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Network Newsletter 2.09 - Science

Dresden, Germany, June 2009



What's new in diabetes prevention?

Report from the 69th Scientific Sessions of the American Diabetes Association June 5 - 9, 2009, New Orleans, Louisiana

With this newsletter we would like to give you the information about what was presented at the American Diabetes Association, 69th scientific session in New Orleans this year.

On Sunday at the ADA we attended a session about lifestyle changes that last evidence from the prevention trials. At this session updates from the China DaQing Prevention Study, the Finnish Diabetes Prevention Study, the American Diabetes Prevention Programme Outcome Study and the Look Ahead Study were given. The most efficient way to manage diabetes and its complications is to prevent diabetes from developing. Fortunately, recent studies have convincingly demonstrated that prevention of type 2 diabetes is possible. The best method of intervention for preventing diabetes is still not clear, but there is overwhelming evidence that diabetes can be prevented or delayed in high risk population through lifestyle modification or pharmacological interventions.

[China's Da Qing Diabetes Prevention Study](#) Ping Zhang, PhD

As we know the DaQing diabetes prevention study has recruited and screened 110,600 subjects. As part of the screening 630 new diabetes patients were diagnosed but also 577 patients with IGT were detected. From those 530 were randomized into the study which consisted of four arms. 130 patients were included in a diet-only arm, 141 in an exercise-only arm, 126 in a combination of diet and exercise, and 133 were included into the control group. After the initial intervention period risk reductions were 31% with diet, 46% with exercise, and 42% with diet plus exercise in this study. The aim of the presentation at the ADA meeting was to present the 20 years follow up data.

At the end of December in 2006 all the patients which were included in the study were tried to reach for a revisit. Furthermore medical records, personal interviews and proxy-interviews were taken, and for the patients available a medical investigation was performed. 436 patients were able to get recruited into the follow up investigations. 9 were unavailable and 142 were already dead.

What were the results?: Regarding the BMI actually a greater reduction of BMI from 1.57 versus 1.47 in the intensive intervention group was achieved, followed also with the blood sugar reduction 13.8 mg/dl versus 11.5 in the intensive intervention group.



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After 20 years of the study, the diabetes incidence in the control group was 93% and in the intervention group 80%. Looking at the patients with a BMI above 25 the diabetes incidence in the control group, diet group and exercise group was 95% versus 91% versus 86 % and the same data in the group with a BMI less than 25 was 88%, 72 % and 59%. The combined hazard ratio was 0.57.

This corresponds to a diabetes preventive effect of relative risk reduction from 43% which leads to a delay of diabetes onset from 3.6 years. Furthermore data were presented regarding the protection of retinopathy, nephropathy and neuropathy. Beside a mild effect in retinopathy no effect was visible for those complications of the disease. Another aim was to look for cardiovascular disease in all course, death and mortality. No significant difference was visible. The data between control group and intensive intervention group were regarding the first CVD event 44% versus 41%, cardiovascular death 17% versus 13%, all course mortality 29% versus 25%. None of them were significant.

The questions as result of the 20 years follow up study were: Can we prevent cardiovascular disease with a diabetes preventive intervention? and Why can we not show this in the DaQing study?

The authors of the study discussed this issue intensively and argued with several limitations of the DaQing study. One was that the analyses regarding behavioural aspects, psychological aspects and physical activity entertainment were very limited and difficult to analyze. Furthermore the number of subjects investigated actually did not allow presenting a cardiovascular protection, and another argument was that due to the fact that nearly all of the patients in the control group developed diabetes, they maybe have been too sick to show cardiovascular protection. A possible pathophysiological explanation could be a legacy effect and metabolic memory that the cardiovascular lesions already existed before the onset of this study and that with a change in lifestyle the intervention to prevent cardiovascular disease came still too late for these people in this study.

[Finnish Diabetes Prevention Study](#) - Jaana Lindstrom, PhD

As a second presentation Jaana Lindström from the National Institute of Health and Welfare from Helsinki, Finland talked about the follow up data from the Finnish Diabetes Prevention Study (DPS). As it is known the DPS study started in 1993, recruited 522 overweight subjects, comprised of intervention in 5 clinics and randomized the subjects into an intensive lifestyle intervention group and a control group. The aim of the lifestyle intervention was to fulfil the known 5 goals from the diabetes prevention study.

Jaana Lindström presented the results of the 7 years follow up data that means after the 4 years intensive intervention period in the DPS another 3 additional follow up years without intervention. After 4 years intensive intervention, 58% of the diabetes cases were prevented due to the intervention. After follow up years the hazard ratio was 0.57 corresponding to a relative risk reduction of 43% in the intervention group after 7 years.

Analyzing only the post intervention follow up, 49% of the diabetes cases were prevented after the end of the intervention in the intervention group. Jaana Lindström now discussed why this success was reached and she argued that it was a good balance between knowledge and

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motivation within the participants. This was indicated by a drop out rate over 2 years from only 6% of the participants, and the overall argument from the participants that the procedures in the intervention were very practical. During the intervention they did not talk about nutrients, they talked about food. They did not argue about the amount of food, they argued with quality of food. Major aims were to use whole grains instead of grain. They used the plate model to make it practical how to eat and how to prepare the food and argued often to use vegetable oil instead of others. This helped the participants to easily understand the intervention and making use of the practical suggestions in the home environment.

Jaana Lindström discussed that behavioural change is a continuous process which needs a continuous empowerment of the patient with a supportive feedback, arguing that a small step should lead to a concrete action which are reached and will finally lead to a success. Analyzing the 5 core goals showed that after the intensive intervention the highest number of people fulfilled this 5 core goals and this number reduced steadily in the follow up period. Only the physical activity was sustained also during the follow up period for those people who became physical active. The best indicator for reaching this 5 core goals was the weight reduction: the more of these goals the people reached the more weight reduction was achieved.

Looking for the success scores and analyzing how many out of 100 subjects developed diabetes, corresponding to fulfilling the 5 key goals in those people that were not able to fulfil any of the score, 8 people developed diabetes; with fulfilling 1 of the goals 6 people; 2 goals 5 people; 3 goals 5 people; 4 goals 3 people and all those people who were able to achieve all 5 core goals - none of them developed diabetes.

Jaana Lindström summarized and showed an example of one of the participants who is nearly representative for the personal environment in the DPS study. The participants argued often that they wanted to do something to protect themselves of not getting sick.

They were trained to set realistic goals, they used practical instruments, they always received a positive feedback, they often had supportive social and family environment and some of them argued that they felt like a VIP (Very Important Person) as being part of the study.

Jaana Lindström mentioned that a sustained lifestyle change is possible. It often does not need a very intensive and challenging intervention, nothing extreme but always realistic.

[Diabetes Prevention Program Outcomes Study](#) - David Marrero, PhD

As next presenter David Marrero was supposed to present the data from the Diabetes Prevention Programme Outcome Study (DPPOS) – the follow up of the Diabetes Prevention Programme (DPP).

The initial aim of the DPP was to motivate people to lose about 7% of body weight, to reduce the daily amount of fat to less than 25% of the daily energy intake and to encourage people to perform a minimum of 150 minutes physical activity per week. Furthermore, a case manager was assisting all participants on individual basis. The results of the diabetes prevention programme were that in the intensive intervention group 58% of the diabetes cases were prevented and in the Metformin arm 31% of the diabetes cases were prevented. The subgroup analysis showed that men and older people were more successful in preventing diabetes, also

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age, sex, ethnicity and physical activity had no independent effect on the affectivity of weight loss. All these lead to the conclusion that weight loss as primary predictor of prevention success was directly related to calorie intake. Specifically the weight loss revealed that 1kg weight loss was similar to 13% relative risk reduction in diabetes.

As a follow up of the DPP, the DPPOS was established. The aim of this follow up study was to analyze the maintenance of the preventive effect after finishing the intensive intervention, analyzing the effect from the intervention on cardiovascular death and the development of complications of diabetes. At the time when David Marrero was supposed to present the data of the diabetes prevention outcome study, he unfortunately positioned himself that he cannot present any data due to the fact that they are embargoed by submission for publication. This was very unfortunate because most of the participants of the session were keen to hear about the results of the outcome study. He gave some ideas that in the DPPOS 3104 participants were included whereas 82% of the original DPP subjects participated. He finished his short talk with statements about what he believed was working in the diabetes prevention programme. He sad that the major indicators for prevention success were:

- establishing a behaviour change and behaviour motivation
- successful self-monitoring
- efficient stimulus control - especially control of eating habits
- cognitive restructure
- setting realistic goal change and analyzing the individual response
- stress management
- Social support
- Modus 500-1000kcl reduction which was followed by about 1kg weight reduction and from the nutritional side the reduction in fat intake was one of the major indicators for prevention success.

It was very sad that David Marrero was not presenting any data about the outcome study because the people expected to hear it but now we will look forward to the future hearing more about this study.

Look AHEAD - Thomas Wadden, PhD

As last speaker Thomas Wadden presented the current stage of the “Look Ahead” study. Look Ahead is a multicentre randomized control trial including patients with diabetes and establishing an DPP-like lifestyle intervention program. This is 13.5 years follow up focusing initially in cardiovascular death in patients with type 2 diabetes. 5145 patients were included in a two-arm study. Both arms got medical care whereas one arm received the diabetes specialized education and the other arm an intensive lifestyle intervention. A four years intensive lifestyle intervention was included in the study plan similar to the DPP, but here this intervention was done in patients with type 2 diabetes. Primary outcome measure was cardiovascular disease, cardiovascular death, myocardial infarction and stroke, as well as the diabetes outcome. In general for the intervention, several of the DPP intervention strategies were taken but modified for the Look Ahead study. The aim was also to reach a 7% weight reduction.

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Furthermore the intervention was completely based on group interventions, interposed with individualized sessions. Meal replacement formulations were used to help people to lose weight easier, every two weeks a maintenance visit was established and a DPP-like tool box including orlistate was established.

The Look Ahead study will go on until 2015. The recommendations for the lifestyle changes were that every participant should walk a minimum of 10,000 steps per day or performing 175 minutes physical activity per week. After that Thomas Wadden presented the one year outcome data. 96% of the participants were still participating in the study and reached a one year result of 8.6% weight loss in the intensive intervention group. In the so called control group only 0.7% weight loss was reached. The view on the 4 years data showed that the effect was significantly reduced and only a 3.5% difference between both groups existed. Extremely interestingly was to see a significant effect on HDL elevation and blood pressure reduction parallel to blood pressure medication reduction. Furthermore, the people changed significantly their physical activity status.

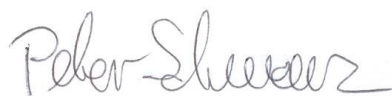
Interestingly older people were much more successful in reaching a weight loss up to 9.4%. Furthermore the attendance of the programme was directly correlated with achievement of weight loss. People who only attended up to 50% of the sessions reached an average weight loss of 4.6%. People who attended 99% of the sessions reached 11% weight loss. Moreover the amount of usage of meal replacement formulations was as well directly correlated to weight loss. People who substituted 117 replaced meals a year reached 5.9 kg weight loss and with 608 meal replacements a year 11.2 kg weight loss was reached. Also physical activity showed the same trend: People who were maximal 26 minutes physical active a week reached 4.5% weight loss. People with more than 287 minutes physical activity per week reached 11.9% weight loss. A sub-analysis revealed that physical activity counted to 16% independently on the weight loss difference.

Thomas Wadden summarized that one of the strongest factors indicating success in the Look Ahead study was the adherence to the program which explains the difference in reached success.

Finalizing his talk, he showed data sub-classifying people based on their weight loss effect and he indicated that a large amount (about 20%) of the people were successful in losing some weight but also unfortunately regained weight and sometimes more than the baseline body weight. The whole message was that more than 20% of the people lost more than 10% of their weight up to 16 – 17% of weight loss and maintained this up to 4 years in the analyses.

Summarizing this, the last aspect is a very hopeful message that in this kind of intervention studies, one out of five people can be very successful in losing weight and maintaining it which makes it worth to invest in this kind of intervention programmes.

Yours sincerely



Peter Schwarz