

## **To evaluate efficacy and safety of a novel device that combines an inferior vena cava (IVC) filter and central venous catheter (CVC) for prevention of pulmonary embolism (PE) in critically ill patients” Tapson et al (2017).**

### Abstract:

**PURPOSE:** To evaluate efficacy and safety of a novel device that combines an inferior vena cava (IVC) filter and central venous catheter (CVC) for prevention of pulmonary embolism (PE) in critically ill patients.

**MATERIALS AND METHODS:** In a multicenter, prospective, single-arm clinical trial, the device was inserted at the bedside without fluoroscopy and subsequently retrieved before transfer from the intensive care unit (ICU). The primary efficacy endpoint was freedom from clinically significant PE or fatal PE 72 hours after device removal or discharge, whichever occurred first. Secondary endpoints were incidence of acute proximal deep venous thrombosis (DVT), catheter-related thrombosis, catheter-related bloodstream infections, major bleeding events, and clinically significant thrombus (occupying > 25% of volume of filter) detected by cavography before retrieval.

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**RESULTS:** The device was placed in 163 critically ill patients with contraindications to anticoagulation; 151 (93%) were critically ill trauma patients, 129 (85%) had head or spine trauma, and 102 (79%) had intracranial bleeding. The primary efficacy endpoint was achieved for all 163 (100%) patients (95% confidence interval , 97.8%-100%,  $P < .01$ ). Diagnosis of new or worsening acute proximal DVT was time dependent with 11 (7%) occurring during the first 7 days. There were no (0%) catheter-related bloodstream infections. There were 5 (3.1%) major bleeding events. Significant thrombus in the IVC filter occurred in 14 (8.6%) patients. Prophylactic anticoagulation was not initiated for a mean of 5.5 days  $\pm$  4.3 after ICU admission.



**CONCLUSIONS:** This novel device prevented clinically significant and fatal PE among critically ill trauma patients with low risk of complications.

**Reference:**

Tapson, V.F., Hazelton, J.P., Myers, J., Robertson, C., Gilani, R., Dunn, J.A., Bukur, M., Croce, M.A., Peick, A., West, S., Lottenberg, L., Doucet, J., Miller, P.R., Crookes, B., Gandhi, R.R., Croft, C.A., Manasia, A., Hoey, B.A., Lieberman, H., Guillaumondegui, O.D., Novack, V., Piazza, G. and Goldhaber, S.Z. (2017) Evaluation of a Device Combining an Inferior Vena Cava Filter and a Central Venous Catheter for Preventing Pulmonary Embolism Among Critically Ill Trauma Patients. *Journal of Vascular and Interventional Radiology*. June 20th. .

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