EFFECTIVENESS AND SAFETY OF INCLISIRAN IN REAL-WORLD EVIDENCE: A MULTICENTRE EXPERIENCE IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA

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BACKGROUND AND IMPORTANCE

Inadequate control of LDL-cholesterol persists in a considerable proportion of patients with dyslipidaemia despite intensive treatment with statins and ezetimibe.

Inclisiran, a small interfering ribonucleic acid that inhibits hepatic synthesis of PCSK9, represents an innovative therapeutic alternative with a twice-yearly dosing schedule after the initial phase.

AIM AND OBJECTIVES

To evaluate the effectiveness and safety of inclisiran in patients with primary hypercholesterolaemia or mixed dyslipidaemia in real-world clinical practice.

MATERIAL AND METHODS

- A retrospective multicentre observational **study** → treatment with inclisiran up to September 2025.
- **Primary variables** were median and interquartile range (IQR) of % reduction from baseline in LDL-cholesterol, total cholesterol, non-HDL cholesterol, HDL cholesterol and triglycerides at 90 and 270 days.
- **Safety** was assessed adverse events and treatment discontinuations.
- **Adherence** to concomitant lipid-lowering therapies was evaluated according to dispensing records.

RESULTS

PATIENTS

A total of 63 patients were included (mean age 64 ± 11 years; 63% male).

EFFICACY

Variable	90 days	270 days
LDL cholesterol	↓ 36% (IQR 6–62)	↓ 39% (IQR 26–51)
Total cholesterol	↓ 23% (IQR 0–42)	↓ 24% (IQR 17–34)
Non-HDL cholesterol	↓ 33% (IQR 1–56)	↓ 36% (IQR 19–50)
HDL cholesterol	↓ 3% (IQR 0–11)	0% (IQR 0–9)
Triglycerides	↓ 12% (IQR 0–29)	↓ 7% (IQR 0–22)

SAFETY

No serious adverse events were reported; however, 8% (5/63) experienced local injection-site reactions and 3% (2/63) discontinued treatment due to lack of effectiveness.

ADHERENCE

Adherence to concomitant lipid-lowering therapies was >80% in 82% (52/63) of patients.

CONCLUSION AND RELEVANCE

Inclisiran was associated with reductions in LDL-cholesterol and total cholesterol in real-world clinical practice, with an acceptable safety profile. Nevertheless, the magnitude of LDL-cholesterol reduction was lower than that reported in pivotal clinical trials.