▶ Patients with congestive heart failure, respiratory illness, and infectious or inflammatory disease, are potentially at risk of venous thromboembolism.
- ▶ There is still uncertainty about the risk for venous thromboembolism and the effectiveness of thromboprophylaxis in these patients.
- ▶ Thus, the systematic application of thromboprophylaxis has been limited in these patients.
- ▶ Fondaparinux effectively reduces postoperative venous thromboembolism after orthopedic surgery.

Objective

The study aimed to evaluate the efficacy and safety of the anticoagulant fondaparinux in older acute medical inpatients at moderate to high risk of venous thromboembolism.



Study details



Inclusion criteria:

Acutely ill patients with congestive heart failure class III/IV, acute respiratory illness in the presence of chronic lung disease, or clinically diagnosed acute infections or inflammatory disorders. Patients had to be at least 60 years old and expected to remain in bed for at least four days.

Outcome measured

Primary efficacy endpoint: Venous thromboembolism and symptomatic venous thromboembolism up to day 15.

Secondary outcomes: Bleeding and death.

Results

Incidence of venous thromboembolism

- ▶ Venous thromboembolism was detected by routine bilateral venography and symptomatic venous thromboembolism up to day 15 in both the groups (Table; relative risk reduction 46.7%, $P = 0.029$).
- ▶ Incidence of the total, proximal, and distal deep vein thrombosis reported consistent reductions.
- ▶ 5 fatal cases of pulmonary emboli in the placebo group.

Table: Venous thromboembolic events in older medical patients in both the groups

Primary efficacy outcome	Fondaparinux group	Placebo group
Venous thromboembolic events:		
Any	18	29
Proximal deep vein thrombosis	5	7
Distal deep vein thrombosis	13	22
Symptomatic deep vein thrombosis	0	0
Non-fatal pulmonary embolism	0	0
Fatal pulmonary embolism	0	5
Total no (%)	18/321 (5.6%)	34/323 (10.5%)

Safety outcomes

- ▶ 0.2% of patients in each group had major bleeding.
- ▶ Minor bleeding was seen in 2.6% of patients in the fondaparinux group and 1% in the placebo group.
- ▶ The survival rate at one month is as seen in the figure ($P = 0.06$).

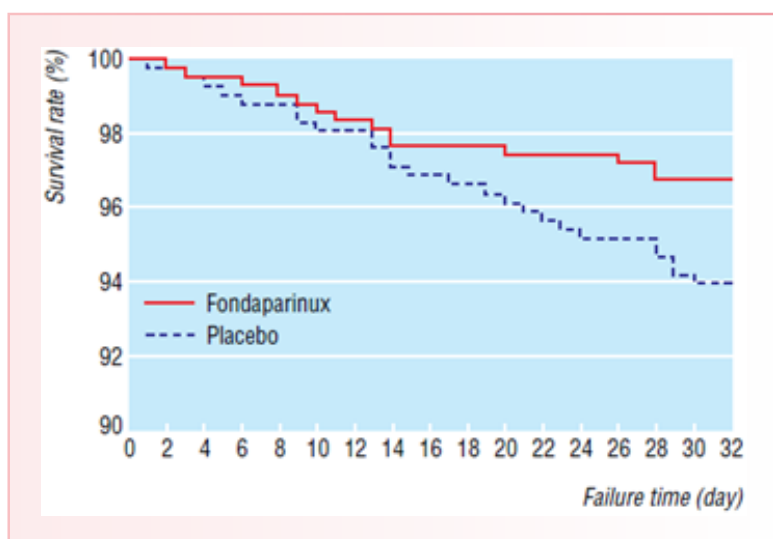


Figure: Survival estimates of older (≥ 60 years) acute medical patients treated with the anticoagulant fondaparinux or placebo

Conclusion

In older acute medical patients fondaparinux is effective in the prevention of asymptomatic and symptomatic venous thromboembolic events.



Take home points

1

Older medical inpatients are a clinically diverse group.

2

Daily subcutaneous injections of 2.5 mg fondaparinux almost halved the rate of venous thromboembolism in older acute medical patients.

3

No patients in the fondaparinux group had symptomatic fatal or nonfatal pulmonary embolism.

4

The efficacy data supports fondaparinux in the prevention as well as treatment of venous thromboembolism.

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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Reference:

Cohen AT, Davidson BL, Gallus AS, Lassen MR, Prins MH, Tomkowski W, et al. Efficacy and safety of fondaparinux for the prevention of venous thromboembolism in older acute medical patients: randomized placebo-controlled trial. *BMJ*. 2006 Feb 11;332(7537):325-9.