Correction

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CORRECTION

Schneider PA, Laird JR, Doros G, Gao Q, Ansel G, Brodmann M, Micari A, Shishehbor MH, Tepe G, Zeller T

Mortality Not Correlated with Paclitaxel Exposure: An Independent Patient-Level Meta-Analysis of A Drug-Coated Balloon

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This is a Correction Notification of the manuscript originally published January 25, 2019. The published manuscript DOES NOT currently reflect these corrections. A new version of the manuscript will be forthcoming that will reflect these changes.

A source code programming error that occurred several years ago was recently identified in the study sponsor's database for the IN.PACT Global post-market study resulting in the omission of some events from the summary tables of mortality included in the statistical analysis. This error was isolated to mortality data pertaining to the two- and three-year follow-up periods in the IN.PACT Global post-market study; events were captured in the appropriate study exit forms, and adjudicated by an independent clinical events committee but omitted from summary tables. Raw numbers have shifted in all tables and figures in the manuscript, and some in the supplement. The manuscript and supplement have been corrected. In addition, analyses regarding the Standard Cohort of DCB (n=712) compared to PTA (n=143) have been clarified throughout.

Specifically, the following are the essential data impacted by the aforementioned error:

- Nominal paclitaxel dose comparing patients who died and survived (Table 5).

	Died	Survived	p-value
Original	11,829.8±7,347.6 µg	11,419.6±7,414.8 µg	0.529
Updated	12,202.06±7,721.66 µg	11,368.72±7,371.19 µg	0.186

- Freedom from all-cause mortality through 5 years by paclitaxel dose levels (Figure 1).

	Lower	Mid	Upper	p-value

Original	90.6%	90.0%	91.7%	0.700
Updated	85.8%	84.2%	88.2%	0.731

- Safety outcomes in Table 2.

As originally published:

Table 2. Safety outcomes using Kaplan-Meier estimates through 5 years

Safety outcomes through 5 years of patients treated with DCB compared to PTA are reported.

	IN.PACT Admiral DCB (N=1837 patients)	95% CI of DCB	**PTA (N=143 patients)**	95% CI of PTA	**Hazard Ratio [95% CI]***	**P value***
MAE Composite [†]	35.21% (541)	(29.98%, 41.05%)	45.39% (59)	(31.87%, 61.46%)	0.71 [0.51, 0.98]	0.036
Death (all-cause)	9.29% (140)	(6.45%, 13.30%)	11.15% (12)	(4.86%, 24.47%)	1.32 [0.69, 2.50]	0.399
CD-TVR [‡]	27.72% (407)	(22.67%, 33.62%)	37.17% (49)	(23.81%, 54.82%)	0.60 [0.41, 0.86]	0.005
Major Target Limb Amputation	0.94% (12)	(0.27%, 3.25%)	0.00% (0)	(0.00%, 0.00%)	--	--
Thrombosis	4.85% (79)	(2.82%, 8.28%)	3.59% (5)	(0.70%, 17.30%)	0.74 [0.25, 2.16]	0.581
CD-TLR [§]	26.54% (389)	(21.58%, 32.39%)	32.56% (43)	(19.59%, 50.94%)	0.61 [0.42, 0.90]	0.012
Any TVR	28.41% (418)	(23.31%, 34.35%)	36.78% (49)	(23.44%, 54.49%)	0.61 [0.43, 0.87]	0.007
Any TLR [‖]	27.19% (399)	(22.16%, 33.09%)	34.50% (46)	(21.33%, 52.58%)	0.59 [0.41, 0.85]	0.005

Values are % (N); % = Kaplan-Meier estimate; N = number of events

CD-TLR = clinically-driven target lesion revascularization; CD-TVR = clinically-driven target vessel revascularization; MAE = Major Adverse Events; TLR = target lesion revascularization; TVR = target vessel revascularization;

[*] HR and P-values are from frailty model with study as random effect.

[†] A composite of death from any cause, CD-TVR, target limb major amputation, and thrombosis.

[‡] Defined as any reintervention within the target vessel due to symptoms or drop of ankle-brachial index (ABI) ≥ 20% or >0.15 when compared to post-procedure baseline ABI or toe-brachial index (TBI).

[§] Defined as any reintervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared with post-procedure baseline ABI/TBI.

[‖] Includes clinically-driven and incidental or duplex-driven TLR

Updated in this manuscript:

Table 2A. Safety outcomes of all patients using Kaplan-Meier estimates through five years
Unadjusted safety outcomes through five years of all patients treated with DCB compared to PTA are reported.

	IN.PACT Admiral DCB (N=1837 patients)	95% CI of DCB	**PTA (N=143 patients)**	95% CI of PTA	**Hazard Ratio [95% CI]***	**P value***
MAE Composite †	43.57% (534)	(34.70%, 53.61%)	45.39% (59)	(31.87%, 61.46%)	0.73 [0.53, 1.00]	0.051
Death (all-cause)	15.12% (181)	(9.31%, 24.02%)	11.15% (12)	(4.86%, 24.47%)	1.70 [0.92, 3.15]	0.092
CD-TVR ‡	32.40% (368)	(23.68%, 43.30%)	37.17% (49)	(23.81%, 54.82%)	0.61 [0.42, 0.87]	0.007
Major Target Limb Amputation	1.35% (12)	(0.21%, 8.47%)	0.00% (0)	(0.00%, 0.00%)	--	--
Thrombosis	4.85% (79)	(1.87%, 12.30%)	3.59% (5)	(0.70%, 17.30%)	0.74 [0.25, 2.16]	0.584
CD-TLR §	30.99% (350)	(22.53%, 41.67%)	32.56% (43)	(19.59%, 50.94%)	0.63 [0.43, 0.92]	0.017
Any TVR	33.00% (378)	(24.18%, 43.97%)	36.78% (49)	(23.44%, 54.49%)	0.63 [0.44, 0.89]	0.010
Any TLR ‖	31.62% (359)	(23.00%, 42.46%)	34.50% (46)	(21.33%, 52.58%)	0.61 [0.42, 0.88]	0.008

Values are % (N); % = Kaplan-Meier estimate; N = number of events
CD-TLR = clinically-driven target lesion revascularization; CD-TVR = clinically-driven target vessel revascularization; MAE = Major Adverse Events; TLR = target lesion revascularization; TVR = target vessel revascularization;
* HR and P-values are from frailty model with study as random effect. No other covariate was included.
† A composite of death from any cause, CD-TVR, target limb major amputation, and thrombosis.
‡ Defined as any reintervention within the target vessel due to symptoms or drop of ankle-brachial index (ABI) ≥ 20% or >0.15 when compared to post-procedure baseline ABI or toe-brachial index (TBI).
§ Defined as any reintervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared with post-procedure baseline ABI/TBI.
‖ Includes clinically-driven and incidental or duplex-driven TLR

- All-cause mortality in the Standard Cohort through 5 years (Table 2B).*

	DCB n=712	PTA n=143	p-value
Original^	Not included	Not included	Not included
Updated	13.16% (58)	10.98% (12)	0.188

* To provide additional analyses regarding the effects of paclitaxel, survival in patients treated with DCB versus PTA was evaluated. PTA patients were only included in the IN.PACT SFA and IN.PACT Japan trials in a 2:1 randomization protocol. This resulted in a baseline imbalance between PTA and DCB which was adjusted by identifying a subgroup of DCB patients who met the inclusion criteria for the pivotal studies (IN.PACT SFA, IN.PACT Japan, and IN.PACT China). This group of DCB patients, termed Standard DCB group (n=712), included patients with RCC 2-4, single de novo lesions ≤20 cm in length, mild lesion calcification, and no ISR. The Standard DCB group was first reported at the 2018 Vascular Interventional Advances (VIVA) conference and was included in the original Supplement.(13) Survival was compared between Standard DCB- and PTA-treated patients with the use of propensity scores and IPTW adjustment.

^All-cause mortality in the Standard DCB Cohort was reported in original manuscript in Supplemental Figure 1 in terciles; in the current manuscript it is reported in Table 2B and in terciles in Supplemental Figure 1.

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