Change in lipids: characteristics and response to Obeticholic Acid (OCA) in TARGET-PBC, a diverse, large United States (US) real-world cohort





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INTRODUCTION

- Hyperlipidemia is often associated with primary biliary cholangitis (PBC) but does not appear to increase cardiovascular risk.
- Use of obeticholic acid (OCA) in PBC has been associated with a reduction in total cholesterol (TC) primarily related to lowering high-density lipoproteins (HDL).
- A mild increase in low-density lipoproteins (LDL) is also observed in patients with PBC treated with OCA
- The aim of this study was to determine the impact of OCA on lipid profile when treating patients with PBC in a real-world setting.

METHODS

Cohort

- TARGET-PBC is an ongoing longitudinal, observational cohort of patients with PBC managed according to local practice standards at 35 academic and community sites in the United States.
- Participating clinics provided redacted medical records (structured and unstructured data) from consented patients. Patient narratives, laboratory, pathology, and imaging data were extracted and stored in a secured database.
 Patient reported outcome (PRO) measures were also collected on an annual basis.
 Patients contributed blood samples to a biospecimen repository for biomarker validation and translational research.

Study Population

Our study population included 108 patients enrolled in TARGET-PBC between November 9, 2016 and February 14, 2019 and treated with OCA for at least three months.

Outcome Measure

- Statin use was estimated as any documented use of a statin medication from the time of enrollment through February 14, 2019 or in the three years prior to enrollment.
- Cholesterol measurements from the medical record were ascertained before statin use and at the last documented visit during the follow up period.

Statistical Analysis

• The mean percent change in lipid values among patients treated with OCA was compared by statin and cirrhosis status use using chi squared tests.

ACKNOWLEDGEMENTS

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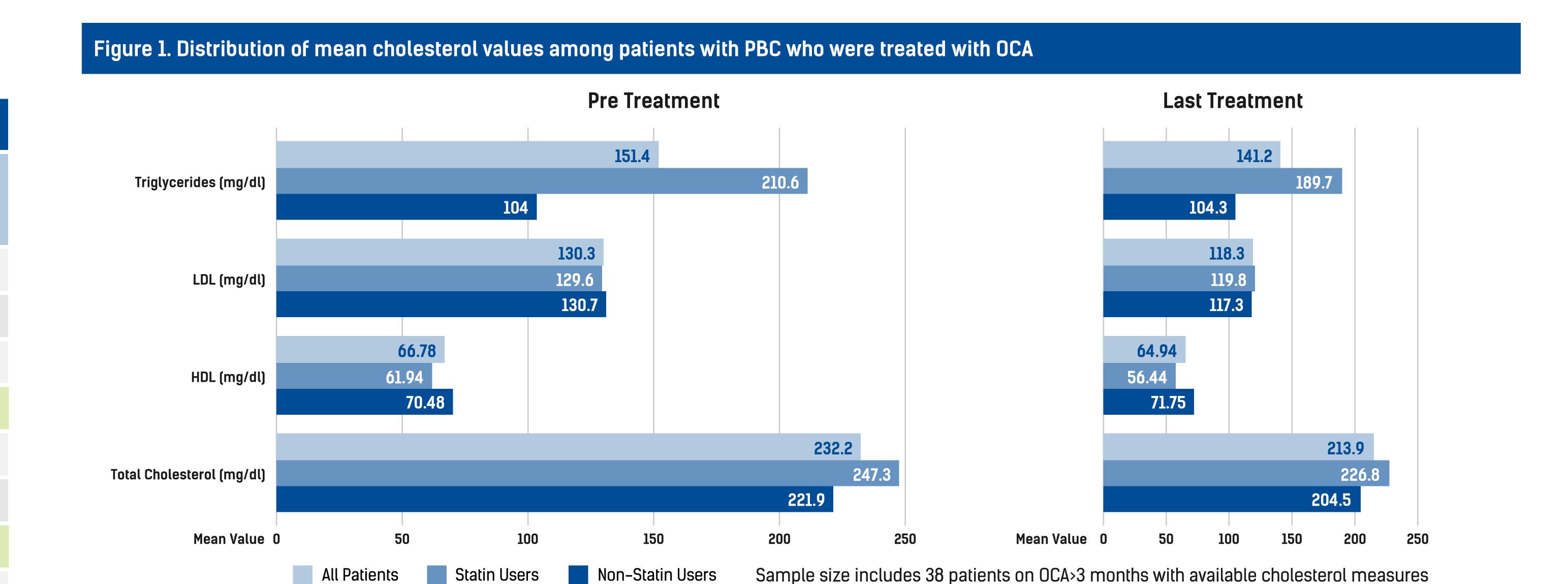
Dr. Levy consults for Target, Blade, Pliant and Cara Therapeutics. She received research grants from Gilead, Intercept, Tobira, NGM, Shire, HighTide, Durect, Novartis, CymaBay, GlaxoSmithKline, Enanta, Genkyotek, Genfit, Zydus and Lilly. She received royalties from Uptodate.

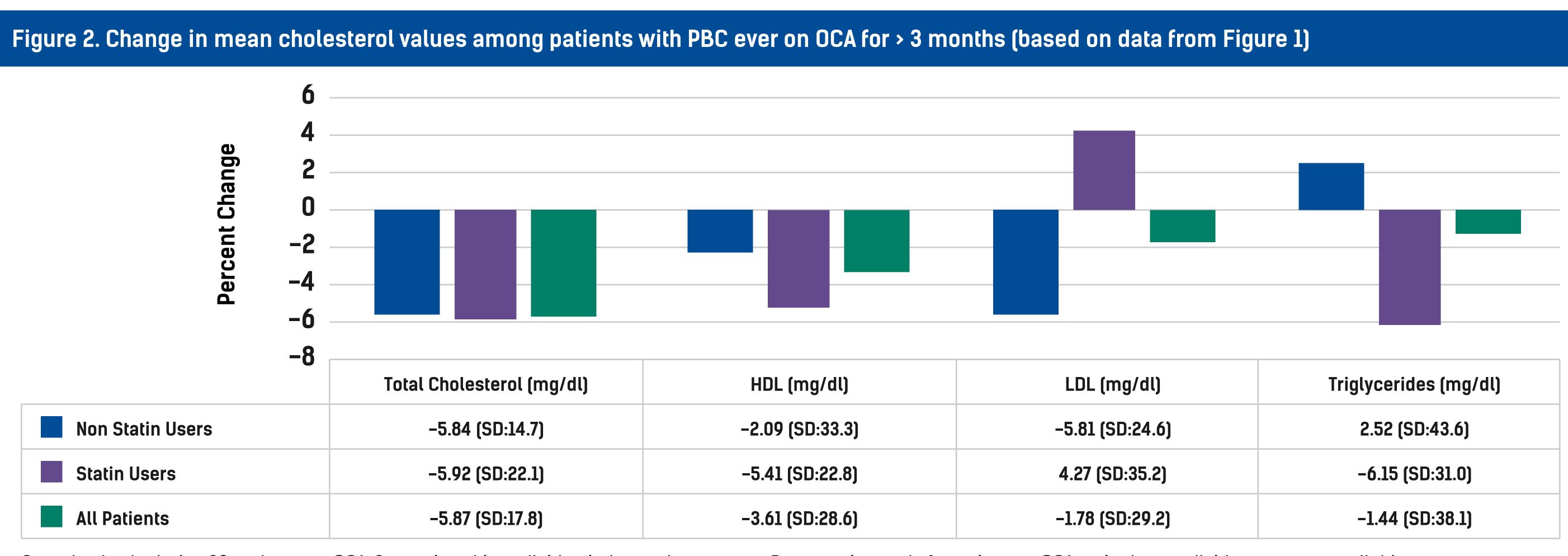
RESULTS

Table 1. Descriptive characteristics	
Patient Characteristics	Patients on OCA > 3 months (N=108) N(%)
Age at Study Entry; Mean (SD)	58.2 (10.89)
Length of OCA treatment months: Mean (SD)	18.6 (11.80)
Min-Max (months)	4-70
Sex	
Female	99 (91.7)
Not Available	_
Race	
White	87 (80.6)
Black	5 (4.6)
Other	5 (4.6)
Not Available	11 (10.2)
Ethnicity	
Hispanic or Latino	27 (25.0)
Not Available	11 (10.2)
Autoimmune Overlap Syndrome	
Yes	12 (11.1)
History of Cirrhosis	
Yes	53 (49.1)
Statin Use	
Any Use	38 (35.2)
Non User	70 (64.8)
Not Available	_

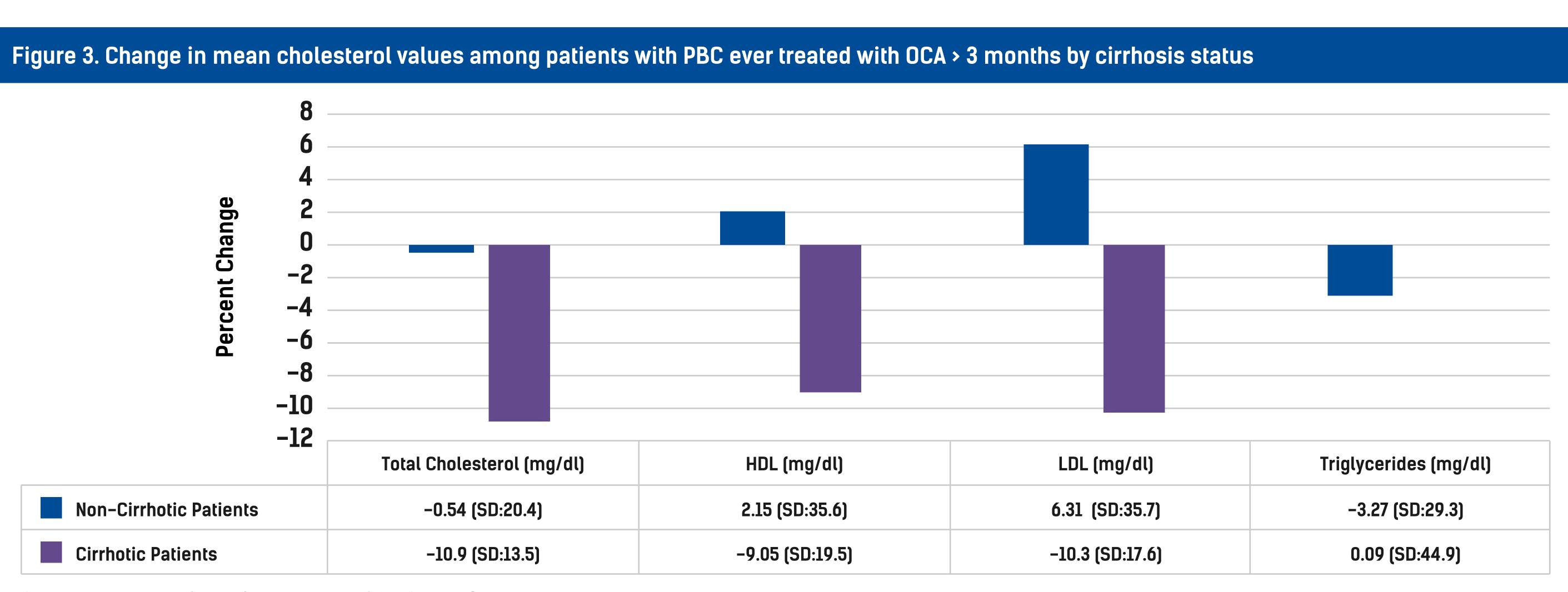
CONCLUSIONS

- Use of OCA was associated with a reduction in HDL and total cholesterol
- The mean change in LDL was significantly greater for patients treated with OCA who were statin users compared to patients not using a statin medication
- OCA was associated with an increase in LDL among patient without cirrhosis, but rather a decrease in LDL among patients with cirrhosis possibly related to natural history of disease
- Additional studies are required to understand the impact of OCA on the lipid profile of patients.





Sample size includes 38 patients on OCA>3 months with available cholesterol measures. Percent change is from the pre-OCA to the last available on treatment lipid measurement. Percent Change in LDL: P=0.04



Sample size includes 108 patients on OCA>3 months Percentage Change Total Cholesterol: p=0.04 Percentage Change in LDL: p=0.05