



Background

Diseases of the heart and circulatory system (cardiovascular disease or CVD) are the main cause of death in the UK: accounting for just under 233,000 deaths in 2003.¹

More than one in three people (38%) die from CVD.

- The main forms of CVD are coronary heart disease (CHD) and stroke.
- About half of all deaths from CVD are from CHD and about a quarter are from stroke (Table 1.2).
- CHD by itself is the most common cause of death in the UK. Around one in five men and one in six women die from the disease.
- CHD caused just under 114,000 deaths in the UK in 2003 (Table 1.3 and Figs 1.3a and 1.3b).
- CVD is one of the main causes of the 63,000 premature death in the UK (death before the age of 75). 34% of premature deaths in men and 25% of premature deaths in women are from CVD (Figs 1.3c and 1.3d).

The National Service Framework for Coronary Heart Disease Guidelines for achieving the national target to reduce death from coronary heart disease (CHD), stroke and related disorders by 40% in people aged under 75 years by the year 2010.²

Sadly, at this time one in four men and one in five women will die from CHD which is the commonest cause of death in the UK.

- One of the factors involved is the level of circulating cholesterol in the blood.
- The National Service Framework for Coronary Heart Disease Guidelines recommends Statin therapy only for those patients with pre-existing disease or a 10 year risk of 30% or more.
- 100,000's of people who are not within this risk sector are therefore offered no alternative but lifestyle changes to maintain healthy their cholesterol levels.

Recently, the EU and FDA have approved the use of Plant Sterols as safe for use in food products such as margarines and yoghurts.

VITACHOL contains Plant Sterols derived from wood processing. Wood derived Plant Sterols have been shown to reduce high cholesterol levels within 30 days versus placebo.

VITACHOL is formulated with a pleasant new vanilla flavour in a chewable capsule which is taken at the time of eating or can be sprinkled onto food.

What Are Cholesterol and Lipids?

Most people think that cholesterol is bad for them. In fact cholesterol and many other lipids are essential nutrients in the body. Lipids are fats or fat-like substances found in plants and animals and Cholesterol is an important lipid, which in spite of its bad press, is an essential nutrient necessary for:

- repairing cell membranes,
- manufacturing vitamin D on the skin's surface,
- creating hormones, such as oestrogen and testosterone.

Two thirds of the cholesterol we need is manufactured in the liver when stimulated by eating saturated fat and the rest is supplied by the diet.

Lipids, including cholesterol are transported around the body in spherical-shaped bodies called lipoproteins. These lipoproteins are categorised according to size and include, low density lipoproteins (LDL), and high density lipoproteins (HDL).

Low Density Lipoproteins (LDL)

The primary villain in the cholesterol story is low density lipoprotein (LDL). This lipid, which transports about 75% of the blood's cholesterol to the body's cells, is normally a major criteria for needing to lower high cholesterol levels. LDL can be easily oxidised by free radicals at blood vessels walls and attach to the lining causing plaque or atheromas to form. These are the basis of blocked arteries causing Coronary Heart Disease (CHD) or Cardiovascular Disease (CVD).

High Density Lipoproteins (HDL)

High levels of high density lipoprotein (HDL) are important for health. HDL serves to remove cholesterol from the walls of the arteries and return it to the liver. High HDL levels (above 1.0mmol/l) appear to protect arteries from dangerous narrowing and so help prevent heart attacks. Lower HDL levels are associated with an increased risk of CHD.

LDL and Coronary Heart Disease.

Free Radicals are released naturally during the body's chemical processes. If LDL collects on arterial walls, free radicals released from the wall membranes attack and modify its form resulting in oxidized LDL. This in turn triggers white blood cells in the immune system to gather at the site, forming a fatty substance called plaque and causing inflammation. As the plaque builds up, the arterial walls slowly constrict, reducing blood flow. This process -- atherosclerosis -- is the major contributor to the development of coronary heart disease when vital tissues in the heart fail to receive enough of the blood-borne oxygen they need and are damaged.

Cholesterol Guidelines

A number of studies have now demonstrated that reducing LDL and total cholesterol levels and boosting HDL levels have improved survival and prevented heart attacks in people with or without heart disease, even when their cholesterol levels were considered normal. Many experts now urge that everyone should strive for total cholesterol levels of 5mmol/l or below and LDL cholesterol level of 3mmol/l or below.

Risk factors include

- a family history of heart problems
- smoking,
- high blood pressure,
- diabetes,

- being older (over 45 for men and 55 for women),
- Lack of exercise.

People with existing heart disease should aim for LDL levels of below 3mmol/l. High HDL-cholesterol levels are as important as low LDL levels, particularly in women; experts recommend 1mol/l and above.

What Can Be Done About It?

- Even modest lowering of cholesterol in those whose levels are high, whether through drug therapy or lifestyle changes, reduces the risk of disability and death from heart disease.
- Every time a person's cholesterol level drops by 1%, the risk of heart disease drops by 2%.

Lifestyle changes to lower high cholesterol levels a careful diet, healthy lifestyle and **reduction in cholesterol absorption**.

VITACHOL

Naturally occurring plant sterols to help maintain healthy cholesterol levels and Cardiovascular Health.

Introduction

These days everyone is aware of cholesterol levels and the importance of keeping these within normal ranges.

How can Plant Sterols Help?

- ❑ Plant sterols naturally exists in plants and are destroyed when food is processed.
- ❑ Plant sterols can play a role in helping to maintain normal cholesterol levels as part of a healthy diet and lifestyle.
- ❑ **VITACHOL** contains the naturally occurring plant sterols and stanols that may help to support a healthy cardiovascular system.
- ❑ **VITACHOL** plant sterols are unesterified and reduce the risk of impaired fat-soluble vitamin and Beta-carotene absorption.

What are Plant Sterols?

- ✓ Plant sterols (sometimes called Phytosterols), are natural components found in virtually all plants and are naturally part of our diet. In the western hemisphere we eat far less plant sterols per day than in other parts of the world.
- ✓ Plant sterols are easily destroyed when food is produced industrially.
- ✓ There are 40 plant sterols but the most abundant is Beta-sitosterol.

Why are they useful to us?

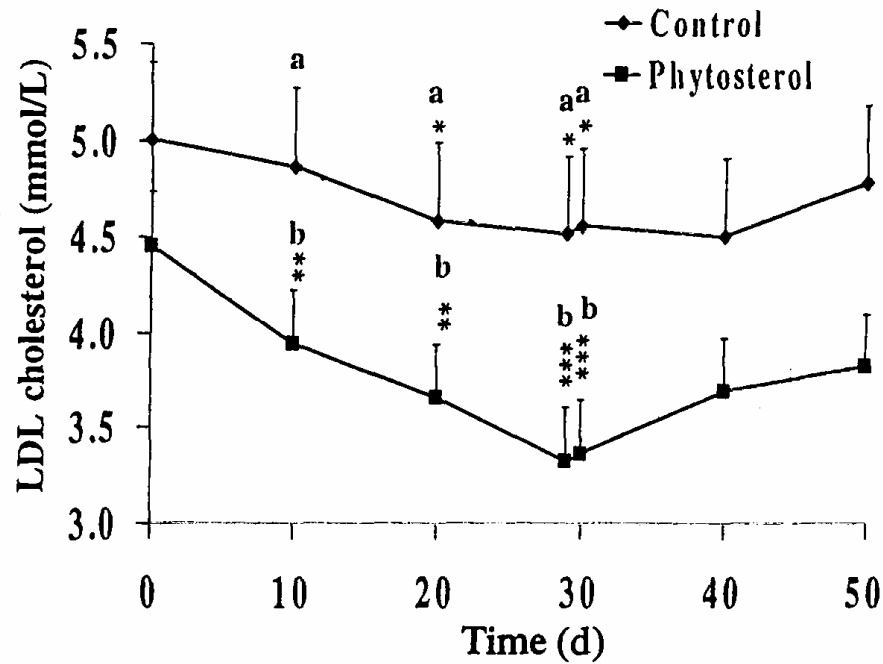
- ✓ Plant sterols have a similar structure to cholesterol and when eaten lower the absorption of cholesterol from the digestive system into the blood. This is very useful if you wish to maintain normal healthy cholesterol levels.
- ✓ Because they are similar in chemistry to cholesterol, they dilute the cholesterol and so less is absorbed following digestion.
- ✓ There are many studies from the 1950's to 2004 showing the benefits of plant sterols and how safe they are.

Phytosterols And Regulatory Position

Phytosterols are being incorporated into food products such as margarine, yoghurts etc. They have been assessed by both the European Union (EU) and FDA. In the EU, phytosterols have been approved as safe for food use by the European Food Safety Agency (EFSA) in 2004. In the USA, the FDA has granted phytosterols the recognition of *Generally Regarded As Safe (GRAS)* so allowing for their use in food products.

Recent studies indicate that eating 1-2g per day of plant sterols can significantly reduce LDL blood levels according to age.

Effect of VITACHOL-Like Ingredients Upon LDL Cholesterol Levels.



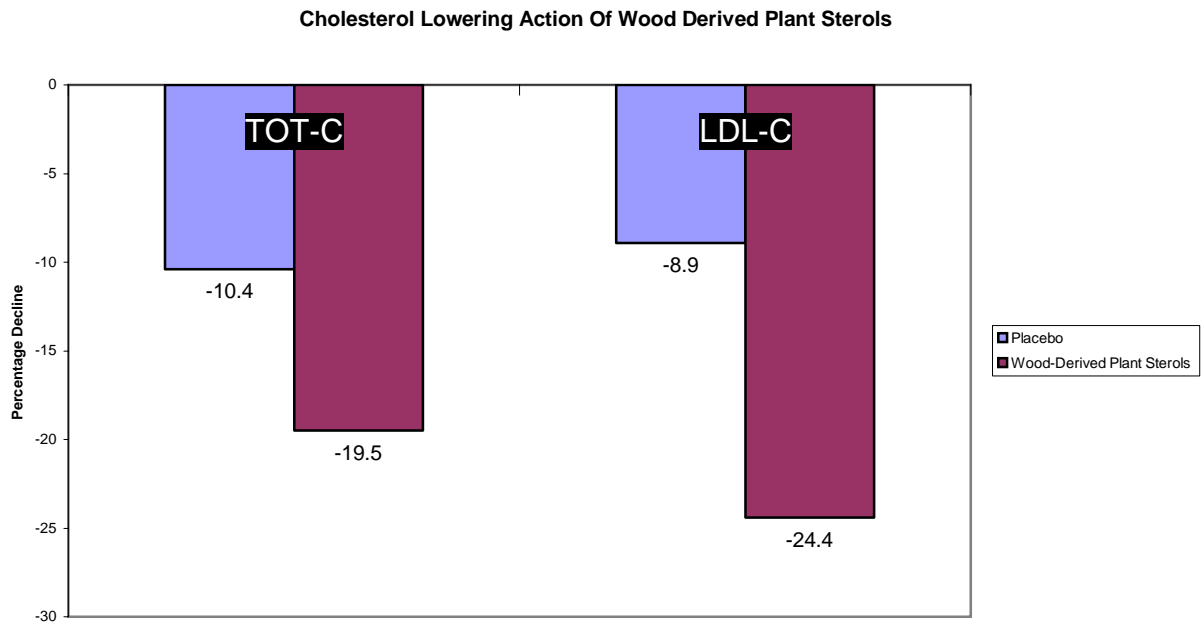
Conclusion:

Addition of blended phytosterols to a prudent North American diet improved plasma LDL cholesterol concentrations by mechanisms that did not result in significant changes in endogenous cholesterol synthesis in hypercholesterolaemic men.

Am J Clin Nutr 1999

This study used phytosterols extracted from wood processing which is the source of **VITACHOL** materials. MAXAVITA also use phyto sterols extracted from wood processing with the same mixture and composition as used in the study referenced.

Effect Of VITACHOL Ingredients Upon Total Cholesterol and LDL Cholesterol vs. Placebo.



“Cholesterol-lowering efficacy of a sitostanol-containing phytosterol mixture with a prudent diet in hyperlipidaemic men.”

Am J Clin Nutr 1999;69:1144–50.

- VITACHOL contains plant sterols in amounts used in the modern studies recently published.
- VITACHOL plant sterols help to reduce the uptake of cholesterol from food.
- Studies indicate that up to a 25% reduction in heart disease would be expected if 2g of plant sterol or stanol were to be ingested daily.

VITACHOL might be a useful in people wishing to maintain healthy cholesterol levels as part of a healthy lifestyle regime.

Direct comparison of a dietary portfolio of cholesterol-lowering foods with a statin in hypercholesterolemic participants.

Am J Clin Nutr. 2005 Feb;81(2):380-7

Jenkins DJ

OBJECTIVE: The objective was to compare, in the same subjects, the cholesterol-lowering potential of a dietary portfolio with that of a statin.

DESIGN: Thirty-four hyperlipidemic participants underwent all three 1-month randomised treatments as outpatients.

Control Diet:- A very low-saturated-fat diet.

Statin Diet:- the same diet plus 20 mg lovastatin.

Portfolio Diet:- diet high in plant sterols (1.0 g/1000 kcal), soy-protein foods (including soy milks and soy burgers, 21.4 g/1000 kcal), almonds (14 g/1000 kcal), viscous fibers from oats, barley, psyllium, and the vegetables okra and eggplant (10 g/1000 kcal).

RESULTS:

| | Placebo Diet | Statin Diet | Portfolio/Sterol Diet |
|------------|----------------------|-----------------------|-----------------------|
| LDL | 8.5 +/- 1.9%, | 33.3 +/- 1.9%, | 29.6 +/- 1.3% |

Although the absolute difference between the statin and the portfolio treatments was significant at 4 wk ($P = 0.013$),

9 participants (26%) achieved their lowest LDL-cholesterol concentrations with the portfolio diet.

Moreover, the statin ($n = 27$) and the portfolio ($n = 24$) diets did not differ significantly ($P = 0.288$) in their ability to reduce LDL cholesterol below the 3.4-mmol/L primary prevention cut-off.

CONCLUSIONS: Dietary combinations may not differ in potency from first-generation statins in achieving current lipid goals for primary prevention. They may, therefore, bridge the treatment gap between current therapeutic diets and newer statins.