GLAR
German Lipoprotein Apheresis Registry

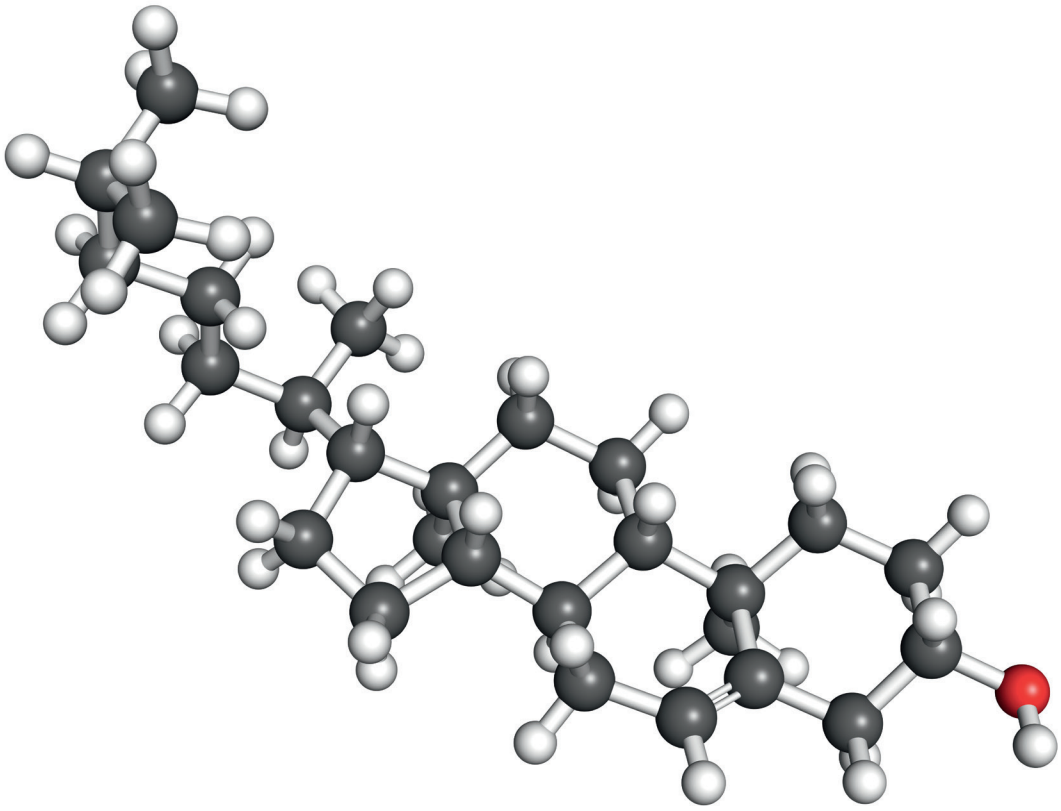
German Lipoprotein Apheresis Registry

Annual Report 2020

Summary

submitted by the Scientific Advisory Board of the Registry

August 2021



DGFF
Wissen, was zählt –
für Herz und Gefäße

Deutsche Gesellschaft
zur Bekämpfung von
Fettstoffwechselstörungen
und ihren Folgeerkrankungen
DGFF (Lipid-Liga) e.V.

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Summary

Objectives of the GLAR
The Federal Joint Committee (G-BA), the highest decision-making body of the joint self-government of physicians, dentists, hospitals and statutory health insurances in Germany defined the indications for lipoprotein apheresis (LA) in its decisions of 2003 and 2008. The 2008 decision requested the recording of patient and treatment data in a registry in an anonymous format. The suggested protocol of a randomized controlled trial did not receive ethical approval. The registry is the only source to prove the effectiveness, safety and therapeutic benefits of LA. In this registry prospective observational data of patients undergoing LA treatment of high LDL-cholesterol (LDL-C) levels and/or high lipoprotein(a) (Lp(a)) levels suffering from progressive cardiovascular disease (CVD) were recorded.

The German Lipoprotein Apheresis Registry (GLAR) was launched in 2012. The data is evaluated on a yearly basis and presented in annual reports. The present report contains the data of 2020 recorded by participating LA centers until 30 April 2021. For comparison, data of the two preceding years are presented as well.

General patient data and formation of subgroups
A total of 6,791 LA treatments were documented in 2020 by 44 LA centers for 1,111 patients. The majority of patients were over the age of 60. More than 40 percent of the patients have been receiving treatment for 1-5 years and approximately one half for more than 5 years. The average treatment frequency was to approximately 4 LA treatments per patient per month for the years under examination.

The following subgroups were stratified based on the lipid profile of the patients at the start of their extracorporeal treatment:

Group A — **Patients with isolated elevation of LDL-C (n = 180)**
LDL-C > 100 mg/dL (2.6 mmol/L) and Lp(a) < 60 mg/dL or < 120 nmol/L or no Lp(a) value indicated

Group B — **Patients with isolated elevation of Lp(a) (n = 500)**
Lp(a) ≥ 60 mg/dL or 120 nmol/L and LDL-C < 100 mg/dL (2.6 mmol/L)

Group C — **Patients with combined elevation of LDL-C and Lp(a) (n = 228)**
LDL-C > 100 mg/dL (2.6 mmol/L) and Lp(a) > 60 mg/dL or 120 nmol/L (this subgroup does not exist in the decisions of the G-BA, nor in the quality report of the National Association of Statutory Health Insurance Physicians (KBV))

Stratifying these subgroups is related to the decisions of G-BA and the experience that LA treatment is considerably more effective regarding cardiac and non-cardiac endpoints for patients with raised Lp(a) levels.

The Lp(a) concentrations are given in mg/dL by certain centers and in nmol/L by others. Since for objective reasons it is not possible to convert one unit to another, the Lp(a) evaluations had to be carried out separately for the two units.

Patients undergoing LA treatment were also examined in observational periods (2, 3, 4, 5, 6 and 7 year follow-up).

In terms of cardiac and non-cardiac endpoints MACE (Major Adverse Cardiac Events) and MANCE (Major Adverse Non-Cardiac Events) of patients were analyzed and compared to the incidence rate before the start of LA (-2 years, -1 year) and prospectively the years with regular LA (+1 year, +2 years…).

Effects of LA on lipid concentrations
Concentrations of LDL-C and Lp(a) were recorded before and after the LA treatments, allowing for calculating their reduction rate. Also, the median values of these concentrations were calculated, representing the patients' actual lipid load, as this level increases during the days between the LA treatments.

The LA's effect on the LDL-C level in groups A and C can be summarized as follow:

Group	A (isolated LDL-C elevation)	C (combined LDL-C and Lp(a) elevation)
Acute reduction	68.25 %	69.84 %
Median level	77.34 mg/dL or 2.00 mmol/L	61.50 mg/dL or 1.59 mmol/L

The LA's effect on the Lp(a) level in groups B and C are summarized in the following table:

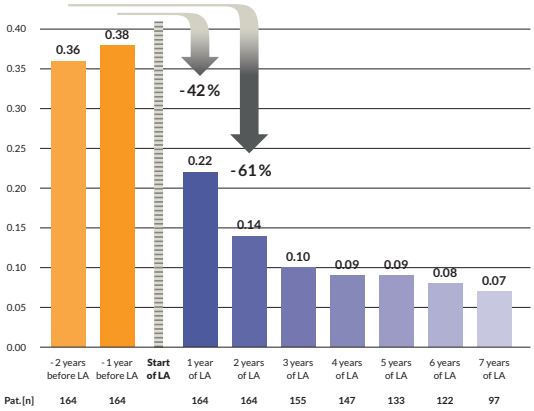
Group	B (isolated Lp(a) elevation)	C (combined LDL-C and Lp(a) elevation)
Acute reduction	72.09 %	73.81 %
Median level	54.20 mg/dL or 98.60 nmol/L	61.50 mg/dL or 104.75 nmol/L

In its 2003 resolution, GB-A stipulated that reduction of LDL-C concentration by a single LA treament must be at least 60 % of the pre-LA concentration. This value is exceeded in all subgroups.

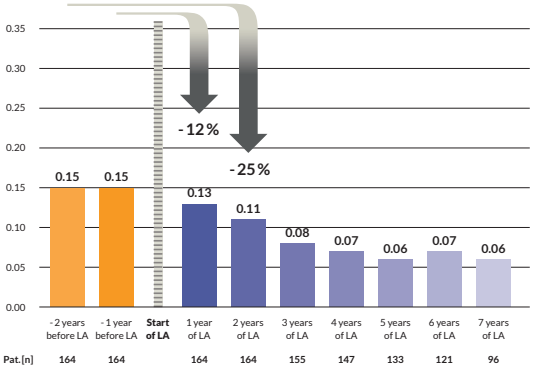
The Lp(a) data indicates a high degree of effectiveness of LA in subgroups B and C as evidenced both by the acute reductions (over 70 %) and the median levels.

Effects of LA on cardiac and non-cardiac endpoints

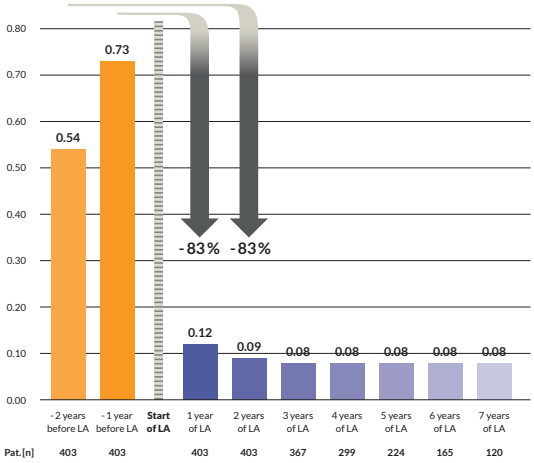
MACE rate of patients with isolated elevation of in LDL-C*



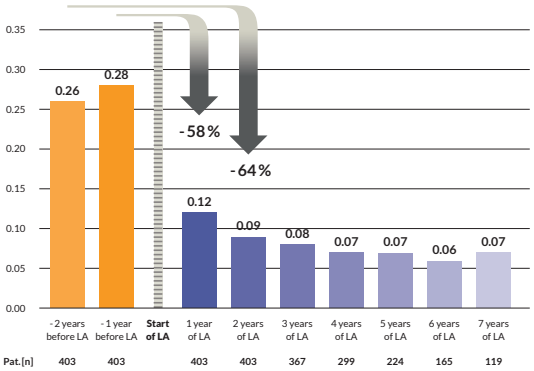
MANCE rate of patients with isolated elevation of LDL-C*



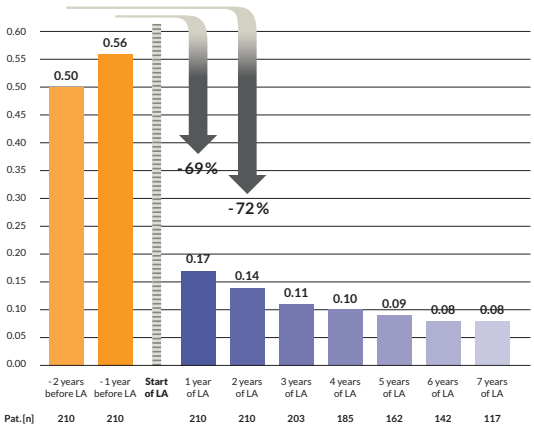
MACE rate of patients with isolated elevation of Lp(a)*



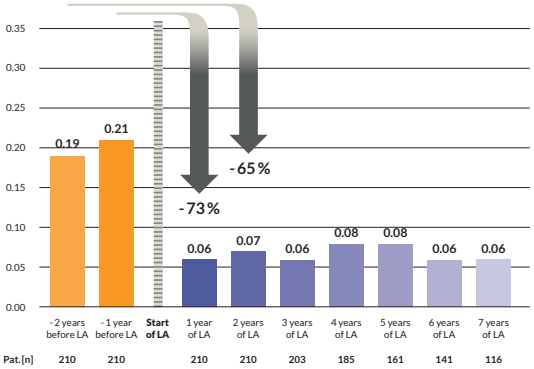
MANCE-Rate of patients with isolated elevation of Lp(a)*



MACE rate of patients with combined elevation of LDL-C and Lp(a)*



MANCE rate of patients with combined elevation of LDL-C and Lp(a)*



* summary average annual rates of the years

MACE and MANCE were effectively reduced in all three subgroups with the exception of MANCE rates in patients with isolated elevation of LDL-C. In these patients time intervals between previous events and commencing chronic LA were longer resulting in a low initial MANCE rate. However, after commencing LA even this rate was 12 % lower in the first year and 25 % lower in the second year.

Such overall clear results were not yet documented in a patient group with comparable extremely high cardiovascular risk with any other lipid lowering treatment. Incidence rates of cardiovascular events continued to be low during regular LA for up to seven years.

Data presented here confirmed that LA treatment was in particular effective in patients with elevated Lp(a) concentrations.

Sponsors/Scientific Advisory Board/Imprint

The German Lipoprotein Apheresis Registry (GLAR) is financially supported by:

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- DIAMED Medizintechnik GmbH, Köln
- Fresenius Medical Care Deutschland GmbH, Bad Homburg
- Kaneka Medical Europe N.V., Eschborn
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Imprint

The GLAR Scientific Advisory Board is responsible for this annual report.

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Database extract dated: April 30, 2021.

www.lipid-liga.de/apherese/apherese-register/