

Study Population Characteristics According to Baseline Treatment

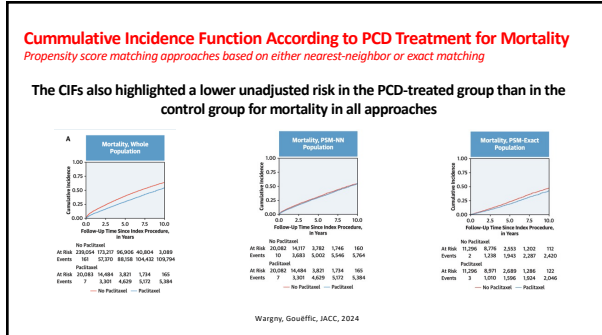
The medical history was unbalanced but not systematically in favor of one group.

	Control group (n: N= 239,054)	PCD treatment group (n = 20,083)	P value
Noninterference	99,976 (42.2%)	10,097 (50.3%)	<0.001
Coronary artery disease	92,194 (38.6%)	11,383 (56.7%)	<0.001
Peripheral artery disease	40,722 (17.0%)	4,961 (24.7%)	<0.001
Stroke	20,813 (8.7%)	3,576 (17.8%)	<0.001
Diabetes mellitus	42,953 (18.0%)	5,148 (25.6%)	<0.001
Chronic kidney disease	14,799 (6.2%)	1,829 (9.1%)	<0.001
Chronic heart failure	22,910 (9.6%)	2,874 (14.3%)	<0.001
Major lower limb amputation	8,581 (3.6%)	1,241 (6.2%)	<0.001
Diabetes mellitus	97,342 (41.1%)	11,725 (58.4%)	<0.001
Chronic kidney disease	46,131 (19.3%)	5,761 (28.7%)	<0.001
Chronic heart failure	46,068 (19.3%)	5,807 (28.9%)	<0.001
Diabetes mellitus	1,094 (0.5%)	132 (0.7%)	<0.001
Major lower limb amputation	17,611 (7.4%)	2,542 (12.7%)	<0.001
Diabetes mellitus	40,921 (17.1%)	4,974 (24.8%)	<0.001
Chronic kidney disease	22,224 (9.3%)	2,724 (13.6%)	<0.001
Stroke	10,844 (4.5%)	1,768 (8.8%)	<0.001

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The PCD group was more likely to present with a history of coronary artery disease (40.0% vs. 37.5%, respectively), peripheral artery disease (68.0% vs. 64.6%), and other lower limb artery procedure (12.5% vs. 9.9%)

The control group was more likely to present with a history of stroke (7.8% vs. 8.6%), major lower limb amputation (1.3% vs. 2.6%), and diabetes mellitus (39.7% vs. 41.7%).

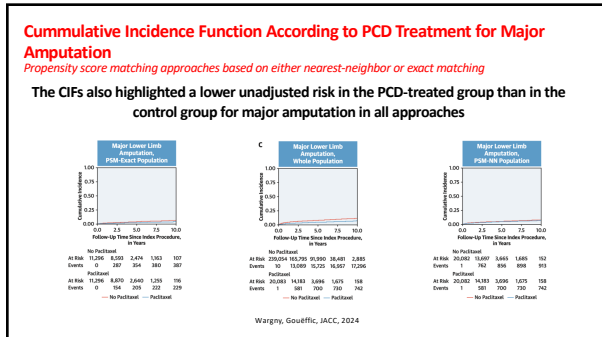


Multivariable Analyses of the Different Outcomes of Interest According to Treatment Status for Paclitaxel-Coated Devices

PCD-treated group had a lower risk of mortality than the control group without and with adjustment

	Events/Pop.	HR (95%CI)	P value	HR (95%CI)	P value	HR (95%CI)	P value
Mortality	114 (0.00059)	0.69 (0.62-0.77)	<0.001	0.70 (0.74-0.76)	<0.001	0.80 (0.84-0.85)	<0.001
MI/AI-m	98 (0.00051)	0.83 (0.86-1.05)	0.029	1.04 (1.01-1.07)	0.002	1.05 (1.02-1.08)	<0.001
MACE-A	134 (0.00061)	0.72 (0.70-0.73)	<0.001	0.77 (0.75-0.79)	<0.001	0.87 (0.84-0.89)	<0.001
Major lower limb amputation	1 (0.0000059)	0.54 (0.50-0.58)	<0.001	0.56 (0.52-0.60)	<0.001	0.70 (0.64-0.75)	<0.001
Lower limb artery procedure	91 (0.00046)	1.00 (1.02-1.12)	<0.001	1.10 (1.07-1.13)	<0.001	1.08 (1.06-1.11)	<0.001
Myocardial infarction	148 (0.00079)	1.04 (0.97-1.10)	0.23	1.03 (0.97-1.10)	0.36	1.02 (0.96-1.09)	0.51
Stroke	115 (0.00059)	0.85 (0.79-0.91)	<0.001	0.92 (0.84-0.99)	0.028	0.97 (0.90-1.04)	0.40

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Multivariable Analyses of the Different Outcomes of Interest According to Treatment Status for Paclitaxel-Coated Devices

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A significantly lower risk was observed for MACE-A and major amputation

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Multivariable analysis of the different outcomes of interest according to treatment status for DCB or DES

In multivariable model, compared to control group, treatments with DCB without DES and DES without DCB were associated with a lower risk for major amputation

Outcomes: Major lower limb amputation	Events/No.	HR (95%CI)	P-value	HR (95%CI)	P-value	HR (95%CI)	P-value
DCB (+DES) - DES excluded	1751/2415(62)	0.56 (0.49-0.64)	<0.001	0.61 (0.51-0.69)	<0.001	0.51 (0.44-0.58)	<0.001
DES (+DCB) - DCB excluded	1776/2514(54)	0.53 (0.46-0.59)	<0.001	0.55 (0.50-0.60)	<0.001	0.68 (0.63-0.75)	<0.001

HR (no adjustment), MD (adjustment for age, sex, duration of the limb ischaemia (stage of follow-up), end protection scheme, MI, MI+ adjustment for a) median drug use (antiplatelet agent, antidiabetic, ACEi, statin), b) patient history (previous artery disease, stroke, heart failure, peripheral artery disease, lower limb ischaemia, abdominal aortic aneurysm, cardiovascular surgery, stroke, diabetes, malignant tumor, joint/orthopedic surgery, heart failure), c) other procedure (angioplasty, balloon aortic valvuloplasty, aortic valve replacement, cardiac resynchronization therapy, cardiac surgery, history of aneurysm/dissection) via the Hazard ratio, d) in regard dependent event (perforation and/or acute lower limb pain, procedure leading to event, amputation), DES (+ DCB) excluded (DES (+ DCB) without DCB), DES (+ DCB) included (DES (+ DCB) without DCB and/or DES (+ DCB) with DCB), DCB (+ DES) included (DCB (+ DES) without DCB and/or DCB (+ DES) with DCB), DCB (+ DES) excluded (DCB (+ DES) without DCB and/or DCB (+ DES) with DCB)

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Take Home message

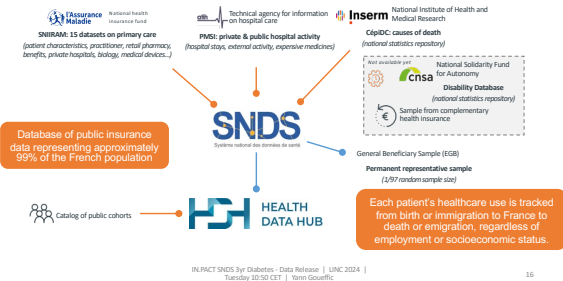
- The DETECT study is a real-world data from a 10-year, nationwide, nearly exhaustive, of about 260,000 patients followed after endovascular revascularization for lower limb peripheral artery disease using or not using a PCD, with a minimum of 2 years of follow-up.
- In this population accounting for the main confounding factors, PCD treatment **was not** associated with a higher risk of late **mortality**.
- The other sub-analyses in patients with PCD, DCB only or DES only, highlight an **lower risk** associated in term of **major amputation**.

Paclitaxel-Eluting Devices Decrease Major Amputation Rates In Peripheral Arterial Disease Without Increasing Mortality: From The French Nationwide DETECT Study

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The French National Health Data System (SNDS) Positions France as a Key Country for Research



HLPRCT SNDS 3yr Diabetes - Data Release | LINC 2024 | Tuesday 20/03/24 | Yann Gouëffic

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Study Limitations

- No causal inference can be made. Indeed, the indication bias between patients treated and not treated with PCD could not be fully controlled
- Data set limitations: from 2011 to 2021, the time used to retrieve medical history was shorter for patients included near October 2011.
- The lack of data regarding the laterality of the procedure strongly limits the interest of the "new lower limb artery procedure" outcome. Indeed, although it may be a reintervention caused by the restenosis of the initial lesion, this procedure may also be contralateral.