

Materials: The retrospective IRB approved study investigates the treatment group of 25 patients who underwent catheter based therapy consisting of single, or combination mechanical and chemical lytic therapy. The controls were patients with PE matched for similar severity of disease RV/LV ratio and other risk other factors. Controls were given medical management including systemic anticoagulation only. All available pre- and postprocedural cardiac imaging including CTA, and Echo were used to assess RV strain. Strain was measured using an established comparison of RV to LV diameters.

Results: Over a one year, 25+patients at a single institution underwent catheter based therapy. Two devices had been used, either alone or in combination; Penumbra's Indigo, and BTG's Ekos were used. A roughly equal total dose of lytics (TPA) was given in both groups averaging 28 mg administered either single dose or 22hr infusion. Average preprocedure diagnosis was 1 day, and post procedure follow-up 1.8 days. RV/LV ratios between the two groups suggested a significant improvement right ventricular strain as measured by a change in RV/LV ratio.

Conclusions: Catheter based therapy showed improvement in outcome measure vs medical management alone comparing right heart strain. A combination of catheter based tools including mechanical aspiration of clot, and directed lytics may be used in intermediate and high-risk PE patients safely. If widely available, catheter based therapy stands also to change the practices of Interventional physician's approach analogous to other cardiac emergencies such as STEMI creating the expectation expectation to provide emergent or semi-emergent responses.

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Abstract No. 228

Ultrasound-assisted catheter-directed thrombolysis for submassive pulmonary embolism: efficacy in relief of right heart strain

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Purpose: To determine the outcomes, safety profile, and efficacy of ultrasound-assisted catheter-directed thrombolysis for pulmonary embolism with right heart strain.

Materials: The charts of 30 consecutive patients who underwent CDT as treatment for pulmonary embolism were reviewed. Risk factors for bleeding were noted. Indicators of right heart strain on computed tomography and echocardiogram, as well as degree of pulmonary vascular obstruction, were recorded before and after CDT. Thirty-day mortality and occurrence of bleeding events were recorded.

Results: Right ventricular systolic pressure decreased from an average of 53.1 mm Hg to 38.5 mm Hg (p = <0.001) and average Qanadli index of pulmonary vascular obstruction decreased from 49 to 34 (p = <0.001) after CDT. The average ratio of RV/LV diameter decreased from 1.48 to 1.17 (p = <0.001) The number of patients with RV hypokinesis decreased significantly (p = 0.016) from 19 (95% of those with available data) to 12 (60%). The number of patients with RV dilation decreased significantly (p = 0.031) from 19 (95% of those with available data) to 13 (65%).

Nine (30%) patients had three or more minor contraindications to thrombolysis and fourteen (47%) had had major surgery in the month prior to CDT. No patients experienced major or moderate bleeding attributed to CDT.

Conclusions: In our experience CDT proved effective in the rapid alleviation of right heart strain with minimal bleeding risk. Right heart strain is associated with increased mortality and long-term morbidity in pulmonary embolism and CDT may allow for a safe means of improving outcomes in submassive pulmonary embolism. We found CDT to be a safe alternative to systemic thrombolysis in patients with risk factors for bleeding such as prior surgery.

Measures of Right Heart Strain Before and After CDT

	Pre-CDT Mean	SD	Post-CDT Mean	SD	Difference Mean	SD	P Value
RVSP	53.1	15.1	38.5	10.2	14.5	12.6	<0.001
RV/LV	1.48	0.32	1.17	0.26	0.32	2.16	<0.001
Qanadli Index	49	18	34	13	15.4	10.1	<0.001

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Abstract No. 229

The thromboaspiration with INDIGO system reduces the time and dose of fibrinolysis and improves the results in massive pulmonary embolism in comparison with catheter fragmentation (previous cohort study)

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Purpose: Determine if thromboaspiration with indigo system improves short- and medium-term outcomes compared with interventional treatment of choice for pulmonary embolism (PE) (mechanical thrombolysis + catheter-directed thrombolytic therapy).

Materials: From Apr-2016 to Aug-2017, 43 patients diagnosed massive PE and a comparative with previous study of 111 patients with massive PE. In the first cohort all patients were treated with thromboaspiration + catheter-directed thrombolytic therapy (TAs) and the other cohort were treated with conventionally according to our protocol: thrombolysis + catheter fragmentation (MFT). There were no significant differences in age, sex and the angiographic pulmonary index (Miller index). Pulmonary pressures after fibrinolysis and one month later were compared. The total dose and the total time of fibrinolysis were also compared in both groups.

Results: Postoperative mean pulmonary arterial pressure (PAPm) was 34.06 ± 5.81 mm Hg TAs and 39.46 ± 6.39 mm Hg MFT,

without showing significant differences in both groups regarding the 24 hours and after 1-month angiographic control. There were significant differences in the total dose administered of urokinase (UK) (1.38 ± 0.25 IU of UK TAs MFT vs 2.82 ± 0.89 million IU of UK MFT) and the total time of UK perfusion (13.05 ± 1.70 hours TAs vs 21.69 ± 11.92 hours MFT). Four patients (9.3%) died in the follow-up in the cohort TAs with only 1 (2.3%) related to PE vs. 7 patients (6.3%) with only 4 (3.6%) related to PE or complications of endovascular treatment MFT.

Conclusions: Thromboaspiration improves the results of conventional mechanical fragmentation and catheter-directed thrombolytic therapy, decreasing the time and total dosage of fibrinolysis and also decreasing PAP more rapidly.

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Abstract No. 230

Length of hospital stay in submassive pulmonary embolism patients who underwent ultrasound-assisted catheter-directed thrombolysis

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Purpose: Emerging evidence suggests ultrasound-assisted catheter-directed thrombolysis (UACDT) decreases right ventricular dilation, reduces pulmonary hypertension, and minimizes risk of intracranial hemorrhage in patients with acute submassive pulmonary embolism (PE). It is important to identify clinical factors that may affect these patients' hospital stays to facilitate patient care. We aimed to evaluate factors associated with the length of intensive care unit (ICU) and hospital stays in acute submassive PE patients who underwent UACDT.

Materials: Clinical data of patients who underwent UACDT (EkoSonic™ Endovascular System, Bothell, Washington) for submassive PE between 1/2016 and 7/2017 was reviewed. Tissue-plasminogen activator was administered at 1 mg/h for 12 hours and titrated per Fibrinogen levels. Linear regression was used to evaluate the association with log-transformation of non-parametric length of stay data.

Results: Among the 31 patients enrolled, 17 were male. The mean (\pm SD) age was 54 ± 17 years. The mean (\pm SD) Pulmonary Embolism Severity Index and RV/LV ratio were 92 ± 38 and 1.34 ± 0.36 , respectively. The median troponin and BNP levels were 0.117 and 251, respectively. The median length of ICU and hospital stays were 45 hours and 5 days, respectively. There were no complications. After adjusting for all factors in the regression model, the RV/LV ratio was significantly associated with longer ICU (β -coefficient = 0.87, 95%CI 0.29,1.45, $p = 0.005$) and hospital stays (β -coefficient = 1.27, 95%CI 0.52,2.01, $p = 0.002$).

Conclusions: UACDT is safe for submassive (intermediate-high risk) PE patients with the median length of ICU and hospital stays of 45 hours and 5 days, respectively. Increased RV/LV ratio is associated with longer ICU and hospital stays. Our data suggests that RV dilation is an important prognostic factor of these patients.

Scientific Session 24

Dialysis

Tuesday, March 20, 2018

3:00 PM–4:30 PM

Room: 404B

3:00 PM

Abstract No. 231

■ DISTINGUISHED ABSTRACT

The pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistulae creation for hemodialysis access

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Purpose: To evaluate the safety and efficacy of the percutaneous arteriovenous fistulae (pAVF) created with a thermal resistance anastomosis device (TRAD).

Materials: One hundred seven patients were enrolled in a prospective single arm trial at 5 sites. Patients underwent ultrasound-guided anastomosis creation between the proximal radial artery and perforating vein with the Ellipsys® Vascular Access System followed by separate maturation procedures. The primary endpoints were brachial artery flow volume ≥ 500 mL/min and target vein diameter ≥ 4 mm in $> 49\%$ of patients, and absence of device related complications at 90 days.

Results: Arteriovenous fistulae with fused anastomoses were created in 95% (102/107) patients. Maturation procedures included anastomotic balloon dilation in 72% (77/107), brachial vein embolization in 32% (34/107), cubital vein ligation in 31% (33/107), and surgical transposition in 26% (28/107). The primary flow and diameter endpoints were achieved in 86.0% (92/107) of patients exceeding the performance goal of 49% ($p < 0.0001$). There were no major adverse events attributed to the device. Cumulative patency was 91.6%, 89.3%, 86.7% at 90, 180, and 360 days, respectively. The target dialysis vein was the cephalic, basilic, and brachial veins in 74% (73/99), 24% (24/99), 2% (2/99), respectively. 2-needle dialysis was achieved in 88% (71/81) of patients on hemodialysis at a mean of 114.3 ± 66.2 days. Functional patency was 98.4%, 98.4%, and 92.3% at 90, 180, and 360 days, respectively.

Conclusions: The Ellipsys® Vascular Access System met the primary safety, and efficacy endpoint goals in the United States pivotal trial.