

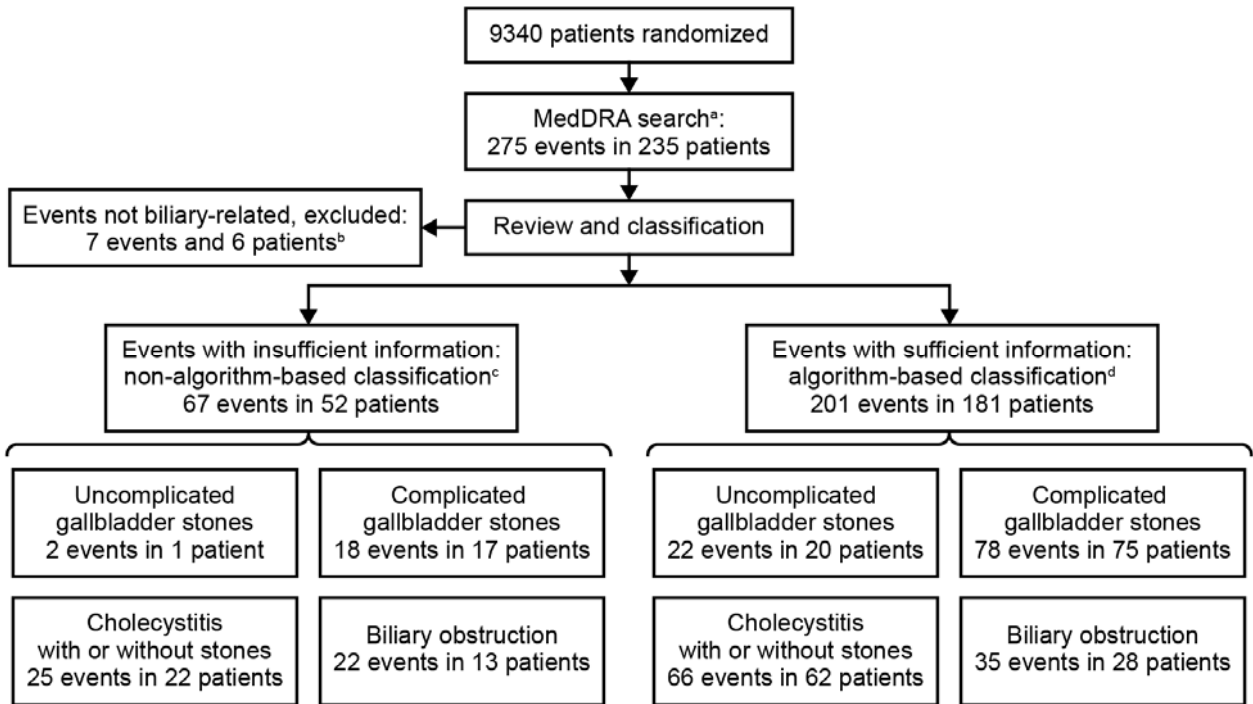
SUPPLEMENTARY DATA

**Effects of liraglutide compared with placebo on events of acute gallbladder or biliary disease in patients with type 2 diabetes at high risk for cardiovascular events in the LEADER randomized trial**

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**Supplementary Figure S1. Schematic of *post hoc* event categorization**



<sup>a</sup>MedDRA search based on SMQs, version 18.0, ‘Functional, inflammatory and gallstone related biliary disorders’ and ‘Infectious biliary disorders’.

<sup>b</sup>The seven excluded events occurred in seven patients, but as one of the patients also had another gallbladder- or biliary tract-related event, this patient was included in the analyses for the other event.

<sup>c</sup>Classification based on clinical judgement and all available information.

<sup>d</sup>Few algorithm-based events underwent additional clinical review (see Table 1 for details). Events of cholestasis but no bile duct stone and events of complicated gallbladder stone and fever were reviewed and regrouped as needed.

MedDRA, medical dictionary for regulatory activities; SMQs, Standard MedDRA Queries.

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**Supplementary Table S1. Events excluded from the analysis**

Patient	Event term*	Treatment group	Baseline demographics (age/sex/BMI)	Reason for exclusion from analyses
1	Biliary fistula	Liraglutide	68 years/M/31.9 kg/m <sup>2</sup>	Biliary fistula found together with a bacterial liver abscess, which was judged to have caused sepsis and subsequent death
2 <sup>†</sup>	Cholangitis	Liraglutide	67 years/M/27.2 kg/m <sup>2</sup>	Treatment for pancreatic cancer; not biliary-related
3	Hyperplastic cholecystopathy	Liraglutide	66 years/M/32.1 kg/m <sup>2</sup>	Asymptomatic gallbladder polyp
4	Jaundice	Liraglutide	52 years/F/28.3 kg/m <sup>2</sup>	Hospitalized with pruritus and jaundice. Hepatitis and biliary origin ruled out
5	Jaundice, cholestatic	Liraglutide	67 years/M/37.8 kg/m <sup>2</sup>	Hospitalized and developed multi-organ failure. No specific biliary disease was found
6	Cholangitis	Placebo	66 years/M/33.5 kg/m <sup>2</sup>	Cholangitis without biliary obstruction due to leukemia
7	Biliary colic	Placebo	79 years/M/31.5 kg/m <sup>2</sup>	Medical history of heart failure and hospitalized with breathlessness and indigestion-type pain. No findings on repeated ultrasound confirming biliary disease

\*The event term presented is the MedDRA-coded ‘preferred term’ based on the investigator-reported term. <sup>†</sup>Another cholangitis event was reported for this patient 3 months later during the trial and that cholangitis event was included in the *post hoc* analysis. Data for all other patients included in this table were excluded from the analysis. BMI, body mass index; F, female; M, male; MedDRA, medical dictionary for regulatory activities.

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**Supplementary Table S2. Category of gallbladder or biliary disease (split by algorithm-based and non-algorithm-based events)**

Category of gallbladder or biliary complication	Events with sufficient information: identified using the algorithm-based classification									Events with insufficient information: identified using the non-algorithm-based classification*								
	Liraglutide, n=4668			Placebo, n=4672			Total, n=9340			Liraglutide, n=4668			Placebo, n=4672			Total, n=9340		
	N	%	E	N	%	E	N	%	E	N	%	E	N	%	E	N	%	E
All events	109	2.34	115	72	1.54	86	181	1.94	201	34	0.73	40	18	0.39	27	52	0.56	67
Uncomplicated gallbladder stones	15	0.32	15	5	0.11	7	20	0.21	22	1	0.02	2	0	0.00	0	1	0.01	2
Complicated gallbladder stones	40	0.86	41	35	0.75	37	75	0.80	78	12	0.26	13	5	0.11	5	17	0.18	18
Leading to cholecystectomy	24	0.51	24	17	0.36	17	41	0.44	41	7	0.15	8	5	0.11	5	12	0.13	13
Cholecystitis	37	0.79	40	25	0.54	26	62	0.66	66	14	0.30	16	8	0.17	9	22	0.24	25
Without gallbladder stones	14	0.30	16	5	0.11	5	19	0.20	21	5	0.11	5	3	0.06	3	8	0.09	8
With gallbladder stones	23	0.49	24	20	0.43	21	43	0.46	45	7	0.15	9	2	0.04	3	9	0.10	12
Unknown stone status	0	0.00	0	0	0.00	0	0	0.00	0	2	0.04	2	3	0.06	3	5	0.05	5
Leading to cholecystectomy	28	0.60	30	19	0.41	20	47	0.50	50	11	0.24	13	7	0.15	8	18	0.19	21
Biliary obstruction	17	0.36	19	11	0.24	16	28	0.30	35	8	0.17	9	5	0.11	13	13	0.14	22
Bile duct stones	16	0.34	18	10	0.21	15	26	0.28	33	6	0.13	6	3	0.06	3	9	0.10	9

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Bile duct stenosis	1	0.02	1	1	0.02	1	2	0.02	2	2	0.04	3	2	0.04	10	4	0.04	13
Intervention																		
ERCP	6	0.13	7	5	0.11	9	11	0.12	16	3	0.06	4	1	0.02	9	4	0.04	13
Papillotomy	4	0.09	5	5	0.11	9	9	0.10	14	0	0.00	0	1	0.02	1	1	0.01	1
Stenting (biliary prosthesis)	0	0.00	0	1	0.02	3	1	0.01	3	1	0.02	2	1	0.02	8	2	0.02	10
Cholecystectomy	10	0.21	11	7	0.15	8	17	0.18	19	2	0.04	2	1	0.02	1	3	0.03	3

\*Based on all available data and clinical assessment of the event as a whole. This analysis mainly relied on the clinical diagnoses provided by the investigators, even if there was limited additive information. %, proportion of patients with an event; E, number of events; ERCP, endoscopic retrograde cholangiopancreatography; *n*, number of patients; N, number of patients with an event.

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