SUPPLEMENT 2

Introduction of the devices used in this trial

1. Devices

In our study, two CGMs and a blood glucose meter will be applied: blood glucose meter for strip test, retrospective CGM for assistance, and FGM for interpretation. Both CGMs recorded glucose data collected in the interstitial fluid at different time intervals. Details would be described below.

1.1 Retrospective CGM system

The retrospective CGM system (Ipro2®, Medtronic, USA) consists of an inserted sensor and a recorder connected. The sensor will be implanted on the back of the patients' upper arms and data is stored in the recorder every 5minute, thus 288 glucose values will be collected per day in total [1]. The lifetime of each sensor is usually from 3 to 7 days. The mean absolute relative difference (MARD) of Ipro2 is 9.9% in adults and was the lowest in the 240-400mg/dl range (6.8% in adults) [2]. During the wearing time, the sensor data derived are not visible and only after the removal of the sensor and data download with retrospective SMBG data calibrations, the glycemic metrics and ambulatory glucose profile will be accessible to the patients and investigators. Therefore, the retrospective CGM is thought to be a perfect tool in the research with less interpretation.

1.2 FGM system

The FGM system (FreeStyle Libre®; Abbott Diabetes Care, Witney, Oxon, UK) is a novel sensor-based intermittently scanned glucose monitoring system [3]. The sensor is around 1*1 cm and implanted by a single-use applicator, and automatically measures glucose every 15 minutes for up to 14 days without finger-stick calibrations. The sensor will be implanted on the back of the upper arms which is thought to be more accurate [4]. The MARD tested in adult patients is 8.8-12.9% compared with venous glucose reference and YSI pairs (Yellow Springs, OH) [5,6]. The most frequent safety problem of FGM is erythema, as shown in the system reviews about FGM [7,8].

1.3 Blood Glucose Meter (Bayer®)

The blood Glucose Meter (Bayer®; Bayer Consumer Care AG) is a reliable home-use device to perform finger-stick strip tests and meet the predetermined accuracy standard illustrated in a recent study [9,10]. Therefore, it will be distributed into each patient as a tool to perform any finger-stick tests during the trial.

2. Questionnaires

In our study, the Chinese version of the DDS, HFS, EQ-5D-5L will be used to evaluate the change in distress from diabetes, the fear of hypoglycemia, and the quality of life

after the intervention. The excellent reliability and validity of the scales in Chinese Version had been proved [11-13].

2.1 Diabetes Distress Scale (DDS)

The Chinese version of the DDS is to evaluate diabetes-related emotional distress in patients with diabetes [12]. The scale consists of 17 items, contains four domains including emotional burden sub-scale, physician-related distress subscale, regimen-related distress subscale, and diabetes-related interpersonal distress. Each item is rated on a 6-point Likert scale from 1(no problem) to 6(serious problem). An average score ≥3 is the cut-off point which is considered to more than the moderate problem.

2.2 Hypoglycemia Fear Scale (HFS)

The Chinses version of the HFS is to evaluate psychological status for diabetic patients [13]. These validated surveys consist of 18 questions that measure dimensions of anxiety and fear surrounding hypoglycemia. Each item is rated on a 5-point Likert scale from 0(never related) to 4(very related). Patients with higher scores are considered with more anxieties and fear of hypoglycemia.

2.3 European Quality of Life (EQ-5D-5L) Scale

The Chinese version of the EQ-5D-5L is widely used to evaluate the quality of life in Chinese [11]. The EQ-5D-5L is converted to a single summary index by applying a formula that essentially attaches weights to each of the levels in each dimension. It contains the health description system and Visual Analogue Score (VAS). The health description system includes 5 dimensions including mobility, self-care, usual activities, pain or discomfort, and anxiety/depression. Each item is rated on 5 levels from 1(no problem) to 5(extreme problem). And the VAS is to evaluate the health condition assessed by patients. The top score (100) means the best health conditions and the bottom one (0) means the worst.

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