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Safe and Effective Use of the Single-Use Pen for Injection of Once Weekly Dulaglutide in Injection-Naïve Patients with Type 2 Diabetes

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Patients and clinicians often avoid initiating injectable therapy in type 2 diabetes (T2D)—fearing pain and complexity. The single-use pen (SUP) device contains a pre-filled syringe and automates needle insertion and retraction, and drug delivery. It was designed for subcutaneous delivery of 0.5 mL of dulaglutide, a once-weekly glucagon-like peptide-1 receptor agonist.

The objective of this 4-week, phase 3b, multicentre, open-label, single-arm outpatient study was to demonstrate the safe and effective use of the SUP containing 0.5 mL of placebo in injection-naïve T2D patients as demonstrated by the final injection success rate (ISR) (primary outcome) and the initial ISR following training (key secondary outcome). Patient-reported outcomes for pain, ease of use, willingness to continue using the SUP and fear of self-injection were also reported.

Mean baseline patient demographics (n=211) were: age 61 years, duration of diabetes 7.7 years and BMI 31.7 kg/m². The final ISR was 99.1% (95% CI: 96.6, 99.7), the initial ISR was 97.2% (95% CI: 93.9, 98.7), meeting the primary and key secondary objectives. On a scale of 0 (no pain) to 10, the mean (SD) pain scores across injections was 1.0 (1.1). 99.0% of patients found the device easy to use and 96.7% would be willing to continue to use the SUP after the study. There was a significant reduction in patients' fear of self-injecting.

The SUP was a safe and effective device for injection-naïve T2D patients. Improvements in injection experience may be an important factor for some patients and providers when initiating injectable therapy.

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The Development and Pilot Testing of the Body Knowledge Questionnaire (BKQ)

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Long-term success of various weight loss programs is poor. Also, insufficient attention has been given to the experience aspect of weight management, a perspective that is critical to understanding this failure and in identifying factors needed to ensure long-term success.

The theoretical framework for this research was Hernandez (1991) theory of integration. Twenty-seven items measuring attitudes, preferences and behaviour associated with weight management were identified through a review of the literature and the theory of integration. The resulting BKQ was pilot tested in

38 normal or obese weight individuals, with or without type 2 diabetes.

Evidence for construct validity was shown through exploratory factor analysis. Criterion-related validity was demonstrated through discriminant function analysis and logistic regression. Discriminant function analysis indicated that the 2 BKQ subscales did differentiate between the normal and obese weight individuals, and logistic regression demonstrated that the total BKQ could reliably classify 89% of the participants as either obese or normal weight. Internal consistency reliability was $\alpha=.87$ for the BKQ and $\alpha=.91$ and $.73$ for the 2 subscales.

The BKQ was shown to have initial validity and reliability, thus warranting further development and testing with a larger sample. The BKQ shows promise for use in the field of weight management with potential use in identifying problematic attitudes, preferences or behaviours that predispose individuals to obesity, possibly pointing to new weight management strategies, and as a tool to predict BMI category.

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Barriers and Coping Strategies of Women with Gestational Diabetes to Follow Dietary Advice

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Objective: To understand barriers and coping strategies of women with gestational diabetes (GDM) to follow dietary advice.

Design: Qualitative study.

Participants: Thirty women with GDM from the Winnipeg area participated. Each participant completed a food choice map (FCM) semi-structured interview and a demographic questionnaire.

Major outcome measures: Underlying beliefs of women with GDM and factors that hinder following dietary advice.

Analysis: Qualitative data analyzed using constant comparative method to identify emergent themes of factors and beliefs that affected following dietary advice. Themes were categorized within the Integrative Model of Behavioral Prediction.

Results: GDM women faced challenges and barriers when 1) personal food preference conflicted with dietary advice; 2) eating in different social environments where food choice and portions were out of control and food choice decisions were affected by social norms; 3) lack of knowledge and skills in dietary management and lack of a tailored dietary plan and 4) limited time for dietary changes.

Conclusions and implications: Quick adaptation to dietary management in a short time period created challenges and emotional distress for women with GDM. Tailored educational and mental health consultation with consideration of the barriers may promote dietary compliance and overall better health.