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Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes

Response to Nathan et al.

Although stating that lifestyle interventions "should [. . .] be included as part of diabetes management," the American Diabetes Association/European Association for the Study of Diabetes consensus (1) on managing hyperglycemia in type 2 diabetes dismisses lifestyle interventions because of their "limited long-term success"; hence, the recommendation to immediately start newly diagnosed patients on lifestyle intervention plus metformin. The consensus even suggests that increased physical activity may lead to "potential problems associated with neuropathy, such as foot trauma and ulcers" (a statement not supported by a reference) and that "the most convincing long-term data that weight loss effectively lowers glycemia have been generated in [. . .] type 2 diabetic patients who have had bariatric surgery," which is hardly a model of lifestyle intervention.

A growing body of literature shows that lifestyle intervention is both feasible and effective in achieving and reinforcing the goals sought by pharmacological means (2–4). It cannot, however, be prescribed. Health operators, who are mainly trained to treat acute conditions, should stop thinking of their chronically ill patients as pill-popping automata who are "noncompliant" when they fail to ingest 10–15 tablets, walk 30 min, and perform other tedious tasks everyday. Adults learn and apply new concepts if they perceive them as reasonable, useful, and related to personal experience. Realistic self-management plans can only stem from alliances between patients and operators within reorganized working practices.

Some recent *Cochrane Database System Review* studies suggest that lifestyle intervention in type 2 diabetes is especially effective when implemented by interactive group education (2–4). Group education is far superior to the individual approach because of peer-to-peer relationships, dynamics, and other positive aspects of group education that are impossible to elicit in traditional one-to-one, usually top-down consultations. Group education also generates higher satisfaction in patients and operators. In our experience, substituting individual visits with group visits in routine care of type 2 diabetic patients achieved long-term (5 years) sustained weight loss, stabilization of A1C, and amelioration of cardiovascular risk factors while reducing prescribed medication (5). Over the first 4 years, group care cost an additional 56.7 U.S. dollars per patient to keep A1C one percentage point lower and 2.12 U.S. dollars per point gained in the quality-of-life score.

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Response to Nathan et al.

Recently, a joint consensus statement by the American Diabetes Association/European Association for the Study of Diabetes (1) recommended starting insulin therapy for type 2 diabetes with basal insulin and increasing doses until a fasting glucose <130 mg/dl was

obtained. The use of rapid-acting, mealtime insulin is considered only when the AlC target is not reached, despite optimal control of fasting glucose.

We observed a consecutive series of 490 outpatients (267 women and 223 men) whose type 2 diabetes was unsatisfactorily controlled (A1C ≥7%) by combined treatment with metformin and insulin secretagogues and for whom glucose self-monitoring data were available (at least four determinations after an overnight fast 2 h after breakfast in the previous month). The average of available values was considered for analysis. Patients included in the analysis had mean ± SD age of 64.8 ± 10.2 years, duration of diabetes 16.0 ± 11.1 years, and BMI 28.3 ± 4.8 kg/m^2.

Fasting plasma glucose (FPG), postprandial glucose (PPG), and A1C were 187.4 ± 51.3 mg/dl, 229.0 ± 57.9 mg/dl, and 9.0 ± 3.5%, respectively; 59 (12.0%), 181 (36.9%), and 250 (51.0%) patients showed FPG <130, 130–180, and >180 mg/dl, respectively. PPG was >30% of FPG in 190 (38.8%) patients. The proportion of patients with postprandial hyperglycemia (PPH) was 69.5, 55.2, and 19.6% among those with FPG <130, 130–180, and >180 mg/dl, respectively.

Insulin treatment was initiated in 156 (31.8%) patients. A 6-month follow-up was available for 151 subjects. Of those, 46 (30.5%) patients showed FPG <180 mg/dl and PPG >30% of PPG (PPH), while 39 (25.8%) patients had FPG >130 mg/dl and PPG <30% of FPG (fasting hyperglycemia [FPH]). Among patients with PPH, 30.4, 45.7, and 23.9% received treatment with basal (NPH/glargine) insulin only, prandial (regular/rapid-acting analogs) insulin only, or both, respectively. Corresponding estimates for patients with FPH were 76.6, 29.0, and 42.3%.

Of the patients treated with insulin, 62 (41.1%) showed a reduction of A1C >15% of baseline and/or A1C <7% at 6 months. The proportion of success, defined as above, in patients with PPH was 21.0, 71.4, and 18.2% in those receiving basal insulin only, prandial insulin only, or both, respectively ($P < 0.05$ for prandial only vs. basal only).

Unsatisfactory glucose control in patients on oral therapy can be due to FPH, PPH, or both. Not surprisingly, patients with PPH alone seem to have a better response to treatment with prandial insulin than with basal insulin. These limited data, obtained through an observational approach, do not have the strength of randomized clinical trials. However, they are coherent with known pharmacokinetics of available insulin formulations.

The greater body of available evidence leads many authors to prefer basal insulin as a first choice for insulin treatment of type 2 diabetes. On the other hand, there is no demonstration of the superiority of basal over prandial insulin in the treatment of oral therapy failure. We feel there is a need for clinical trials specifically designed to compare the two approaches, in which an accurate assessment of phenotype of glucose profiles is obtained through self-monitoring. Until results of such trials are available, any recommendation in favor of either basal or prandial insulin (or both) is somewhat arbitrary.

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Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes

Response to Cryer, Porta and Trento, and Parkin and Davidson

We anticipated that our consensus algorithm (1) would generate some controversy, but we are pleased with the general level of appreciation expressed in the letters, albeit with some disagreements. Dr. Cryer (2) specifically endorses the recommendation in our consensus algorithm to use insulin earlier in the treatment course of type 2 diabetes but takes issue with the relatively low frequency of severe hypoglycemia that we cited for insulin-treated type 2 diabetes, which was defined in accordance with the Diabetes Control and Complications Trial and compared with the rate in type 1 diabetes. As Dr. Cryer notes, our estimates were based on data from "clinical trials aimed at normoglycemia and achieving a mean A1C of ~7%." Dr. Cryer cited review articles (including some referenced by us) and other empiric studies (uncontrolled clinical trials) that suggested a much higher risk for severe hypoglycemia in insulin-treated type 2 diabetic patients than we described.

The reasons that we chose data from controlled clinical trials to establish the expected risk for severe hypoglycemia with insulin therapy, rather than refer to other clinical data referenced by Dr. Cryer, include their more careful and uniform assessment of adverse events, such as hypoglycemia; their use of consensus definitions established a priori; their ability to compare frequency of hypoglycemia among trials using intensive therapy in type 1 and type 2 diabetes; and, perhaps most importantly, their ability to examine the risk for hypoglycemia in the setting of