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Supplementary appendix

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Impact of Primary Kidney Disease on the Effects of Empagliflozin in Patients with Chronic Kidney Disease: Secondary Analyses of the EMPA-KIDNEY trial

Supplementary Materials

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Supplementary Statistical Methods

Shared parameter models for analyses of estimated GFR over time

Mean annual rates of change in estimated glomerular filtration rate (GFR) from baseline to the final follow-up visit (“total slopes”), and from 2 months to the final follow-up visit (“chronic slopes”) by treatment allocation were estimated using shared parameter models¹ adjusted for age, sex, prior diabetes, urinary albumin-to-creatinine ratio (ACR), and region (all in the categories pre-specified for the minimization process). Models estimating chronic slope were additionally adjusted for baseline estimated GFR (as a continuous variable) and the interaction between baseline estimated GFR and follow-up time. This approach jointly models: (a) the annual rate of change in estimated GFR using a linear mixed model (with random effects for each patient’s slope and intercept); and (b) the time to event for end-stage kidney disease (ESKD) or death (using a Weibull survival model in which the scale parameter is assumed to be linearly related to the random effects from the linear mixed model).

Specifically, the linear mixed model component is

$$Y_{ij} = (\beta_0 + u_{0i}) + \beta_1 X_i + (\beta_2 + u_{1i})t_{ij} + \beta_3 X_i t_{ij} + e_{ij}$$

and the Weibull model for time to ESKD or death has hazard function

$$h(t_{ij}) = \gamma \exp(\varphi + \eta_0 u_{0i} + \eta_1 u_{1i} + \alpha X_i)^\gamma t_{ij}^{\gamma-1}$$

where t_{ij} is the time (in years) of visit j for patient i , Y_{ij} is the observed value of estimated GFR at visit j for patient i , X_i is the treatment allocation for patient i , β_0 is the mean estimated GFR at baseline in the placebo arm, β_1 is the mean difference in baseline estimated GFR between treatment allocations, β_2 is the mean estimated GFR slope in the placebo arm, and β_3 is the mean difference in estimated GFR slopes between treatment allocations. u_{1i} and u_{0i} are the random effects for each patient’s slope and intercept respectively, which are assumed to be independent multivariate normal random vectors with mean 0 and an unstructured covariance matrix. e_{ij} is the random error at time t_{ij} , which are assumed to be independent and normally distributed with mean zero and constant variance.

Analyses used all available central laboratory estimated GFR measurements prior to the development of ESKD. The advantage of the above modelling approach (over a standard linear mixed model) is that it additionally allows for the dependence between the annual rate of change in estimated GFR and the time to ESKD or death (which is important because those with faster rates of change in estimated GFR will generally have a shorter time to ESKD or death). The mean slopes provided by the shared parameter model (total or chronic) may be thought of as the average of the patient-specific slopes, conditional on the baseline covariates in the model, and in the hypothetical scenario where estimated GFR had continued to be measured beyond the time of ESKD or death. As with other methods, the estimates they provide merely reflect averages over the follow-up period of interest (and hence, in the context of a drug which has an initial acute effect, the “total slope” requires careful interpretation).

Mixed model for repeated measures (MMRM)

Linear mixed models for repeated measures (MMRM) analyses were used to estimate effects of empagliflozin on study-average urinary ACR and blood pressure. These models were adjusted for baseline measurements (as a continuous variable), age, sex, prior diabetes, estimated GFR, urinary ACR (for analyses of blood pressure only) and region (all in the same categories pre-specified for the minimization process), treatment allocation, follow-up time point and the interaction between baseline measurement and follow-up time point. A further interaction term between treatment allocation and follow-up time point was then included in order to enable separate estimation of means at each follow-up time point for each treatment arm, conditional on the other factors in the model. No violations of the assumptions underlying the MMRM were identified. The within-person error correlations were assumed to be unstructured. These models assume that any missing values can be predicted by the non-missing data for other individuals together with the other covariates in the model (i.e. that they are ‘missing at random’).

A weighted average of these baseline-adjusted mean follow-up values is then used (with weights proportional to the amount of time between visits) to calculate the study average mean in each treatment arm along with the differences in these study average means. For urinary ACR, log-transformed values are used in the model which are then back transformed to give geometric means of study average urinary ACR along with the relative differences in the geometric means.

References

¹ Vonesh EF, Greene T, Schluchter MD. Shared parameter models for the joint analysis of longitudinal data and event times. *Statistics in Medicine* 2006; **25**(1): 143-63.

SUPPLEMENTARY TABLES

Supplementary Table 1: Primary kidney disease listing

Term	Primary kidney diagnosis		Kidney biopsy	
		N		n (%)
Diabetic kidney disease		2057		136 (6.6)
Diabetic nephropathy in type 2 diabetes		1999		133 (6.7)
Diabetic nephropathy in type 1 diabetes		58		3 (5.2)
Glomerular disease		1669		1312 (78.6)
IgA nephropathy		800		769 (96.1)
Glomerulonephritis		322		99 (30.7)
Focal segmental glomerulosclerosis		159		148 (93.1)
Glomerulonephritis membranous		96		92 (95.8)
Glomerulonephritis - histologically indeterminate		61		14 (23.0)
Focal segmental glomerulosclerosis (FSGS) secondary to obesity		36		28 (77.8)
Focal and segmental proliferative glomerulonephritis		31		25 (80.6)
Lupus nephritis		27		25 (92.6)
Glomerulonephritis proliferative		19		16 (84.2)
Granulomatosis with polyangiitis		17		15 (88.2)
Henoch-Schonlein purpura nephritis (included in the IgA nephropathy group)		17		13 (76.5)
Glomerulonephritis minimal lesion		14		13 (92.9)
Microscopic polyangiitis		14		13 (92.9)
Glomerulonephritis membranoproliferative		13		13 (100.0)
Glomerulonephritis - secondary to other systemic disease		12		8 (66.7)
Other glomerular disease term*		31		21 (67.7)
Hypertensive/renovascular disease		1445		184 (12.7)
Chronic hypertensive nephropathy		1233		157 (12.7)
Ischaemic nephropathy		113		12 (10.6)
Malignant renal hypertension		50		12 (24.0)
Renal artery stenosis		33		2 (6.1)
Other hypertensive/renovascular disease term*		16		1 (6.3)
Other/Unknown		1438		230 (16.0)
Chronic kidney disease/aetiology unknown		629		70 (11.1)
Drug-induced nephropathy		140		22 (15.7)
Tubulointerstitial nephritis		66		30 (45.5)
Cardiorenal syndrome		60		4 (6.7)
Obstructive nephropathy		57		2 (3.5)
Single functional kidney		48		5 (10.4)
Ageing kidney - no histology		44		1 (2.3)
Primary reflux nephropathy – sporadic		44		1 (2.3)
Chronic kidney disease caused by tumour nephrectomy		43		12 (27.9)
Glomerulocystic disease		33		12 (36.4)
Renal stones/calculus nephropathy		26		2 (7.7)
Urate nephropathy		26		0 (0.0)
Alport's syndrome		23		19 (82.6)
Other specific infection		19		5 (26.3)
Familial nephropathy		17		4 (23.5)
Congenital dysplasia/hypoplasia		16		2 (12.5)
Thin basement membrane disease		12		11 (91.7)
Chronic kidney disease due to traumatic loss of kidney		11		2 (18.2)
Other term*		124		26 (21.0)
TOTAL		6609		1862 (28.2)

*Terms used for <10 participants are grouped in the final row of each section as "other term". Participant-reported primary kidney disease was confirmed by local lead investigators (without further independent adjudication) and all participants were asked if they had had a kidney biopsy. No other data were collected.

Supplementary Table 2: Other characteristics of participants at recruitment by primary kidney disease

	Diabetic kidney disease (N= 2057)	Hypertensive/ renovascular disease (N= 1445)	Glomerular disease (N= 1669)	Other/unknown (N= 1438)
DEMOGRAPHICS				
Age at randomisation (years)				
Mean (SD)	68.2 (9.8)	68.4 (11.9)	53.5 (13.6)	65.0 (14.7)
<60	392 (19.1)	297 (20.6)	1112 (66.6)	451 (31.4)
≥60 <70	668 (32.5)	393 (27.2)	340 (20.4)	319 (22.2)
≥70	997 (48.5)	755 (52.2)	217 (13.0)	668 (46.5)
Region				
Europe (UK, Germany, Italy)	558 (27.1)	634 (43.9)	681 (40.8)	775 (53.9)
North America (USA, Canada)	788 (38.3)	448 (31.0)	156 (9.3)	325 (22.6)
China and Malaysia	508 (24.7)	277 (19.2)	637 (38.2)	210 (14.6)
Japan	203 (9.9)	86 (6.0)	195 (11.7)	128 (8.9)
History of heart failure				
Yes	265 (12.9)	178 (12.3)	44 (2.6)	171 (11.9)
No or missing	1792 (87.1)	1267 (87.7)	1625 (97.4)	1267 (88.1)
History of peripheral arterial disease				
Yes	216 (10.5)	149 (10.3)	26 (1.6)	79 (5.5)
No	1841 (89.5)	1296 (89.7)	1643 (98.4)	1359 (94.5)
CLINICAL MEASUREMENTS				
Systolic blood pressure, (mmHg)				
Mean (SD)	139.9 (19.2)	138.0 (18.4)	132.8 (16.0)	134.6 (18.3)
<130	638 (31.0)	472 (32.7)	716 (42.9)	572 (39.8)
≥130 <145	622 (30.2)	484 (33.5)	597 (35.8)	486 (33.8)
≥145	797 (38.7)	489 (33.8)	356 (21.3)	380 (26.4)
Diastolic blood pressure, (mmHg)				
Mean (SD)	75.2 (11.6)	78.0 (12.2)	82.0 (10.8)	77.7 (11.7)
<75	1014 (49.3)	578 (40.0)	403 (24.1)	585 (40.7)
≥75 <85	584 (28.4)	452 (31.3)	578 (34.6)	438 (30.5)
≥85	459 (22.3)	415 (28.7)	688 (41.2)	415 (28.9)
Body mass index (kg/m²)				
Mean (SD)	31.7 (7.1)	30.0 (6.3)	27.2 (5.8)	29.6 (6.7)
<25	333 (16.2)	275 (19.0)	658 (39.4)	353 (24.5)
≥25 <30	623 (30.3)	561 (38.8)	587 (35.2)	526 (36.6)
≥30	1093 (53.1)	607 (42.0)	423 (25.3)	554 (38.5)
Missing	8 (0.4)	2 (0.1)	1 (0.1)	5 (0.3)
LABORATORY MEASUREMENTS				
Glycated haemoglobin (mmol/mol)				
Mean (SD)	56.6 (15.0)	41.1 (8.9)	37.2 (6.6)	41.4 (10.4)
<39	124 (6.0)	664 (46.0)	1177 (70.5)	717 (49.9)
≥39 <48	473 (23.0)	515 (35.6)	396 (23.7)	453 (31.5)
≥48 <75	1207 (58.7)	214 (14.8)	81 (4.9)	222 (15.4)
≥75	215 (10.5)	15 (1.0)	2 (0.1)	20 (1.4)
Missing	38 (1.8)	37 (2.6)	13 (0.8)	26 (1.8)
NT-proBNP (ng/L)				
Geometric mean (SD)	234 (4.0)	221 (4.1)	86 (3.6)	182 (3.9)
Median (Q1-Q3)	220 (94-566)	207 (93-526)	88 (37-181)	175 (75-437)
<110	610 (29.7)	426 (29.5)	964 (57.8)	510 (35.5)
≥110 <330	660 (32.1)	476 (32.9)	462 (27.7)	463 (32.2)
≥300	771 (37.5)	527 (36.5)	231 (13.8)	447 (31.1)
Missing	16 (0.8)	16 (1.1)	12 (0.7)	18 (1.3)
Haematocrit (%)				
Mean (SD)	37.9 (5.1)	39.5 (5.0)	39.7 (5.1)	39.5 (5.0)
<37%	695 (33.8)	360 (24.9)	418 (25.0)	345 (24.0)
≥37 <41%	598 (29.1)	404 (28.0)	476 (28.5)	413 (28.7)
≥41%	497 (24.2)	540 (37.4)	687 (41.2)	527 (36.6)

Missing	267 (13·0)	141 (9·8)	88 (5·3)	153 (10·6)
KDIGO risk category				
Low, moderate or high	444 (21·6)	424 (29·3)	386 (23·1)	418 (29·1)
Very high	1613 (78·4)	1021 (70·7)	1283 (76·9)	1020 (70·9)
CONCOMITANT MEDICATION USE				
Any diuretic	1109 (53·9)	720 (49·8)	430 (25·8)	556 (38·7)
Loop diuretic	738 (35·9)	431 (29·8)	225 (13·5)	353 (24·5)
Thiazide diuretic	445 (21·6)	304 (21·0)	173 (10·4)	200 (13·9)
Mineralocorticoid receptor antagonist	147 (7·1)	128 (8·9)	84 (5·0)	116 (8·1)
Potassium sparing & other	13 (0·6)	10 (0·7)	6 (0·4)	9 (0·6)
Beta blocker	1053 (51·2)	765 (52·9)	399 (23·9)	544 (37·8)
Anticoagulant	103 (5·0)	89 (6·2)	42 (2·5)	82 (5·7)
Antiplatelet therapy	988 (48·0)	586 (40·6)	249 (14·9)	416 (28·9)
Diabetes treatment	1927 (93·7)	316 (21·9)	124 (7·4)	328 (22·8)
Biguanide (e.g. metformin)	460 (22·4)	84 (5·8)	35 (2·1)	90 (6·3)
Sulphonylurea	433 (21·1)	66 (4·6)	28 (1·7)	58 (4·0)
Insulin	1320 (64·2)	141 (9·8)	37 (2·2)	165 (11·5)
DPP-4 inhibitor	586 (28·5)	112 (7·8)	51 (3·1)	133 (9·2)
GLP-1 agonist	255 (12·4)	34 (2·4)	8 (0·5)	40 (2·8)
Other antidiabetic agent	220 (10·7)	31 (2·1)	27 (1·6)	36 (2·5)

Figures are n (%) or mean (SD) or median (Q1-Q3). Abbreviations: NT-proBNP=N-terminal pro B-type natriuretic peptide; DPP-4=dipeptidyl peptidase-4; GLP-1=glucagon-like peptide-1. Those with missing data for KDIGO risk (n=) not presented in relevant rows. Minor differences between the baseline characteristics presented here and the previously published baseline paper in *Nephrol Dial Transplant.* 2022 Jun 23;37(7):1317-1329. doi: 10.1093/ndt/gfac040 are due to data error corrections applied to the final analysis dataset.

Supplementary Table 3: Characteristics of participants at recruitment by glomerular disease

	IgA Nephropathy[§] (N=817)	Focal Segmental Glomerulosclerosis (N=195)	Other Glomerulonephritis (N=657)
DEMOGRAPHICS			
Age at randomisation (years)	50.6 (12.7)	54.3 (14.5)	56.9 (13.7)
Mean (SD)			
Sex			
Female	282 (34.5)	67 (34.4)	247 (37.6)
Race (all regions)			
White	361 (44.2)	123 (63.1)	281 (42.8)
Black	1 (0.1)	10 (5.1)	11 (1.7)
Asian	442 (54.1)	59 (30.3)	362 (55.1)
Mixed	4 (0.5)	1 (0.5)	0 (0.0)
Other	9 (1.1)	2 (1.0)	3 (0.5)
PRIOR DISEASE			
Prior diabetes			
Yes	59 (7.2)	34 (17.4)	79 (12.0)
No	758 (92.8)	161 (82.6)	578 (88.0)
Prior diabetes type			
Type 1	0 (0.0)	0 (0.0)	0 (0.0)
Type 2	58 (7.1)	33 (16.9)	77 (11.7)
Other/unknown	1 (0.1)	1 (0.5)	2 (0.3)
History of cardiovascular disease*			
Yes	48 (5.9)	24 (12.3)	72 (11.0)
No	769 (94.1)	171 (87.7)	585 (89.0)
CLINICAL MEASUREMENTS			
Blood pressure (mmHg)			
Mean systolic (SD)	131.8 (15.1)	131.9 (15.9)	134.3 (16.9)
Mean diastolic (SD)	82.5 (10.4)	79.8 (10.2)	82.0 (11.4)
Body mass index (kg/m²)			
Mean (SD)	26.8 (5.5)	30.3 (6.9)	26.7 (5.6)
LABORATORY MEASUREMENTS			
Estimated GFR (mL/min/1.73m²)[†]			
Mean (SD)	43.3 (17.5)	40.9 (17.5)	41.9 (18.4)
<30	195 (23.9)	63 (32.3)	194 (29.5)
≥30 <45	317 (38.8)	66 (33.8)	253 (38.5)
≥45	305 (37.3)	66 (33.8)	210 (32.0)
Urinary albumin-to-creatinine ratio (mg/g)[†]			
Geometric mean (SD)	590 (3.1)	723 (3.7)	524 (4.7)
Median (Q1-Q3)	662 (331-1265)	902 (426-1997)	693 (264-1509)
<30	20 (2.4)	5 (2.6)	41 (6.2)
≥30 ≤300	165 (20.2)	34 (17.4)	145 (22.1)
>300	632 (77.4)	156 (80.0)	471 (71.7)
CONCOMITANT MEDICATION USE			
RAS inhibitor	770 (94.2)	179 (91.8)	586 (89.2)
Immunosuppression	53 (6.5)	10 (5.1)	76 (11.6)
Kidney Biopsy	782 (95.7)	176 (90.3)	354 (53.9)

Figures are n (%) or mean (SD) or median (Q1-Q3). * Defined as self-reported history of myocardial infarction, heart failure, stroke, transient ischaemic attack, or peripheral arterial disease. † Uses central measurement taken at the randomisation visit, or more recent local laboratory result before randomisation. Prior diabetes defined as: participant-reported history of diabetes of any type, use of glucose-lowering medication or baseline HbA1c ≥48 mmol/mol at randomisation visit. § The IgA nephropathy grouping includes IgA nephropathy plus Henoch-Schonlein purpura nephritis. Abbreviations: GFR = glomerular filtration rate; ACR = albumin-to-creatinine ratio; RAS = renin-angiotensin system.

Supplementary Table 4: Key secondary and tertiary outcomes by primary kidney disease

	Empagliflozin		Placebo		Hazard Ratio (95% CI)	P _{het}
	N (%)	Rate	N (%)	Rate		
KEY SECONDARY OUTCOMES						
Hospitalisation for heart failure or death from cardiovascular causes						1.00
Diabetic kidney disease	69 (6.7)	3.40	80 (7.8)	3.98	0.83 (0.60-1.15)	
Hypertensive/ renovascular disease	30 (4.2)	2.15	35 (4.7)	2.49	0.85 (0.52-1.38)	
Glomerular disease	6 (0.7)	0.37	7 (0.9)	0.45	0.82 (0.28-2.44)	
Other/unknown	26 (3.6)	1.87	30 (4.1)	2.08	0.89 (0.52-1.50)	
Overall	131 (4.0)	2.04	152 (4.6)	2.37	0.84 (0.67-1.07)	
Hospitalisation for any cause*						
Diabetic kidney disease		30.04		35.30	0.84 (0.71-1.00)	0.23
Hypertensive/ renovascular disease		27.04		29.59	0.88 (0.72-1.09)	
Glomerular disease		14.78		20.59	0.72 (0.58-0.90)	
Other/unknown		26.39		29.46	0.99 (0.80-1.22)	
Overall		24.80		29.20	0.86 (0.78-0.95)	
Death from any cause						0.29
Diabetic kidney disease	71 (6.9)	3.43	88 (8.6)	4.29	0.78 (0.57-1.07)	
Hypertensive/ renovascular disease	30 (4.2)	2.13	33 (4.5)	2.31	0.88 (0.54-1.44)	
Glomerular disease	5 (0.6)	0.31	10 (1.2)	0.65	0.48 (0.16-1.40)	
Other/unknown	42 (5.9)	3.00	36 (5.0)	2.46	1.21 (0.77-1.89)	
Overall	148 (4.5)	2.28	167 (5.1)	2.58	0.87 (0.70-1.08)	
OTHER TERTIARY OUTCOME						
Major cardiovascular event[†]						0.73
Diabetic kidney disease	93 (9.0)	4.63	106 (10.3)	5.34	0.85 (0.64-1.12)	
Hypertensive/ renovascular disease	50 (7.1)	3.65	46 (6.2)	3.30	1.10 (0.73-1.64)	
Glomerular disease	17 (2.0)	1.06	15 (1.8)	0.98	1.10 (0.55-2.20)	
Other/unknown	40 (5.6)	2.91	46 (6.3)	3.21	0.90 (0.59-1.37)	
Overall	200 (6.1)	3.15	213 (6.4)	3.36	0.93 (0.76-1.12)	

A Cox proportional-hazards regression model with adjustment for baseline variables specified in the minimisation algorithm (age, sex, diabetes, estimated GFR, urinary albumin-to-creatinine ratio, and region) was used to estimate the hazard ratio and 95% CIs for empagliflozin as compared with placebo for time-to-event analyses.

* A semiparametric joint frailty model was used for the analysis of the outcome of the first and subsequent hospitalizations for any cause, so only the rates are shown; 1346 hospitalisations occurred among 772 participants with diabetic kidney disease, 803 hospitalisations occurred among 433 participants with hypertensive/renovascular disease, 557 hospitalisations occurred among 340 participants with glomerular disease and 800 hospitalisations occurred among 450 participants with other/unknown causes of kidney disease.

† The pre-specified major cardiovascular event outcome was defined as the composite of cardiovascular death, myocardial infarction, stroke or hospitalisation for heart failure.

Supplementary Table 5: Urinary albumin-to-creatinine ratio and blood pressure assessments by glomerular disease

	IgA Nephropathy (N=817)	Focal Segmental Glomerulosclerosis (N=195)	Other Glomerulonephritis (N=657)	
URINARY ALBUMIN-TO-CREATININE RATIO (uACR), mg/g				P_{het}
Proportional reduction in study average uACR compared to placebo	-24% (-33%, -13%)	-23% (-42%, 2%)	-2% (-17%, 15%)	0·06
BLOOD PRESSURE, mmHg				
Study average change in systolic blood pressure compared to placebo	-2·8 (-4·7, -0·9)	-2·1 (-5·6, 1·5)	-1·9 (-3·9, 0·1)	0·81
Study average change in diastolic blood pressure compared to placebo	-1·1 (-2·4, 0·1)	0·0 (-2·2, 2·3)	0·5 (-0·8, 1·8)	0·20
<p>Data are study-average differences (95% CI) estimated using a pre-specified adjusted MMRM approach (see supplementary statistical methods). Analysis of effects on urinary albumin-to-creatinine ratio uses central laboratory measurements at follow-up time points 2, 18, 24 and 30 months. Analysis of effects on blood pressure uses measurements obtained at follow-up time points: 2, 6, 12, 18, 24, 30 and 36 months. Analyses required participants to have at least one follow-up measurement of the outcome variable and excluded participants with missing baseline measurements (urinary albumin-to-creatinine ratio 203/6609 [3%]; no missing baseline blood pressure measurements for analysed participants).</p>				

Supplementary Table 6: Safety outcomes by primary kidney diagnosis

	Empagliflozin		Placebo		Hazard Ratio (95% CI)	P _{het}
	N (%)	Rate	N (%)	Rate		
Serious urinary tract infection						0.92
Diabetic kidney disease	23 (2.2)	1.12	20 (2.0)	0.98		
Hypertensive/ renovascular disease	9 (1.3)	0.64	11 (1.5)	0.78		
Glomerular disease	7 (0.8)	0.44	8 (1.0)	0.52		
Other/unknown	13 (1.8)	0.94	15 (2.1)	1.03		
Overall	52 (1.6)	0.81	54 (1.6)	0.84	0.94 (0.64-1.37)	
Serious genital infection						
Diabetic kidney disease	0 (0.0)	0.00	1 (0.1)	0.05		
Hypertensive/ renovascular disease	1 (0.1)	0.07	0 (0.0)	0.00		
Glomerular disease	0 (0.0)	0.00	0 (0.0)	0.00		
Other/unknown	0 (0.0)	0.00	0 (0.0)	0.00		
Overall	1 (<0.1)	0.02	1 (<0.1)	0.02		
Serious hyperkalemia						0.90
Diabetic kidney disease	30 (2.9)	1.48	38 (3.7)	1.89		
Hypertensive/ renovascular disease	24 (3.4)	1.74	25 (3.4)	1.80		
Glomerular disease	15 (1.8)	0.94	20 (2.5)	1.32		
Other/unknown	23 (3.2)	1.67	26 (3.6)	1.81		
Overall	92 (2.8)	1.44	109 (3.3)	1.72	0.83 (0.63-1.09)	
Serious acute kidney injury						0.28
Diabetic kidney disease	49 (4.7)	2.42	61 (6.0)	3.03		
Hypertensive/ renovascular disease	17 (2.4)	1.22	28 (3.8)	2.00		
Glomerular disease	12 (1.4)	0.75	20 (2.5)	1.31		
Other/unknown	29 (4.1)	2.11	26 (3.6)	1.80		
Overall	107 (3.2)	1.67	135 (4.1)	2.11	0.78 (0.60-1.00)	
Serious dehydration						
Diabetic kidney disease	16 (1.6)	0.78	8 (0.8)	0.39		
Hypertensive/ renovascular disease	2 (0.3)	0.14	6 (0.8)	0.42		
Glomerular disease	1 (0.1)	0.06	4 (0.5)	0.26		
Other/unknown	11 (1.5)	0.79	6 (0.8)	0.41		
Overall	30 (0.9)	0.46	24 (0.7)	0.37	1.25 (0.73-2.14)	
Liver injury						
Diabetic kidney disease	7 (0.7)	0.34	5 (0.5)	0.24		
Hypertensive/ renovascular disease	1 (0.1)	0.07	0 (0.0)	0.00		
Glomerular disease	2 (0.2)	0.12	4 (0.5)	0.26		
Other/unknown	3 (0.4)	0.21	3 (0.4)	0.21		
Overall	13 (0.4)	0.20	12 (0.4)	0.19	1.09 (0.50-2.38)	

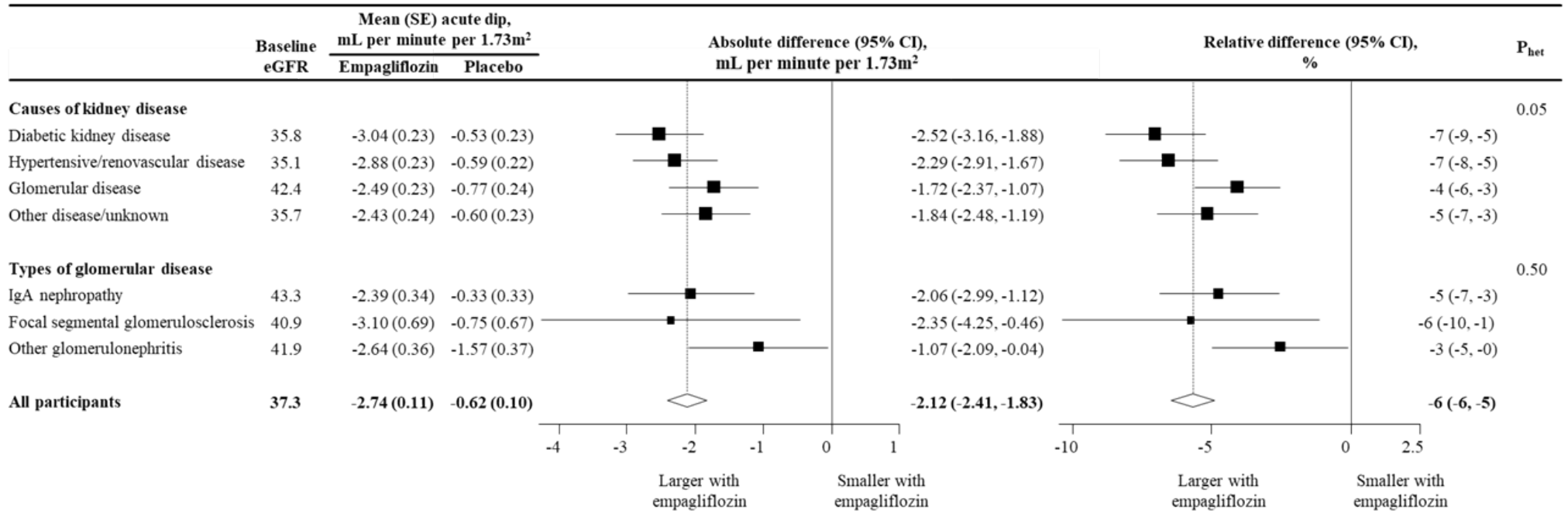
Supplementary Table 6: Safety outcomes by primary kidney diagnosis (continued)

	Empagliflozin		Placebo		Hazard Ratio (95% CI)	P _{het}
	N (%)	Rate	N (%)	Rate		
Ketoacidosis						
Diabetic kidney disease	5 (0·5)	0·24	1 (0·1)	0·05		
Hypertensive/ renovascular disease	0 (0·0)	0·00	0 (0·0)	0·00		
Glomerular disease	0 (0·0)	0·00	0 (0·0)	0·00		
Other/unknown	1 (0·1)	0·07	0 (0·0)	0·00		
Overall	6 (0·2)	0·09	1 (<0·1)	0·02	-	
Lower limb amputation						
Diabetic kidney disease	21 (2·0)	1·03	13 (1·3)	0·64		
Hypertensive/ renovascular disease	3 (0·4)	0·21	2 (0·3)	0·14		
Glomerular disease	1 (0·1)	0·06	1 (0·1)	0·06		
Other/unknown	3 (0·4)	0·22	3 (0·4)	0·21		
Overall	28 (0·8)	0·43	19 (0·6)	0·29	1·43 (0·80-2·57)	
Bone fracture						
Diabetic kidney disease	47 (4·6)	2·32	45 (4·4)	2·24		0·43
Hypertensive/ renovascular disease	26 (3·7)	1·89	32 (4·3)	2·28		
Glomerular disease	24 (2·8)	1·51	21 (2·6)	1·38		
Other/unknown	36 (5·0)	2·64	25 (3·4)	1·74		
Overall	133 (4·0)	2·09	123 (3·7)	1·93	1·08 (0·84-1·38)	
Severe hypoglycaemia[#]						
Diabetic kidney disease	57 (5·5)	2·85	55 (5·4)	2·78		
Hypertensive/ renovascular disease	4 (0·6)	0·28	10 (1·4)	0·71		
Glomerular disease	5 (0·6)	0·31	2 (0·2)	0·13		
Other/unknown	11 (1·5)	0·79	10 (1·4)	0·69		
Overall	77 (2·3)	1·20	77 (2·3)	1·21	1·00 (0·73-1·37)	
Symptomatic dehydration[*]						
Diabetic kidney disease	30 (2·9)	1·47	26 (2·5)	1·29		0·90
Hypertensive/ renovascular disease	18 (2·5)	1·30	17 (2·3)	1·21		
Glomerular disease	12 (1·4)	0·75	13 (1·6)	0·85		
Other/unknown	23 (3·2)	1·68	20 (2·8)	1·39		
Overall	83 (2·5)	1·30	76 (2·3)	1·19	1·10 (0·81-1·51)	

A Cox proportional-hazards regression model with adjustment for baseline variables specified in the minimisation algorithm (age, sex, diabetes, estimated GFR, urinary albumin-to-creatinine ratio, and region) was used to estimate the hazard ratio and 95% CIs for empagliflozin as compared with placebo. Rate = Events per 100 person-years. Hazard ratios were not calculated for outcomes with fewer than 10 events in both treatment groups overall. The p value shown is the p value for heterogeneity between categories of primary kidney diagnosis and is not shown for outcomes with fewer than 10 events in any category of primary kidney diagnosis. # Defined as low blood sugar causing severe cognitive impairment which requires assistance from another person for recovery. * Defined as whether or not a participant has experienced symptoms they attribute to dehydration, such as feeling faint or fainting.

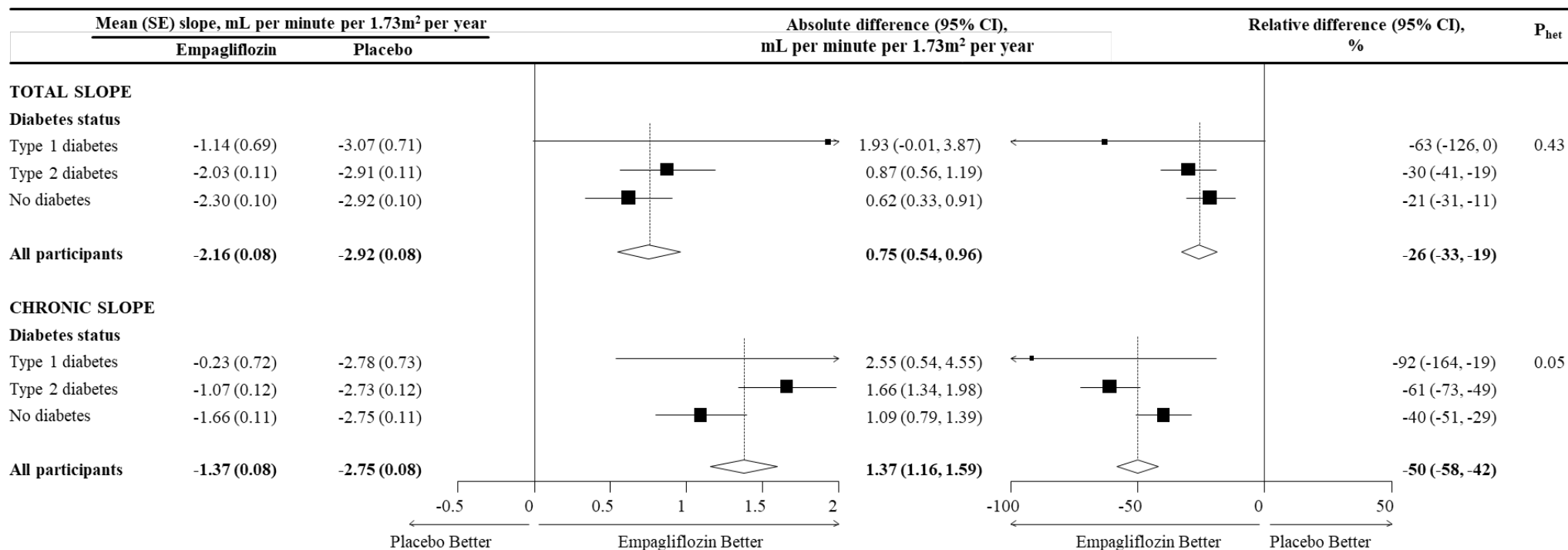
SUPPLEMENTARY FIGURES

Supplementary Figure 1: Effect of empagliflozin on the acute change in estimated GFR by primary kidney disease



Acute dips in estimated GFR were calculated as the difference in estimated GFR between baseline and the 2 month follow-up visit, with the mean values by treatment allocation (and the absolute difference between them) estimated using linear regression models adjusted for age, sex, prior diabetes, estimated GFR category, urinary ACR category, and region. Relative difference is the absolute difference as a fraction of the baseline estimated GFR in the subgroup, expressed as a percentage. The heterogeneity p values shown are calculated from the relative differences.

Supplementary Figure 2: Effect of empagliflozin on annual rate of change in estimated GFR by diabetes type



Mean annual rates of change in estimated GFR from baseline to the final follow-up visit (“total slopes”), and from 2 months to the final follow-up visit (“chronic slopes”) by treatment allocation were estimated using shared parameter models adjusted for age, sex, prior diabetes, urinary ACR category, and region. Models estimating chronic slope were additionally adjusted for baseline estimated GFR (as a continuous variable) and the interaction between baseline estimated GFR and follow-up time. This approach jointly models the annual rate of change in estimated GFR and the time to event for end-stage kidney disease (ESKD) or death. Analyses used all available central laboratory estimated GFR measurements prior to the development of ESKD. Relative difference is the absolute difference as a fraction of the mean slope in the placebo group, expressed as a percentage. The heterogeneity p values shown are calculated from the relative differences.