

PHYSIO DAY

JOURNÉES DE PHYSIOLOGIE
EN CARDIOLOGIE INTERVENTIONNELLE

FFR-DWP

Stimulation directe sur guide de pression: une révolution « Française »?

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5 & 6 AVRIL 2024

HÔTEL SHERATON · NICE



Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Grant/Research Support

French ministry of research and innovation, Fondation de l'avenir

Consulting Fees/Honoraria

Asahi, Boston Scientific, SMT, Teleflex, Terumo

Major Stock Shareholder/Equity

4C Medical, Electroducer

Royalty Income

None

Ownership/Founder

Electroducer

Intellectual Property Rights

Electroducer

Other Financial Benefit

None

The idea :



- **Temporary trans-coronary pacing during PCI**
- **B. Meier : 1985, first description**

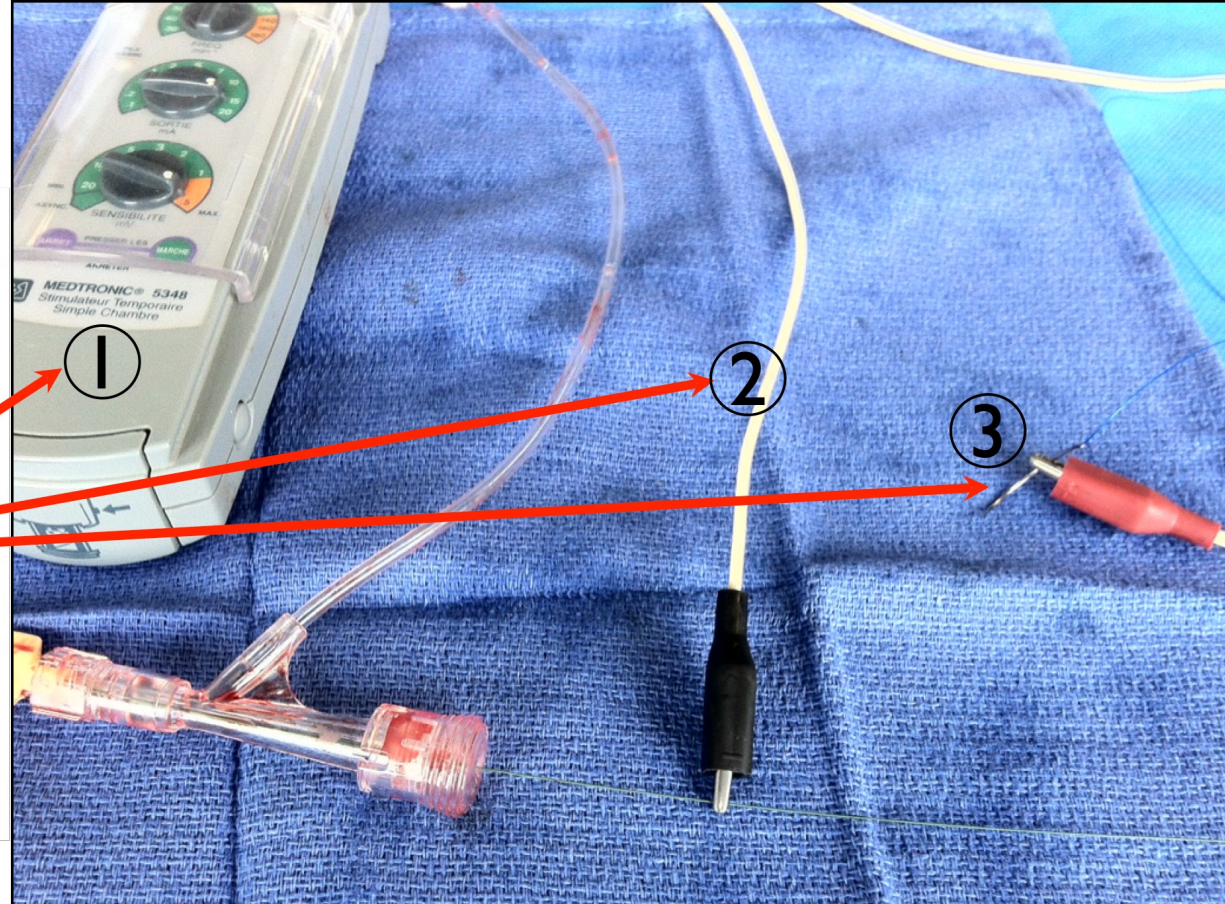
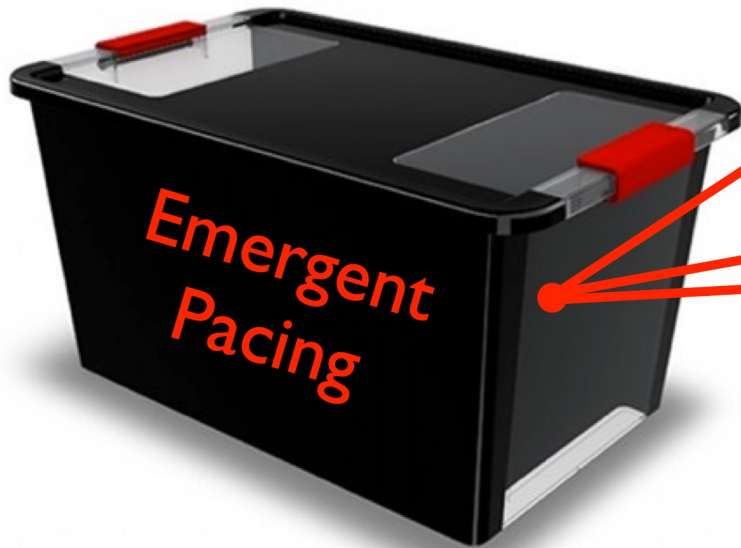


[Coronary pacing during percutaneous transluminal coronary angioplasty.](#)

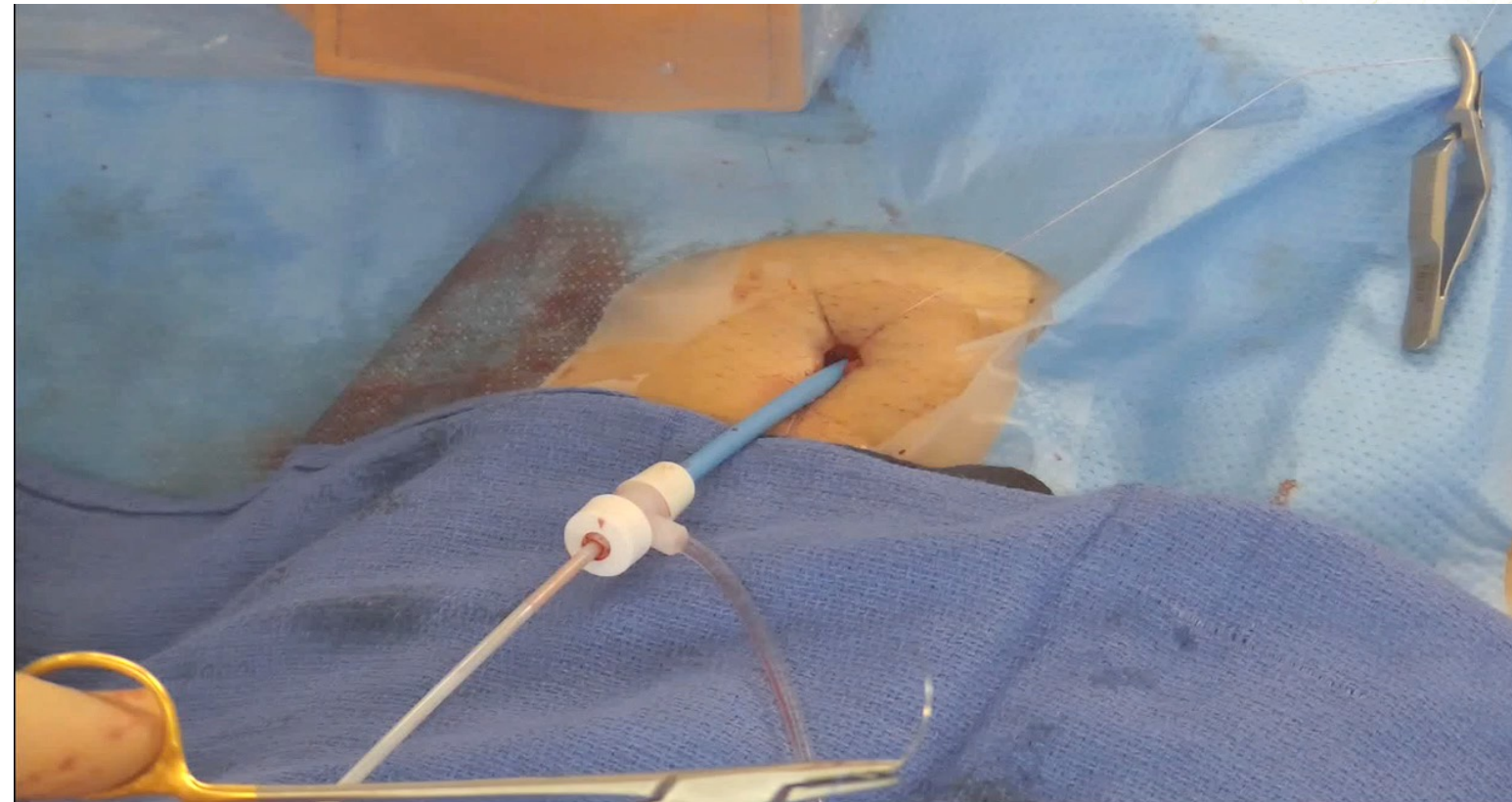
Meier B, Rutishauser W.

Circulation. 1985 Mar;71(3):557-61.

Genesis



Direct Left Ventricular Rapid Pacing Proof of concept



[Rapid pacing using the left ventricular guidewire: Reviving an old technique to simplify BAV and TAVI procedures.](#)
Faurie B, Abdellaoui M, Wautot F, Staat P, Champagnac D, Wintzer-Wehekind J, Vanzetto G, Bertrand B, Monségu J.
Catheter Cardiovasc Interv. 2016 Nov 15;88(6):988-993

Original Studies

Rapid Pacing Using the Left Ventricular Guidewire: Reviving an Old Technique to Simplify BAV and TAVI Procedures

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Patrick Staat,² MD, Didier Champagnac,² MD, Jérôme Wintzer-Wehekind,¹ MD,
Gérald Vanzetto,³ MD, Bernard Bertrand,³ MD, and Jacques Monségu,¹ MD

Objectives: We sought to demonstrate the safety and efficacy of rapid left ventricular (LV) pacing through the guidewire during balloon aortic valvuloplasty (BAV) and Transaortic valve implantation (TAVI). **Background:** Right ventricular temporary pacing during TAVI and BAV is time-consuming and associated with vascular and pericardial complications. **Methods:** Rapid left ventricular pacing was provided via the back-up 0.035" guidewire. The cathode of an external pacemaker was placed on the tip of the 0.035" wire and the anode on a needle inserted into the groin. Insulation was ensured by the balloon or TAVI catheter. **Results:** 38 BAV and 87 TAVI procedures were performed in 113 consecutive patients in three centers with one for one pacing (160–200 bpm) in all patients. A significant reduction in blood pressure was achieved with a mean systolic pressure of 44 mm Hg during stimulation. Mean procedural time was 49.7 ± 31 min for BAV and 68.7 ± 30.9 for TAVI. A temporary venous pacemaker was required in 12 patients; only 12% of TAVI patients had a femoral central venous catheter. Femoral venous puncture was not performed in BAV patients. No venous vascular complications were observed. One case of successfully treated tamponade (0.8%) occurred 8 hr post procedure. In-hospital mortality rates were 4.6% and 2.6% in the TAVI and BAV groups, respectively. **Conclusions:** Use of the LV guidewire for rapid pacing during BAV and TAVI was shown to be simple, reproducible, and prevented complications associated with RV temporary leads thus potentially simplifying TAVI and enhancing its safety. © 2016 Wiley Periodicals, Inc.

Key words: TAVI; balloon aortic valvuloplasty; rapid pacing

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become a widely accepted technical strategy in patients with severe aortic stenosis who are not eligible for surgical valve replacement because of their high-risk profile. Initially intended for non-operable patients, the technique is gradually being extended to include lower-risk patients.

Since TAVI was first carried out using the percutaneous valve developed by Prof. Alain Cribier in 2002 [1], the volume of procedures performed worldwide has been growing exponentially.

The TAVI strategy has now come of age, and a number of technical improvements have already been implemented to simplify the procedure, decrease its duration and, above all, reduce the incidence of complications in

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Conflict of interest: The authors have no conflict of interest to declare

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Direct Left Ventricular Rapid Pacing Proof of superiority

Direct Wire Pacing (DWP) superior to temporary-PM*

EASY TAVI

**Direct left ventricular rapid pacing
via the valve delivery guide wire in TAVI:
A randomized study (EASY TAVI)**

300 Patients

**Benjamin FAURIE for EASY TAVI investigators
Cardiovascular Institute of Grenoble
Grenoble, France**

Géraud Souteyrand M.D., Patrick Staat M.D., Mathieu Godin M.D., Christophe Caussin M.D., Eric Van Belle M.D., Ph.D., Lionel Mangin M.D., Pierre Meyer M.D., Nicolas Dumonteil M.D., Mohamed Abdellaoui M.D., Jacques Monségu M.D. Isabelle Durand-Zaleski M.D., PhD, Thierry Lefèvre M.D.



PRAGMATIC-PACE

Left Ventricular Rapid Pacing in Transcatheter Aortic Valve Replacement TAVR: A Prospective, Multicenter, Registry-Based Randomized study

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Tamim Nazif, MD

Mitchell Krucoff, MD

Shmuel Chen, MD, PhD

Ori Ben-Yehuda, MD

Bjorn Redfors, MD, PhD

Sreekanth Vemulapalli, MD

Arsalan Abu-Much, MD

4000 Patients

tct2019



CRF Clinical Trials Center

* B. Faurie & al. EASY TAVI . JACC Cardiovasc Interv. 2019;12.

Direct Wire Pacing – DWP®

Transcoronary pacing

Direct RV wire pacing

Direct LV wire pacing



LV pacing

Pacing over the wire

Transvascular nerve pacing

Background



European Heart Journal (2010) 31, 2501–2555
doi:10.1093/eurheartj/ehq277

ESC/EACTS GUIDELINES



Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)[‡]

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ESC Committee for Practice Guidelines: Alec Vahanian (Chairperson) (France), Angelo Auricchio (Switzerland), Jeroen Bax (The Netherlands), Claudio Ceconi (Italy), Veronica Dean (France), Gerasimos Filippatos (Greece), Christian Funck-Brentano (France), Richard Hobbs (UK), Peter Kearney (Ireland), Theresa McDonagh (UK), Bogdan A. Popescu (Romania), Zeljko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Sirnes (Norway), Michal Tendera (Poland), Panos E. Vardas (Greece), Petr Widimsky (Czech Republic)

EACTS Clinical Guidelines Committee: Philippe Kolh (Chairperson) (Belgium), Ottavio Alfieri (Italy), Joel Dunning (UK), Stefano Elia (Italy), Pieter Kappetein (The Netherlands), Ulf Lockowandt (Sweden), George Sarris (Greece), Pascal Vouhe (France)

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[‡] Other ESC entities having participated in the development of this document:

Associations: Heart Failure Association (HFA), European Association for Cardiovascular Prevention and Rehabilitation (EACPR), European Heart Rhythm Association (EHRA), European Association of Echocardiography (EAE).

- FFR included in European guidelines since 2010
- Max hyperemia : Adenosine
- But... Adenosine
- contraindications
- Side-effects (brady-arrhythmias, sinus pauses, AV block)
- So...
- Limit FFR adoption
- Rest ratio indexes (iFR, dPR, dFR..)
- Virtual angioFFR

Background

Coronary Physiologic Assessment and Imaging

Discordance Between Resting and Hyperemic Indices of Coronary Stenosis Severity

The VERIFY 2 Study (A Comparative Study of Resting Coronary Pressure Gradient, Instantaneous Wave-Free Ratio and Fractional Flow Reserve in an Unselected Population Referred for Invasive Angiography)

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Colin Berry, MBChB, MD, PhD; Nils Johnson, MD, MS; John McClure, PhD;
Peter McCartney, MBChB; Margaret B. McEntegart, MBChB, PhD; Hany Eteiba, MBChB, MD;
Mark C. Petrie, MBChB, BSc; Paul Rocchiccioli, MBChB, MD; Richard Good, MBBS, MD;
Martin M. Lindsay, MBChB, MD; Stuart Hood, MBChB, MD; Stuart Watkins, MBChB, MD

Background—Distal coronary to aortic pressure ratio (Pd/Pa) and instantaneous wave-free ratio (iFR) are indices of functional significance of a coronary stenosis measured without hyperemia. It has been suggested that iFR has superior diagnostic accuracy to Pd/Pa when compared with fractional flow reserve (FFR). We hypothesized that in comparison with FFR, revascularization decisions based on either binary cutoff values for iFR and Pd/Pa or hybrid strategies incorporating iFR or Pd/Pa will result in similar levels of disagreement.

Methods and Results—This is a prospective study in consecutive patients undergoing FFR for clinical indications using

Conclusions—Binary cutoff values for iFR and Pd/Pa result in misclassification of 1 in 5 lesions. Using a hybrid strategy, approximately half of the patients do not receive adenosine, but 1 in 10 lesions are still misclassified. The use of nonhyperemic indices of stenosis severity cannot be recommended for decision making in the catheterization laboratory.

Conclusions—Binary cutoff values for iFR and Pd/Pa result in misclassification of 1 in 5 lesions. Using a hybrid strategy, approximately half of the patients do not receive adenosine, but 1 in 10 lesions are still misclassified. The use of nonhyperemic indices of stenosis severity cannot be recommended for decision making in the catheterization laboratory.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT02377310.

(*Circ Cardiovasc Interv.* 2016;9:e004016. DOI: 10.1161/CIRCINTERVENTIONS.116.004016.)

iFR ≠ FFR

Up to 20% misclassification!

Background



FFR value:

- After severe pauses?
- After cuffing efforts?

Hypothesis

DWP is effective other most of coronary guidewires

DWP avoids conductance disturbances

FFR measurements for intermediate stenosis:

FFR-DWP is non-inferior to Standard-FFR

FFR-DWP circumvent Adenosine drawbacks

Methods

Randomized, non-inferiority, crossover trial

All lesions requiring FFR evaluation with optical (optical fiber
OptoWire™, OpSens Medical)

Randomization sequence 1:1:

FFR-DWP then FFR-Standard and vice versa



Centre de Recherche
Cardio-Vasculaire des Alpes

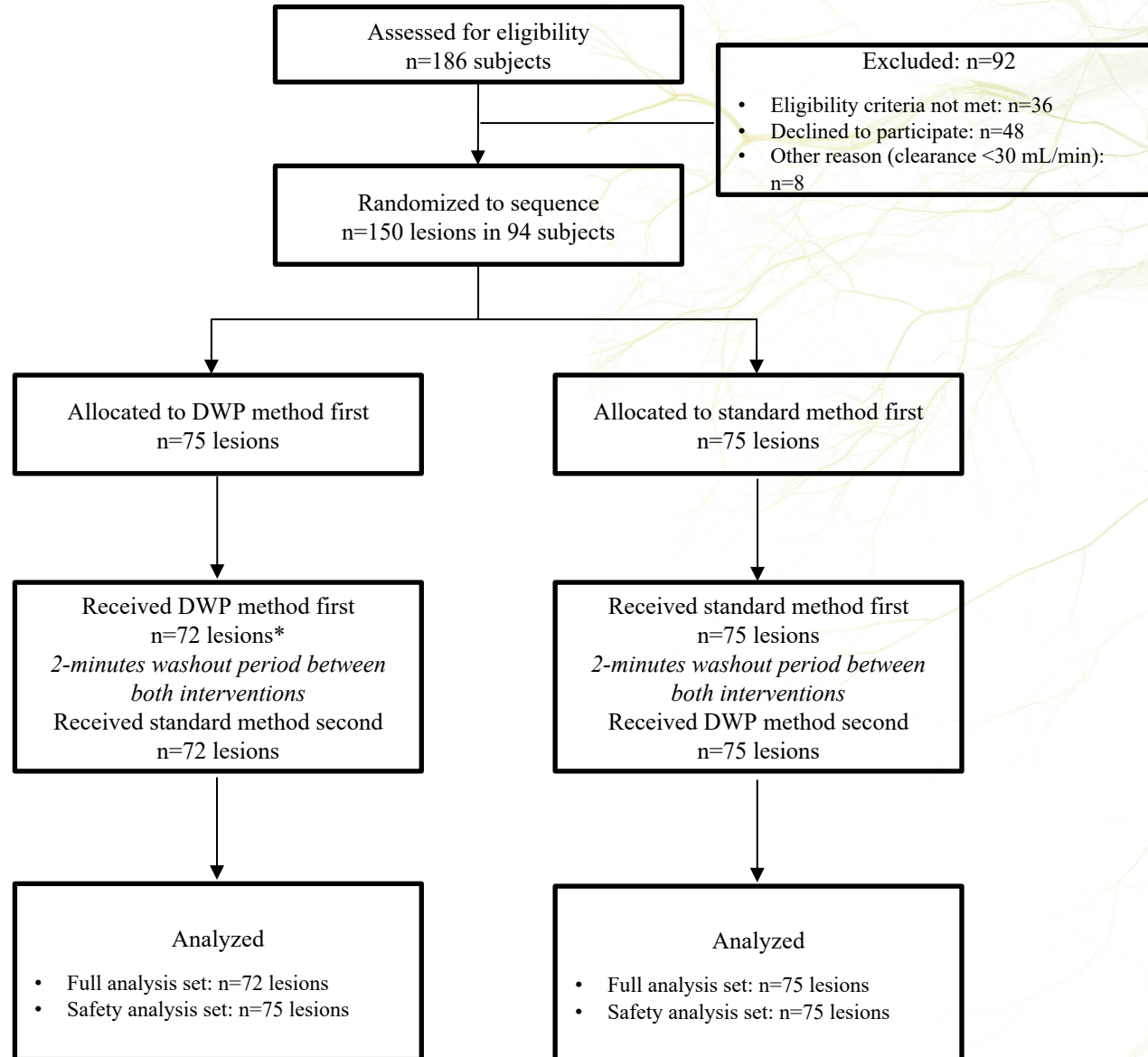
Endpoints:

I - **Reproducibility** of FFR measurement

II - **Safety** of both methods: adverse events

- **Tolerance** of both methods= chest discomfort (0-4)
& electrical sensation (NRS 0-10)

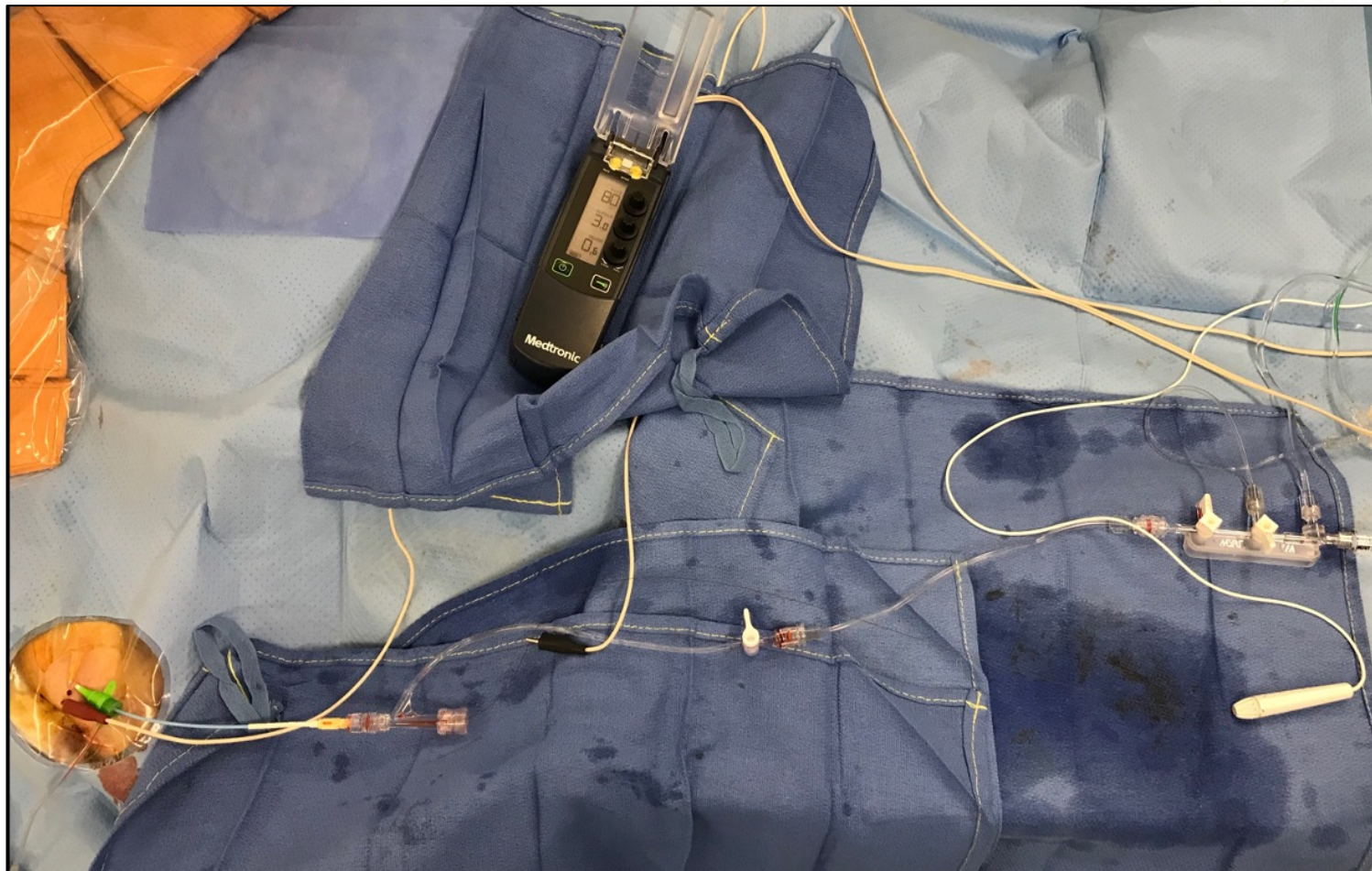
Methods



Sample size determination:

- 0.02-0.03 difference is commonly accepted
- ICV pre-study: 150 lesions= **0.0194** (CI 0.0151 to 0.0237)

Methods



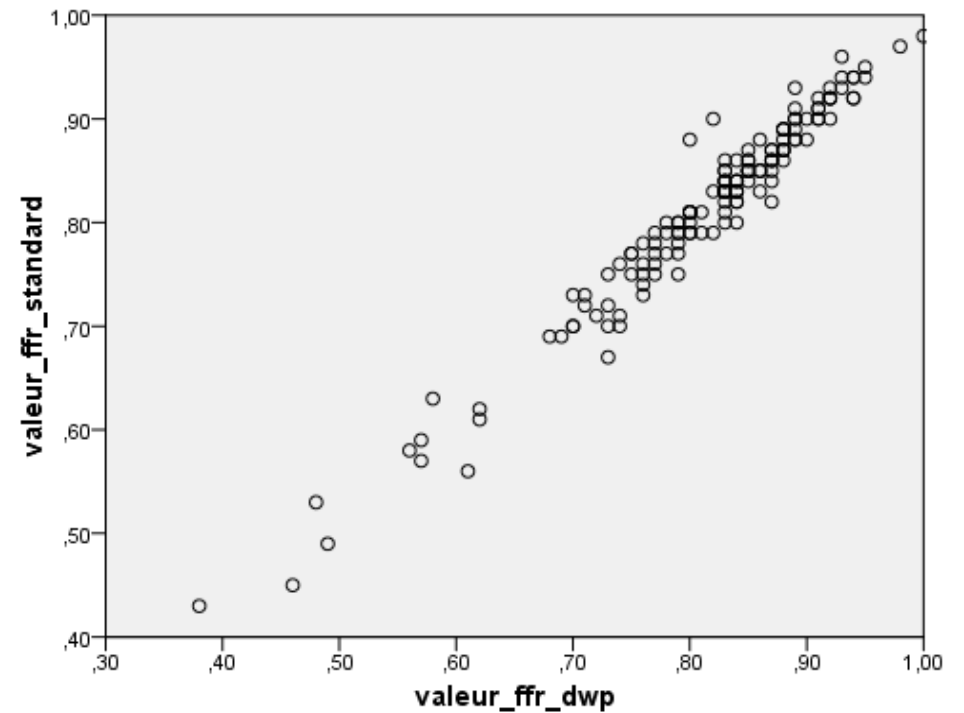
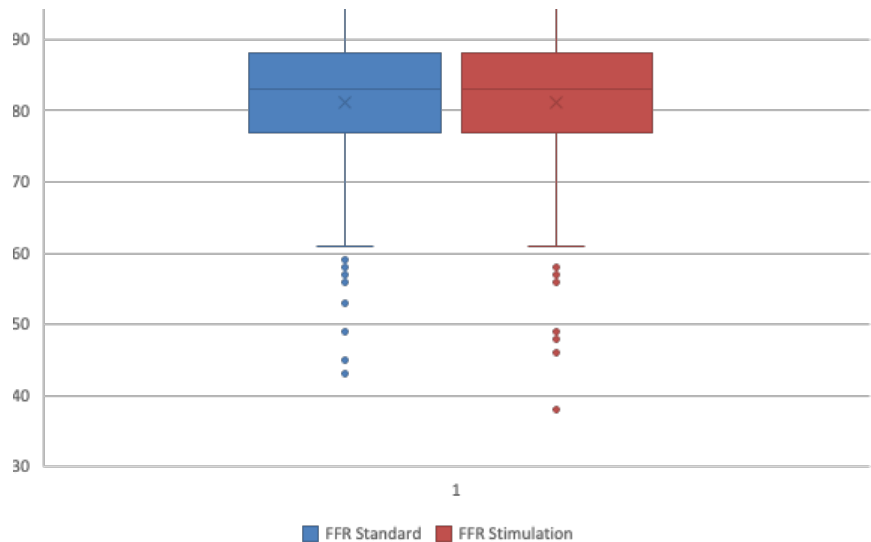
« Home-made FFR-DWP »:

- Alligator clamps
- Stimulation 10 beats above resting heart rate
- Asynchrone PM-mode
- Pacing threshold assessement

PHYSIODAY Results - I

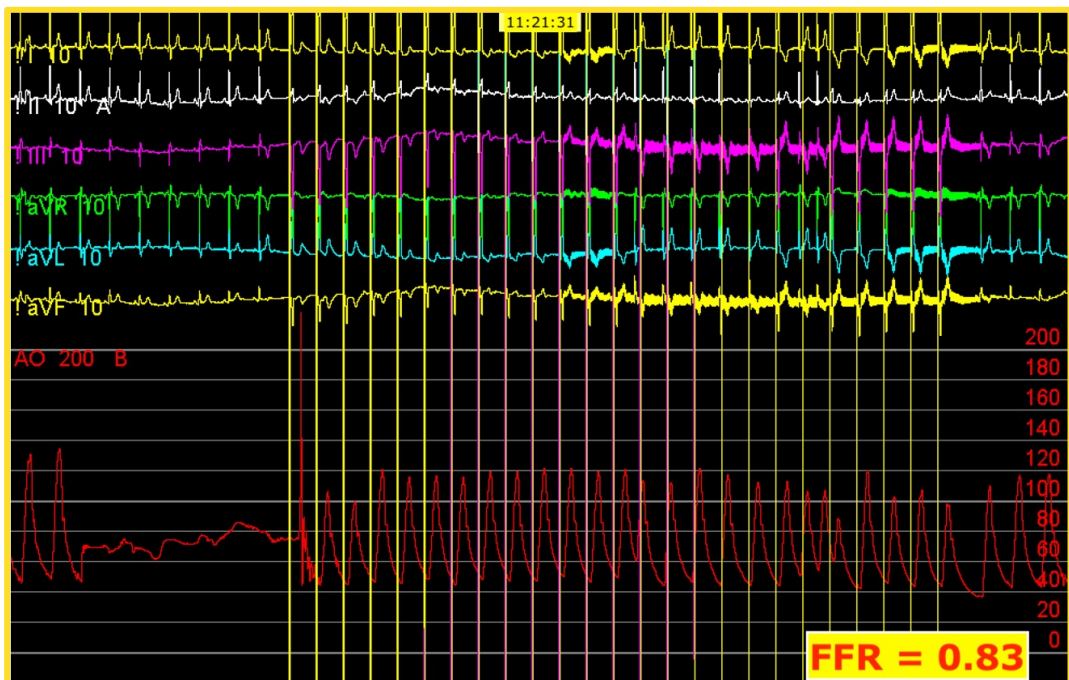
FFR values highly reproducible

Δ FFR value = 0.00054 with high correlation degree (R=0.98, p=0.005)



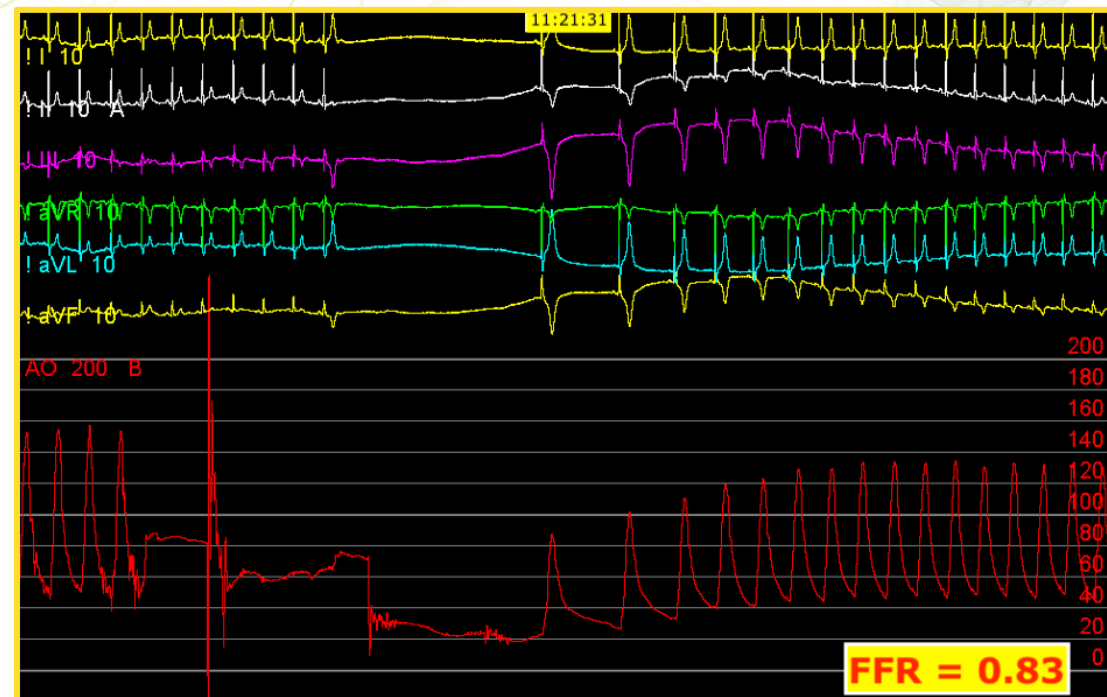
Results - I

FFR-DWP



=

FFR-Standard



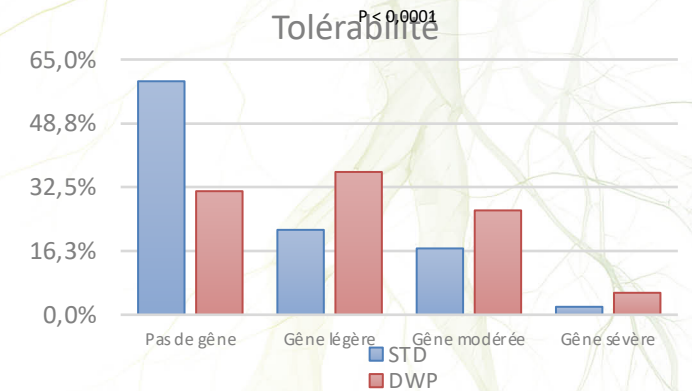
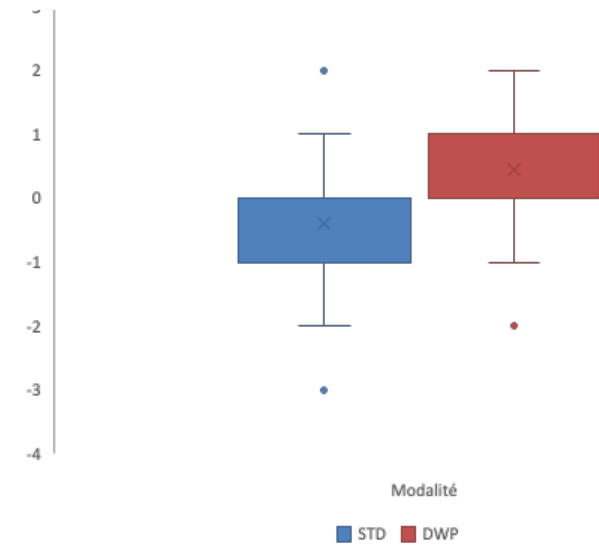
PHYSIODAY Results - II

Tolerance - Chest discomfort: FFR-Standard 1st better tolerance

Tolerance:

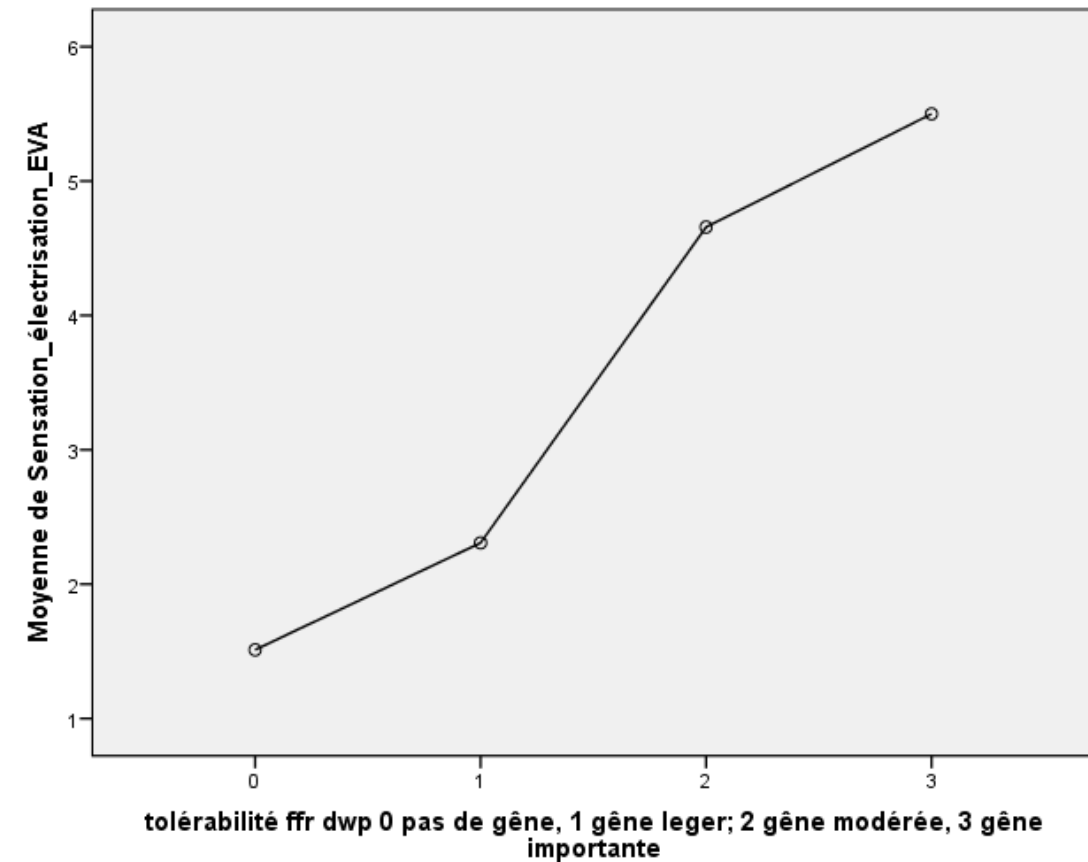
FFR-standard= 0.61 /4

FFR-DWP= 1.05 /4



Results - II

Tolerance - Chest discomfort: Why FFR-standard 1st better tolerance?



Electrical sensation of FFR-DWP

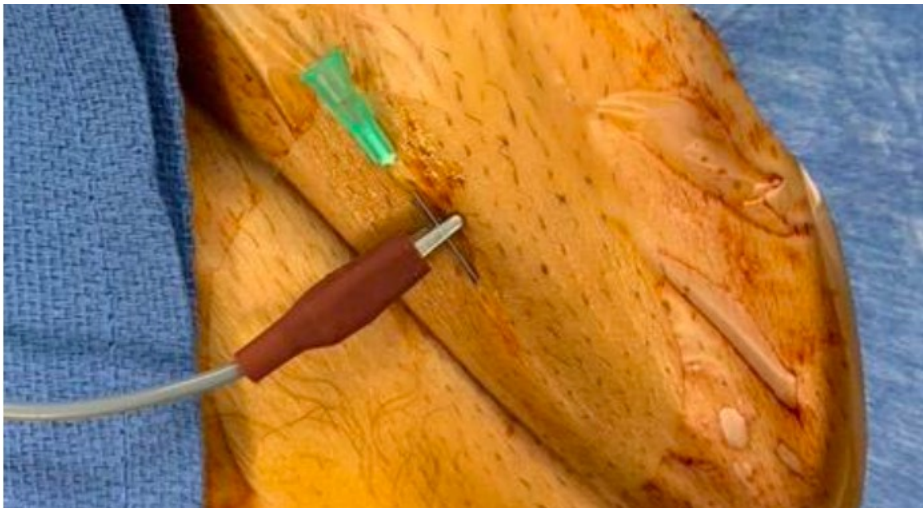
=

2.86 / 10

Correlation between :
Electrisation sensation
&
Chest discomfort

Ⓢ Electrical sensation

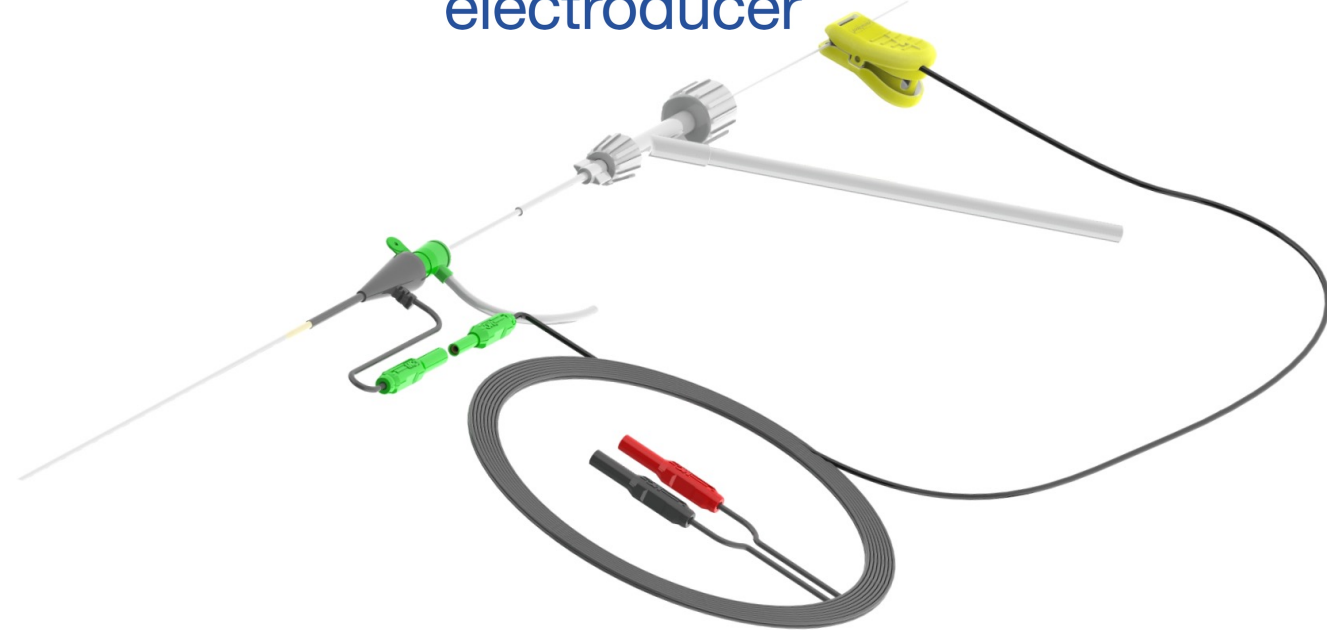
« Home-made DWP »



Electrical sensation of FFR-DWP

=

2.86



Electrical sensation of DWP[®] device

=

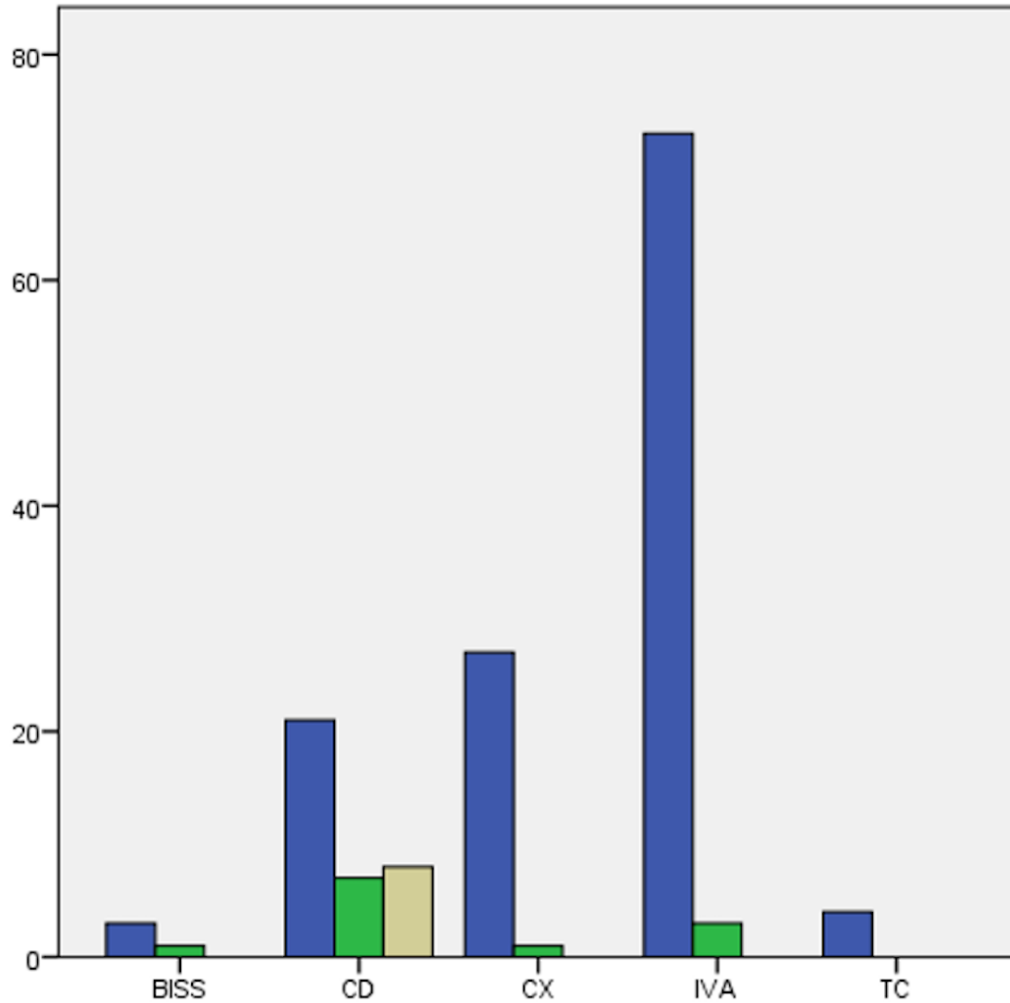
0.51

Safety

No pause in FFR-DWP group

1 occlusive dissection with FFR wire

Graphique à barres



Safety

- Pauses occurred in 13.5%
 - < 3s: 8.1%
 - > 3s: 5.4%
- Most pauses >3s occurred in RCA (75%)
- RCA: 41.6% sinus pause

■ 0 = pas de pause
■ 1 = pause inférieure à 3 secondes
■ 2 = pause supérieure à 3 secondes

Limitations

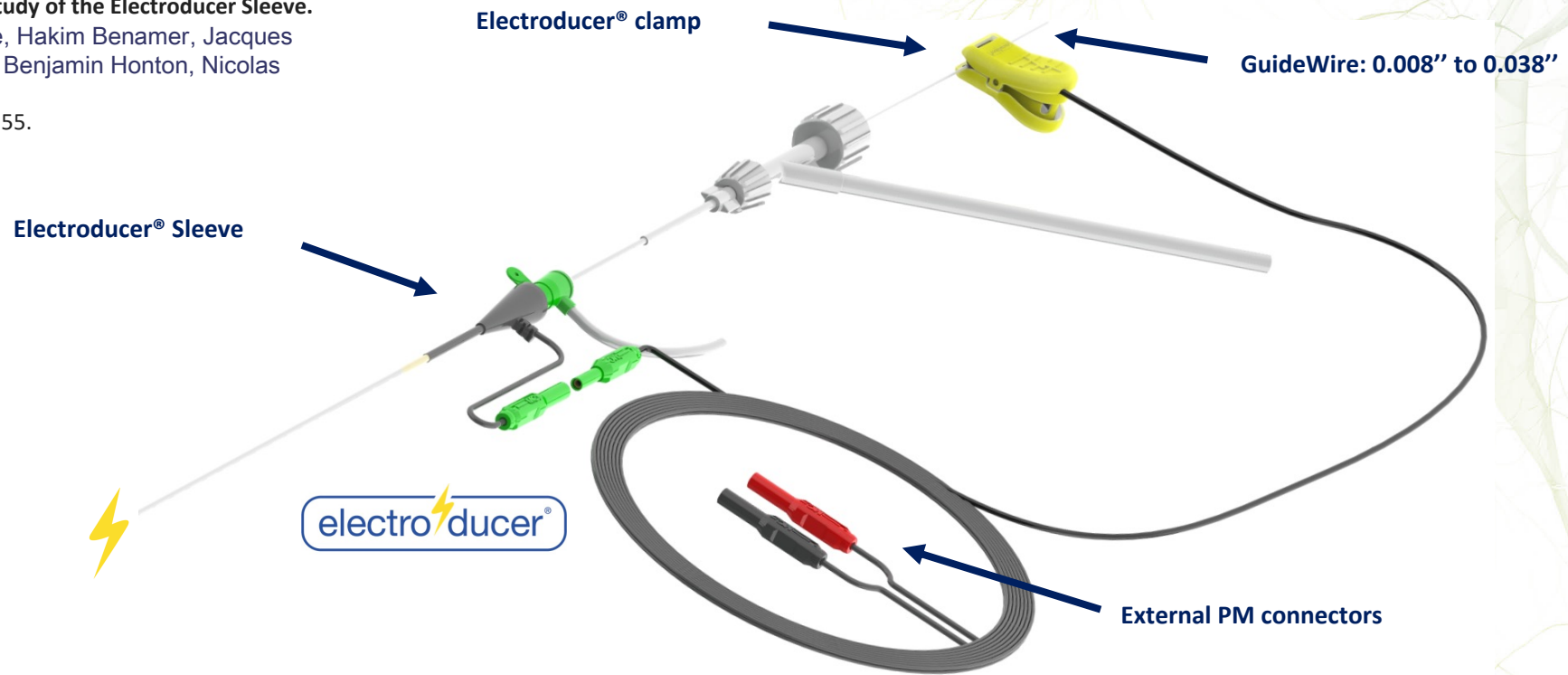
- **Mono-centric study**
- **Interobserver variability: 4 operators**
- **But: subjects act as their own control**
- **Optical fibre FFR wire only (piezoelectric?...)**

Purpose-built device

Electroducer® Sleeve turns wires into temporary Pacemaker leads

⇒ **DWP** (Direct Wire Pacing)

A direct wire pacing device for transcatheter heart valve and coronary interventions: a first-in-human, multicentre study of the Electroducer Sleeve.
Jérôme Wintzer-Wehekind, Thierry Lefevre, Hakim Benamer, Jacques Monsegu, Didier Tchetché, Philippe Garot, Benjamin Honton, Nicolas Dumonteil, Mohamed Abdellaoui,
EuroIntervention. 2023 Feb 20;18(14):1150-1555.



Take-home message

First randomized trial showing that DWP during FFR

- accurate and reproducible for FFR values**
- allow use of maximal hyperaemia without adverse event**

Frontiers in
Cardiovascular Medicine

A journal by  frontiers

Direct wire pacing during measurement of fractional flow reserve: A randomized proof-of-concept noninferiority crossover trial.

Faurie B, Acheampong A, Abdellaoui M, Dessus I, Monsegu J, Wintzer-Wehekind J
Front Cardiovasc Med. 2023 Oct 23;10:1137309.