**Background**

Despite showing a significant decrease in the last few years, coronary heart disease is still the most common cause of death in the UK where it is directly responsible for over 38% of total deaths\(^1\). Coronary heart disease is more common in men (where it causes around one in five deaths), than women (where it is responsible for one in eight deaths)\(^1\).

Coronary heart disease results from a decreased blood flow through the arteries of the heart. This decrease occurs when atherosclerotic plaques - lumps of cell debris, cholesterol and fatty acids - form on the inner walls of coronary arteries. These plaque deposits can harden, narrowing the space within the artery, in a process called stenosis. Where the blood flow is merely reduced the symptoms of angina, (e.g. pain and tightness on exercising), may occur. When the blood flow stops completely and heart muscle dies this is called a heart attack, or myocardial infarction. This may lead to sudden death.

It used to be thought that most heart attacks resulted from sudden stopping of blood flow through very narrowed coronary arteries that had finally become completely blocked. It is now thought that many heart attacks are actually caused by the rupture of soft, so-called vulnerable plaques within the walls of coronary arteries that may not be already significantly narrowed\(^2\). The rupture of the thin, fibrous covering of these plaques causes a clot to form which can then break off to block the artery further down\(^3\).

**Current Practice**

Current treatments to reduce the risk from vulnerable plaques are those which are used to prevent heart disease, including lifestyle change (diet, weight loss and increasing exercise) and drug therapy such as statins to reduce blood levels of lipids; aspirin, beta-blockers and angiotensin converting enzyme inhibitors\(^3\). Where an individual vulnerable plaque has been identified and it is thought to be at high risk of rupture, the decision may be made to perform an operation to bypass that part of the coronary artery (coronary artery bypass grafting) or to insert a stent to stabilise that plaque. Current stents are most likely to be expanded by inflation of a balloon after insertion via a catheter\(^3\).
New Technology

Produced by Prescient Medical the vProtect Luminal Shield is thought by the company to be the first product designed specifically to stabilise soft coronary plaques that may be vulnerable to rupture. The self-expanding vProtect Luminal Shield is delivered via a catheter to the required site in the coronary artery. Once in place the device expands and stabilises the vessel wall then promotes the growth of endothelial cells over the plaque to reduce its chance of rupture. Due to its self-expanding design, the vProtect Luminal Shield may cause less arterial injury than balloon expanded stents, and show reduced foreshortening (that is, it maintains its length rather than shortening and pulling away from the vessel walls)⁴.

The vProtect Luminal Shield is CE marked and the company plan to make it available in the UK from late 2010 to early 2011⁵.

Clinical Studies and Research Questions

Although still undergoing clinical evaluation, some data have been published proposing advantages of the vProtect Luminal Shield over conventional treatments.

Prescient Medical’s vProtect Luminal Shield is currently undergoing clinical assessment in the SECRITT (Santorini Criteria for Investigating and Treating Thin Capped Fibroatheroma) trial in the Netherlands. This investigator sponsored, randomised trial is examining the effect of treatment after 6 months with the vProtect Luminal Shield against no treatment for non-culprit lesions in 30 patients with vulnerable plaques, with a primary endpoint of evidence of vulnerable plaque stabilisation.

A study compared the implant associated vessel wall injury between the vProtect Luminal Shield and conventional balloon-expandable stents in 45 vessels in 40 patients. The authors reported that the 9 vessels in which the vProtect Luminal Shield was implanted showed a significant decrease in vessel prolapse, intra-stent dissection and edge dissection compared with the 36 vessels in which conventional balloon expanding stents were implanted⁷.

Trials are currently underway to assess the risks and benefits of identifying and treating vulnerable plaques⁶. Further research is also required to determine if the use of the vProtect Luminal Shield reduces the incidence of acute coronary syndrome, heart attack or sudden cardiac death compared with treatment with traditional balloon expanding stents.

Potential Impact

Coronary heart disease causes a high level of morbidity and mortality in the UK. If the current research on identification and treatment of vulnerable plaques shows that the benefits outweigh the risks, the vProtect Luminal Shield may have a role to play in the prevention of death from heart attacks due to these plaques. This would have a significant impact upon a large patient group.

Treatment of previously untreated vulnerable plaques would incur extra healthcare costs, but could lead to cost savings in the long term if there were a concomitant reduction in complications and mortality following a heart attack.

References


