

Supplementary to

O-SEMA-FAST: A prospective, non-interventional study investigating oral semaglutide use in adults with type 2 diabetes mellitus during Ramadan

Author block

Mohamed Hassanein¹, Fatheya Alawadi¹, Ibrahim AlKadhim², Hazem Aly³, Dalila Bajawi⁴, Tarhan Cinar⁵, Dinesh Dhanwal⁶, Abdul Jabbar⁷, Said Khader⁸, Khaled Khudadah⁹, Talal Muzaffar¹⁰, Mary Ngome⁵, Jalal Nafach¹¹, Amna Shaghoul¹²

O-SEMA-FAST Investigators: Dr Abdulghani Alsaeed, Dr Abuljaboor Haroon, MBBS; Dr Anwar Al Jammah, MD; Dr Alaaeldin Bashier; Dr Aref Atta, MD; Dr Ayham Nassar; Dr Dhafir Mahmood, MD; Dr Fauzia Rashid; Dr Habib Steitieh, MD; Dr Hammad Bajwa, MD; Dr Hussain Al Quraini, MD; Dr Khaled Aldossari, MD; Dr Mahir Jallo, MD; Dr Mohamed Hatahet, MD; Muneera Alrandi, MD; Dr Nedal Abu Zied; Dr Rita Nader, MD; Dr Sarah El Baba, MD; Dr Yasmeen Ajaz, MD

Affiliations

1. Dubai Hospital, Dubai Health, United Arab Emirates
2. Almoosa Specialist Hospital, Kingdom of Saudi Arabia
3. Novo Nordisk Pharma Gulf FZE, Dubai, UAE
4. Sulaiman Alhabeeb Medical Group, Kingdom of Saudi Arabia
5. Novo Nordisk Saglik Urunleri Tic. Ltd. Sti, Istanbul, Turkey
6. NMC Specialty Hospital, Dubai, UAE
7. Medcare Hospital, Dubai, UAE
8. Sulaiman Al-Habib Hospital Al Olaya, Kingdom of Saudi Arabia
9. Kuwait Oil Company Hospital, Kuwait
10. Al-Amiri Hospital, Kuwait
11. Dubai Diabetes Center, Dubai, UAE
12. Adan Hospital, Kuwait

Corresponding Author: Mohamed Hassanein

+971556676217

E-mail: mhassanein148@hotmail.com

Short running title: Real-world use of oral semaglutide during Ramadan

Table S1: Descriptive summary of diabetes history and associated complications at baseline

Characteristics	Summary Statistics
Total Patients	257
Duration of T2DM (Years)	
N	251 (97.7%)
Mean (SD)	8.7 (6.6)
Median (Q1-Q3)	7.0 (4.0-12.0)
Min, Max	1.0, 36.0
Missing	6 (2.3%)
Duration of T2DM	
N	251 (97.7%)
≤ 1 Year	30 (12.0%)
2 – 5 Years	58 (23.1%)
6 – 10 Years	85 (33.7%)
> 10 Years	78 (31.1%)
Missing	6 (2.3%)
Diabetic retinopathy	
N	257 (100.0%)
No	235 (91.4%)
Yes	22 (8.6%)
Duration of Diabetic retinopathy (Years)	
N	21 (95.5%)
Mean (SD)	6.1 (4.9)
Median (Q1-Q3)	5.0 (3.0-8.0)
Min, Max	1.0, 18.0
Missing	1 (4.6%)
Diabetic Neuropathy	
N	257 (100.0%)
No	199 (77.4%)
Yes	58 (22.6%)
Duration of Diabetic Neuropathy (Years)	
N	43 (74.1%)
Mean (SD)	6.1 (5.7)
Median (Q1-Q3)	4.0 (2.0-8.0)
Min, Max	0.0, 22.0
Missing	15 (25.9%)

Diabetic Nephropathy	
N	257 (100.0%)
No	237 (92.2%)
Yes	20 (7.8%)
Duration of Diabetic Nephropathy (Years)	
N	18 (90.0%)
Mean (SD)	5.33 (4.1)
Median (Q1-Q3)	4.5 (3.0-6.0)
Min, Max	0.0, 15.0
Missing	2 (10.0%)
Cardiovascular Disease	
N	257 (100.0%)
No	204 (79.4%)
Yes	53 (20.6%)
Duration of Cardiovascular Disease (Years)	
N	46 (86.8%)
Mean (SD)	10.15 (7.6)
Median (Q1-Q3)	8.0 (5.0-13.0)
Min, Max	1.0, 33.0
Missing	7 (13.2%)
Cerebrovascular Disease	
N	257 (100.0%)
No	256 (99.6%)
Yes	1 (0.4%)
Duration of Cerebrovascular Disease (Years)	
N	1 (100.0%)
Mean	2.0
Median (Q1-Q3)	2.0 (2.0-2.0)
Min, Max	2.0, 2.0
Peripheral Artery Disease	
N	257 (100.0%)
No	257 (100.0%)
<i>N: Total number of patients used to calculate summary statistics</i> <i>SD: Standard deviation, Q1: 1st Quartile, Q3: 3rd Quartile, Min: Minimum value, Max: Maximum value, T2DM: Type 2 Diabetes Mellitus</i>	

Table S2: Descriptive summary of diabetes medication history of patients at baseline

Characteristics	Summary Statistics
Total Patients	257
Diabetes Medication*	
N	237 (92.2%)
Acarbose	2 (0.8%)
Canagliflozin	6 (2.5%)
Dapagliflozin	102 (43.0%)
Empagliflozin	92 (38.8%)
Ertugliflozin	2 (0.8%)
Gliclazide	55 (23.2%)
Glimepiride	15 (6.3%)
Glyburide	2 (0.8%)
Linagliptin	5 (2.1%)
Metformin	209 (88.2%)
Ozempic	1 (0.4%)
Pioglitazone	16 (6.8%)
Repaglinide	2 (0.8%)
Sitagliptin	22 (9.3%)
Vildagliptin	10 (4.2%)
Missing/Patients were not taking any drugs	20 (7.8%)
Diabetes Medication grouped by Class	
Alpha glucosidase inhibitors	2 (0.8%)
Biguanides	209 (88.2%)
Dipeptidyl peptidase 4 (DPP-4) inhibitors	37 (15.6%)
Glucagon-like peptide-1 (GLP-1) analogues	1 (0.4%)
Other blood glucose lowering drugs, excl. insulins	2 (0.8%)
Sodium-glucose co-transporter 2 (SGLT-2) inhibitors	196 (82.7%)
Sulphonylureas	71 (30.0%)
Thiazolidinediones	16 (6.8%)
Missing/Patients were not taking any drugs	20 (7.8%)
Number of distinct OADs	
n	237
1	50 (21.1%)
2	106 (44.7%)
3	56 (23.6%)
4	16 (6.8%)
5	7 (3.0%)
6	2 (0.8%)

N: Total number of patients used to calculate summary statistics

**Multiple response variable (Patient with multiple drugs)*

OADs, Oral antidiabetic drugs

Table S3: Descriptive summary of concomitant medication other than OADs at baseline

Characteristics	Overall
Total Patients	257
Total Patients with medication	225
Diabetes Medication * (ATC 4)	
N	225 (87.6%)
Hmg Coa Reductase Inhibitors	135 (60.0%)
Angiotensin II Receptor Blockers (Arbs), Plain	67 (29.8%)
Ace Inhibitors and Diuretics	61 (27.1%)
Other Lipid Modifying Agents	43 (19.1%)
Dihydropyridine Derivatives	29 (12.9%)
Ace Inhibitors, plain	27 (12.0%)
Thyroid Hormones	23 (10.2%)
Beta Blocking Agents, Selective	21 (9.3%)
Fibrates	16 (7.1%)
Sulphonamides, plain	13 (5.8%)
Platelet Aggregation Inhibitors Excl. Heparin	11 (4.9%)
Thiazides, plain	10 (4.4%)
Vitamin D And Analogues	9 (4.0%)
Angiotensin II Receptor Blockers (ARBs) And Calcium Channel Blockers	8 (3.6%)
Proton Pump Inhibitors	5 (2.2%)
Aldosterone Antagonists	3 (1.3%)
Angiotensin II Receptor Blockers (Arbs) And Diuretics	3 (1.3%)
Other Drugs Used in Benign Prostatic Hypertrophy	3 (1.3%)
Preparations Inhibiting Uric Acid Production	3 (1.3%)
Testosterone-5-Alpha Reductase Inhibitors	3 (1.3%)
Vitamin B1, plain	3 (1.3%)
Herbal Cholesterol and Triglyceride Reducers	2 (0.9%)
Other Alimentary Tract and Metabolism Products	2 (0.9%)
3-Oxoandrosten (4) Derivatives	1 (0.4%)
Ace Inhibitors and Calcium Channel Blockers	1 (0.4%)
Alpha-Adrenoreceptor Antagonists	1 (0.4%)
Calcium	1 (0.4%)
Carboxamide Derivatives	1 (0.4%)
Combinations Of Various Lipid Modifying Agents	1 (0.4%)
Combinations Of Vitamins	1 (0.4%)
Direct Factor Xa Inhibitors	1 (0.4%)
Direct Thrombin Inhibitors	1 (0.4%)
Dopamine Agonists	1 (0.4%)
Drugs For Treatment of Hyperkalaemia and Hyperphosphatemia	1 (0.4%)
Other Cardiac Combination Products	1 (0.4%)
Other Nervous System Drugs	1 (0.4%)
Other Plain Vitamin Preparations	1 (0.4%)

Sulphur-Containing Imidazole Derivatives	1 (0.4%)
Vitamin B12 (Cyanocobalamin and Analogues)	1 (0.4%)
Missing	32 (12.5%)
Indication*	
N	225 (87.6%)
Hypertension	110 (48.9%)
Anti-Hypertensive	103 (45.8%)
Dyslipidaemia	92 (40.9%)
Hyperlipidaemia	92 (40.9%)
Hypothyroidism	23 (10.2%)
Hypercholesteremia	13 (5.8%)
Vitamin D Deficiency	10 (4.4%)
Benign Prostatic Hyperplasia	5 (2.2%)
Hypertriglyceridemia	5 (2.2%)
High Cholesterol	4 (1.8%)
Ischemic Heart Disease	3 (1.3%)
Atherosclerotic Cardiovascular Disease	2 (0.9%)
Cardiovascular Disease	2 (0.9%)
Coronary Artery Disease	2 (0.9%)
Hyperuricaemia	2 (0.9%)
Vitamin B Deficiency	2 (0.9%)
Acid Reflux	1 (0.4%)
Anti-Ischaemic	1 (0.4%)
Atrial Fibrillation	1 (0.4%)
Calcium Deficiency	1 (0.4%)
Deep Vein Thrombosis	1 (0.4%)
Dyspepsia	1 (0.4%)
Elevated Uric Acid	1 (0.4%)
Epilepsy	1 (0.4%)
Gastroesophageal Reflux Disease	1 (0.4%)
Gastrointestinal Disorder	1 (0.4%)
Hyperglycaemia	1 (0.4%)
Hyperkalaemia	1 (0.4%)
Hyperthyroidism	1 (0.4%)
Hypogonadism	1 (0.4%)
Microalbuminuria	1 (0.4%)
Neuropathy	1 (0.4%)
Pituitary Microadenoma	1 (0.4%)
Renal And Ureteric Calculus	1 (0.4%)
Unstable Angina	1 (0.4%)
Missing	32 (12.5%)
<i>N: Total number of patients used to calculate summary statistics</i>	

ATC: Anatomical Therapeutic Chemical, OAD: Oral antidiabetic drugs

**Multiple response variable (Patient with multiple drugs and class)*

Table S4: Descriptive summary of demographical and clinical characteristics at baseline for all patients and among patients with hypoglycaemic events vs patients without hypoglycaemic events

Characteristics	Patients with hypoglycaemic events	Patients without hypoglycaemic events	Overall
Total Patients	67	149	216
Age (Years)			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
Mean (SD)	51.03 (9.69)	53.28 (9.54)	52.58 (9.62)
Median (Q1 - Q3)	51.00 (44.00-58.00)	54.00 (47.00-60.00)	53.00 (47.00-60.00)
Min, Max	28.00, 72.00	27.00, 74.00	27.00, 74.00
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Age group			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
18 - 30	1 (1.49%)	2 (1.34%)	3 (1.39%)
31 - 49	26 (38.81%)	50 (33.56%)	76 (35.19%)
50 - 64	35 (52.24%)	80 (53.69%)	115 (53.24%)
> 65	5 (7.46%)	17 (11.41%)	22 (10.19%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sex			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
Male	45 (67.16%)	85 (57.05%)	130 (60.19%)
Female	22 (32.84%)	64 (42.95%)	86 (39.81%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Duration of T2DM (Years)			
N	67 (100.0%)	144 (96.64%)	211 (97.69%)
Mean (SD)	9.16 (5.18)	7.92 (6.70)	8.32 (6.27)
Median (Q1 - Q3)	9.00 (5.00-13.00)	6.00 (3.00-11.00)	7.00 (4.00-11.00)
Min, Max	1.00, 22.00	1.00, 36.00	1.00, 36.00
Missing (N)	0 (0.00%)	5 (3.36%)	5 (2.31%)
Duration of T2DM			
N	67 (100.0%)	144 (96.64%)	211 (97.69%)
<= 1 Year	5 (7.46%)	21 (14.58%)	26 (12.32%)
2 – 5 Years	13 (19.40%)	38 (26.39%)	51 (24.17%)

6 – 10 Years	25 (37.31%)	47 (32.64%)	72 (34.12%)
> 10 Years	24 (35.82%)	38 (26.39%)	62 (29.38%)
Missing (N)	0 (0.00%)	5 (3.36%)	5 (2.31%)
BMI (kg/m^2)			
N	67 (100.0%)	146 (97.99%)	213 (98.61%)
Mean (SD)	31.67 (5.01)	32.88 (6.21)	32.50 (5.87)
Median (Q1 - Q3)	31.55 (28.01-35.15)	31.37 (28.73-35.67)	31.38 (28.73-35.43)
Min, Max	19.50, 45.31	21.64, 54.48	19.50, 54.48
Missing(N)	0 (0.00%)	3 (2.01%)	3 (1.39%)
BMI categories			
N	67 (100.0%)	146 (97.99%)	213 (98.61%)
Underweight (BMI < 18.5)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Normal weight (18.5 < BMI < 25)	5 (7.46%)	9 (6.16%)	14 (6.57%)
Overweight (25 < BMI < 30)	19 (28.36%)	44 (30.14%)	63 (29.58%)
Obese (BMI > 30)	43 (64.18%)	93 (63.70%)	136 (63.85%)
Missing (N)	0 (0.00%)	3 (2.01%)	3 (1.39%)
HBA1c (%)			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
Mean (SD)	6.99 (1.22)	6.66 (1.17)	6.76 (1.19)
Median (Q1 - Q3)	6.90 (6.20-7.60)	6.40 (5.96-7.10)	6.50 (6.00-7.30)
Min, Max	4.70, 12.00	4.92, 11.50	4.70ssss, 12.00
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
HbA1c (%) level			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
< 7%	36 (53.73%)	107 (71.81%)	143 (66.20%)
7%-8%	20 (29.85%)	27 (18.12%)	47 (21.76%)
8%-9%	8 (11.94%)	5 (3.36%)	13 (6.02%)
> 9%	3 (4.48%)	10 (6.71%)	13 (6.02%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diagnosis			
N	63 (94.03%)	130 (87.25%)	193 (89.35%)
Hyperlipidaemia	59 (93.65%)	117 (90.00%)	176 (91.19%)
Hypertension	34 (53.97%)	74 (56.92%)	108 (55.96%)
Other	5 (7.94%)	31 (23.85%)	36 (18.65%)
Missing (N)	4 (5.97%)	19 (12.75%)	23 (10.65%)

Diabetes Medication**			
N	64 (95.52%)	135 (90.60%)	199 (92.13%)
	58 (90.63%)	117 (86.67%)	175 (87.94%)
Sodium-glucose co-transporter 2 (SGLT2) inhibitors	55 (85.94%)	109 (80.74%)	164 (82.41%)
Sulfonylureas	21 (32.81%)	35 (25.93%)	56 (28.14%)
Dipeptidyl peptidase 4 (DPP-4) inhibitors	13 (20.31%)	15 (11.11%)	28 (14.07%)
Thiazolidinediones	4 (6.25%)	10 (7.41%)	14 (7.04%)
Alpha glucosidase inhibitors	1 (1.56%)	1 (0.74%)	2 (1.01%)
Other blood glucose lowering drugs, excl. insulins	1 (1.56%)	1 (0.74%)	2 (1.01%)
Glucagon-like peptide-1 (GLP-1) analogues	0 (0.00%)	1 (0.74%)	1 (0.50%)
Missing (N)	3 (4.48%)	14 (9.40%)	17 (7.87%)
Concomitant Medication**			
N	61 (91.04%)	128 (85.91%)	189 (87.50%)
Hmg Coa Reductase Inhibitors	38 (62.30%)	74 (57.81%)	112 (59.26%)
Angiotensin II Receptor Blockers (Arbs), Plain	14 (22.95%)	42 (32.81%)	56 (29.63%)
Ace Inhibitors and Diuretics	17 (27.87%)	37 (28.91%)	54 (28.57%)
Other Lipid Modifying Agents	16 (26.23%)	22 (17.19%)	38 (20.11%)
Dihydropyridine Derivatives	11 (18.03%)	12 (9.38%)	23 (12.17%)
Ace Inhibitors, plain	5 (8.20%)	16 (12.50%)	21 (11.11%)
Beta Blocking Agents, Selective	5 (8.20%)	14 (10.94%)	19 (10.05%)
Thyroid Hormones	3 (4.92%)	16 (12.50%)	19 (10.05%)
Fibrates	4 (6.56%)	10 (7.81%)	14 (7.41%)
Thiazides, plain	3 (4.92%)	7 (5.47%)	10 (5.29%)
Sulphonamides, plain	3 (4.92%)	6 (4.69%)	9 (4.76%)
Platelet Aggregation Inhibitors Excl. Heparin	3 (4.92%)	5 (3.91%)	8 (4.23%)
Angiotensin II Receptor Blockers (Arbs) And Calcium channel blockers	1 (1.64%)	6 (4.69%)	7 (3.70%)
Vitamin D And Analogues	3 (4.92%)	3 (2.34%)	6 (3.17%)
Proton Pump Inhibitors	2 (3.28%)	2 (1.56%)	4 (2.12%)
Preparations Inhibiting Uric Acid Production	0 (0.00%)	3 (2.34%)	3 (1.59%)
Aldosterone Antagonists	1 (1.64%)	1 (0.78%)	2 (1.06%)
Angiotensin II Receptor Blockers (Arbs) And Diuretics	1 (1.64%)	1 (0.78%)	2 (1.06%)
Vitamin B1, plain	1 (1.64%)	1 (0.78%)	2 (1.06%)
Other Alimentary Tract and Metabolism Products	0 (0.00%)	2 (1.56%)	2 (1.06%)
Drugs For Treatment of Hyperkalaemia and Hyperphosphatemia	1 (1.64%)	0 (0.00%)	1 (0.53%)
Herbal Cholesterol and Triglyceride Reducers	1 (1.64%)	0 (0.00%)	1 (0.53%)
3-Oxoandrosten (4) Derivatives	0 (0.00%)	1 (0.78%)	1 (0.53%)
Ace Inhibitors and Calcium Channel Blockers	0 (0.00%)	1 (0.78%)	1 (0.53%)

Calcium	0 (0.00%)	1 (0.78%)	1 (0.53%)
Carboxamide Derivatives	0 (0.00%)	1 (0.78%)	1 (0.53%)
Combinations Of Various Lipid Modifying Agents	0 (0.00%)	1 (0.78%)	1 (0.53%)
Combinations Of Vitamins	0 (0.00%)	1 (0.78%)	1 (0.53%)
Direct Factor Xa Inhibitors	0 (0.00%)	1 (0.78%)	1 (0.53%)
Dopamine Agonists	0 (0.00%)	1 (0.78%)	1 (0.53%)
Other Cardiac Combination Products	0 (0.00%)	1 (0.78%)	1 (0.53%)
Other Drugs Used in Benign Prostatic Hypertrophy	0 (0.00%)	1 (0.78%)	1 (0.53%)
Testosterone-5-Alpha Reductase Inhibitors	0 (0.00%)	1 (0.78%)	1 (0.53%)
Vitamin B12 (Cyanocobalamin and Analogues)	0 (0.00%)	1 (0.78%)	1 (0.53%)
Missing (N)	6 (8.96%)	21 (14.09%)	27 (12.50%)
Number of days of fasting (Days)			
N	67 (100.0%)	145 (97.32%)	212 (98.15%)
Mean (SD)	28.93 (0.80)	28.74 (1.50)	28.80 (1.32)
Median (Q1 - Q3)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)
Min, Max	24.00, 30.00	20.00, 30.00	20.00, 30.00
Missing (N)	0 (0.00%)	4 (2.68%)	4 (1.85%)
Adherence to dosing instructions*			
N	67 (100.0%)	148 (100.0%)	215 (100.0%)
Adherent	45 (67.16%)	102 (68.92%)	147 (68.37%)
Not Adherent	22 (32.84%)	46 (31.08%)	68 (31.63%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Highest Dose			
N	67 (100.0%)	149 (100.0%)	216 (100.0%)
7 mg	36 (53.73%)	60 (40.27%)	96 (44.44%)
14 mg	31 (46.27%)	89 (59.73%)	120 (55.56%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<i>N: Total number of patients used to calculate summary statistics</i> <i>SD: Standard deviation, Q1: 1st Quartile, Q3: 3rd Quartile, Min: Minimum value, Max: Maximum value</i> <i>*Adherent patients: patients who (1) took oral semaglutide on an empty stomach, (2) with up to 120 ml of water, and (3) waited at least 30 minutes after taking the medication before eating</i> <i>*Adherent: Considered patients who have fulfilled all the above 3 criteria for at least 80% of days the diary was filled during Ramadan period</i> <i>**Multiple response variable (Patient with multiple drugs and class)</i>			

Table S5: Demographic and clinical characteristics at baseline for all patients and among patients with hypoglycaemic events vs patients without hypoglycaemic events by treatment period (Pre-Ramadan, Ramadan and post-Ramadan period)

Characteristics	Patients with hypoglycaemic events (Pre-Ramadan)	Patients without hypoglycaemic events (Pre-Ramadan)	Overall (Pre-Ramadan)	Patients with hypoglycaemic events (During Ramadan)	Patients without hypoglycaemic events (During Ramadan)	Overall (During Ramadan)	Patients with hypoglycaemic events (post-Ramadan)	Patients without hypoglycaemic events (post-Ramadan)	Overall (post-Ramadan)
Total Patients	11	118	129	52	163	215	13	117	130
Age (Years)									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Mean (SD)	47.55 (9.48)	52.06 (10.10)	51.67 (10.10)	51.69 (10.06)	53.02 (9.30)	52.70 (9.49)	48.69 (10.04)	52.81 (9.85)	52.40 (9.91)
Median (Q1 - Q3)	49.00 (41.00-57.00)	52.00 (45.00-60.00)	51.00 (45.00-59.00)	52.00 (45.50-58.50)	53.00 (47.00-60.00)	53.00 (47.00-60.00)	48.00 (42.00-55.00)	53.00 (45.00-60.00)	53.00 (45.00-60.00)
Min, Max	28.00, 59.00	27.00, 74.00	27.00, 74.00	28.00, 72.00	30.00, 74.00	28.00, 74.00	31.00, 68.00	30.00, 74.00	30.00, 74.00
Missing(N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Age group									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
18 - 30	1 (9.09%)	2 (1.69%)	3 (2.33%)	1 (1.92%)	1 (0.61%)	2 (0.93%)	0 (0.00%)	1 (0.85%)	1 (0.77%)
31 - 49	5 (45.45%)	46 (38.98%)	51 (39.53%)	19 (36.54%)	57 (34.97%)	76 (35.35%)	7 (53.85%)	41 (35.04%)	48 (36.92%)
50 - 64	5 (45.45%)	58 (49.15%)	63 (48.84%)	27 (51.92%)	88 (53.99%)	115 (53.49%)	5 (38.46%)	61 (52.14%)	66 (50.77%)
> 65	0 (0.00%)	12 (10.17%)	12 (9.30%)	5 (9.62%)	17 (10.43%)	22 (10.23%)	1 (7.69%)	14 (11.97%)	15 (11.54%)

Missing(N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sex									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Male	6 (54.55%)	76 (64.41%)	82 (63.57%)	34 (65.38%)	95 (58.28%)	129 (60.00%)	10 (76.92%)	71 (60.68%)	81 (62.31%)
Female	5 (45.45%)	42 (35.59%)	47 (36.43%)	18 (34.62%)	68 (41.72%)	86 (40.00%)	3 (23.08%)	46 (39.32%)	49 (37.69%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Duration of T2DM (Years)									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	158 (96.93%)	210 (97.67%)	13 (100.0%)	115 (98.29%)	128 (98.46%)
Mean (SD)	10.27 (6.97)	7.86 (6.36)	8.07 (6.42)	9.00 (4.89)	8.13 (6.67)	8.35 (6.27)	8.85 (4.95)	8.16 (6.46)	8.23 (6.31)
Median (Q1 - Q3)	8.00 (5.00-18.00)	6.50 (3.00-11.00)	7.00 (3.00-11.00)	8.50 (5.00-13.00)	6.50 (3.00-11.00)	7.00 (4.00-11.00)	10.00 (6.00-11.00)	7.00 (3.00-12.00)	7.00 (3.00-12.00)
Min, Max	1.00, 19.00	1.00, 33.00	1.00, 33.00	1.00, 22.00	1.00, 36.00	1.00, 36.00	1.00, 19.00	1.00, 33.00	1.00, 33.00
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (3.07%)	5 (2.33%)	0 (0.00%)	2 (1.71%)	2 (1.54%)
Duration of T2DM									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	158 (96.93%)	210 (97.67%)	13 (100.0%)	115 (98.29%)	128 (98.46%)
<= 1 Year	2 (18.18%)	21 (17.80%)	23 (17.83%)	2 (3.85%)	24 (15.19%)	26 (12.38%)	2 (15.38%)	19 (16.52%)	21 (16.41%)
2 – 5 Years	1 (9.09%)	26 (22.03%)	27 (20.93%)	12 (23.08%)	38 (24.05%)	50 (23.81%)	1 (7.69%)	26 (22.61%)	27 (21.09%)

6 – 10 Years	3 (27.27%)	37 (31.36%)	40 (31.01%)	21 (40.38%)	51 (32.28%)	72 (34.29%)	6 (46.15%)	33 (28.70%)	39 (30.47%)
> 10 Years	5 (45.45%)	34 (28.81%)	39 (30.23%)	17 (32.69%)	45 (28.48%)	62 (29.52%)	4 (30.77%)	37 (32.17%)	41 (32.03%)
Missing(N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (3.07%)	5 (2.33%)	0 (0.00%)	2 (1.71%)	2 (1.54%)
BMI (kg/m^2)									
N	11 (100.0%)	117 (99.15%)	128 (99.22%)	52 (100.0%)	161 (98.77%)	213 (99.07%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Mean (SD)	33.57 (4.17)	32.91 (5.83)	32.97 (5.70)	31.52 (5.36)	32.81 (6.01)	32.50 (5.87)	31.31 (3.56)	33.17 (5.63)	32.98 (5.48)
Median (Q1 - Q3)	34.53 (31.02- 37.22)	31.64 (29.24- 34.62)	31.82 (29.31- 35.01)	31.12 (27.79- 35.18)	31.64 (29.00- 35.64)	31.38 (28.73- 35.43)	31.85 (29.58- 33.76)	32.17 (29.24- 35.67)	32.13 (29.24- 35.64)
Min, Max	25.64, 37.38	22.65, 54.48	22.65, 54.48	19.50, 45.31	21.64, 54.48	19.50, 54.48	25.64, 36.29	23.12, 51.65	23.12, 51.65
Missing (N)	0 (0.00%)	1 (0.85%)	1 (0.78%)	0 (0.00%)	2 (1.23%)	2 (0.93%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
BMI categories									
N	11 (100.0%)	117 (99.15%)	128 (99.22%)	52 (100.0%)	161 (98.77%)	213 (99.07%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Underweight (BMI < 18.5)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Normal weight (18.5 < BMI < 25)	0 (0.00%)	4 (3.42%)	4 (3.13%)	5 (9.62%)	9 (5.59%)	14 (6.57%)	0 (0.00%)	6 (5.13%)	6 (4.62%)
Overweight (25 < BMI < 30)	2 (18.18%)	35 (29.91%)	37 (28.91%)	16 (30.77%)	47 (29.19%)	63 (29.58%)	4 (30.77%)	31 (26.50%)	35 (26.92%)
Obese (BMI > 30)	9 (81.82%)	78 (66.67%)	87 (67.97%)	31 (59.62%)	105 (65.22%)	136 (63.85%)	9 (69.23%)	80 (68.38%)	89 (68.46%)
Missing (N)	0 (0.00%)	1 (0.85%)	1 (0.78%)	0 (0.00%)	2 (1.23%)	2 (0.93%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

HbA1c (%)									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Mean (SD)	7.10 (0.68)	6.58 (1.09)	6.63 (1.07)	7.06 (1.22)	6.67 (1.17)	6.76 (1.19)	6.56 (1.27)	6.64 (1.06)	6.63 (1.08)
Median (Q1 - Q3)	7.20 (6.60-7.60)	6.40 (6.00-7.10)	6.45 (6.00-7.20)	7.00 (6.20-7.55)	6.40 (5.90-7.20)	6.50 (6.00-7.30)	6.60 (5.60-6.90)	6.50 (6.10-7.10)	6.50 (6.00-7.10)
Min, Max	5.90, 8.10	4.70, 11.50	4.70, 11.50	5.20, 12.00	4.70, 11.50	4.70, 12.00	4.70, 9.50	4.92, 11.50	4.70, 11.50
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
HbA1c (%) level									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
< 7%	3 (27.27%)	88 (74.58%)	91 (70.54%)	27 (51.92%)	115 (70.55%)	142 (66.05%)	10 (76.92%)	85 (72.65%)	95 (73.08%)
7%-8%	7 (63.64%)	22 (18.64%)	29 (22.48%)	16 (30.77%)	31 (19.02%)	47 (21.86%)	1 (7.69%)	25 (21.37%)	26 (20.00%)
8%-9%	1 (9.09%)	2 (1.69%)	3 (2.33%)	7 (13.46%)	6 (3.68%)	13 (6.05%)	1 (7.69%)	1 (0.85%)	2 (1.54%)
> 9%	0 (0.00%)	6 (5.08%)	6 (4.65%)	2 (3.85%)	11 (6.75%)	13 (6.05%)	1 (7.69%)	6 (5.13%)	7 (5.38%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diagnosis									
N	9 (81.82%)	101 (85.59%)	110 (85.27%)	49 (94.23%)	143 (87.73%)	192 (89.30%)	12 (92.31%)	100 (85.47%)	112 (86.15%)
Hyperlipidaemia	9 (100.0%)	89 (88.12%)	98 (89.09%)	46 (93.88%)	129 (90.21%)	175 (91.15%)	11 (91.67%)	92 (92.00%)	103 (91.96%)

Concomitant Medication**									
N	10 (90.91%)	100 (84.75%)	110 (85.27%)	47 (90.38%)	141 (86.50%)	188 (87.44%)	12 (92.31%)	97 (82.91%)	109 (83.85%)
Hmg Coa Reductase Inhibitors	5 (50.00%)	63 (63.00%)	68 (61.82%)	29 (61.70%)	82 (58.16%)	111 (59.04%)	9 (75.00%)	65 (67.01%)	74 (67.89%)
Angiotensin II Receptor Blockers (Arbs), Plain	3 (30.00%)	36 (36.00%)	39 (35.45%)	11 (23.40%)	45 (31.91%)	56 (29.79%)	2 (16.67%)	33 (34.02%)	35 (32.11%)
Ace Inhibitors and Diuretics	4 (40.00%)	22 (22.00%)	26 (23.64%)	13 (27.66%)	41 (29.08%)	54 (28.72%)	2 (16.67%)	22 (22.68%)	24 (22.02%)
Other Lipid Modifying Agents	1 (10.00%)	20 (20.00%)	21 (19.09%)	12 (25.53%)	26 (18.44%)	38 (20.21%)	6 (50.00%)	15 (15.46%)	21 (19.27%)
Fibrates	2 (20.00%)	11 (11.00%)	13 (11.82%)	2 (4.26%)	12 (8.51%)	14 (7.45%)	1 (8.33%)	10 (10.31%)	11 (10.09%)
Beta Blocking Agents, Selective	0 (0.00%)	10 (10.00%)	10 (9.09%)	5 (10.64%)	14 (9.93%)	19 (10.11%)	0 (0.00%)	9 (9.28%)	9 (8.26%)
Dihydropyridine Derivatives	2 (20.00%)	8 (8.00%)	10 (9.09%)	9 (19.15%)	14 (9.93%)	23 (12.23%)	0 (0.00%)	12 (12.37%)	12 (11.01%)
Ace Inhibitors, plain	0 (0.00%)	9 (9.00%)	9 (8.18%)	4 (8.51%)	17 (12.06%)	21 (11.17%)	1 (8.33%)	8 (8.25%)	9 (8.26%)
Thyroid Hormones	0 (0.00%)	7 (7.00%)	7 (6.36%)	3 (6.38%)	16 (11.35%)	19 (10.11%)	0 (0.00%)	10 (10.31%)	10 (9.17%)
Angiotensin II Receptor Blockers (Arbs) And Calcium channel blockers	0 (0.00%)	6 (6.00%)	6 (5.45%)	0 (0.00%)	7 (4.96%)	7 (3.72%)	1 (8.33%)	5 (5.15%)	6 (5.50%)
Platelet Aggregation Inhibitors Excl. Heparin	0 (0.00%)	6 (6.00%)	6 (5.45%)	3 (6.38%)	5 (3.55%)	8 (4.26%)	0 (0.00%)	7 (7.22%)	7 (6.42%)
Sulphonamides, plain	0 (0.00%)	5 (5.00%)	5 (4.55%)	3 (6.38%)	6 (4.26%)	9 (4.79%)	0 (0.00%)	4 (4.12%)	4 (3.67%)
Vitamin D And Analogues	1 (10.00%)	4 (4.00%)	5 (4.55%)	2 (4.26%)	4 (2.84%)	6 (3.19%)	1 (8.33%)	4 (4.12%)	5 (4.59%)
Proton Pump Inhibitors	1 (10.00%)	3 (3.00%)	4 (3.64%)	1 (2.13%)	3 (2.13%)	4 (2.13%)	0 (0.00%)	2 (2.06%)	2 (1.83%)

Thiazides, plain	0 (0.00%)	4 (4.00%)	4 (3.64%)	3 (6.38%)	7 (4.96%)	10 (5.32%)	0 (0.00%)	5 (5.15%)	5 (4.59%)
Preparations Inhibiting Uric Acid Production	0 (0.00%)	3 (3.00%)	3 (2.73%)	0 (0.00%)	3 (2.13%)	3 (1.60%)	0 (0.00%)	2 (2.06%)	2 (1.83%)
Aldosterone Antagonists	0 (0.00%)	2 (2.00%)	2 (1.82%)	0 (0.00%)	2 (1.42%)	2 (1.06%)	1 (8.33%)	1 (1.03%)	2 (1.83%)
Other Alimentary Tract and Metabolism Products	0 (0.00%)	2 (2.00%)	2 (1.82%)	0 (0.00%)	2 (1.42%)	2 (1.06%)	0 (0.00%)	2 (2.06%)	2 (1.83%)
Vitamin B1, plain	0 (0.00%)	2 (2.00%)	2 (1.82%)	1 (2.13%)	1 (0.71%)	2 (1.06%)	0 (0.00%)	2 (2.06%)	2 (1.83%)
3-Oxoandrostens (4) Derivatives	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)			
Ace Inhibitors and Calcium Channel Blockers	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)
Carboxamide Derivatives	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)
Combinations Of Various Lipid Modifying Agents	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)
Combinations Of Vitamins	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dopamine Agonists	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Drugs For Treatment of Hyperkalaemia and Hyperphosphatemia	1 (10.00%)	0 (0.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)
Other Cardiac Combination Products	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)

Other Drugs Used in Benign Prostatic Hypertrophy	0 (0.00%)	1 (1.00%)	1 (0.91%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	1 (1.03%)	1 (0.92%)
Herbal Cholesterol and Triglyceride Reducers	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)	0 (0.00%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Direct Factor Xa Inhibitors	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angiotensin II Receptor Blockers (Arbs) And Diuretics	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)	1 (0.71%)	2 (1.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Calcium	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Testosterone-5-Alpha Reductase Inhibitors	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin B12 (Cyanocobalamin and Analogues)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.71%)	1 (0.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Missing (N)	1 (9.09%)	18 (15.25%)	19 (14.73%)	5 (9.62%)	22 (13.50%)	27 (12.56%)	1 (7.69%)	20 (17.09%)	21 (16.15%)
Number of days of fasting (Days)									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	159 (97.55%)	211 (98.14%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Mean (SD)	28.82 (0.40)	28.74 (1.26)	28.74 (1.21)	28.92 (0.90)	28.76 (1.44)	28.80 (1.33)	29.08 (0.28)	28.85 (1.10)	28.88 (1.05)
Median (Q1 - Q3)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)	29.00 (29.00-29.00)
Min, Max	28.00, 29.00	20.00, 30.00	20.00, 30.00	24.00, 30.00	20.00, 30.00	20.00, 30.00	29.00, 30.00	21.00, 30.00	21.00, 30.00
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (2.45%)	4 (1.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Adherence to dosing instructions*									
N	11 (100.0%)	117 (100.0%)	128 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
Adherent	3 (27.27%)	87 (74.36%)	90 (70.31%)	36 (69.23%)	111 (68.10%)	147 (68.37%)	10 (76.92%)	82 (70.09%)	92 (70.77%)
Not Adherent	8 (72.73%)	30 (25.64%)	38 (29.69%)	16 (30.77%)	52 (31.90%)	68 (31.63%)	3 (23.08%)	35 (29.91%)	38 (29.23%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Highest Dose									
N	11 (100.0%)	118 (100.0%)	129 (100.0%)	52 (100.0%)	163 (100.0%)	215 (100.0%)	13 (100.0%)	117 (100.0%)	130 (100.0%)
7 mg	4 (36.36%)	45 (38.14%)	49 (37.98%)	30 (57.69%)	65 (39.88%)	95 (44.19%)	5 (38.46%)	52 (44.44%)	57 (43.85%)
14 mg	7 (63.64%)	73 (61.86%)	80 (62.02%)	22 (42.31%)	98 (60.12%)	120 (55.81%)	8 (61.54%)	65 (55.56%)	73 (56.15%)
Missing (N)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
N: Total number of patients used to calculate summary statistics SD: Standard deviation, Q1: 1st Quartile, Q3: 3rd Quartile, Min: Minimum value, Max: Maximum value BMI, body mass index; HbA1c, glycated haemoglobin; Hmg Coa, 3-Hydroxy-3-methylglutaryl-coenzyme A; T2DM, type 2 diabetes mellitus									

Table S6: Adverse Events by SOC and PT of patients during the study period

Characteristics	Summary Statistics	
	Patients	AEs
Total Patients	257	382
Number of Patients with any AE	105 (40.86%)	-
Primary System Organ Class		
Eye Disorders	1 (0.39%)	1 (0.26%)
Vision Blurred	1 (0.39%)	1 (0.26%)
Gastrointestinal Disorders	98 (38.13%)	324 (84.82%)
Abdominal Discomfort	1 (0.39%)	1 (0.26%)
Abdominal Pain	2 (0.78%)	3 (0.79%)
Constipation	40 (15.56%)	67 (17.54%)
Diarrhoea	38 (14.79%)	60 (15.71%)
Dry Mouth	2 (0.78%)	5 (1.31%)
Dyspepsia	1 (0.39%)	2 (0.52%)
Gastrointestinal Disorder	1 (0.39%)	1 (0.26%)
Hyperchlorhydria	1 (0.39%)	1 (0.26%)
Nausea	71 (27.63%)	135 (35.34%)
Vomiting	33 (12.84%)	49 (12.83%)
General Disorders and Administration Site Conditions	2 (0.78%)	2 (0.52%)
Asthenia	1 (0.39%)	1 (0.26%)
Fatigue	1 (0.39%)	1 (0.26%)
Immune System Disorders		
Drug Hypersensitivity	1 (0.39%)	1 (0.26%)
Infections And Infestations	4 (1.56%)	6 (1.57%)
Covid 19	1 (0.39%)	1 (0.26%)
Nasopharyngitis	1 (0.39%)	2 (0.52%)
Upper Respiratory Tract Infection	1 (0.39%)	2 (0.52%)
Urinary Tract Infection	1 (0.39%)	1 (0.26%)
Metabolism And Nutrition Disorders	15 (5.84%)	42 (10.99%)
Decreased Appetite	2 (0.78%)	2 (0.52%)
Hypoglycaemia	13 (5.06%)	40 (10.47%)
Nervous System Disorders	4 (1.56%)	4 (1.05%)
Dizziness	3 (1.17%)	3 (0.79%)
Headache	1 (0.39%)	1 (0.26%)
Skin And Subcutaneous Tissue Disorders	2 (0.78%)	2 (0.52%)
Dry Skin	1 (0.39%)	1 (0.26%)
Urticaria	1 (0.39%)	1 (0.26%)
Oral Semaglutide administered prior to AE onset		

Yes	105 (40.86%)	382 (100.0%)
No	0 (0.00%)	0 (0.00%)
Causality		
Possible	7 (2.72%)	15 (3.94%)
Probable	90 (35.02%)	331 (86.88%)
Unlikely	15 (5.84%)	35 (9.19%)
Death		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
Life-threatening AE		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
In-patient hospitalization/prolongation of existing hospitalization		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
Persistent disability/incapacity		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
Congenital Anomaly/birth defect		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
Important medical event		
No	105 (40.86%)	382 (100.0%)
Yes	0 (0.00%)	0 (0.00%)
Mild	101 (39.30%)	374 (97.91%)
Moderate	6 (2.33%)	7 (1.83%)
Severe	1 (0.39%)	1 (0.26%)
AE related to a technical complaint (TC)	105 (40.86%)	382 (100.0%)
No	105 (40.86%)	381 (99.74%)
Yes	1 (0.39%)	1 (0.26%)
Outcome of adverse event*	105	382
Recovered/resolved	94 (89.52%)	358 (93.72%)
Recovering/resolving	0 (0.00%)	0 (0.00%)
Recovered/resolved with sequelae	3 (2.86%)	4 (1.05%)
Recovering/resolving	3 (2.86%)	4 (1.05%)
Not recovered/ Not resolved	0 (0.00%)	0 (0.00%)
Fatal	0 (0.00%)	0 (0.00%)
Unknown	13 (12.38%)	16 (4.19%)
<i>AE: Adverse event, SOC: System Organ Class, PT: Preferred Term</i> <i>AE reported over total study population</i> <i>*Percentages calculated by number of patients with any AE</i>		

Table S7: Descriptive Summary of patients for whom physician have filled NIS Safety form.

Characteristics	Summary Statistics
Age at time of event (Years)	
N	105 (100.0%)
Mean (SD)	52.10 (9.17)
Median (Q1-Q3)	54.00 (48.00-59.00)
Min, Max	28.00, 68.00
Gender	
N	105 (100.0%)
Female	43 (40.95%)
Male	62 (59.05%)
Height (cm)	
N	105 (100.0%)
Mean (SD)	167.1 (9.93)
Median (Q1-Q3)	167.0 (159.0-175.0)
Min, Max	148.0, 187.0
Body Weight (kg)	
N	92 (87.62%)
Mean (SD)	87.65 (16.16)
Median (Q1-Q3)	88.00 (74.00-97.70)
Min, Max	52.00, 128.0
Missing	13 (12.38%)
Dose	
N	105 (100.0%)
7 mg	44 (41.90%)
14 mg	61 (58.10%)
Action taken to the study product	
N	105 (100.0%)
Dose Increased	1 (0.95%)
Dose not changed	81 (77.14%)
Dose reduced	2 (1.90%)
Drug interrupted	6 (5.71%)
Drug withdrawn	9 (8.57%)
NA	6 (5.71%)
Indication	
N	105 (100.0%)
Diabetes Mellitus	105 (100.0%)
Physician's Alternative Aetiology	
N	22 (20.95%)

Other	4 (18.18%)
Underlying disease	1 (4.55%)
Unknown	17 (77.27%)
Missing	83 (79.05%)
<i>N: Total number of patients used to calculate summary statistics</i> <i>SD: Standard deviation, Q1: 1st Quartile, Q3: 3rd Quartile, Min: Minimum value, Max: Maximum value, NIS: non-interventional study</i>	