PCSK9 INHIBITORS: VARIATION IN THE LIPID PROFILE IN A REAL WORLD SETTING

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BACKGROUND

- Proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9i), Evolocumab and Alirocumab, are a new approach in order to obtain a large reduction of cLDL, which is traditionally linked to cardiovascular events.

OBJECTIVES

- To shed light on the variation in the lipidic profile of patients treated with PCSK9i in a setting that differs from clinical trials (Real World Data).

MATERIAL & METHODS

- Observational retrospective study, patients treated with a PCSK9i in our Hospital from Sep 2016 to Feb 2019.

Data from Electronic Clinical History	demographic variables
	diagnosis
	drug and posology
	previous treatment
	prescription for primary or secondary prevention
	adverse events and discontinuation
	Total cholesterol (TC), cLDL, cHDL, and triglycerides (TG)*

Table 1. Variables of the study

*For analitics variables, Before (1 determination) and after (1 to 3 determinations) PCSK9i were obtained.

- Data was statistically analyzed in R statistical software (Version 3.6.1)

RESULTS

Results	N (%)
Diagnoses:	
• heterozygous familial hypercholesterolemia	34 (64%)
• homozygous familial hypercholesterolemia	1 (2%)
• dyslipidemia	18 (34%)
iPCSK9:	
• Evolocumab 140mg/14d	36 (68%)
• Evolocumab 420mg/28d	1 (2%)
• Alirocumab 75mg/14d	14(26%)
• Alirocumab 150mg/14d	2 (4%)
Previous treatments:	
• Ezetimibe	44 (83%)
• Statins	39 (73%)
Adverse effects	8 (15%)
Discontinuance	4 (7%)

Table 2. Results obtained from electronic clinical history

- 53 patients (33[62%] males)
- Median age: 64 years (range 35-83)

	Before iPCSK9 (mean)	After iPCSK9 (mean)	% of change	Mean of the differences	CI 95%	P value
TC	268±84mg/dL	163±75mg/dL	40%	107mg/dL	90-124 mg/dL	<0.0001
cLDL	188±79mg/dL	85±68mg/dL	55%	105mg/dL	90-121 mg/dL	<0.0001
cHDL	49±16mg/dL	52±17mg/dL	4%	-3mg/dL	(-6)-(-1) mg/dL	0.0112
TG	161±95mg/dl	149±103mg/dL	7%	19mg/dl	(-7)-44 mg/dL	0.1563

Table 3. Variation of the lipidic profile

CONCLUSION

- A high decrease of TC and cLDL is observed.
- A slight increase of cHDL levels can be assumed, though clinical trials refer a higher rise.
- No statistically significant reduction of TG was observed in this study as opposed to clinical trials.
- These findings reveal the importance of Real World Data studies, in a context where all the variables are not under control, to disclose the real efficacy of new drugs.

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