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Master Thesis

Mobile Diabetes Education and Care: Intervention for Children and Youth with Type 1 Diabetes in Rural Areas of Northern Germany

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1. Introduction

Diabetes mellitus is a metabolic disorder of multiple aetiology. It is a chronic illness, characterized by increased blood glucose levels (hyperglycemia) due to defective insulin secretion or insulin action or both. Insulin is a hormone, which is produced in the beta-cells of the pancreas. It enables cells to extract glucose from the blood and use it for energy. There are two main types of diabetes: in patients with type 1 diabetes, the pancreas does not produce insulin anymore. It is the most common type in childhood. In patients with type 2 diabetes, the body can not use the insulin effectively. Type 2 diabetes is the most common type in adulthood and accounts for 90-95% of all diabetes worldwide. The prevention of diabetes development and its complications is crucial, because the disease produces high costs for individuals, patients with diabetes and their families, healthcare sector as well as the society .

2. Classification

2.1. Type 1 Diabetes in Childhood

Diabetes mellitus type 1 is the most frequent endocrine disorder in childhood. The disease is most often associated with a genetically determined predisposition, the presence of autoimmune markers and aggressive beta-cell destruction which leads to complete insulin deficiency and thereby hyperglycaemia. Symptoms of diabetes onset includes excessive thirst (polydipsia), excessive passing of urine (polyuria), weight loss and lack of energy. Diagnostic criteria are symptoms, glucosuria, random hyperglyaemia ≥ 11.1 mmol/l, and possible ketonuria. Measurement of islet cell autoantibody markers are in type 1 diabetes patients most often positive for at least one autoantibody. In borderline cases an oral glucose tolerance test (OGTT) is carried out. Diagnostic criteria of the American Diabetes Association are a fasting plasma glucose ≥ 7.0 mmol/l, and/or 2-h plasma glucose. Once more than 80 % of the beta-cells are destroyed, the typical symptoms of hyperglycaemia occur, and an insulin replacement therapy by daily insulin injections is needed lifelong. The disease is not curable yet.

2.2. Type 2 Diabetes in Childhood

Diabetes mellitus type 2 occurs mainly in adults and is much more common than type 1 diabetes. It is now also increasingly found in children and adolescents in association with rising rates of obesity (1,2). Type 2 diabetes is characterized by insulin resistance and relative insulin deficiency. The aetiology is not yet fully known, but polygenetic factors are known to be important. Lifestyle factors (overeating, little exercise, sedentary lifestyle) have an influence as well as the later consequences of intrauterine growth retardation. Some certain ethnic groups are known to be at particular risk e.g. pima Indians (3). Diagnostic criteria for young patients are under development. At the time of diagnosis, 80-90 % of the patients are obese, asymptomatic or have only minimal symptoms. Ketonuria are seldom and autoantibodies are never found. In general, patients with type 2 diabetes may require oral hypoglycemic drugs and may also need insulin replacement therapy.

2.3. Others

There are some rare types of diabetes which occur mainly in childhood:

1. Genetic defects of beta-cell function: maturity-onset diabetes of the young (MODY)
2. Disease of endocrine pancreas: e.g. cystic fibrosis-related diabetes, Thalassemia
3. Genetic syndromes associated with diabetes: e.g. Prader-Willi-Syndrome

3. Epidemiology

Prevalence and incidence varies considerably in different regions worldwide, within countries and between different ethnic populations. This variability may partly be due to the different distribution of risk genes as well as environmental exposures. In the European region a minted North-South gradient with only one regional exception is found notably, Sardinia. The highest diabetes incidence for children 0-14 years is found in Finland with 43.9 patients per 100,000 per year, the lowest in Macedonia with 3.6 patients per 100,000 per year (4). The incidences worldwide are shown in map 2.1 (5). The incidence of type 1 diabetes in childhood is increasing in many countries worldwide with an estimated overall annual increase of around 3 % (6). Diabetes type 1 affects boys and girls approximately in the same frequency. In general, diabetes below the age of 1 year is extremely rare. Diabetes incidence increases with age and peaks in onset at age 4-6 and shows highest rates between 10-14 years. Many European studies found an increase which is greatest in children aged younger than 5 years (7,8).

3.1. Diabetes in Childhood: Germany

The prevalence of all diabetes types in the whole German population is 5-8% (9). Most diabetes patients (90%) are adults and suffer from type 2 diabetes. Type 1 diabetes is the main form of the disease in childhood. Approximately 10,000-15,000 children and teenagers (0-14 years) with type 1 diabetes live in Germany (10,11). Detailed data on incidences and distributions of diabetes in Germany do not exist, due to the lack of a central diabetes register, but some states have build up local registers in the last decade. While in the nineties incidence rates of 12.9 per 100,000 per year were found (11), current surveys in Baden-Wurttemberg calculated an incidence for children 0-14 years with 16.2 per 100,000 per year (12). Overall the incidence rate is increasing by 3 % per year (12).

Sound data of prevalence or incidence of type 2 diabetes in the young do not exist. Approximately 210 children and adolescents aged 5-19 years develop diabetes type 2 every year (13).

4. Principles of Therapy

The general aim of therapy is to achieve optimal glycemic control by balancing insulin, nutrition and exercise and to avoid acute and long-term diabetes complications. To reach that goal, children and adolescents with type 1 diabetes should be treated by a specialized diabetes team with expertise in the medical and psychosocial needs of young patients and their families. Diabetes long-term care not offered by a specialized team can have adverse effects (14).

<u>Optimal glycemic control is defined as</u>

1.glycated haemoglobin (HbA_{1c}) level < 7.6 % as a parameter of the quality of long-term glycemic control,

2.fasting blood glucose level 4.0-7.0 mmol/l,

3.postprandial blood glucose level 5.0-11.0 mmol/l,

4.nocturnal blood glucose level not < 3.6 mmol/l,

5.few mild, but no severe very low blood glucose level (hypoglycemia) and

6.no symptoms of hyperglycemia (15).

Optimal glycemic control includes prevention of acute metabolic deterioration (severe hypoglycemia, ketoacidosis, and diabetic coma), prevention of diabetes complications and aims to achieve normal physical and psychosocial development. To reach that aim, regular insulin injections, frequent assessment by blood glucose (BG) monitoring and balancing food energy and carbohydrates to insulin action profiles and exercise.
The choice of insulin regimen depends on many factors including: age, duration of diabetes, lifestyle, targets of metabolic control, financial support of health systems (e.g. insulin analogues or pump therapy) and patients/family preferences. The aims of nutritional management are to provide optimal growth, development and good health and to encourage healthy lifelong eating habits. An ideal body weight should be achieved and maintained. The daily energy intake should be distributed approximately as follows: 50 % carbohydrates (higher fiber carbohydrate, moderate sucrose intake), 30-35 % fat, 10-15 % protein (15). Independent from widely varying dietary habits, insulin injections need to be balanced against the carbohydrate intake. Many methods of counting carbohydrates are commonly used, e.g. grams, carbohydrate exchanges or glycemic index. In Germany carbohydrate exchanges and insulin-to-carbohydrate ratios are widely used.

The therapy principles in type 2 diabetes differ from those in type 1 diabetes: Weight control and reduction of obesity are the most important goals which can be reached by reduction of energy intake, regular exercise and healthy lifestyle. Oral hypoglycaemic agents, e.g. metformin and sulfonylureas are used to improve insulin secretion and effectiveness in the organs. If optimal glycemic control can not be reached insulin treatment is started following the same principles as described above.

4.1. Diabetes Education

Diabetes education based on structured and evaluated concepts is a cornerstone of diabetes management (15,16,17,18). Education is placed at the centre of clinical management. It provides the necessary knowledge base which covers pathophysiology, insulin secretion, action and physiology, normal BG levels and glucose targets, basic practical skills (insulin injections, blood testing), basic dietetic advice, hypoglycemia treatment and simple advice for sick days. Moreover, if diabetes education is provided in a patient-centred style and appropriate for the age and maturity of the young person

and the culture of the family, it becomes the vehicle for optimal self-management (15). The Diabetes Control and Complication Trial (19) provided clear evidence that successful intensification of management reduces microvascular complications but this requires effective diabetes self-management skills with high-level educational input and continuing support. The priority for diabetes education is to reach families and patients' attitudes, beliefs, learning style, ability and readiness to learn, existing knowledge and goals. Although children's total dependence on insulin and need for appropriate nutrition is the same as in adults with type 1 diabetes, there are major differences in needs arising from the stages of growth and development. Thus, education must reach parents as the main care providers for infants, pre-school and primary school children.
Education is a continuous process and should be repeated to ensure effectiveness. Continuing training covers subjects as problem-solving, insulin adjustment, dealing with sick days, school trips, holiday planning and travelling. Knowledge of diabetes does not necessarily correlate with good metabolic control (20). Successful education must empower and motivate young patients and their parents to use knowledge and practical skills in problem-solving and self-management (21,22,23). Interventions to improve problem-solving and coping strategies in diabetes self-care have been shown to improve metabolic control (24,25). Moreover, a good metabolic control was found to be associated with better quality of life (26,27,28).

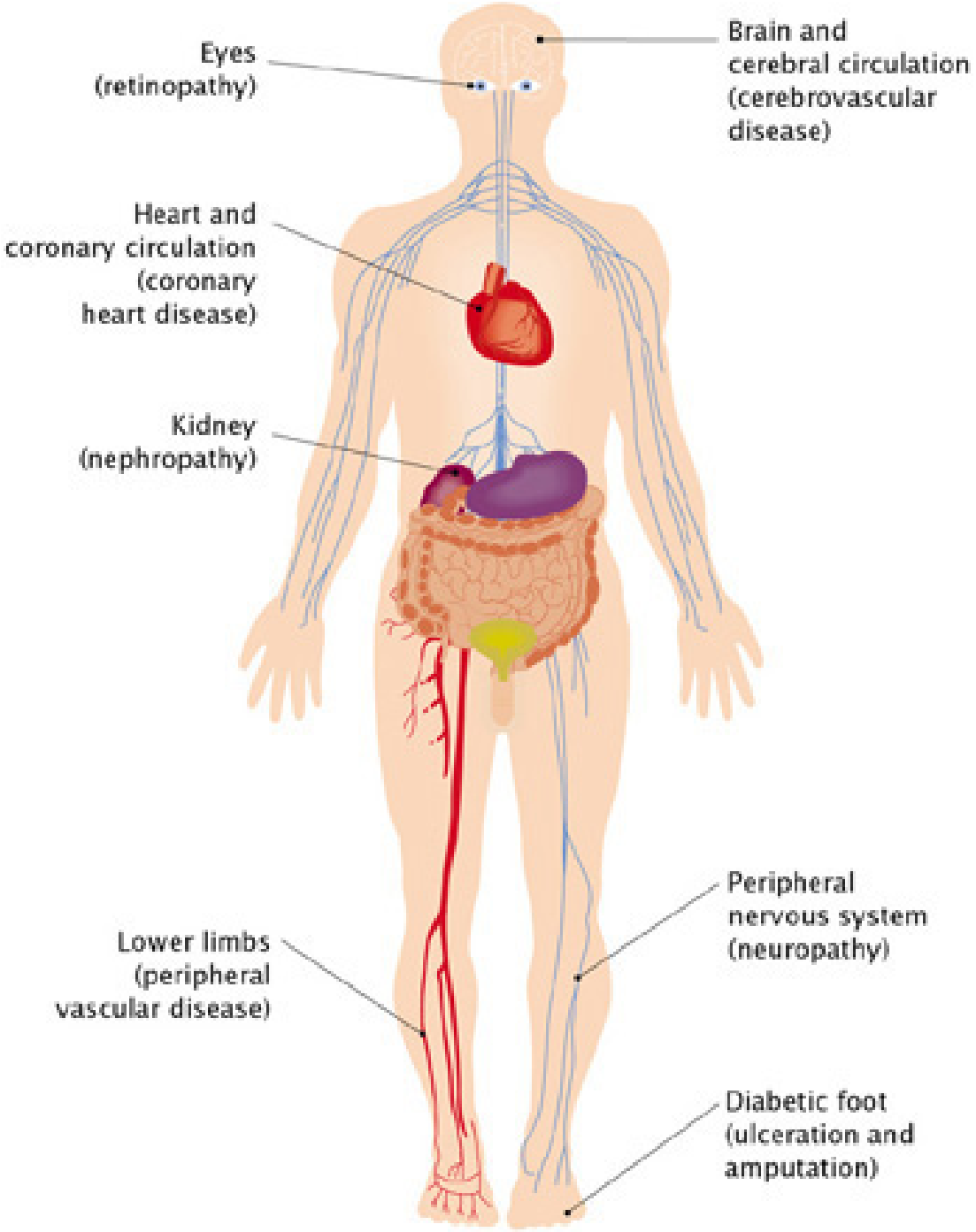
The mode of education depends on local experience and facilities. In most countries, it is dominated initially by individual teaching and backed up by written guidelines and other media. Continuing education is delivered in one-to-one sessions, group teaching sessions with young people and/or parents, educational holiday camps and training courses using many different materials. Every mode of education aims to optimise diabetes management, improve self-management skills, self-confidence and independence in order to enable unimpaired growth.

5. Diabetes Complications

The major diabetes complications are caused by the toxic effects of high glucose levels, along with the impact of elevated blood pressure, abnormal lipid levels and abnormalities of small blood vessels, see figure 1.

Figure 1

The major diabetic complications



Source: *Diabetes Atlas* second edition, © International Diabetes Federation, 2003

Macrovascular complications:

Cardiovascular disease (CVD) : it is the major cause of death in diabetes

1. Myocardial infarction
2. Hypertension
3. Early appearance of arteriosclerosis
4. Loss of artery blood circulation in feet and legs, which could lead to lower limb amputation

Recently, the EURODIAB Prospective Complications Trial has supported the strong predictive role of baseline albuminuria (first stage of diabetic nephropathy) in the pathogenesis of coronary heart disease (CHD) in type 1 diabetes and sex-specific risk factors were assessed, such as systolic blood pressure and fasting triglycerides (29).

Microvascular complications:

1.Nephropathy: leads to kidney failure which requires dialysis or kidney transplantation. The development of nephropathy can be forced by poor metabolic control (30), hypertension (31), smoking (32,33), high protein intake (34) and it is assumed that there is a genetic risk factor for nephropathy (35).

2.Neuropathy: wide range of effects on peripheral nervous system. Most common is sensory loss in the feet. This is a high risk for unnoticed injuries, which result in foot ulceration. As a consequence of deficient blood circulation, diabetic foot ulcers a difficult to cure and therefore amputation is frequent inevitable.

3.Retinopathy: First vascular alterations and later vascular and bleeding of the retina are identifiable by routine retinal scan and general treatable with laser technique (36,37). The relative risk for loss of sight is 5 times higher than in the average population (38).

Hyperglycemia is regarded as an independent risk factor for vascular complications. As type 2 diabetes often remains undiagnosed, the majority of patients with type 2 diabetes suffer already from diabetes complications at the time of diabetes onset, even teenagers with type 2 diabetes. Therefore, all patients must strive for optimal metabolic control which is the only option to delay or prevent further complications. Unfortunately, there is no HbA1c threshold below which diabetes complications do not occur.

All diabetes patients get an annual screening for complications to treat and possibly stop problems at an early stage. Especially for children and youth with type 1 diabetes, risk factors for the development of microvascular complications are to be at a younger age at onset, long duration of diabetes, poor glycemic control, family history of diabetes complications, hypertension, smoking and abnormal lipid levels (15). In developed societies, diabetes is ranked among the leading causes of blindness, renal failure and lower limb amputation. The main relevance of diabetes complications in a public health perspective is the relationship to human suffering and disability and the huge socio-economic costs through morbidity and mortality.

6. Diabetes Care

From the first day of diagnosis the child with diabetes and its family should be cared for, educated and emotionally supported by a multidisciplinary pediatric diabetes care team. Essential members of such a team are a pediatrician specialized in diabetes/endocrinology, a diabetes nurse and/or diabetes educator and dietician. Ideally other health care professionals should be part of the specialist team: psychologist and pediatric social worker. These recommendations will be impossible in areas of low population density or areas where childhood diabetes rarely occurs. The organization of diabetes care in rural and urban regions depends on geographical and demographic characteristics and the options of the health care system itself. At onset of diabetes inpatient and/or outpatient care and first individual education in hospital or at home is offered depending on local facilities. A “good start” to the early education of young people with diabetes can not be overemphasised. This aim is more likely to be reached by specialized diabetes teams in centers of excellence. In the following months after diabetes onset the families need frequent contact to the diabetes team to manage changing requirements in the early phase of diabetes. Contact may be clinic appointments, home visits, telephone advice or via internet. In rural areas new models of diabetes management via telemedicine is more frequent tried out in the last years (39,40,41) but there is still little evidence of clinical benefits. After the first six months it is common practice to review children and adolescents at least four times a year or more often for regular, consistent follow-up outpatient consultations. In general, provision for easy access to the diabetes care team (24-h a day) should be provided for all families to obtain advice in critical situations and to avoid diabetic ketoacidosis during acute illness which would otherwise consequently lead to hospital admission

(42). Diabetes education is the cornerstone to successful diabetes management. In many countries further diabetes education has been organized in specialized camps and educational activity holidays. Those activities have been proven to bolster self-confidence, enhance independence and improve self-management skills, but it has not been possible to measure the long-term benefits of camps (43). Nevertheless, diabetes differs from almost all other diseases in one crucial aspect: the end results of management depend critically on the affected person's ability to carry out daily self-management. Effective management through education and professional support improves outcome and is a sound investment.

6.1. Structures of Diabetes Care in Germany

A nationwide German study in 1998 found that the majority of German children with diabetes received continuing outpatient care in children's hospitals or departments meeting the standards of paediatric diabetes care. A tendency to centralise diabetes care in paediatric diabetes centers was ascertained. Inpatient treatment was in 26.5 % due to therapy and education in case of diabetes onset and 46.5% due to diabetes education and improvement and alteration of therapy. The majority of diabetes training courses were undertaken in an in-hospital one-to-one or group setting. Outpatient training courses were rarely assessed in that survey. The supply of diabetes training courses did not cover needs. The access to specialized diabetes care was different in the federal states and varied due to urban or rural regions (44). In rural areas, German families often face difficulties in reaching a paediatric diabetes centre within a reasonable time period. Therefore, they obtained treatment from paediatricians or other physicians in their region, although many of these professionals did not possess the necessary expertise in this field. Owing to low patient numbers, local hospitals had difficulties in gaining diabetes experience.

6.2. Mobile Diabetes Education and Care

The Mobile Diabetes Education and Care for children and adolescents with diabetes mellitus type 1 in Schleswig-Holstein (MDSH) is a new mode of diabetes care in Germany. The aim is to optimise diabetes care for children, and adolescents and their families in a rural community through access to standardized diabetes treatment and structured diabetes training courses and further education of hospital staff.

The MDSH was established in 1999 and belongs to the Lübeck diabetes center. It consists of a pediatric diabetologist and a pediatric nurse specialized in diabetes education.

The MDSH offers 24 diabetes training courses for children and their parents every year. The courses are offered in a five day (Monday to Friday) in-hospital group setting and are held in eight different hospitals of the State. Four to six children at the same age form a group. The courses are based on structured and evaluated educational programs for children and adolescents. In general, the training aims to improve diabetes knowledge, self-confidence, age appropriate independence and self-management abilities. The second objective of the MDSH is to offer education for health care professionals. The MDSH cooperates intensively with the local hospitals teams and offers continuing education on diabetes care, teaching skills, teaching material and a comprehensive curriculum. Teamwork with the mobile diabetes team during the training courses should enable the local teams to transfer their knowledge to primary and long-term diabetes care in their region and thus improve the quality of care.

7. Prevention of Type 1 Diabetes

Although patients with type 1 diabetes represents only less than 10% of all forms of diabetes, the number of patients will definitely increase in the coming years. Preventing type 1 diabetes still seems to be out of reach, but remarkable progress has been made to understand the mechanisms of the disease, to identify what is inherited and what may be due to environmental factors and to identify those who are at high risk. The natural history of type 1 diabetes includes four stages: 1. pre-clinical beta-cell autoimmune destruction, 2. onset of clinical diabetes, 3. transient remission, and 4. established diabetes associated with acute and chronic complications and premature death. Prevention differs according to disease stage. Primary prevention is classified as prevention of autoimmune destruction of beta cells in the pancreas, secondary prevention is e.g. prevention of the development of diabetes after the onset of autoimmunity. Primary and secondary prevention protects susceptible individuals from developing diabetes. Tertiary prevention is classified as prevention of complications and premature mortality. An overview is given in table 1 (45).

7.1. Primary Prevention of Type 1 Diabetes

Primary prevention is classified as prevention of autoimmune destruction of beta cells in the pancreas. Primary prevention of autoimmunity can prevent type 1 diabetes, but it requires an understanding of causes and interactions of risk factors which can be modified. The association between cow's milk and autoimmunity and diabetes remains controversial. A meta-analysis of selected studies suggested that children with diabetes are more likely to have had an early exposure to cow's milk than nondiabetic children (46).

Germany is participating in one of the current large international studies of primary diabetes prevention in childhood, the "Trial to Reduce IDDM in Genetically at Risk", TRIGR study (47). The TRIGR study is a multicenter, randomized controlled, double-blind, placebo controlled trial to determine if weaning to a intensive hydrolysed casein formula in infancy after or parallel to breastfeeding in the first eight months of life (intervention) can prevent or delay the onset of type 1 diabetes compared with feeding slightly hydrolysed casein formula (control group). The study aims to enrol 8,000 babies worldwide, of which 240 will be German babies. Inclusion criteria are relatives (father, mother or siblings) with type 1 diabetes. The study subjects are to be followed up for 10 years with periodic growth assessment and blood test (diabetes associated autoantibodies) to monitor the development of diabetes.

The current German "BABY DIÄT" pilot study tries to reach the same goal as the TRIGR intervention, but instead of hydrolysed casein formula, the intervention is a gluten-free diet in the first year of life for those children with high risk for the development of type 1 diabetes (intervention) or gluten exposition after the age of six months (control group). The study included 150 children who must have one parent or sibling with type 1 diabetes and high risk genes. Children with these prerequisites have an increased diabetes risk compared to the overall population (0,3%).The follow-up period is three years. Some research is currently being undertaken to evaluate the effect of high-dose vitamin D in prevention of type 1 diabetes as some previous studies have shown a preventive effect (48,49,50).

7.2. Secondary Prevention of Type 1 Diabetes

Siblings of a patient with type 1 diabetes can be tested for diabetes associated antibodies. It has been shown that the risk for developing type 1 diabetes increases with the number and some combinations of these antibodies: islet-cell antibodies (ICA), insulin autoantibodies (IAA, IA-2) and glutamic acid decarboxylase (GAD). PRO-DIAB is a current double-blinded, randomised controlled trial, which aims to investigate, if proteases may stop the activated autoimmune process in those subjects (3-40 years of age) with at least two auto-antibodies. The Diabetes Prevention Trial (DPT-1) was a randomised, controlled trial designed to determine if it was possible to prevent or delay the onset of type 1 diabetes in people predicted to be at risk for this disease. The study started in 1994. Study subjects were given oral or subcutaneous insulin. This intervention should influence the t-cell function and introduce an immune-tolerance. Unfortunately, after the study follow-up period of six years it was seen that this trial was not successful. In Finland, the country with the highest incidence of type 1 diabetes worldwide, a secondary prevention trial, the "Diabetes Prediction and Prevention Trial" (DIPP) is being carried out for the whole population. All newborns are screened for a genetic risk and those with high risk and positively tested for ICA are asked to take part in a placebo-controlled, double-blinded trial with insulin, applied with a nose spray.

7.3. Tertiary Prevention of Type 1 Diabetes

Tertiary prevention includes early detection, prevention and treatment of complications. Screening programmes for retinopathy, nephropathy, high blood pressure and raised blood lipids, as well as the control of blood glucose levels, effective foot-care, diabetes education and measures to reduce tobacco consumption, can substantially reduce the risk for developing complications and slow down their progression. Drugs which suppress the immune system and its action against beta-cells can prolong the remission phase, e.g. cyclosporin A, but they have severe side-effects. Angiotensin-converting-enzyme-inhibitors (ACE-inhibitors) are drugs to treat hypertension and have the positive side-effect to stop the progression of the first stage of diabetic nephropathy and may very often have a reversible effect (51).

Table 1: Natural history of type 1 diabetes and preventive opportunities (45)

Prevention	**Pre-Clinical stage**	**Clinical stage**	**Remission**	**Long-standing diabetes**
Clinical problems				
	In most cases no symptoms	Polyuria, polydipsia, weight loss, DKA	Rarely acute or long-term complications	Severe hypoglycaemia., DKA, infections. Major complications
Risk factors				
Genetic	HLA-risk genes associated with initiation and progression of diabetes	HLA-risk genes associated with progression of diabetes	Cell regeneration genes ?	High-risk genes for nephropathy, retinopathy, CVD ?
Metabolic (insulin secretion)	Progressive loss of acute insulin response	Hypoinsulinaemia	Relative hypoinsulinaemia	Lack of endogenous insulin
Blood Glucose	Normal	Severe hyperglycaemia	Mild hyperglycaemia	Depends on treatment
Environmental	Cow´s milk protein, gluten, lack of vitamin D, nitrosamines/nitrates?	?	?	Saturated fat, high cholesterol and triglycerides
Infections	Viruses and initiation of autoimmunity? Endogenous retro-viruses ?	Viruses ?		
Others	"Stress"?			Cigarette smoking, alcohol consumption
Prevention				
Primary	Autoimmune process	---	---	---
Secondary	Progression to diabetes	Remission induction	Remission extension	---
Tertiary	---	Onset mortality and morbidity	Acute complications	Diabetes associated complications

Abbreviations: Cardiovascular disease (CVD), diabetic ketoacidosis (DKA), human leukocyte antigen (HLA)

8. Prevention of Type 2 Diabetes

Today, 194 million people worldwide suffer from diabetes, most of them have type 2 diabetes. In 2025, 333 million people are expected to be affected, which is a reason of great concern (map 1.2; 1.3) (5). Contrary to type 1 diabetes, risk factors of type 2 diabetes are known, e.g. ethnicity, obesity and genetic factors of insulin resistance (52,53) Weight reduction, more exercise, low cost medication metformin and acarbose. have shown to be effective in prevention.(54,55,56). Despite recent progress in the understanding of genetics and immunology of the disease, the high and increasing incidence rate, associated severe morbidity, mortality and enormous health care expenditures (57) makes diabetes a prime target for prevention.

9. The Global Burden of Diabetes

Diabetes is one of the most common non-communicable diseases globally and one of the leading causes of death in most developed countries and in many developing and newly industrialized nations. Complications from diabetes type 1 and 2, such as CVD, stroke, diabetic nephropathy, foot amputation and blindness result in increasing disability, reduced life expectancy and enormous health costs. The costs of diabetes consist in direct costs, costs of lost production and intangible costs. Direct costs include medical care, drugs, insulin, hospital services, physician services, laboratory tests and the daily management of diabetes. For most countries, the largest single item of diabetes expenditure is hospital admission for treatment of long-term complications. Costs of lost production result from sickness, absence, disability, premature retirement or mortality. Pain, anxiety, inconvenience and other factors which decrease quality of life are intangible costs.

In Germany more than 75 % of all diabetes patients die of heart failure and its consequences (e.g. shock,). Fifty percent of all German diabetes patients suffer from diabetic retinopathy and of those 3,000 – 4,000 go blind every year. Blindness is five times more likely in diabetes patients than in the whole population. Every year approximately 8,000 diabetes patients have to start dialysis therapy. Annually, 31,000 lower limb amputations are carried out. Major burden for the health system results in costs for inpatient treatment (4.6 billions Euro a year), but the whole costs for diabetes treatment in Germany are more than 20 billions Euro every year (58).

In addition to diabetes type 1 and 2, the condition of impaired glucose tolerance (IGT) also constitutes a major public health problem. IGT is an asymptomatic condition defined by elevated (though not diabetic) levels of blood glucose in the OGTT. It is a stage in the transition from normality to diabetes. It is associated with obesity, advanced age, insulin resistance, insulin secretory defect and the increased risk of cardiovascular disease. (5). The projected numbers of IGT put all previous numbers of type 2 diabetes in the shade. By 2003 approximately 314 million people worldwide and by 2025, 472 million or 9.0% of the adult population will have IGT (5) and therefore will be at high risk for type 2 diabetes. In face of these numbers and to reduce the burden for future generations, it is absolutely imperative to identify and apply cost-effective measures to prevent diabetes or diabetes complications and to promote smoking cessation, as all late complications are exacerbated by smoking.

Effective prevention also means more cost-effective healthcare. There are a couple of major studies which provide effective interventions in primary, secondary or tertiary diabetes prevention (table 2).

Table 2: Examples of major studies providing effectiveness evidence in diabetes

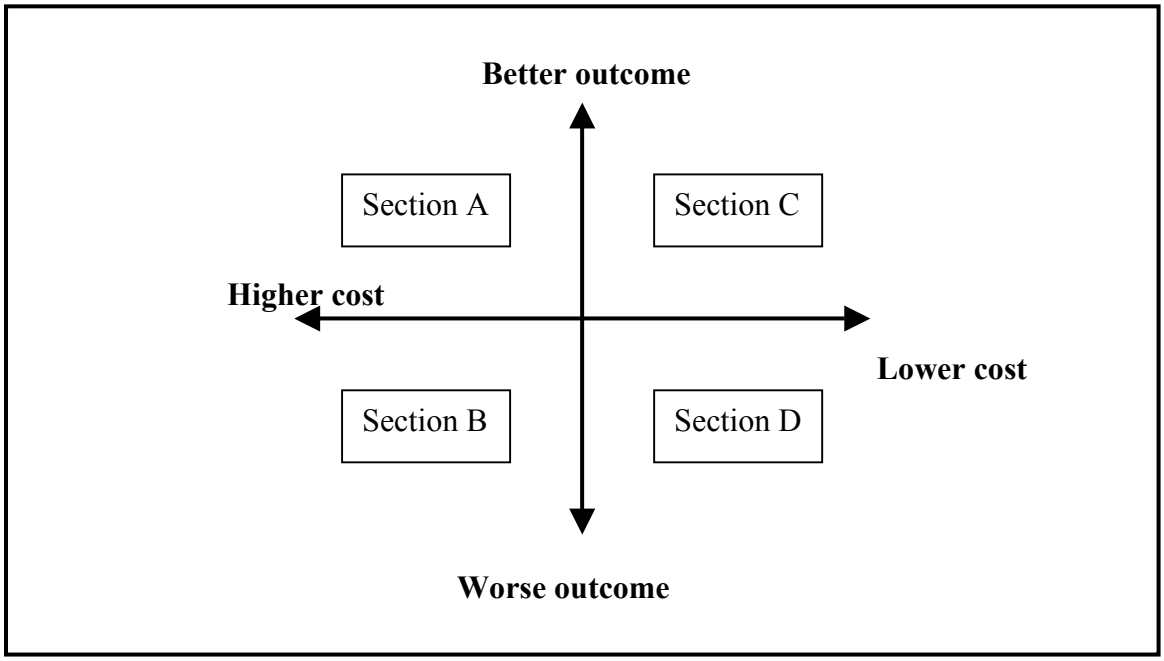
Topic	Action	Effective in…	Source of information
Primary prevention	Weight reduction and increased physical activity in people with IGT[a] / Acarbose [b]	Preventing or delaying progression of IGT to type 2 diabetes	Finnish Diabetes Prevention Study (54) Stop-NIDDM- Trial (55)
Tertiary prevention	Treatment with ACE-inhibitors	Prevention or delaying the progression of nephropathy	Microalbuminuria Captopril Study Group (51), DCCT (30)
Tertiary prevention	Control of high blood pressure	Preventing macrovascular complications	UK Prospective diabetes study (UKPDS) (31)

Impaired Glucose Tolerance (IGT), Acarbose = oral antidiabetic

Captopril = drug of ACE-inhibitor group for treatment of hypertension and diabetic nephropathy

To assess the cost-effectiveness of interventions, information on the savings to hospitalisation and late complications would be useful. Unfortunately, most new therapeutic strategies have a higher cost than those that are already in place, but produce better outcomes (section A in figure 2). We have only few interventions of the kind included in section C, which produce better outcomes at lower costs.

Figure 2: cost and outcome of interventions (59)



"Global awareness, advocacy and action in diabetes" is a program developed by the Word Health Organisation (WHO) and the International Diabetes Federation (IDF) to enhance awareness of diabetes and its complications amongst the public, health professionals and decision makers, with a major emphasis on prevention (60). Such programs are very important as otherwise the number of people with diabetes which may be reached in 2025, will qualify diabetes as one of the largest epidemics which we have experienced in modern times.

10. Conclusions

Type 1 diabetes is an outstanding chronic illness in childhood, for which self-management abilities and disease specific education play a central role. Managing one's diabetes is a complex task, especially for parents of young children, that touches nearly every important aspect of daily life. In order to make a normal psychosocial and physical development for affected children possible and to delay or even prevent diabetes complications, access to treatment and education offered by a specialized diabetes health care team have highest priority.

The increasing rates of type 2 diabetes in the young as well as of obesity, is a cause of great concern and is becoming a global public health issue with the same serious health outcomes as known for type 2 diabetes in adults.

Considering the enormous individual disease burden, the costs of diabetes treatment and diabetes-related complications, it is a public health issue to provide access to high-quality diabetes care for all patients with type 1 diabetes, independent from their place of residence. Parallelly, interventions which encourage more physical activity and change in dietary habits are needed to slow down the increasing prevalence of type 2 diabetes in the whole population.

11. Appendices

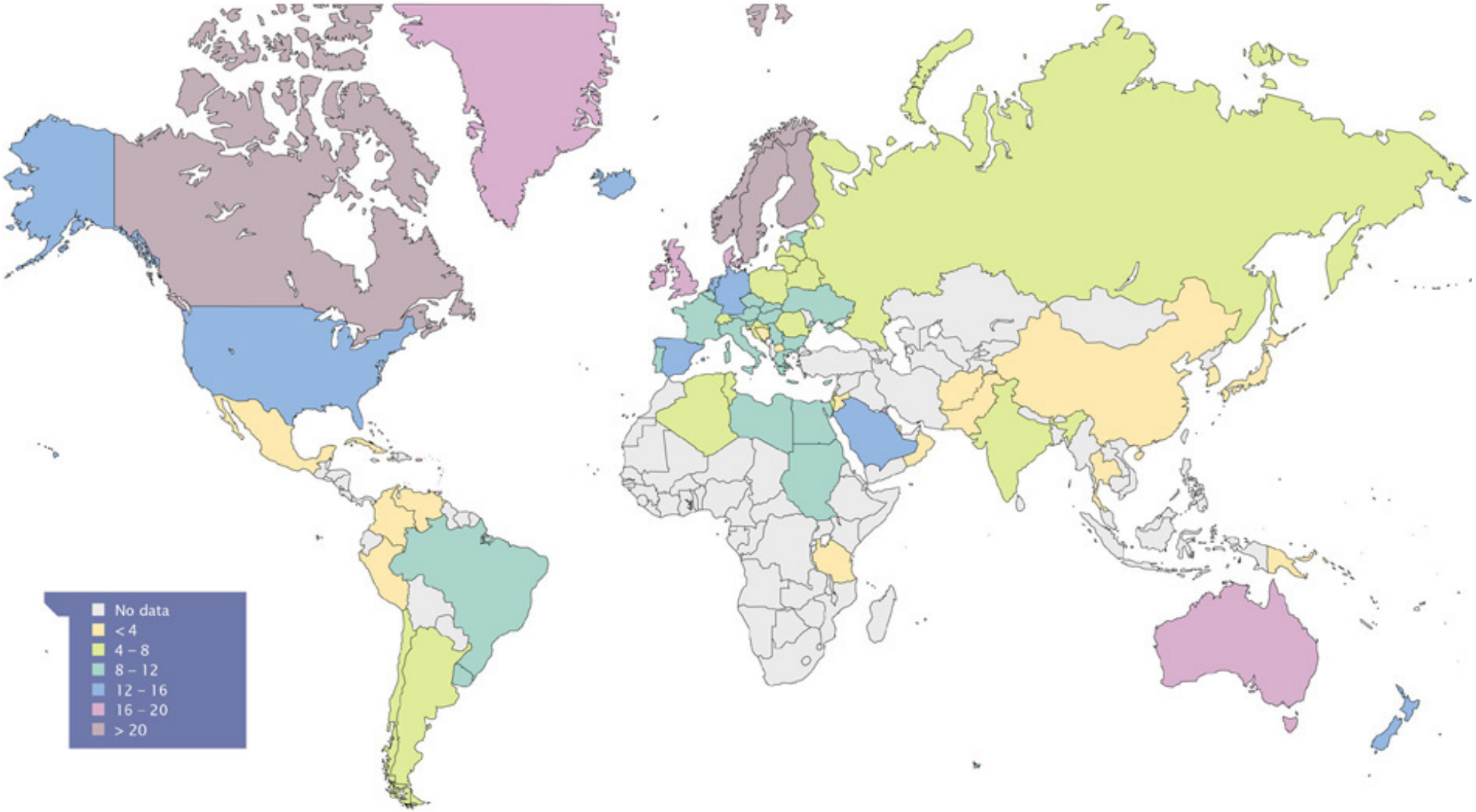
Map 2.1 Published incidence rates of type 1 diabetes in children

Map 1.2 Prevalence estimates of diabetes, 2003

Map 1.3 Prevalence estimates of diabetes, 2025

Map 2.1

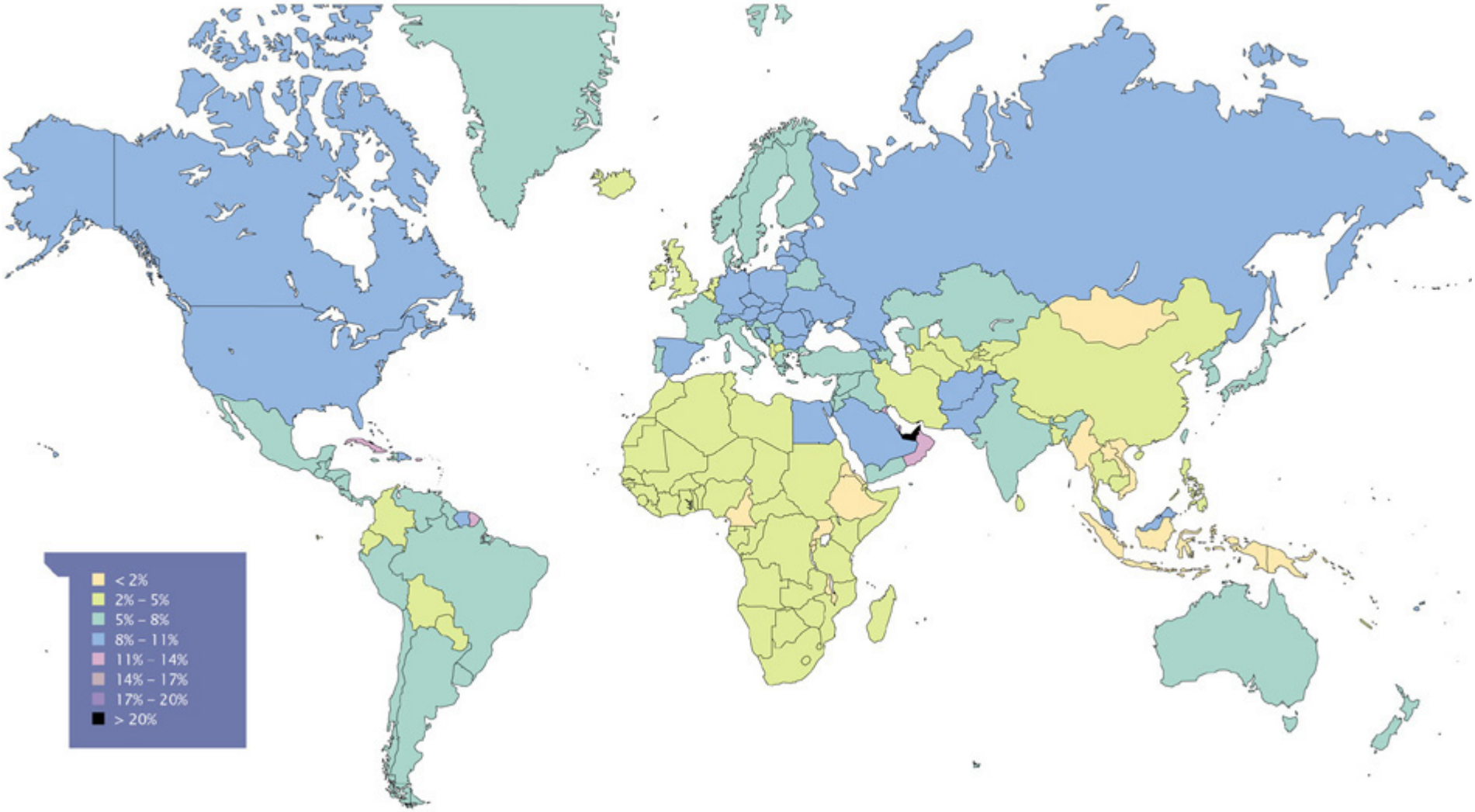
Published incidence rates of type 1 diabetes in children (0-14 age range)
(cases per 100,000 population per year)



Source: *Diabetes Atlas* second edition, ©International Diabetes Federation, 2003

Map 1.1

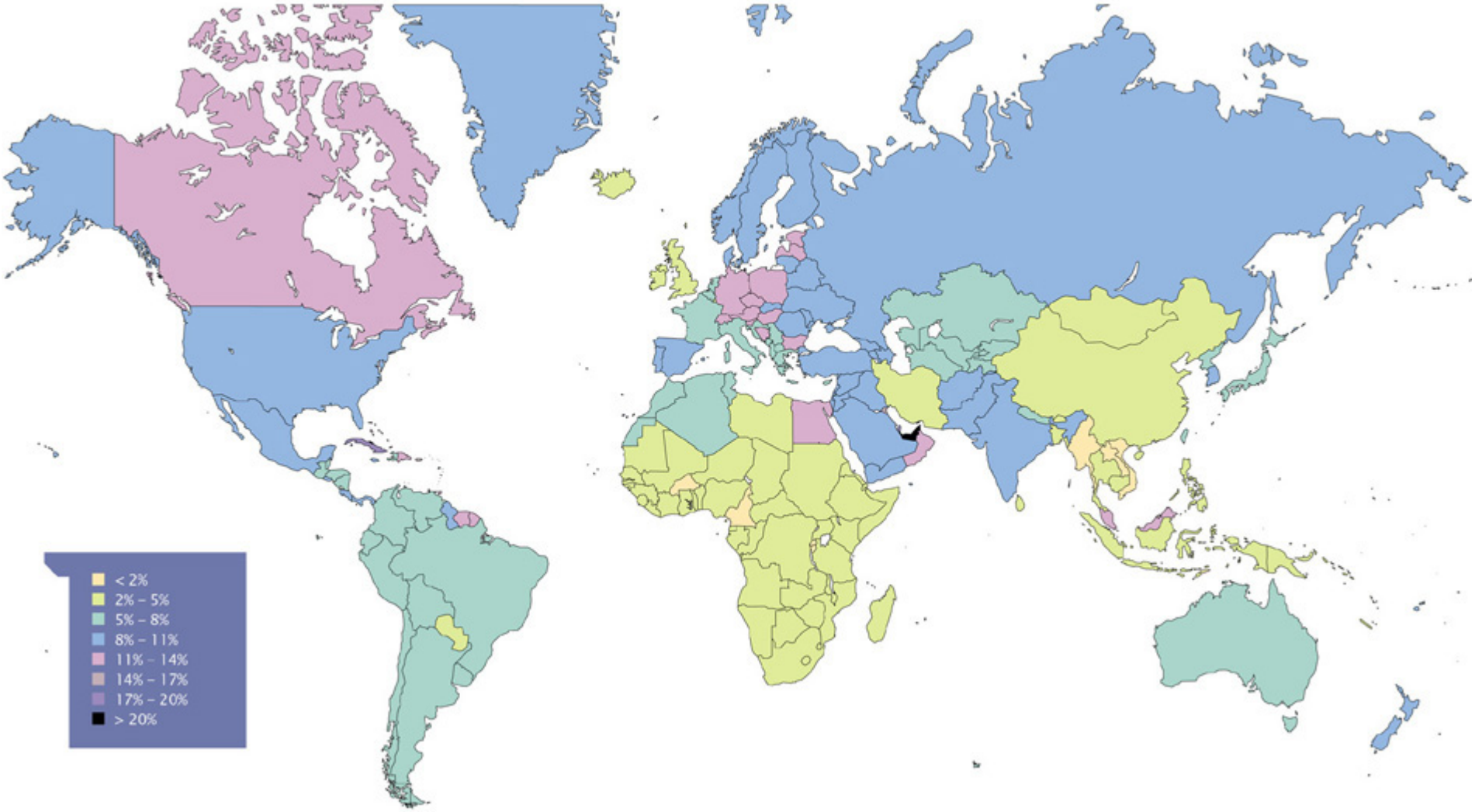
Prevalence estimates of diabetes, 2003



Source: *Diabetes Atlas* second edition, © International Diabetes Federation, 2003

Map 1.2

Prevalence estimates of diabetes, 2025



Source: *Diabetes Atlas* second edition, © International Diabetes Federation, 2003

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13. Article to be Submitted to "Diabetes Care"

Mobile Diabetes Education and Care: Intervention for Children and Youth with Type 1 Diabetes in Rural Areas of Northern Germany

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ABSTRACT

OBJECTIVE Intervention to improve quality of care of children with type 1 diabetes and limited access to speciality diabetes care in rural areas by a mobile diabetes education and care team, which is affiliated with a pediatric diabetes center of a university hospital.

RESEARCH DESIGN AND METHODS A cohort study with 107 participating children and their families from eight rural hospitals was carried out between July 2000 and July 2002. Parameters on quality of metabolic control (HbA_{1c}, hospitalisation rate and number of severe hypoglycemia), diabetes knowledge and quality of life at baseline (t_0), six weeks (t_1) and six months (t_2) after the interventions were investigated.

RESULTS Mean HbA_{1c} value was 7.9 % + 1.4 % at t_0. Low HbA_{1c} values < 6.8 % increased significantly ($p < 0.05$) and high HbA_{1c} values > 8.0 % decreased significantly ($p < 0.01$) at t_1 and t_2. The rate of hospitalisation fell significantly by 9.4 %, from 16.2 % at baseline to 6.8 % at t_2 ($p < 0.05$). The children reported significantly better diabetes specific quality of life ($p < 0.05$) and higher self esteem ($p < 0.01$) after the intervention. Theoretical diabetes knowledge was increased both in the short and long-term ($p < 0.05$).

CONCLUSIONS The intervention was effective for improving metabolic control, diabetes knowledge and diabetes specific quality of life. Our findings suggest that mobile diabetes education and care teams can improve the quality of diabetes care in rural areas.

Type 1 diabetes is the most frequent endocrine disorder in childhood**.** Achievement of optimal glycemic control without appearance of complications and a normal physical and social development are the goals of diabetes care. The long-term prognosis of young diabetes patients depends decisively on access to high-quality diabetes care, which ideally should be provided by a multidisciplinary pediatric diabetes team (1,2). Such teams or other health care providers need expertise in and understanding of medical and psychosocial needs of young people and their families and should also have resources for diabetes training and counseling (3). Diabetes education based on structured and evaluated concepts is a cornerstone of diabetes management (1,3,4). It is a continuous process and should be repeated to ensure effectiveness. Successful education must empower and motivate young patients and their parents to use knowledge and practical skills in problem-solving and self-management (5,6,7,8). This strategy has been shown to be more efficient in changing behaviour and improving metabolic control than only teaching diabetes knowledge (6,7,9,10). Health care professionals should have access to continuing training in diabetes education (3). Methods of delivering education should be appropriate and depend on local experience and facilities. Although a nationwide German study in 1998 found out that the majority of children in Germany with diabetes received continuing outpatient care in children's hospitals or departments meeting the standards of pediatric diabetes care (11), in rural areas diabetes education programs are not sufficiently provided. Here families often face difficulties in assessing a pediatric diabetes center within a reasonable time period. Owing to low numbers of patients, local hospitals in rural areas lack sufficient expertise in treating patients with diabetes. The intervention took place in Schleswig-Holstein, which is a rural state in Germany with a population density of 179 residents/km^2. In- and outpatient treatment is provided in ten pediatric hospitals and in doctors' offices. The pediatric department of the University Hospital in Lübeck is the sole facility with a specialized diabetes team according to the requirements of the German Diabetes Association (DDG). Unfortunately, the center is unfavourably located, at the Eastern border of the state. Thus, for many families access is not easy. The objective of Mobile Diabetes Education and Care for children and adolescents with diabetes mellitus type 1 in Schleswig-Holstein (MDSH) is to optimize diabetes care in a rural community through access to standardized diabetes treatment and structured diabetes education. The MDSH team, which was established in 1999 and is affiliated with the Lübeck

diabetes center consists of a pediatric diabetologist and a pediatric nurse trained in diabetes education.

We conducted a cohort study to evaluate the effectiveness of a standardized and structured diabetes education program carried out by a mobile diabetes team.

RESEARCH DESIGN AND METHODS

Study Population and Study Design

Subjects were recruited and assessed continuously between July 2000 and July 2002. Inclusion criteria for subjects were as follows: over 8 and under 16 years of age, no remissions phase, diabetes duration of more than six months, no insulin pump therapy, no learning disabilities, sufficient German literacy to answer questionnaires and written consent by the parents as well as the children's verbal consent. Illness specific data and socio-demographic data (age, gender, school type, parents´ school education, marital and employment status) were obtained. The primary outcome measurements were HbA_{1c} level, number of hospital days and number of severe complications before and after intervention. Questionnaires were used to investigate diabetes knowledge, quality of life, and patients´ satisfaction with the intervention.

Data were collected at baseline (t_0), six weeks (t_1) and six months (t_2) after the training program by interviews, self-report questionnaires, physical assessments and central laboratory testing. Three trained study coordinators conducted interviews and collected information. Physical examinations were carried out and blood samples were taken by local hospital pediatricians. Standardized physical examinations were used to record weight and height. Blood samples were collected locally with standardized equipment but analyzed centrally to determine HbA_{1c} levels, assessed by high-performance liquid chromatography (Pharmacia, Freiburg; mean $\pm$ SD: 5.89 $\pm$ 0.42 %). The parents were asked the number of episodes of severe hypoglycaemia (according to International Society for Paediatric and Adolescent Diabetes (ISPAD) Guidelines 2000, grade two and three) and diabetes associated hospital stays in the time period six months before and six months after the intervention.

Instruments

Diabetes Knowledge

Two different, age-adapted questionnaires were used to determine the children's diabetes knowledge. The questionnaire for children under 12 years includes 19 items and was developed in the context of the German standard education program for this age group (12). The diabetes knowledge test for children over 12 years of age and adolescents includes 31 items and is a validated questionnaire with good internal consistency ($\alpha > 0.70$) and satisfactory construct and criterion validity as well as sensitivity to change (13,14). Both questionnaires pertain to pathophysiology of diabetes, disease management, nutrition and prevention of complications. Higher scores represent better diabetes knowledge.

Health Related Quality of Life

Health related Quality of life (HRQOL) was assessed in children using the revised German KINDL(R) quality of life questionnaire (15,16), a modular instrument yielding six dimensions and a total score as well as a diabetes module. The generic core of the questionnaire includes 24 items relating to the following subscales: physical and emotional well-being, self-esteem, family, friends, school. The additional diabetes specific scale includes 17 diabetes related items, e.g. "Last week diabetes was ruling my day", "Injecting annoyed me, my parents checked up on me too often", "I felt uncomfortable about measuring my blood sugar level in class". The response scale is a 5-point Likert scale asking for the frequency of feelings and experiences during the last week. Scores are summarized and transformed to a 0 – 100 scale. Higher scores indicate better HRQOL. The instrument has been psychometrically tested with good internal consistency (all Cronbach's $\alpha > .70$ for most scales) and convergent and discriminant validity.

Satisfaction with the Intervention

Parents' satisfaction with the intervention was assessed using the ZUF-8 questionnaire (17), the German version of a CSQ-8 Client Satisfaction Questionnaire (18). Higher scores indicate less satisfaction with the intervention. Children's satisfaction with the education program was assessed using a rating-scale with five response choices ("very good", "good", "ok", "fair" , "did not like it").

Intervention

The MDSH offers 24 follow-up diabetes education programs for children and their parents every year. The courses are offered in a five-day (Monday to Friday) in-patient group setting and are held in eight different hospitals in the state. A group is formed of four to six children of the same age level. The program aims to improve diabetes knowledge, self-confidence, age appropriate independence and self-management abilities. The courses are based on structured and evaluated educational programs for children and adolescents (12,19). Skills taught include information on type 1 diabetes , function of insulin, insulin therapy, insulin delivery methods and techniques, self-monitoring of blood glucose, self-injection of insulin, carbohydrate counting and estimation of exchange units and healthy eating. Furthermore, the modular course covers the subjects hypoglycemia, hyperglycemia, diabetes and sick days, sport, leisure times activities, problems at school and with peers, and fear of diabetes complications. Teenagers obtain further education on the subjects of school trips, traveling abroad, alcohol consumption, smoking, conception and legal advice on job and driver licence applications. The parents are trained once or twice a week in the evening in a group or in one to one sessions. The training focuses on insulin function and empowering the parents to cope with insulin adjustment, sick days and the challenges in everyday life. If it is necessary or desired, an adjustment of diabetes therapy is carried out. The MDSH cooperates intensively with local hospital teams and offers continuing education on diabetes care, teaching skills, teaching materials and a comprehensive curriculum.

Statistical Analysis

The statistical software package SPSS 11.0 for Windows was used for all analyses. Descriptive statistics were expressed as frequencies or means ± SD or percentages. Effects of the intervention on the main outcome parameters (HbA_{1c}, HRQOL, diabetes knowledge) were analyzed using Friedman test and post-hoc pair comparison using Wilcoxon test, α-level being adapted to multiple testing. The effects on the number of severe hypoglycemia and inpatient stays were analysed using McNemar test. To identify determinants of metabolic control, we used Spearman Rank correlation coefficients for associations of two continuous variables and Mann-Whitney-test for group comparisons. Significant predictors from the bivariate analysis were included in a linear

regression to analyze the independent effect of these determinants. Significance was attributed at $p < 0.05$ for all tests.

RESULTS

145 families participated in a diabetes education program during the study period. The inclusion criteria were fulfilled by 110 families. The final sample size analysed was 107 children and adolescents (60 girls, 47 boys) and 102 parents at baseline t_0. Children's socio-demographic and medical characteristics at baseline t_0 are demonstrated in table 1. The first follow-up assessment (t_1) was undertaken by 104 children and adolescents and 95 parents and six months later, 89 children and adolescents and 81 parents participated in the second follow-up assessment (t_2). Comparing t_0 and t_2 the loss due to follow-up was 17 % for children and 21 % for parents.

Quality of Metabolic Control

HbA_{1c}

Children with poor metabolic control at baseline, which was defined as a HbA_{1c} level > 8.0 %, (more than mean + 5 SD) showed significantly improved metabolic control between t_0 and t_1, and t_0 and t_2 ($p < 0.01$). This result in this subgroup was not found to be dependent on changes in insulin therapy, use of Semilente-insulin for the night (insulin zinc suspension, pork insulin, Novo Nordisk), use of insulin analogs or number of blood glucose measurements per day. Children with a very low HbA_{1c} level, which was defined as < 6.8 % at baseline t_0, (less than mean + 2 SD) showed an increase in HbA_{1c} levels between t_0 and t_1 (p = ns), and t_0 and t_2. ($p < 0.05$) The overall HbA_{1c} levels at the three assessments in the entire sample did not differ (p = ns) (Figure 1). Intervention effects on HbA1c were independent of mothers' and children's socio-economic status (gender, age, school type, family structure, mothers' educational status, mother's employment status, place of residence).

Severe Hypoglycaemia

The number of severe hypoglycemia did not significantly change: six months before intervention 22.9 events per 100 patient years and six months after the intervention 21.2 events per 100 patient years (p = ns).

Hospital Treatment

Six months before the intervention 17 hospital treatment (16.2 %; n = 105) were recorded and six months after the intervention 7 hospital treatments (6.7 %; n = 103) were reported. Analysing only the children (n = 100) who took part in both examinations at t_0 and t_2, and we found a significant reduction in hospital admission (McNemar test, $p < 0.05$).

Diabetes Knowledge

Children under 12 years increased their diabetes knowledge (t_0 10.3; t_1 13.3; t_2 13.2 of 19 possible points) and as well as children and adolescents over 12 years (t_0 14.3; t_1 16.8; t_2 16.4 of 31 possible points). Children and adolescents showed better diabetes knowledge in both follow-up assessments (t_1 and t_2) compared to baseline (children < 12 years: $p< 0.01$; children > 12 years: $p < 0.05$). The effects on diabetes knowledge were independent of HbA1c level at baseline and socio-economic status (gender, school type, ,mother's educational status, mother's employment status, place of residence). However, adolescents living in households with a single-parent showed higher increase in diabetes knowledge compared to those, living with two parents ($p < 0.05$).

Quality of Life

Children reported significantly better diabetes -specific Quality of life (QOL) at both follow-up assessments (t_0 66.19 $\pm$ 14.39; t_1 69.09 $\pm$ 15.6; t_2 71.00 $\pm$ 16.0; t_0 - t_1: $p < 0.05$; $t_0 - t_2$: $p < 0.01$) Assessing generic HRQOL we found significantly higher scores for self-esteem after the intervention (t_0 55.8 $\pm$ 24.02; t_1 65.99 $\pm$ 20.84; t_2 64.37 + 20.42; $t_0 - t_1$, $t_0 - t_2$: $p < 0.01$). The effects on QOL were independent of initial HbA_{1c} level and socio-economic status (gender, age, school type, family structure, mother's educational status, mother's employment status, place of residence).

Determinants of Metabolic Control

Socio-demographic and medical parameters were examined as possible influencing factors of metabolic control, HbA_{1c} level at baseline (t_0) being the dependent variable. Performing bivariate analysis, we found a significant association (Spearman rank correlation coefficient) between HbA_{1c} and age ($R = 0.383$, $p < 0.001$), diabetes

duration (R = 0.230, p < 0.05) and body mass index (BMI) (R = 0.265, p < 0.01). HbA_{1c} value rose with higher age and longer diabetes duration.

However, performing a linear regression analysis including these determinants, only child's age showed an independent significant influence on HbA_{1c} level. Other socio-demographic and medical factors showed no significant influence (such as gender, school type, family structure, mother's educational status, mother's employment status, number of daily injections).

Satisfaction with the Intervention

The overall satisfaction with the intervention was very good, in detail: the questionnaire was answered by 94 children at the first follow-up assessment. 57.4 % graded the education program as "very good", 27.2 % as "good", 11.7 % as "ok", 1.1 % "fair" and 2.1 % said "I did not like it". The parents predominantly graded the intervention with the best or second best of four response options (mean 1.4, SD ± 0.4).

CONCLUSIONS

The study describes the evaluation of a new concept of diabetes care in Northern Germany. Two target groups were reached with the intervention, children with low and high HbA_{1c} values (< 6.8 %, > 8.0 %) being at risk for acute complications such as severe hypoglycemia, ketoacidosis and secondary complications. Since we did not find significant influencing factors, the result may be explained due to increased theoretical and practical therapy competence of parents and children. Furthermore, we observed less hospital in-patient treatments after the intervention, which accounts for less health care costs. Avoidance of in-patient treatment due to hypoglycemia, ketoacidosis and further diabetes complications are not only important for individual burden, but also for economic aspects. In Germany, children and adolescents with diabetes have a three times higher risk for hospital treatment compared to healthy individuals of the same age and these costs are largely disproportionate (20). Moreover, the distance between place of residence and the location of the nearest diabetes center was associated with longer hospital treatment (21). A recent study investigated diabetes-related direct costs for care of children and adolescents in Germany. The highest economic burden was found to be due to glucose self measurement, hospitalization and insulin. Costs for hospitalization was associated with pubertal age and poor metabolic control (22).

The findings underline the importance of education programs targeting children with poor metabolic control.

In our study, we expected an increase of diabetes knowledge due to the intervention. Nevertheless, more important in everyday life is the transfer of knowledge into daily practice. Since there was no difference in results of diabetes knowledge between t_1 and t_2, we presume that the effect was due to the intervention and not resulted from normal mental development.

Type 1 diabetes mellitus affects the patients' and their families' psychological and emotional well-being. Therefore, QOL is beside the HbA1c level a main outcome parameter for education programs and diabetes care. In a large-scaled investigation, better metabolic control was found to be associated with better QOL (23). In our investigation, the children reported better diabetes-specific QOL and self-esteem even independent of the HbA_{1c} level at baseline.

However, the positive results of the evaluation advises us to be cautious, because families, who are highly motivated in diabetes therapy may endeavour to participate more often in diabetes education programs. Also, in the absence of a diabetes registry it was not possible to ascertain whether our sample is representative for the entire population of children with diabetes in the state of Schleswig-Holstein. Therefore, a recruitment bias can not be ruled out. In addition, we were unable to randomize children for intervention and control groups, since the intervention took place at hospitals with small numbers of patients, and children and adolescents with poor metabolic control should immediately be given the opportunity to take part in a course near their residence. Regarding ethical considerations it would have been questionable to delay the participation of those children.

Type 1 diabetes is an outstanding chronic illness in childhood, for which self-management abilities and disease specific education play a central role. Managing diabetes in children is a complex task for families, because diabetes treatment touches nearly every important aspect of daily life. In order to make a normal psychosocial and physical development possible for affected children and to delay or even prevent diabetes complications, access to treatment and education offered by a specialized

diabetes health care team has highest priority. Considering the enormous individual disease burden as well as the costs of diabetes treatment and diabetes-related complications, it is a public health issue to ensure access to high-quality diabetes care for all patients with type 1 diabetes, independent from their place of residence. In rural areas, a mobile diabetes education and care team can improve the structure and quality of diabetes care for those not having access to a diabetes center. The described mobile diabetes education and care program could serve as a model for other rural communities.

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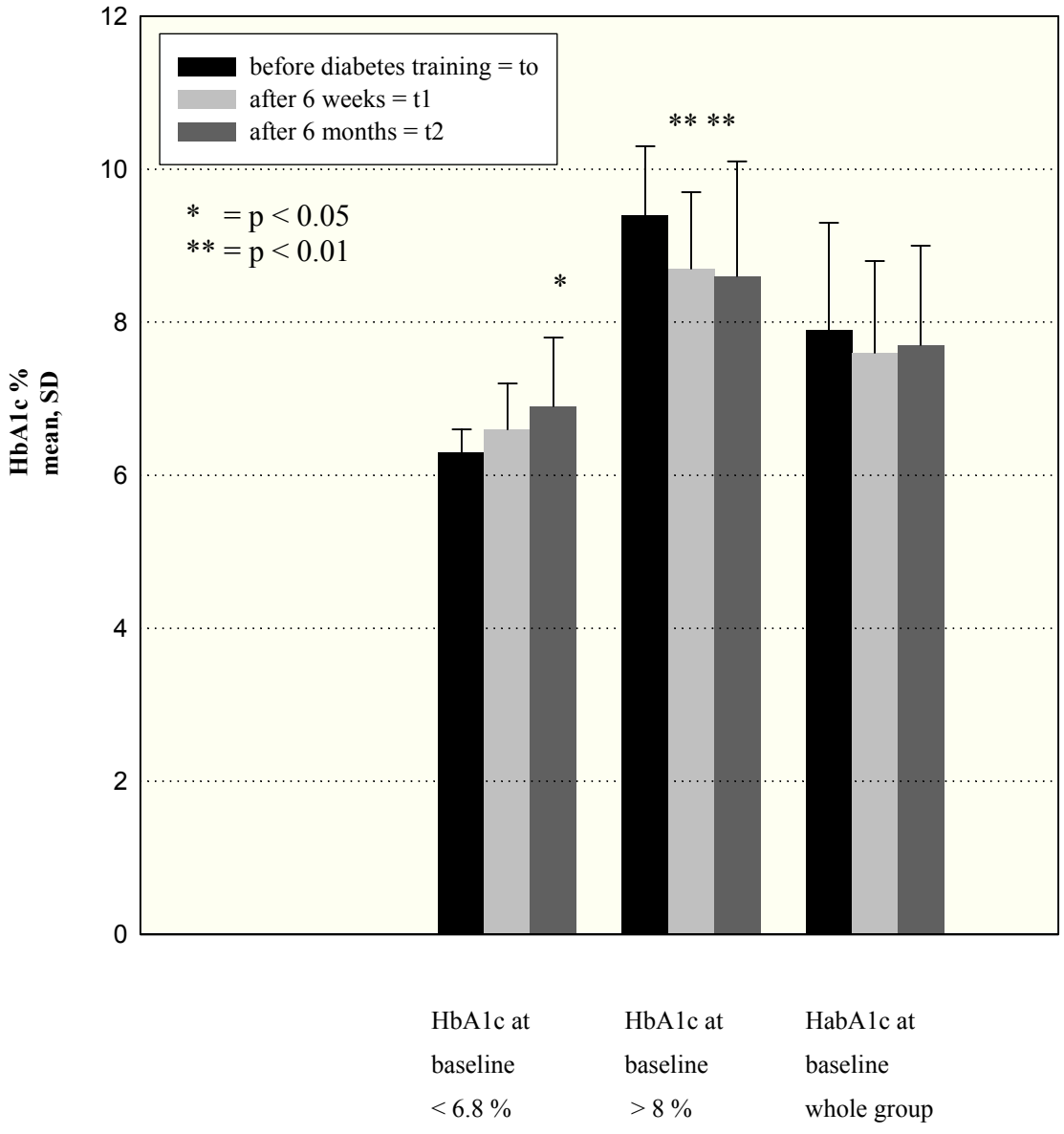
Table 1 : Children's´ socio-demographic and clinical characteristics at baseline t_0

n = 107 (t_0)	**Means**	**± SD**
Age (years)	11.1	2.5
Diabetes duration (years)	4.3	3.0
HbA1c %	7.9	1.4
BMI (n = 102) kg m^2	19.3	3.2
	n	**%**
Female	60	56.1
Male	47	43.9
School type		
Elementary school	46	43.0
Secondary school	13	12.1
Junior High school	26	24.3
High school	14	13.1
Others	8	7.5
Insulin therapy		
Two injections daily	3	2.8
Three injections daily	13	12.1
Four injections daily or more	91	85.1
Use of rapid acting anlogs	11	10.2
Use of intermediate-acting Semilente-insulin at night	25	23.3
Family structure (n = 102)		
Single parent	23	22.5
Two parents	79	77.5

Figure 1: Course of HbA1c level in the whole group and subgroups



Eidesstattliche Erklärung

Die vorliegende Arbeit wurde von mir selbständig und nur unter Verwendung der von mir angegebenen Quellen angefertigt.

Die Arbeit hat in dieser oder ähnlicher Form noch keiner Prüfungsbehörde vorgelegen.

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Dr. Simone von Sengbusch

Lübeck, den 19. August 2004