

# Diabetic Retinopathy: More Patients, Less Laser

## A longitudinal population-based study in Tayside, Scotland

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**OBJECTIVE** — We aim to correlate the incidence of diabetic retinopathy and maculopathy requiring laser treatment with the control of risk factors in the diabetic population of Tayside, Scotland, for the years 2001–2006.

**RESEARCH DESIGN AND METHODS** — Retinal laser treatment, retinal screening, and diabetes care databases were linked for calendar years 2001–2006. Primary end points were the numbers of patients undergoing first or any laser treatment for diabetic retinopathy or maculopathy. Mean A1C and blood pressure and retinal screening rates were followed over the study period.

**RESULTS** — Over 6 years, the number of patients with diabetes in Tayside increased from 9,694 to 15,207 (57% increase). The number of patients receiving laser treatment decreased from 222 to 138 and first laser treatments decreased from 100 (1.03% of diabetic population) to 56 (0.37%). The number of patients with type 2 diabetes treated for maculopathy decreased from 180 in 2001 to 103 in 2006 (43% reduction,  $P = 0.03$ ). Mean A1C decreased for type 1 and type 2 diabetic populations ( $P < 0.01$ ) and a reduction in blood pressure was observed in type 2 diabetic patients ( $P < 0.01$ ). The number of patients attending annual digital photographic retinopathy screening increased from 3,012 to 11,932.

**CONCLUSIONS** — Laser treatment for diabetic maculopathy in type 2 diabetic patients has decreased in Tayside over a six-year period, despite an increased prevalence of diabetes and increased screening effort. We propose that earlier identification of type 2 diabetes and improved risk factor control has reduced the incidence of maculopathy severe enough to require laser treatment.

*Diabetes Care* 31:1126–1131, 2008

A number of recent studies have reported a lower incidence and prevalence of severe diabetic retinopathy and maculopathy (1–5). Reduction in blindness in patients with diabetes has also been reported, but this observation is not universal (6–8). The use of blindness as an end point for studies of diabetic eye disease is often rendered imprecise by reliance on incomplete blindness registration data and by difficulty in attributing visual loss to di-

abetic retinal disease (9). The majority of visual impairment in patients with diabetes is not due to diabetic retinopathy (10), and accordingly the incidence of retinopathy requiring therapeutic intervention (laser) is a more accurate reflection of incident diabetic retinal disease provided population and treatment records are complete.

National Health Service (NHS) Tayside serves a predominantly Caucasian

rural and urban population, which increased from 338,750 in 2001 to 391,639 in 2006 (11). A retinal screening program has been in place since 1990, using digital photography since 2000 (12). In 2003, Scotland introduced a national screening program (13) using annual single-field digital photography with staged mydriasis, a standardized grading system (14), trained screeners, and rigorous quality assurance (15). Tayside also benefits from an established national diabetes database (16–18). Laser treatments take place at a single site within the region and are recorded on a single database using the same unique patient identifier, allowing easy case linkage studies. Using these data sources, we describe trends in laser utilization, retinal screening, and the control of retinopathy risk factors in Tayside for the years 2001–2006.

### RESEARCH DESIGN AND METHODS

— We performed a historical cohort study of retinal laser in Tayside, Scotland. The data sources used in this study were databases of regional laser treatment, retinal screening (“Eyestore”), and the national diabetes register (Scottish Care Information–Diabetes Collaboration [SCI-DC]) for the complete calendar years 2001–2006.

Retinal laser within Tayside is recorded on a custom-designed database, including treatment given and date. The primary end points for this study obtained from this dataset were first laser treatments for diabetic retinopathy or maculopathy and number of patients receiving any laser for diabetic retinopathy or maculopathy per annum.

The SCI-DC database uses hierarchical multiple data source captures to create a real-time national diabetes register. Independent data sources (e.g., community prescribing, regional biochemistry database) are integrated using custom-designed software (16). The health board regions are clearly demarcated and therefore can be accurately constrained to the Tayside population (16,18). Population risk factors for laser extracted from

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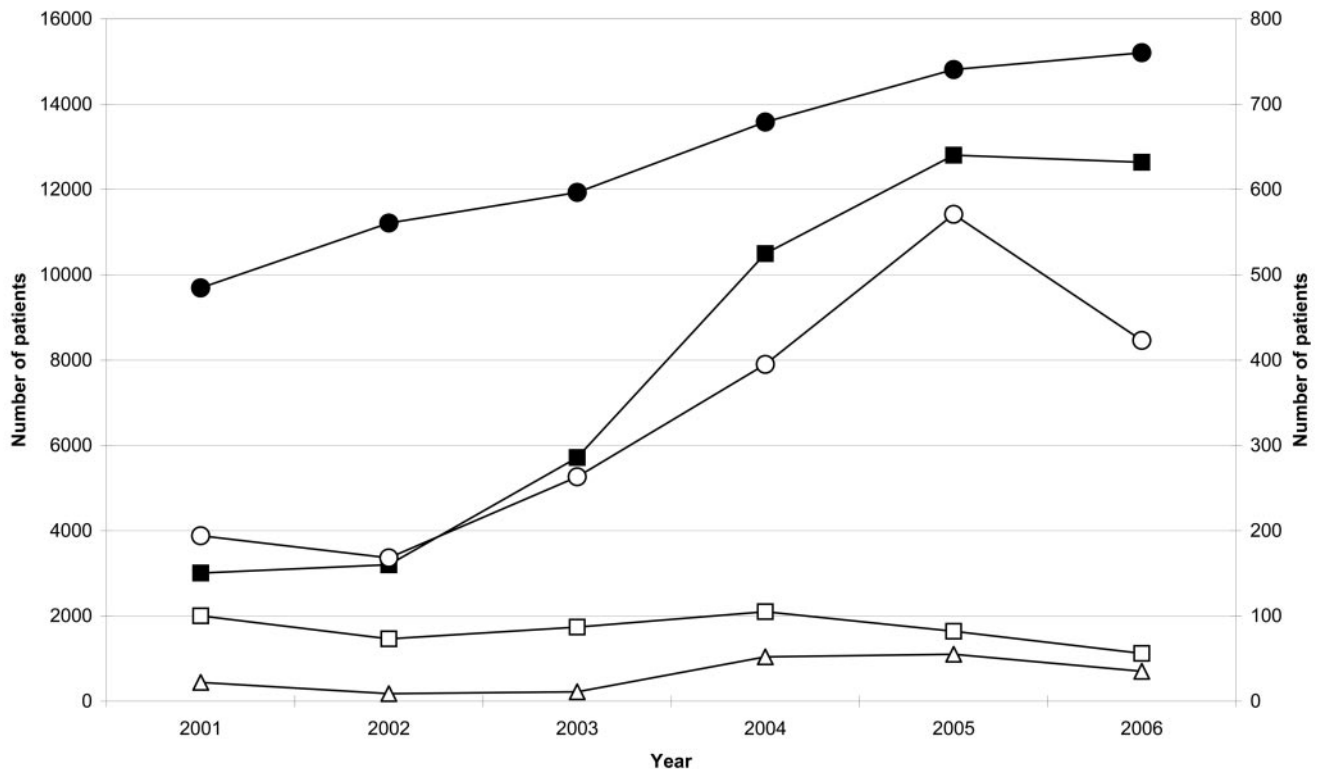
Received for publication 1 August 2007 and accepted in revised form 3 March 2008.

Published ahead of print at <http://care.diabetesjournals.org> on 17 March 2008. DOI: 10.2337/dc07-1498.

Abbreviations: NHS, National Health Service; SCI-DC, Scottish Care Information–Diabetes Collaboration.

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**Figure 1**— The relationship between the known diabetic population of Tayside, digital retinal photographic retinopathy screening, and progression to laser treatment for the years 2001–2006. On the primary axis: ● = total number of patients with diabetes and ■ = patients undergoing digital retinal photographic retinopathy screening in that year. On the secondary axis: ○ = patients graded as having referable retinopathy at screening as defined by national guidelines, □ = all patients undergoing any form of laser treatment in that year, and △ = number of patients undergoing laser within 6 months of a screening event detecting referable disease.

SCI-DC were A1C, duration of diabetes, and blood pressure. BMI, cholesterol, and method of diabetic treatment were also extracted.

Eyestore contains all information from digital retinal screening performed in Tayside including date of screening and grading outcome (12). Data drawn from Eyestore were total number of screening events and number of events at which referable retinopathy or maculopathy were identified for each year. Referable retinopathy and maculopathy were as defined in the national screening framework (14). For the purposes of this study, a screening event resulting in treatment was defined as one that occurred no more than 6 months before laser. This definition was used to state with reasonable confidence that screening had identified treatable pathology, not merely referable pathology. This assumption could not be made for laser occurring >6 months after screening, since this could well encompass new pathology arising during ophthalmic clinic follow-up.

The three databases were checked for internal validity (Modulus 11 algorithm,

identification and exclusion of nonincident laser events), and external cross-references between the databases were made. Where discrepancies were identified, arbitration was sought from biochemical and clinic attendance records. In addition to the data described above, unique patient identifiers were obtained and matched between the relevant databases, before anonymization of the data by a third party.

The opinion of the local medical research ethics committee was sought. They indicated that Caldicott Guardian approval alone was required. This was obtained, and the principles of data protection were adhered to throughout this study.

#### Statistical analysis

The administration of SCI-DC changed after the first 2 years of the study period. As a result, with the exception of disease duration, only means of variables were available for 2001 and 2002. Nevertheless, the large sample sizes meant that this was an acceptable representation of the group. To demonstrate trends in these

variables, weighted linear regression was performed, using  $(N/SD^2)$  to calculate weight (SPSS, Chicago, IL). Since accurate measures of  $N$  and  $SD$  were not available for 2001 and 2002, the weights were estimated allowing for low patient numbers and high  $SD$ s. The robustness of this technique was tested and validated through comparison with the full dataset for duration of disease. Statistical analysis was performed under the supervision of the statistician for NHS Tayside.

**RESULTS**— From 2001–2006 the number of registered diabetic patients increased from 9,694 to 15,207 (57% increase). The number of first laser treatments per annum fell from 100 to 56 (44% decrease), and the total number of patients receiving laser fell from 222 to 138 (38% decrease). The number of patients undergoing digital retinal photographic screening annually rose from 3,012 in 2001 to 12,035 in 2005. A total of 55,103 retinal screening events were performed (47,864 patients), 1,884 (3.4%) of which identified referable retinopathy. However, of patients referred

## Diabetic retinopathy

**Table 1—Number of patients with diabetes, number of patients undergoing digital retinal photographic screening, and number of patients undergoing first or any laser treatment in the years 2001–2006**

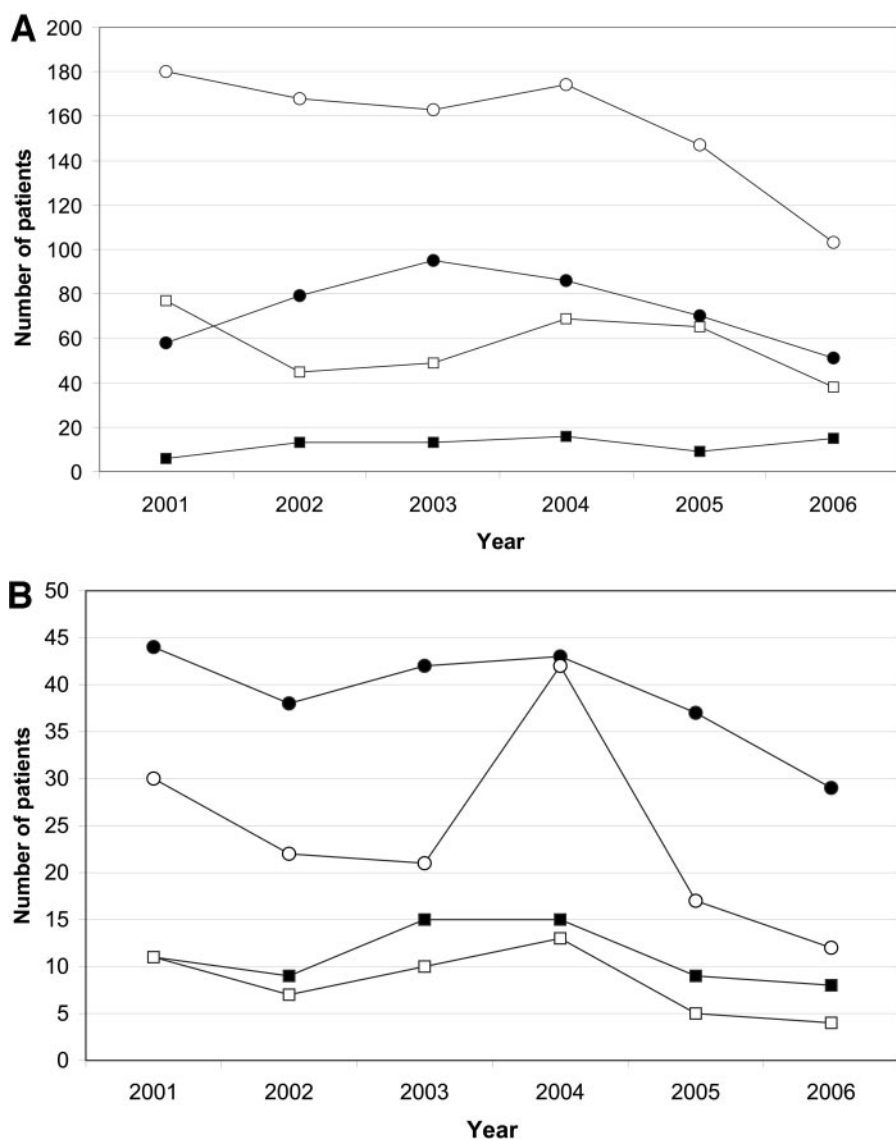
	2001	2002	2003	2004	2005	2006
Patients with diabetes†	9,694	11,216	11,932	13,582	14,811	15,207
Prevalence of diabetes in Tayside (%)	2.5	2.9	3.1	3.5	3.8	3.9
Patients undergoing digital retinal photographic screening†	3,012	3,238	6,216	10,294	12,035	11,932
Patients with referable retinopathy from photography	189	149	262	425	302	343
Percentage of patients screened with referable retinopathy (%)†	6.3	4.6	4.2	4.1	2.5	2.9
All patients receiving laser for diabetes	222	201	202	252	199	138
% of all patients with diabetes receiving laser†	2.3	1.8	1.7	1.9	1.3	0.9
Patients receiving first laser for diabetes	100	73	87	105	82	56
% of all patients with diabetes receiving first laser*	1.0	0.7	0.7	0.8	0.6	0.4
Laser ≤6 months after screening	22	9	11	52	55	35
Laser within 6 months of screening as a percentage of patients screened (%)	0.7	0.3	0.2	0.5	0.5	0.3

Data are n or %. \* $P < 0.01$ , † $P < 0.05$  over the study period.

**Table 2—Number of patients with type 2 diabetes, number of type 2 diabetic patients undergoing digital retinal photographic screening, and number of patients undergoing first or any laser treatments in the years 2001–2006 correlated with the type 2 diabetic population mean risk factors and hypoglycemic treatment**

	2001	2002	2003	2004	2005	2006
Type 2 diabetic patients*	8,593	9,935	10,594	12,112	13,352	13,660
Patients undergoing digital retinal photographic screening*	4,979	6,339	6,706	8,933	10,676	10,619
Patients with referable retinopathy from photography†	295	342	409	495	476	441
Patients with referable retinopathy as a percentage of all patients screened (%)†	5.9	5.4	6.1	5.5	4.5	4.2
Laser						
All laser						
Macular†	180	168	163	174	147	103
Macular as % of all patients*	2.11	1.69	1.54	1.44	1.1	0.75
Panretinal	58	79	95	86	70	51
Panretinal as % of all patients	0.67	0.8	0.9	0.71	0.52	0.37
First laser						
Macular	77	45	49	69	65	38
Macular as % of all patients	0.9	0.45	0.46	0.57	0.49	0.28
Panretinal	6	13	13	16	9	15
Panretinal as % of all patients	0.07	0.13	0.12	0.13	0.07	0.11
Risk factors						
Mean A1C (%)*	7.9	7.6	7.4	7.4	7.5	7.4
Mean systolic blood pressure (mmHg)*	142	141	141	141	138	137
Mean diastolic blood pressure (mmHg)*	79	78	77	76	75	75
Mean age (years)	66.5	66.8	66.9	66.3	66.4	66.6
Mean duration of diabetes (years)*	7.7	7.5	7.5	7.3	7.3	7.4
Mean BMI (kg/m <sup>2</sup> )*	30.0	30.1	30.3	30.5	30.7	30.9
Mean total cholesterol (mmol/l)*	5.0	4.9	4.8	4.6	4.4	4.3
Treatment						
Insulin only (%)*	16.0	15.0	15.0	13.6	12.3	11.8
Insulin and oral hypoglycemics (%)†	0.7	1.1	0.9	1.5	3.3	4.4
Oral hypoglycemics (%)	54	55.8	53.7	53.8	50.6	52.0
Diet only (%)†	26	26.1	27.8	28.3	30.7	29
Not known (%)	3.3	2.0	3.3	2.8	2.9	2.8

Data are n, %, or mean. \* $P < 0.01$ , † $P < 0.05$  over the study period.



**Figure 2**—Trends in laser treatment during 2001–2006 for patients with type 2 diabetes (A) and patients with type 1 diabetes (B). ○, All patients treated with macular laser; □, all patients receiving first macular laser treatment; ●, all patients treated with panretinal laser; ■, all patients receiving first panretinal laser.

to ophthalmology, only 184 (9.8%) proceeded to laser intervention within the following 6 months (Fig. 1, Table 1).

Between 2001 and 2006, the number of patients with type 2 diabetes rose from 8,936 to 13,660 (53% increase, Table 2). The most frequently performed treatment was macular laser in type 2 diabetic patients. A total of 180 type 2 diabetic patients (2.1% of the type 2 diabetic population) received macular treatment in 2001 and 103 (0.75% of the type 2 diabetic population) in 2006, a 43% decrease ( $P = 0.03$ ). Type 2 panretinal treatments peaked in 2004 with 95 patients receiving treatment, falling back to 51 pa-

tients in 2006 (Fig. 2A) with no statistically significant trend over the 6-year period as a whole.

The type 1 diabetic population grew from 1,158 to 1,547 (34% increase, Table 3) over the same period. Macular treatments in type 1 diabetic patients similarly peaked in 2004 at 42 patients, falling to 12 in 2006 (Fig. 2B). Type 1 diabetic patients undergoing panretinal treatment fell from 44 in 2001 to 29 in 2006. This was a significant reduction when viewed as a percentage of the type 1 diabetic population ( $P < 0.01$ , Table 3).

In type 1 diabetic patients, an increase in systolic blood pressure was observed during the study period ( $P < 0.01$ ),

whereas for type 2 diabetic patients, mean systolic blood pressure fell by 5 mmHg ( $P < 0.01$ ) and diastolic blood pressure fell by 4 mmHg ( $P < 0.01$ ). Mean A1C fell from 9.1% to 8.8% in type 1 diabetic patients ( $P < 0.01$ ) and from 7.9% to 7.4% in type 2 diabetic patients ( $P < 0.01$ ). Mean duration of diabetes decreased from 7.7 to 7.4 years in type 2 diabetic patients ( $P < 0.01$ ). Mean BMI rose for both type 1 and type 2 diabetic populations and mean cholesterol decreased in both groups (Tables 2 and 3).

The percentage of type 2 diabetic patients whose only treatment was dietary advice increased from 26% in 2001 to 29% in 2006 ( $P = 0.01$ ). There was no significant change in the proportion of type 2 diabetic patients using insulin (16.7% in 2001, 16.2% in 2006,  $P = 0.45$ ).

**CONCLUSIONS**— In the Tayside population, the absolute number of patients with type 2 diabetes requiring laser treatment for maculopathy fell by 43% between 2001 and 2006. When taken as a proportion of all patients with type 2 diabetes, this represented a threefold decrease in those requiring treatment. The number of type 2 diabetic patients requiring panretinal photocoagulation and the number of type 1 diabetic patients requiring either macular or panretinal laser decreased, but not enough to achieve statistical significance. Over the same period, the prevalence of diabetes and diabetic retinopathy screening effort have both increased. Why was there no concomitant increase in individuals with retinopathy or maculopathy severe enough to require laser treatment?

One potential explanation would be a change in the criteria for laser treatment. During the period of the study, there have been no changes in national or local guidelines for the use of laser in diabetic eye disease and no local changes in personnel or practice (19,20). No patients received intravitreal treatment over this period, and indications for surgical practice were unaltered. We failed to identify any patients with disease severity (e.g., persistent vitreous hemorrhage, tractional retinal detachment) sufficient to require immediate surgery without first attempting argon laser treatment. However, it is difficult to exclude an unannounced change in practice in the application of macular photocoagulation in patients with “good” visual acuity. Populations in which screening has been established report a lower incidence and

Table 3—Number of patients with type 1 diabetes, number of type 1 diabetic patients undergoing digital retinal photographic screening, and number of patients undergoing first or any laser treatments in the years 2001–2006 correlated with type 1 diabetes population mean risk factors

	2001	2002	2003	2004	2005	2006
Number of patients*	1,158	1,281	1,338	1,470	1,548	1,547
Patients undergoing digital retinal photographic screening*	676	817	847	1,080	1,238	1,128
Patients with referable retinopathy from photography	92	97	154	173	218	145
Patients with referable retinopathy as a percentage of all patients screened (%)	13.6	11.9	18.2	16.0	17.6	12.9
Laser						
Any laser						
Macular	30	22	21	42	17	12
Macular as % of all patients	2.59	1.72	1.57	2.86	1.1	0.78
Panretinal	44	38	42	43	37	29
Panretinal as % of all patients*	3.80	2.97	3.14	2.93	2.39	1.87
First laser						
Macular	11	7	10	13	5	4
Macular as % of all patients	0.95	0.55	0.75	0.88	0.32	0.26
Panretinal	11	9	15	15	9	8
Panretinal as % of all patients	0.95	0.55	0.75	0.88	0.32	0.26
Risk factors						
Mean A1C (%)*	9.1	8.9	8.8	8.9	8.9	8.8
Mean systolic blood pressure (mmHg)*	129	129	132	132	132	132
Mean diastolic blood pressure (mmHg)	76	75	75	75	75	75
Mean age (years)*	35.9	36.4	36.7	36.7	37.9	38.2
Mean duration of diabetes (years)	17.5	17.5	17.4	17.1	17.4	17.7
Mean BMI (kg/m <sup>2</sup> )*	25.4	25.6	25.7	25.0	26.6	26.6
Mean total cholesterol (mmol/l)*	5.1	5.0	4.9	4.9	4.6	4.6

Data are n, %, or mean. \* $P < 0.01$  over the study period.

prevalence of diabetic visual loss (3,21), but it is difficult to separate the beneficial effect of screening from the effect of better general diabetic disease management, since the two factors frequently coexist. After 2003, digital retinal photography became almost the sole means of screening in Tayside for patients with diabetes. There was a small prevalence screen effect with laser activity peaking in 2004 before falling over the final 2 years of the study. This effect was particularly marked for type 1 maculopathy and it is possible that decreases in 2005 and 2006 could be a result of earlier identification of pathology under the new annual screening system. In contrast, in the type 2 diabetic population, only a small peak in incident maculopathy treatment was seen in 2004, and comprehensive digital retinal photography screening had little impact on the overall trend of decreasing laser treatment. This may be due to relatively adequate screening in Tayside before comprehensive digital photography. In areas where historically there have been fewer resources, the impact of the national screening program has been

greater, with a more sizeable initial surge of patients with previously unrecognized sight-threatening retinopathy requiring laser treatment (22,23).

A reduction in the mean disease duration and the proportion of type 2 diabetic patients treated with insulin and/or oral hypoglycemic agents suggests that patients are being diagnosed with diabetes earlier, reducing the period of subclinical dysglycemia. This will increase the prevalence of individuals with clinical type 2 diabetes and might be predicted to translate into a drop in the proportion of patients requiring laser treatment. However, we observed a reduction in the absolute numbers of type 2 diabetic patients requiring treatment for maculopathy and not simply a drop in the proportion, indicating this is an inadequate sole explanation for the trends observed.

Another consequence of earlier identification of type 2 diabetic patients is the possibility that patients are receiving treatment early enough in the disease process to avoid the development of sight-threatening maculopathy. Mean diastolic blood pressure in our type 2 diabetic pop-

ulation decreased by 4 mmHg over 6 years to a final mean population blood pressure of 137/75 mmHg. The U.K. Prospective Diabetes Study Group (24) compared tight control of blood pressure (mean 144/82 mmHg) with less tight control (mean 154/87 mmHg) in type 2 diabetic patients and showed a 34% risk reduction for progression of retinopathy by two or more steps over 7.5 years. Furthermore, there was a 47% risk reduction for loss of three or more lines of Early Treatment of Diabetic Retinopathy Study visual acuity and a 35% reduction in individuals undergoing laser treatment over this period. Since diabetic maculopathy is the main cause of visual impairment in type 2 diabetes, this reduction in visual loss suggests tight blood pressure control reduces the risk of maculopathy. In our study, the mean diastolic blood pressure achieved for the entire population is 7 mmHg lower than the U.K. Prospective Diabetes Study tight control group.

A statistically significant fall in A1C was also observed. The 2006 population mean of 7.4% is comparable with the tight control group of newly diagnosed type 2

diabetic patients reported in the U.K. Prospective Diabetes Study 33 (25). This group had a 29% lower risk of retinal photocoagulation over 10 years from diagnosis when compared with individuals receiving “conventional” treatment (mean A1C 7.9%). Mean total cholesterol also decreased significantly over the study period, and although plasma lipids have not been conclusively proven to influence the course of diabetic retinopathy or maculopathy, the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study demonstrated a reduction in laser treatment in those treated with fenofibrate (26).

In conclusion, the incidence of maculopathy requiring laser treatment in type 2 diabetic patients in Tayside has decreased over the last 6 years despite increased prevalence of type 2 diabetes and increased screening effort. The national screening program contributed a greater number of patients receiving first laser, but did not alter the overall trend to less laser treatment for this group. We suggest that earlier diagnosis and improved management of the risk factors for diabetic maculopathy is reducing the incidence of maculopathy severe enough to require laser treatment in type 2 diabetes.

**Acknowledgments**— This study was funded by the Wellcome Trust, Speed Pollock Memorial Trust.

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