

Efficacy and Safety of Biphasic Insulin Aspart 30/70 in Type 2 Diabetes Suboptimally Controlled on Oral Antidiabetic Therapy in Korea: A Multicenter, Open-Label, Single-Arm Study (*Diabetes Metab J* 2013;37:117-24)

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Little controversies remain that the initiation of insulin is an effective therapy to achieve glycemic control when escalating doses of oral hypoglycemic agents (OHAs) are no longer effective in achieving and maintaining a patient's target HbA1c levels. However, there are some dissent within clinicians on the optimal approach for initiating insulin analogue therapy, including when to start insulin, types of insulin preparations (postprandial, basal, basal and bolus, and premixed insulins) and how to implement insulin regimen (calculating starting insulin doses, numbers of injections and morning to evening ratio in total dose of twice daily premixed insulin regimen etc.). Despite the lack of established guidelines clearly providing answers for the above questions, some consensus have been made and recommended on these issues [1-3].

In the current study by Song et al. [4], they clearly demonstrated the efficacy and safety of biphasic insulin aspart 30/70 (henceforth biphasic insulin analogue [BIA]) with improving A1c from 9.2% to 8.2%. In the recent results of A1chieve® study conducted in Korea (henceforth Kor-A1chieve®) [5], it showed a definite 24-week reductions in HbA1c from 10.0% to 8.3% in subjects treated with BIA +/- OHAs. Based on the consensus on how to use insulin analogues [1-3], we raise the queries

on their study design and its relevance A1c reduction.

First, Song et al. [4] adopted the initial daily dose of 0.3 U/kg body weight with single injection (≤ 30 units) at breakfast or twice daily (> 30 units) at morning and evening with 2:1 ratio. In current consensus [2,3] and Sapporo 1-2-3 study [6] conducted in Japan, they recommended and adopted 1:1 ratio in total dose of twice daily BIA. Furthermore, Sapporo 1-2-3 study adopted an evening single injection. However, no rational explanations on time of insulin injection and split dose of BIA were given by investigators.

Second, Song et al. [4] also adopted the protocol of stopping all previous OHAs during the transition to BIA. The consensus statement on BIA [3] recommended the discontinuation of sulfonylurea and continuation of metformin when switching to BIA. Although the authors commented on the need for OHAs combination in the use of BIA, they did not suggest on how to use OHAs in the initiation of BIA.

Third, Song et al. [4] showed a 2.7 kg weight gain at 16-week study endpoint. In contrary to previous reports on BIA studies conducted in Korea (Kor-A1chieve® reference, [5,7]), weight gains by the initiation of insulin were significant in this study.

Finally, it could be of interest that might tell us whom to and

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how to initiate the BIA in Korean subjects.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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