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Hypoglycemia, Cardiovascular Outcomes, and Death: the LEADER Experience

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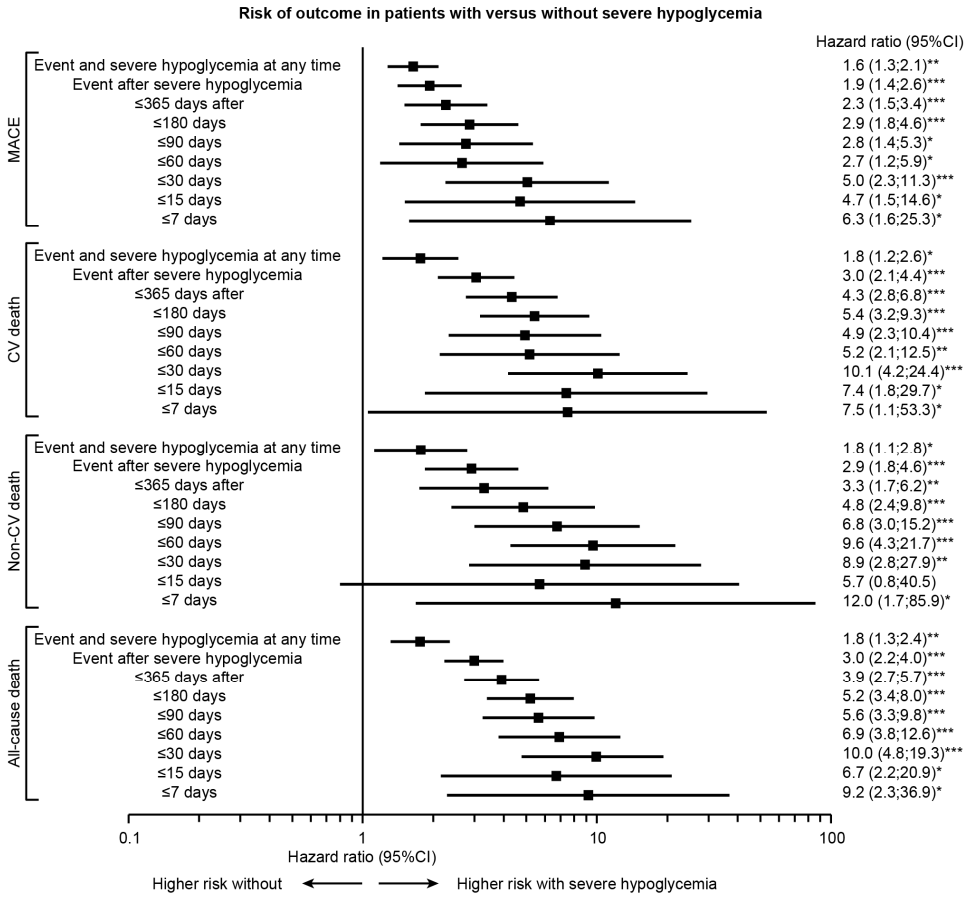

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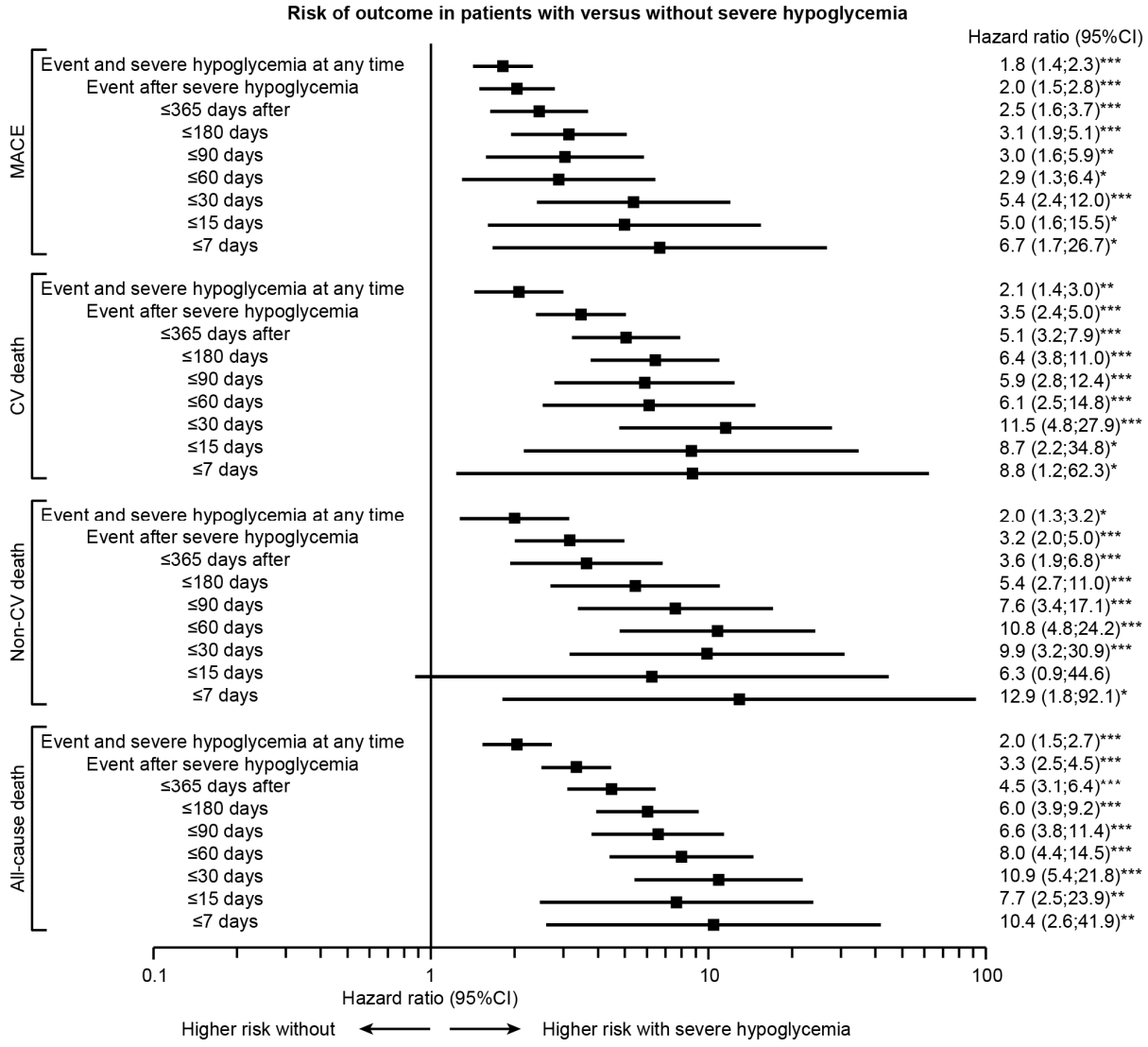

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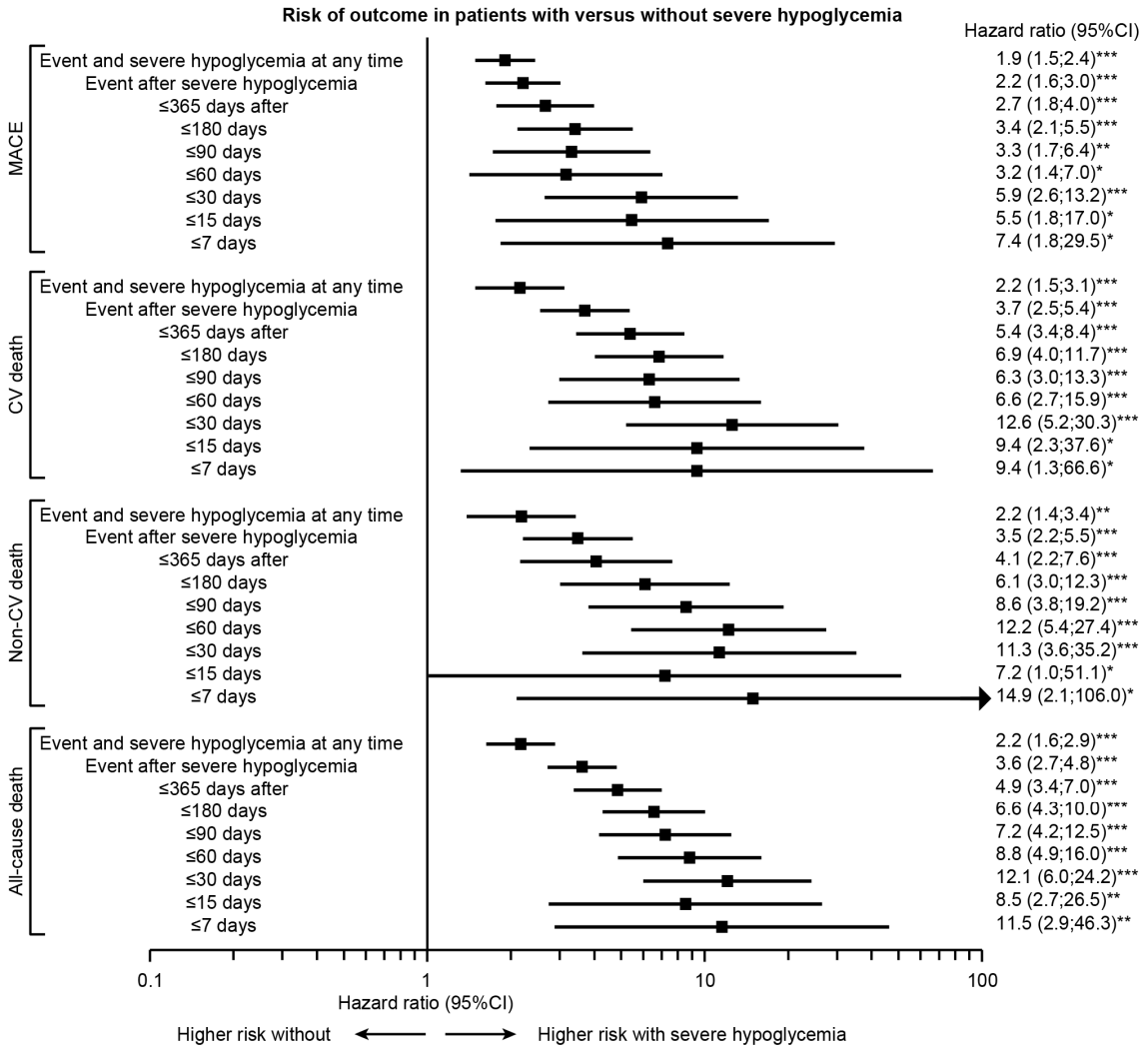

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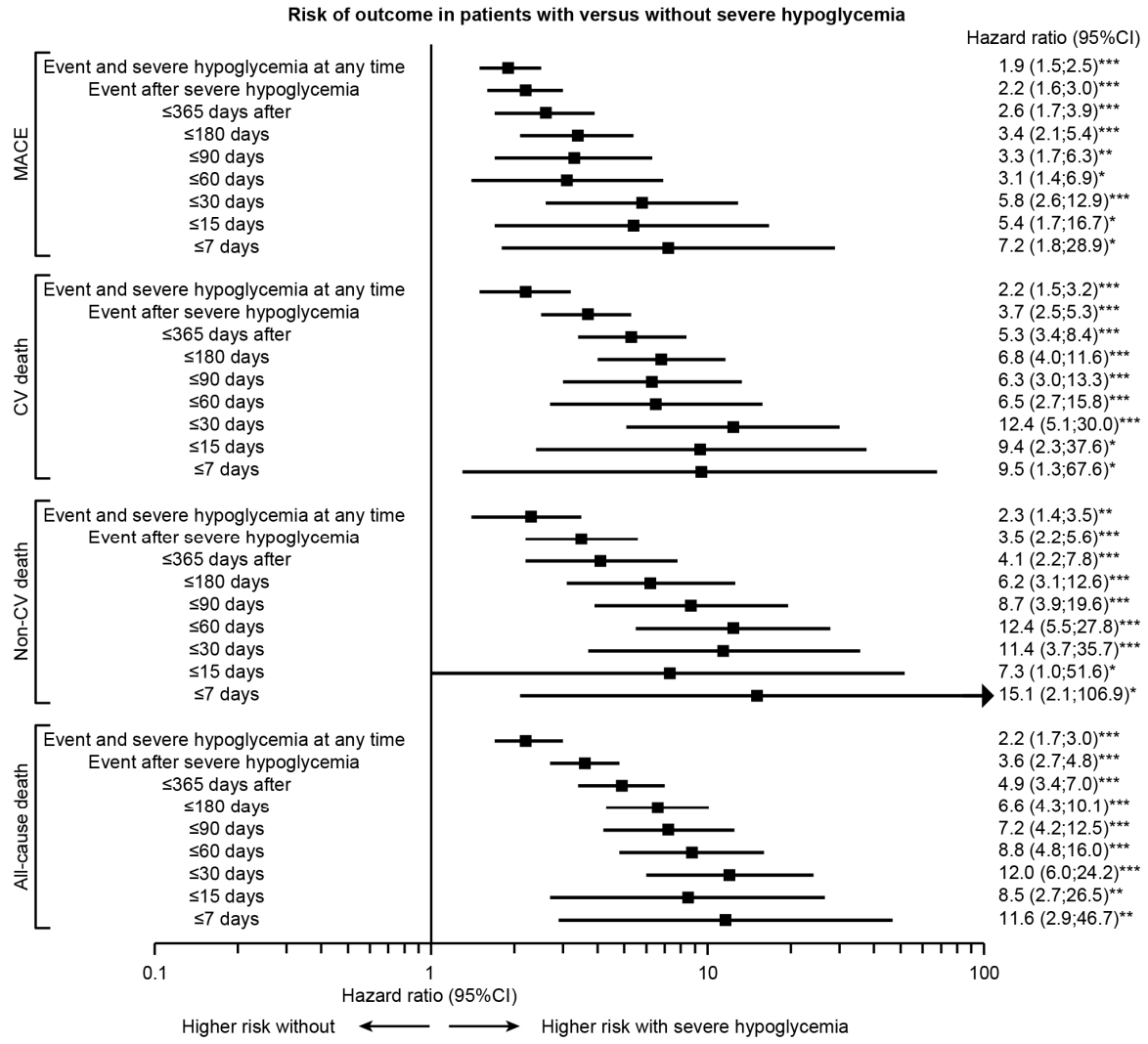

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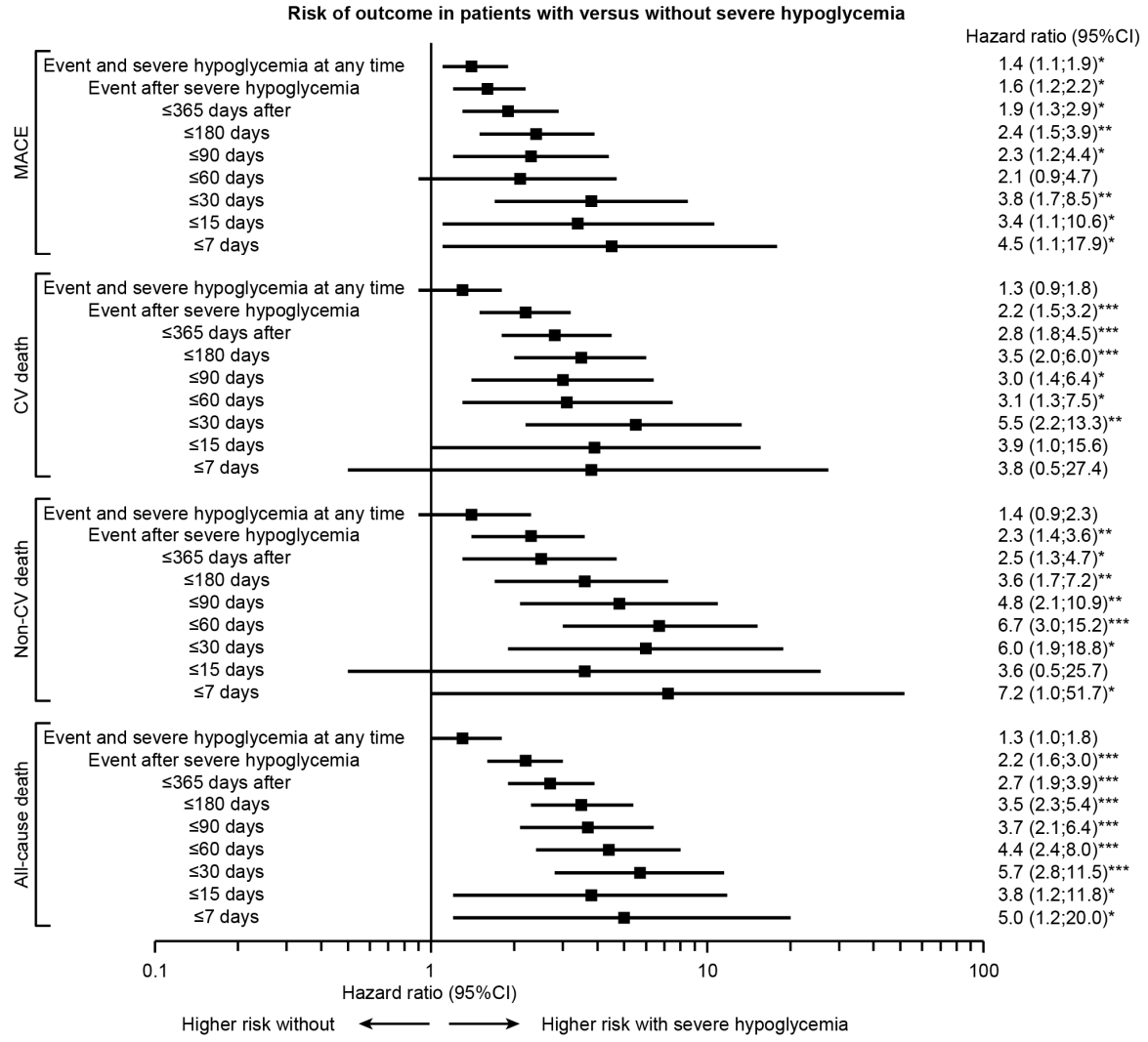

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*$P < 0.05$; **$P < 0.001$; ***$P < 0.0001$.

Risk of outcome with event and severe hypoglycemia at any time is based on analysis of time to first MACE, CV death, non-CV death, or all-cause death, using Cox regression with severe hypoglycemia (yes/no) at any time as a factor.

Risk of outcome with events after severe hypoglycemia based on severe hypoglycemic episodes prior to MACE, CV death, non-CV death, or all-cause death, using a time-dependent covariate Cox regression: all events (follow-up until last contact date), follow-up within 7, 15, 30, 60, 90, 180, and 365 days.

Adjusted for baseline covariates (glucose-lowering medication, sex, age, HbA_{1c}, diabetes duration), concomitant insulin use during the trial (insulin use as a time-dependent covariate), HbA_{1c} at the time of the hypoglycemic episode (absolute values and change from baseline, HbA_{1c} as a time-dependent covariate), concomitant sulfonylurea/glinide use during the trial (sulfonylurea/glinide use as a time-dependent covariate), eGFR at the time of the hypoglycemic episode (absolute values and change from baseline, eGFR as a time-dependent covariate) and event adjudication committee-confirmed hospitalization for heart failure during the trial (hospitalization for heart failure as a time-dependent covariate).

CI, confidence interval; CV, cardiovascular; MACE, major adverse cardiovascular event.

Supplementary Table S1. Hypoglycemia according to insulin use.

Insulin use during trial	Severe hypoglycemia			Confirmed hypoglycemia		
	***n* (%)**	**Episodes**	**Rate, episodes/100 PYO**	***n* (%)**	**Episodes**	**Rate, episodes/100 PYO**
No insulin use at baseline (*n* = 5171)	87 (1.7)	106	0.5	1848 (35.7)	9322	48.1
Insulin use at baseline (*n* = 4169)	180 (4.3)	327	2.1	2321 (55.7)	18611	122.2
Insulin initiated after baseline (*n* = 1998)	55 (2.8)	71	0.9	847 (42.4)	5051	66.7

%, proportion of patients within insulin use sub-group who experienced severe or confirmed hypoglycemia; *n*, number of patients who experienced at least one episode of severe or confirmed hypoglycemia; PYO, patient-year of observation.

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Supplementary Table S2. Hypoglycemia according to treatment group and glucose-lowering medication at baseline.

Glucose-lowering medication at baseline	Severe hypoglycemia						Confirmed hypoglycemia					
	Liraglutide (*n* = 4668)			Placebo (*n* = 4672)			Liraglutide (*n* = 4668)			Placebo (*n* = 4672)		
	n (%)	E	R	*n* (%)	E	R	*n* (%)	E	R	*n* (%)	E	R
Insulin	54 (4.3)	86	1.9	68 (5.1)	142	2.9	658 (51.7)	4873	105.9	770 (57.7)	6848	141.8
Insulin plus sulfonylurea/glinides	22 (2.9)	44	1.5	36 (4.5)	55	1.9	450 (58.8)	3043	107.0	443 (55.6)	3847	130.2
Sulfonylurea/glinides	27 (1.7)	37	0.6	34 (2.2)	40	0.7	679 (42.3)	3212	53.1	659 (42.1)	3884	66.2
Not on insulin or sulfonylurea/glinides	11 (1.1)	11	0.3	15 (1.5)	18	0.5	252 (24.6)	1049	27.3	258 (26.5)	1177	32.4

%, proportion of patients within treatment group using glucose-lowering medication who experienced hypoglycemia; E, episodes; *n*, number of patients who experienced at least one episode of severe or confirmed hypoglycemia; PYO, patient-year of observation; R, rate: episodes per 100 PYO.

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Supplementary Table S3. Association between severe hypoglycemia and cardiovascular events or death according to insulin use.

Outcome	Risk of outcome in patients with versus without severe hypoglycemia, hazard ratio (95% CI), *P*-value		
	No insulin use at baseline	**Insulin use at baseline**	**Insulin initiated after baseline**
MACE	2.2 (1.4;3.3); $P < 0.001$	1.7 (1.3;2.3); $P < 0.001$	1.6 (0.9;2.9); $P = 0.09$
CV death	3.2 (1.8;5.6); $P < 0.001$	1.7 (1.0;2.7); $P = 0.04$	5.4 (2.8;10.4); $P < 0.0001$
Non-CV death	1.5 (0.6; 4.1); $P = 0.40$	2.4 (1.4; 4.0); $P = 0.001$	2.3 (0.8; 6.2); $P = 0.11$
All-cause death	2.5 (1.5;4.1); $P < 0.001$	1.9 (1.4;2.8); $P < 0.001$	3.9 (2.2;6.7); $P < 0.0001$

Time to first MACE, CV death, non-CV death, or all-cause death, analyzed using Cox regression with severe hypoglycemia (yes/no) at any time as a factor.
CV, cardiovascular; MACE, major adverse cardiovascular event.

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Supplementary Table S4. Association between severe hypoglycemia and cardiovascular events or death according to sulfonyurea or glinide use.

Outcome	Risk of outcome in patients with versus without severe hypoglycemia, hazard ratio (95% CI), *P*-value		
	No SU/glinide use at baseline	**SU/glinide use at baseline**	**SU/glinide initiated after baseline**
MACE	2.0 (1.4;2.8); $P < 0.0001$	1.8 (1.3;2.6); $P = 0.001$	2.6 (1.1;5.9); $P = 0.02$
CV death	1.9 (1.1;3.3); $P = 0.02$	2.5 (1.5;4.2); $P = 0.0004$	3.6 (0.9;15.4); $P = 0.08$
Non-CV death	2.2 (1.2; 4.2); $P = 0.02$	2.4 (1.2; 4.5); $P = 0.009$	3.9 (0.9; 16.8); $P = 0.07$
All-cause death	2.0 (1.3;3.1); $P < 0.001$	2.4 (1.6;3.6); $P < 0.0001$	3.8 (1.4;10.5); $P = 0.01$

Time to first MACE, CV death, non-CV death, or all-cause death, analyzed using Cox regression with severe hypoglycemia (yes/no) at any time as a factor.
CV, cardiovascular; MACE, major adverse cardiovascular event; SU, sulfonylurea.

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Supplementary Table S5. Association between severe hypoglycemia and cardiovascular events or death according to insulin, sulfonyurea or glinide use.

Outcome	Risk of outcome in patients with versus without severe hypoglycemia, hazard ratio (95% CI), *P*-value		
	No insulin, or SU/glinide use at baseline	Insulin, or SU/glinide use at baseline	Insulin or SU/glinide initiated after baseline
MACE	1.4 (0.5;3.7); $P = 0.52$	1.9 (1.5;2.5); $P < 0.0001$	2.1 (1.3;3.3); $P = 0.003$
CV death	1.9 (0.5;7.9); $P = 0.36$	2.2 (1.5;3.2); $P < 0.0001$	5.2 (2.8;9.5); $P < 0.0001$
Non-CV death	1.4 (0.2;10.0); $P = 0.75$	2.3 (1.4;3.6); $P < 0.001$	3.0 (1.3;6.8); $P = 0.01$
All-cause death	1.7 (0.5;5.4); $P = 0.36$	2.2 (1.7;3.0); $P < 0.0001$	4.2 (2.6;6.8); $P < 0.0001$

Time to first MACE, CV death, non-CV death, or all-cause death, analyzed using Cox regression with severe hypoglycemia (yes/no) at any time as a factor.
CV, cardiovascular; MACE, major adverse cardiovascular event; SU, sulfonylurea.

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