

Welcome to the real world



Pam Brown
GP in Swansea

Many of us view the outcomes achieved in randomised trials of diabetes management with a healthy hint of scepticism, aware that similar outcomes are unlikely in the real world. Many of these studies are from other countries with different healthcare systems and resources, making translation to UK practice challenging. I was therefore interested in two studies of “real world” outcome data from large, validated, UK primary care databases published early this year.

“Real world data”

Despite concerns that individual lifestyle change programmes alone will be inadequate to stem the rising tide of type 2 diabetes (Barry et al, 2015), the NHS Diabetes Prevention Programme pilot aims to screen 10 000 people for prediabetes in seven demonstrator sites this year prior to the national roll out. The anticipated reduction in type 2 diabetes incidence is 26% (Barry et al, 2015). The identification element of the programme will take place through the English NHS Health Check programme, which has just published its first 4-year evaluation (Robson et al, 2016). NHS Health Checks aim to reduce cardiovascular disease (CVD) risk through a rolling 5-year programme of structured clinical assessment and management of adults aged 40–74 years not yet diagnosed with diabetes, chronic kidney disease or CVD and who are not on statins.

The evaluation, published in January 2016, used QResearch, the validated nationally representative database of EMIS practices covering 13 million patients, to collect data from the first 4 years of the Health Check programme, evaluating new comorbidities and medications during the 12 months following each check. Although uptake continues to be lower than anticipated, it has increased incrementally from 5.8% of those eligible in 2010 to 30.1% in 2012.

A total of 80% of those attending an NHS Health Check had a QRISK2 score recorded compared with 29% of non-attenders, and of those attenders scored, around 50% had a 10-year

risk of 10% or higher, compared to 27% of non-attenders scored, suggesting the programme is attracting some of the higher-risk population. Attendance amongst some Asian ethnic groups suggests good reach into these communities, with nearly 30% of eligible Bangladeshi and 17.7% of Indian people attending, compared with 17.4% of the white eligible population. In total, 15.1% of Pakistani and 14.6% of other Asian eligible groups attended. It is hoped that uptake across all groups can be improved in future years.

In 12 months following the Health Check, one new case of diabetes was documented for every 110 health checks, almost double the rate coded in those not attending. Previous health checks used fasting and random glucose only and sought to replicate the two-step process recommended in the NICE prevention guideline (NICE, 2012), with only those at highest risk (around 50%) having glucose testing. More than 1 in 5 of those screened had one or more measurement (blood glucose, blood pressure or obesity) requiring follow up, demonstrating that the NHS Health Check generates significant workload within practices.

Of the 27 624 people with a CVD risk of >20%, 19.3% were started on statins and 8.8% were on new anti-hypertensive medication within 12 months of a check, and the authors conclude that it is likely that this will have contributed to important reductions in CVD events (Robson et al, 2016). However, higher statin initiation would increase impact.

Real world weight loss following bariatric surgery

In the UK in 2013, 5558 bariatric operations were carried out, less than 15% of the 37 300 procedures undertaken in France. This is despite recommendations in the NICE (2014) obesity guideline that surgery should be the first-line option for those with a BMI of 50 kg/m² or more when other interventions have failed, an option in those with a BMI of 40 kg/m² or more, or a BMI of 35–40 kg/m² and obesity-related comorbidities who have failed to achieve sustained

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weight loss with other treatments, as well as being considered at a lower BMI for those with recently diagnosed type 2 diabetes.

An observational retrospective cohort study (Douglas et al, 2015) using the validated UK Clinical Practice Research Datalink (CPRD) compared 3882 obese people who had received bariatric surgery with matched individuals who had not received surgery, and looked at body weight changes, development of new chronic disease including diabetes and resolution of hypertension and diabetes. Both cohorts had an average age of 45 years, and around 80% were female. Significant sustained weight loss was maintained over 4 years following surgery. Patients undergoing surgery (average BMI of 44.7 kg/m² versus average BMI of 42.1 kg/m² in those not receiving surgery) lost weight rapidly in the first 4 months (average loss around 5 kg a month), followed by slower weight loss thereafter. This compared favourably with no weight loss in the non-surgery group. In line with previous studies, gastric bypass and sleeve gastrectomy resulted in faster weight loss than gastric banding and, at 4 years, the average weight losses were 38 kg following gastric bypass, 31 kg with sleeve gastrectomy and 20 kg following gastric banding. Interestingly, those with type 2 diabetes or CVD lost weight faster initially than those without.

Overall, surgery was associated with reduced incidence of new type 2 diabetes (hazard ratio [HR], 0.68; 95% confidence interval [CI], 0.55–0.83), reduced risk of initiation of oral anti-diabetes therapy (HR, 0.26; 95% CI, 0.18–0.37) and insulin (HR, 0.22; 95% CI, 0.11–0.43), and reduced risk of being diagnosed with angina, hypertension, myocardial infarction (MI) or obstructive sleep apnoea. Those with pre-existing type 2 diabetes prior to surgery had increased rates of diabetes resolution (HR, 9.29; 95% CI, 6.84–12.62) compared to those who did not receive surgery, with resolution more likely following gastric bypass or sleeve gastrectomy than gastric banding. Importantly, there was no evidence of association between surgery and fractures or cancer. Unlike in other studies, no significant mortality reduction was demonstrated although it was proposed that this may relate to the short study duration.

So how does this compare with other studies of bariatric surgery in the UK and elsewhere? These results mirror the findings of an observational study from the US (individuals who had a gastric band lost 20 kg, and individuals who had a gastric bypass lost 41 kg; Courcoulas et al, 2013). Another study using data from the CPRD (Booth et al, 2014) demonstrated a much greater protective effect against developing type 2 diabetes with a HR of 0.2 compared with 0.68 in this study, and it is postulated this reflects different diagnostic criteria for type 2 diabetes (Douglas et al, 2015).

Weight loss in these observational studies is within the range demonstrated in randomised trials: 29–50.6 kg following gastric bypass over 2 years (Sovik et al, 2010; Mingrone et al, 2012; Schauer et al, 2012), 25.1–29.5 kg for sleeve gastrectomy (Ogden et al, 2014) and 17–21.1 kg for gastric banding (Himpens et al, 2006; Dixon et al, 2008).

Currently, it is estimated that around 1% of those who could benefit from bariatric surgery are able to receive it in the UK. The authors of this study (Douglas et al, 2015) conclude that assuming the associations reported are causal, which seems likely since they reflect the randomised controlled trial evidence, increasing bariatric surgery availability in the UK could lead to “substantial health benefits for many people who are morbidly obese” and prevent more than 40 000 new cases of diabetes per year. This is the largest population study looking at bariatric surgery outcomes in a UK population and helps us understand the potential benefits of bariatric surgery for our patients.

Real world audit

As our Editorial Board discussed recently, undertaking simple audits and reflecting and acting on our findings can be a powerful way to change practice and improve the care we deliver. In our new series, Dr Sam Seidu will introduce simple, easy-to-run audits. The first audit is on diabetes screening in women previously diagnosed with gestational diabetes (page 18). We hope these hands-on “how to” audit guides will provide the practical guidance (e.g. Read Codes and search parameters) and motivation we all need to take action in the limited time available. As

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well as the reflection, discussion and changes we make at a practice level, we will have the opportunity to compare our baseline data with that from colleagues across the UK, so please join in and send us your top-line aggregated findings to dpc@sbcommunicationsgroup.com.

Real world education

The PCDS focus on developing and delivering practical education at regional and national meetings and conferences, but we are aware that in the real world it is difficult to achieve time out of our practice to attend face-to-face education. The education provided within the pages of the journal, including the rolling programme of modules covering the International Diabetes Federation core curriculum, are designed to help us stay up to date without leaving the practice and can be read when time permits. Completing the online assessment at www.cpd.diabetesonthenet.com generates a certificate of completion for use in appraisal and revalidation.

During 2015, insulin safety education was our priority as it was a largely unmet need, as tight Clinical Commissioning Group and Health Board budgets meant that many other insulin educational resources would no longer be funded. PCDS and TREND-UK developed the “Six Steps to Insulin Safety” module, which is hosted on *Diabetes on the Net* (www.bit.ly/1SE7Lt0; accessed 08.02.16), and is free to all healthcare professionals. A certificate of completion is available once the assessment is completed. The module is endorsed by NHS England, the Welsh Endocrine and Diabetes Society, Diabetes UK, the Joint British Diabetes Societies for Inpatient Care (JBDS-IP) Group and the Diabetes Inpatient Specialist Nurse (DISN) UK Group. We are grateful to Lilly, Novo Nordisk and Sanofi for their educational grants towards development of this module, grants provided independently of any editorial control.

Virtually all of us initiate, intensify or administer insulin or sign prescriptions, which means we have a personal responsibility to ensure we are up to date with this aspect of our education and fully aware of safety issues around insulin use. Initial feedback on the module has been excellent and we would strongly encourage you to take the opportunity to update your knowledge.

Encouraged by the rapid uptake of this e-learning resource, the PCDS are excited to announce that we have been awarded an educational grant from the Welsh Assembly Government to develop three e-learning modules based on clearly identified educational needs amongst our members and wider primary and community care teams. These modules will cover prediabetes, pregnancy and preconception care, and for the first time will provide a core diabetes module for healthcare assistants in the community, care homes and practices. The modules will be available free from Spring 2016 on www.diabetesonthenet.com, ensuring all healthcare professionals have access to the education needed to help support safe and quality care delivery.

So whether you prefer meetings and conferences, webinars, e-learning modules or print-based articles for personal or practice use, the PCDS will offer a range of brand new resources for 2016. Enjoy learning with us again this year and let us know what does and doesn’t work so that you can help shape the education we offer in 2017. ■

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