Author's response to reviews

Title: Family physician and endocrinologist coordination as the basis for diabetes care in clinical practice

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Version: 6 Date: 24 January 2008

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TO REVIEWER 1: Mark F Harris

We thank the reviewer for his thorough and thoughtful evaluation of the manuscript as well as critical and helpful comments. According to reviewer comments we insert in the m.s. some paragraph, reedited the discussion section and tables and included two references. In relation to the specific concerns, we have the following comments:

1. Previous data from Griffin S. (BMJ 1998,317,390) has been included (reference 9) and comments have been included in the introduction and discussion.

2. The inclusion of patients at very high risk and their implications for diabetes services and clinical practice has been highlighted more extensively.

3. Since 1991 Diabetes Programme is available in our Area. Since 1993 a foot care programme was included. In our organization model, FP had full access to nurse educators, particularly to nurse specialized in foot programme, podiatry and foot unit depending on the Endocrine Service at the hospital, as reported in the paper. These services are for diabetic patients with neuropathy or PVD. Since 2003, after Steno-2 study, a specific multifactorial intervention programme in type 2 diabetic patients at very high risk is being carried out. FP
physicians of the endocrinology service are coordinated in order to schedule the diabetes care. The hypothesis of this study is that FP, in these circumstances of continuous coordination, may achieve follow up and metabolic control at least as good as endocrinologist. We did not increase the resources for the design of this study, but a more early and adequate use of resource available.

4. Steno-2 study reported in September 2002 and published in January, 2003. This intervention involving multiple modifiable risk factors showed a reduction of both cardiovascular and microvascular events in a very high risk diabetes population. Similarly, our population is considered at very high risk. The Steno targets were applied in our study and the stepwise implementation of pharmacological treatment. In similar way, we used weight and waist circumference targets after ATP III recommendations and nutrition intervention based in Diabetes Nutrition and Complications trial, because this study was conducted in our country. The justification for the targets used was included in the m.s.

5. Visits at the beginning of the study and every 6 months until completing a 30 months follow-up period included a physical exam and laboratory tests, in order to collect clinical and laboratory data. Two nurses were responsible for these visits, including body weight, waist circumference and blood pressure.

6. Since 2003 the Foot Care programme in Area 7 of Madrid, includes also specific strategies to improve the management of diabetic patients with PVD by empowering family physicians (FP) at primary health centres to carry out multifactorial pharmacologic therapy. Meanwhile a smooth and continuous contact between FP and endocrinology service physicians is maintained. We considered that in these circumstances FP may achieve follow up and metabolic control at least as good as endocrinologist. In order to assess this hypothesis, the impact of these interventions on metabolic control of diabetic patients with PVD treated in a Primary Health Care Level was prospectively assessed over 30 months and the outcomes compared with those patients followed by endocrinologist. These comments were included in the m.s.

7. The primary 60-months end-point of HbA1c differences >0.5% between groups was used for sample size calculation. The following assumptions had been made: - HbA1c differences reported in Spain in cross-sectional studies are >1%. - Drop-out rate, 10%. - Alpha 5%. Others outcome measures are, progression of peripheral vascular disease, the new onset of micro and macrovascular poor controlled diabetes-related complications and mortality after 60 month follow up. We include comments about sample size calculation.

8. The primary outcome measures was to estimate the proportion of diabetic patients at very high cardiovascular risk (diagnosed as having PVD) treated at a primary health care site who meet Steno-2 and ATP III targets of metabolic control considered at low risk, and to compare with the proportion of patients treated by endocrinologist. Theses comments were included in the m.s.

9. The description of the results has been increased in the m.s.

10. Table 2 shows trend crude data and table 3 shows proportion of patients achieved low risk values of all targets of metabolic control. Both tables are
important. The main focus of this study included all targets of modifiable metabolic control. We think all data may be displayed.

11. The discussion has been reedited following your comments.

12. We agree with reviewer that the difficulty reducing weight in patients with type 2 diabetes is well known. Educational programmes using behaviour modification are useful to induce weight reduction during 1-year of follow up. 15 years ago, our group reported this finding (26), but 5-years later, physical exercise remains as the main long-term predictor for weight loss (27). These strategies were used in the current study, but DPs with PVD have a reduced exercise capacity, and this can be operative in our results. After Xendos study, orlistat (Xenical) may induce weight loss and remains after 5 years of follow up. In Spain orlistat have to be paid by the patients, and in our study, none received xenical, probably by this reason. Other interventions, including surgical procedures are not considered in patients with BMI <40 kg.m-2. We included some comments about this concern.

13. The paper has been reedited and grammatical mistakes corrected.

14. Tables 2 and 3 have been reedited.

TO REVIEWER 2: David Simmons

Thank you very much by your comments about our m.s. According to reviewer comments we insert in the m.s. some paragraph, reedited the discussion section and tables and included two references. In relation to the specific concerns, we have the following comments:

1. The paper has been reedited and grammatical errors corrected.

2. Costs in both groups were not evaluated because the resources were not increased for the design of the study. In our public health system doctors are not paid by number of medical interventions. Since 1991 Diabetes Programme is available in our Area. Since 1993 a foot care programme was included. In our organization model FP had full access to nurse educators, particularly to nurse specialized in foot programme, podiatry and foot unit depending on the Endocrine Service at the hospital, as reported in the paper. However these resources are usually taken too late. Since 2003 a specific multifactorial intervention programme in type 2 diabetic patients at very high risk is being carried out. FP and physicians of the endocrinology service are coordinated in order to schedule the diabetes care. Training and coordination of clinical programme with general practitioners are included in our specialist consultants¿ job description. The hypothesis of this study is that FP, in these circumstances of continuous coordination, may achieve follow up and metabolic control at least as good as endocrinologist. We did not increase the resources for the design of this study, but a more early and adequate use of resource available.

3. As we describe in the m.s. diabetic patients had a treatment period of 3-6 months in the Diabetes Unit of the St Carlos Hospital, where a stepwise
implementation of pharmacological treatment was adjusted to achieve BP<130/80 mmHg, LDL<100 mg/dl, TG<150 mg/dl, HDL>40/50 (M/W), pre-prandial capillary glucose between 70-120 mg/dl, post-prandial capillary glucose between 70-135 mg/dl in 60% of the determinations and HbA1c<6.5%. Patients were revaluated at least every 2 to 4 weeks after each adjustment. In addition, nutritional and exercise modifications were recommended.

4. Interventions are displayed in experimental design section. Interventions were designed in order to improve the management of type 2 DPts by empowering FP of primary health centres, but not directly on patients. In short, all FP received yearly orientation about the trial in a 3 days meeting (08.30-20.00 h), with lectures and discussion of multifactorial intervention. In addition, 2-hours sessions at each health care centre were carried out 9 times a year, where FP from 3 to 7 health care teams join to physicians from the endocrinology service to discuss Steno-based algorithms developed by endocrinologist and FP leaders of each health care centre. Continuous communications between FP and endocrinologist were open, by mail, phone and face to face. The number of these contact were not evaluated. Communications between FP and allied health care providers such as podiatrists, nurses, were not evaluated.

5. Parametric, ANOVA and non-parametric U Mann-Whitney and Kruskall-Walis test were used in order to determine whether there are significant differences between two independent groups. Differences between group A and B were not found.

6. We discuss further the importance of integrated care. We compare our data with previous research assessing the quality of care provided by endocrinologists and FP. We also comment on the implications for clinical practice and future complications of diabetic patients with PVD.

7. Baseline data included in tables 1 has been deleted.