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CORRECTION

Low Wang CC, Blomster JI, Heizer G, Berger JS, Baumgartner I, Fowkes GR, Held P, Katona BG, Norgren L, Jones WS, Lopes RD, Olin JW, Rockhold FW, Mahaffey KW, Patel MR, Hiatt WR,
on behalf of the EUCLID Trial Executive Committee and Investigators

Cardiovascular and Limb Outcomes in Patients With Diabetes and Peripheral Artery Disease: The EUCLID Trial

J Am Coll Cardiol 2018;72:3274–84.

In the Results section of the abstract, the second sentence read:

> The primary endpoint occurred in 15.9% of patients with PAD and diabetes as compared with 10.4% of those without diabetes (absolute risk difference 5.5%; adjusted hazard ratio: 1.56; 95% confidence interval [CI]: 1.41 to 1.72; $p < 0.001$).

But should have read:

> The primary endpoint occurred in 15.9% of patients with PAD and diabetes as compared with 10.4% of those without diabetes (absolute risk difference 5.5%; adjusted hazard ratio: 1.43; 95% confidence interval [CI]: 1.28 to 1.61; $p < 0.001$).

In the Conclusions section of the abstract, the second sentence read:

> Every 1% increase in HbA_{1c} was associated with a 14.2% increased relative risk for MACE (95% CI: 1.09 to 1.20; $p < 0.0001$).

But should have read:

> Every 1% increase in HbA_{1c} in patients with a history of diabetes mellitus was associated with a 14.2% increased relative risk for MACE (95% CI: 1.09 to 1.20; $p < 0.0001$).

On page 3277, left column, ninth sentence read:

> Even if study treatment (ticagrelor/clopidogrel) was not selected by the stepwise process, it was added to the model. Interaction terms of treatment for diabetes and the randomized treatment were included only if statistically significant at a p value of 0.05.

But should have read:

> Even if study treatment (ticagrelor/clopidogrel) was not selected by the stepwise process, it was added to the model. Interaction terms of diabetes and the randomized treatment were included only if statistically significant at a p value of 0.05.

On page 3278, the second column, the second sentence read:

> After adjustment, the HR was 1.41 (95% CI: 1.25 to 1.59; $p < 0.0001$) (Table 2).

But should have read:

> After adjustment, the HR was 1.43 (95% CI: 1.28 to 1.61; $p < 0.0001$) (Table 2).

On page 3278, the sixth sentence read:

> Patients with diabetes had a 96% increased risk for major amputation ($p < 0.0001$), a 25% increased risk for lower extremity revascularization ($p < 0.0001$), and a 35% increased risk for carotid revascularization ($p = 0.0002$) as compared with those without diabetes.

But should have read:

> Patients with diabetes had a 86% increased risk for major amputation ($p < 0.0001$), a 22% increased risk for lower extremity revascularization ($p < 0.0001$), and a 39% increased risk for carotid revascularization ($p < 0.0001$) as compared with those without diabetes.

On page 3278, right column, second paragraph read:

> Conversely, the unadjusted risk for on-treatment TIMI major bleeding in patients with diabetes was similar to those without diabetes (0.81 vs. 0.70 per 100 patient-years, with an adjusted HR of 1.03; 95% CI: 0.76 to 1.38; p = 0.87). The cumulative incidence by 36 months of on-treatment TIMI major bleeding was 2.3% in patients with diabetes (91 of 5,327 patients in the safety analysis set) compared with 2.0% in those without diabetes (131 of 9,515 patients in the safety analysis set) (HR: 1.15; 95% CI: 0.88 to 1.50; p = 0.32) (Online Figure 1). By contrast, patients with diabetes had an adjusted 68% increase in intracranial hemorrhage (p = 0.054) and a nonsignificant 99% increase in fatal bleeding compared with those without diabetes.

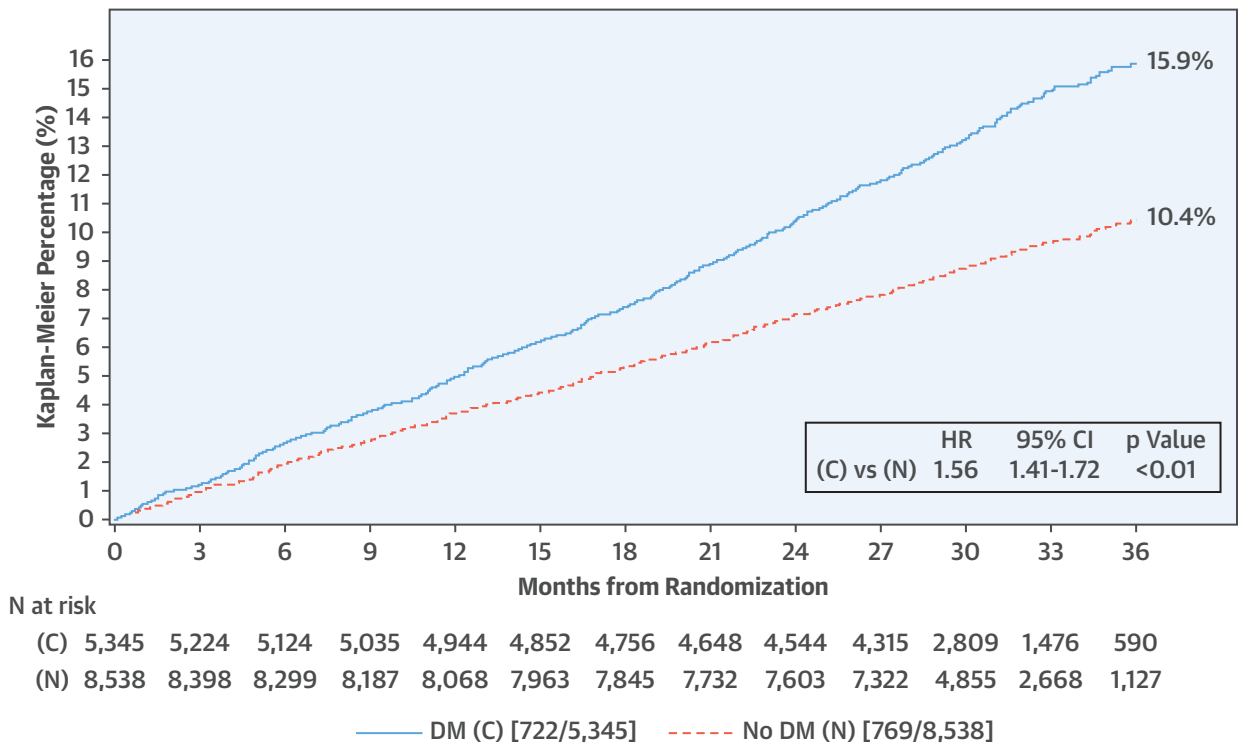
But should have read:

> Conversely, the unadjusted risk for on-treatment TIMI major bleeding in patients with diabetes was similar to those without diabetes (0.81 vs. 0.70 per 100 patient-years, with an adjusted HR of 1.06; 95% CI: 0.79 to 1.40; p = 0.71). The cumulative incidence by 36 months of on-treatment TIMI major bleeding was 2.3% in patients with diabetes (91 of 5,327 patients in the safety analysis set) compared with 2.0% in those without diabetes (131 of 8,515 patients in the safety analysis set) (HR: 1.15; 95% CI: 0.88 to 1.50; p = 0.32) (Online Figure 1). By contrast, patients with diabetes had an adjusted 75% increase in intracranial hemorrhage (p = 0.03) and a nonsignificant 65% increase in fatal bleeding compared with those without diabetes.

In the Central Illustration, the following value in the No Diabetes Group read: 8,540 but should have been 8,538.

The revised Central Illustration has been printed below.

CENTRAL ILLUSTRATION Cardiovascular and Limb Outcomes in Diabetes and Peripheral Artery Disease: Kaplan-Meier Plot of Primary Efficacy Endpoint



These data are a composite of cardiovascular death, myocardial infarction, and ischemic stroke (full analysis set). C = diabetes group; CI = confidence interval; DM = diabetes mellitus; HR = hazard ratio; N = no diabetes group.

On page 3279, the second paragraph, left column, the third and fourth sentence read:

> By contrast, for every 1 mmol/mol difference in HbA_{1c} at baseline, there was a 1.2% increased risk for the primary composite endpoint (HR: 1.012; 95% CI: 1.008 to 1.017; $p < 0.0001$), and a 14.2% increase in risk for every percentage point difference in HbA_{1c} level at baseline (HR: 1.142; 95% CI: 1.088 to 1.198; $p < 0.0001$) (Table 3). Using diet-only as the reference, neither insulin treatment nor oral agent treatment was associated with a significant HR for the primary endpoint (adjusted HR: 1.19; 95% CI: 0.88 to 1.61; $p = 0.25$; HR: 0.99; 95% CI: 0.74 to 1.33; $p = 0.95$, respectively). There was no statistically significant association between HbA_{1c} and HR for major amputation (Online Table 2).

But should have read:

> By contrast, for every 1 mmol/mol increase in HbA_{1c} at baseline, there was a 1.2% increased risk for the primary composite endpoint (HR: 1.012; 95% CI: 1.008 to 1.017; $p < 0.0001$), and a 14.2% increase in risk for every percentage point increase in HbA_{1c} level at baseline (HR: 1.142; 95% CI: 1.088 to 1.198; $p < 0.0001$) (Table 3). Using diet-only as the reference, neither insulin treatment nor oral agent treatment was associated with a significant HR for the primary endpoint (adjusted HR: 1.20; 95% CI: 0.89 to 1.61; $p = 0.24$; HR: 0.99; 95% CI: 0.74 to 1.33; $p = 0.97$, respectively). There was no statistically significant association between HbA_{1c} and major amputation, but insulin treatment was associated with a HR of 3.56 (95% CI: 1.11 to 11.45) for major amputation (Online Table 2).

In Table 2, the values in the Adjusted HR (95% CI) and p values columns have been modified.

The revised Table 2 is printed below.

TABLE 2 Association Between History of Diabetes and Major Endpoints (in All Patients, but in Safety Population for Safety Endpoints)

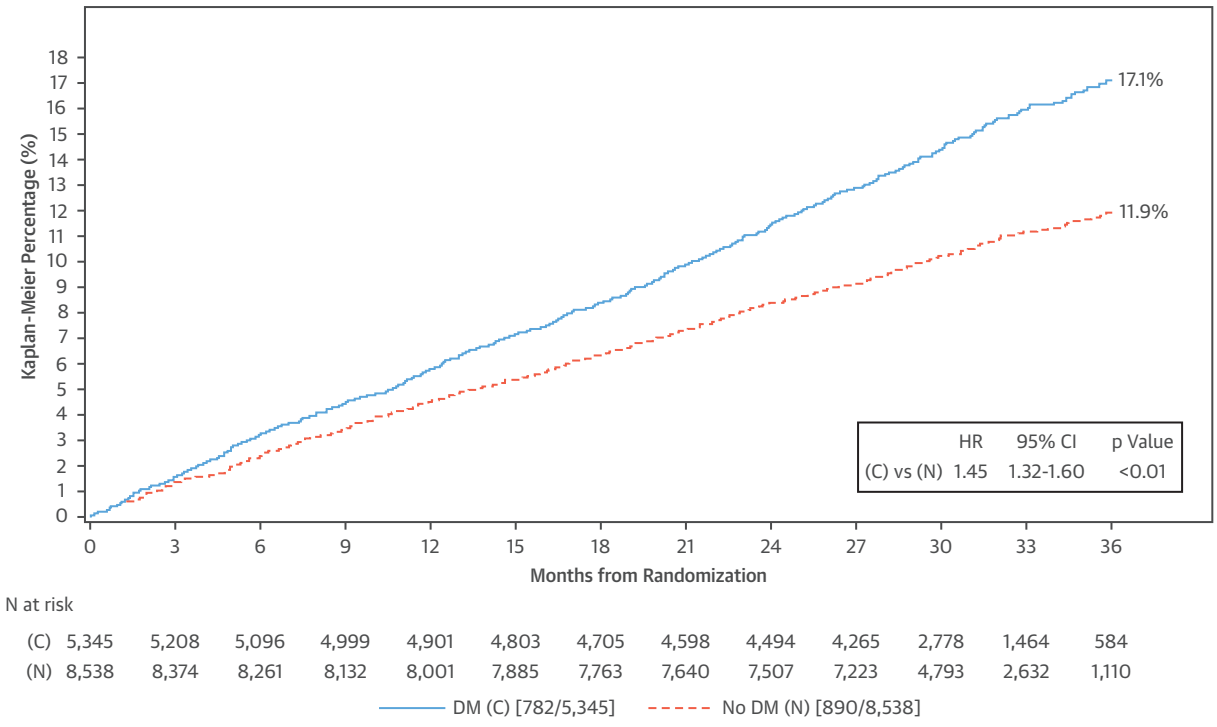
	100 Pt-Yrs Rate (95% CI)		Unadjusted		Adjusted*	
	DM	No DM	HR (95% CI)	p Value	HR (95% CI)	p Value
Primary endpoint	5.68 (5.28–6.11)	3.65 (3.40–3.92)	1.557 (1.406–1.723)	<0.0001	1.431 (1.276–1.605)	<0.0001
Secondary endpoint†	6.20 (5.78–6.65)	4.26 (3.99–4.55)	1.454 (1.321–1.601)	<0.0001	1.359 (1.219–1.516)	<0.0001
CV death	2.53 (2.27–2.81)	1.71 (1.54–1.89)	1.481 (1.277–1.716)	<0.0001	1.324 (1.124–1.560)	0.0008
MI	2.72 (2.45–3.02)	1.57 (1.41–1.75)	1.727 (1.486–2.006)	<0.0001	1.583 (1.344–1.865)	<0.0001
Ischemic stroke	1.10 (0.94–1.30)	0.73 (0.62–0.85)	1.512 (1.206–1.896)	0.0003	1.409 (1.101–1.802)	0.0064
CV death, MI, all-cause stroke	5.85 (5.44–6.28)	3.72 (3.47–3.99)	1.573 (1.422–1.739)	<0.0001	1.446 (1.291–1.620)	<0.0001
Major amputation	0.94 (0.78–1.12)	0.44 (0.36–0.54)	2.119 (1.619–2.773)	<0.0001	1.863 (1.372–2.531)	<0.0001
Lower extremity revascularization	5.92 (5.51–6.37)	5.07 (4.77–5.39)	1.164 (1.058–1.281)	0.0018	1.223 (1.105–1.355)	<0.0001
Carotid revascularization	2.85 (2.57–3.16)	1.93 (1.76–2.13)	1.473 (1.279–1.697)	<0.0001	1.393 (1.200–1.616)	<0.0001
All revascularization	8.80 (8.28–9.35)	7.32 (6.95–7.71)	1.198 (1.106–1.298)	<0.0001	1.213 (1.113–1.321)	<0.0001
All-cause death	4.21 (3.87–4.57)	3.19 (2.96–3.43)	1.320 (1.182–1.475)	<0.0001	1.219 (1.075–1.383)	0.0020
TIMI major bleed	0.81 (0.66–0.99)	0.70 (0.59–0.83)	1.147 (0.878–1.499)	0.3153	1.055 (0.794–1.403)	0.7108
Intracranial bleeding	0.33 (0.24–0.45)	0.17 (0.12–0.24)	1.970 (1.223–3.176)	0.0053	1.751 (1.056–2.905)	0.0299
Fatal bleeding	0.15 (0.09–0.24)	0.07 (0.04–0.12)	2.157 (1.048–4.442)	0.0369	1.648 (0.772–3.520)	0.1967
TIMI minor bleeding	0.57 (0.45–0.73)	0.47 (0.38–0.58)	1.212 (0.878–1.674)	0.2431	1.118 (0.788–1.584)	0.5321

*Each model was adjusted for a subset of the following baseline characteristics depending on the endpoint: female, inclusion criteria, region, number of vascular beds, Rutherford class at baseline, prior MI, statins, tobacco use, major amputation, minor amputation, age, estimated glomerular filtration rate, ABI, weight. The diabetes treatment and study treatment variables were included in every model. †Primary endpoint plus ALI.

ALI = acute limb ischemia; CI = confidence interval; CV = cardiovascular; DM = diabetes mellitus; HR = hazard ratio; MI = myocardial infarction; PT-Yrs = patient-years; TIMI = Thrombolysis In Myocardial Infarction.

In Figure 1, the following value in the No Diabetes Group read: 8,540 but should have been 8,538.
The revised Figure 1 has been printed below.

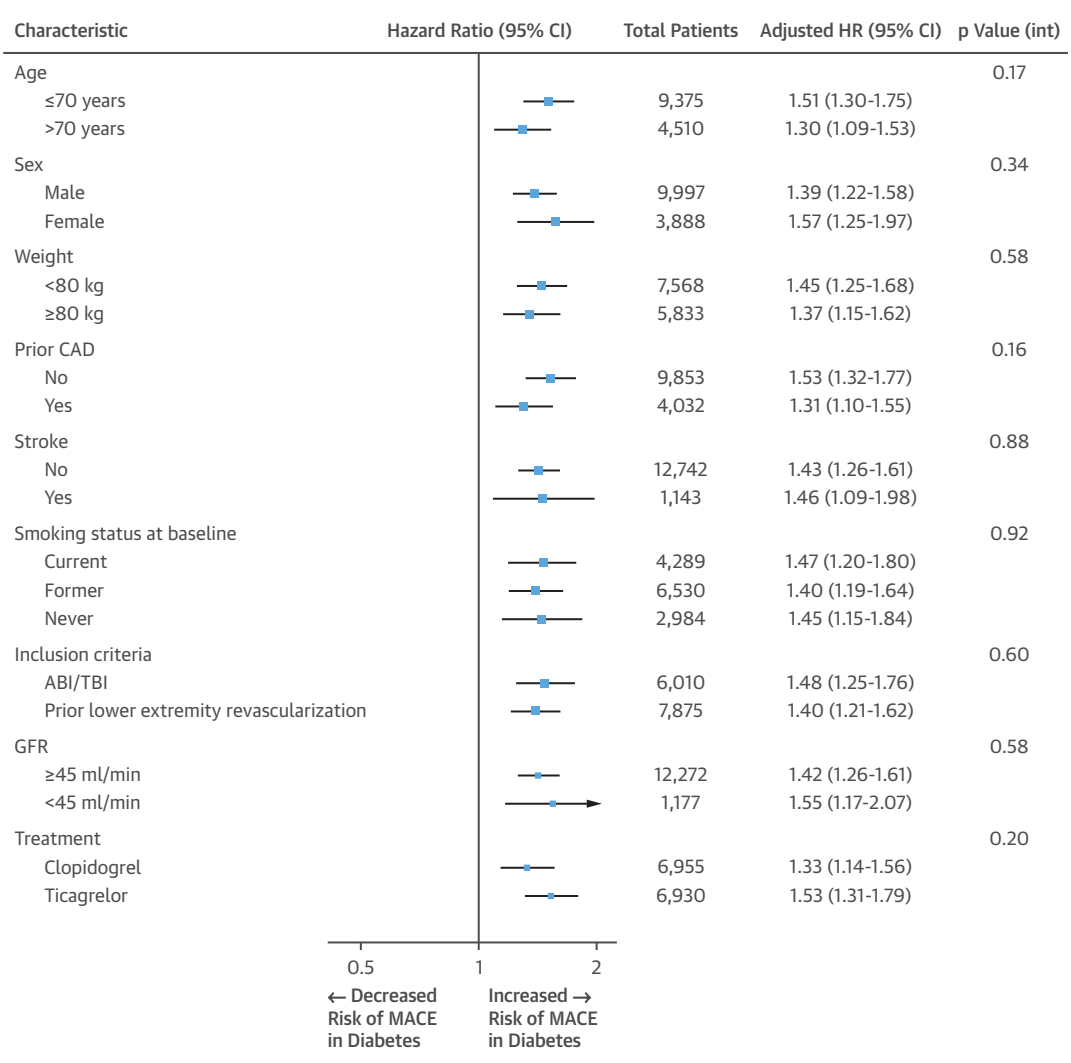
FIGURE 1 Kaplan-Meier Plot of Composite of CV Death, MI, Ischemic Stroke, and ALI (Full Analysis Set)



ALI = acute limb ischemia; C = diabetes group; CI = confidence interval; CV = cardiovascular; DM = diabetes mellitus; HR = hazard ratio; MI = myocardial infarct; N = no diabetes group.

In Figure 2, the values in the Adjusted HR (95% CI) and p Value columns have been modified. The revised figure 2 has been printed below.

FIGURE 2 Adjusted HRs for the Primary Composite Endpoint in Subgroups of Patients With PAD



The differential effects of diabetes are shown after testing for the presence of each factor. ABI = ankle-brachial index; CAD = coronary artery disease; GFR = glomerular filtration rate; MACE = major adverse cardiovascular event(s); PAD = peripheral artery disease; TBI = toe-brachial index; other abbreviations as in Figure 1.

In Table 3, the values in the Adjusted HR (95% CI) column for DM type, HbA1c (mmol/mol), and DM treatment have been modified and the p values for DM type and DM treatment have been modified. The revised Table 3 has been printed below.

TABLE 3 Effect of Diabetes-Specific Factors on Primary Endpoint After Adjusting for Other Covariates, Only in Patients With Diabetes

Factor of Interest	Comparison Level	Adjusted HR (95% CI)*	p Value
DM type*	Type I	0.789 (0.517–1.205)	0.2728
HbA_{1c}, mmol/mol†		1.012 (1.008–1.017)	<0.0001
HbA1c, %†		1.142 (1.088–1.198)	<0.0001
DM treatment	Overall	—	0.0905
	Insulin vs. diet-only	1.196 (0.887–1.613)	0.2406
	Oral agents vs. diet-only	0.994 (0.744–1.329)	0.9678

*Each model was adjusted for a subset of the following baseline characteristics: diabetes treatment, dm*groupvar (diabetes and treatment group [ticagrelor/clopidogrel] variables) female, inclusion criteria, region, number of vascular beds, Rutherford class at baseline, prior MI, statins, tobacco use, major amputation, minor amputation, age, estimated glomerular filtration rate, ABI, weight. †The HR refers to every 1 mmol/mol increment in HbA_{1c} or every 1% increment in HbA_{1c}, respectively.

Abbreviations as in Tables 1 and 2.

On page 3282, right column, first sentence in the second paragraph read:

> The risk of major amputation was almost doubled in patients with PAD and diabetes (adjusted HR: 1.96; 95% CI: 1.43 to 2.68; $p < 0.0001$).

But should have read:

> The risk of major amputation was almost doubled in patients with PAD and diabetes (adjusted HR: 1.86; 95% CI: 1.37 to 2.53; $p < 0.0001$).

On page 3282, right column, the first 2 sentences in the third paragraph read:

> Patients with diabetes had a HR of 1.03 for TIMI major bleeding, which was not statistically increased; the estimated HR for intracranial bleeding was 1.68, and fatal bleeding was 1.99 as compared with those without diabetes. Although these risks were not statistically increased due to their relative infrequency, the potential magnitude of the risk for intracranial bleeding (defined as the upper bound of the 95% CI) was up to 3-fold higher, and the risk for fatal bleeding was up to 4.3-fold higher.

But should have read:

> Patients with diabetes had a HR of 1.06 for TIMI major bleeding, which was not statistically significant; the estimated HR for intracranial bleeding was 1.75 ($p = 0.03$), and fatal bleeding was 1.65 as compared with those without diabetes. Although the risks of the latter were not statistically significant due to the relative infrequency, the potential magnitude of the risk for intracranial bleeding (defined as the upper bound of the 95% CI) was up to 2.9-fold higher, and the risk for fatal bleeding was up to 3.5-fold higher.

Please note that modifications have also been made to the Online Appendix of this article.

The authors apologize for these errors.

The online version of the article has been corrected to reflect these changes.

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