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ORIGINAL ARTICLE

A Multicenter Trial of Vena Cava Filters in Severely Injured Patients

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RobotReviewer report

Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
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Characteristics of studies

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Population	1. Trial Population Eligible patients were 18 years of age or older and had an estimated Injury Severity Score of more than 15 and a contraindication to receipt of pro- phylactic anticoagulation within 72 hours after admission for the injury. 2. Key exclusion criteria were imminent death, confirmed pulmonary embolism on admission to the trial center, systemic antico- agulant treatment before injury, pregnancy, and unavailability of an interventional radiologist to insert the filter within 72 hours after admission. 3. In this multicenter, ran- domized, controlled trial, we assessed whether insertion of a retrievable vena cava filter within 72 hours after admission for trauma would result in a lower incidence of pulmonary embolism than no filter in this group of patients.
Interventio n	1. In the prespecified subgroup of pa- tients who survived 7 days and did not receive prophylactic anticoagulation within 7 days after injury (46 patients in the vena cava filter group and 34 in the control group), none of the patients in the vena cava filter group had symptomatic pulmonary embolism between day 8 and day 90, whereas 5 patients (14.7%) in the control group had a symptomatic pulmonary embolism during that period (all occurred between day 9 and day 19 after the injury) (relative risk with the filter, 0; 95% CI, 0.00 to 0.55)
Outcomes	1. The primary end point was a composite of symp- tomatic pulmonary embolism

(segmental pulmo- nary embolism on CT pulmonary angiography, confirmed by an independent consultant radiol- ogist or by postmortem examination) or death from any cause at 90 days after enrollment.
2. Prespecified secondary end points included symptomatic pulmonary embo- lism in the subgroup of patients who survived at least 7 days and who did not receive prophylactic anticoagulation within 7 days after injury, com- plications related to the vena cava filters, death at 90 days, and major and nonmajor bleeding at 90 days.
3. The primary and secondary end points assessed in this trial are described in Table S2 in the Supplementary Appendix.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomization and Procedures Patients were randomly assigned to receive either a retrievable filter (vena cava filter group) or no filter (control group). 2. Randomization was per- formed with the use of a permuted-block scheme, with stratification according to trial center. 3. The charac- teristics of the patients were balanced between the two groups (Table 1, and Table S4 in the Sup- plementary Appendix).
Allocation concealment	low	1. Randomization was per- formed with the use of a permuted-block scheme, with stratification according to trial center. 2. Randomization and Procedures Patients were randomly assigned to receive either a retrievable filter (vena cava filter group) or no filter (control group). 3. If patients were not competent to provide consent, their next of kin agreed to enrollment and signed an acknowledgment document; pa- tients provided written informed consent after they regained competence.
Blinding of participants and personnel	high/ unclear	1. For safety reasons, patients and the treating clinicians were aware of the group assignments. 2. An independent statistical company main- tained the Web-response randomization portal, held the clinical database, and conducted all analy- ses independent of the investigators. 3. 24 The trial was designed and conducted by clinical investigators at the four tertiary hospi- tals in Australia where patients were treated after enrollment.
Blinding of outcome assessment	high/ unclear	1. An independent statistical company main- tained the Web-response randomization portal, held the clinical database, and conducted all analy- ses independent of the investigators. 2. 24 The trial was designed and conducted by clinical investigators at the four tertiary hospi- tals in Australia where patients were treated after enrollment. 3. The primary end point was a composite of symp- tomatic pulmonary embolism (segmental pulmo- nary embolism on CT pulmonary angiography, confirmed by an independent consultant radiol- ogist or by postmortem examination) or death from any cause at 90 days after enrollment.

References

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