Reviewer's report

Title: How to Analyze and Monitor Patients' Therapeutic Decisions in Self-Administered Insulin Therapy: Proposal of a Method and Indicators

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Reviewer: A Michael Albisser

Reviewer's report:

This report is a retrospective, observational study that compares patient behavior to a set of written dosing guidelines devised to assist patients in self-determining insulin doses. The data source is drawn from the written records kept in SMBG diaries of children with T1DM attending a summer camp. A statistical programming tool was used to formalize the guidelines as an aid for the investigators in their evaluation of the diary-data.

Using a 2-dimensional matrix to classify the comparisons into ranges from AA (absolute agreement) to ED (extreme disagreement), the authors show that just 75% of dosing decisions are in a clinically acceptable range with 25% outside this range. A regression analysis over the 2-week period of observation in the 28 campers showed a tendency of adherence to the guidelines to ameliorate.

This report poses a common clinical question and goes on to suggest that adolescent patients with T1DM are indeed capable of understanding and executing a simple set of guidelines on their own behalf, especially when motivated to do so in a group/summer/camp setting.

The authors raise an important issue about Who was right? The patients or the guideline? They show an instance where one patient's dosing choice is superior.

The methods are appropriate for the nature of the study and have been used by some of the authors previously. The data are sound, collected under supervision and representative of the T1DM population. An appendix and a data deposit have been provided which have been immensely useful to this reviewer's effort. The reporting and interpretation are accurate and balanced. Some of the limitations are discussed and the references are adequate insofar as the work is an observational study. The computer program devised to assist in the evaluation may actually not be necessary but lends a certain objectivity which clinical bias may otherwise not provide. The title is somewhat misleading in that the study is retrospective and the proposed method is off-line. The tool used by this reviewer to re-examine the authors' dataset is prospective (See below). Perhaps the title could be shortened to something like, "Patients' Conformance to Insulin Dosing Guidelines in a Supervised Setting". The writing is clear and would benefit in places from English language editing.

Critique
This reviewer subjected the appended data to an evaluation using a newly released electronic database (MyDiaBse) that includes a diabetes prescription (Rx) analyzer. A description of the device as well as the training available to health professionals to use the device are given at http://www.nidm.org. The tool uses current SMBG, much like the campers supplied, and offers a portable electronic database to the user. With 2 or more days of SMBG that are sufficient to form a profile, a prediction engine shows the user not only their overall SMBG profile but also their risks of both hyper- and hypo-glycemia. Then, using a mouse, the user can simply click buttons to increment or decrement the current doses of their prescribed medications. The device visually displays the predicted impact these changes will have on the patient’s future SMBG, emphasizing the consequences of OT (over-treatment) and UT (under-treatment). It also estimates the impact such changes will have on A1c. The tool does a full diabetes prescription check, much like a second opinion. It inherently guarantees that the user is following the guidelines appropriate to their prescription.

The criticisms that follow are based in part on the reviewer’s application of the authors’ data to the MyDiaBase device.

**Major Compulsory Revisions**

none

**Discretionary Revisions**

Studies have shown that injections of insulin lispro are far more rapidly absorbed when compared with soluble human insulin. This results in stronger metabolic effects in the first 2h which in turn suggests that before meal AND after meal SMBGs would be more appropriate to guide its dosing than pre meal measurements alone. The authors should clarify why they elected to use guidelines adapted to Actrapid and Regular insulins when the patients’ prescription is for Lispro insulin before meals. Should not the dose of Lispro depend mainly on the CHO counts and the resulting post meal rise in Bg? Would not over-treatment with Lispro result in post-prandial hypoglycemia with a likely delayed rebound at the next meal? Would not using the wrong guidelines then cause the patient to add more insulin when they should in fact be decreasing the dose?

The authors’ written guidelines handle retrospectively single hypoglycemia events with a reduction in one insulin dose. Using the MyDiaBase tool this reviewer was able to demonstrate prospectively the impact on all SMBG profile points of any change(s) contemplated at every injection time. Would not this add a new dimension to the guidelines, ie, avoiding changes that might impact adversely in the near future?

Finally the rich dataset provided is amenable to further analysis, possibly by comparing the first and the second weeks using a lag plot as recently described Diabetes Technol Ther. 2005 Dec;7(6):863-75.
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

This reviewer holds the intellectual property rights to the MyDiaBase technology as described in http://www.nidm.org