Prescribing....

Dec 2012

Omega-3 fatty acids

- December's bulletin looks at the prescribing of Omega-3 fatty acids (Omacor®) following the results of the latest in a series of studies which have found no effect on major cardiovascular outcomes such as death, stroke or MI.
- NICE guidance on the secondary prevention of myocardial infarction is that people with a recent MI eat more oily fish.
- This will result in individuals getting more of other essential nutrients, reducing their consumption of other foods such as red meat and hence further lowering their CV risk.
- For patients truly unable to do so, then NICE says that prescribers may consider prescribing a licensed treatment for secondary prevention for up to four years.
- Prescribing is much higher locally than in the UK. In the year to September 2012 there were 8,128 prescriptions for Omacor, costing £197,738, dispensed with extremely large inter-practice variability.

What is the current advice?

Omacor® is not recommended for prescribing for the routine primary prevention of CVD. Simvastatin or another statin with similar efficacy and acquisition costs prescribed on a "fire and forget" basis is recommended by NICE for primary prevention. Fish oil supplements are available to buy from pharmacies and health food stores for any patients who wish to try them.

NICE guidance on type 2 diabetes recommends that omega 3 fish oil preparations not be prescribed for the primary prevention of cardiovascular disease. This recommendation does not apply to people with hypertriglyceridaemia receiving advice from a healthcare professional with special expertise in blood lipid management. However a trial of these products may be considered in people with refactory hypertriglyceridaemia if lifestyle measures and fibrate therapy have failed.

NICE guidance on the secondary prevention of MI is currently under review. It includes a recommendation that patients should be advised to consume two to four portions of oily fish per week. If this is truly not possible then consideration **may be given to prescribing for up to four years,** but **only** when started **within three months.**

This prescribing guidance was based on the results of two trials, GISSI-Prevenzione Investigators 1999 and GISSI-HF Investigators 2008, which showed a benefit over placebo over four years in people who had an MI in the previous three months. However these were open label studies, which may have biased the results. **Even more importantly far fewer people in the 1999 study were on current evidence-based treatments such as ACEIs and aspirin than residents of the Bailiwick of Guernsey in 2012.Therefore the relevance & applicability of to our current practice is debatable.** More recent research, **including the OMEGA study, a meta-analysis on secondary prevention and a trial reported in JAMA have also failed to indicate any improvement in hard outcomes.**

What is the new evidence ?

The new evidence relates to the ORIGIN study, a large RCT which included 12,536 high risk people with impaired fasting glucose, impaired glucose tolerance or type 2 diabetes. They were at least 50 years old and had evidence of CV disease. At baseline 59% had had an MI or stroke or had undergone

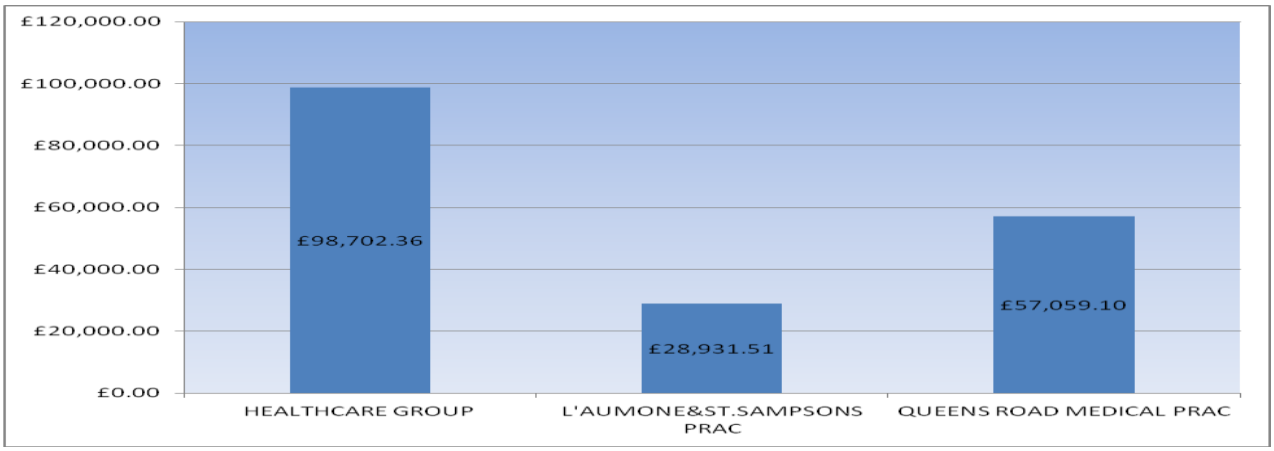
revascularisation. They were given either one Omacor® capsule per day or one placebo capsule. Over a median of 6.2 years Omacor® was not found to significantly reduce the rate of death from cardiovascular causes compared with placebo (9.1% vs 9.3%, p = 0.72). It also had no significant effect on the rates of major cardiovascular events such as MI or stroke, death from any cause, death from arrhythmia or any other pre-defined study outcome. **Triglyceride levels were reduced, but this did not result in improvements in patient-oriented outcomes over 6.2 years.**

So what?

ORIGIN was a large RCT which looked at hard outcomes in high risk patients over a long period of time. So its results are important, particularly as they were the same as all but two previous studies. These strongly support current advice from NICE, which is that that **Omacor® should not be prescribed for the primary prevention of CV disease, even in diabetics**.

It would seem to be prudent to continue to advise people with a recent MI should eat more fish, as this will results in improved intake of essential nutrients and probable reduced consumption of fatty or red meats. If this is truly impossible then please be aware that the advice is that Omacor "may" be considered and not that it "must be prescribed" to all patients.

Reducing the prescribing of Omacor® is now a priority in most UK primary care organisations. Local prescribing is extremely high, the cost of which for the year ending September 2012 is shown below.



Individual prescribing data at doctor level is being circulated to all practices with this bulletin. Clinicians are strongly advised to review the use of Omacor® in view of these trial results as follows.

- Diabetics prescribed Omacor® by a non-specialist should be stopped at their next review.
- Post-MI patients who were commenced on Omacor® more than three months after their event or those for whom four years have elapsed should also be stopped.
- For people who have had a recent MI and don't like fish, balance any benefits from prescribing Omacor® with the evidence base, our patient's considerable pill burden and the very high cost.

It is also helpful to remember that

- For primary prevention, NICE recommends simvastatin 40mg on a "fire and forget" basis, unless it is contra indicated or the patient is on an in teracting drug.
- For people truly intolerant of simvastatin, atorvastatin is now a good value option.
- Rosuvastatin may only be prescribed, by Dr Patterson or Dr Oswald, to patients with documented intolerance of at least two statins, but is unlicensed for secondary prevention.

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References : NICE Eyes on Evidence, NICE, EPACT, BNF no 64