Safety of individualised variable interval screening for referable diabetic retinopathy – baseline data from the ISDR randomised controlled study

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**Purpose:**

To report rates of acceptance and baseline characteristics of people invited into a randomised controlled trial comparing variable interval individualised screening with annual screening in an established community based screening programme.

**Methods:**

People in the Liverpool Diabetic Eye Screening Programme who attended for routine screening were considered for inclusion if they had gradeable images in both eyes. After informed consent, participants underwent dilated 2 field 45 degree retinal photography, graded by accredited graders: R0,R0 no DR in either eye, R1,R0 mild nonproliferative (NPDR) one eye, R1,R1 mild NPDR both eyes. Demographic, retinopathy and clinical data were integrated into a purpose built real-time data warehouse.

**Results:**

4811 of 8314 invited consented to join the trial. 1532 of 3503 (43.7%) wished to retain annual screening or did not want variable intervals, 849 (24.3%) did not want to take part in research or be randomised and 318 (9.1%) did not give a reason. 273 participants who gave consent were excluded: 96 screen +ve, 38 new diagnosis of other disease, 107 unassessable/unobtainable images, 19 withdrew consent, 13 other.

 4538 entered the study: 60.2% male, 94.6% Caucasian, median age 63.0 years (IQR 55-71, range 14-100), 4.0% type 1. Glycaemia, BP and lipid control (median (IQR)) were generally fair/good: HbA1c 51.0 mmol/mol (44-62), systolic 130 mmHg (122-138)), total cholesterol 4.0 mmol/L (3.4-4.7). Retinopathy grades (two eyes) were: R0,R0 81.4%, R1,R0 12.3%, R1,R1 6.3%. Comparing the 3 stepwise DR groups, the no DR group were more likely to be older (p<0.01), type 2 (p<0.001), female (p=0.02), have shorter disease duration p<0.001), have better glycaemic control (p<0.001). No differences were observed for BP or lipids.

**Conclusions:**

Nearly half of those invited to participate in variable interval screening declined for reasons related to the change in interval. Rates of mild NPDR were low. Significant differences were observed for people with no DR, one eye and both eyes involved. People with diabetes undergoing routine screening in the setting of a long established programme generally have fair or good control of major risk factors for progression.

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