



Thrombolex Announces Significant New Insights from the Prospective Multicenter RESCUE Trial with the BASHIR™ Endovascular Catheter in a Manuscript Published in the Journal of the American College of Cardiology (JACC): Advances

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NEW BRITAIN, PA (October 24, 2023) Thrombolex, Inc., a medical device company focused on developing innovative products for the treatment of arterial and venous thromboembolic diseases, announced never-before-reported major reductions in obstruction in all of the segmental pulmonary arteries (PA), based on independent core lab data analysis of 107 patients from 18 sites in the USA, with acute intermediate-risk pulmonary embolism (PE), using the BASHIR™ Endovascular Catheter and small doses of tPA. The NIH sponsored RESCUE trial also showed unsurpassed efficacy and safety in this patient population compared to recently published studies with other FDA- cleared devices. These new data have just been published in the Journal of the American College of Cardiology (JACC): Advances on-line.

The RESCUE trial demonstrated that pharmaco-mechanical catheter-directed thrombolysis (PM-CDT) therapy using the BASHIR™ Endovascular Catheter to administer r-tPA in small doses (7mg for unilateral and 14 mg for bilateral PE over 5 hours) resulted in a 71.1% (40.5% to 11.7%; $P < 0.0001$) reduction in the number of segmental PA branches with total or subtotal occlusions at 48 hours, using contrast-enhanced chest computed tomography angiography. Proximal PA branch total or subtotal occlusions decreased by 61.3% (28.7% to 11.0%; $P < 0.0001$). The reduction in segmental artery occlusions correlated significantly with the reduction in right ventricular/left ventricular (RV/LV) ratio ($P = 0.0026$) whereas that in the proximal PA did not ($P = 0.173$).

Gregory Piazza, MD, MS, Associate Professor of Medicine, Harvard Medical School and chairman of the RESCUE Data Safety Monitoring Board noted: "A growing body of literature supports the hypothesis that reperfusion of the distal pulmonary vasculature is a critical therapeutic target, influencing right ventricular recovery, symptom relief, and gas exchange."

"The critical finding in the present study is that by using the BASHIR™ Endovascular Catheter and small doses of tPA we are able to markedly reduce segmental and main pulmonary arterial occlusions. Assessment of segmental artery patency after catheter-based therapies of acute PE may be critical to understanding the long-term benefits of these therapies and should be part of all future clinical trials in acute PE", said Brian G. Firth, MD, PhD, FACC, MBA, Chief Scientific Officer, Thrombolex, Inc.

About Thrombolex, Inc.

Founded in 2016, Thrombolex is engaged in the design, development, and distribution of innovative endovascular catheters used in interventional procedures, particularly in pharmaco-mechanical catheter-directed thrombolysis (PM-CDT) in patients who suffer from arterial and venous thromboembolic (A&VTE) conditions. The Company is currently marketing eight (8) different FDA-cleared devices that are all based on the BASHIR™ Endovascular Catheter platform technology.

For More Information

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