ELECTRA & RHYTHM

Symposium Mort Subite

Quand faut-il proposer un gilet défibrillateur?

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20/05/2022
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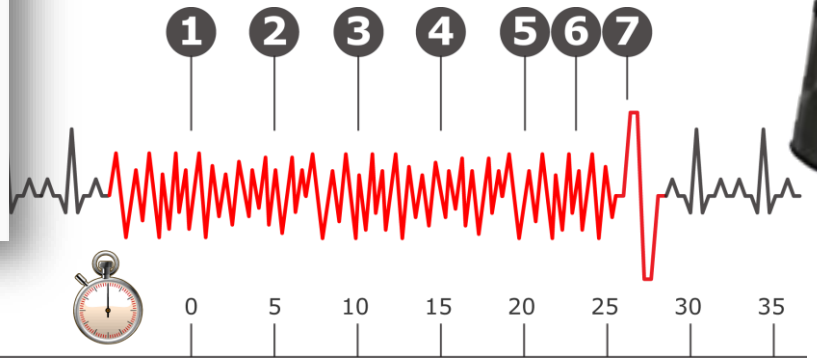
The Wearable Cardiac Defibrillator (WCD)



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Main WCD Pts Real-Life Cohorts

WEARIT-II
Kutyifa et al.
Circulation 2015

- **USA**
- **Prospective**
- **Multicentre**
- **2011–2016**
- **2,000 pts**
- **70% male**
- **ø62 y/o**
- **Median LVEF 25%**

German National Experience
Wäßnig et al.
Circulation 2016

- **Germany**
- **Retrospective**
- **Multicentre**
- **2010–2013**
- **6,043 pts**
- **78% male**
- **ø57 y/o**
- **-**

Swiss National Experience
Boldizsar et al.
Swiss Medical Weekly 2019

- **Switzerland**
- **Retrospective**
- **Multicentre**
- **2011-2018**
- **456 pts**
- **82% male**
- **ø57 y/o**
- **Mean LVEF 32%**

WEARIT-France
Garcia et al.
Europace 2020

- **France**
- **Retro-/prospective**
- **Multicentre**
- **2015-2018**
- **1,157 pts**
- **74% male**
- **ø60 y/o**
- **Median LVEF 27%**

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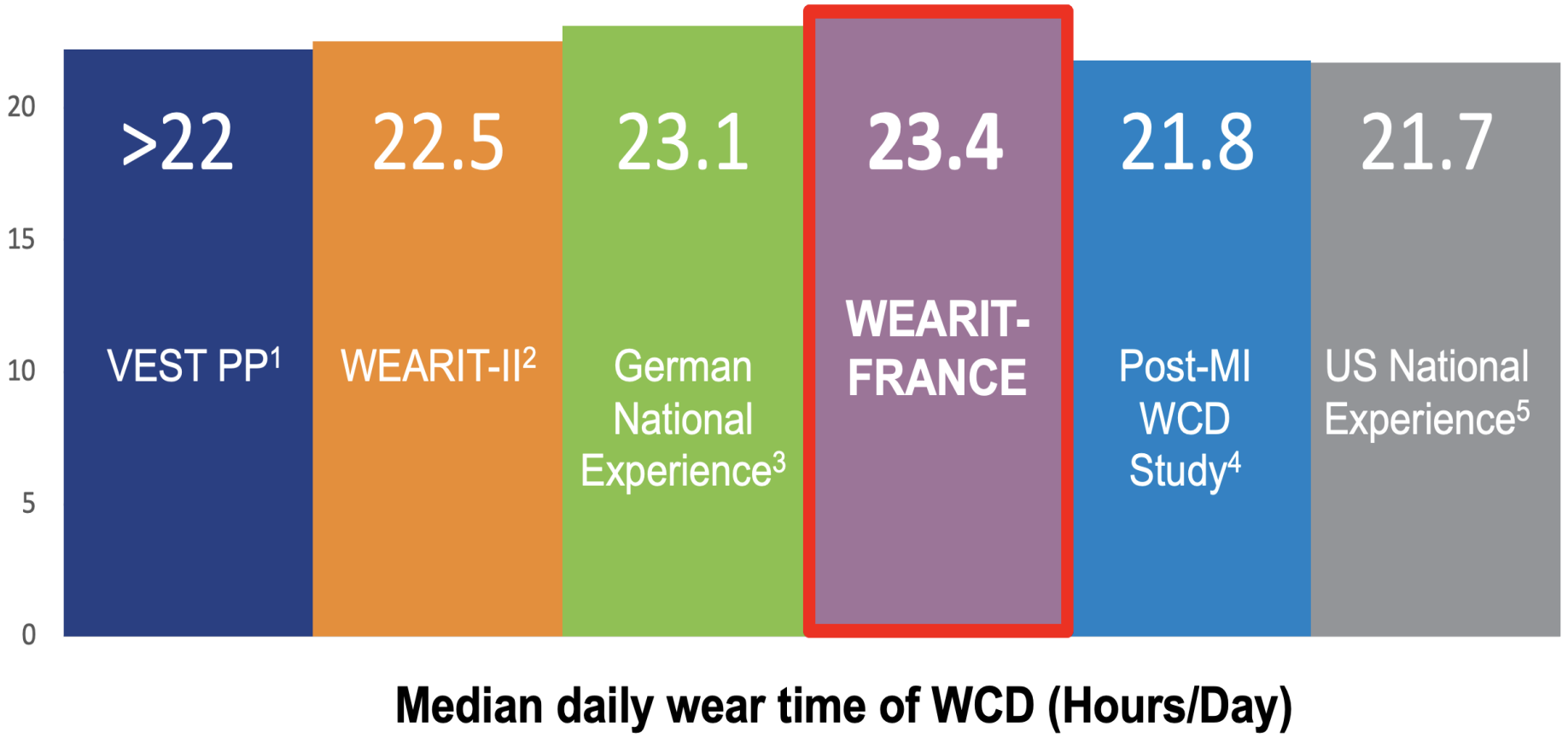
Adherence to WCD



Median daily wear time of WCD (Hours/Day)

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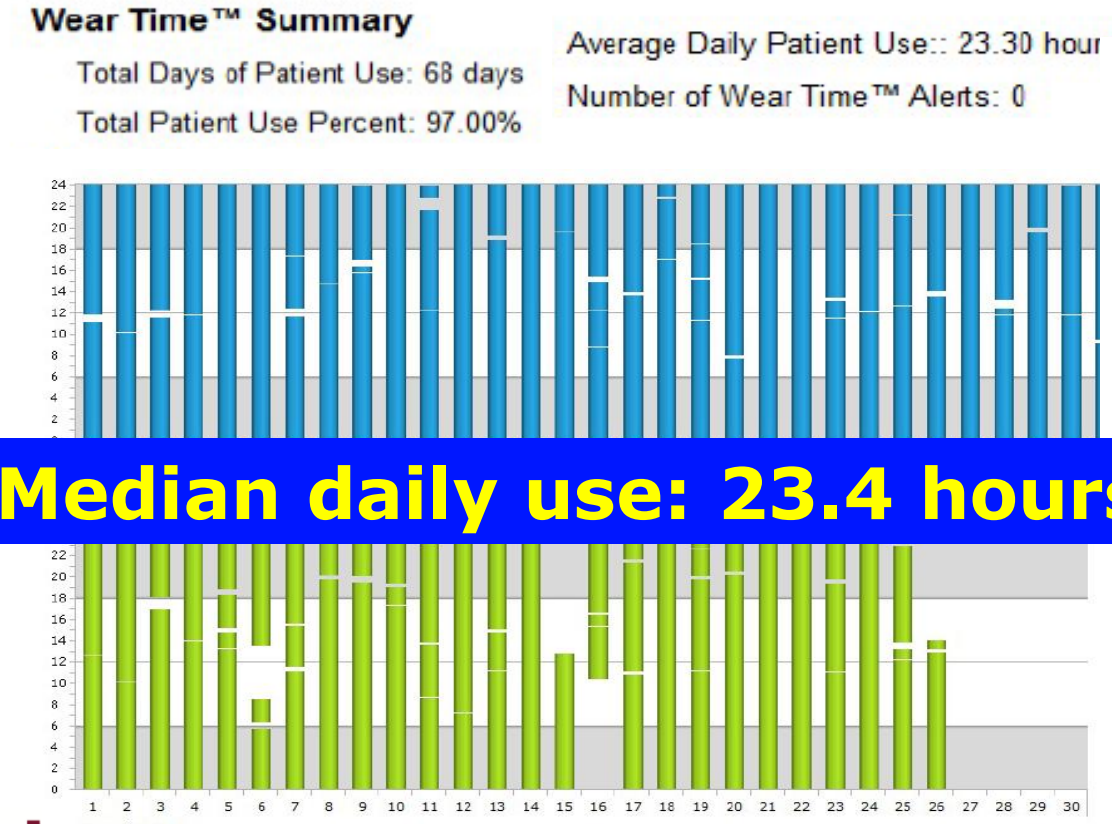
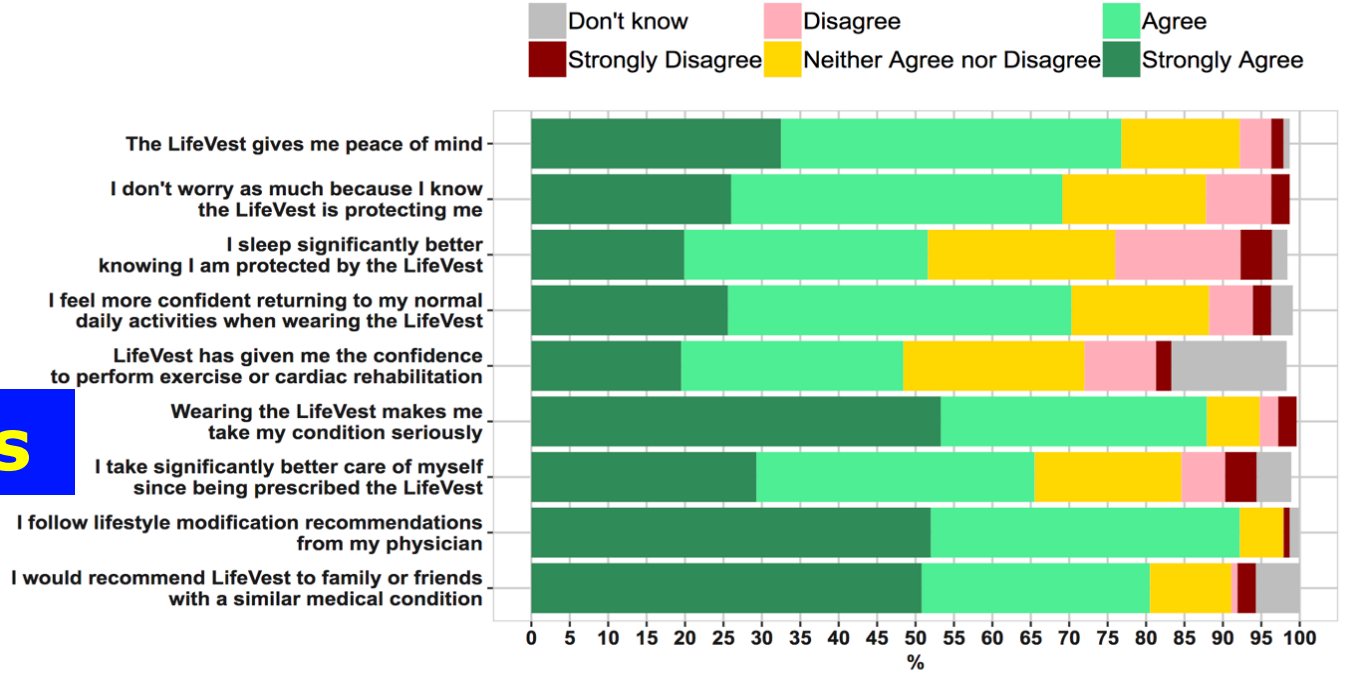
Overall, 1,157 patients
Median age 60 yo., men 74%
Median LVEF 27%
Median FU 2 months

WEARIT FRANCE



Median daily use: 23.4 hours



Whiting et al. J Innov Cardiac Rhythm Manag. 2012

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Younger age was the only independent predictor to lower compliance (OR 1.03, 95%CI 1.01-1.05)

Garcia R et al. Europace 2021

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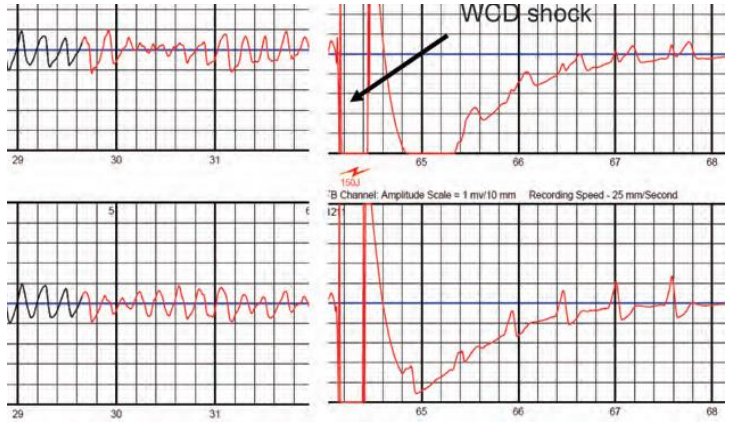
Outcomes With WCD

WEARIT-II
Kutyifa et al.
Circulation 2015

German National Experience
Wäßnig et al.
Circulation 2016



41% LVEF improved	**na% LVEF improved**
42% ICD implanted	**na% ICD implanted**
1.1% appropriate shocks	**1.6% appropriate shocks**
0.5% inappropriate shocks	**0.4% inappropriate shocks**
100% shock conversion	**94% shock conversion**

Swiss National Experience
Boldizsar et al.
Swiss Medical Weekly 2019

WEARIT-France
Garcia et al.
Europace 2020

52% LVEF improved
48% ICD implanted
1.4% appropriate shocks
0% inappropriate shocks
-

49% LVEF improved
51% ICD implanted
1.6% appropriate shocks
0.7% inappropriate shocks
100% shock conversion

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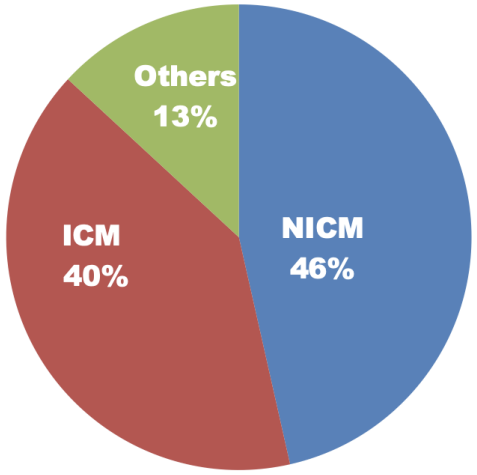
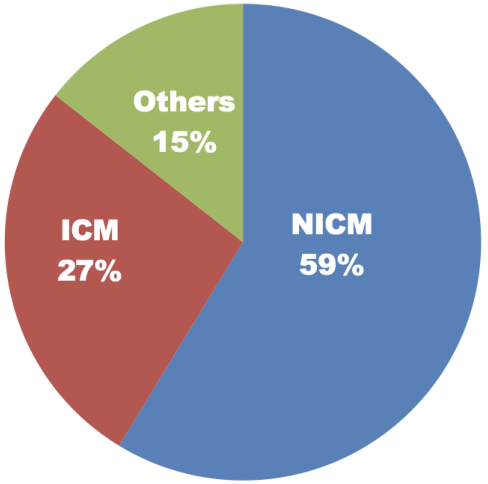
WCD Patients' Characteristics

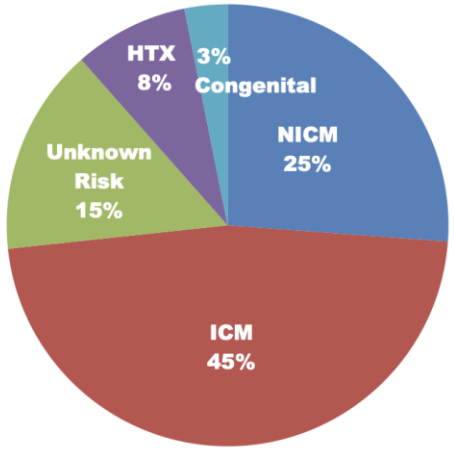
WEARIT-II
Kutyifa et al.
Circulation 2015



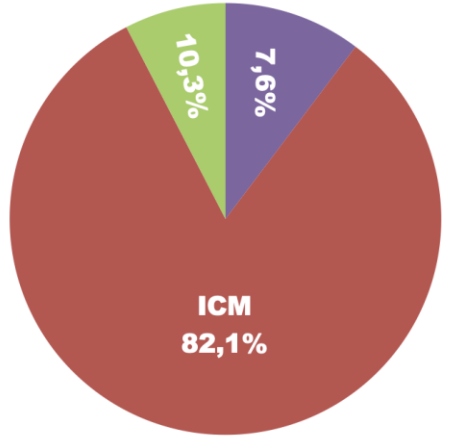
German National Experience
Wäßnig et al.
Circulation 2016



Swiss National Experience
Boldizsar et al.
Swiss Medical Weekly 2019



WEARIT-France
Garcia et al.
Europace 2020



Ischemic
Explant
Transplant

Garcia R et al. Europace 2021

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1998–2018 Observational Evidence

Study	No. of pts	Inclusion criteria	Design	Main findings
Auricchio *et al.*[3]	10	Pts undergoing EPS for VT/VF	Observational, clinical testing	10/10 episodes of induced VT/VF were successfully terminated with first 230 J monophasic shock in 10 Pts
Reek *et al.*[7]	12	Pts undergoing EPS for VT/VF	Observational, clinical testing	22/22 episodes of induced VT/VF were successfully terminated with first 70 J or 100 J biphasic shock in 12 Pts

- ***Newly diagnosed HF pts with LV dysfunction (1 to 2.4%...)***
- ***Myocarditis (up to 10%)***
- ***Peripartum CM (3 to 10%), Tako-tsubo...***

			registry data	long-term mortality than no WCD use in high-risk Pts after CABG or PCI; 12/18 (1.3% event rate) VT/VF episodes were successfully terminated
Epstein *et al.*[13]	8453	Recent MI with LVEF ≤ 35%	Retrospective, registry data	133 Pts (1.6%) received 309 shocks for VT/VF during 40-day and 3-month waiting periods after MI; 91% were successfully resuscitated
Duncker *et al.*[14]	7	PPCM	Prospective cohort study	Four episodes of VF were successfully terminated by the first WCD shock in 3/7 Pts during mean wear time of 81 days

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ESC HEART FAILURE
ESC Heart Failure (2021)
Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/ehf2.13586

ORIGINAL RESEARCH ARTICLE

Extended follow-up after wearable cardioverter-defibrillator period: the PROLONG-II study

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Abstract

Aim The wearable cardioverter-defibrillator (WCD) is used for temporary protection from sudden cardiac death (SCD) in patients with newly diagnosed heart failure with reduced ejection fraction before considering an implantable cardioverter-defibrillator (ICD). However, the prognostic significance of the WCD remains controversial due to conflicting evidence. The aim of the present study was to evaluate prognosis of patients receiving life-saving WCD shocks.

Methods and results All patients receiving a WCD at Hannover Medical School for heart failure with reduced ejection fraction between 2012 and 2017 were included. Data were acquired at baseline, at 3 months and at last available follow-up (FU). Three hundred and fifty-three patients were included (69% male; age 56 ± 15 years; left ventricular ejection fraction 25 ± 8%). FU after the WCD was 2.8 ± 1.5 years with a maximum of 6.8 years. Daily WCD wear time was 22 ± 4 h. Fourteen patients (4%) received appropriate WCD shocks. Two patients (0.6%) died during the WCD period. Thirty patients (9%) died during extended FU. Mean estimated survival after the WCD was similar between patients with and without WCD shocks. Patients without an ICD recommendation after WCD prescription did not experience SCD during FU.

Conclusions Patients with WCD shocks showed a favourable survival. Patients without an ICD recommendation after WCD prescription had no SCD during FU. These findings support the practice of careful risk stratification before considering an ICD and the use of the WCD for temporary protection from SCD.

Keywords Heart failure; Sudden cardiac death; Wearable cardioverter-defibrillator; Implantable cardioverter-defibrillator

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Johanna Mueller-Leisse and Johanna Brunn shared first authorship. Christian Veltmann and David Duncker shared senior authorship.

Introduction

The wearable cardioverter-defibrillator (WCD) is currently used for temporary protection from sudden cardiac death (SCD) in patients with newly diagnosed heart failure with reduced ejection fraction (HFrEF) before considering an implantable cardioverter-defibrillator (ICD). These patients have a temporary risk for SCD, but their long-term risk is unknown at the time of diagnosis.[1] According to guidelines, decision on ICD implantation should not be made before 3 months of optimized heart failure therapy.[2] However, ICDs are often implanted earlier in clinical practice.[3]

In the PROLONG study, we have shown that a prolonged WCD prescription for optimization of medical therapy can avoid ICD implantations in certain patients.[4] However, whether these patients actually stay free from arrhythmia and SCD is currently unknown.

Data on long-term survival of patients wearing the WCD and receiving WCD shocks are limited. It is currently unknown whether WCD shocks convey a long-term survival benefit, a question that seems highly relevant in cost-effectiveness considerations regarding the WCD. The aim of the present study was to present longer term survival data of patients after the WCD period, especially those receiving appropriate WCD shocks. Furthermore, this study evaluated the

PROLONG II Study

- Hannover Medical School
- Period: 2012-2017
- 353 pts with newly diagnosed with low EF (mean LVEF 25%)
- 2/3 non-ischemic
- 4% of non-ischemic with appropriate shock (majority during the first 3 months)

Mueller-Leisse J et al. ESC Heart Fail 2021

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Indications remboursées en France

Extrait de l'arrêté du 3 décembre 2019

EXPLANT	**Après explantation d'un système de défibrillation implantable pour infection**, de la loge ou des électrodes, jusqu'à la réimplantation (guérison de l'infection).
TRANSPLANT	**En attente de transplantation cardiaque.** L'indication doit être réévaluée tous les 3 mois (évaluation du rapport bénéfices/risques et de l'observance).
POST INFARCTUS	**Au décours d'un infarctus du myocarde aigu si la FEVG est inférieure à 35 % après les 48 premières heures**, jusqu'à la réévaluation de la FEVG et discussion de l'indication d'un défibrillateur automatique implantable au terme du 1er mois et du 3ème mois. **Après revascularisation myocardique si la fraction d'éjection ventriculaire gauche (FEVG) est inférieure à 35 %**, jusqu'à la réévaluation de la FEVG et discussion de l'indication d'un défibrillateur automatique implantable au terme du 1er et du 3ème mois.
INSUFFISANCE CARDIAQUE	**Patients avec une cardiomyopathie ischémique et une FEVG ≤ 35%**, jusqu'à ce que l'indication d'implantation d'un défibrillateur automatique implantable (DAI) soit clairement établie, ou jusqu'à réduction significative du risque avec amélioration de la FEVG > 35 % (à l'exclusion des indications dans le post-infarctus du myocarde avec FEVG < 35 %, revascularisés ou non pour lequel LIFEVEST est déjà pris en charge).

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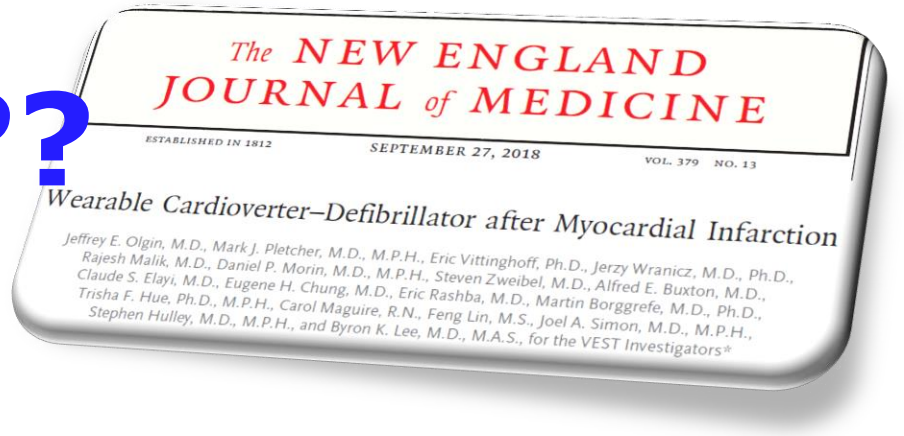
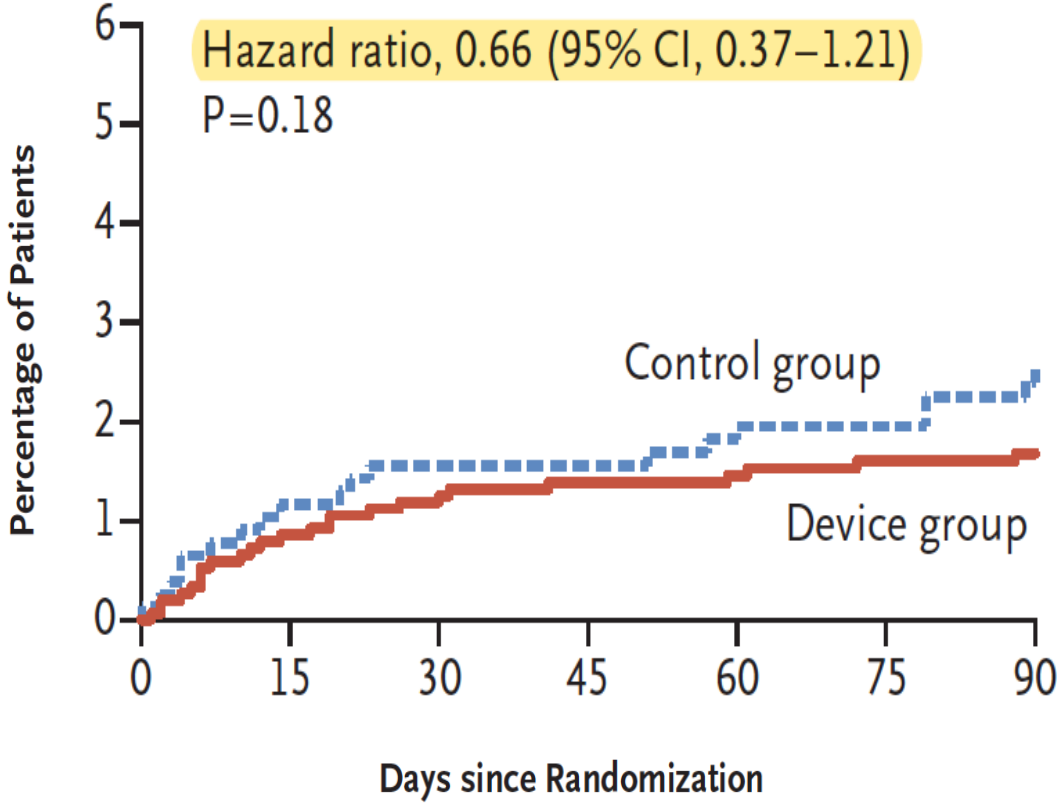
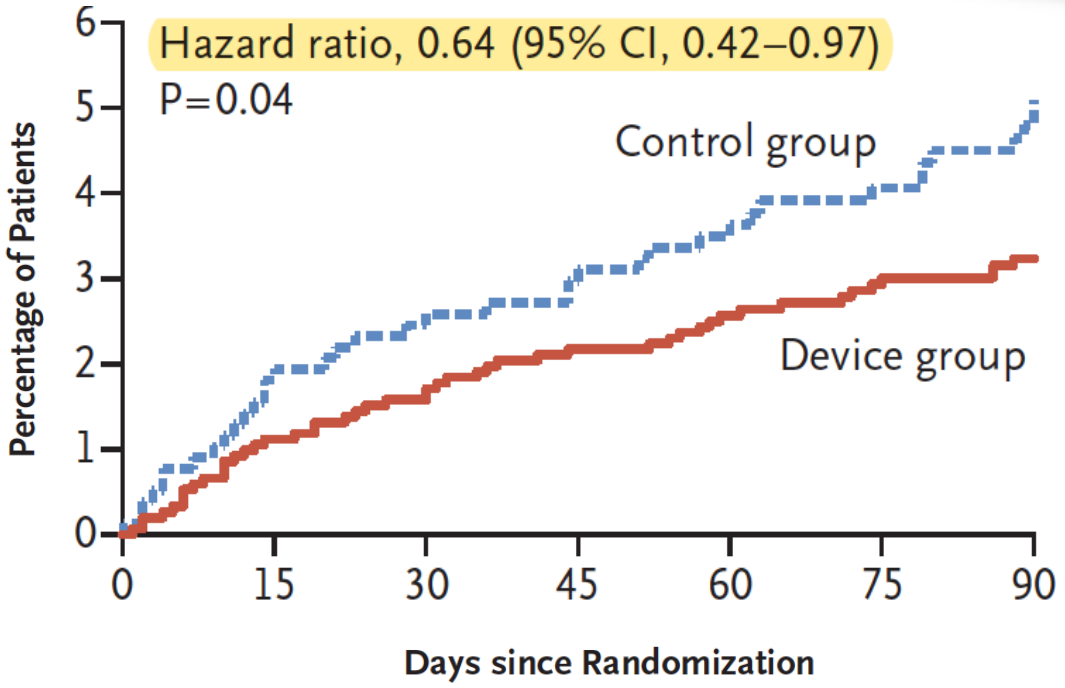
VEST Trial – Pro/Con??





I^{ary} Outcome – SCD

(Total SCD among 1524+778: 44/86 [51%])



2^{ary} Outcome – Overall Mortality

Olgin et al. NEJM 2018

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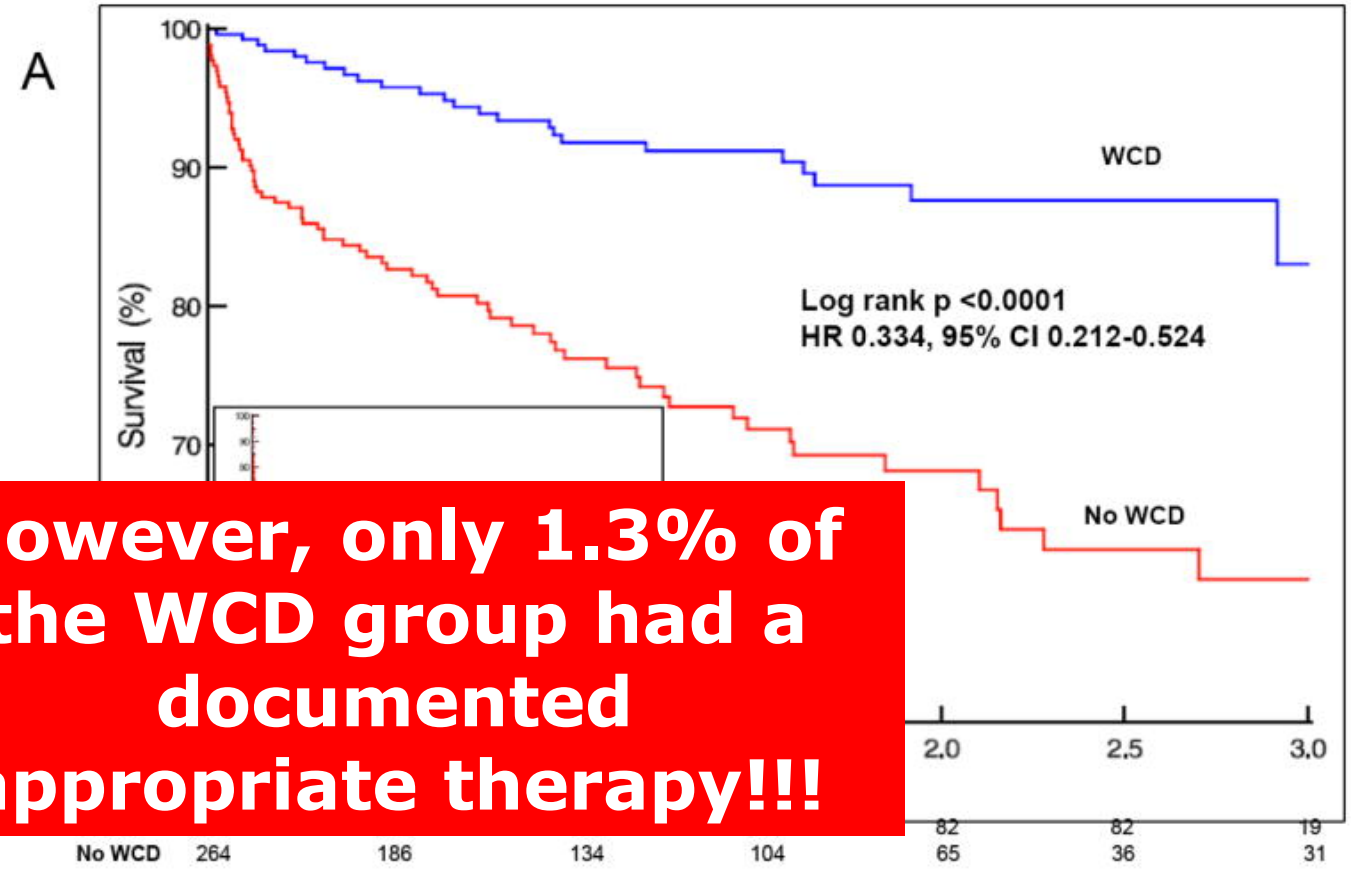
Indirect WCD Effect (> Defibrillation Effect)??



However, only 1.3% of the WCD group had a documented appropriate therapy!!!

After PCI among Patients With Low LVEF

Absolute reduction in Total Mortality about 11% at 3 Months

Zishiri et al. Circulation EP 2013

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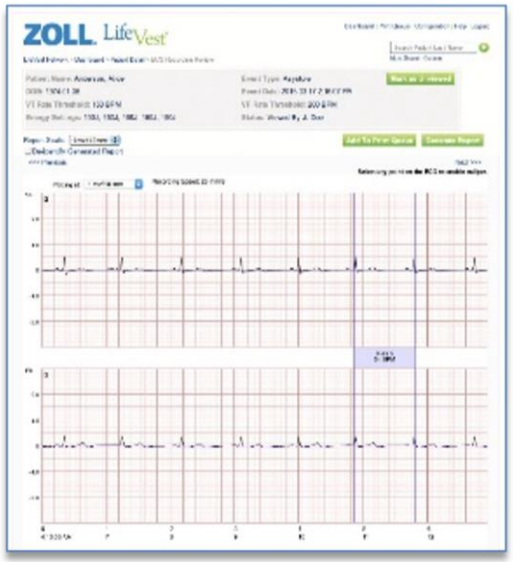
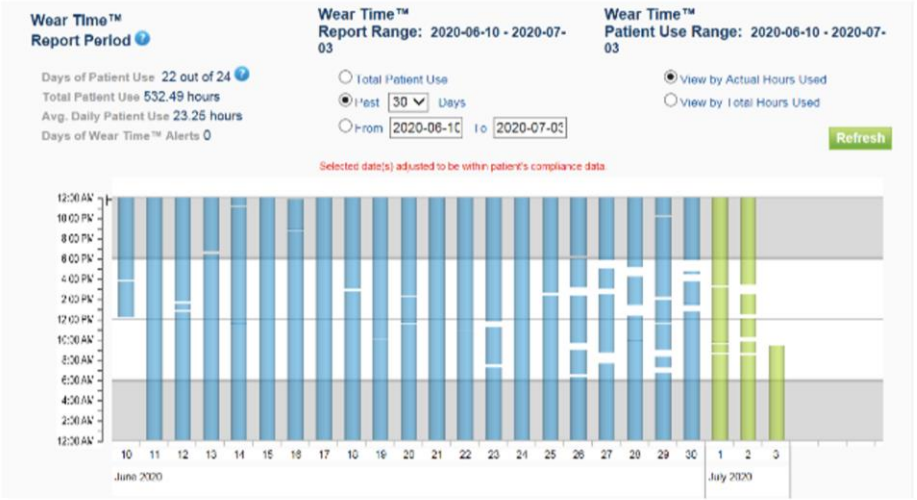
WCD = Vest + NetWork…!!!

ECG



Compliance Report



Physical Activity

Heart Rate

Abnormal Heart Rhythms

Exercise Tolerance

Patient Reported Symptoms

Night Time Elevation Angle

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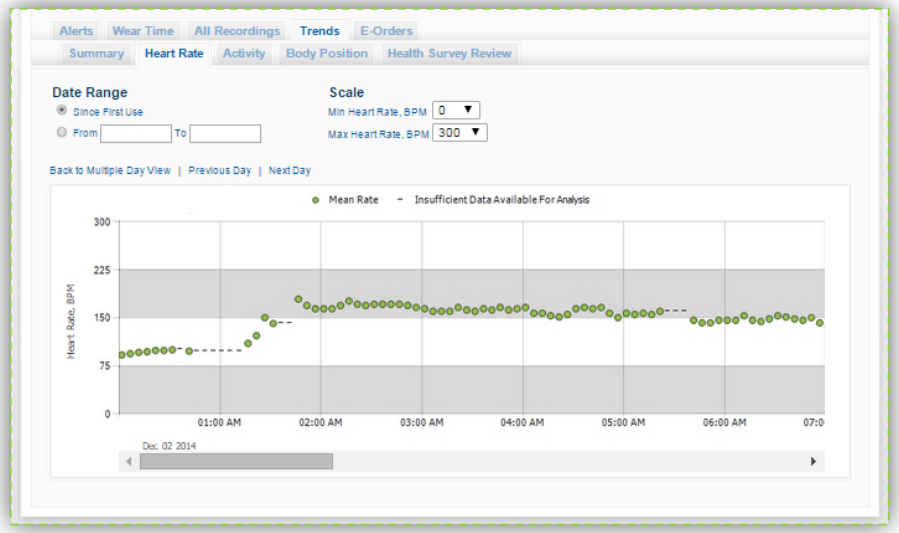
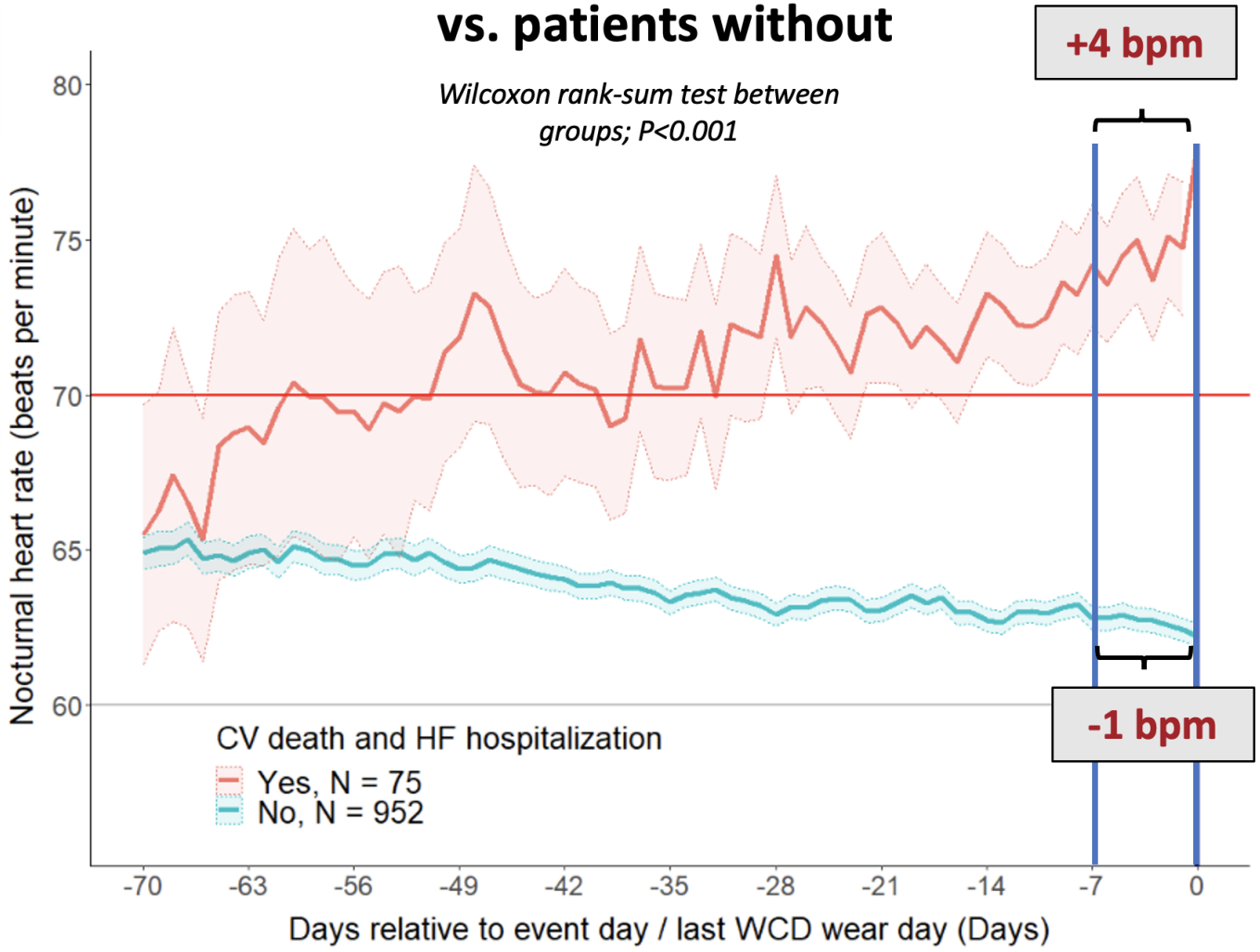
Dynamics of Nocturnal HR

Preemptive Action and Near-Term Prevention



Patients with Primary Endpoint
vs. patients without



Garcia R et al.
Late Breaking Sciences
ESC 2021

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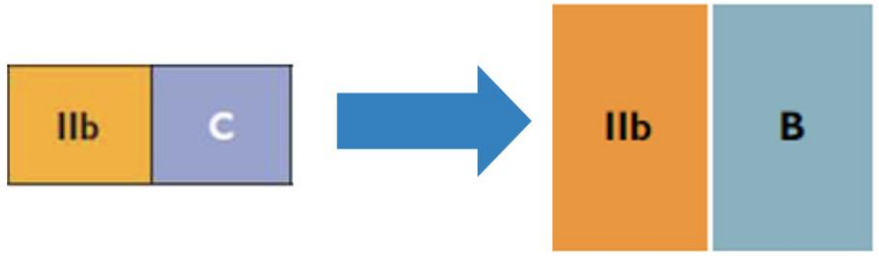
WCD in HF 2021 Guidelines

- Chez les patients insuffisants cardiaques à FE basse, **il est toujours recommandé d'attendre au moins 3 mois de traitement médical optimisé** avant de prendre la décision d'implanter un DAI

- **La LifeVest est une solution temporaire pendant cette période transitoire à haut risque. Le niveau de recommandation reste le même IIb mais avec niveau de preuve accru b**



Recommendations	Class[a]	Level[b]
Primary prevention		
An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of an ischaemic aetiology (unless they have had a MI in the prior 40 days—see below), and an LVEF ≤35% despite ≥3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.[161,165]	I	A
An ICD should be considered to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of a non-ischaemic aetiology, and an LVEF ≤35% despite ≥3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.[161,166,167]	IIa	A
Patients should be carefully evaluated by an experienced cardiologist before generator replacement, because management goals, the patient's needs and clinical status may have changed.[168–172]	IIa	B
A wearable ICD may be considered for patients with HF who are at risk of sudden cardiac death for a limited period or as a bridge to an implanted device.[173–176]	IIb	B
ICD implantation is not recommended within 40 days of a MI as implantation at this time does not improve prognosis.[177,178]	III	A

Take-Home Messages

Quand Faut-Il Proposer un Gilet Défibrillateur?

- Think “WCD” when dealing with patients with a significant transient risk of SCD
- Give time to HF pharmacological therapy!
- Waiting for for more consideration of non-ischemic patients
- Time to acknowledge indirect effect of defibrillation devices!

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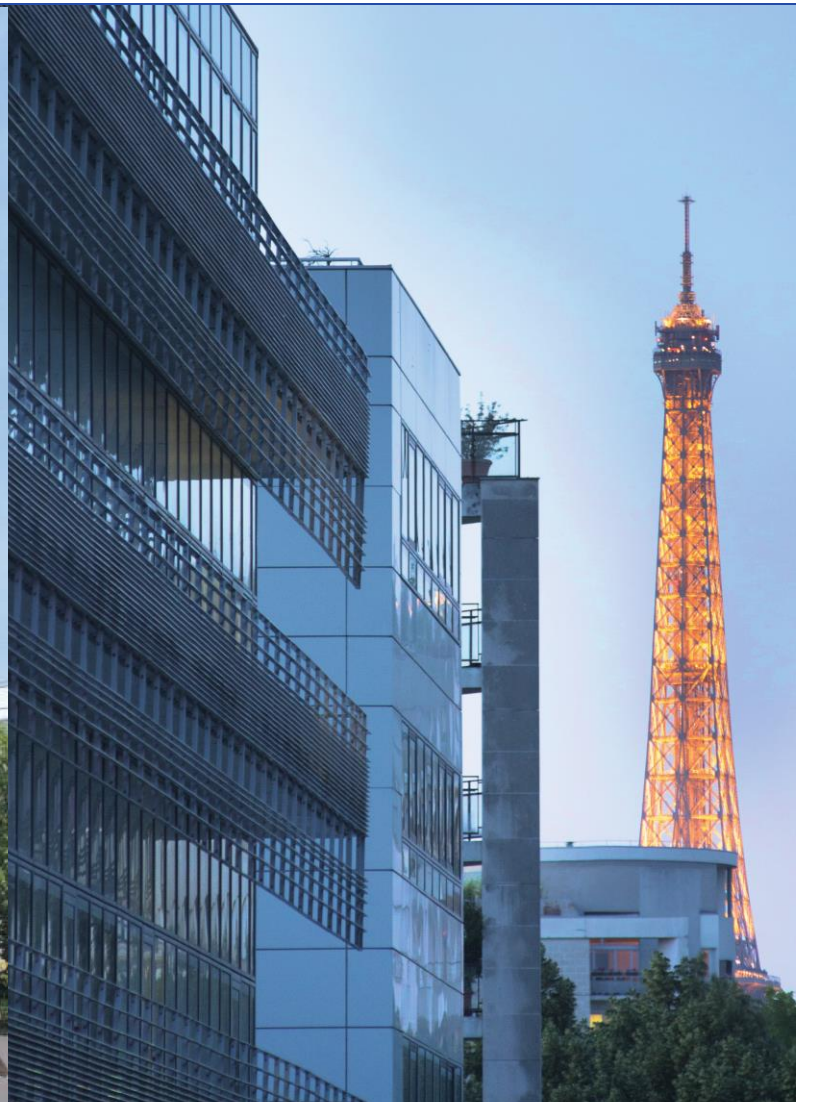
Merci pour votre Attention!



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