The rate of diabetic vitrectomy in a defined geographical part of North East England

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Running head: Diabetic vitrectomy in North East England

Abstract

Purpose

To assess the yearly incidence of vitrectomy for proliferative diabetic retinopathy over an 11 year period, in a geographically defined part of North East England. The time period covered the introduction of diabetic retinopathy screening.

Methods

All patients undergoing vitrectomy for diabetic retinopathy in the Sunderland and South Tyneside area were recorded from 2000 to 2010. Incidence rates of vitrectomy specifically for the complications of proliferative diabetic retinopathy for the observed diabetic population, the estimated diabetic population and the population with known proliferative diabetic retinopathy (PDR) were calculated.

Results

There was a gradual and significant decline in the vitrectomy rate from 157 (95% confidence limits 135-187) to 103 (98-109) per 100,000 of the observed diabetic population in 2000 and 2010 respectively. The rate in the estimated diabetic population showed no significant change at 68 (48-87) in 2002 and 77 (55-103) in 2010. The rate in the PDR population, which comprised 2.4% of the known diabetic population in 2002 and 1.8% in 2010, declined significantly from 7.7% in 2002 to 5.7% in 2010.

Conclusion

This study evaluated vitrectomy rates for proliferative diabetic retinopathy in an area of North East England. There were apparent declining rates of vitrectomy for PDR

following the introduction of diabetic retinopathy screening but these have to be interpreted in the light of several confounding factors.

Key words: diabetic population; diabetic retinopathy; incidence; prevalence; diabetic vitrectomy.

Introduction

Although vitrectomy is a proven and effective treatment for the complications of proliferative diabetic retinopathy (PDR)[1], the proportion of patients requiring the procedure is poorly defined. Some vitrectomies are probably inevitable despite optimum treatment. Indeed, 4% of eyes treated with laser for high risk PDR in the Early Treatment Diabetic Retinopathy Study (ETDRS)[1] went on to require vitrectomy within 5 years despite the rigid inclusion criteria and protocol follow up. Several modifiable factors are likely to influence the rate of vitrectomy in PDR, these include glycaemic and hypertensive control, screening for early sight-threatening retinopathy and attendance for, and adequacy of laser treatment.[2] Thus in the 'real world' vitrectomy rate is probably variable and higher than found in the ETDRS. Indeed Kaiser et al. reported that 10% of patients presenting *de novo* with any stage of PDR in a tertiary referral centre in the USA required vitrectomy within 1 year of presentation.[3] The yearly overall population rate of vitrectomy for PDR will also be affected by the known increasing prevalence of diabetes and furthermore the rate in the diabetic population will be affected by the size of the true diabetic population as opposed to the known observed diabetic population, between which there is known to be a variable mismatch.[4] To add to the complexity of the situation, the indications for vitrectomy surgery are gradually evolving with non PDR related tractional macular oedema now being routinely operated upon.[5, 6, 7]. Finally, there has been a steady reduction in the surgical complication rate [6-8] meaning that a lowering of the threshold for surgery has probably occurred.

We devised this study to assess the yearly incidence rate of diabetic vitrectomy in a defined geographical area over an 11 year period. Importantly, the period covered the introduction of systematic diabetic retinopathy screening into the area in 2002.

Method

The population studied was the Sunderland and South Tyneside primary care trust areas of North East England which had a total over 16 years old population of 355,254 in 2000 and 403,754 in 2010.[9] Vitrectomy was carried out at Sunderland Eye Infirmary by the same three surgeons during the study period. All vitrectomies carried out on patients with diabetic retinopathy from January 2000 to Dec 2010 were collated using surgical databases and searching of theatre lists during the period. Case notes and audit forms were examined to check the indications for surgery. Cases where the primary indication was not diabetic retinopathy were excluded, and cases where surgery was performed for non PDR associated traction were identified. . Patients' postcodes were recorded and patients outside the catchment area were excluded. The area studied was surrounded by localities also served by Sunderland Eye Infirmary but the completeness of case finding was also checked in two other ways. Neighbouring units and private providers carrying out vitrectomy were asked to check for cases in the postcode area during the study period. As part of the local screening service, patients with diabetes requiring vitrectomy were collated yearly from 2002 and these lists and the current register were examined for any extra cases.

Local over 16 year old prevalence figures from practice registers were used to calculate the observed diabetes prevalence within the PCT areas. The UK Association of Public Health Observatories (APHO) Diabetes Prevalence model was used to estimate true diabetes prevalence in 2001 and 2010 in the area studied. This prevalence model is based on data from the Health Survey for England and takes into account age, sex, ethnicity, deprivation and obesity trends in individual localities. The model provides uncertainty limits around the point prevalence estimates and

uses a definition of diabetes based on either self-reported doctor diagnosis of diabetes or an HbA1c of 48 mmol/mol (6.5%) or greater, in keeping with recommendations from the American Diabetes Association. [10]

Data from the local Diabetic retinopathy screening service were used to calculate local prevalence of PDR in 2002 and 2010. These were cross checked with hospital data to ensure accuracy. Only the first eye of patients undergoing vitrectomy was included in the analysis and rates are given per person. To assess relevant demographic changes in the population undergoing vitrectomy, a detailed audit of the indications, presentation, systemic control and other variables was carried out on patients having vitrectomy in 2000 and 2001 and then in 2009 and 2010. The study complies with the tenets of the Declaration of Helsinki. All data used in this study were anonymised and collected as part of routine care and was thus classified as audit confirmed by the Sunderland Area Ethics Committee.

Statistical analysis

Differences in variables between the two audit periods were compared using non paired t test for continuous variables, and Fisher's exact test for categorical data. Pearson's correlation coefficient was used to examine the relationship between vitrectomy rate and year.

Results

The observed local over 16 year old diabetes prevalence in Sunderland increased from 2.8% in 2000 to 5.5% in 2010. The corresponding figures in South Tyneside

were 3% increasing to 6.2%. The estimated prevalence of diabetes was 6.8% (95% uncertainty limits 5.3-9.6%) and 7.3% (5.7-10.4%) in Sunderland and South Tyneside respectively in 2001 and 7.6% (5.7-10.7%) and 8% (5.9-11.3%) in 2010. During the eleven year study period there were 226 first eye vitrectomies performed for the complications of PDR with a further 35 performed for non PDR associated macular traction. The percentage of the diabetic population with PDR was calculated to be 2.4% in 2002 and 1.8% in 2010. Table 1 shows the yearly population numbers observed diabetes prevalence, estimated prevalence and percentage of patients with PDR.

Table 2 shows the rates of vitrectomy for PDR in the observed diabetic population, the PDR population and the estimated diabetic population. The rate of vitrectomy in the observed diabetic population was 157(135-187) per 100,000 in 2000 and 103(98-109) per 100,000 in 2010. There was a significant downwards trend in the rate of vitrectomy from 2000 to 2010 in vitrectomies for the complications of PDR in the observed diabetic population (Pearson's r = -0.729, p=0.011). (Figure 1) although the point rate of vitrectomy between 2000 and 2010 was not significantly different (p = 0.23, 95% CI = 0.75 to 2.98). The number of patients with PDR requiring vitrectomy showed a significant reduction from 7.7% in 2002 to 5.7% in 2010. (OR = 1.81, p < .0001 respectively). There was no significant change in the rate of vitrectomy in the estimated diabetic population from 68 (48-87) per 100,000 in 2001 to 77(55-103) in 2010 (p=0.51).

Table 3 presents detailed data on the 34 patients who underwent vitrectomy in 2000-2001 and the 59 patients who underwent vitrectomy in 2009-2010. There were significant reductions in mean HbA1c at vitrectomy and the percentage of patients undergoing vitrectomy who presented with established proliferative diabetic

retinopathy. Similarly, there was a significant increase in the duration of known diabetes prior to vitrectomy and evidence of a lowering of the surgical threshold with an improvement in visual acuities prior to vitrectomy. In 2000/1 79% of cases had a visual acuity of 6/60 or worse prior to vitrectomy compared to 49% in 2009/10.

Discussion

The rate for vitrectomy for PDR in the observed diabetic population in 2010 was 103 per 100,000 of the diabetic population. There is little to compare this with in the published literature. Gupta et al. [6] found a rate of 200; higher than our rate but broadly in the same range. It should be noted that the actual rate of diabetic vitrectomy in the area was higher because 34% of patients underwent fellow eye surgery, concurring with previous studies[11] and 6% underwent revision surgery for various post-operative problems. There are several reasons why vitrectomy rate may vary between areas, including the ethnicity of the studied population. The area of North East England studied in this paper was predominantly (95.5%) white Caucasian compared to the UK average of 88.2% [12] and 67% in the study by Gupta et al.[6]

We found a rate of vitrectomy for PDR of 5.7% in 2010. This compared to the 5 year vitrectomy rate of 5.3% per person with PDR reported by ETDRS with a cumulative rate of 11% at 9 years[1], and Kaiser et al.'s[3] reported 10% within 1 year of presentation with any stage of PDR. It is difficult to know the exact relationship between the prevalence of PDR in a population and the number of patients requiring vitrectomy as we have done, compared with following a cohort of patients with PDR but it is interesting that they fall within the same range.

The rate of vitrectomy for PDR showed a gradual reduction from 157 in 2000 to 103 in 2010. This was mirrored by a falling rate in the PDR population from 7.7% in 2002 to 5.7% in 2010. Screening was introduced in 2002 which accounts for the number of patients undergoing vitrectomy in 2000/2001 who were referred with PDR at presentation being substantially higher than in 2009/10 suggesting that earlier retinopathy was being detected and referred after the onset of screening. There are, however, several other potential reasons for the vitrectomy rate falling. Scanlon divided the reasons for eyes requiring vitrectomy into potentially modifiable and non-modifiable factors [2]. Non modifiable factors include the ethnicity of the population and the duration of diabetes. The ethnicity of the area was fairly static according to census data [9] but diabetes duration in those undergoing vitrectomy did increase from 2000/1 to 2009/10 perhaps secondary to diabetic care improving and length time bias with earlier diagnosis of diabetes. Potentially modifiable factors include metabolic and hypertensive control and laser treatment. HbA1C in those undergoing vitrectomy improved from 2000/1 to 2009/10 and there is also evidence locally that HbA1C control improved over the study period.[13,14] Long term progression rates to PDR have reduced as metabolic and hypertensive control has improved over the last 25-30 years and this would also be expected to result in a reducing vitrectomy rate [15,16].

The study has several weaknesses in that it was a retrospective observational study of standard clinical practice. There were no predefined protocols for which patients were eligible for vitrectomy and it is well known that surgeons vary in their surgical intervention rates.[17] However, the same surgeons were involved with the care of the patients during the study period and although there is evidence that the surgical threshold reduced during the 11 years, the variability will have been less than if

different surgeons had been involved We did not record patients who declined surgery despite being offered it and we do not know the number of patients for whom it was felt that the disease was too advanced to benefit from surgery.

There are also two other confounders which may have influenced the results. Firstly, there is evidence that the threshold for vitrectomy is decreasing with improving preoperative visual acuities, as noted elsewhere [5, 7].If the indications for vitrectomy used in 2000 had stayed constant then the rate in 2010 would have fallen considerably more than reported here. Importantly, we distinguished vitrectomy for PDR-related complications from vitrectomy for non PDR associated foveal traction, a relatively new indication for surgery. Secondly, an additional confounder is the prevalence of diabetes used. It is widely acknowledged that there is a mismatch between the true number of patients with diabetes and those actually diagnosed. Diabetes prevalence models provide an estimate of total (diagnosed and undiagnosed) diabetes prevalence within a population. Recently, the UK Association of Public Health Observatories (APHO) produced a new diabetes prevalence model[4] which has been validated in an adjacent area of North East England.[18] The gap between the observed and estimated diabetic population was lower between study onset and finish and there is a lower proportion of undiagnosed diabetics in the area now than in 2000. This could in part explain the falling rate in the observed diabetic population with fewer patients presenting at diagnosis with advanced retinopathy and also a length time bias, with a greater number of early milder diabetics included in the population prevalence figures. Indeed our vitrectomy incidence figures, based on the estimated diabetes prevalence albeit with their wide uncertainty limits, show no significant reduction and our reducing incidence of PDR also confers with this. It seems likely that even if modifiable factors continue to improve, some patients will

still require vitrectomy either from retinal neovascularisation progressing despite laser or the later effects of vitreous separation.[1,19] Patient factors also moderate the effects of improving access to healthcare and the resultant requirement for vitrectomy. The uptake of screening in the area was 89% in 2010 despite a wide variety of interventions to improve uptake, and furthermore failure to attend appointments is common.

The strengths of the study include that the area studied had low population growth over the study period with low migration into and out of the area. It was also a circumscribed area served by one eye unit. Case finding was based on surgeon records and cross checked with theatre diaries, neighbouring providers, diabetic vitrectomy annual screening lists and the current screening database which records if diabetic vitrectomy has been carried out, meaning that the chance of missed cases was low.

In conclusion, this study evaluated vitrectomy rates for diabetic retinopathy in an area of North East England. Rates for a diabetic population over an 11 year period are produced for the first time. There was a suggestion of declining rates of vitrectomy for PDR in patients with diabetes following the introduction of diabetic retinopathy screening, although several confounding factors have to be considered.

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