

# Etude ESAT

ENTERPRISE<sup>®</sup> Stent in Aneurysm Treatment

Le stent Enterprise dans le traitement de l'anévrisme intra-crânien : résultats cliniques à 1 mois de l'étude prospective et multicentrique ESAT

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Pour tous les investigateurs de l'étude ESAT

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# Material and Method

- A Prospective, Multicenter, Consecutive & Observational Study carried out in France
  - from Feb. 2009 (First Patient In)
  - to Dec. 2011 (Last Patient In)

# ESAT Investigators

- **15 Neuroradiologists in 13 French Centers**

- **Pr Laurent SPELLE (PI) – Pr Jacques MORET - Hôpital Beaujon – CLICHY**
- **Pr Christophe COGNARD (PI) - Hopital Purpan – TOULOUSE**
- **Dr Ashok VASDEV - CHU Albert Michalon – GRENOBLE**
- **Pr Laurent PIEROT - Hôpital Maison Blanche – REIMS**
- **Dr Hervé BRUNEL - Hôpital de la Timone – MARSEILLE**
- **Pr Laurent SPELLE – Dr Michel PIOTIN – Dr Raphaël BLANC – Pr Jacques MORET  
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- **Pr Emmanuel HOUDART - Hôpital Lariboisière – PARIS**
- **Dr Jérôme BERGE - Dr Xavier BARREAU - Hôpital Pellegrin – BORDEAUX**
- **Pr Xavier LECLERC - CHRU Roger Salengro – LILLE**
- **Pr Alessandra BIONDI - CHU de la Pitié Salpêtrière – PARIS**
- **Pr Alessandra BIONDI - CHU Jean Minjoz – BESANCON**
- **Dr Nader SOUROUR - Dr Betty JEAN - CHU de la Pitié Salpêtrière – PARIS**
- **Pr Hervé DERAMOND - CHU Amiens – AMIENS**

# Material and Method

- DataManagement & Statistical Analysis :  
Medalliance CRO
- Electronic Data Collection System :  
Medalliance eCRF Manager
- Independent CoreLab for angiographic review :  
Pr Alain BONAFE - CHU Montpellier - France
- Independent review of Adverse Events :  
Data Safety Monitoring Board

# Study Population

- Patients with 1 or several intracranial aneurysms, ruptured or non-ruptured, and treated with an Codman ENTERPRISE<sup>®</sup> Stent

- **Inclusion criteria :**

- Patient presenting one or more ruptured or non-ruptured intracranial aneurysms assessed by angiography, and treated with one or more Codman ENTERPRISE<sup>®</sup> stents
- Patient agree to take part in the study, or agreement of a representative of the patient in case of patient inability, after being informed by the investigator and have received information letter

- **Non-inclusion criteria :**

- Patient treated for the same aneurysm with an Codman ENTERPRISE<sup>®</sup> stent in association with another stent
- Patient who does not accept to take part in the study

# Study Endpoints

## Primary Endpoint

Morbidity-Mortality observed during the procedure and up to 1 year Follow-up

## Secondary Endpoints

### Clinical :

- Procedural Morbidity-Mortality (at 30 Days post procedure).
- Rate of survival at one year post-procedure free of SAE.
- Neurological Status (mRS at Baseline/Discharge/1month /1year FU)

### Angiographic :

- Rate of aneurysm occlusion assessed by angiography at the end of the procedure and at 1 year FU (Raymond scale).
- Rate of good stent placement (complete neck bridging) at the end of the procedure and at 1 year FU.
- The rate of intrastent stenosis observed up to 1 year FU.

# Patient Screening

## Screening Result

From Feb. 2009 to Dec. 2011  
262 Stents used in 13 Centers

## ESAT

151 Stents used in 140  
procedures

## Non – ESAT: 111

- 80 stents : Y or telescopic stenting used, including one stent from another brand
- 14 stents : other pathologies (intracranial stenosis, ischemic dissection...)
- 11 Stents : in aneurysm not included for Patient refused or not informed by the investigators
- 6 stents : unknown

Consecutive recruitment!!!

# ESAT

133 Patients, 135 Aneurysms, 151 Stents

## “Non-ruptured” Aneurysms

114 patients/ 115 Aneurysms

Single/Non-ruptured:  
101 Patients

Single/Late ruptured  
( $\geq 1$  Month):  
12 Patients

Double /Non-ruptured:  
1 Patient

- Sacciform: 109 A°
- Fusiform: 6 A° (4.5%) (including 1 dissection & 1 associated with AVM)



# ESAT

133 Patients, 135 Aneurysms, 151 Stents

## “Ruptured” Aneurysms

19 patients/ 20 Aneurysms

Single/Acute ruptured  
( $< 1$  Month):  
18 Patients

Double /Acute-ruptured  
( $< 1$  Month):  
1 Patient

- Sacciform: 14 A<sup>o</sup> (including 1 dissection)
- Fusiform: 6 A<sup>o</sup> (30%) (including 6 dissections)

# Aneurysm Characteristics

Bifurcation : 41.5% (56A° )

## Location

Anterior circulation : 36,3% (49 A° )

- Anterior Cer. Art. : 1,5% (2 A° )

- Anterior Com. : 14,1% (19 A° )

- ICA Bif. : 3,0% (4 A° )

- MCA Bif. : 17,0% (23 A° )

Posterior Circulation : 5,9% (8 A° )

- Basilar Art. Bif. : 5,9% (8 A° )

## Size; mm

Sac Height : 6,15 [1-15,4]

Sac Width : 5,57 [2-11]

Neck Size  $\leq 4$  : 20% (27 A° )

Neck Size  $> 4$  : 21,5% (29 A° )

$\leq 5$  mm : 12,6% (17 A° )

$> 5 - \leq 10$  mm : 25,9% (35 A° )

$> 10 - \leq 15$  mm : 2,2% (3 A° )

$> 15$  mm : 0,7% (1 A° )

## Dome/Neck Ratio

Large neck  $\leq 1,5 \Rightarrow 31,8\%$  (43 A° )

Small neck  $> 1,5 \Rightarrow 9,6\%$  (13 A° )

# Aneurysm Characteristics

Sidewall : 58.5% (79A° )

## Location

Anterior circulation : 48,9% (66 A° )

- ICA Intra Cav. : 2,2% (3 A° )

- ICA SClIn./Opht. : 42,9% (59 A° )

- MCA SideW. : 3,7% (4 A° )

Posterior Circulation : 9,6% (13 A° )

- Basilar Art. SideW. : 2,2% (3 A° )

- Post. Cer. Art. : 3,7% (5 A° )

- Vertebral Art. : 3,7% (5 A° )

## Size; mm

Sac Height : 6,60 [1,9-26]

Sac Width : 6,47 [1,5-32]

Neck Size  $\leq 4$  : 34,1% (46 A° )

Neck Size  $> 4$  : 24,5% (33 A° )

$\leq 5$  mm : 24,5% (33 A° )

$> 5 - \leq 10$  mm : 22,9% (31 A° )

$> 10 - \leq 15$  mm : 7,4% (10 A° )

$> 15$  mm : 3,7% (5 A° )

## Dome/Neck Ratio

Large neck  $\leq 1,5$   $\Rightarrow$  41,5% (56 A° )

Small neck  $> 1,5$   $\Rightarrow$  17,1% (23 A° )

# Procedure Characteristics

## Method used for coiling (135 A° )

✓ Coiling before stent : 21,5% (29 A° )

✓ Coiling after Stenting : 71,8% (97 A° )

Jailing\* : 42,2% (57

A° )

Through the stent\* : 25,9% (35

A° )

Jailing + Trough\* : 3,7% (5 A° )

✓ No coil : Not Approved by the FDA 5,2% (7 A° )

✓ Unknown : 1,5% (2 A° )

## Method used for balloon remodeling (135 A° )

✓ Balloon used : 28,1% (38 A° )

Before Stent : 25,9% (35

A° )

Within Stent : 1,5% (2 A° )

Both : 0,7% (1 A° )

✓ No balloon used : 71,9% (97 A° )

# Procedure Characteristics

## Treatment Characteristics (135 A° )

- ✓ First Treatment : 80,7% (109 A° )
- ✓ Recurrence after EVT : 18,5% (25 A° )
- ✓ Recurrence after Surgery : 0,8% (1 A° )

## Patient Hospitalization - Length of stay (133 Pat.)

- ✓ Patients with Non- Ruptured A° : 4,6 days [1 to 43]
- ✓ Patients with Acute Ruptured A° : 14,5 days [2 to 37]

# Procedure Related Complications

## “Non-Ruptured Aneurysms”

114 Patients / 115 A°

- Wire Perforation or others: 4/114 patients
  - 2 Deaths (11.05 & 11.09), 2 mRs 4 (01.06 & 02.04), 1 mRs 0 (21.09)
- Transient Thrombo-Embolic: 3/114 patients
  - 2 mRs 0 (D4) (21.10) & (Post-proc) (02.16), 1 mRs 1 (Post-proc, Retinal) (15.07)
- Permanent Thrombo-Embolic: 3/114 patients
  - 2 mRs 1 (Post-proc, aphasia) (05.02) & (13.09), 1 mRs 3 discharge (mRs 0 at 2 months (12.01))

# Procedure Related Complications

## “Non-Ruptured Aneurysms”

114 Patients / 115 A°

- **Stent thrombosis: 1/114 Patients**
  - mRs 4 (Day 10) (Pat.02.28)
- **Stent Migration per-procedure: 1/114 patients**
  - mRs 0 (Pat. 06.01) (Stent not covering the neck)
- **Minor:**
  - Femoral: 3 patients
    - Retroperitoneal hematoma (mRs 0 no surgery) (Pat. 20.03)
    - Pseudo aneurysm (stent in both femoral art.) (Pat. 02.31)
    - AVF (surgery) (Pat. 17.02)
  - Epistaxis: 1 patient (Pat. 13.08)
  - Maelena: 2 patients (Pat 13.21; stop aspirin), (Pat. 13.23)

# Morbidity-Mortality

## “Non-Ruptured Aneurysms”

114 Patients / 115 A°

- **Death: 2/114 (1,75%)**
  - Wire perforation (Pat. 11.09)
  - SAH (Perforation or dissection not determined) (Pat. 11-05)
- **Morbidity (mRS >1): 4/114 (3,51%)**
  - Wire perforation: mRS 4 (Pat. 01.06) (Pat. 02.04)
  - TEC: mRS 3 (Pat. 12.01)
  - Stent thrombosis: mRS 4 (Pat. 02.28)



# Morbidity-Mortality

## “Ruptured Aneurysms”

19 Patients / 20 A°

- Death due to initial SAH: 3/19 (15.79%)
  - WFNS IV (Pat. 02.27)
  - WFNS III (Pat. 04.02)
  - WFNS IV (Pat. 16.01)
- Mild morbidity: 1/19 (5.26%)
  - Re-Bleeding (Pat. 15-04)
    - Fusiform Dissecting WFNS II /
    - Minor re-bleeding with mRS 3, 4 Days after procedure
    - mRs 1 at discharge

# CONCLUSION

## ESAT study

- Prospective, Multicenter, Consecutive
- 133 patients / 135 aneurysms
  - 115 non ruptured
  - 20 ruptured

Mortality: 1.75%

Morbidity: 3.5%

# Morbi-Mortality of Coiling and Stenting in a consecutive population:

Ruptured A° (783 A° ):

## Clarity Study

Morbidity: 3.7%

Mortality: 1.2%

Unruptured A° (739 A° ):

## Athena Study

Morbidity: 1.7%

Mortality: 1.4%

Unruptured (1 month FUP)

A° (115 A° ):

## ESAT Study

Morbidity: 4.4%

Mortality: 1.8%

Unruptured (1 year FUP)

A° (107 A° ):

## SENAT Study

Morbidity: 1% (3.4% at 1 month)

Mortality: 1%