EDITORIAL

Glucose Self-Monitoring: An End in Itself or the Holy Grail?

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Editorial to accompany the article "Self-Monitoring of Blood Glucose in Diabetes Mellitus: Arguments for an Individualized Approach" by Nauck et al. in this issue of *Deutsches Ärzteblatt International*

Measuring devices with which patients could check their own blood sugar concentration were a technical innovation of the early 1980s that created new opportunities for optimized insulin treatment. Since then, this valuable advance has been heavily promoted by the marketing activities of glucometer and test-strip manufacturers, and enthusiastic recommendations for glucose self-monitoring have resulted (1). All this happened, needless to say, with the best intentions and out of the conviction that these tools—glucometers and test strips for self-monitoring—would enable all patients to achieve optimal metabolic control, and thereby an optimal quality of life, and to avoid the complications of poor glycemic control.

Nonetheless, because of the diminishing resources available to the health-care system, self-measurement of blood sugar has attracted increasing attention as a cost factor, particularly with regard to patients with type 2 diabetes that are not being treated with insulin (2).

Diabetology, as a specialty, thus faces the challenge of exercising self-criticism and developing adequate recommendations for glucose self-monitoring that are based, as far as possible, on evidence from clinical trials. The article by Nauck and colleagues (3) is devoted to this task.

The benefit of glucose self-monitoring for metabolic control and hypoglycemia (4) and, analogously, for micro- and macrovascular sequelae as well (5) has been unequivocally demonstrated, with evidence of the highest level, for intensified conventional insulin therapy (ICT), which is the gold standard of insulin treatment for patients with type 1 diabetes. There is also a consensus that glucose self-monitoring is useful for patients with type 2 diabetes that are being treated with intensified insulin therapy (6).

Controversial views

The controversies begin when it comes to patients with type 2 diabetes that are being treated with mixed insulin therapy. The most intense debate, however, concerns glucose self-measurement by patients with type 2 diabetes that are not taking insulin at all. The results of recent clinical trials have only intensified this debate (7).

This is due, on the one hand, to inconsistencies in the reported results, and on the other hand to the heterogeneity of the condition being treated. Thus, even though 22 randomized controlled trials of glucose self-monitoring in patients with type 2 diabetes not receiving

insulin have been published to date (8), there is still no general agreement about its benefit. In consequence, we in Germany have neither a uniform recommendation, nor a clearly stated regulation of cost reimbursement. This generates considerable uncertainty for insurers, and, not least, for patients as well.

The subject provided additional grist for the media mill when two new trials, called DIGEM (9) and ESMON (10), were published in 2008. These trials showed that glucose self-monitoring brought no significant improvement in metabolic control for patients with type 2 diabetes being treated with oral antiglycemic drugs (9, 10). Moreover, an evaluation of the patients' responses to questionnaires revealed that those who monitored their own blood sugar had elevated rates of depressivity, and a lower quality of life, than those who did not. There is thus a valid question about the benefit of self-monitoring in these patients, even aside from any economic considerations.

Arguments for a constructive debate

The following arguments should be considered if there is to be a constructive debate on the issue:

- Glucose self-monitoring is a measure intended to improve the care of the diabetic patient in everyday life. Every patient, however, has his or her own, personal and individual roster of daily activities; alongside this variability, there are also individual variations in the manifestations of diabetes, and in the way it is treated out of the multifarious therapeutic options available. These numerous variables can hardly be adequately reflected by randomized controlled studies performed in accordance with the requirements of evidence-based medicine.
- Glucose self-monitoring by the patient is a diagnostic measure, not a therapeutic intervention; nonetheless, clinical trials are performed to assess its effect on the metabolic state. This effect is often falsely equated with the utility of glucose self-monitoring. Doing this is permissible only when there are uniform rules about what steps should be taken in response to each measured value. In the clinical trials, however, very different types of intervention in response to measured values are compared with one another. In some trials, no direction at all was given about what to do in response to the measured values. It should come as no surprise that measuring the blood sugar, and then doing nothing in response to the value obtained, will not

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have any beneficial effect on the patient's metabolic state.

- Alongside optimal metabolic control, another goal in the treatment of patients with diabetes is obviously to avoid endangering them with the treatment itself (hypoglycemia). Thus, the risks of each form of treatment require individual consideration.
- For many patients, the mere knowledge that they can measure their blood sugar at any time they like, and on their own initiative, already confers an improvement in their quality of life.

As unequivocal evidence is still lacking, further study is required as to the possible benefits of glucose self-monitoring for metabolic control, avoidance of hypoglycemia, and quality of life in patients with type 2 diabetes that are not being treated with insulin. Prospective randomized controlled trials should be performed on patient populations that are as homogeneous as possible, and the therapeutic responses to measured values should be clearly laid down.

Amid the difficulties posed by limited economic resources for health care, unclear evidence from clinical trials, and the need for patient-oriented medicine, Nauck et al. give situation-specific recommendations about the use of glucose self-monitoring in each type of diabetes mellitus and for each medical treatment strategy. The individual disease manifestations and life situation of each patient are taken into account. In formulating their recommendations, the authors make use of the current evidence from clinical trials as well as their own comprehensive knowledge and long experience with all the available therapeutic options. Situation-specific, easy-to-follow recommendations for individualized glucose self-monitoring strategies are the result. These can be used as a rational basis, not only for patient-oriented diabetes treatment, but also for a rigorous economic analysis of health policy in this field.

Conflict of interest statement

Professor Seufert has received lecture and/or consulting fees from the following companies: Bayer Vital GmbH, Berlin-Chemie AG, GlaxoSmithKline GmbH & Co. KG, Lifescan, Lilly Deutschland GmbH, MSD Sharp & Dohme GmbH, Novartis

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