New approach for treating people affected by diabetic eye disease

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A new study, published in *Diabetologia*, presents the results of the largest clinical trial for diabetic retinopathy. The study highlights a new approach that could transform diabetic eye screening around the world that also has a significant cost saving for the NHS.

The number of people living with diabetes in the world is over 460 million and is likely to rise to over 700 million in the next 35 years. Diabetes affects the eye by damaging the blood vessels in the retina, and is known as diabetic retinopathy. The high blood sugar causes the fine blood vessels in the retina to leak fluid causing waterlogging or to close resulting in the retina becoming starved of oxygen.

Diabetic retinopathy (DR) is one of the commonest causes of visual loss in the world and can be prevented if it is detected early. A person with DR isn't aware of the problem until vision loss is so reduced that the patient notices, a stage when the damage is often irreversible. Prompt laser treatment, injections of drugs into the eye or complex eye surgery are required to limit the damage.

The UK is at the forefront of screening for DR. People have retinal photographs taken which show the early stages of retinopathy and if present they are referred for close monitoring and/or treatment before vision is affected. Liverpool has been leading research into screening since 1991 and many of the techniques used for screening worldwide have been developed here.

Largest trial of its kind

In an effort to improve screening for DR, researchers, led by Professor Simon Harding, Chair Professor of Clinical Ophthalmology and Head of the University of Liverpool's Department of Eye and Vision Science, and Dr. Deborah Broadbent, Honorary Senior Lecturer in Eye and Vision Science, conducted a study to ascertain whether a personalized/individualized approach to screening was more beneficial than the established yearly screening approach.

The study, entitled "Individualized Screening for Diabetic Retinopathy" (ISDR) recruited more than 4,500 patients over seven years making it

the largest trial of its kind.

Patients recruited to the study were either entered into a control group or a personalized, or individualized, approach group. The control group of patients continued to have their eyes screened every year to detect early changes of diabetic retinopathy, which is the current approach in most countries.

The individualized group underwent a novel, innovative screening method in which the time between each screening episode varied depending on the amount of retinopathy and the level of control of blood sugar, blood pressure and cholesterol. By combining all these important factors, the Liverpool system calculates the risk for each person using their own health information, the "individualized" approach.

Patients were then given six-month appointments if they were classed as at high risk of developing sight threatening disease , a 12-month appointment for medium risk or a 24-month appointment for a low risk.

Results

The results of the seven-year study showed that 81.9% of patients in the individualized group were deemed to be low risk patients and therefore did not need to be screened every year. This meant they only needed to attend an NHS appointment every two years, saving them time off work, travel costs and inconvenience.

The trial showed that 43.2% fewer appointments were required, releasing £27.2 million per year or £19.73 per patient per year. The study also found that there was societal cost saving of £26.19 per patient per year.

The trial also found that sight-threatening diabetic retinopathy was

detected earlier in the high-risk people in the individualized group verses the control group and most importantly the safety of the patient was not compromised by longer screen intervals in the low risk group.

The ISDR trial was been funded by the National Institute for Health Research (NIHR) the NHS Research and Development body. It was hosted by St Paul's Eye Unit, Liverpool University Hospital NHS Foundation Trust and the University of Liverpool.

Digital technologies

Professor Harding, Chief Investigator of the ISDR Program, said: "Attending lots of clinics each year is a huge problem for people with diabetes, especially as many are working. So, reducing these will be a big help to them, and will free up the pressure on NHS eye clinics. There are currently just under eight million ophthalmology appointments required each year, the largest of any speciality. This study shows how introducing new digital technologies can improve routine healthcare. We can more effectively monitor the eyes of people with diabetes, save them money traveling to and from clinics and free up much needed funds for the NHS."

Groundbreaking research

Dr. Broadbent, principle investigator of the ISDR trial, said: "The people of Liverpool have a great track record of contributing to ground breaking research and this is a fantastic example. To recruit over 4,500 patients for any study is a tremendous achievement and I would like to thank our patients for so enthusiastically agreeing to be a part of this ground-breaking study. I would also like to thank our highly motivated patient group who helped us to design the study, the ISDR research team for their painstaking work and the NIHR for funding this study."

The study is titled "Safety and cost-effectiveness of individualized screening for diabetic retinopathy: the ISDR open-label, equivalence RCT."

More information: undefined undefined et al. Safety and cost-effectiveness of individualized screening for diabetic retinopathy: the ISDR open-label, equivalence RCT, *Diabetologia* (2020). DOI: 10.1007/s00125-020-05313-2

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