

Supplement to Dapagliflozin and New-Onset Type 2 Diabetes in Patients with Chronic Kidney Disease or Heart Failure: Pooled Analysis of the DAPA-CKD and DAPA-HF Trials

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Supplementary Table S1: Baseline characteristics of participants without type 2 diabetes, pre-diabetes and normoglycaemia

Characteristic	Total (n=4,003)	Pre-diabetes (n=2,408)	Normoglycaemia (n=1,595)	p-value pre-diabetes vs normoglycaemia
Study, n (%)				
DAPA-HF	2605 (65.1)	1748 (72.6)	857 (53.7)	
DAPA-CKD	1398 (34.9)	660 (27.4)	738 (46.3)	<0.0001
Age, years				
Mean (SD)	62.8 (13.6)	65.7 (11.6)	58.5 (15.1)	<0.0001
≤65 years, n (%)	2081 (52.0)	1082 (44.9)	999 (62.6)	
>65 years, n (%)	1922 (48.0)	1326 (55.1)	596 (37.4)	<0.0001
Sex, n (%)				
Male	2911 (72.7)	1753 (72.8)	1158 (72.6)	
Female	1092 (27.3)	655 (27.2)	437 (27.4)	0.8910
Race, n (%)				
White	2593 (64.8)	1604 (66.6)	989 (62.0)	
Black or African American	152 (3.8)	92 (3.8)	60 (3.8)	
Asian	1160 (29.0)	655 (27.2)	505 (31.7)	
Other	98 (2.4)	57 (2.4)	41 (2.6)	0.0194
Region, n (%)				
Asia	1122 (28.0)	631 (26.2)	491 (30.8)	
Europe	1665 (41.6)	1041 (43.2)	624 (39.1)	
North America	532 (13.3)	343 (14.2)	189 (11.8)	
Latin America	684 (17.1)	393 (16.3)	291 (18.2)	0.0006
Mean HbA1c, % (SD)	5.7 (0.4)	5.9 (0.3)	5.3 (0.3)	<0.0001
eGFR, mL/min/1.73 m²				
Mean (SD)	58.7 (21.0)	60.1 (20.6)	56.6 (21.5)	<0.0001
<30, n (%)	231 (5.8)	114 (4.7)	117 (7.3)	
30 to <45, n (%)	964 (24.1)	534 (22.2)	430 (27.0)	
45 to <60, n (%)	1041 (26.0)	604 (25.1)	437 (27.4)	
≥60, n (%)	1765 (44.1)	1156 (48.0)	609 (38.2)	<0.0001
Systolic blood pressure, mmHg				
Mean (SD)	124.8 (17.2)	124.2 (17.0)	125.7 (17.5)	0.0052
<130, n (%)	2546 (63.6)	1571 (65.2)	975 (61.1)	
≥130, n (%)	1457 (36.4)	837 (34.8)	620 (38.9)	0.0081
Diastolic blood pressure, mmHg, mean (SD)	75.5 (11.1)	74.7 (10.7)	76.7 (11.5)	<0.0001
Body Mass Index, kg/m²				
Mean (SD)	27.5 (5.7)	27.8 (5.8)	26.9 (5.5)	<0.0001
<25, n (%)	1264 (31.6)	711 (29.5)	553 (34.7)	
25 to <30, n (%)	1521 (38.0)	914 (38.0)	607 (38.1)	
≥30, n (%)	1215 (30.4)	781 (32.4)	434 (27.2)	0.0002
Heart failure at baseline, n (%)	2712 (67.7)	1820 (75.6)	892 (55.9)	<0.0001
Coronary heart disease at baseline, n (%)	1630 (40.7)	1146 (47.6)	484 (30.3)	<0.0001

Cardiovascular disease at baseline, n (%)	2934 (73.3)	1957 (81.3)	977 (61.3)	<0.0001
Current smoker, n (%)	594 (14.8)	370 (15.4)	224 (14.0)	0.2495
Baseline medication, n (%)				
Diuretics	2347 (58.6)	1581 (65.7)	766 (48.0)	<0.0001
Loop diuretics	2228 (55.7)	1509 (62.7)	719 (45.1)	<0.0001
Thiazides	433 (10.8)	285 (11.8)	148 (9.3)	0.0108
ACEi/ARB	3804 (95.0)	2289 (95.1)	1515 (95.0)	0.9162
Statins	2319 (57.9)	1571 (65.2)	748 (46.9)	<0.0001
Beta-blocker	2904 (72.5)	1907 (79.2)	997 (62.5)	<0.0001
Mineralocorticoid receptor antagonist	1899 (47.4)	1267 (52.6)	632 (39.6)	<0.0001

Pooled data from the DAPA-CKD and DAPA-HF trials

p-values for comparison between participants with normoglycaemia and pre-diabetes are calculated from a two-sample t test for continuous variables and the chi-square test for categorical variables.

Supplementary Table S2: Baseline characteristics of participants without diabetes at baseline, with and without new-onset diabetes

Characteristic	With new-onset diabetes			Without new-onset diabetes			p-value
	Dapagliflozin 10 mg (n=85)	Placebo (n=126)	Total (n=211)	Dapagliflozin 10 mg (n=1910)	Placebo (n=1882)	Total (n=3792)	
Study, n (%)							
DAPA-HF	64 (75.3)	93 (73.8)	157 (74.4)	1234 (64.6)	1214 (64.5)	2448 (64.6)	
DAPA-CKD	21 (24.7)	33 (26.2)	54 (25.6)	676 (35.4)	668 (35.5)	1344 (35.4)	0.0035
Age, years							
Mean (SD)	67.2 (10.3)	64.6 (11.4)	65.6 (11.0)	62.7 (13.6)	62.6 (13.7)	62.6 (13.7)	0.0018
≤65 years, n (%)	30 (35.3)	62 (49.2)	92 (43.6)	999 (52.3)	990 (52.6)	1989 (52.5)	
>65 years, n (%)	55 (64.7)	64 (50.8)	119 (56.4)	911 (47.7)	892 (47.4)	1803 (47.5)	0.0123
Sex, n (%)							
Male	67 (78.8)	86 (68.3)	153 (72.5)	1389 (72.7)	1369 (72.7)	2758 (72.7)	
Female	18 (21.2)	40 (31.7)	58 (27.5)	521 (27.3)	513 (27.3)	1034 (27.3)	0.9443
Race, n (%)							
White	60 (70.6)	84 (66.7)	144 (68.2)	1231 (64.5)	1218 (64.7)	2449 (64.6)	
Black or African American	5 (5.9)	9 (7.1)	14 (6.6)	73 (3.8)	65 (3.5)	138 (3.6)	
Asian	19 (22.4)	31 (24.6)	50 (23.7)	560 (29.3)	550 (29.2)	1110 (29.3)	
Other	1 (1.2)	2 (1.6)	3 (1.4)	46 (2.4)	49 (2.6)	95 (2.5)	0.0413
Region, n (%)							
Asia	18 (21.2)	29 (23.0)	47 (22.3)	542 (28.4)	533 (28.3)	1075 (28.3)	
Europe	39 (45.9)	54 (42.9)	93 (44.1)	805 (42.1)	767 (40.8)	1572 (41.5)	
North America	9 (10.6)	19 (15.1)	28 (13.3)	258 (13.5)	246 (13.1)	504 (13.3)	
Latin America	19 (22.4)	24 (19.0)	43 (20.4)	305 (16.0)	336 (17.9)	641 (16.9)	0.2238
Glycaemia subgroup, n (%)							
Normoglycaemic	4 (4.7)	8 (6.3)	12 (5.7)	802 (42.0)	781 (41.5)	1583 (41.7)	
Pre-diabetic	81 (95.3)	118 (93.7)	199 (94.3)	1108 (58.0)	1101 (58.5)	2209 (58.3)	<0.0001
Mean HbA1c, % (SD)	6.2 (0.3)	6.2 (0.4)	6.2 (0.3)	5.7 (0.4)	5.7 (0.4)	5.7 (0.4)	<0.0001

eGFR, (mL/min/1.73 m²)							
Mean (SD)	55.8 (17.9)	57.7 (18.1)	57.0 (18.0)	58.8 (21.2)	58.7 (21.2)	58.8 (21.2)	0.2301
<30, n (%)	2 (2.4)	5 (4.0)	7 (3.3)	105 (5.5)	119 (6.3)	224 (5.9)	
30 to <45, n (%)	24 (28.2)	25 (19.8)	49 (23.2)	475 (24.9)	440 (23.4)	915 (24.1)	
45 to <60, n (%)	29 (34.1)	39 (31.0)	68 (32.2)	487 (25.5)	486 (25.8)	973 (25.7)	
≥60, n (%)	30 (35.3)	57 (45.2)	87 (41.2)	842 (44.1)	836 (44.4)	1678 (44.3)	0.1060
Systolic blood pressure (mmHg)							
Mean (SD)	123.0 (16.9)	125.5 (18.5)	124.5 (17.9)	125.1 (17.3)	124.5 (17.2)	124.8 (17.2)	0.7766
<130, n (%)	60 (70.6)	73 (57.9)	133 (63.0)	1203 (63.0)	1210 (64.3)	2413 (63.6)	
≥130, n (%)	25 (29.4)	53 (42.1)	78 (37.0)	707 (37.0)	672 (35.7)	1379 (36.4)	0.8599
Diastolic blood pressure (mmHg), mean (SD)							
	75.1 (10.6)	74.5 (12.6)	74.7 (11.8)	75.7 (11.1)	75.4 (10.9)	75.5 (11.0)	0.2959
Body Mass Index (kg/m²)							
Mean (SD)	28.4 (6.3)	29.3 (6.2)	28.9 (6.2)	27.4 (5.6)	27.3 (5.7)	27.4 (5.6)	0.0001
<25, n (%)	16 (18.8)	24 (19.0)	40 (19.0)	616 (32.3)	608 (32.3)	1224 (32.3)	
25 to <30, n (%)	42 (49.4)	46 (36.5)	88 (41.7)	723 (37.9)	710 (37.7)	1433 (37.8)	
≥30, n (%)	27 (31.8)	56 (44.4)	83 (39.3)	568 (29.7)	564 (30.0)	1132 (29.9)	0.0001
Heart failure at baseline, n (%)							
	68 (80.0)	98 (77.8)	166 (78.7)	1288 (67.4)	1258 (66.8)	2546 (67.1)	0.0005
Coronary heart disease at baseline, n (%)							
	48 (56.5)	66 (52.4)	114 (54.0)	756 (39.6)	760 (40.4)	1516 (40.0)	<0.0001
Cardiovascular disease at baseline, n (%)							
	79 (92.9)	104 (82.5)	183 (86.7)	1392 (72.9)	1359 (72.2)	2751 (72.5)	<0.0001
Current smoker, n (%)							
	10 (11.8)	19 (15.1)	29 (13.7)	267 (14.0)	298 (15.8)	565 (14.9)	0.6458
Baseline medication, n (%)							
Diuretics	60 (70.6)	97 (77.0)	157 (74.4)	1094 (57.3)	1096 (58.2)	2190 (57.8)	<0.0001
Loop diuretics	56 (65.9)	95 (75.4)	151 (71.6)	1042 (54.6)	1035 (55.0)	2077 (54.8)	<0.0001
Thiazides	12 (14.1)	12 (9.5)	24 (11.4)	201 (10.5)	208 (11.1)	409 (10.8)	0.7888
ACEi/ARB	81 (95.3)	119 (94.4)	200 (94.8)	1816 (95.1)	1788 (95.0)	3604 (95.0)	0.8680
Statins	60 (70.6)	85 (67.5)	145 (68.7)	1083 (56.7)	1091 (58.0)	2174 (57.3)	0.0011
Beta-blocker	72 (84.7)	104 (82.5)	176 (83.4)	1387 (72.6)	1341 (71.3)	2728 (71.9)	0.0003

Mineralocorticoid receptor antagonist	42 (49.4)	72 (57.1)	114 (54.0)	898 (47.0)	887 (47.1)	1785 (47.1)	0.0489
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Pooled data from the DAPA-CKD and DAPA-HF trials

ACEi = angiotensin-converting enzyme inhibitor. ARB = angiotensin receptor blocker. eGFR = estimated glomerular filtration rate.

p-values for comparison between participants with and without new-onset diabetes are calculated from a two-sample t test for continuous variables and the chi-square test for categorical variables.

Supplementary Table S3: Adverse events leading to discontinuation and serious adverse events in participants without type 2 diabetes at baseline

Outcome, n (%)	Dapagliflozin (n=1991)	Placebo (n=2004)
Serious adverse event (includes death)	598 (30.0)	648 (32.3)
Discontinuation due to an adverse event	104 (5.2)	88 (4.4)

Pooled data from the DAPA-CKD and DAPA-HF trials

Supplementary Table S4: Adverse events leading to discontinuation in participants without type 2 diabetes at baseline, by system organ class

	Dapagliflozin (N=1991)	Placebo (N=2004)
Discontinuation due to an adverse event, n (%)	104 (5.2)	88 (4.4)
System Organ Class, n (%)		
Infections and infestations	16 (0.8)	8 (0.4)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	10 (0.5)	8 (0.4)
Metabolism and nutrition disorders	6 (0.3)	3 (0.1)
Psychiatric disorders	1 (0.1)	1 (0.0)
Nervous system disorders	7 (0.4)	9 (0.4)
Eye disorders	2 (0.1)	0 (0.0)
Cardiac disorders	14 (0.7)	19 (0.9)
Vascular disorders	3 (0.2)	3 (0.1)
Respiratory, thoracic and mediastinal disorders	2 (0.1)	2 (0.1)
Gastrointestinal disorders	6 (0.3)	3 (0.1)
Hepatobiliary disorders	2 (0.1)	1 (0.0)
Skin and subcutaneous tissue disorders	3 (0.2)	3 (0.1)
Musculoskeletal and connective tissue disorders	2 (0.1)	3 (0.1)
Renal and urinary disorders	17 (0.9)	18 (0.9)
Reproductive system and breast disorders	1 (0.1)	0 (0.0)
General disorders and administration site conditions	4 (0.2)	4 (0.2)
Investigations	10 (0.5)	4 (0.2)
Injury, poisoning and procedural complications	2 (0.1)	1 (0.0)

Pooled data from the DAPA-CKD and DAPA-HF trials