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LipoScan

A new procedure in case of suspected fat metabolism disorders with test for LDL subfractions

SPECIFIC FEATURE

It is a popular fallacy that high cholesterol levels automatically mean an increased heart attack risk. The fact is that nearly half of the patients without heart attack have higher cholesterol levels as well and that a considerable portion of heart attack patients has low cholesterol levels.
Individual differences exist in particular with respect to the LDL levels and here, even more importantly, in the size distribution of the LDL particles. The small LDL particles in particular have a very high atherogenic potential.
Therefore, it is less important how much cholesterol a patient has, but which type of cholesterol is elevated and which size distribution the cholesterol particles have. These are the parameters the risk assessment and the therapy depend on.

LIPOSCAN

is a new procedure that determines the actual heart attack risk by means of a differentiated analysis of HDL and LDL subfractions.

- LipoScan identifies and differentiates all cholesterol particles quantitatively by their size for the first time
- LipoScan differentiates the highly atherogenic, small, dense LDL and IDL from the large, less atherogenic LDL and VLDL and the protective HDL
- LipoScan also determines the recently discussed IDL fractions

FIELD OF APPLICATION

Identifying and treating risk patients with fat metabolism disorders.

CLINICAL BENEFIT

Clinical benefit for screening, treatment decisions and monitoring of lipid disorders associated with risks of coronary artery diseases:

- determination of the patient's true atherogenic risk
- reducing possibly counterproductive drugs
- carefully targeted therapy
- therapy control: particularly important since sometimes, in case of administration of cholesterol-lowering drugs, the total cholesterol decreases, but the atherogenic LDL particles accumulate. In this case, a normal LDL control would suggest a seeming therapy success.

DESCRIPTION

In-vitro diagnostic test for separating and measuring cholesterol in lipoprotein fractions and lipoprotein subfractions.
LipoScan measures the cholesterol level in mg/dl in every lipoprotein (sub)fraction from VLDL to HDL (in all: 14 parameters: total cholesterol, total LDL, HDL, VLDL, 3 IDL fractions, 7 LDL fractions).
The test has been approved by the FDA in the USA.

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Background information

Demographic studies have shown that the classical lipid profiles of patients with coronary artery diseases do not significantly differ from those of healthy persons.
Nearly 50% of the persons who develop a cardiac disease have "normal" cholesterol levels.

LDL cholesterol, the lipid that is most frequently associated with cardiovascular diseases, is heterogeneous (different) and consists of up to seven subfractions. Large circulating LDL particles are less atherogenic.

Small dense LDL particles are associated with a three times higher risk of cardiovascular diseases.

Traditional lipid profiles do not identify the risk of cardiovascular diseases that are caused by the presence of small dense LDL and IDL particles.

Dangerous LDL particles may hide behind normal cholesterol levels and, conversely, elevated cholesterol levels do not inevitably have to be associated with a heart attack risk.

Patients supposed to need treatment (on account of high cholesterol levels) turn out to be not at risk, whereas persons supposed to be healthy (on account of normal cholesterol levels) turn out to be risk patients (see figures 1 and 2).

The testing for small LDL subfractions has been approved by the "National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III)" as a new method that can be used to identify the risk of cardiovascular diseases.

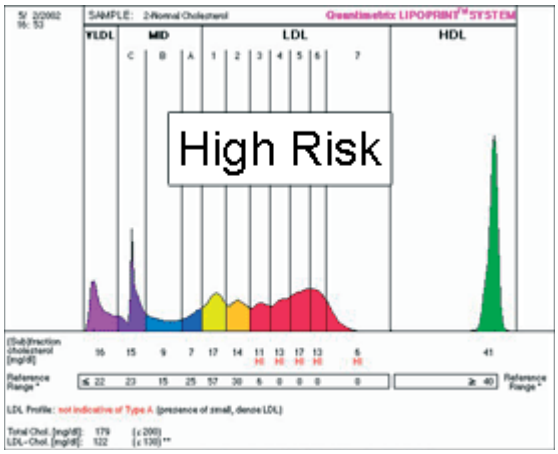

Fig. 1: Example of a high risk despite low cholesterol level of 179 mg/dl (normal LDL level: 122 mg/dl; yet increased level of atherogenic LDL particles).

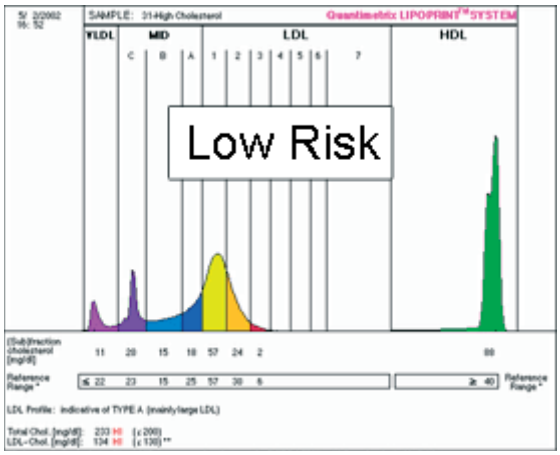

Fig. 2: Example of a small risk despite high cholesterol level of 233 mg/dl (high LDL level: 134 mg/dl)

PRINCIPLE OF ANALYTICS

LipoScan separates and quantifies all lipoprotein (sub)fractions including the "large", less atherogenic LDL-1 and LDL-2 and the "small", highly atherogenic LDL-3 to LDL-7. Patient results are compared according to the NCEP ATP III guidelines.
The test also measures VLDL and IDL cholesterol linked with type III dyslipidaemia and associated hyperlipoproteinaemias.

Case histories

CASE STUDY I

Patient A, 65-year-old male Northern European, had his LipoScan profile made (see figure 3). The profile shows small, dense LDL subfractions 3, 4, and 5 (red portion of the profile) that were associated with an increased risk of cardiovascular diseases.

After three months of niacin therapy, combined with a dietary measure and more physical activity, the patient's LipoScan profile improved significantly and showed a normal distribution of LDL subfractions (figure 4).

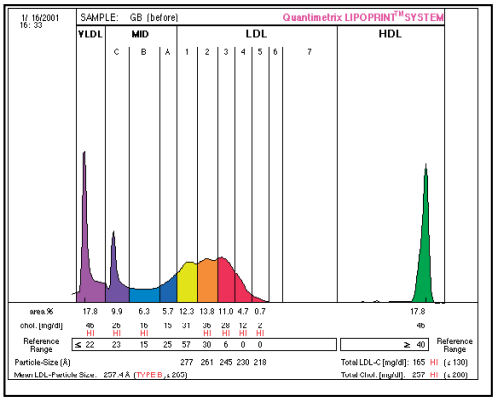

Fig. 3 Patient A - baseline LipoScan profile

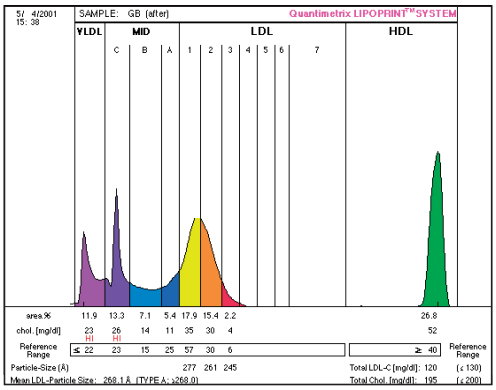

Fig. 4 Patient A – profile after 3 months

CASE STUDY 2

Patient B, 42-year-old male patient, had his LipoScan profile made (see figure 5) while he was following a typical vegetarian-Asian-Indian diet, rich in carbohydrates and fat. In most of the fractions, the profile shows high cholesterol levels with an LDL distribution shifted to atherogenic, small, rather dense subfractions 3 and 4 (red portion of the profile). After two months of vegetarian diet with focus on soybean protein, physical activity and less carbohydrates and fat, the patient's profile became substantially normal (figure 6).

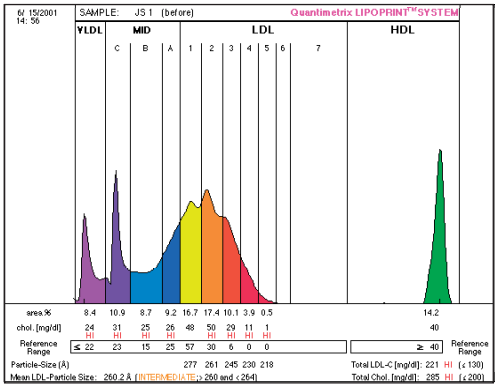

Fig. 5 Patient B – baseline LipoScan profile

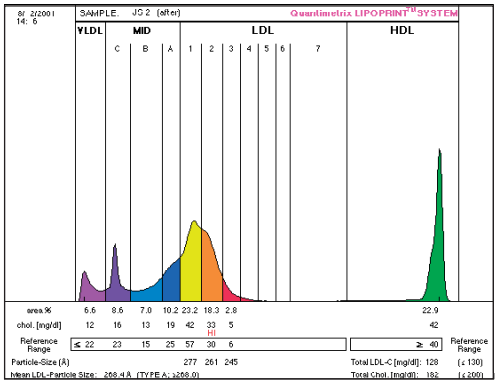

Fig. 6 Patient B – profile after 2 months

FINDINGS

- normal reference ranges, based on the guidelines of the "National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III)"
- levels outside the reference range are marked in red
- easily interpretable profile highlighted in colours distinguishes a normal type A lipid profile from an abnormal non-type A profile

FOLLOW-UP EXAMINATIONS

If high quantities of atherogenic LDL particles have actually been found, there will be the possibility to identify the cause of these findings.
The interaction of various genes may be responsible in this case. They can be identified by means of a simple genetic test. This can be used to derive a specific, individual therapy for the patient. This therapy comprises both allopathic approaches using lipid-lowering drugs and the well-targeted change of living habits and nutrition. It is made clear to the patient using graphics what different ways of living mean in connection with his genetic profile. This makes it possible for the patient to influence this himself / herself.

PRE-ANALYTICS AND PROCEDURE

- Please only send fasting levels as serum or EDTA plasma (12 hours)
- Samples can be stored up to 5 days at 2 to 8 degrees centigrade
- Processing time approx. 1week

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