

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Barter PJ, Caulfield M, Eriksson M, et al. Effects of torcetrapib in patients at high risk for coronary events. *N Engl J Med* 2007;357:2109-22. DOI: 10.1056/NEJMoa0706628.

Web Table 1.		
Cancer deaths by primary site		
Primary Site	Atorvastatin (n=14)	Torcetrapib/ Atorvastatin (n=24)
	n (%)	n (%)
Brain	0 (0)	1 (4)
Lung	9 (64)	8 (33)
Breast	0 (0)	1 (4)
Melanoma	0 (0)	1 (4)
Upper GI	1 (7)	2 (8)
Pancreatic	2 (14)	5 (21)
Colorectal	1 (7)	1 (4)
Bladder	0 (0)	1 (4)
Leukemia	0 (0)	2 (8)
Lymphoma	0 (0)	1 (4)
Multiple myeloma	1 (7)	1 (4)

Web Table 2.**Most common reported serious adverse events by preferred term***

Serious Adverse Event	Atorvastatin (n=7,534)	Torcetrapib/ Atorvastatin (n=7,533)	p-value
	n (%)	n (%)	
Chest Pain	126 (1.67)	165 (2.19)	0.02
Atrial Fibrillation	48 (0.64)	41 (0.54)	0.46
Osteoarthritis	39 (0.52)	48 (0.64)	0.33
Angina Unstable	36 (0.48)	48 (0.64)	0.19
Pneumonia	34 (0.45)	46 (0.61)	0.18
Angina Pectoris	33 (0.44)	42 (0.56)	0.30
Fall	36 (0.48)	38 (0.50)	0.82
Prostate Cancer	30 (0.40)	28 (0.37)	0.79
Chronic Obstructive Pulmonary Disease	25 (0.33)	27 (0.36)	0.78
Non-cardiac Chest Pain	27 (0.36)	22 (0.29)	0.48
Syncope	22 (0.29)	26 (0.35)	0.56
Congestive Cardiac Failure	16 (0.21)	24 (0.32)	0.21
Gastrointestinal Haemorrhage	15 (0.20)	25 (0.33)	0.11
Anaemia	14 (0.19)	25 (0.33)	0.08
Cellulitis	17 (0.23)	22 (0.29)	0.42
Abdominal Pain	18 (0.24)	11 (0.15)	0.19
Cholelithiasis	17 (0.23)	12 (0.16)	0.35
Dyspnoea	16 (0.21)	13 (0.17)	0.58
Urinary Tract Infection	14 (0.19)	13 (0.17)	0.85

Serious

adverse events are treatment emergent with onset following randomization and prior to December 2, 2006. Preferred terms based on MEDRA version 8.0. Adjudicated endpoint events were not to be reported as SAEs and are not included in these counts.

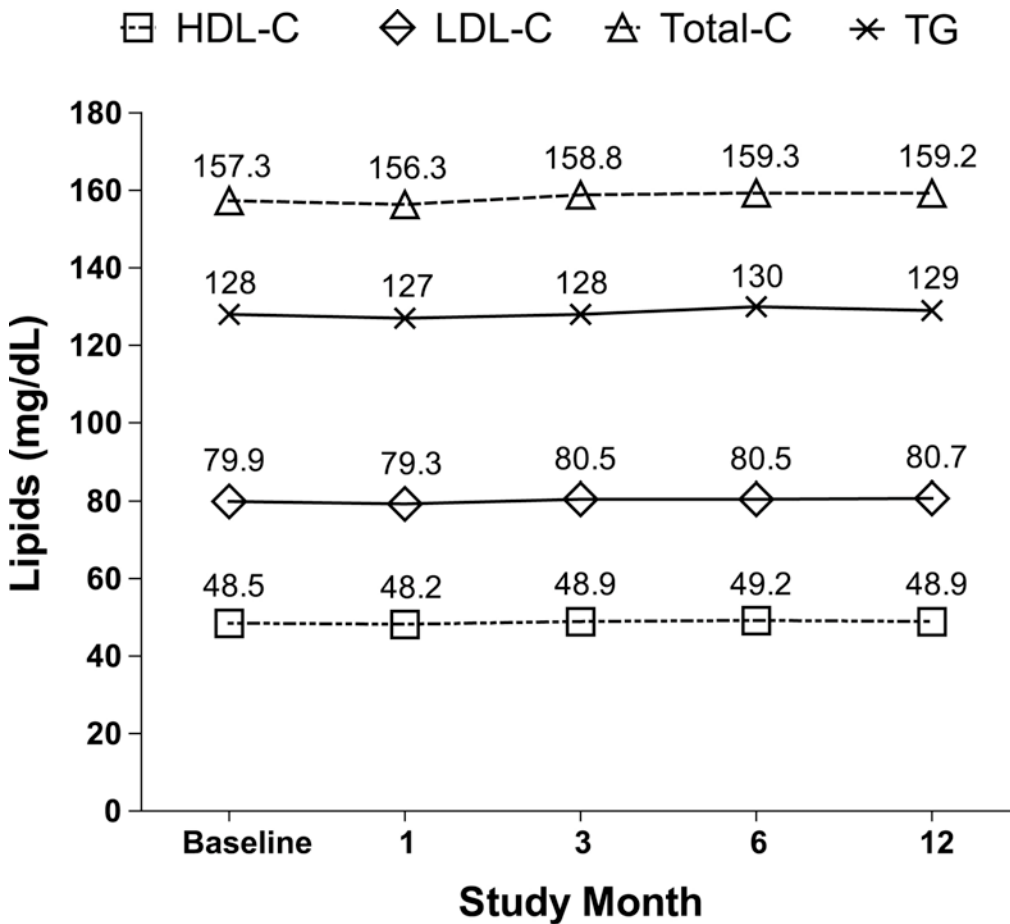
Web Table 3.			
Reported serious adverse events by organ system classification*			
Organ System	Atorvastatin (n=7,534)	Torcetrapib/ Atorvastatin (n=7,533)	p-value
	n (%)	n (%)	
Blood / Lymphatic	23 (0.31)	34 (0.45)	0.14
Cardiac	232 (3.08)	241 (3.20)	0.67
Congenital / Familial / Genetic	4 (0.05)	1 (0.01)	0.18
Ear / Labyrinth	9 (0.12)	6 (0.08)	0.44
Endocrine	2 (0.03)	3 (0.04)	0.66
Eye	6 (0.08)	12 (0.16)	0.16
Gastrointestinal	151 (2.00)	169 (2.24)	0.31
General / Administration Site	176 (2.34)	216 (2.87)	0.04
Hepatobiliary	42 (0.56)	40 (0.53)	0.83
Immune	1 (0.01)	5 (0.07)	0.10
Infections / Infestations	177 (2.35)	182 (2.42)	0.79
Injury / Poisoning / Procedural	89 (1.18)	98 (1.30)	0.51
Investigations	20 (0.27)	17 (0.23)	0.62
Metabolism / Nutrition	34 (0.45)	43 (0.57)	0.30
Musculoskeletal / Connective Tissue	121 (1.61)	127 (1.69)	0.70
Neoplasms, All	136 (1.81)	128 (1.70)	0.62
Nervous System	91 (1.21)	125 (1.66)	0.02
Psychiatric	17 (0.23)	20 (0.27)	0.62
Renal / Urinary	54 (0.72)	58 (0.77)	0.70
Reproductive System / Breast	18 (0.24)	27 (0.36)	0.18
Respiratory / Thoracic / Mediastinal	97 (1.29)	101 (1.34)	0.77
Skin / Subcutaneous Tissue	9 (0.12)	12 (0.16)	0.51
Surgical / Medical Procedure	13 (0.17)	16 (0.21)	0.58
Vascular	74 (0.98)	71 (0.94)	0.80

Serious adverse events are treatment emergent with onset following randomization and prior to December 2, 2006. Organ system classification based on MEDRA version 8.0. Adjudicated endpoint events were not to be reported as SAEs and are not included in these counts.

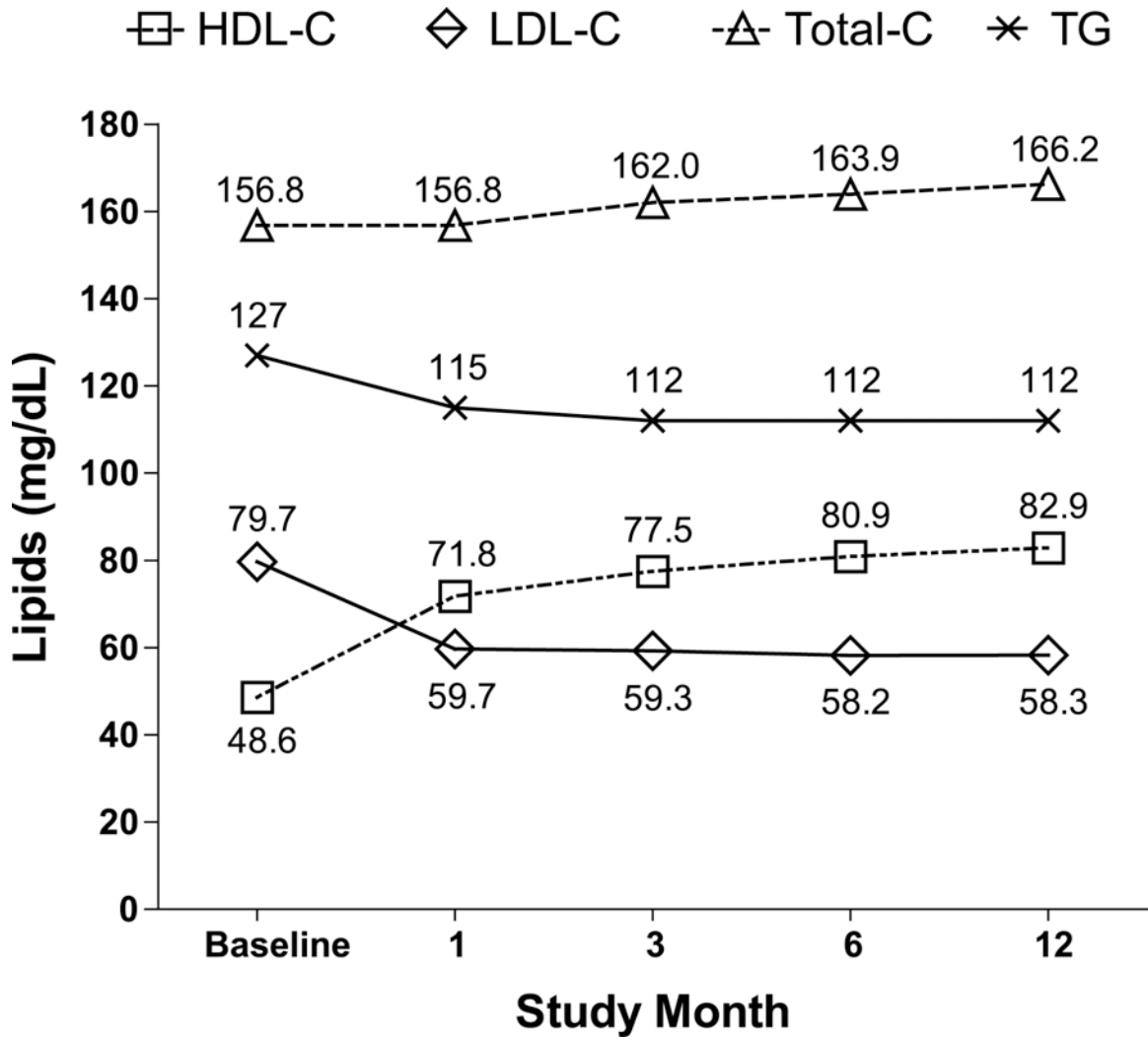
Web Figure 1

Observed on-trial lipid levels by treatment group. High density lipoprotein= HDL, low-density lipoprotein=LDL, triglycerides=TG, C=cholesterol. Values are mean levels except for TG (median). Sample size ranges from 7,502-7,520 at baseline to 6,935-7,033 at month 12. Web Figure 1a is atorvastatin, Web Figure 1b is torcetrapib/atorvastatin.

Web Figure 1a



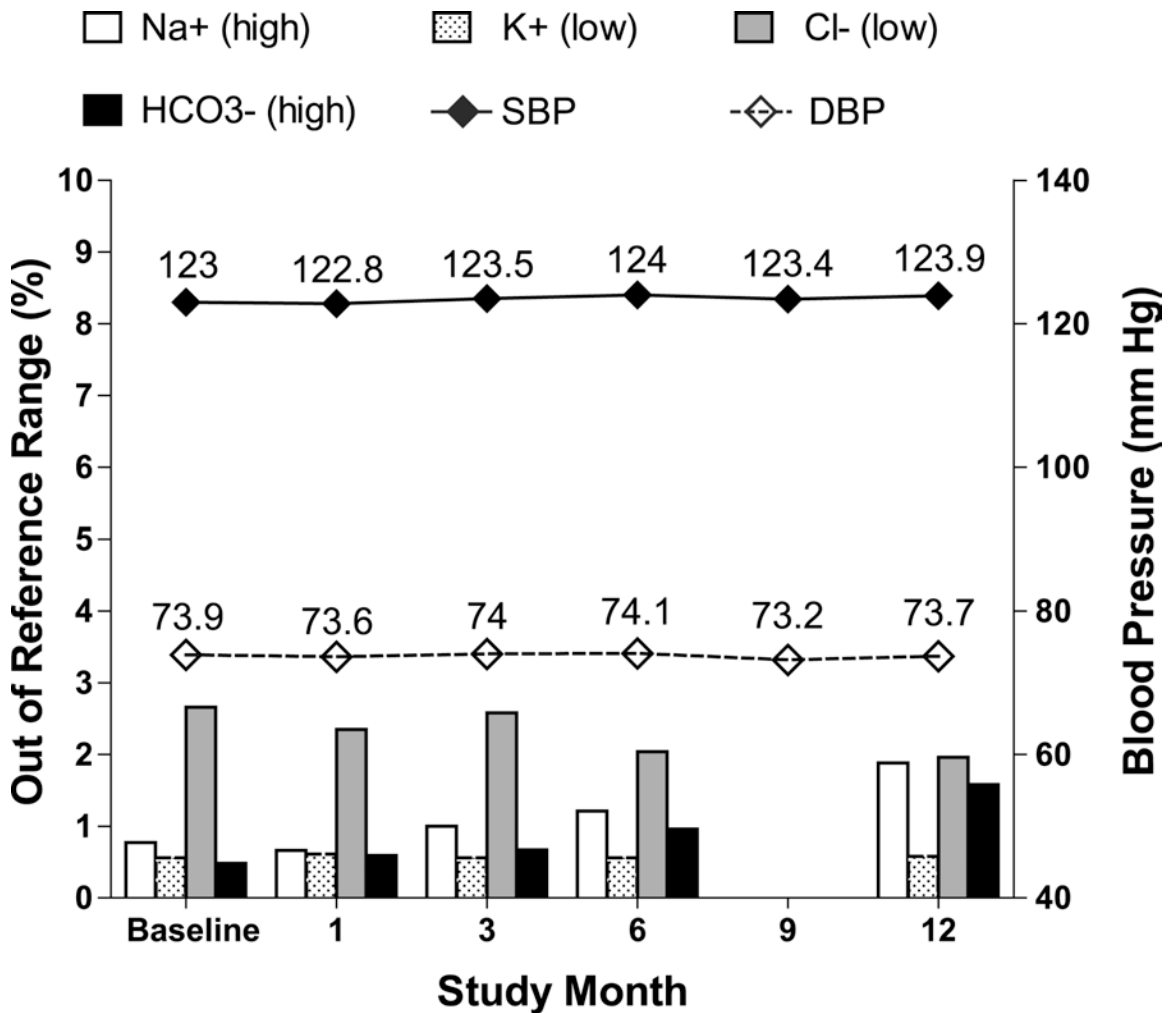
Web Figure 1b



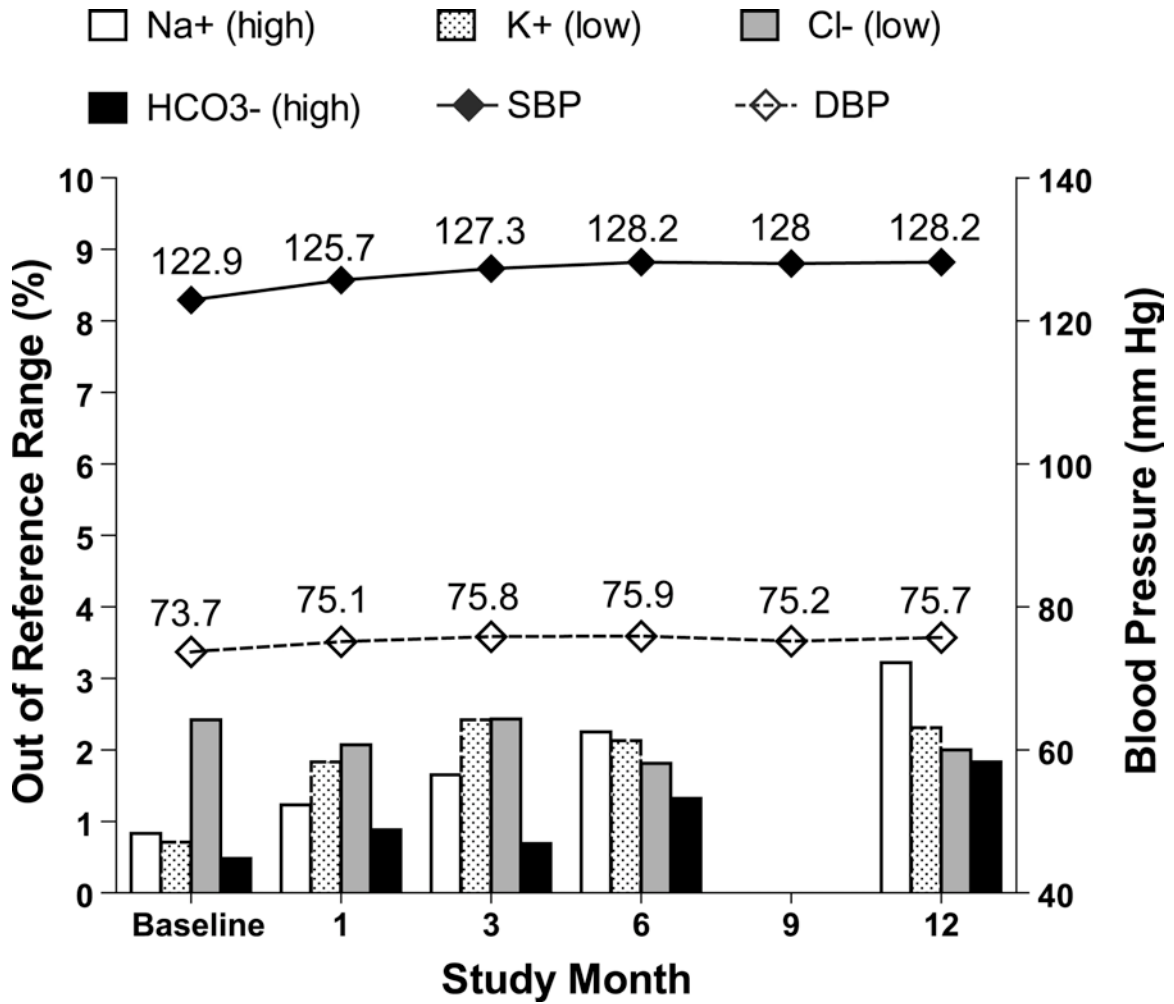
Web Figure 2

Observed blood pressure (BP) and electrolyte abnormalities by treatment group. Systolic=SBP, Diastolic=DBP; values are mean levels. Sodium=Na⁺, potassium=K⁺, chloride=Cl and bicarbonate-HCO₃⁻; values represent the proportion greater than the upper limit of the reference range for Na⁺ (>146 mEq/L) and HCO₃⁻ (>33.3 mEq/L) and below the lower limit of the reference range for K⁺ (<3.5mEq/L) and chloride (<97 mEq/L). Sample size ranges from 7,483-7,554 at baseline to 6,936-7,056 at month 12. Web Figure 2a is atorvastatin, Web Figure 2b is torcetrapib/atorvastatin. Blood samples were not collected at month 9.

Web Figure 2a



Web Figure 2b



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