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COMPARISON OF THRICE-DAILY PREMIXED HUMAN INSULIN WITH BASAL-BOLUS THERAPY AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS: A CROSS-OVER STUDY

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INTRODUCTION
Thrice-daily (TDS) biphasic insulin analogues are suitable alternatives used for intensifying insulin therapy, but the clinical use of TDS premixed human insulin (PHI) is unclear. We hypothesised that TDS PHI is as efficacious as basal-bolus (BB) therapy.

METHODOLOGY
A cross-over study comparing TDS PHI with BB regimens among patients with T2DM was conducted in Penang Hospital between October 2020 and June 2021. Patients receiving TDS PHI or BB regimen were monitored over the first 12 weeks and then crossed over to the other regimen for another 12 weeks. The outcomes measured were HbA1c, fasting plasma glucose (FPG), total daily dose (TDD) of insulin, weight, hypoglycaemia events, and adherence to insulin injection over a 12-week period.

RESULT
Forty-four patients (75% female; mean baseline HbA1c 9.55%) were included. Mean HbA1c in patients receiving TDS PHI and BB regimens was reduced after the 12-week period (-0.62%; $p<0.001$ and -0.56%; $p=0.015$, respectively). However, the change in mean HbA1c and FPG over the 12-week period was similar in patients receiving both regimens. Weight increased in patients receiving TDS PHI regimen (+1.07 ± 1.73 kg), but it decreased in patients receiving BB regimen (-0.30 ± 2.60 kg) over the 12-week period ($p=0.005$). The total daily dose of insulin in patients receiving TDS PHI was reduced (-1.71 ± 6.52 units), whereas it increased in patients receiving BB regimen (+1.95 ± 6.96 units) ($p=0.012$) over the 12-week period. Patients receiving TDS PHI regimen had a higher mean total basal insulin dose (49.22 ± 12.45 units, $p<0.001$), while patients receiving BB regimen had a higher mean total prandial insulin dose (39.67 ± 9.84 units, $p<0.001$). No difference in hypoglycaemia events and adherence rate were observed within and between the groups.

CONCLUSION
Among patients with poorly controlled T2DM on insulin, TDS PHI is a viable intensification therapy with similar efficacy and safety profile as the BB regimen.