



## Five-Year Outcomes of a Randomized Trial of Gastric Band Surgery in Overweight but Not Obese People With Type 2 Diabetes

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John M. Wentworth,<sup>1,2,3</sup> Paul Burton,<sup>1</sup> Cheryl Laurie,<sup>1</sup> Wendy A. Brown,<sup>1</sup> and Paul E. O'Brien<sup>1</sup>

The incremental benefit of bariatric surgery in people who receive good diabetes care is uncertain. So far only one randomized trial of surgery for obese people with type 2 diabetes (T2D) has reported 5-year outcomes. Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion (BPD) reduced the burden of glucose-lowering medication and delivered diabetes remission in 50% of surgical-arm participants (1). We previously reported 2-year outcomes of a randomized trial of laparoscopic adjustable gastric band (GB) surgery in overweight but not obese Australians with T2D of less than 5 years' duration (2). Diabetes remission, defined as fasting glucose <7.0 and 2-h glucose <11.1 mmol/L after a 75-g oral challenge, was observed in 52% of GB participants. The protocol, methods, and extended data are available in the Supplementary Data online.

We now report 5-year outcomes. Of 51 participants who enrolled in the study between 2009 and 2011, 45 (22 randomized to receive GB combined with medical care and 23 to medical care alone [MED]) were followed to 5 years. The mean  $\pm$  SD weight loss (WL) at the end of the study was  $11.2 \pm 7.6\%$  and  $2.6 \pm 6.9\%$  of baseline in GB and MED participants, respectively (difference 8.6%, 95% CI 4.2–13.0). The average WL over the 5 years of the

study was 12.2% in GB and 1.8% in MED participants (difference 10.4%, 95% CI 6.9–13.8) (Fig. 1A). This degree of incremental WL was lower than that seen in the prior surgical study in obese people (23% WL) (1) but superior to levels achieved in predominantly obese T2D populations that received intensive lifestyle intervention for 5 years (3.5% WL) (3) or liraglutide for a year (4% WL) (4).

Diabetes remission at 5 years was observed in five (23%) GB and two (9%) MED participants, equating to a relative risk of diabetes following surgery of 0.85 (95% CI 0.65–1.10;  $P = 0.2427$ ). GB participants used fewer glucose-lowering medications (Fig. 1C), and their averaged HbA<sub>1c</sub> over the 5 years of follow-up was 10.4 mmol/mol (95% CI 3.8–16.9) lower than that of MED participants (Fig. 1B). Blood pressure did not differ significantly between the groups. The mean HDL cholesterol was 0.24 mmol/L (95% CI 0.02–0.46) higher and triglycerides 0.7 mmol/L (95% CI 0.1–1.2) lower in GB participants, while their LDL cholesterol was 0.5 mmol/L (95% CI 0.1–0.9) higher in the context of less frequent use of lipid-lowering drugs.

Quality of life and health utility remained relatively constant in MED participants but showed early and sustained improvement in the GB group (Fig. 1E).

At 5 years, composite scores of physical and mental health in the GB group had increased to above the general population mean  $\pm$  SD of  $50 \pm 10$  to  $53 \pm 8$  and  $54 \pm 10$ , respectively, corresponding to an increase in mean health utility of 0.12 (95% CI 0.06–0.18). This corresponded to a mean difference in health utility after 5 years of 0.10 (0.02–0.18) favoring GB participants. These effects are comparable to the quality-of-life benefit of RYGB and BPD in obese people with T2D (1) and to the health-utility gain following renal transplantation for T2D nephropathy (5).

Analysis of direct health costs in 2016 Australian dollars showed that the per-participant cost of \$13,910 for GB surgery and aftercare in the GB group was partially offset by a mean saving of \$4,257 on drug therapy, contributing to an overall difference in health costs of \$8,661 favoring the MED group.

There were 63 and 72 adverse health events in the GB and MED groups, respectively. GB revision surgery was performed in two participants, and another had abdominoplasty following WL. Four GB participants and three MED participants had upper endoscopies. Three GB participants experienced a total of seven episodes of swallowing difficulty requiring removal of saline from the band. One MED participant developed angina requiring cardiac stent,

<sup>1</sup>Centre for Obesity Research and Education, Monash University, Clayton, Australia

<sup>2</sup>Walter and Eliza Hall Institute of Medical Research, University of Melbourne, Parkville, Australia

<sup>3</sup>Department of Medicine, Royal Melbourne Hospital, Parkville, Australia

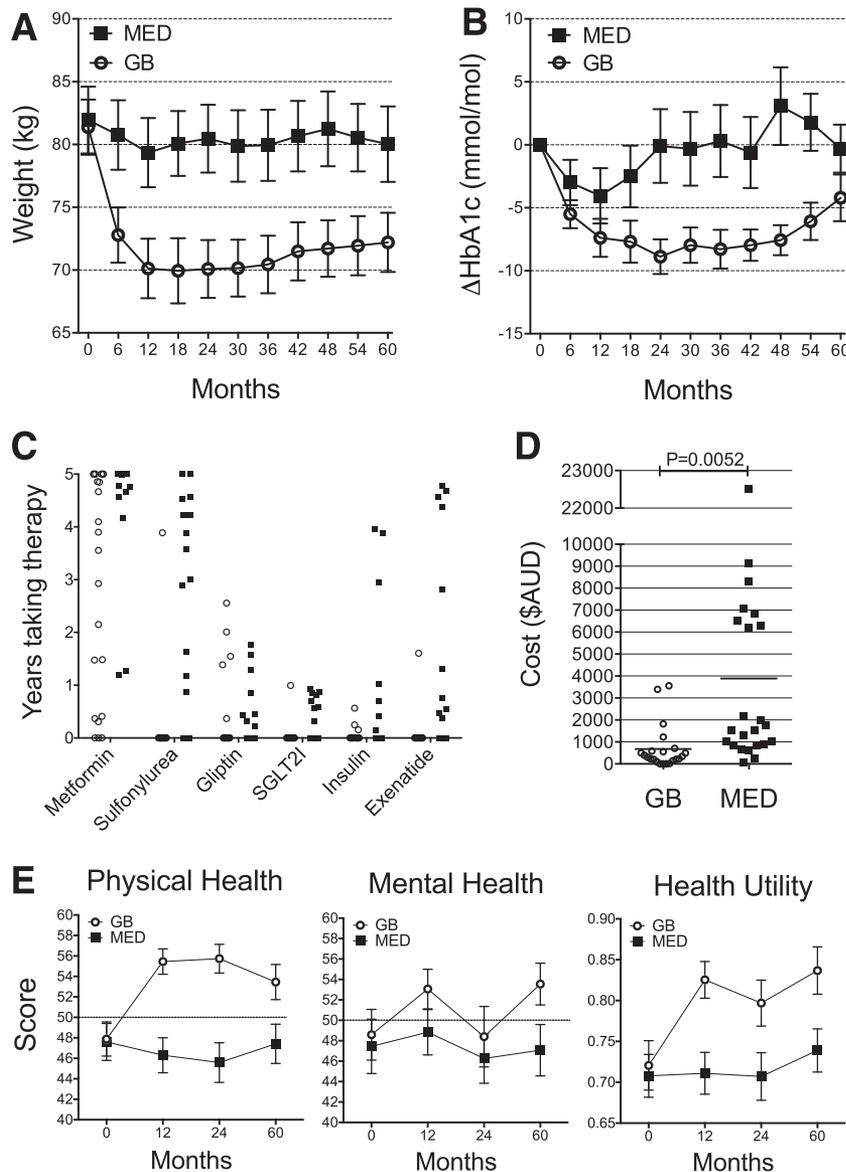
Corresponding author: John M. Wentworth, wentworth@wehi.edu.au.

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**Figure 1**—Weight, glucose, and quality-of-life outcomes over 5 years. Six-month measures of weight (A) and HbA<sub>1c</sub> (B) (change from baseline) are presented as the group mean ± SEM. C: Individual duration of glucose-lowering therapy is presented according to drug class. Duration of use of all therapies other than gliptins was significantly higher in the MED group. D: Costs in 2016 Australian dollars of glucose-lowering therapy over the 5 years of the study were determined using dosage data and the Australian Pharmaceutical Benefits Schedule. E: Quality of life and health utility derived from the 36-Item Short Form Health Survey (SF-36), presented as mean ± SEM. The scores for physical and mental health have been normalized to the Australian population mean ± SD of 50 ± 10. SGLT2i, sodium–glucose cotransporter 2 inhibitors; \$AUD, Australian dollars.

another was hospitalized for stroke, and another underwent retinal photocoagulation. One GB participant experienced proteinuria and an estimated glomerular filtration rate <30 that resolved after stopping sitagliptin, and one MED participant was hospitalized for 2 months with eosinophilic fasciitis attributed to atorvastatin.

This study was limited by a relatively small sample size, which was not powered to detect small differences in rates of

diabetes remission. Government funding rules limited our ability to provide sodium–glucose cotransporter 2 inhibitors and glucagon-like peptide 1 analogs, which may have aided WL in MED participants at the expense of higher medication costs. Also, our findings may not apply to the general population of overweight people with T2D, particularly those with disease duration greater than 5 years and those without access to quality GB surgery and aftercare.

We conclude that sustained WL of 10% body weight is a powerful therapy for overweight but not obese people with T2D because it delivers clinically meaningful improvements in HbA<sub>1c</sub>, HDL cholesterol, and quality of life and decreases the cost of glucose-lowering drug therapy. These metabolic effects are generally comparable to those observed in obese people undergoing RYGB and BPD, although long-term rates of diabetes remission appear to be higher after these more hazardous procedures (1).

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**Author Contributions.** J.M.W. and P.E.O. devised the study. J.M.W. and C.L. oversaw delivery of diabetes care. P.B., W.A.B., and P.E.O. performed GB surgery and oversaw postsurgical follow-up. J.M.W., C.L., and J.P. collated the data, and J.M.W. analyzed them and drafted the manuscript, which all authors reviewed and edited. J.M.W. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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