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ORIGINAL PAPER

Individualized homeopathic treatment in addition to conventional treatment in type II diabetic patients in Hong Kong – a retrospective cohort study

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Objective: **Glycaemic goals are not achieved in most patients with type II diabetes mellitus (T2DM), especially in those with long disease duration and taking multiple oral antidiabetic drugs (OAD). We aimed to investigate the effectiveness of individualized homeopathic treatment in glycaemic control.**
Design: **Retrospective cohort study.**
Setting: **At least 6 months of individualized homeopathic treatment at a private homeopathic centre in Hong Kong.**
Participants: **Twenty-seven adults aged 37–84 years were treated with individualized homeopathic remedies between 2012 and 2015. Published data on 40 T2DM patients under standard conventional treatment in Hong Kong were used as a control.**
Main outcome measure: **Change in fasting plasma glucose (FPG) and glycated haemoglobin (HbA1c) at 12-month or the last follow-up, whichever is earlier.**
Results: **Compared with the conventional treatment only group, the homeopathy group had higher baseline FPG ($p = 0.044$), and more patients had a long (>20 years) duration of diabetes ($p = 0.006$), and a history of cardiac events ($p = 0.022$). The mean difference in FPG in the homeopathy group was significantly greater than in the control after 12 months: −2.24 mmol/L (95% confidence interval [CI]: −3.47 to −1.01) vs 0.16 mmol/L (95% CI: −1.72 to 2.04), $p = 0.001$. The mean difference in glycated haemoglobin (HbA1c) was also significantly greater, −1.11% (95% CI: −2.17 to −0.05) vs 0.08% (95% CI: −1.37 to 1.53), $p = 0.046$. Poorer baseline glycaemic control was associated with better outcome ($r = -0.750$, $p < 0.001$), but not the duration of diabetes ($r = 0.058$, $p = 0.772$). The improvement was robust to sensitivity analyses.**
Conclusion: **Individualized homeopathic treatment was associated with better glycaemic control compared with standard conventional treatment alone.** *Homeopathy* (2017) ■, 1–8.

Keywords: Homeopathy; Individualized treatment; Diabetes; mellitus type II; Cohort study; Hong Kong

Introduction

According to the World Health Organization (WHO), there are approximately 143 million people with diabetes worldwide, and this number is projected to rise to almost 300 million by 2025.[1] The traditional stepwise approach to the management of type II diabetes mellitus (T2DM)

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involves the initiation of lifestyle modification (i.e. medical nutritional therapy and exercise), followed by the addition of oral antidiabetic drug (OAD) therapy if glycated haemoglobin (HbA1c) levels rise above the target of 7.0% recommended in the guidelines issued by the American Diabetes Association/European Association for the Study of Diabetes (ADA/EASD).

Strong evidence from several large-scale studies showed that most patients on monotherapy, regardless of drug class, failed to achieve recommended glycaemic goals (HbA1c $\leq$ 7.0).[3–5] Analyses from the Hong Kong Diabetes Registry[2] showed high percentages of patients receiving multiple medications and high rates of suboptimal glycaemic control (60.3%), especially in patients with long disease duration and those receiving complex regimens. The longer the duration of disease, the higher the rates of OAD failure requiring insulin (23.7%, 39.3%, 57.1% and 75.9% in those with disease duration <5 years, 5–9.9 years, 10–19.9 years and >20 years, respectively).

T2DM has been primarily attributed to progressive loss of beta cell function. Consequently, most patients will require intensification of therapy to maintain glycaemic control by the addition of other anti-hyperglycaemic agents to ongoing treatment, and insulin therapy is needed eventually in many patients (39.2% in the Hong Kong Diabetes Registry[2]). Increasing numbers of OAD are associated with higher HbA1c levels, increasing from 6.7 $\pm$ 1.2% in those taking one OAD to 8.3 $\pm$ 1.6% in those taking four OADs. As the number of OADs is increased, the rate of achieving glycaemic target worsened.

Moreover, though OADs were effective at improving glycaemic control, there were concerns that some classes of OADs may increase the risk of cardiovascular events.[6–9] Epidemiologic studies have shown a relationship between glycated haemoglobin levels and cardiovascular events in patients with T2DM, but the mortality associated with OADs and their net benefit in terms of cardiovascular events is still highly debated.

With the WHO Traditional Medicine Strategy 2014–2023,[10] the use of complementary and alternative medicine (CAM) is gaining considerable recognition and popularity worldwide. In Germany, homeopathy was the most common complementary medicine (14.5%) used by children with type 1 diabetes in four paediatric diabetes centres.[14] In Malaysia, more than half (56%) of patients with diabetes used alternative therapies in conjunction with conventional treatment of diabetes.[15]

Informative controlled animal experiments were carried out on Alloxan-induced diabetes in rats,[20] demonstrating the anti-diabetic effect of Alloxan in a homeopathic dose. Most clinical trials concerning T2DM have focused on a specific homeopathic remedy,[28–30] e.g. selenium, *Gymnema sylvestre*, *Cephalandra indica*, or a complex remedy, rather than on individualized homeopathic treatment. A 12-month observational study was available for individualized homeopathic treatment in 2008, n = 45 in the homeopathic group and n = 32 in the conventional treatment group, a significant improvement was found in the diabetic neuropathy symptoms score (p = 0.016), and a non-significant decrease in fasting plasma glucose (FPG) and HbA1c were observed.[31] A much larger (n = 336) prospective, multi-centric, clinical observational study on individualized homeopathic treatment on diabetic polyneuropathy published in 2013[32] showed a significant improvement in the total symptom score (p = 0.0001) in patients with good diabetic control (HbA1c < 8.0), a reduction in FPG (mean reduction = 0.5 mmol/L, p = 0.0001) and post-prandial plasma glucose (mean reduction = 1.5 mmol/L, p = 0.0001) in 1-year follow-up.

Because there has been no previous clinical study targeting glycaemic control by individualized homeopathic treatment, our trial aimed to explore the potential effect of individualized homeopathic treatment on T2DM patients with different degrees of diabetic control and its association with baseline characteristics. Its result may provide a clue to which group of patients we should focus on in future randomized controlled studies on T2DM.

It was hypothesized that, compared with conventional management alone, the addition of individualized homeopathic treatment would lead to a significant decrease in FPG after at least 6 months of homeopathic treatment for patients with T2DM. It was further hypothesized that the treatment effect would follow the same pattern as the conventional treatment, i.e. higher baseline fasting glucose, increased duration of diabetes and number of OAD would be associated with worse glycaemic control.

The primary objective was to compare the change in FPG before and after the addition of at least 6 months of individualized homeopathic treatment with a control group receiving standard conventional treatment only. The secondary objectives were to compare the demographic and diabetic history of the subjects between the homeopathy group in the private homeopathic centre and the patients under standard conventional treatment in the Hong Kong Diabetic Registry[2]; to compare the change in HbA1c, total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglycerides (TG) before and after the addition of individualized homeopathic treatment and the control group with standard conventional treatment only and to identify if the effect on FPG was associated with any baseline characteristic (demographics and baseline diabetic history).

Methods

This was a retrospective cohort study of individualized homeopathic treatment in addition to conventional treatment compared with standard conventional treatment in T2DM patients in Hong Kong.

Eligibility

Clinical records from 1st Jan 2012 to 31st August 2015 in a private homeopathic centre in Hong Kong were reviewed and the following records were included for analyses.

Subjects were required to fulfil all the following inclusion criteria to be eligible for analyses:

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