EFFICACY, SAFETY AND ACCEPTANCE OF TREATMENT WITH ALIROCUMAB OR EVOLOCUMAB IN PATIENTS WITH DYSLIPIDEMIA

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C10 - Lipid modifying agents

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Background

Alirocumab and evolocumab are two monoclonal antibodies proprotein convertase subtilisin/kexin type 9 inhibitors (iPCSK9) approved for the treatment of hypercholesterolemia.

Objective

Evaluation of the efficacy, safety and patient acceptance of treatment with iPCSK9 in a cohort of patients with dyslipidemia.

Material and methods

Retrospective observational study performed in a university hospital. Included patients started iPCSK9 therapy from September/2016-June/2018.

Data collected: demographic; iPCSK9 dose; prevention; indication; cardiovascular risk factors (CVRF) (excluding dyslipidemia), cardiovascular risk (CVR) (by ESC 2016 guidelines) and statin intolerance.

At baseline (Pre) and 6-12 weeks after starting treatment (Post), LDL value and concomitant lipid lowering agents (LLA) were collected. Additionally, reported adverse events and patient treatment were evaluated through a validated survey (Tatlock, S.et al.,Value in Health, 2015) during the pharmaceutical visit.

Statistics:

- Categorical variables: n (%), Fisher's exact test.
- Quantitative variables: mean ± SD/median (rank), Mann-Whitney U test.

Results

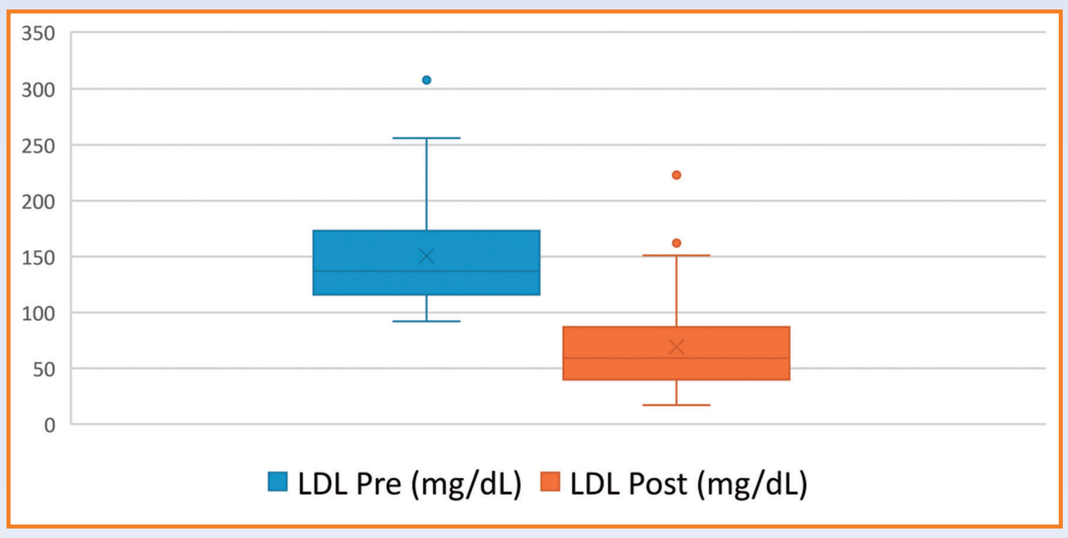
BASELINE	ALIROCUMAB (n=48)	EVOLOCUMAB (n=10)
Male	29 (60.4%)	9 (90.0%)
Age	62.6 ± 8.6	55.8 ± 8.8
Initial dose: 75mg/2weeks	40 (83.3%)	-
Secondary prevention	38 (79.2%)	10 (100.0%)
Indication Polygenic-hypercholesterolemia Familial-hypercholesterolemia Other	 31 (64.6%) 14 (29.2%) 3 (6.3%)	 8 (80.0%) 1 (10.0%) 1 (10.0%)
CVRF 0 1 ≥2	 13 (27.1%) 17 (35.4%) 18 (37.5%)	 1 (10.0%) 2 (20.0%) 7 (70.0%)
High risk CVR	38 (79.2%)	10 (100.0%)
Statin intolerance	25 (52.1%)	4 (40.0%)
Pre LLA	45 (93.7%)	9 (90.0%)

Post: 15 treatment changes in 13 (27.1%) patients with alirocumab (5 (33.3%) alirocumab dose increase, 7 (46.7%) other LLA introduction/dose increase, 3 (20.0%) other LLA suspension/dose decrease). Within evolocumab patients, only one stopped ezetimibe.

Efficacy

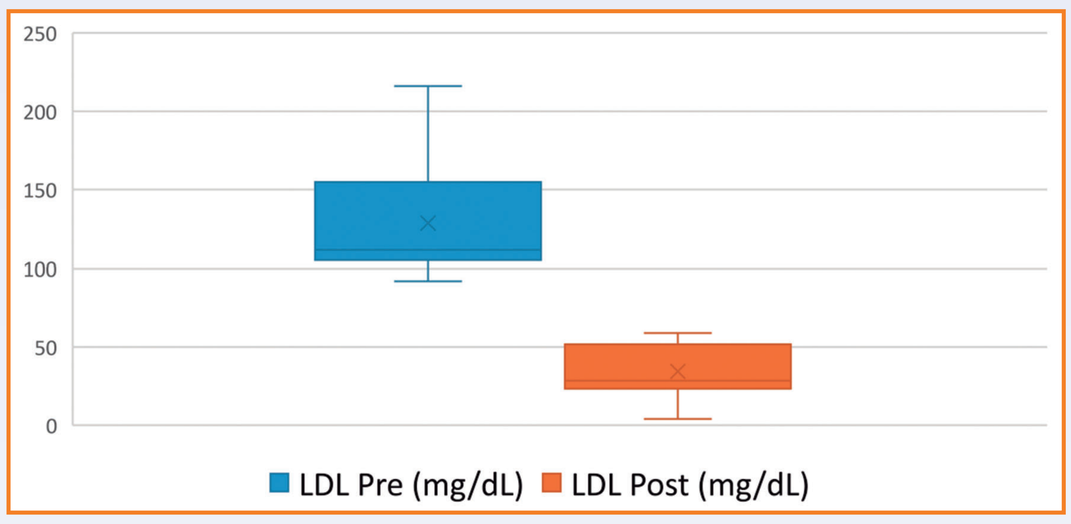
All patients decreased LDL except one patient on alirocumab who was non-adherent.

Alirocumab (n=48)



- The percentage of LDL reduction was 57.7 (13.2-87.5) in alirocumab group and 75.2 (47.3-97.3) in evolocumab group.

Evolocumab (n=10)

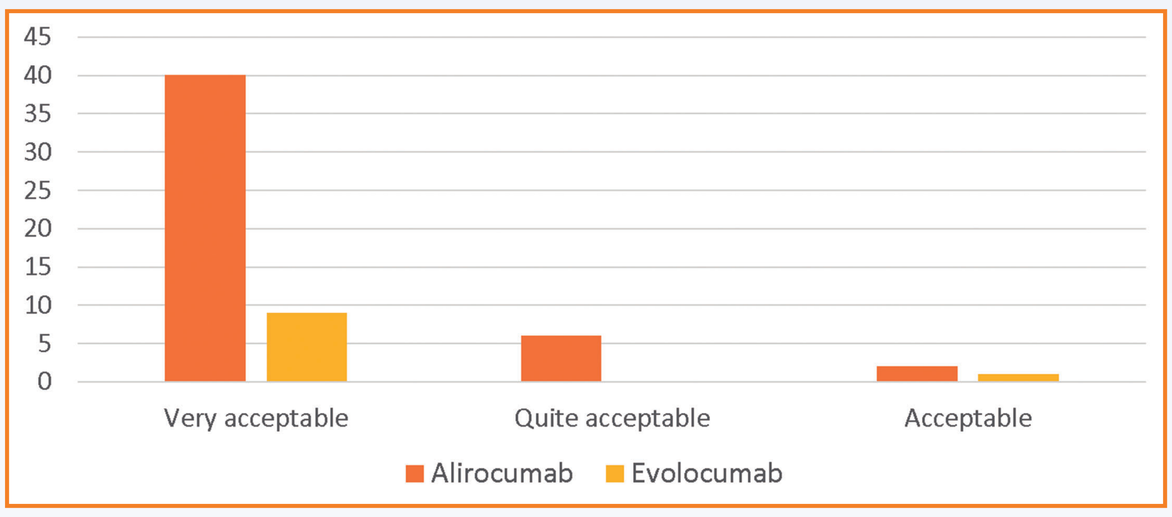


- The number of patients who achieved LDL post <70mg/dL was 29 (60.4%) in alirocumab group and 10 (100%) in evolocumab group.

Acceptance

After the survey, all patients desired to continue iPCSK9.

Treatment acceptance



Safety

Adverse events:

- Alirocumab: 4 patients (pseudogrippal syndrome (3) and constipation (1)).
- Evolocumab: 0 patients.

Conclusions

- After 6-12 weeks of iPCSK9 treatment, all patients reduced LDL level except one that was non-adherent. The LDL reduction ranged between 57%-75% and all patients on evolocumab achieved a LDL<70mg/dL.
- The tolerability was excellent and only mild adverse events in about 8% of patients were experienced.
- A high acceptance of both alirocumab and evolocumab was reported by all patients which would continue iPCSK9 treatment.

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