Background

The macula is an area of the retina that is used to see objects in detail and plays an important role in colour perception. As a person ages the cells in the macula may degenerate resulting in a loss of vision. The cause of this macular degeneration is unknown but free radical damage\(^1\), mitochondrial dysfunction\(^2\) and the accumulation of waste products within the retinal cells\(^3\) have all been suggested as possible causes. In some people with macular degeneration new blood vessels grow behind the retina. These new vessels are fragile and leak blood behind the retina resulting in scarring and rapid visual loss. This condition is known as wet age-related macular degeneration (wet AMD).

It had been estimated that around 11% of the population aged between 65 – 74 years have impaired sight as a result of age-related macular degeneration, and this rises to 28% of the population aged between 75 – 85 years\(^4\). In the UK around 26,000 new cases of wet AMD are diagnosed each year\(^5\) and it is the most common cause of sight loss in the UK.

Current Practice

There are a number of treatments available for wet AMD, all of which aim to prevent the growth of new blood vessels.

The National Institute for Health and Clinical Excellence (NICE) has approved two different anti-vascular endothelial growth factors (anti-VEGF), ranibizumab and pegaptanib for use in the treatment of wet AMD. Injected directly into the eye every 4 – 6 weeks these drugs inhibit the formation of new blood vessels.

A number of other treatments for wet AMD have been used. ‘Hot’ laser photocoagulation can be used to seal leaking blood vessels directly. Photodynamic therapy, where a photosensitive drug is transported into the leaky vessels in the eye by the bloodstream before light from a ‘cold’ laser activates the drug and seals the blood vessels, is another treatment option. A beam of \(\beta\)-radiation emitted from an external source has been used to irradiate the retina and treat wet AMD, although this approach does have a number of problems arising from difficulties in targeting the beam\(^6\).
New Technology

VIDION®, developed by NeoVista® Incorporated, is a system that is designed to be used in a day surgery setting as an one-off adjunct to injections of anti-VEGF drugs to treat wet AMD. The VIDION® hand piece is comprised of a reusable radiation module that contains the strontium 90 beta isotope, and the disposable delivery system, which drives the source to the tip of the cannula. Using standard eye surgery techniques the cannula of the VIDION® hand piece is introduced into the back of the eye. The tip of this probe is held over the macula for around four minutes where the low dose β-particles inhibit formation of new blood vessels7.

VIDION® was CE marked in July 2009 and is currently available in 12 hospitals in the UK that are taking part in the MERLOT trial.

Clinical Studies and Research Questions

A number of multicentre early phase trials have been published:

- In a multicentre feasibility study, the effect of the VIDION® system used in conjunction with the anti-VEGF drug bevacizumab was examined for 36 months in 34 patients with wet AMD. This study reported that after one year around 90% of patients lost fewer than 15 letters on a standard eye chart. 70% of the patients reported their sight was stable or had improved, whilst 60% experienced a clinically significant improvement in their vision. Following treatment, around one in five patients experienced leakage from the new blood vessels and one in four patients developed a cataract8.

- In a non-randomised, multicentre feasibility study the effects of 2 different doses of β-radiation on the sight of patients with wet AMD was examined in 34 patients. 40% of patients who received the lower dose of radiation reported no loss or impaired vision after 12 months. This rose to 72% of patients who received the higher dose9. Two in five patients in this study developed cataracts.

No adverse events in these studies were ascribed to exposure to β-radiation by the authors. People in both studies reported cataract development but NeoVista® believe these to be a side effect of the operation and not a result of the use of the VIDION® system per se8.

The VIDION® system is currently undergoing two phase III randomised controlled trials. The CABERNET study is being undertaken in 493 people with wet AMD. In one arm of this study, people will receive a single exposure to the VIDION® system plus two injections of ranibizumab administered one month apart. In the second arm, the patients will receive an injection of ranibizumab administered monthly for the first three injections followed by quarterly injections. The primary outcome is the patient’s visual acuity score at 12 months. This trial is due to complete in April 201110.

The MERLOT study is being undertaken in around 360 patients with wet AMD. In one arm of this study patients will undergo a single surgical procedure using the VIDION system with ranibizumab administered on a monthly basis as required. In the second arm people will receive ranibizumab alone administered on a monthly basis as required. With the primary outcomes being change in visual acuity and the number of re-treatment injections of ranibizumab required, this trial is due to complete in November 201411.

Potential Impact

If shown to be sufficiently effective, NeoVista®’s VIDION® system may offer a further
treatment option for wet AMD. Trial evidence and long term studies are needed to better characterise the safety profile of the VIDION® system. If the use of VIDION® allows a reduction in the number of injections of anti-VEGF drugs there will be benefits for patients in terms of reduced hospital visits and unpleasant procedures.

Adoption of the VIDION® system would incur additional costs associated with the requirements for eye surgery, plus costs incurred with the use of radioactive substances. It is possible these costs may be recouped if the use of VIDION® reduced the number of injections of anti-VEGF drugs. Further societal cost savings may be made if VIDION® improves vision as this will enable people with wet AMD to retain their independence for longer without resort to assisted care.

References


5. NICE technology appraisal guidance 155. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. www.nice.org.uk/TA155


