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Study Summary

Effects on Diabetes Medications, Weight and A1C Among Patients with Obesity and Diabetes: 6-month Observations From a Full Meal Replacement, Low-Calorie Diet Weight Management Program

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Study Objective: *This retrospective cohort study's aim was to define the interplay of full meal replacement (MR) with various hypoglycemic agents among patients with obesity and type 2 diabetes and to demonstrate that in a full MR medically supervised weight management program, patients with diabetes would lose weight, require less hypoglycemic medications, and have improved glycemic control.*

Background: Obesity and diabetes are strongly related with 80-90% of persons with type 2 diabetes being overweight or obese. Meal replacements have been shown in patients with type 2 diabetes to produce superior weight loss compared with conventional, self-prepared diet plans. The CORE program at the Ottawa Hospital Weight Management Clinic (OHWMC) is a year-long comprehensive, medically-supervised, life-style, behavioral, weight-management program for patients with obesity. It uses a full MR (900 kcal and 90g protein/day — OPTIFAST® 900) for 6-12 weeks and then transitions to regular food. It includes weekly group education session for the first 6-months and follows a protocol for patients with diabetes of decreasing or discontinuing diabetic medications promoting weight gain first (WG) and then titrating medications with no effect on weight (WN).

Materials and Methods: Retrospective cohort study (1992-2009) on weight, glycemic control, and diabetes medications changes in 317 patients with obesity and type 2 diabetes on medications who were enrolled in the CORE program at the OHWMC in Ontario, Canada Patients were classified by medication type; those receiving WG medications and those receiving WN medications.

Results: Glycemic data was available for 2744 patients; 456 (20.1%) had type 2 diabetes, 95 were not on medications for diabetes and 44 were excluded for non-compliance to the CORE program. In the 317 patients included in this study, 235 (74.1%) were in Group WG and 82 (25.9%) in Group WN.

- There was no significant difference between Group WG and Group WN in age, gender, baseline weight or initial BMI. However, baseline A1C was significantly lower in Group WN (7.5% vs 6.6%, p<0.001).
- At 6 months, both groups lost approximately 16% weight. The following medications were decreased or discontinued at 6-months: 92.1% sulfonureas, 86.5% insulin, 78.8% thiazolidinediones, 77.8% alpha-glucosidase inhibitor, 50% meglitinides, 33.3% DPP4 inhibitors, and 32.8% metformin.
- At 6 months compared with baseline, A1C improved in Group WG and Group WN (A1C 6.7% and 5.8% respectively, p<0.0001) with Group WN having significantly better A1C than Group WG (p< 0.0001).
- At 6 months, 30% (n=95) of patients were no longer on diabetes medications and had significantly better % weight loss compared with those on medications (18.6% vs 16%, p=0.002); both groups had improved glycemic control at 6 months (A1C 6.0% vs A1C 6.6%, NS).

Discussion: This study reports on changes in hypoglycemic agents in patients with diabetes following an intensive lifestyle program in conjunction with a full MR diet. The protocol of reducing medications that are weight gaining first and then weight neutral appears safe with significant improvement of A1C levels in the 6-month protocol. Patients who particularly benefited from the full MR were patients who had all their diabetes medications discontinued by 6 months - this group had the greatest amount of weight loss (18.6% weight loss) — and those who had initially been on weight neutral diabetes medications had the best A1C profile at the end of the program — (6 months A1C was 5.8% compared with baseline 6.7 %).

Conclusion: In patients with obesity and type 2 diabetes on medications, a full MR program appears safe with A1C improvement. At 6 months, percent weight loss can be significantly better in patients who no longer require diabetes medications and A1C is best controlled in patients who are on WN medications.

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