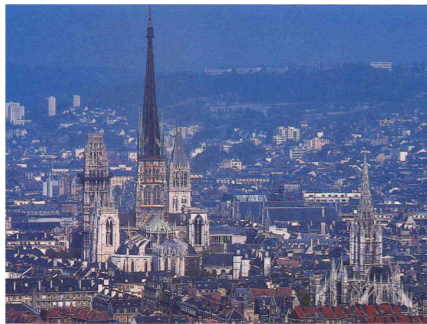


Hémorragies :

arrêt des anticoagulants et des antiagrégants

Anticoagulants and antiplatelet agents stopping

PY Litzler, H Smail, V Barbay
C Nafeh-Bizet, M Redonnet, C Abriou



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CONFLITS D'INTÉRÊTS



CENTRE DE FORMATION EUROPÉEN

PROCTOR POUR L'IMPLANTATION



Edwards Lifesciences

**PROCTOR POUR L'IMPLANTATION
DES VALVES TRANSCATHÉTERS TRANS APICALE**



MEMBRE FONDATEUR

Anticoagulation regimen and HeartMate II

HMII BTT trial (US)*

- aspirin + warfarin INR target : 2.0 to 3.0

Ischemic stroke: 0.13 events / pts-year
Hemorrhagic stroke: 0.05 events / pts-year

0.18 stroke / pts-year

Early European Experience**

Table 3
Agents for use of anticoagulation and inhibition of platelet aggregation in outpatients

Vitamin K antagonist ^a + ASS	45%
Vitamin K antagonist + ASS + clopidogrel ^b	16%
Vitamin K antagonist	8%
Vitamin K antagonist + clopidogrel	6%
ASS	3%
Other	22%

Ischemic stroke: 0.07 events / pts-year
Hemorrhagic stroke: 0.05 events / pts-year

0.12 stroke / pts-year

*Miller LW *et al.*; N Engl J Med 2007;357:885-896.

**Struber M *et al.*; Eur J Cardiothorac Surg 2008;34:289-294.

No Anticoagulation - No antiplatelet agents !

doi:10.1510/icvts.2010.240747

INTERACTIVE
CARDIOVASCULAR AND
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Interactive CardioVascular and Thoracic Surgery 11 (2010) 503-506

www.icvts.org

Case report - Cardiac general

Discontinuation of antithrombotic therapy for a year or more in patients with continuous-flow left ventricular assist devices[☆]

Naveen L. Pereira^{a,*}, Dong Chen^b, Sudhir S. Kushwaha^a, Soon J. Park^c

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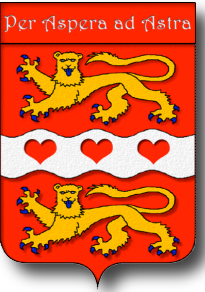
^cDivision of Cardiovascular Surgery, Mayo Clinic, Rochester, MN, USA

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2 patients
29 patient-months of follow-up
No stroke
Acquired vWF syndrome

....In fact, assuming a Poisson process for the incidence of thrombotic events, the authors would have required 40 patient-years of follow-up with a thrombotic incidence of just 5%/patient-year, or a thrombotic incidence of 80%/patient-year with a follow-up of 2.42 patient-years in order to have a)85% probability to be able to detect at least one event!....

Anticoagulation regimen and HeartMate II in Rouen



In Our experience (since 02/2006)

- 4 patients with aspirin for 6, 15, 60, 460 days
- due to GI bleeding, epistaxis (1 death)

➔ Aspirin was discontinued

Anticoagulation protocol

Heparin : 6 hours after HMII implantation

Vitamin K antagonist: fluindione (INR target: 2-2.5)

➔ Mean INR: 2.59 ± 0.74

NO ANTIPLATELET THERAPY

Population

February 2006 - September 2011

HeartMate II - Thoratec Corporation

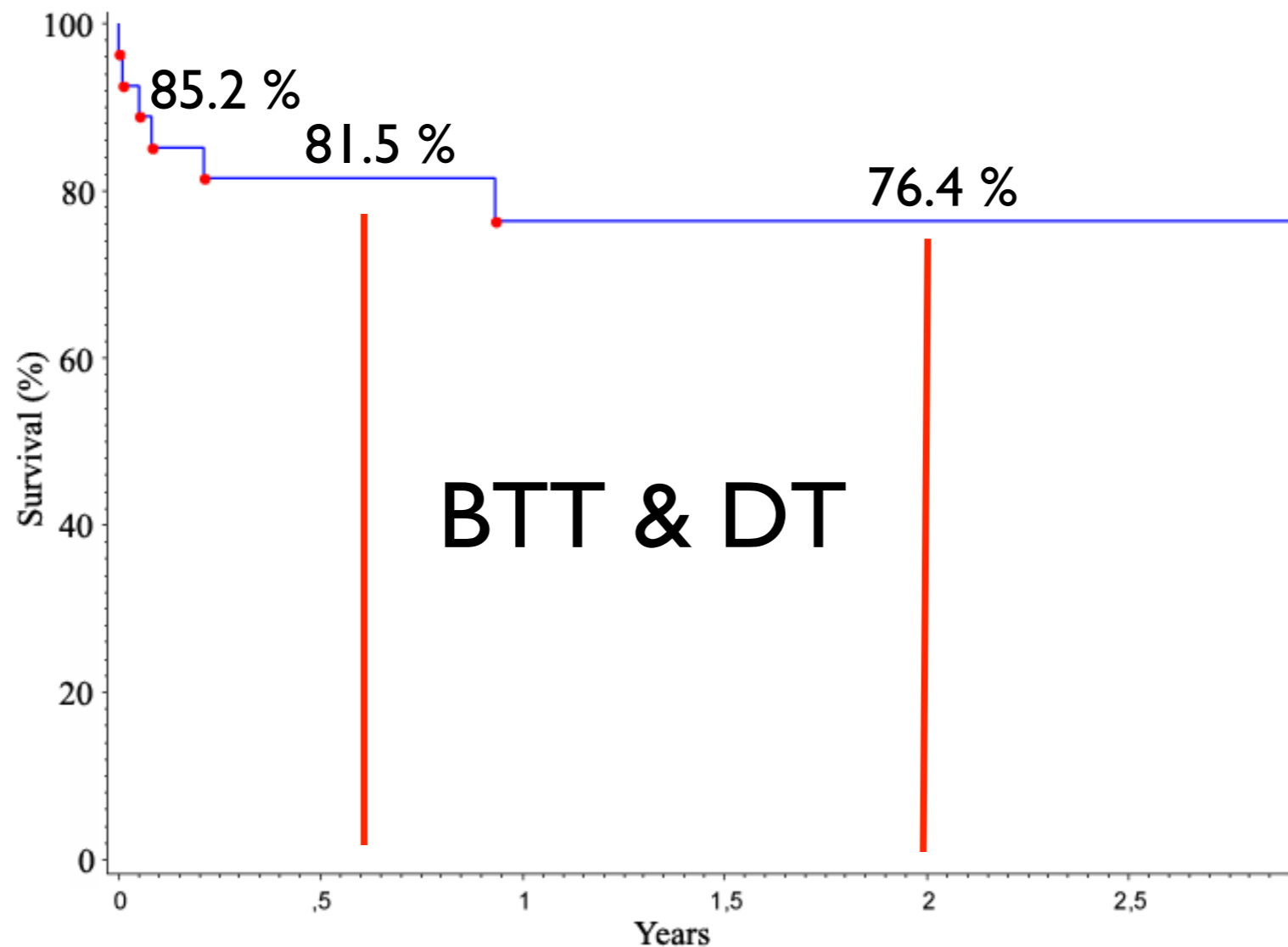
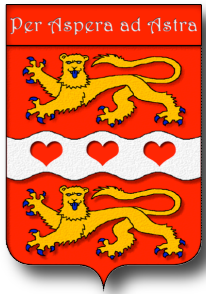


N	27
Age, mean (range) (years)	55,7 (30 -71)
Sex: men (%)	26 (96%)
BSA, mean (range) (m²)	1.91 ± 0.2 (1.61- 2.33)
Diabetes mellitus, n (%)	5 (18.5%)
Hypertension, n (%)	6 (22.2%)
Tabaco, n (%)	18 (66.7%)
Ischemic etiology, n (%)	16 (59.3%)
Dilative etiology, n (%)	11 (40.7%)
Previous Coronary by-pass surgery, n (%)	4 (14.8%)
LVEF, mean±SD (%)	21 ± 9.0
INTERMACS levels 1 or 2, n (%)	14 (51.8%)
Previous ECMO	12 (44.4%)

Mean Duration of support : 479 ± 436 days
35.4 patient years on support

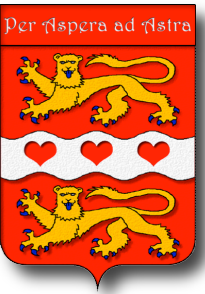
Actuarial survival under support

March 2012



Kaplan–Meier analysis of survival with data censored for heart transplantation and recovery.

Von Willebrand factor analysis

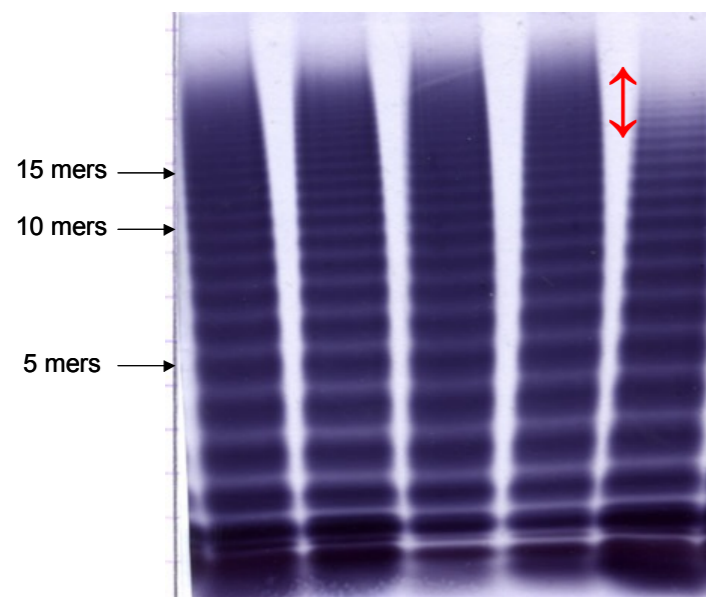


Beginning in June 2006 for patients with non-surgical bleeding

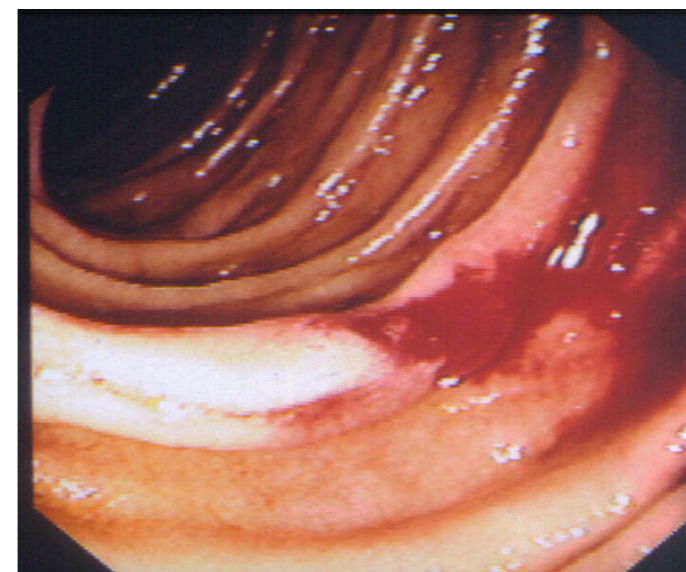
15/27 patients tested

Acquired Von Willebrand Disease in 7/15 patients FvW (RCO/Ag) < 0.65

5 / 7 presented non surgical bleeding (epistaxis and GI bleeding)



Témoin | après transplantation | assistance



Thrombo-embolic and Hemorrhagic events

Thrombo-embolic stroke

2 patients at 1 and 8 months

→ 0.059 ischemic stroke / patient year

No Hemorrhagic stroke

→ 0.059 stroke / patient year

Non Surgical Bleeding

10 patients

(Epistaxis: 7, Hemoptysis: 1, GI: 4)

Re-Thoracotomy

18 patients

	Mean duration	Stroke / pt year
Miller <i>et al.</i> [5]	169	0.28
Frazier <i>et al.</i> [25]	258	0.06
John <i>et al.</i> [26]	238	0.03
Loforte <i>et al.</i> [24]	217	0.09
Granfeldt <i>et al.</i> [27]	214	0.31
Pagani <i>et al.</i> [6]	155	0.18
Slaughter <i>et al.</i> [7]	621	0.29
Slaughter <i>et al.</i> [8] ^b	293	0.13
Slaughter <i>et al.</i> [8] ^b	293	0.12
Slaughter <i>et al.</i> [8] ^b	293	0.11
Total		0.18

Eur J Cardiothorac Surg

European Journal of Cardio-Thoracic Surgery 0 (2013) 1–6
doi:10.1093/ejcts/ezt228 Advance Access publication 00 Month 0000

ORIGINAL ARTICLE

Is anti-platelet therapy needed in continuous flow left ventricular assist device patients? A single-centre experience[†]

Pierre-Yves Litzler^{a,b,*}, Hassiba Smail^a, Virginie Barbay^c, Catherine Nafeh-Bizet^a, François Bouchart^a,
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Why do we obtain these good results ?

Use of CBP leading to visualization and removal of thrombus in the left ventricle ?

Variable but systematic alteration of the platelet function in patients with axial flow LVAD ? *

Acquired von Willebrand Disease appears in the early post-operative phase ? **

Impact of the use of fluindione (long half-life Vitamin K antagonist) ?

*Steinlechner B *et al.* Ann Thorac Surg 2009;87:131-137.

** Heilmann C *et al.* Eur J Cardiothorac Surg 2011;40:1328-1333;

Low stroke rate and few thrombo-embolic events after HeartMate II implantation under mild anticoagulation[†]

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Received 8 September 2011; received in revised form 21 November 2011; accepted 27 November 2011

40 patients
INR 2.0-2.5
Aspirin if age < 55 years
2 strokes
1 pump thrombosis

“These included seven prospective and three retrospective cohort studies with a total of **538 patients** with axial-flow left ventricular assist device (LVAD) (**HeartMate II, Jarvik 2000, INCOR, Thoratec assist device**) implanted across the world as destination therapy or bridge to transplantation.”

Interactive CardioVascular and Thoracic Surgery Advance Access published July 3, 2012

Interactive CardioVascular and Thoracic Surgery 0 (2012) 1–8
doi:10.1093/icvts/ivs297

BEST EVIDENCE TOPIC

What is the optimal anticoagulation in patients with a left ventricular assist device?

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Received 6 March 2012; received in revised form 17 May 2012; accepted 31 May 2012

What happens since March 2012 ?

39 patients

60.7 patient years

No new stroke  0.033 stroke / patient year

1 pump thrombosis (exchange) but no stroke

Vitamin K antagonist monotherapy
Does not increase thromboembolic events
Could lead to a diminished risk of hemorrhagic stroke

But controlled studies are needed to confirm our findings.

TRACE

Observational Study sponsored by Thoratec Corporation

Study purpose:

Obtain multi-center data on patients managed on Monotherapy:

- Aspirin only
- Warfarin/Vitamin K antagonist only
- No anticoagulation nor antiplatelet agents

Primary Study Objective:

Determine the rate of thromboembolic and hemorrhagic events in HMII outpatients on reduced therapy

Secondary Study Objective:

Characterize the patient population who can be safely maintained on reduced therapy

100 patients to be enrolled in Europe & 100 patients in US

