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Application of Meal Replacement in Patients with Type 2 Diabetes

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Medical nutrition therapy (MNT) is the foundation of standardized diabetes management. According to guidelines, healthcare providers should customize diet plans to align with patients' personal and cultural values, preferences, and treatment goals to ensure optimal adherence and benefits. Nevertheless, due to the limited medical resources, many patients with type 2 diabetes mellitus (T2DM) could not access to the guidance of MNT. Meal replacement (MR) provides a practical solution for portion control and caloric restriction. It is a commercial pre-packaged selection of foods, which typically consists of a combination of carbohydrates, fats, and proteins with added vitamins and minerals, in the form of milkshakes, nutrition bars, or soup. MR is commonly utilized to replace one or two main meals (partial meal replacement, PMR), or all meals (total meal replacement, TMR) per day. It has been demonstrated to improve dietary quality, weight management, and glycemic control of patients with T2DM [1-4].

Some guidelines recommend diabetic patients to use MR [5,6], but the optimal prescription of MR for patients with T2DM and its applicable objects remain uncertain. A prior meta-analysis explored the role of MR in the management of T2DM, which showed that MR led to significant reductions in body weight, BMI, HbA_{1c} and fasting glucose compared with traditional weight loss diets [4]. However, due to the limited RCT clinical evidence available at that time, the certainty and precision of the effect estimates were restricted. As the evidence has been growing, a more comprehensive analysis of the efficacy and safety of MR, especially investigating the treatment effect of different MR administration manners in patients with different clinical backgrounds, is necessary for more detailed clinical recommendations. Therefore, we conducted a meta-analysis and systematic review with subgroup analyses to provide novel information that helps to guide MR applications in different clinical settings [7].

Overall Effects of MR on Patients with Type 2 Diabetes

A total of 17 randomized controlled trials involving 2112 participants were ultimately included in the study. Compared with conventional diabetic diets (CDs), MR significantly reduced HbA1c (MD -0.46%, P<0.001), fasting blood glucose (FBG, -0.62mmol/L, P<0.001), body weight (-2.43kg, P<0.001) and BMI (-0.65kg/m^2, P<0.001), as well as improved other cardiometabolic risk factors. The MR-based dietary pattern further improved the glycemic control and adipose indicators in T2D patients. Our primary findings are similar to previous study and demonstrate the benefits of MR in the management of T2DM. Moreover, due to the increased number of included trials and a larger sample size, we were able to evaluate the impact of various patient characteristics and MR interventions on outcomes through subgroup analysis.

Tailoring MR Strategies for Diabetes Management

There were significant discrepancies in MR prescription and clinical characteristics of the included patients among studies investigating the efficacy of MR in patients with T2DM. For instance, MR was administered for varying duration, prescribed as TMR or PMR, and utilized with or without caloric restriction and exercise. Additionally, these studies included both those involving insulin users and those excluding them, with the minimum BMI criteria ranging from 18.5 kg/m^2 to 30 kg/m^2. The huge variability in clinical trials is not conducive to the precise utilization of MR. In order to identify who are more suitable for MR interventions, and determine the appropriate MR prescriptions for diverse clinical situations, we performed subgroup analyses in the systematic review and meta-analysis.

TMR *vs.* PMR

Several studies using TMR had similar interventions methods. The intervention consisted of total meal replacement (800-853 kcal/day MR for about 12 weeks), stepped food reintroduction (2-8 weeks), and structured support for long-term weight loss maintenance. The safety and efficacy of this intervention mode have been validated. Our subgroup analyses revealed that TMR led to greater improvement in HbA1c (-0.72% *vs.* -0.32%, P=0.01), FBG (-1.45 *vs.* -0.56mmol/L, P=0.02), body weight (-6.57 vs. -1.58kg, P<0.001), and BMI (-2.78 vs. -0.37kg/m^2, P<0.001) than PMR. Therefore, for the purpose of improving both glycemic control and weight management, TMR under the guidance of professional doctors and nutritionist may be a preferred option for patients with T2DM.

MR with or Without Caloric Restriction

Several studies using MR additionally implemented caloric restriction, with restriction levels including 800-850 kcal/d, 500 kcal or a 25% energy deficit, and 20 kcal/kg·d. In our subgroup analyses, MR with caloric restriction showed more reductions in body weight (-3.20 vs. -0.75kg, P<0.001) and BMI (-0.84 vs. -0.24

kg/m^2, *P*=0.003) compared with those without caloric restriction. MR with caloric restriction had a more favorable impact on weight management, highlighting the important role of caloric restriction in the management of T2DM, as emphasized in the guideline [8]. Meal replacement is a viable method to achieve portion control and caloric restriction.

MR and Anti-diabetes Treatment

Insulin

Compared to non-insulin users, patients on insulin are likely to have diabetes of increased severity and may have compromised pancreatic function [9]. Thus, many lifestyle intervention studies excluded patients treated with insulin. *Brown et al.* conducted a trial involving 90 participants with T2DM who were receiving insulin therapy and had a median duration of diabetes of 13.0 (9.0-20.0) years. They found that these participants achieved greater weight loss, glycemic control and quality of life through TMR intervention. In our subgroup analyses, MR showed comparable benefits in studies that included patients using insulin and those that didn't (HbA1c -0.42% [-0.67, -0.16] *vs.* -0.54% [-0.83, -0.25], *P*=0.53; FBG -0.63 mmol/L [-1.48, 0.21] *vs.* -0.67 mmol/L [-1.05, -0.30], *P*=0.93; weight loss -4.23 kg [-7.08, -1.39] vs. -2.52 kg [-3.59, -1.44], P=0.27; BMI -2.36 kg/m^2 [-4.49, -0.23] v s. -0.63 kg/m^2 [-0.90, -0.36], *P*=0.11). Our study increases the evidence showing that MR usage is advantageous for both patients treated with or without insulin.

Some studies have reported the impact of MR on insulin treatment. *Brown et al.* and *Kempf et al.* have suggested the advantages of MR in terms of insulin discontinuation and reduction of insulin dosage. After one year of intervention, the changes in insulin dose were -47.3 ± 36.4U/day and -16.6 ± 33.6U/day in the MR intervention group in the two studies, compared to -33.3 ± 52.9 U/day and -1.4 ± 25.2 U/day in the control group, respectively [10,11]. But *Shirai et al.* did not observe significant difference in insulin discontinuation or reduction of insulin dose after a 24-week PMR intervention [12].

Oral Anti-diabetic Drugs

Besides, MR interventions have been reported to significantly reduce the use of oral anti-diabetes drugs [13-15], among which sulfonylureas were reported most frequently [10,12,16]. When using intensive MR intervention, such as TMR, it is advisable to presciently reduce the dose of anti-diabetes drugs, avoiding the occurrence of hypoglycemic events.

Overall, individuals on anti-diabetic drugs can safely use meal replacements, potentially reducing therapy intensity. However, high-quality trials are needed due to variability in previous studies.

MR and the Remission of T2DM

Recent studies indicated that MR, as part of lifestyle intervention, also holds significant potential in reversing T2DM. The DiRECT used TMR (825-853 kcal/day formula diet for 3-5 months), stepped food reintroduction and structured support for long-term weight loss maintenance. Diabetes remission rates was 46% at 1 year [14] and over 30% at 2 years [17]. The DIADEM-I trial adopted a dietary strategy similar to DiRECT, achieving 61% remission at 1 year [15]. These findings are clinically important as they demonstrated that MR, as part of intensive lifestyle intervention, is feasible in inducing T2DM remission in community settings.

Conclusion

MR holds a significant position in the medical nutrition therapy for patients with T2DM. The challenge of its application lies in tailoring MR interventions to suit individual characteristics. Current data suggests that appropriate calorie restriction and TMR may yield greater benefits, while both patients treated with or without insulin could similarly benefit from MR usage. Nonetheless, MR and structured support may be challenging for some patients, and long-term adherence to MR and lifestyle changes may be difficult to maintain. The current studies have laid the groundwork for personalized MR strategies, but more clinical studies are needed to ultimately refine the precise and effective MR utilization in the management of T2DM.

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