CRRIC

Hôpital Privé de Clairval

MANIFEST-PF

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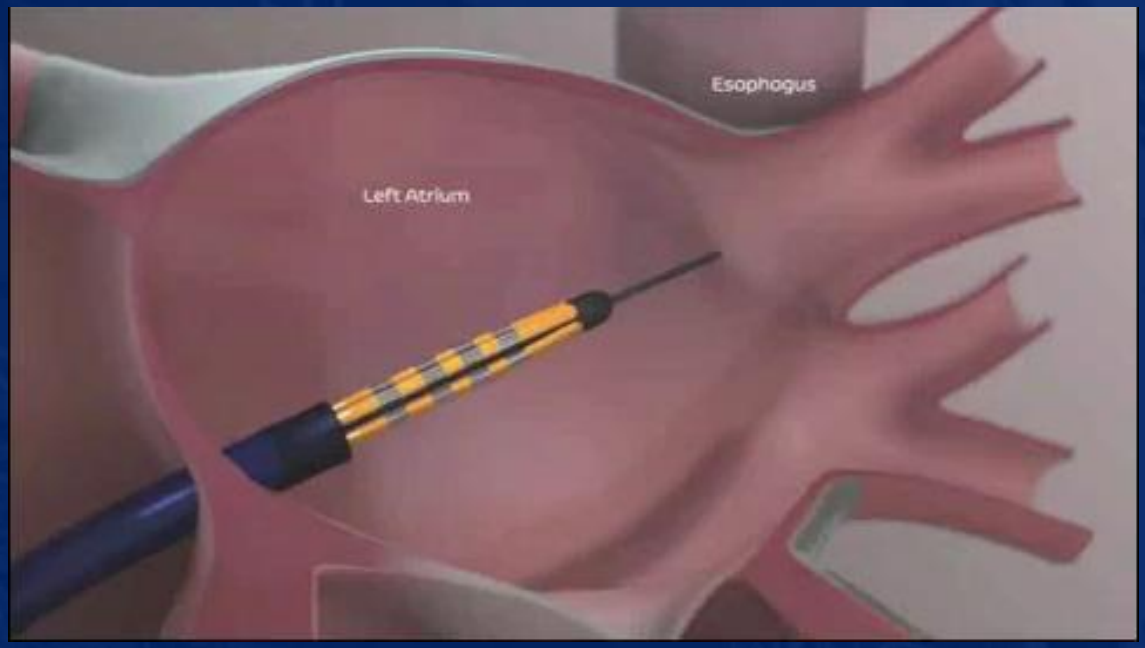
Ablation de FA: Electroporation



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Only video from Vivek Y. Reddy et al. Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation, JACC 2020 Sep, 76 (9) 1068-1080

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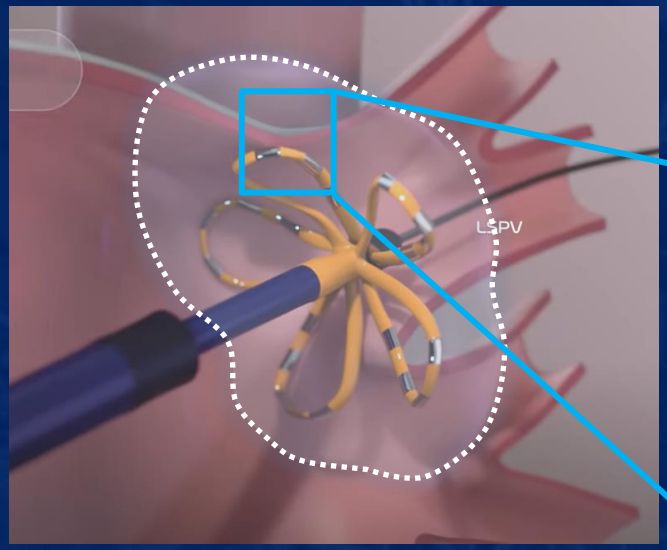

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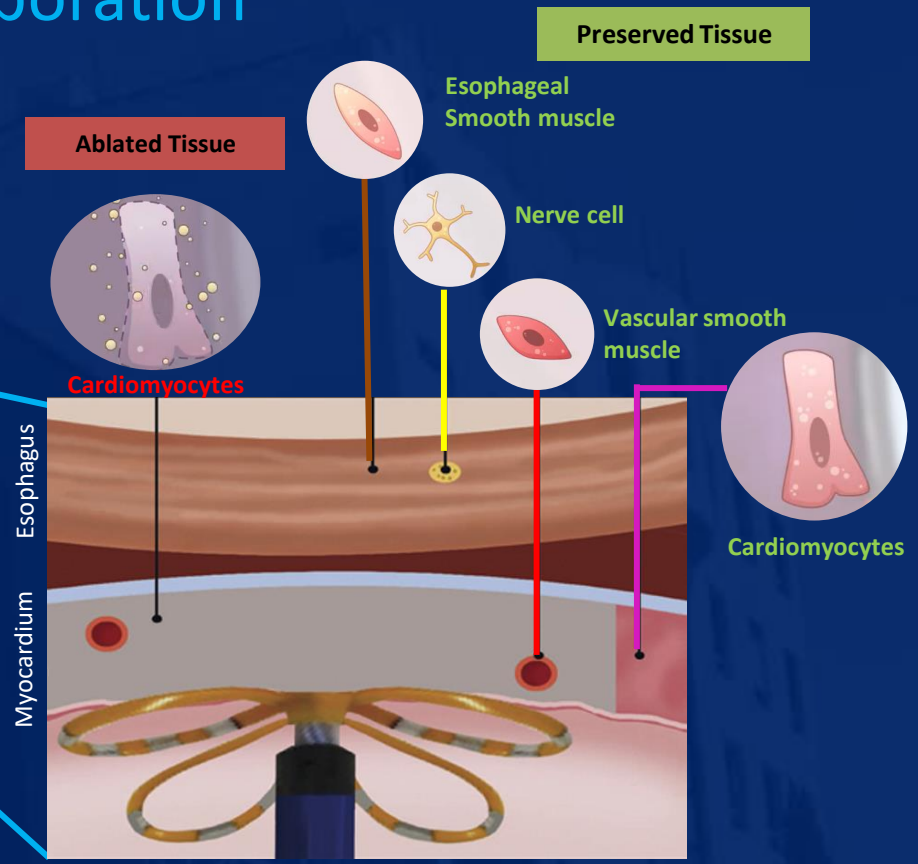


- Ablation par méthode non thermique
- Champ électrique pulsé de haute amplitude et courte durée

- Formation de pores membranaires
- Lésions des cardiomyocytes épargnant les cellules adjacentes

Adapted from Vivek Y. Reddy et al. Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation, JACC 2020 Sep, 76 (9) 1068-1080

Ablation de FA: IMPULSE, PEFCAT and PAFCATII*

0%

Fistule AE, lésion du nerf phrénique, sténose des VP ou AVC

96%

Isolation des VP à 3 mois

84.5 % ± 5%

De patients sans récidive d'arythmie atriale à 12 mois

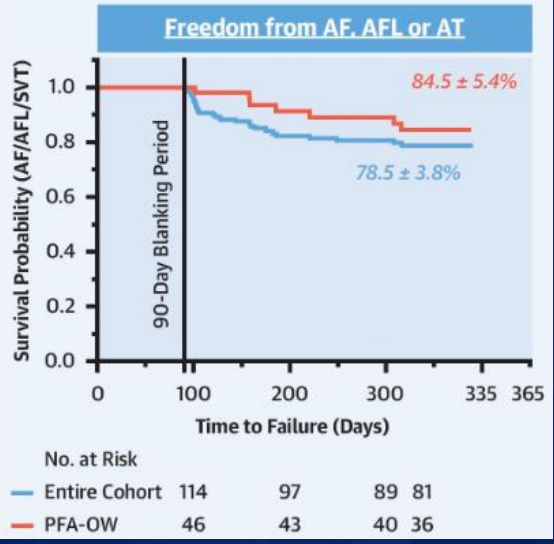
Safety

• *Esophageal Damage*	*0%*
◦ *Esophageal Dysmotility*	*0%*
◦ *Atrioesophageal Fistula*	*0%*
• *Pulmonary Vein Stenosis*	*0%*
• *Phrenic Nerve Injury*	*0%*
• *Stroke*	*0%*
◦ *Transient Ischemic Attack*	*0.9%*
• *Pericardial Effusion*	*0.8%*
• *Vascular injury*	*1.7%*
• *Death*	*0%*

Efficacy

Durability of PV Isolation (Invasive Remapping)

PFA Waveform	Per PV Basis		Per Pt Basis	
	No.%	Durable	No.%	Durable
All	429	84.8%	110	64.5%
PFA-OW	173	96.0%	44	84.1%



*Reddy VY, Dukkipati SR, Neuzil P, et al. Pulsed field ablation of paroxysmal atrial fibrillation: 1-year outcomes of IMPULSE, PEFCAT, and PEFCAT II. JACC Clin Electrophysiol. 2021 May;7(5):614-27

MANIFEST-PF

EHRA-2022: Late-Breaking Clinical Trial

MANIFEST-PF: Multi-national Survey On Methods, Efficacy And Safety: ON The Post-approval Clinical Use Of Pulsed Field Ablation

Vivek REDDY

D 'après la communication du Dr Vivek Reddy [EHRA 2022]:MANIFEST-PF: Multi-national Survey On Methods, Efficacy And Safety: ON The Post-approval Clinical Use Of Pulsed Field Ablation

MANIFEST-PF: Méthodologie

Formulaire envoyé a 24 centres

100% de participation sur les 24 centres en Europe

90 Opérateurs
1,758 Patients

	n=24 centers
Practice Type	
Academic (%)	**70.8**
Semi-Academic (%)	**8.3**
Private (%)	**20.8**
No. of Operators, mean (min-max)	**3.8 (2-11)**
Years in Practice, mean (min-max)	**13.2 (5.3-22.5)**
Annual No. of AF ablations/center, mean (min-max)	**704 (300-2200)**
Total No. of PFA cases	**1,758**
No. of PFA cases, mean (min-max)	**73.3 (7-291)**
Date of First PFA case, month/year (earliest-latest)	**7/2021 (3/2021 - 12/2021)**

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MANIFEST-PF: Méthodologie

Procédural Parameters	
General Anesthesia / Intubation (%)	**17.8%**
Deep Sedation / No Intubation (%)	**82.1%**
No. of Transeptal Punctures, n (%)	**1 (100%)**
PVI success rate (%), mean (min-max)	**99.9% (98.9-100)**
Procedure Time (minutes), mean (min-max)	**65 (38-215)**
Fluoroscopy Time (minutes), mean (min-max)	**13.7 (4.5-33)**
Same Day Discharge (%)	**15.8%**

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MANIFEST-PF: Caractéristiques des patients

Demographics	
Age (years), mean (min-max)	**61.6 (19-92)**
Female, %	**34.2%**
BMI (kg/m^2), mean (min-max)	**26.7 (15-52)**
CHA_2DS_2-Vasc score, mean (min-max)	**2.1 (0-9)**
Medications	
Failed Class I or III AAD (%)	**38.2%**
Failed Class I, II, III or IV AAD (%)	**65.4%**
Vitamin K Antagonist (%)	**5.1%**
NOAC (%)	**88.3%**
No Prior Oral Anticoagulation (%)	**7.7%**
Echocardiography parameters	
LA Diameter (mm), mean (min-max)	**39 (16-73)**
LVEF (%), mean (min-max)	**54.7% (14-80)**
Patients with LVEF<40%, %	**4.7%**
Indication for Ablation	
Paroxysmal AF(%)	**57.5%**
Persistent AF(%)	**35.2%**
Long Standing Persistent AF(%)	**3.9%**
Atrial Flutter (%)	**1.1%**
Other (%)	**2.9%**
First-Ever Ablation Procedure (%)	**93.5%**

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MANIFEST-PF: Complications

	n (%)
Major Complications	**29 (1.6%)**
Esophageal Fistula	**0**
Esophageal Dysmotility	**0**
Pulmonary Vein Stenosis	**0**
Pericardial Tamponade	**17 (0.97)**
Percutaneous Treatment	**13 (0.74)**
Surgical Treatment	**4 (0.23)**
Stroke	**7 (0.40) ***
Phrenic Nerve Injury (persistent) †	**0**
Vascular complications requiring surgery	**4 (0.23)**
Coronary artery spasm	**1 (0.06)**
Death	**1 (0.06) ***

	n (%)
Minor Complications	**68 (3.87%)**
TIA	**2 (0.11)**
Phrenic Nerve Injury (transient) §	
Transient Effect	**8 (0.46)**
Vascular	**56 (3.19)**
Hematoma	**43 (2.45)**
Pseudoaneurysm	**4 (0.23)**
AV Fistula	**3 (0.17)**
Other	**6 (0.34)**
Other complications	
Hemoptysis Requiring Bronchoscopy	**1 (0.06)**
Persistent Dry Cough x 6 wks	**1 (0.06)**

* One patient who sustained a stroke subsequently died

† Defined as persisting beyond hospital discharge

§ Defined as recovering before hospital discharge

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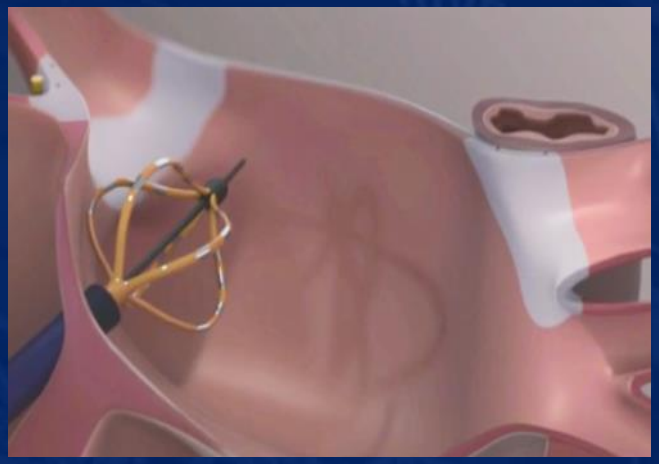
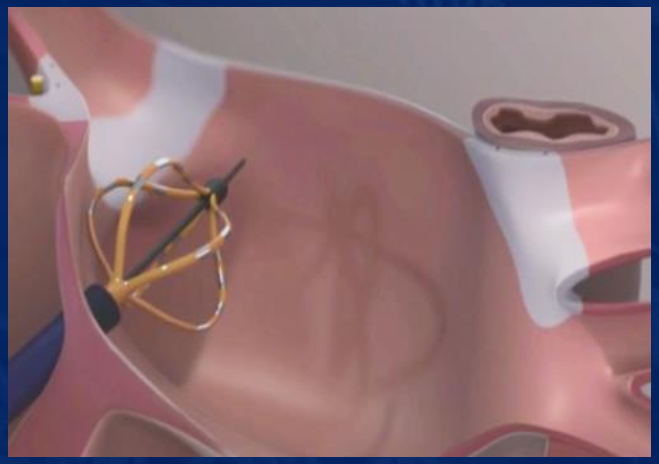
MANIFEST-PF: Efficacité



	Value (%)
Mean PVI success rate (%)	**99,90%**
Median PVI success rate (%)	**100%**
Range of PVI success across centers, min-max	**98,9%-100%**

MANIFEST-PF: Conclusions



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- 99,9% isolation des veines pulmonaires
- Temps de procédure raisonnable
- Utilisation dans la FA pers et FA parox
- Sécurité d'utilisation (absence de lésions œsophagiennes, de sténose de VP ou de lésion persistante du nerf phénique)
- Peu de complications

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