

A Novel Procedure for Cardiovascular Risk Assessment

Introduction

Cardiovascular disease is the leading cause of death in the developed world. Due to the high mortality rate many studies have been performed in order to understand what the main cardiovascular risk factors are. The term “cardiovascular risk factor” refers to the series of traits, factors, and characteristics predisposing to development of atherosclerosis. Atherosclerosis is a chronic inflammatory and autoimmune disease.

Elevated total homocysteine (tHcy) levels are regarded as a “candidate” vascular risk factor because of their statistical association to an increased risk of developing vascular disease. Candidate molecules/autoantigens include Heat Shock Proteins (HSPs); Among them, HSPA1A (Hsp 70) is one of the most studied ones. As HSPA1A has anti-inflammatory properties, low levels would promote a proinflammatory state and increase the vulnerability of the arterial wall to the damaging action of vascular risk factors. Possible polymorphisms (SNPs) of the regulatory region of HSPA1A could affect HSPA1A protein synthesis, determining diminished, normal or increased HSPA1A-producing phenotypes.

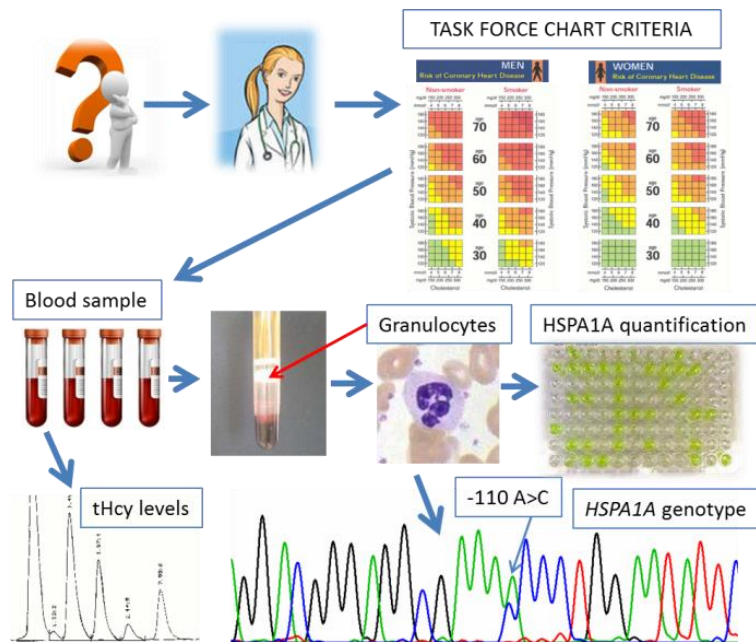
A study was made to identify SNPs in the *HSPA1A* regulatory region and evaluate whether any of them could affect HSPA1A synthesis and to establish whether moderately elevated homocysteine levels is associated to an increased risk of atherosclerosis.

Invention

The invention is a procedure to evaluate the degree of cardiovascular risk. Firstly, a classification of the risk level is done according Task Force Chart Criteria based in the joint assessment of classical cardiovascular risk factors present. Secondly, the novel procedure takes into account the possible influence of the total homocysteine levels, intraleukocytic HSPA1A protein concentration and the polymorphisms of the gene *HSPA1A* allowing the reclassification of the risk group. Thereafter, if necessary, preventive measures and additional medications are determined in order to avoid the occurrence of a cardiovascular event.

State of Development

The procedure is based on an observational, epidemiological study of 452 (both sexes aged 40–60 years) subjects; a randomly selected Spanish population was studied. The study identified that moderate elevated homocysteine levels are associated to the development of atherosclerosis, regardless the C677T genotype. The -110A/C and +190G/C polymorphisms of the *HSPA1A* regulatory region effectively are related to a decrease in the production of intragranulocytic HSPA1A, and thus a reduction in its anti-inflammatory properties, therefore representing a possible genetic marker of risk for the development of atherosclerosis. The procedure needs further validation with a larger sample before entering daily clinical practice.



Advantages

The procedure has the following advantages:

- Combines and enhances the current methodologies for cardiovascular risk evaluation.
- A simple venous blood sample is used.
- Is based on a study of a representative sample of the Spanish population.

Application

The procedure has a clinical application.

Market Potential

The global high mortality rates due to cardiovascular disease incur a tremendous cost for the society and create a need for development of novel preventive strategies, cardiovascular risk evaluation being one of the fundamental ones.

IPR Position

Spanish Patent granted. Application number P200901923.

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Opportunity

The novel procedure is available for licensing.

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