P-MAX Study: Mechanical Thrombectomy For Iliofemoral DVT with Aspirex – 24-Month Results

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Aspirex is a trademark of Becton, Dickinson and Company

Disclosure

Speaker name:
Michael Lichtenberg
I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

P-MAX Study Design

- Principle Investigator (PI)
  - Michael Lichtenberg
- Study Design
  - Prospective, multi-center, post-market observational study
- Study Purpose
  - Evaluate outcomes of Aspirex
- Study Population
  - Main
    - DVT of pelvis, legs, IVC
  - Additional
    - Dialysis shunts/bypasses; vena subclavian; vena brachiocephalic;
    - SVC; TIPS; vena porta; vena splenica; vena mesenterica superior/inferior

DVT = Deep Vein Thrombosis IVC = Inferior Vena Cava SVC = Superior Vena Cava TIPS = Transjugular intrahepatic portosystemic shunt

P-MAX Study Design

- Study Centers
  - Nine (9) located within the EU
- Study follow-up
  - Post-index procedure (discharge)
  - 1 month
  - 6 months
  - 12 months
  - 24 months presented today
  - 36 months

P-MAX Study Design

Inclusion Criteria

- Acute thrombotic or thromboembolic occlusion (onset of pain < 14 days)
- Age > 18 years
- Written informed consent form

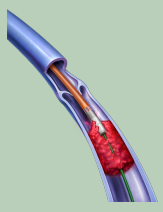
Key Exclusion Criteria

- Subject not suitable for thrombectomy
- Fracture area of broken stents
- Persistent vasospasms
- Known, unhealed pre-existing mechanical damage to the vessel wall (caused by surgical procedures or interventional complications)
- Immature or not fully healed dialysis accesses or bypass grafts

Aspirex Device - Components

Mechanical Aspiration Thrombectomy System

Capital Components and Catheter Set



P-MAX Study Update

- Study Status
  - Enrollment
    - 81 subjects enrolled, consented, treated with Aspirex
      - Mean age (years)= 49.3 ± 17.4 (*SD)
      - Male/Female, % = 50.6/49.4
  - Follow-up
    - 80 (98.8%) subjects completed 1-Month follow-up
    - 78 (96.3%) subjects completed 6-Month follow-up
    - 74 (91.4%) subjects completed 12-Month follow-up
    - 66 (81.5%) subjects completed 24-Month follow-up
  - Data Analysis – Full cohort and post-hoc subset analyses
    - 24-Month results presented today

*Standard deviation

P-MAX Study – Key Medical History

Vascular Systemic Risk Factors, n/N (%)	
Smoker	21/81 (25.9)
Diabetes mellitus	5/81 (6.2)
Hypertension (> 140 / > 90)	29/81 (35.8)
Systemic Contraceptives	11/81 (13.6)
Cortisone therapy	3/81 (3.7)

Full analysis population

P-MAX Study – Medical History

Vascular Local Risk Factors, n/N (%)	
Varicosis	32/81 (39.5)
Ulcus cruris or further dermal lesion	2/81 (2.5)
Phlebitis	2/81 (2.5)
Previous thrombosis	42/81 (51.9)
'Acute on chronic' occlusion	33/42 (78.6)
Has a longer history (e.g. DVT)	28/42 (66.7)
Has been treated	32/41 (78.0)
Left Side	29/38 (76.3)
Same leg as the current occlusion	33/38 (86.8)
Same vesset segment as the current occlusion	26/39 (66.7)
Previous pulmonary embolism	15/81 (18.5)
Previous target lesion interventions	24/81 (29.6)
Thrombolysis	5/81 (6.2)
Ultrasound enhanced thrombolysis	0/81 (0)
Percutaneous transluminal angioplasty	23/81 (28.4)
Stenting	23/81 (28.4)
Mechanical thrombectomy (e.g. Aspirex)	5/81 (6.2)
Aspiration thrombectomy	3/81 (3.7)
Surgical thrombectomy	3/81 (3.7)
Rheolytic thrombectomy (e.g. AngioJet)	0/81 (0)

Full analysis population

P-MAX Study – Key Lesion Characteristics

Subjects Treated N = 81	
Mean Target Lesion Length (mm)	204.9
Type of Vessel Occluded	n, (%)
Vein	57, (70.4)
Stented	20, (24.7)
Dialysis Access	4, (4.9)
Thrombus Location	
Popliteal	9, (11.1)
Common Femoral Vein	40 (49.4)
Femoral Vein	29 (35.8
External Iliac Vein	60, (74.1)
Common Iliac Vein	54, (66.7)
Brachial Vein	0
Axillary Vein	0
Subclavian Vein	6, (7.4)
Other	14 (17.3)

Full analysis population

P-MAX Study – Key Endpoint Results Overall Population

Procedural Success: defined as intervention with Aspirex, with or without adjunctive treatment, was sufficient

- to remove the thrombus
- maintain restored blood flow at least 72 hours post-intervention
- be without critical injuries at access site, route of catheter and target site
- be absent acute distal embolism respective of pulmonary embolism

Procedural Success – Subgroup	
Procedural Success, n/N, % [95% CI]	79/81, 97.5% [90.9, 99.8][1]

Technical Success: defined as successful thrombectomy

N = 81 (95% CL)	
Technical Success, n/N, % [95% CI]	79/81, 97.5% [90.9, 99.8][1]

[1]95%-CI (Agresti-Coull); CI = Confidence Interval

P-MAX Study – Key Endpoint Results Overall Population

Primary Patency: defined as Freedom from Re-Intervention*

N = 81	
Discharge n/n, % [95% CI]	79/80, 98.8% [92.6, 100][1]
1 Month n/n, % [95% CI]	75/80, 93.8% [85.9, 97.6][1]
6 Month n/n, % [95% CI]	70/79, 88.6% [79.5, 94.1][1]
12 Month n/n, % [95% CI]	62/72, 82.7% [72.4, 89.7][1]
24 Month n/n, % [95% CL]	53/68, 77.9% [66.6, 86.3][1]

*Primary Patency is defined as freedom from Re-Intervention.
Inclusion of patients:
Patients with DVT of the pelvis or leg including vena cava inferior are included, if DVT symptoms are absent or 70% of blood flow is restored at index procedure
Patients with other indications are included, if 70% of blood flow is restored at index procedure.

[1]95%-CI (Agresti-Coull); CI = Confidence Interval

Full analysis population

P-MAX Study – Key Endpoint Results Overall Population

Safety: Defined as follows:

- Serious Adverse Events (SAE) rate at 1, 6, 12 and 24 Months
- Procedure-related Adverse Events (AE) rate at 1, 6, 12, and 24 Months
- Serious Adverse Device Events (SADE) rate at 1, 6, 12 and 24 Months

N = 81				
	1 Month	6 Month	12 Month	24 Month
SAE rate n/n, % [95%CI]	27/81, 33.3% [24.0, 44.2][1]	34/81, 42.0% [31.8, 52.9][1]	40/80, 50.0% [39.3, 60.7][1]	46/77, 59.7% [48.6, 70.0][1]
Procedure-related AE rate n/n, % [95% CI]	11/80, 13.8% [7.7, 23.1][1]	11/79, 13.9% [7.8, 23.4][1]	11/74, 14.9% [8.3, 24.9][1]	11/66, 16.7% [9.4, 27.6][1]
SADE rate n/n, % [95% CI]	2/80, 2.5% [0.2, 9.2][1]	2/79, 2.5% [0.2, 9.3][1]	2/74, 2.7% [0.2, 9.9][1]	2/64, 3.1% [0.2, 11.3][1]

[1]95%-CI (Agresti-Coull) CI = Confidence Interval

Full analysis population

P-MAX Study – Key Endpoint Results Overall Population

Secondary Endpoints:

- Venous Clinical Severity Score (VCSS)[1] Pain Score

Timepoint	Pain Score
Screening, Mean (SD)	1.92 (0.69)
Discharge, Mean (SD)	0.43 (0.59)
1 month, Mean (SD)	0.31 (0.47)
6 month, Mean (SD)	0.30 (0.56)
12 month, Mean (SD)	0.30 (0.49)
24 month, Mean (SD)	0.40 (0.72)

Full analysis population

[1]Each attribute is scored on a severity scale from 0 to 3 (Absent = 0, Mild = 1, Moderate = 2, Severe = 3)
[2]VDS (Venous Disability Score) is scored on a scale of 0 to 3 (Asymptomatic = 0, Symptomatic but able to carry out usual activities without compressive therapy = 1, Can carry out usual activities only with compression and / or limb elevation = 2, Unable to carry out usual activities even with compression and / or limb elevation = 3). Usual activities = Patient's activities before onset of disability from venous disease. SD = Standard Deviation

P-MAX Study – Key Endpoint Results Overall Population

Secondary Endpoints:

- Venous Disability Score (VDS)[2]

Timepoint	Score
Screening, Mean (SD)	2.26 (0.85)
Discharge, Mean (SD)	0.79 (0.83)
1 month, Mean (SD)	0.51 (0.69)
6 month, Mean (SD)	0.38 (0.58)
12 month, Mean (SD)	0.39 (0.52)
24 month, Mean (SD)	0.48 (0.61)

Full analysis population

[1]Each attribute is scored on a severity scale from 0 to 3 (Absent = 0, Mild = 1, Moderate = 2, Severe = 3)
[2]VDS (Venous Disability Score) is scored on a scale of 0 to 3 (Asymptomatic = 0, Symptomatic but able to carry out usual activities without compressive therapy = 1, Can carry out usual activities only with compression and / or limb elevation = 2, Unable to carry out usual activities even with compression and / or limb elevation = 3). Usual activities = Patient's activities before onset of disability from venous disease. SD = Standard Deviation

P-MAX Study – Key Endpoint Results Overall Population

Secondary Endpoints:

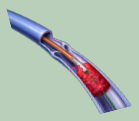
- Clinical-Etiology-Anatomic-Pathophysiologic Score (CEAP)

Clinical classification by visit	Screening		Discharge		1 month		6 month		12 month		24 Month	
	N	%	N	%	N	%	N	%	N	%	N	%
C0	0	0	11	16.7	18	29.0	15	24.2	15	24.2	15	28.3
C1-C3	62	93.9	53	80.3	41	66.1	46	74.2	44	71.0	32	60.4
C4-C6	4	6.1	2	3.0	3	4.8	1	1.6	3	4.8	6	11.3
Total	66	100	66	100	62	100	62	100	62	100	53	100

Full analysis population

P-MAX Study – Summary of Outcomes

- Procedural Success: 97.5%
- Technical Success: 97.5%
- Primary Patency – Overall Population
  - Discharge: 98.8%
  - 1 month: 93.8%
  - 6 month: 88.6%
  - 12 month: 82.7%
  - 24 month: 77.9%
- Safety rates at 1month/ 6 month/ 12 month/ 24 month
  - SAE rate: 33.3%/ 42.0%/ 50.0%/ 59.7%
  - Procedure-related AE rate: 13.8%, 13.9%, 14.9%, 16.7%
  - SADE rate: 2.5%/ 2.5%/ 2.7%, 3.1%
- Score Improvement from Baseline VCSS, VDS, and CEAP (observational)
  - Sustained through the 24-month follow-up



P-MAX Study Observational Data Key Subgroups

- Iliofemoral DVT Native Occlusions
- Iliofemoral DVT In-stent Occlusions
- Upper Venous System Occlusions (native excluding AVF/AVG)

DVT = Deep Vein Thrombosis; AVF = Arteriovenous Fistula; AVG = Arteriovenous Graft

P-MAX Study – Observations
Subgroup Populations

Procedural Success: defined previously

Procedural Success – Subgroup Analysis			
Subgroup – Lesion Location	N/N	%	CI[1]
Iliofemoral DVT Native	48/49	98.0	[88.3, 100]
Iliofemoral DVT In-stent	16/16	100	[77.3, 100]
Upper Venous System Native	5/5	100	[51.1, 100]
FAS[2]	79/81	97.5	[90.9, 99.8]

Technical Success: defined previously

Technical Success – Subgroup Analysis			
Subgroup – Lesion Location	N/N	%	CI[1]
Iliofemoral DVT Native	47/49	95.9	[85.5, 99.6]
Iliofemoral DVT In-stent	16/16	100	[77.3, 100]
Upper Venous System Native	5/5	100	[51.1, 100]
FAS[2]	79/81	97.5	[90.9, 99.9]

[1]95%-CI (Agresti-Coull) CI = Confidence Interval
[2]Full Analysis Set

P-MAX Study – Observations
Subgroup Populations

Primary Patency: defined previously

Primary Patency – Subgroup Analysis			
Subgroup – Lesion Location	N/N	%	CI[1]
Iliofemoral DVT Native - Discharge	49/49	100	[91.3, 100]
1 Month	47/49	95.9	[85.5, 99.6]
6 Month	45/48	93.8	[82.5, 98.5]
12 Month	42/47	89.4	[77.0, 95.8]
24 Month	36/41	87.8	[74.0, 95.1]
Iliofemoral DVT In-stent - Discharge	16/16	100	[77.3, 100]
1 Month	15/16	93.8	[69.7, 100]
6 Month	13/16	81.3	[56.2, 94.2]
12 Month	11/15	73.3	[47.6, 89.5]
24 Month	9/15	60.0	[35.7, 80.2]
Upper Venous System Native -Discharge	4/4	100	[45.4, 100]
1 Month	4/4	100	[45.4, 100]
6 Month	4/4	100	[45.4, 100]
12 Month	4/4	100	[45.4, 100]
24 Month	4/4	100	[45.4, 100]

[1]95%-CI (Agresti-Coull) CI = Confidence Interval

Mechanical thrombectomy with Aspirex 10F for treatment of acute venous stent thrombosis

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THANK YOU