

## Intensified Insulin Treatment, Pumps and Sensors I

P/WED/67

### Intensive insulin treatment in the first four years of type 1 diabetes in children

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**Background:** Studies comparing conventional (CT) and intensive insulin therapy (IT) before puberty are scarce.

**Objective:** To evaluate metabolic control, insulin requirement and safety of IT versus CT over the first four years of type 1 diabetes evolution in prepubertal children.

**Subjects and methods:** Two cohorts of children with type 1 diabetes, virtually identical at study entry, were compared: 31 (aged  $5.2 \pm 2.8$  year; 13 females) on IT, diagnosed in 2000–2002, and 35 (aged  $4.6 \pm 2.6$  year; 13 females) on CT diagnosed before year 1996. IT group received three injections of mixture of intermediate-acting insulin NPH and short-acting insulin analogue lispro and CT two injections daily of a fixed mixture of regular and NPH. Variables at 0, 1, 2, 3 and 4 years were compared between groups by two-sided t-Student and  $\chi^2$  tests.

**Results:** No significant differences were found between groups throughout the study period in terms of metabolic control, insulin dose and weight: at four years A1C hemoglobin was  $7.63 \pm 0.85\%$  vs.  $7.76 \pm 1.07$  ( $p = 0.6$ ), body mass index - standard deviation score was  $0.29 \pm 0.51$  vs.  $0.20 \pm 0.67$  ( $p = 0.6$ ), and total daily insulin requirements were  $0.81 \pm 0.15$  UI/kg vs.  $0.87 \pm 0.17$  ( $p = 0.09$ ). Incidence of severe hypoglycemia was lower in the IT group ( $0.02 \pm 0.09$  episodes/patient/year vs.  $0.19 \pm 0.32$  ( $p = 0.004$ )) and incidence of diabetic ketoacidosis was  $0.01 \pm 0.04$  episodes/patient/year vs.  $0.05 \pm 0.18$  ( $p = 0.29$ ).

**Conclusion:** During the first four years of type 1 diabetes in prepubertal patients, IT was safer than CT, decreasing the risk of severe hypoglycemia. Both therapies have similar effects in terms of metabolic control, weight and insulin requirement.

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### Carbohydrate to insulin matching on a South African urban diet in adolescents with type 1 diabetes

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**Objectives:** Optimal diabetes control requires insulin administration in conjunction with a meal plan that takes into consideration social, economic and logistical factors. Analog insulins improve postprandial blood sugars while reducing late postprandial hypoglycaemia, but most T1DM patients in South Africa do not have access to them. To assess the impact of 'traditional' carbohydrate intake on blood glucose excursions and attempt to find the 'ideal' bolus insulin: carbohydrate match on a typical South African diet.

**Methods:** Observational prospective/cohort study of 12 adolescent patients with T1DM > 1 year duration attending the Johannesburg diabetes clinic. Ethics approval and consent/assent was obtained. The glycaemic response to a fixed dose (50 g) of available carbohydrates from 4 staple food groups (rice, bread, maize porridge and a wheat cereal) was assessed. A personalized insulin to carbohydrate ratio was used to calculate the dose of each of the study insulins administered (Humalog® at 0 min (H), Actrapid® at 0 (Act0) and -30 min (Act-30)). Blood glucoses were

monitored for 5 hrs to assess the best match between carbohydrate meal and administered insulin (type and timing).

**Results:** Glucose profiles were similar for the 4 food types assessed within each insulin group. Baseline to peak glucose was greatest with Act0 and least with Act-30, intermediate with H. Time to peak H 66 min, Act0 100 min and Act-30 110 min. H time to baseline was 126 min, Act0 178 min and Act-30 212 min. Act-30 was associated with a risk of pre-meal hypoglycaemia. In both Actrapid groups blood sugars were still decreasing between 4 and 5 hours after administration.

**Conclusions:** Analog insulin was superior to regular human insulin given at 0 min or -30 min in reducing postprandial hyperglycaemia and late postprandial hypoglycaemia. Between meal snacks are still required on regular human insulin. Analog insulins should be included in the state hospital armamentarium.

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### Continuous subcutaneous insulin infusion therapy in children and adolescents with diabetes mellitus type 1: a systematic review

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**Objectives:** To investigate possible clinical benefits of continuous subcutaneous insulin infusion (CSII) therapy compared to multiple daily insulin injection (MDI) therapy in children and adolescents with diabetes mellitus type 1 with regard to glycaemic control, insulin requirements, hypoglycaemia and adverse events.

**Methods:** We systematically searched electronic databases (MEDLINE, EMBASE, CENTRAL) for randomised controlled trials (RCT) up to March 2007. Two reviewers independently evaluated the relevance of studies and their quality. A systematic review was performed.

**Results:** We identified 3 RCTs relevant to our question. The number of included patients ranged from 20 to 32. Follow up was between 16 and 52 weeks. Regular insulin was used as the pump and bolus insulin in one study (Schiffrin), and short acting insulin analogues in the two other studies. Study quality was judged to be low for the study by Schiffrin and medium for the two other studies. In trials including adolescents the difference in HbA1c at study end was 0.9% (Doyle) and 0.8% (Schiffrin) favouring CSII therapy, statistically significant in the study by Schiffrin only. The study on young children (Wilson) showed a statistically not significant difference in HbA1c of 0.2% favouring MDI. Decrease of HbA1c (from beginning to end of study) was more pronounced under CSII therapy in all studies, particularly in those including adolescents, without reaching statistical significance. Lower insulin requirements in the CSII groups at the study end were found in the studies on adolescents by Doyle ( $p = 0.003$ ) and Schiffrin ( $p < 0.001$ ). No statistically significant differences between treatment groups were found for the number of severe hypoglycaemic or ketoacidotic events.

RCT	HbA1c in %		Insulin dose in IU/kg/d		SH	KA
	Beginning	End of study	Beginning	End of study		
n, age of patients					events	events
CSII vs. MDI						
Doyle(2004) n = 32, 13 y	8.1 vs. 8.2	7.2 vs. 8.1	1.4 vs. 1.1	0.9 vs. 1.2; s	1 vs. 4	1 vs. 1
Schiffrin(1983) n = 20, 15 y	13.3 vs. 13.3	8.9 vs. 9.7; s	0.95 vs. 0.95	0.73 vs. > ; s	1 vs. 1	n.a.
Wilson(2005) n = 22, 4 y	8.1 vs. 7.7	7.9 vs. 7.7	0.54 vs. 0.70	0.62 vs. 0.73	1 vs. 1	0 vs. 0

KA, ketoacidosis; SH, severe hypoglycaemia; n, number of patients; n.a., not available; s, statistically significant; y, years.

**Conclusions:** Currently available data suggest that CSII is a safe therapy option in adolescents and children and that a better

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glycaemic control, despite lower insulin requirements, might be reached in adolescents compared to MDI therapy.

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### Glycaemic control in the first two years of CSII therapy in children and adolescents with type 1 diabetes

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**Objective:** Although CSII is the most physiologic method of insulin delivery, there is still a debate about the advantages in terms of reducing HbA<sub>1c</sub>, severe hypoglycaemia (SH) and diabetic ketoacidosis (DKA). In several studies, a short-term improvement in HbA<sub>1c</sub> has been found. This study aimed to update our previous reports with data of the second year of CSII in a large cohort of paediatric patients.

**Methods:** Between 2001 and 2005, 98 patients started with CSII and were followed every 3 months for two years. Seven patients discontinued CSII or were lost to follow-up. Thus, 91 patients could be included into the study (38 boys; mean age 10.4 ± 4.3 years; diabetes duration 4.1 ± 3.5 years). Insulin dose, mean HbA<sub>1c</sub>, and incidence of SH and DKA were separately calculated for the year before as well as in the first and second year of CSII.

**Results:** Daily insulin dose of the first year was 0.84 U/kg and increased significantly to 0.87 U/kg in the second year ( $P = 0.044$ ). HbA<sub>1c</sub> of the second year (8.25 ± 1.16%) had significantly increased compared with the first year (7.84 ± 0.95%,  $P < 0.001$ ) and with the year before CSII (8.05 ± 0.96%,  $P = 0.001$ ) independently from gender, indication for CSII, and year of CSII begin. HbA<sub>1c</sub> deterioration was not seen in patients < 10 years of age ( $P = 0.647$ ), but was even more pronounced in those aged ≥ 10 years ( $P < 0.001$ ). Incidence of SH decreased steadily from 18.7 to 13.2 and 3.3 events per patient, 100 years before and in the first and second year ( $P = 0.016$ ), respectively. In the year before CSII, there was no episode of DKA, whereas 7.7 events/100 years occurred in the first and 3.3 in the second year of treatment ( $P = 0.083$ ).

**Conclusion:** Beyond one year of CSII, the risk of acute diabetic complications could be substantially reduced, probably because patients get more experienced over the time. On the other hand, we found an unsatisfactory impairment of HbA<sub>1c</sub> in the second year. Thus, attention should be paid to long-term glycaemic control during CSII, particularly in adolescent patients.

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### Insulin pump therapy versus multiple insulin injection in type 1 DM

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**Aim:** The present study analyzes the efficiency of insulin pump therapy.

**Methods:** We included 11 patients (4 boys and 7 girls) aged between 9–17 1/2 years, duration of type 1 DM below 1 year (2 cases) above 5 years (5 cases) and above 10 years (4 cases). The selection of the patients respected the treatment criteria with the insulin pump. In all cases rapid acting insulin analogues were used. Recommended diet was fix concerning the carbohydrate intake at the same time. We analyzed the level of HbA<sub>1c</sub> depending on the anatomic site of catheter implantation (belly or buttocks), duration of catheter insertion, the evolution of the basal rate in time. The somatometric

indexes (height, weight, BMI) were recorded monthly. Blood glucose levels obtained depending on the basal rates and the boluses administrated were determined twice a month, while HbA<sub>1c</sub> was measured quarterly. The degree of metabolic equilibrium was compared with that previous to using the insulin pump.

**Results:** No significant differences related to the absorption rate between injection sites (belly or buttocks) were found. After the third day since the implant of the catheter in all cases we observed an increase of the blood glucose while in 1 case 3 hyperglycaemic accidents were encountered with blood glucose above 400 mg% in different moments of the day, which were corrected, even under the circumstances of keeping the catheter in the same site, only by supplementary boluses. The degree of the glycaemic equilibrium was significantly better than with the multiple injections therapy, attaining and maintaining HbA<sub>1c</sub> levels below 7%, in the absence of medium or severe hypoglycaemic accidents. The adjustment of the basal rate in the second half of the night led to the disappearance of the dawn phenomenon.

**Conclusions:** The comfort of patients is increased by the reduction of injections number to 'only one' every three days. Insulin pump is now the most efficient method in controlling the « down » phenomenon.

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### Relationship between self-monitored plasma glucose (SMPG) and HbA<sub>1c</sub> in paediatric subjects 4–18 years of age with type 1 diabetes (T1D) treated with continuous subcutaneous insulin infusion (CSII) using insulin aspart or insulin lispro

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**Objective:** The purpose of the present study was to investigate the relationship between SMPG and HbA<sub>1c</sub> in 298 T1D paediatric subjects treated with CSII using an insulin analogue.

**Methods:** Using data collected during a randomised, 16-wk study comparing insulin aspart vs. insulin lispro in youth (4–18 years) with T1D (≥ 1 year) during CSII therapy, we compared HbA<sub>1c</sub> and SMPG (pre-prandial and bedtime) at weeks 8, 12, and 16 (end of study [EOS]). Linear regression analysis was performed.

**Results:** Mean HbA<sub>1c</sub> and SMPG values were not significantly different between treatment groups at EOS. SMPG (pre-prandial and at bedtime) and HbA<sub>1c</sub> at EOS were directly correlated by linear regression, but the correlation was generally weak (Table). A higher correlation appeared when all SMPG time points were included. Pre-dinner and bedtime SMPG values were more strongly correlated to HbA<sub>1c</sub> than pre-breakfast and pre-lunch SMPG values. Change in HbA<sub>1c</sub> from baseline at EOS generally did not correlate with SMPG ( $p > 0.05$ ) with the exception of pre-

Table: Relationship between SMPG and HbA<sub>1c</sub> or change in HbA<sub>1c</sub> from baseline at end of study

SMPG testing time	N	HbA <sub>1c</sub>		Change in HbA <sub>1c</sub> from Baseline	
		p-value	r	p-value	r
Before breakfast	286	0.0063	0.161	NS	-
Before lunch	285	0.0103	0.151	NS	-
Before dinner	286	< 0.0001	0.265	0.0207	0.137
At bedtime	280	< 0.0001	0.281	NS	-
All timepoints	572	< 0.0001	0.366	0.0020	0.129

LOCF imputation. N, number of observations used; r, coefficient of correlation; NS, not significant ( $p > 0.05$ ).

dinner SMPG and when all SMPG timepoints were combined (lower SMPG related to a greater decline in the EOS HbA<sub>1c</sub>).

**Conclusions:** In a cohort of T1D paediatric subjects treated with insulin analogue CSII, a stronger correlation was observed between HbA<sub>1c</sub> and pre-dinner and bedtime SMPG values than pre-breakfast and pre-lunch SMPG values. In paediatric patients, greater correlation between SMPG values and HbA<sub>1c</sub> likely requires more frequent SMPG testing or data from continuous sensing.

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### Effect and safety of continuous subcutaneous insulin infusion (CSII) in patients with juvenile-onset type 1 diabetes-indications for pump therapy

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**Objective:** We examined the effect and safety of CSII in juvenile-onset patients with type 1 diabetes and consider the indications for pump therapy.

**Method:** The subjects consisted of 12 Japanese patients, 4 males and 8 females, aged  $17.2 \pm 10.5$  years, with type 1 diabetes diagnosed until 15 years old. All the patients changed multiple daily insulin injections (MDI) to CSII using a quick-acting insulin analog. HbA<sub>1c</sub> levels were compared before and 1, 3, 6, 9, 12 months after the administration of CSII, and the frequencies of severe hypoglycaemia (SH) and DKA were compared before and 12 months after the use of CSII.

**Results:** 1) Reasons for using CSII were as follows; inadequate diabetes control: 3 patients, frequent hypoglycaemia: 2 patients, irregular lifestyles: 3 patients, and management of pregnancy: 4 patients. 2) HbA<sub>1c</sub> levels significantly declined after the use of CSII ( $7.5 \pm 1.3\%$ : at baseline versus  $7.0 \pm 1.3\%$ : 1 month,  $p = 0.01$ ,  $6.9 \pm 1.1\%$ : 3 months,  $p = 0.02$ ,  $7.2 \pm 1.0\%$ , 6 months,  $p = 0.03$ ,  $6.9 \pm 1.4\%$ : 9 months,  $p = 0.04$ ). However, we did not find the significant difference in HbA<sub>1c</sub> value at 12 months ( $7.1 \pm 1.8\%$ ,  $p = 0.07$ ). 3) Five patients had SH and one had DKA during one-year period before the use of CSII, while 2 patients had SH and another 2 had DKA during the study period because of inexperienced use of the pump. 4) All the patients had a feeling of improvement in their QOL and wanted to continue the pump therapy.

**Conclusion:** After the administration of CSII, the frequencies of SH decreased and serial HbA<sub>1c</sub> values significantly decreased. Although two patients experienced DKA and another two had SH during the use of CSII, neither SH nor DKA occurred after they mastered how to use the pump. We consider that CSII is effective and safe in young persons with type 1 diabetes. The indications for the use of CSII are not only to need improvement of diabetes control and decrease of the episodes of hypoglycaemia but to need optimal insulin therapy matching their lifestyles.

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### In children with diabetes under 5 years old CSII gives significantly better glycemic control than conventional insulin regimes without side effects such as hypoglycaemia

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**Introduction:** Children with diabetes under 5 years of age are difficult to manage on conventional therapy. The main factors limiting achievement of glycemic control are the risk of

hypoglycaemia and unpredictable appetite. Hence, the target HbA<sub>1c</sub> has been set higher in this age bracket than would be accepted for older age groups.

**Aims:** To study the effectiveness of CSII in under 5 year olds.

**Methods:** Children under 4 years old with T1DM were started on CSII and followed for a minimum of 12 months until 5 years of age. There were no selection criteria for initiation of CSII. Data was collected prospectively from this group and from controls (two controls for each case matched for age at diagnosis and sex). Clinic follow up was identical for both groups.

**Results:** Out of 13 children, 8 male and 5 females; age range 14 months to 44 months, were started on CSII and followed for 12 to 33 months. Clinic visits and HbA<sub>1c</sub> occurred 3 monthly. The average HbA<sub>1c</sub> for the CSII group was 8.8% at initiation and 6.65% over the 3 year period (range 6.31 – 7.12%) while the average HbA<sub>1c</sub> for the conventional group was 10.7% (at diagnosis) and 8.42% (range 7.9 – 8.75%) on established therapy. The CSII group had an average HbA<sub>1c</sub> 1.78% lower (range 1.32 – 2.22%) than the conventionally treated group ( $p < 0.008$  at each 3 month time point). Three patients had had grade 4 hypoglycaemic episodes before starting CSII. One patient had a grade 4 hypoglycaemic seizure on CSII during an episode of gastroenteritis. Before starting CSII this patient had had recurrent, hypoglycaemic seizures (2–3 per day). There were no grade 4 hypoglycaemic episodes in the control group. Other complications in the CSII group included contact dermatitis and site infections (one patient was taken off CSII due to recurrent site infections). Family satisfaction with CSII was high.

**Conclusion:** CSII is safe in young children and gives consistently excellent glycemic control.

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### Insulin pump therapy in diabetic patients: the results of 3 years follow-up

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An adequate glycemic control remains a real problem for children and adolescents with Diabetes Mellitus type 1. The uses of new insulin analogs and intensive insulin therapy are not always available to reach the target levels of glycemia and glycohemoglobin (HbA<sub>1c</sub>). At the present time, insulin pump is more effective tool for patients which can help to improve glycemic control.

**Objective:** To evaluate the results of metabolic control before and after the start of insulin pump therapy.

**Materials and Methods:** Out of 40 patients (23 M/17 F) with diabetes type 1 aged 5–21 yrs ( $13.09 \pm 4.0$  years) and duration of disease 0.5–17 years ( $4.69 \pm 3.29$  years) took part in this study. The insulin pumps 'Minimed 508', 'MiniMed 712', 'Minimed 722' (Medtronic MiniMed, Sylmar, CA) were used. For correction of insulin doses 33 patients stayed in hospital for 10–15 days and 7 patients visited doctor 3–5 times during 5–7 days. Glucose self-control was performed 4–6 times in day. HbA<sub>1c</sub> level before and in 3, 12, 24 and 36 month after the start of insulin pump treatment, the frequency of severe hypoglycaemia and diabetic ketoacidosis, convenience of pump using were analyzed.

**Results:** HbA<sub>1c</sub> level before insulin pump was 5.7–14.7% ( $9.83\% \pm 2.15\%$ ); in 3 months of insulin pump usage HbA<sub>1c</sub> was 6.3%–13.1% ( $8.8 \pm 1.42\%$ ); in 12 months 7.5%–13.3% ( $8.95 \pm 2.21\%$ ); in 24 and 36 months 5.4%–11.9% ( $8.75\% \pm 1.62\%$ ) and 5.4%–10.2% ( $9.03\% \pm 0.8\%$ ) respectively. None of patients suffered from episodes of severe hypoglycaemia during the evaluation period. Diabetic ketoacidosis occurred in two patients due catheter occlusions. All patients marked convenience of pump uses.

**Conclusion:** Insulin pump therapy significantly improves the metabolic control, upon condition the adequate self control performing.

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### Low risk of poor metabolic control in pre-pubertal diabetic children treated with insulin pump. Results of the Polish Prospective Pump Study

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Continues subcutaneous insulin infusion (CSII) as an alternative method is becoming one of the common method uses in pediatric patients; however the best option of replacement insulin therapy in young T1DM is still disputed. The aim of the study was to assess the efficacy of pump therapy in pre-pubertal children comparing with multiply daily injection.

**Materials and methods:** The cohort, multi-center study was conducted in 17 centres in Poland according to the protocol of the Polish Prospective Pump Study. The data was collected electronically from November 2006 to February 2007 during follow-up visits. HbA1c was assessed in central laboratory using BioRad method (HPLC).

**Results:** A study group consisted of 538 pre-pubertal children treated with CSII; mean age was  $8.03 \pm 2.4$ ;  $< 1,5-12$  years  $>$  mean diabetes duration  $3.6 \pm 2.1$  years; mean pump treatment duration was  $2.0 \pm 1.3$  years. 245 subjects were enrolled into the control group; there are no significant differences in age and diabetes duration between two groups. HbA1c for study group was  $7.38 \pm 0.9\%$  vs.  $7.33 \pm 1.1\%$ ; ns. The analysis was given in three age related groups: I  $< 5$  years, II 5–9 years and III 9–12 years shows the best control in preschoolers ( $7.24 \pm 0.7\%$  vs.  $7.39 \pm 0.9\%$  vs.  $7.42 \pm 1.0\%$ ; ns) in both CSII and MDI groups. The risk of poor glycemic control (HbA1c  $> 8$ ) was 23% in individuals treated with CSII. The significant differences were noticed in insulin requirement CSII  $0.73 \pm 0.21$  vs. MDI  $-0.65 \pm 0.26$  and growth development parameters. In study group the mean BMI in group III ( $17.57 \pm 2.3$  vs.  $17.76 \pm 2.23$  kg/m<sup>2</sup>  $p < 0.05$ ) and in group I ( $16.43 \pm 1.32$  vs.  $18.16 \pm 4.83$   $p < 0.05$ ) were lower, respectively.

**Conclusions:** Continuous subcutaneous insulin infusion is an effective method of insulin treatment for pre-pubertal children with type 1 diabetes and the risk of high HbA1c is lower if the CSII is used. The growth development consists with physiology was only in patients treated with pump.

## Intensified Insulin Treatment, Pumps and Sensors II

P/WED/77

### Meal-type rather than bolus-type determines postprandial glycaemia in children with type 1 diabetes on insulin pump therapy

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**Objective:** Meals of high and low glycaemic load (GL) have distinct effects on postprandial glycaemia. Optimal bolus types are

yet to be defined for meals of varying GL. We sought to compare the impact of GL combined with varying meal bolus type on postprandial glycaemia (PPG).

**Methods:** Participants comprised children and adolescents with T1DM using insulin pump therapy for  $> 3$  months with HbA1c  $< 8.6\%$ . Test meals had equal macronutrient (CHO, fat, protein), fibre and energy composition and differed only in terms of glycaemic index and load. Meals of the same GL were eaten on consecutive days with either a standard (100%) or dual-wave (50:50% delivered over 2 hours) bolus given each day. Total pre-meal insulin was calculated using the '500' rule and was constant in a given individual for each meal. The test meal was eaten 3 hours after a standard breakfast. CGMS was used to monitor glycaemic profiles over a 3 hour postprandial period. Data from control participants was used to establish mean normal glycaemic response to each meal type. Primary endpoint was percent time spent within  $\pm 2$  SD from pre-meal glucose.

**Results:** Postprandial hyperglycaemia was significantly more common after a high GL (51%) than low GL meal (30%), regardless of bolus type. In low GL meals, use of a dual-wave bolus resulted in a significant increase in percent time spent within  $\pm 2$ SD of pre-meal glucose (OR 2.6,  $p < 0.01$ ), indicating less glycaemic excursion with this meal-bolus combination. Hypoglycaemia requiring treatment was most frequent after low GI meals with standard bolus administration.

**Discussion:** Hyperglycaemic excursions were common after high GL meals in patients with T1DM using insulin pump therapy. Use of a dual-wave bolus for low GL meals is associated with less postprandial glycaemic excursion and less hypoglycaemia. This data supports the use of low GL meals to optimise PPG in T1DM patients on insulin pump therapy.

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### Timing of boluses in children with type 1 diabetes using insulin pump therapy (TiBoDi Study). Preliminary results

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**Objectives:** To date very few it is known about the right time to inject the bolus dose in order to avoid the glycaemic spike often seen after meals. The aim of our study is to determine the most-effective timing of bolus infusion pre-mealtime in children with T1DM using insulin pump therapy.

**Methods:** We evaluated 20 patients (10 M and 10 F), aged 6–20 years (mean  $14.6 \pm 3.9$  years), with a diabetes duration of  $7.5 \pm 4$  years, BMI  $22.1 \pm 4.1$  m/kg<sup>2</sup> in therapy with subcutaneous insulin infusion (insulin requirement  $0.78 \pm 0.28$  U/kg/day). Each subject was admitted at hospital for a period of 3 days. Each day they consumed a meal with the same amount of carbohydrates, lipids, and proteins; the meals were cooked in the hospital dietetic kitchen and supervised by a registered dietician. The patients wear a PRT system, combining a pump infusion system and a continuous glucose monitoring sensor. On the day 1, they injected their bolus dose (calculated for each patient using a personalised insulin: CHO ratio and insulin sensitivity factor) 15 minutes before consuming the meal; on the day 2 just before meal and on day 3 just after the meal. Patients should measure their capillary glucose before meal and after 1, 2 and 3 hours after eating. Each day they injected the same dose of

insulin. Statistical analysis was carried out using mean  $\pm$  standard deviations and comparing data using student's T test for paired data.

**Results:** The main results from capillary glycemia are shown in the table. Analysis of the PRT monitoring will be presented at the meeting.

	Premeal	After 1 hour	After 2 hours	After 3 hours
Bolus 15 min BM	126 $\pm$ 33 (a)	136 $\pm$ 52 (d)	141 $\pm$ 59 (g)	150 $\pm$ 58 (j)
Bolus just BM	131 $\pm$ 43 (b)	130 $\pm$ 54 (e)	132 $\pm$ 41 (h)	132 $\pm$ 94 (l)
Bolus just AM	112 $\pm$ 34 (c)	177 $\pm$ 71 (f)	144 $\pm$ 69 (i)	152 $\pm$ 63 (m)
P	NS	(d) vs. (f) = 0.044 vs. (f) = 0.024	NS	NS

**Conclusion:** It seems that the best time to inject bolus before a meal could be just before consuming it or some minutes before (15 minutes in our experience). We could exclude the injection of the bolus dose after consuming the meal, also if the patient has a hypoglycaemia before meal. In this case could be wise to correct the hypoglycaemia, and then eat the meal. A larger study involving more patients is now on going.

#### P/WED/79

### Dermatological complications of insulin pump use in the paediatric population

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**Objectives:** To describe the dermatological changes associated with continuous subcutaneous insulin infusion (CSII) therapy in children and adolescents with type 1 diabetes. To assess if the severity of changes was associated with duration of CSII use, age, adiposity, HbA1c, insulin dose, insulin brand, infusion set used or site location.

**Methods:** In a tertiary diabetes clinic, a cross-sectional study of 50 consecutive patients with type 1 diabetes using CSII for at least 6 months was conducted (26 female, mean  $\pm$  SD age 13.3  $\pm$  3.5 years, CSII duration 2.8  $\pm$  1.7 years, HbA1c 7.7  $\pm$  1.1%). A grading scale was devised based on severity and extent of potential skin changes. Photographs were obtained. Ultrasounds of CSII sites and adjacent areas were performed in 8 subjects. Pearson's correlation coefficients and unpaired Student t-tests were determined.

**Results:** The mean  $\pm$  SD severity score was 6.3  $\pm$  3.5 (range 0–14, maximum possible 69). The most common changes were scars < 3 mm diameter (94% of patients), erythema not associated with nodules (66%), subcutaneous nodules (62%) and lipohypertrophy (48%). Other observed changes were bruising (4%), scars  $\geq$  3 mm (12%), altered pigmentation not associated with scars (6%), epidermal abrasion (8%) and lipoatrophy (4%). There was a significant negative correlation between severity score and BMI z-score ( $r = -0.30$ ,  $p = 0.039$ ). Severity score was not associated with HbA1c, insulin brand or regional location of sites. Infusion sets inserted at 90° were associated with lower scores than those inserted at a smaller angle ( $p = 0.03$ ). Less than 5% of patients and parents considered stopping CSII due to skin concerns. Sonographic features of CSII sites revealed only mild increased echogenicity of the dermis and hypodermis.

**Conclusions:** Dermatological changes were frequent, with increased severity associated with lower adiposity. However, these complications were not associated with glycaemic control, nor did they prompt most to consider stopping CSII.

#### P/WED/80

### Measuring quality of life in children with type 1 diabetes using insulin infusion pumps

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**Objectives:** To look at quality of life (QOL) of young people with diabetes on pump therapy compared to those on conventional therapy of multiple daily injections and to their peers without diabetes.

**Methods:** All patients attending the Leeds paediatric diabetes clinics on continuous subcutaneous insulin infusion pumps (CSII) were enrolled. They were matched to two control groups, one with diabetes on multiple daily injections (MDI) and the other without diabetes. QOL was assessed using PedsQL Paediatric QOL inventory and diabetes module (Varni 2001, 2003), for both young person and their parents. The CSII group was given a study designed pump questionnaire. Demographic details and HbA1c were also collected. The results were analysed using SPSS.

**Results:** There were 45 patients on CSII for type 1 diabetes. The young people on CSII had comparable overall QOL scores with both the MDI and non-diabetic groups. In the areas of child report of emotional well-being the diabetic groups scored more highly than the non-diabetic group but parent report of school functioning was lower in the diabetic groups. There was evidence to show that the longer a patient remains on a pump the better their QOL score becomes, with every additional year on a pump the QOL score increases by 5 points. Children's feelings towards their pumps were generally positive. There was a non-significant trend towards improving QOL with better glycaemic control in the pump group.

**Conclusions:** QOL improves the longer a patient stays on the insulin infusion pump. There is no short-term difference in QOL between CSII and MDI groups. The children on intensive regimes for their diabetes had equal or improved QOL to their non-diabetic peers, except in the area of parent reported school functioning.

#### P/WED/81

### Improvements in mood and behaviour following commencement of insulin pump therapy in children with type 1 diabetes mellitus (T1DM)

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**Objectives:** Anecdotally, parents and teachers report improvement in mood and behaviour in children with T1DM with insulin pump therapy (continuous subcutaneous insulin infusion; CSII). We assessed changes in glycaemic parameters, mood and behaviour associated with commencement of CSII.

**Methods:** Thirty children with T1DM aged 6–16 years commencing CSII were recruited at CHW, Sydney (n = 15) and RCH, Melbourne (n = 15). Mood and behaviour were assessed using the parent, self and teacher forms of the behaviour assessment system for children-second edition (BASC-2) 1 week before and 6–8 weeks after commencing CSII. HbA1c was measured and continuous glucose monitoring sensors (CGMS) were used to assess 72-hour periods of glycaemic control at each time point.

**Results:** Mean HbA1c improved from 8.21 to 7.47% ( $p < 0.001$ ). CGMS showed less hyperglycaemia ( $p < 0.05$ ), more

## Posters

normoglycemia ( $p < 0.05$ ) and unchanged hypoglycaemia. Paired t-tests indicated significant improvement in Internalising Problems (e.g., anxiety, depression) as reported by parents ( $p < 0.001$ ), children ( $p < 0.05$ ) and teachers ( $p < 0.01$ ). Parents ( $p < 0.001$ ) also reported significant improvement in Externalising Problems (e.g., hyperactivity, aggression), although not teachers. Behavioural variables were not correlated with 72-hour CGMS parameters at testing points.

**Conclusions:** Children with T1DM demonstrated significant improvements in mood, behaviour and glycaemic control following commencement of CSII. These data add further to evidence supporting benefits of CSII in children with T1DM.

### P/WED/82

#### The laboratory evaluation of insulin pumps

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**Objectives:** Necessity and efficiency of prolonged and controlled infusion of insulin in diabetes mellitus were presented at many reports. These methods are necessary to implement the requirements of EEC 93/385 and local Russian Federation safety directives. That is why methods of testing of these medical devices are very important.

**Methods:** We developed laboratory methods for assessment of accuracy insulin pump working at: normal conditions, during cooling-heating of catheter and pump, periodical motion of a pump. Also we assess accuracy of dosage and insulin volume for alarm signal during occlusion distal catheter. Paradigm 712 pump, Medtronic, USA was tested. We offer two methods: 1) the spectroscopy registration insulin passing into a glass tube with water (we registered spectrum of absorbance every 1.5 min at  $\lambda = 200$  nm AGILENT 8453, USA). 2 is direct registration of insulin passing into a capillary  $d = 0.446$  in a special device.

**Results:** Spectroscopy registration indicated insulin passing decrease during changing of temperature of catheter from 0 to 40 centigrade degree. It was caused by increasing of volume of catheter 0.1 IU/40 degree (basic rate 2 IU/h was established). Heating of the pump produced more apparent effect - insulin passage decrease of 0.38 IU/40 degree. Cooling of the pump, on the contrary, caused increased insulin passage. Motion of the pump (2 Hz and 25 cm amplitude) did not influence on insulin passage (2 IU/h). Error of insulin dosage was determined by direct registration of insulin passage into a capillary. Its value was estimated as 3.4%, that was some higher than 2% manufacture describes. Accuracy of this method was 0.002 IU that was 4% of min. dosage 0.5 IU. 'Alarm dosage' after total distal occlusion of catheter was: 1.55 IU averages, 1.8 max, 1.4 min.

**Conclusions:** Two methods of laboratory evaluation of the insulin pumps functions were developed.

### P/WED/83

#### Imposing exclusion criteria for continuous subcutaneous insulin infusion (CSII) in children is not clinically justified

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**Objectives:** Published guidance suggests a variety of criteria be used to select those children suitable for CSII, although no objective

evidence exists to justify this exclusive approach. On starting an insulin pump service in north east England in 2003, no exclusion criteria were applied for those wanting an insulin pump, enabling a prospective study of outcomes with unrestricted access to CSII.

**Method:** From 1989 with the agreement of children and their families' comprehensive data on management, growth, control and complications, relating to childhood diabetes were prospectively collected. The only additional education and support received by children starting CSII was pump specific. For this analysis data from the year before and subsequent to starting CSII was compared. Just over half the subjects were using three or more injections daily before starting CSII the remainder twice daily with three starting CSII at diagnosis.

**Results:** By April 2007, 83 individuals had started CSII (age 0.5–30 years) with 79 current users, including two blind children and seven subjects with repeated admissions for diabetic ketoacidosis (DKA). There were highly significant and sustained reductions in the frequency of severe hypoglycaemia and DKA with a significant improvement in HbA1c (Table 1). The greatest improvement was seen in those with the worst prior control ( $r = -0.49$ ,  $p < 0.0001$ ).

Table 1:

Outcome	1 year before CSII	1 year after CSII	2 year after CSII	3 year after CSII
DKA rates /100 patient years	67	8	6	14
Severe Hypoglycaemia rates / 100 patient years	102	6	6	5
Mean HbA1c (numbers)	9.0% (81)	8.3% (78)	8.2% (33)	8.4% (23)
Proportion with HbA1c < 7.5%	18.4%	34.2%	30.3%	23.1%

**Conclusion:** Over half the children using CSII would not have satisfied many published criteria, yet these individuals had amongst the best outcomes. This study does not support the use of restrictive selection of children for CSII.

### P/WED/84

#### Insulin pump treatment in children and adolescents: our criteria for introducing (continuous subcutaneous insulin infusion) CSII

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**Introduction:** Insulin pumps are the most popular and most efficient kind of therapy for children and adolescents with T1D (diabetes mellitus TYPE 1). But its double cost comparing with other kinds of insulin therapy makes it not available for all patients. In the circumstances of limited financial support choice of patients for insulin pump therapy become very difficult.

**Aim:** To establish our criteria for introducing CSII therapy regarding leading medical and non-medical reasons, and evaluation of success of our choice by following patients' HbA1c.

**Methods:** To determine medical and non- medical reasons for CSII introducing in T1D pediatric and adolescent patients and to evaluate their metabolic control at the beginning and 6 month after CSII started.

**Results:** All 27 patients (16M/11F), mean age 12.4 years (8–19), mean diabetes duration 3.7 years (2–11) and with mean HbA1c 8.8% (6.9–11.2) were interested for insulin pump therapy at least 6 months before its introduction. All patients had excellent compliance to previous treatment. Main medical reason for 14 patients was high level of antiinsulin antibodies (mean 35.6-referent < 5.5), and for 13 left was unsatisfactory level of HbA1c (> 8%). Main non-medical reason for CSII introduction in all

patients was unsatisfactory life quality (QoL questionnaire) with mean total scores 1.7. 6 months later mean HbA1c was 7.3% ( $p < 0.0001$ ) and mean total score of life quality 3.8 ( $p = 0.0002$ ). **Conclusion:** Mean criteria for introducing insulin pump therapy are interest for it and awareness of low life quality during insulin therapy by pen. Those highly motivated patients with CSII therapy can exceed all medical reasons and generally make their HbA1c results to those near for very good controlled T1D.

P/WED/85

### The treatment with continuous subcutaneous insulin infusion in Emilia-Romagna

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**Background:** To improve both metabolic control and quality of life, the use of continuous subcutaneous insulin infusion (CSII) in pediatric patients with type 1 diabetes (T1DM) is increased during the last years. However, literature reports conflicting results about long-term efficacy of CSII.

**Aim:** Estimate the frequency of CSII treatment in T1DM subjects from Emilia-Romagna (ER) (Italy) and retrospectively evaluate long-term safety and effectiveness of CSII in children and adolescents with T1DM already submitted to intensive insulin treatment (IT).

**Methods:** The patients treated with CSII in ER (27/814; mean age  $16.10 \pm 5.13$  years; 13 males) were studied. Data on annual mean HbA1c, insulin requirements (UI/kg per day), body mass index (BMI) and adverse events (severe hypoglycemia and diabetic ketoacidosis/patients per years) were retrospectively recorded in the year before and after at least 1 year of CSII (mean duration  $33.57 \pm 23.16$  months).

**Results:** Mean HbA1c levels resulted slightly lower during CSII than during IT ( $7.74 \pm 1.3$  vs.  $8.22 \pm 1.18\%$ ) as well as the total insulin dose was lower during CSII than during IT treatment ( $0.88 \pm 0.18$  vs.  $1.02 \pm 0.21$  UI/kg/day, respectively). The BMI don't increase with CSII treatment. Severe hypoglycemia was experienced by 7% of patients as well as 9% presented ketoacidosis. CSII was discontinued spontaneous in 7% of patients.

**Conclusion:** CSII in ER is a treatment used only in few cases (3.3%). In these selected patients, however, CSII seems to be a long-term safe and effective therapeutic alternative to IT with a positive impact on quality of life.

P/WED/86

### Characteristics of paediatric insulin pump users in a Singaporean user financed care model

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**Background:** In our hospital, 16 out of 350 paediatric diabetes patients use insulin pumps, including 15 with Type 1 diabetes mellitus (5% of T1DM) and one with Type 2 diabetes mellitus (1% of T2DM). Health care is heavily subsidised in Singapore, but non-standard items e.g. insulin analogues, glucose meters, glucose test strips and insulin pumps are self funded. The first insulin pump in a paediatric patient in Singapore was initiated in our hospital in

2002, but the next 4 years saw only nine more pump starts (2.25/year). However, from January to April 2007, a further six children started insulin pumps in our centre, a 700% increase per annum. Although, there were no changes in government health care funding, a new vendor had initiated a more affordable commercial lend-lease package for an existing insulin pump.

**Premise:** Perceived limitations to more frequent use of insulin pumps as a modality of care known to reliably lower HbA1c safely include cost, complexity and cultural acceptance. We therefore reviewed the characteristics of our 16 insulin pump users to better understand to whom and when we should recommend the use of insulin pumps in paediatric diabetes.

**Results:** Racial distribution: Chinese nine, Indians four, Non-Singaporean three Sex: Males 10, Females 6 Age at diagnosis: 1.5–15 years (7.2 years) Age at pump start: 3–20 years (mean 10.8 years) Time to pump start: 0.1–10 years (mean 3.8 years) Parents Income band: Business two (12.5%) Professional seven (44%) Middle income four (25%), Lower middle three (19%), Funding of pumps: parents 12 (75%), insurance three (20%), health charity one (6%) Reasons for pump: Family wanted better control 10 (62.5%), flexibility 2 (12.5%), Difficult diabetes 2 (12.5%), multiple admissions 2 (12.5%).

**Conclusions:** Consumer choice, patient education, and perceived affordable pricing drive the decision to start on an insulin pump. Doctors should present all options and not presume patients don't want or cannot afford an insulin pump.

### Diabetes Care, Education, Psychosocial Issues – Insulin Therapy and Metabolic Control

P/FRI/01

#### Characteristics of Pediatric Pumpers in Good vs. Suboptimal Metabolic Control

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A sample of 45 children on insulin pumps with type 1 diabetes (T1DM) of > 1-year's duration was analyzed to identify which factors contributed to optimal vs. suboptimal metabolic control. Three groups were identified and are defined in the table below (mean  $\pm$  SD): Groups 1 and 2 did not differ in any respect except for HbA1c. Compared to both Groups 1 and 2, those in Group 3 were older ( $p = 0.02$ ), had a longer duration of T1DM ( $p < 0.001$ ), were more likely to be from an ethnic minority group, checked their BG less often ( $p = 0.003$ ), had fewer basal segments ( $p < 0.001$ ), and received more insulin by basal when analyzed in both units/kg/day ( $p = 0.007$ ) and as % of total daily dose (TDD;  $p = 0.005$ ). Furthermore, age correlated with receiving a higher % of insulin as basal (vs. bolus;  $r = 0.296$ ,  $p < 0.05$ ), a  $\downarrow$  frequency of BGM ( $r = -0.699$ ,  $p < 0.001$ ), and an incr. HbA1c ( $r = 0.300$ ,  $p < 0.05$ ). HbA1c values also correlated with a longer duration of T1DM ( $r = 0.474$ ,  $p = 0.002$ ) and a higher % of TDD as basal insulin ( $r = 0.551$ ,  $p < 0.001$ ), and inversely correlated with the # of basal segments ( $r = -0.558$ ,  $p < 0.001$ ) and the frequency of BGM ( $r = -0.434$ ,  $p = 0.003$ ). Our data show that older children with higher HbA1c's, especially those from an ethnic minority, tend not to perform diabetes self care tasks as diligently and also tend to have fewer basal segments compared to their counterparts with HbA1c < 10%. These children may need a different model of diabetes care and education than they are currently receiving. Further research should look at how this group should be treated best.

	Group 1:HbA1c < 8% (n = 16)	Group 2:HbA1c 8–10% (n = 16)	Group 3:HbA1c > 10% (n = 13)
Age (years)	10.6 ± 4.7	11.6 ± 3.3	14.3 ± 3.0
% minority	44%	38%	85%
Diabetes duration (years)	3.8 ± 2.0	4.1 ± 2.6	8.0 ± 3.5
HbA1c (%)	7.28 ± 0.48	8.58 ± 0.57	12.08 ± 1.75
Frequency of BG monitoring (BGM)	5.3 ± 2.1	4.8 ± 1.3	2.8 ± 2.2
# of basal segments	4.9 ± 1.9	4.3 ± 1.4	2.3 ± 1.4
Basal as % TDD	51.6 ± 13.2%	52.0 ± 16.0%	70.6 ± 19.8%
U/kg/day	0.82 ± 0.24	0.93 ± 0.33	0.89 ± 0.44

P/FRI/02

**A prospective study of metabolic outcomes according to method of insulin delivery**

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**Objectives:** It is generally assumed that multiple injection therapy (MDI) is superior to twice-daily injections (BD) and as good as continuous subcutaneous insulin infusion (CSII). The introduction of insulin pumps into an established children’s diabetes service from 2003 allowed for a prospective evaluation of these different modalities.

**Methods:** Data on management, control and complications have been prospectively collected in a small British diabetes clinic with the agreement of children and their families since 1989. After diagnosis, modality of insulin delivery was at the choice of the child and family. Age banding was the only differentiation made within the clinic.

**Results:** The table demonstrates changes in numbers and control according to treatment modality. Overall HbA<sub>1c</sub> was significantly lower in the CSII group compared with BD and MDI, but not between BD and MDI users. The frequency of severe hypoglycaemia was 10 times lower in the CSII users, while overall DKA rates were similar (12/100 patient years) in all three groups. A greater overall proportion of MDI users had a mean HbA<sub>1c</sub> > 9%.

	Twice daily			Multiple injection			CSII		
	% Use	Mean HbA <sub>1c</sub>	% HbA <sub>1c</sub> < 7.5	% Use	Mean HbA <sub>1c</sub>	% HbA <sub>1c</sub> < 7.5	% Use	Mean HbA <sub>1c</sub>	% HbA <sub>1c</sub> < 7.5
2003	84	8.58	24.2	15	9.2	15.4	1	6.3	100
2004	68	8.02	31.6	26	8.38	27.8	6	8.73	0
2005	56	8.19	20.8	19	8.12	33.3	25	7.65	47.6
2006	38	8.09	33.3	22	8.29	26.7	40	7.56	54.8
2007	25	9.12	0	25	8.84	25	50	8.24	33.3
Overall	54.3	8.4	22	21.5	8.56	25.6	24.2	7.7	47.2

**Conclusion:** In this clinical setting the best overall metabolic control with the lowest incidence of severe hypoglycaemia was seen with children using CSII. MDI had no advantages over BD insulin with respect to control and short term complications.

P/FRI/03

**A comparison of (continuous subcutaneous insulin infusion) CSII vs. MDI from the time of diagnosis of type 1 diabetes in children < 7 years old**

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Recent research has found insulin pump therapy (CSII) started from the time of diagnosis (dx) of type 1 diabetes (T1DM) to be both feasible and beneficial for youngsters. We compared children < 7 years old who had been started on CSII at the time of dx of T1DM vs. those who had been started on multiple daily injections (MDI) to see the difference, if any, of these two treatment regimens in this subset during the first 12 months after dx. The CSII group (n = 12.25%M) had an average age of 4.2 ± 2.2 years and a HbA<sub>1c</sub> of 10.89 ± 1.88% at dx. The MDI group (n = 10.50%M) had an average age of 3.7 ± 2.2 years and a HbA<sub>1c</sub> of 7.89 ± 2.26% at dx. The two groups were comparable at baseline except for HbA<sub>1c</sub> (p = 0.004). In the CSII group, HbA<sub>1c</sub> decreased to 6.50 ± 0.73% by 3 months (p < 0.01 compared to baseline and 12 months) and hovered < 8% for the duration of the first year (HbA<sub>1c</sub> max = 7.98 ± 1.31% at 6 months; HbA<sub>1c</sub> at 12 months = 7.86 ± 0.79%, p < 0.05 vs. baseline, others p = NS). The average total daily insulin dose never achieved honeymoon levels (0.55–0.77 u/kg/day), and though it decreased after dx, there was no significant difference in u/kg/day over the first year after dx. In the MDI group, HbA<sub>1c</sub> did not significantly vary over the first year (7.32 ± 1.16% at 6 months, 8.26 ± 0.87% at 12 months, p = NS). Total daily insulin dose ranged from 0.59–0.79 u/kg/day (p = NS). The two groups did not differ metabolically at any time point with the exception of baseline HbA<sub>1c</sub>. As this was a retrospective study, quality of life measures were not collected, though anecdotal evidence tended to prefer CSII. The findings above suggest that the treatment modality started at the time of dx of T1DM does not have a significant effect on glycemic control during the first 12 months after dx in children < 7 years old. However, there may be a significant impact on psychosocial aspects. Further research needs to be done to determine if there are non-numerical benefits of one therapy over the other in these youngsters.

P/FRI/04

**Functional insulin therapy: experience in a French paediatric diabetes care department**

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Functional insulin therapy (FIT) is a teaching approach of intensified insulin therapy. The principles of FIT have been largely described for adult diabetes 1 patients. However this practice has not been published for diabetes type 1 child and any consensus has not been yet established.

**Objectives:** We developed a specific teaching program for diabetes type 1 children.

**Methods:** All included patients were treated with intensive approaches (CSII or multiple daily insulin injection regimens with insulin analogue). Three groups were designed depending of their chronological age (younger than 6 years, 6–12 years old children, teenagers older than 12). FIT was taught during in our conventional hospitalization 5 days along. Clinical and biological evaluation was performed each 3 months after FIT initiation.

**Results:** A total of 14 patients have been included (age < 6 years old: 6, 6–12 years old: 6, > 12 years: 4) and followed 7.6 ± 3.6 months. Total insulin infusion does not change before formation, after hospitalization and during follow up (0.90 ± 0.34 IU/kg/d, 0.86 ± 0.32 UI/kg/d, 0.85 ± 0.32 UI/kg/d). Basal insulin dose were reduced during hospitalization to 32% of total insulin infusion and remained lower than bolus during follow up. BMI slightly increased (17.1 ± 1.62 kg/m<sup>2</sup> vs. 17.43 ± 1.17 kg/m<sup>2</sup>). HbA1c decreased from 8 ± 0.5% to 7.7 ± 1.1%. The frequency of hypoglycaemic events decreased after using FIT (no severe hypoglycaemia). Quality-of-life of patients and family was reported as improved.

**Conclusions:** This short-term study revealed that FIT developed in pediatrician diabetes department was associated with high treatment satisfaction and improvement of glycemic control. A large prospective study should confirm these preliminary results.

#### P/FRI/05

### Medical care independent factors related with glycemic control in children and adolescents with type 1 diabetes mellitus

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**Objectives:** To investigate the effect of healthcare management independent factors in glycemic control of children and adolescents with type 1 diabetes mellitus (DM1).

**Methods:** A total of 66 children with DM1 (37 girls, 29 boys) aged 2.2–17.3 years were asked to include anonymously individual and family variables in a cross-sectional analysis of glycemic control measured by HbA1c over a years period. Age, age at diagnosis, diabetes duration, BMI-Zscore, parental age, income and education were associated with HbA1c as a continuous dependent variable. Inclusion criteria requested at least three HbA1c measurements with 8 weeks intervals.

**Results:** The table shows the proportion of subjects with good (HbA1c < 8%), moderate (HbA1c 8–9.5%), poor (HbA1c 9.5–12%) and very poor (HbA1c > 12%) glycemic control related with factors showed statistically significant association (p < 0.05). Factors such as age at diagnosis and parental socioeconomic status especially maternal educational level seem to have an effect in glycemic control in children with DM1. Although, BMI Z-score is not a purely medical care independent factor it also seems to have an effect as a psychosocial and/or medical variable.

HbA1c	< 8%	8–9.5%	9.5–12%	> 12%
Age at diagnosis	39/42/53/68	22/20/11/17	28/25/21/08	11/13/15/07
/0–4/5–9/10–14/ > 14				
Duration of diabetes	72/48/39/27	12/16/13/21	17/22/29/29	09/14/19/23
/ < 1 year/1–2 years/				
2–4 years/ > 4 years				
BMI Z-score / –2.00	44/39/52/45/56	21/19/12/23/29	24/36/28/19/08	11/06/09/13/07
or less/ –1.00 to -				
2.00/ + –1.00/ + 1.00 to +				
2.00/ + 2.0 or more				
Parental education	29/33/38/41	17/13/22/30	48/46/29/21	06/08/11/08
(father) /basic/3 year				
high school/6 year				
high s./higher				
Parental education (mother) /	19/31/46/64	13/18/19/21	52/38/26/11	16/13/09/04
basic/3 year high school/				
6 year high s./ higher				
Annual family income (CYP)	33/39/38/47	21/25/35/45	35/27/23/08	11/02/04/00
< 10000/10000–17000/17000–				
25000/25000–45000/ > 45000				

**Conclusions:** Families with lower educational status and income as well as children with longer diabetes duration should receive more support in achieving adequate glycemic control when dealing with DM1.

#### P/FRI/06

### Factors influencing glycemic control in children and adolescents with type 1 diabetes in two Belgian university hospital centers

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Striking differences in average HbA1c have been found between centers in Europe (Hvidore Study). Up to now, no comparisons have been made between Belgian centers. In the University hospitals of Gent and Brussels a multidisciplinary approach is officially organised since 1997 with a similar clinical support and insulin regimen propagation: basal bolus or insulin pump therapy in the older patients (> 12 year) and two injections in the younger, using self-mixing in the one and premixed insulin in the other center. The aim was to evaluate differences in HbA1c (DCCT standardized) between both centers and to assess the influence of the type of mixing and of other potential factors associated with glycemic control. We collected clinical information and HbA1c in children and adolescents with type 1 diabetes, available during the last trimester of 2003 (123 in center 1 and 167 in center 2, > 95% of those registered in both centers). Median age was 11.8 years; median duration 4.2 years and males comprised 52% (comparable between the centers). Average (SD) HbA1c concentration was similar in both centers (8.1(1.2)% vs. 7.9(1.4)%; p = 0.19). HbA1c level was lower than 7% in 18.3% of the included patients and more than 10% in 6.8%. Mean HbA1c level was significantly higher in the Moroccan children compared to the non-Magrebians: 8.6 (1.8) vs. 7.9 (1.3)%, in the older (> 14.8 year) vs. the younger (< 8.4 year) patients: 8.2(1.3) vs. 7.7 (1.1)%. Mean HbA1c was similar in non-Magrebians young children mixing (n = 76) or using premixed insulin in two injections (n = 33). In conclusion, glycemic control was comparable between type 1 diabetes children, followed in two Belgian centers, and better than the mean level in the Hvidore study. Despite a similar support and insulin regimen, Moroccan children have a poorer glycemic control. Our data confirm that the use of premixed insulin in young children treated with two insulin injections is not associated with a poorer glycemic control.

#### P/FRI/07

### Metabolic control in type 1 diabetes - evolution since 2001 to 2006

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**Introduction:** The purpose of treatment in type 1 diabetes is to obtain a very good metabolic control without severe hypoglycaemias. The treatment did not affect the quality of life and does prevent microvascular complications.

**Aim:** 1. To compare the HbA1c levels in the year of 2001 and 2006. 2. To evaluate the variables to correlate with HbA1c evolution.

**Methods:** Two Transversal studies of diabetic children: 132 at 2001 and 150 at 2006. The mean HbA1c (DCA 2000) during 1-year at the years 2001 and 2006 were evaluated. Sex, age, diabetes duration, age at diagnosis, number of the blood glucose tests carried out per week, therapy and age at the onset of multiple insulin doses were evaluated at the last HbA1c determination. Statistical analysis: SPPS (unpaired student t-test). In our Unit, just to 2006, we did not use insulin pumps.

**Results:** Comparing the year 2001 with 2006, the mean HbA1c was 9.0 ± 1.5% vs. 8.1 ± 1.1% (p < 0.0001), the number of the

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blood tests carried out per week was  $23 \pm 6$  vs.  $35 \pm 4$  ( $P < 0.0001$ ), diabetic children with conventional therapy vs. multiple insulin doses was 85 vs. 48 and 60 vs. 91 ( $P < 0.0001$ ), and multiple insulin doses was initiated at a mean age of  $12.3 \pm 2.1$  years vs.  $10.9 \pm 1.8$  years; the mean HbA1c at 2006 decrease significantly in both sex ( $P < 0.0001$ ), all age groups ( $P < 0.0001$ ) and disease duration groups ( $P < 0.0001$ ). Between 2001 and 2006, it had a significantly reduction of the HbA1c correlated with a significantly increase of the number of blood glucose testes, of the number of children that used multiples insulin doses in younger ages. The number of ketoacidosis and of severe hypoglycaemias did not rise.

**Conclusions:** In diabetic children, more frequent blood glucose tests associated with frequent adjustment of insulin doses led to a metabolic control improvement, without increasing the number of severe hypoglycaemias.

P/FRI/08

### Metamorphoses in childhood type 1 diabetes mellitus in Romania between years 1998 and 2006

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**Objectives:** The aim of the present paper was to assess the changes that occurred in the management of type I diabetes mellitus (T1DM) in Romania between years 1998 and 2006 regarding: i) Incidence; ii) Insulin strategies; iii) Blood glucose self-monitoring; and iv) Glycemic control.

**Methods:** The data were retrieved from the medical records of the patients admitted in the Clinical Center 'Cristian Serban' Buzias. Information concerning epidemiology was obtained from the Romanian Childhood Diabetes Registry. The statistical methods used were unpaired t-test and Fisher's exact test.

**Results:** i) Incidence of T1DM increased from 4.1/100 000 in 1998 to 5.86/100 000 in 2006. Incidence is higher in boys than in girls; ii) The changes in insulin strategies consisted in a decrease in the percentage of patients using two-daily insulin injections from 13.7% to 3.6% ( $P = 0.0041$ ) and of those using three-daily insulin injections from 60% to 21.4% ( $P < 0.0001$ ). Consequently, the proportion of patients using four-daily insulin injections (basal-bolus therapy) increased from 26.3% in 1998 to 75% in 2006 ( $P < 0.0001$ );

iii) Glucometer possession significantly increased from 65% in 1998 to 93% in 2006 ( $P < 0.0001$ ). Though, there are few children with optimal self-monitoring (4.5% in 1998 vs. 14.3% in 2006,  $P = 0.0009$ ). There was a significant increase in the proportion of patients having suboptimal monitoring (from 31.8% in 1998 to 58% in 2006,  $P < 0.0001$ ); and

iv) Mean HbA1c at first admission decreased from  $10.9 \pm 2.6\%$  in 1998 to  $9.1 \pm 2.7\%$  in 2006 ( $P < 0.0001$ ). The percentage of patients in target (HbA1c  $< 7\%$ ) increased from 3.8% to 26.6% ( $P < 0.0001$ ).

**Conclusions:** i) T1DM incidence in children from Romania tends to increase, but still has low values;

ii) Most children with T1DM use multiple insulin injections regimens;

iii) Home blood glucose self-monitoring has improved, but is optimal in a small proportion of patients; and

iv) HbA1c has decreased since 1998 but remains unsatisfactory.

P/FRI/09

### HbA1c in children and adolescents with type I diabetes in Croatia (2003–2005) – multicenter study

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**Objective:** To evaluate HbA1c concentrations in Croatian children and adolescents in 2003, 2004, and 2005 year and to assess the factors that have an influence on these concentrations.

**Methods:** A total of 402 children aged 2–18 years (212 boys; 52.7%, 190 girls; 47.3%) with diabetes of  $> 1$  years duration were included in the multicenter study. HbA1c was measured using Bayer DCA 2000. Data on age, sex, diabetes duration, an insulin dose, blood glucose monitoring frequency, frequency of clinical visits, parental educational level and marital status were included in questionnaire. Statistical analysis was performed using Spearman's correlation test and Mann-Whitney test.

**Results:** Mean HbA1c during studied period was  $8.89\% \pm 1.35$  (range 5.9% to 13.3%): 9.02%, 8.97% and 8.76% in 2003, 2004, and 2005, respectively. Only 18.6% of children achieved satisfactory glycemic control (HbA1c  $< 8\%$ ). HbA1c was significantly higher in older children ( $r = 0.23$ ,  $P < 0.001$ ), with longer diabetes duration ( $r = 0.24$ ,  $P < 0.001$ ), higher insulin dose ( $r = 0.14$ ,  $P < 0.05$ ), and less frequent blood glucose monitoring (BGM) (less than three BGM 9.82%, four to five BGM 8.99%, six and more BGM 8.16%,  $P < 0.01$ ).

**Conclusion:** The overall glycemic control of diabetic children in Croatia is unsatisfactory, placing them at high risk of developing microvascular complications. Recognizing the risk factors and children at risk enables specific diabetes team interventions.

P/FRI/10

### Adolescents on basal-bolus insulin can fast during Ramadan

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**Objectives:** i) Audit the incidence of mild or severe hypoglycaemia, DKA and duration of successful fasting (number of days) in children and adolescents who have T1DM wishing to fast during Ramadan 2006 (23/9 to 23/10); ii) Compare those on a 'conventional' twice daily insulin regimen with this using basal-bolus insulin; and iii) Suggest recommendations for children and adolescents with T1DM wishing to fast.

**Methods:** A total of 29 children (16F; 13M) aged 9–16 years were recruited to the study. Six girls withdrew, because they were not able to fast or because they did not perform sufficiently frequent blood glucose monitoring. They were classified into two age, sex and puberty matched groups. Group I: 13 patients (6F; 7M) on basal-bolus insulin, Group II: nine patients (4F; 5M) on conventional twice daily regimen. Four patients (3:1) fasted for  $< 4$  days; 18 (10:8) fasted for  $> 13$  days.

## Results:

	Group I	Group II
Fast broken > 1 day(hyperglycaemia)	1/13 (7.6%)	5/9 (55%)
Withdrew (hyperglycaemia)	0	1
Ketones plus hyperglycaemia > 1 day	0	2
Fast broken > 1 day(hypoglycaemia)	8/13 (61.5%)	4/9 (44.4%)
Withdrew (hypoglycaemia)	2	0
Withdrew (other reasons)	1	0
Hypoglycaemia corrected (insulin reduced by 8–16%)	3/6 (50%)	1
No dose change, remained hypo	3/6 (50%)	3
No hypoglycaemia	4/10 (40%)	5/8 (62.5%)

**Conclusions:** i) Diabetic children on basal-bolus are liable to get hypoglycaemic episodes during fasting;  
 ii) Any tendency to hypoglycaemia is preventable by reducing the basal insulin dose;  
 iii) Children on twice daily dose are more liable to get hyperglycaemia with or without ketones;  
 iv) Those children on basal-bolus insulin achieved smooth correction of hyperglycaemia with additional doses of rapid-acting insulin; and  
 v) We recommend that adolescents with T1DM on basal-bolus regimen can fast during Ramadan, but they should reduce the basal insulin by 10-20% to prevent hypoglycaemia.

## Diabetes Care, Education, Psychosocial Issues – Quality of Life

P/FRI/11

### Quality of life in children and adolescents with diabetes mellitus type 1

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Good metabolic control and high level of quality of life are the most important goals in treatment of patients with diabetes.

**Aim:** To evaluate quality of life (QL) in children and adolescents with diabetes mellitus type 1.

**Patients and methods:** A total of 100 children and adolescents and their parents took part in investigation. Aspects of the QL (physical, psychological, social function) evaluated with the help of PedsQL (3.0) Diabetes Module. Data were analyzed, taking into account: age patients (5–7 years old, 8–12 years old, 13–18 years old.), sex (for adolescents), disease duration (less than 1 year, from 1 to 5 years, from 6 to 10 years, more than 10 years), level of HbA1c, kind of leisure, type and method of insulin therapy.

**Results:** Boy's physical status was significantly better as compared with girls. QL in children and adolescents with HbA1c ≤ 8% was higher than in patients with HbA1c ≥ 9%. The patients, who have active leisure, evaluated physical and social function higher than other groups of patients. Insulin pump therapy improved children's physical function and adolescents' social function.

**Conclusions:** Good metabolic control, sport, active leisure, modern method of insulin therapy are necessary for children and adolescents with diabetes mellitus type 1 to reach good quality of life.

P/FRI/12

### The burden of having diabetes: An overview of children's needs and worries

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**Objective:** To identify needs and worries of the children's with diabetes.

**Methods:** Children and adolescents aged 6–16 years with type-1 diabetes, attending diabetes summer camps were eligible. Those who agreed to participate filled in a questionnaire about living with diabetes. The survey was conducted July–September 2006 in 19 diabetes summer camps all over Spain.

**Results:** A total of 414 questionnaires were completed and validated. Children's median age: 12 years. Median diabetes evolution: 5 years. Family & friends: Onset of diabetes had no impact on family relationship (77%); 26% hide diabetic condition; 13% felt some rejection because of diabetes; 32% suffered disparaging comments from colleagues; however 77% said colleagues understood their condition. School: Children were attending public (65%) subsidised (20%) and private schools (13%); most of them were Spanish nationals 95%. Adaptation to school life was good before (77%) and after diabetes was diagnosed (76%); teachers (92%) and colleagues (91%) knew about their diabetes condition; support came from teachers (60%) and colleagues (79%); 94% performed physical exercise and 89% excursions. Treatment: 97% performed self-injections and 96% self glucose monitoring; 25% expressed annoyance at injections; nearly 100% carry sugar-like products around with them; 34% had at least another chronic illnesses apart from diabetes; 21% had visited a psychologist due to diabetes. Worries: Children aged 13 and over expressed worries relating mainly to social life, future health, and job access. There were significant differences according to sex, age, and duration of condition.

**Conclusions:** Diabetes diagnosis did not have a negative impact on family relationship nor on school performances; children showed adequate training on diabetes self-management; approximately 25% displayed problems in social adjustment and worries about their future life with diabetes. Psychological support should be part of diabetes treatment.

P/FRI/13

### Adolescents and young adults with diabetes type 1 at camp-D: quality of life, metabolic control and satisfaction with long-term care during the phase of transition

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**Aims:** To assess treatment satisfaction, quality of life, diabetes related psychosocial burden and metabolic control in adolescents and young adults during this first phase of developing personal autonomy.

**Methods:** A total of 409 participants of CAMP-D (German nationwide diabetes-camp) aged 16–25 years. (mean: 19.6 ± 3.2 years.) Completed questionnaires on their well-being (WHO-5), diabetes related psychosocial stress (PAID), satisfaction with diabetes care, diabetes therapy and psychosocial situation. HbA1c was measured (DCA2000+).

**Results:** A total of 97% of the participants were on intensified insulin therapy (37% insulin pump). Median of HbA1c was 8.0% (37% of participants HbA1c < 7.5%; 28% HbA1c > 9%). While

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diabetes related psychosocial stress (PAID) scored quite low (PAID total:  $19.7 \pm 13.6$ ), well-being (WHO-5) was rather poor (mean  $14.6 \pm 4.6$ ). Multivariate analysis revealed systematic relationships between HbA1c and well-being ( $\rho = -0.13$ ;  $p = 0.02$ ) and diabetes related stress ( $\rho = 0.16$ ;  $p = 0.001$ ). All three variables were related to educational level and parents' marital status (living together or apart/divorced; each  $p < 0.05$ ). Overall diabetes care was rated positive (score:  $1.8 \pm 1.0$ , range 1–6), while nutritional advice (score:  $2.6 \pm 1.3$ ) and psychosocial care (score  $2.6 \pm 1.4$ ) were less positive. There was a strong association between satisfaction with diabetes-team and satisfaction with psychological care ( $\rho = 0.52$ ;  $p = 0.001$ ).

**Conclusions:** Despite good technical equipment and qualified care, only 37% of the nationwide sample achieved the therapeutic goal of HbA1c  $< 7.5\%$ . In one third of the young people the psychological well-being was poor. One predictor for both of these variables was the situation of the parents (living together or apart). Correspondingly, the participants mentioned deficits in psychosocial care. The multi-professional team concept of paediatric care concentrating on both the somatic and the psychosocial situation of young people with diabetes should be extended to young adulthood.

P/FRI/14

### Health-related quality of life of adolescents with diabetes mellitus and those with congenital hypothyroidism detected by newborn screening

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**Objectives:** To compare health-related quality of life (QOL), between adolescent's with diabetes and those with congenital hypothyroidism detected by newborn screening.

**Materials and methods:** Subjects were all high school students including 252 patients with type 1 diabetes (male 105, female 147; junior 117, senior 135), 88 patients with type 2 diabetes (m 35, f 53; junior 45, senior 43), and 98 patients with congenital hypothyroidism detected by newborn screening (m 32, f 66; junior 58, senior 40). This nationwide survey was performed as a part of the research project of the Ministry of Health, Labour and Welfare of Japan. The questionnaire to assess health-related QOL for junior high school students (37 items, six domains and Cronbach's alpha coefficient 0.90) and those for senior high school students (40 items, eight domains and Cronbach's alpha coefficient 0.91) were developed respectively and used for measurements in this study. Patients who gave consent after receiving an explanation from their physicians filled in questionnaires at home and sent them by mail. The overall QOL score and the score of each domain were compared among these groups.

**Results:** The overall QOL scores of type 2 diabetes (junior  $124.9 \pm 18.0$ , senior  $124.6 \pm 18.5$ ) were significantly lower than those of congenital hypothyroidism (junior  $136.1 \pm 21.7$ , senior  $136.2 \pm 20.5$ ,  $p > 0.05$ ) but not those of type 1 diabetes (junior  $128.8 \pm 18.4$ , senior  $131.9 \pm 22.1$ ). The scores of some domains of type 2 diabetes were significantly lower than those of congenital hypothyroidism and those of type 1 diabetes.

**Conclusions:** Health-related QOL of adolescents with type 2 diabetes were lower than those of patients with congenital hypothyroidism.

P/FRI/15

### Diabetes Attitudes Wishes and Needs (DAWN) in Polish children and youths with type 1 diabetes mellitus (T1DM) in two time points: at the onset and after 1 year T1DM duration – cross-sectional national study

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Diagnose prevalent attitudes in children at the onset and after 1-year DM duration. Analysis of 881 questionnaires with multiple/single/binary range scale based on DAWN study was performed in 15 diabetes centers, at diagnosis and after 1-year DM duration, 2005–6, Poland; age groups:  $< 6$  GI (189), 7–12 GII (320), 12–18 years GIII (277). Questionnaires were filled in by parents in GI,II. Statistical significance of below findings was revealed: -the reaction to diagnosis 'as never experienced anything similar' was stronger in GI,II ( $p < 0.05$ ) than in GIII and drop in GI,III ( $p < 0.05$ ) after 1 year; -intensity of feeling 'relieved at diagnosis' was reduced in all groups ( $p < 0.05$ ) after 1 year, mostly GIII ( $p < 0.001$ ); -perceiving diagnosis 'as a new challenge' was stronger in GIII vs. GI ( $p < 0.001$ ) at onset but lost motivation after 1 year ( $p < 0.001$ ); -perception diagnosis as 'catastrophes/punishment/injustice' rose in GI,III after 1 year ( $p < 0.05$ ); -support at diagnosis from family/doctor/nurse was expected by 90% of responders, decreased in time in GII,III ( $p < 0.001$ ); -responsibility for diabetic care resting on the doctor was more often in GII,III vs. GI ( $p < 0.05$ ), later decreased in GII,III ( $p < 0.05$ ); -anxiety of DM influence on 'the next 5 years of life' in GII,III ( $p < 0.05$ ), 'physical activity' in GII ( $p < 0.05$ ), 'being a family burden' in GII,III ( $p < 0.05$ ) increased in time. DM was stable cause of: sadness, worry and future school problems in 70% of responders. 90% declared self-responsibility for DM care-remained constant. Half of all responders expected psychological support and it was not changed by DM duration. More than 80% of children look for new treatment methods. T1DM is a psychosocial crisis for both - children and parents, which become deeper realistic feeling according to diabetes duration. The level of self-responsibility awareness is high and stable, however, depressed parents of diabetic children and youths do not believe in psychological support. This study was supported by Novo Nordisk Pharma.

P/FRI/16

### Functional outcome in T1DM 12–15 years after disease onset

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**Objectives:** We have documented central nervous system (CNS) effects (structural brain changes, altered neurometabolite profiles and lower IQ) in a controlled study of a T1DM cohort followed prospectively from disease onset 12–15 years previously. The functional implications of CNS changes are important, given increasing interest in the psychological morbidity and impact on quality of life of growing up with diabetes.

**Methods:** Participants: T1DM ( $n = 106$ , mean age 20.5 years, SD 4.3) previously managed at Royal Children's Hospital, Melbourne

(RCH) and healthy community controls [C] (n = 76, mean age 20.7 years, SD 4.0) who were recruited initially at the time of T1DM onset of the clinical participants. There were no group differences on baseline IQ, assessed on study entry 12–15 years previously, SES, gender ratio or age. Measures: A semi structured interview was used to record educational and work history, contact with mental health services, and diabetes care.

**Results:** T1DM were significantly less likely to have completed Year 12 than C, (31.6% vs. 14.5%,  $\chi^2 = 5.02$ ,  $p < 0.05$ ), and significantly more likely to have been referred for mental health services since diabetes-onset (37% vs. 17.1%,  $\chi^2 = 10.21$ ,  $p < 0.01$ ). There were no group differences in the number in full-time study or employment. Despite a formal program of transition to a tertiary service at age 18 or school leaving, only 57% of the cohort no longer attending RCH reported endocrinologist or hospital clinic diabetes care at follow-up. Eighteen percent reported diabetes care with their general practitioner and 24% said they had no regular contact with any particular doctor or clinic.

**Conclusions:** These data suggest that T1DM are at increased risk for early school leaving and mental health problems, highlighting the need for clinicians to be alert to educational and behavioural difficulties in their young patients. The high number receiving sub-optimal diabetes care following transition from a paediatric clinic is also of concern.

P/FRI/17

### Children with type 1 diabetes within the Greek school environment

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**Aim:** The purpose of the study was to examine how children with type 1 diabetes and their parents interact with the school staff within the school environment of our country and to detect possible associated problems.

**Method:** Relative information was collected after interviewing the parents of 30 children with type 1 diabetes (13 boys–17 girls), whose average age at diagnosis was 7.6 years.

**Results:** A total of 92.8% of parents of diabetic children had informed school teachers of their child's problem, whereas 7.2% did not. 42.8% of the classmates of diabetics knew about their friend's problem. (Younger diabetics talked to their classmates more often about their condition ( $p < 0.05$ ). Diabetic girls disclosed their problem more frequently (62.5%) than boys (16.6%) ( $p < 0.01$ ). 42.8% of parents consider their diabetic child was treated favourably in school, whereas 7.1% unfavourably. Younger male diabetics were treated more favourably than elders ( $p < 0.01$ ). 21.4% of parents report modification of insulin dose due to school attendance, 35.7% modification during meals and 28.6% skipped glucose measurements. 57.2% of children presented with clinically evident episodes of hypoglycemia (50% reported more than one episode). All parents claimed school teachers lacked specific knowledge on the subject and 64.3% believe they couldn't adequately cope with emergencies related to their children's condition. Had school teachers been appropriately educated, 92.8% of parents would feel secure, 71.4% would change their occupational habits and 14.3% of children would follow a more intensive regimen. None of the children had attended all-day school (42.8% due to parental and teacher insecurity reasons).

**Conclusion:** It is evident that special training of Greek school teachers regarding diabetes must be implemented in order to

- i) Fully integrate the diabetic child into the school environment;
- ii) Deal with diabetes emergencies more efficiently; and
- iii) Improve the parent's quality of life.

P/FRI/18

### DAWN YOUTH – a South African pilot study

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**Objective:** The DAWN YOUTH programme recognises and acknowledges the importance of psychological and sociological management in the overall care and treatment of the diabetic child. A pilot programme to evaluate the problems and concerns of South African diabetic youth were undertaken.

**Method:** A total of 27 diabetic children aged 12–18 years (13 boys; 14 girls) were interviewed. 27 interviews with the parents of these children were conducted. The discussion was done in their home language. Discussions were audio taped and transcribed and translated back into English. Content analysis was done once all transcripts were received.

**Results:** In terms of day-to-day adjustment, parents and children appear to accept the discipline of regular testing and injecting. The most difficult aspect of the condition and the one producing the most anxiety is eating correctly. Children don't want to feel different from their peers, but their condition, often very publicly illustrates their 'differences' on a daily basis. Feelings of depression occurred when children and parents dwelt on the unrelenting nature of managing diabetes. Children rely on their parents, particularly their mothers, for emotional and physical support. For some parents there was an added financial burden. The children have to maintain a healthy diet and parents are faced with additional expenses in terms of doctor's visits, hospital treatment and the child's monthly insulin requirements. Financial stresses are responsible for family arguments. Parents, children, and particularly teachers need more information about the condition, diet and treatment. Children want this information given to them verbally rather than in print.

**Conclusion:** Educating diabetic patients and their family should in future address the aspects that make these children feel different from their peers. In South Africa, the financial burden in the lower economic group should be addressed.

P/FRI/19

### The picture of diabetes issues in rural population in Cameroon

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**Objectives:** Surveying the impact of the activities of diabetes care, education and psychosocial support issues, in a resource limited area like Mutengene village in Cameroon.

**Methods:** Socio-economic factors are major factors noted greatly influencing the lifestyles and activities of health for the masses here especially with the diabetics. This is ascertained after reviewing answered 2006 random questionnaires from the masses, interviews and reviewing clinic's archives for changes and possible causes behind the changes-both positive and negative for the past 3 years.

**Results:** Diabetes care and management here is still far backward, and very little effort is carried out by existing health units to assist the diabetics here, hence high rates of complications, misery and often suffering from psychosocial trauma and deaths among them are very common. Major factors disclosed as the major keys behind ineffective health promotion-diabetes care and management inclusive; coupled with disease prevention and public health enhancement activities in such a rural community set up were: - unemployment, poverty, cultural beliefs, illiteracy, marginalization, inadequate healthcare resources. Persisting ailments of malaria, pneumonia, TB, HIV/AIDS have impoverished the masses that are already poor, less educated and less sensitised. Few clinics and hospitals here are involved in diabetes enhancement programs:

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implying that only few diabetics here are able to access proper care and services.

**Conclusion:** Very much effort is still needed for the masses here to be able to have access to and benefit adequately from good diabetes care services and especially in rural populations like this of Mutengene, Cameroon. Yet empowerment of the diabetics through education remains the most effective and cheapest means of helping them to achieve good control especially in resource limited nations like Cameroon.

P/FRI/20

### Is regular tooth brushing an indicator for a healthier lifestyle, better metabolic outcome and better perception of health in adolescents with diabetes?

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**Background:** Low tooth brushing frequency has been reported to be associated with increased risk behaviour in adolescents.

**Objective:** To evaluate the relationship between tooth brushing frequency, nutrition, regular physical activity, risk behaviour, metabolic outcome and perception of health in a large cohort of adolescents with diabetes.

**Methods:** Questionnaires were completed by adolescents and their parents/carers attending sequentially in 21 international centers. Questionnaires investigated age, gender, diabetes duration, insulin regimens, insulin adjustments and glycaemic targets. HbA1c (DCCT adjusted) was measured centrally.

**Results:** A total of 2269 adolescents (age  $14.5 \pm 2.0$  years; duration  $6.1 \pm 3.5$  years, 49% female) participated, The grand mean HbA1c for the whole sample was  $8.2 \pm 1.4\%$ . Individuals who brushed their teeth more often reported doing more homework for school ( $\leq 1x/day$ : mean: 8.3 hrs homework/week;  $\geq 2 x/day$ : mean 9.6 h homework/week;  $t = 3.77$ ;  $d.f = 1990$ ;  $p < 0.001$ ), but there was no difference for hours spent watching TV, physical activity, drinking or smoking behaviour. More frequent tooth brushing is associated with greater consumption of fruit and vegetables specifically ( $r=0.14$ ;  $p < 0.001$ ), more healthy food in generally ( $r = 1.3$ ) and lower consumption of high calorie dense foods ( $r = 0.10$ ;  $p < 0.001$ ). Furthermore, individuals who brush their teeth twice or more a day have lower HbA1c (vs. those brushing less than twice a day (mean:  $8.0 \pm 1.3\%$  vs.  $8.3 \pm 1.5\%$ ;  $t = 4.4$ ;  $d.f = 1996$ ;  $p < 0.001$ ). Life ladder and health perception were significantly better in those who brush their teeth at least twice daily.

**Conclusion:** In a large cohort of adolescents with type diabetes, frequent tooth brushing is related to a healthier lifestyle, better metabolic outcome and a better perception of health.

### Diabetes Care, Education, Psychosocial Issues – Nutrition and Quality of Care

P/FRI/21

#### A successful consortium between user group and health care professionals equates to good glycaemic control

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**Background:** A qualitative questionnaire based study<sup>1</sup> on user group satisfaction was done in 2006 to evaluate the effectiveness of transitional care clinic for adolescent diabetics.

**Aims:** The second phase of the study was carried out to do a quantitative assessment and evaluation of the successful transition of the same group of patients.

**Methods:** A total of 36 patients were identified from the database. A prospective study was done to monitor the patients' attendance rate and other quality parameters including HbA1c in the Transition Clinic and subsequently in the Young Adult Clinic over a period of 12 months.

**Results:** i) The mean age at the transition for study group: 16 year 3 months;

ii) The attendance rate in the transition clinic was 88%;

iii) Attended transition clinic group (88%):

- Had mean HbA1c of 8.5% (SD 0.31) before transfer and 8.3% (SD 0.36) after transfer (over a period of 12 months)

- Had a mean YAC attendance rate of 100%.

iv) Did not attend the Transitional Clinic group (12%):

- Had a mean HbA1c of 7.4% (SD 0.18) pre transfer and 9.6 (SD 0.36) after transfer

- Had a mean YAC attendance rate of 76%.

**Conclusion:** The current clinic model seems to be unique where the user group seems to be satisfied largely (authors' previous study confirming a high satisfaction rate<sup>1</sup> and a stable HbA1c of the user group during and after their transition in to adult care). At the same time, involved health care system seems to be providing a flawless and cost effective service with nearly 100% attendance rate.

**Recommendations:** This unique and highly desirable practice in the local clinic needs to be disseminated and then can be recommended to be adopted by relevant health care professionals to make any health care system more effective and efficient across the globe. (YAC-Young Adult Clinic, HbA1c- Glycosylated hemoglobin, <sup>1</sup>: Pediatric Diabetes Volume 7 Issue s5 Page 71 - August 2006).

P/FRI/22

#### Better outcome in type 1 children and youth who received their care in a specialized diabetes center form onset onwards compared to those referred later from general pediatric clinics

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Several studies suggest that the first year(s) of diabetes care are determining the longterm outcome. Moreover, some studies suggest that the complexity of diabetes problems and care in specialized centers may hamper improvement in the treated group (inertia). We evaluated these effects by looking at outcome of both patients referred at onset and those referred later in their diabetes career in our specialized center.

**Methods:** The study includes 347 patients with type 1 diabetes (over the last 10 years) with data collected in an EMR, evaluation and analysis program (Vcare). HbA1c's were stratified in high (HR), medium(MR) and low risk(LR) according to their age (based on ISPAD/ADA guidelines). In both groups pump treatment was used in comparable numbers.

**Results:** One hundred patients (PRIM) were seen since onset (duration  $3.5 \pm 3$  years; age  $11.4 \pm 4.8$  years, HR-A1c in 11%, MR-A1c 20%, LR-A1c 69% of patients) and 247 were referred (SEC; dmduration  $7.5 \pm 4.4$  years; age  $13.6 \pm 4.5$  years, HR-A1c in 25%, MR-A1c 30%, LR-A1c 45% of patients). First year A1c's were excluded in all analyses. Over 2000 days A1c values were evaluated per patient and in groups as well as in other cardiovascular risk factors.

days ago	PRIM n	Aver A1c	SD	SEC n	Aver A1c	SD	Pvalue (prim vs. sec)
- 2000	31	8.54	1.22	69	9.08	1.28	0.05
- 1000	56	7.92	1.04	95	8.47	1.32	< 0.01
0	100	7.64	1.44	247	8.04	1.22	< 0.01

**Conclusions:** i) Center size is positively influencing outcome and despite center growth average A1c was lowered over the study period; ii) Patients treated from onset (PRIM) had better A1c values, which remained over time; iii) SEC patients improve, but retain significantly higher A1c values; iv) Use of an EPD greatly improve the constant analysis of center performance; andv) Substudies revealed that young children (< 5) showed the most significant improvement in A1c.

#### P/FRI/23

### Diabetes care utilization and glycemic control in young adults with type 1 diabetes mellitus

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**Objectives:** To explore how glycemic control in young adults is related to the incidence of acute and long term complications and diabetes care utilisation during transition to adult diabetes care and if those variables differ between males and females.

**Methods:** A retrospective and longitudinal design was used where patients' records were followed from paediatric to adult diabetes outpatient care from 18 until 24 years of age. Adolescents in five age groups (n = 121) connected to one single paediatric outpatient clinic in Sweden were included. Excluded patients were those with missing records or not possible to follow after transfer, leaving 104 patients. Data as sex, the age at diagnosis and transfer and yearly HbA1c %; BMI; severe HG and DKA; diabetes related retinopathy and diabetes outpatient care utilisation were collected.

**Results:** HbA1c showed decreased levels over time for females (p = 0.004) but not for males. Less than 10% of the patients showed HbA1c levels according to recommended levels (< 7.1%, DCCT-standard) during the whole study period. BMI was increasing during the period (p < 0.001). The prevalence of severe HG and DKA were not significantly decreasing. Simplex retinopathy was increasing from 5% of the patients at the age of 18 to 29% at 24 years of age (p < 0.001). Mean transfer age was 19.8 (SD 1.28, range 17–26). The youths visited the paediatric clinic more often than the adult clinic (p < 0.001) and females visited adult care more often than males. There was a steady decrease in the number of visits/year over time, i.e. 18–24 years of age (p < 0.001).

**Conclusions:** Males and females in this cohort differed regarding pattern of glycemic control and some aspects of diabetes care utilisation but not in the incidence of diabetes retinopathy.

#### P/FRI/24

### Evaluation of accuracy of Linus, a new blood glucose meter

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**Objectives:** Aim of the study was to evaluate the accuracy of Linus, a new blood glucose meter and compare it with two other meters, One Touch Ultra (OTU) and Free Style Mini (FSM).

**Methods:** Seventy three subjects (38 males, mean age ± SD 12.49 ± 6.59 years), 20 healthy controls and 53 with Type 1 Diabetes were tested for capillary blood glucose (CBG) checked simultaneously at three different meters Linus, OTU and FSM. Laboratory serum blood glucose (LG) and haematocrit were also evaluated. Three children (one with high and two with normal LG performed 20 measurements by each of the three meters.

**Results:** Mean blood glucose (SD) was 187 (86.12), 168.09 (77.07), 178.4 (82.29) and 160.28 (75.01) mg/dl for Linus, OTU, FSM and LG respectively. No difference was found in multiple comparisons by ANOVA among the three meters and LG. CBG from the three meters had very good correlation with LG values (p < 0.0005 and r = 0.965, r = 0.963 r = 0.967 for Linus, OTU and FSM respectively). The within-patient percentage mean (SD) absolute deviation of CBG from LG was 18.61 (14.25), 10.36 (11.33) 14.59 (13.49)% for Linus, OTU and FSM respectively. All glucose measurements were within A and B zone according to Clarke's Error Grid analysis (64.62, 87.69 and 76.92% of Linus, OTU and FSM measurements were in A zone respectively and 35.38, 12.31 and 23.08% in B). Linus and FSM tended to overestimate glucose values compared to LG and OTU to underestimate. The intra-patient percentage mean (SD) absolute deviation of CBG from LG was higher for Linus compared to the two other meters for normal and high LG [18.67 (9.36)% vs. 6.68 (4.97) in OTU and 13.65 (8.87) in FSM for normal LG values and 22.39 (10.86)% vs. 5.0 (4.1) for OTU and 7.9 (6.06) for FSM for high LG values].

**Conclusions:** Linus glucose meter is a very accurate meter; however it has a higher percentage absolute deviation from LG compared to OTU and FSM meters.

#### P/FRI/25

### Use of Accu-Chek products in clinical practice; evaluation of co-ordinated use of insulin pump, glucose meter and a handheld

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**Objectives:** To evaluate the effect of co-ordinated Accu-Chek (Roche) products; insulin pump, glucose meter and handheld used as a unit.

**Methods:** A total of 40 children, age: 15.5 (4.7–18), and duration: 6.3 (0.6–16.9) at four different pediatric clinics used the products during 1 year. Twenty were new pump users and consecutively included. The other twenty were using another kind of insulin pump since earlier. HbA1c, BMI and number of acute complications were controlled every third month. Questionnaires regarding satisfaction with the products were filled in by both patients and personnel. Wilcoxon Signed Ranks Test was used for statistical analysis.

**Results:** Five children choose to discontinue and one moved from the region. Primary indication/-s for treatment with CSII; Poor metabolic control: 53%, QoL: 45%, Fluctuating PG: 12% and Pain: 12%. HbA1c was not improved while BMI on the other hand was increased. DKA was present at 6 occasions; 0.15 p patient/year. Severe HG was present at three occasions; 0.08 p patient/year. The patients had a significantly positive attitude in relation to the insulin pump and glucose meters whereas the attitude to the handheld was more undefined. The attitude among the personnel was in accordance to this. Though the handheld was the weak link in the co-ordinated use of the products, an improvement of this product could be of use. 37% of the patients could imagine that downloaded information, together with a phone call from the diabetes clinic, could replace one of the ordinary appointments. Information from downloaded insulin pumps and glucose meters

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at the clinic was a significantly positive experience for both patient and personnel.

**Conclusion:** No improvement of HbA1c, but a significantly positive attitude in relation to the insulin pumps and glucose meters after usage of co-ordinated Accu-Chek products. The results after download at the clinic are of great use while the process of downloaded products at home needs to be further improved.

P/FRI/26

### Glycemic index and preprandial insulin affect postprandial glucose control more than insulin type

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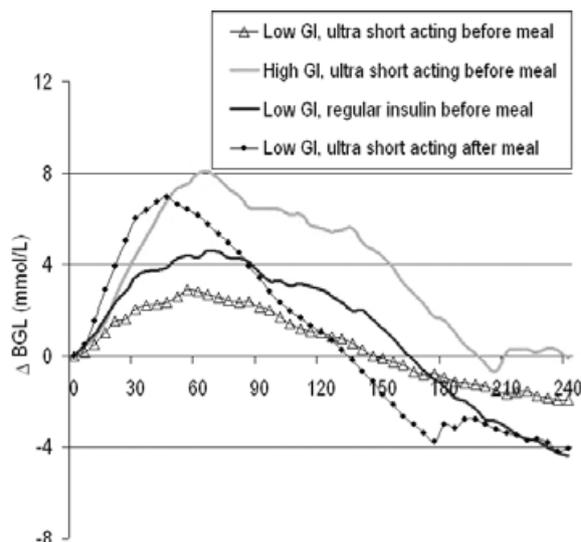
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**Objectives:** To quantify the effect of glycemic index (GI) on postprandial BGL in children with type 1 diabetes on multiple daily injections (MDI). To determine the most appropriate insulin therapy for a low GI meal.

**Methods:** A total of 15 subjects aged 7–17 years, on MDI with HbA1c < 8.6% consumed four test breakfasts on consecutive days. Each meal contained 60 g carbohydrate. Each child's insulin dose was constant. A high and low GI meal (GI: 84 vs. 48) were given with preprandial ultra short acting insulin on day one and two. On days three and four, low GI meals were given with either preprandial regular insulin or postprandial ultra short acting insulin (15 min after the meal commenced). Continuous glucose monitoring was analysed for 4 h post meal.

#### Results:

The 25–135 min  $\Delta$  BGL was statistically different for the high GI meal and the low GI meal with ultra short acting insulin before (P < 0.05). Maximum difference was 5.9 mmol/l. The 30–50 min  $\Delta$  BGL was statistically different for the low GI meal with regular insulin compared to ultra short acting insulin before (P < 0.05). Maximum difference was 1.9 mmol/l. The 15–60 min  $\Delta$  BGL was statistically different for the low GI meal with ultra short acting insulin before and after the meal (P < 0.05).



[Postprandial glucose excursions]

**Conclusion:** GI significantly affects post prandial BGL in children on MDI. This difference is considerably larger than the difference seen when regular and ultra short acting insulin is compared. Postprandial insulin gives poor glycemic control.

P/FRI/27

### Amount of food group variety consumed by Belgian diabetic children 12 to 18 years of age

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**Introduction:** Adequate nutrition is one of the cornerstones in the management of IDDM. In the present study we compared the food intake of children and adolescents with IDDM with that of healthy, non-related age-matched subjects and determined whether the intake meets the current recommendations of the Flemish Institute for Health Promotion.

**Methods:** The dietary intake of 18 IDDM children (group D; 10 girls; median (range) age: 13.1 (11.2–18.0) years; duration of IDDM: 3.4 (0.8–12.1) years) and of 28 non-diabetic children (group H; 15 girls; age: 14.1 (11.2–18.0) years) was studied by a semiquantitative food frequency questionnaire (FFQ). The FFQ was validated by a 7-day food record. Foods were divided into six groups: low fat (LF, starch products), vegetables, fruits, milk, high proteins (HP) and high fat and sweets (HFS). Consumed food is expressed as daily intake.

**Results:** The table shows the daily food intake for the various groups. The % indicates the percentage of subjects that did not attain the minimum recommendation or that exceeded the maximum recommendation.

	Group D	%	Group H	%	Recommendations
LF (g)	298 (135–729)	28	331 (123–569)	18	240–350
Vegetables (g)	108 (51–236)	100	87 (0–199)	100	300
Fruits (g)	101 (0–518)	94	160 (0–615)	84	375
Milk (ml)	279 (0–450)	94	143 (0–690)*	86	450–600
HP (g)	381 (140–543)	100	248 (17–800)	93	100
HFS (g)	110 (20–440)	100	359 (63–1225)**	100	0

\*P < 0.05; \*\* P < 0.001

**Conclusions:** The dietary intake of these IDDM children was healthier than that of non-diabetic subjects. Nevertheless none of them attained the recommendations for vegetables intake, and they all had a too large intake of high protein food, and high fat food and sweets. Continuous nutritional education and advice remain indicated at least once a year.

P/FRI/28

### Amount of fluid group variety consumed by Belgian diabetic children 6 to 18 years of age

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**Introduction:** Adequate fluid intake is essential for all children. Water is an important calorie-free thirst-quencher. Milk is an important source of calcium. We compared the fluid intake of children and adolescents with IDDM with that of healthy, non-related age-matched subjects and determined whether the intake meets the current recommendations of the Flemish Institute for Health Promotion (fluid intake: 1500 ml/day; milk intake: 450–600 ml/day).

**Methods:** The fluid intake of 25 IDDM children (12 girls; mean  $\pm$  SD (range) age:  $12.7 \pm 3.1$  (6.3–18.0) years; duration of IDDM:  $4.0 \pm 3.1$  (0.5–12.1) years) and of 37 non-diabetic children (21 girls; age:  $12.9 \pm 2.8$  (7.8–18.0) years) was studied by a semiquantitative food frequency questionnaire (FFQ). The FFQ was validated by a 7-day food record. Five fluid groups were evaluated (cfr. table). Milk intake was evaluated separately. Subgroups were expressed as % of total fluid or milk intake. Results are expressed as median (range).

**Results:** The table shows the total daily fluid intake and the distribution for the various groups. The % indicates the percentage of subjects that consumed elements of the fluid group.

	IDDM		Controls	
	%	amount	%	amount
Total fluid (ml)	100	793 (338–1278)	100	889 (196–2350)
Water (%)	96	55 (19–93)	97	49 (1–84)
Soft drinks (%)	44	10 (1–35)***	92	30 (3–93)
Light soft drinks (%)	92	25 (4–56)***	41	7 (2–56)
Fruit juice (%)	36	7 (2–59)*	62	11 (3–35)
Soup (%)	60	16 (6–43)	78	11 (1–30)
Milk (ml)	96	294 (44–421)	89	190 (14–690)
Milk with added sugar (%)	52	16 (2–68)**	65	50 (1–100)

\*P < 0.05; \*\* P < 0.01; \*\*\* P < 0.001

**Conclusions:** Fluid and milk intake of the IDDM children was below the recommendation. IDDM children consumed more light soft drinks and less soft drinks, fruit juice and milk with added sugar than non-IDDM subjects. Strategies should be developed to increase water and milk intake in all children.

#### P/FRI/29

### Children on intensive insulin therapy only need to count to 10 g carbohydrate portions to maintain good glycemic control

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**Introduction:** Carbohydrate counting is taught to children on intensified insulin regimes to adjust insulin dose to food intake.

**Aim:** To determine the precision required in carbohydrate counting to achieve good postprandial blood glucose control.

**Methods:** A total of 36 children on intensive insulin therapy (mean age  $13.3 \pm 2.0$  years, mean HbA1c  $7.7 \pm 0.7\%$ , mean diabetes duration  $5.0 \pm 3.1$  years) were recruited from two centers; insulin pump therapy (n = 20) from Newcastle, Australia and multiple daily injections (n = 16) from Oxford, UK. Standardised test meals containing 50, 60 and 70 g of carbohydrate were given in random order at lunchtime on three consecutive days. For each child the insulin dose was the same for each meal, based on their usual insulin: carbohydrate ratio for 60 g of carbohydrate. Activity was standardised. CGMS was used to measure postprandial blood glucose values.

**Results:** Mean blood glucose levels at baseline, 1, 2 and 3 h postprandially for the 50 g load were  $6.8 \pm 3.5$ ,  $9.1 \pm 3.5$ ,  $8.0 \pm$

$3.5$ ,  $6.7 \pm 3.5$  mmol/l; 60 g load were  $7.2 \pm 3.2$ ,  $9.3 \pm 3.8$ ,  $8.0 \pm 3.3$ ,  $6.5 \pm 2.9$  mmol/l and 70 g load were  $6.5 \pm 2.7$ ,  $8.8 \pm 2.7$ ,  $8.6 \pm 2.9$ ,  $8.0 \pm 3.3$  mmol/l. There was no difference between the 50 and 60 g or the 60 and 70 g loads. There was a difference between the 50 and 70 g loads only at 2.5 h (p = 0.04). No difference was found between the pump and MDI patients at any time point or carbohydrate load. The mean post-meal glycemic rise was  $4.0 \pm 3.5$ ,  $3.3 \pm 3.0$ , and  $4.3 \pm 3.1$  mmol/l for the 50, 60, and 70 g loads respectively. There was no difference in the number of hypos between carbohydrate loads or treatment groups.

**Conclusion:** Children on insulin pump or multiple injection therapies do not need to count precise grams of carbohydrate to maintain good postprandial blood glucose control. Educating children and their families to estimate carbohydrate quantity to within 10 g portions is practical, less laborious than strict carbohydrate counting and will not have an effect on postprandial blood glucose.

#### P/FRI/30

### Screening frequency for coeliac disease in children with type 1 diabetes mellitus in a multicenter survey

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**Objectives:** The association between type 1 diabetes mellitus (T1DM) and other autoimmune diseases such as coeliac disease (CD) and Hashimoto thyroiditis is well known, but there is still no consensus about the frequency of screening. The aim of our study was to evaluate the screening frequency for CD in a multicenter survey in Germany and Austria.

**Methods:** The DPV-Wiss-Project consists of anonymous data of patients with diabetes. Data from 31 341 patients < 18 years of age (52% males, mean age  $13.1 \pm 4.2$  years; mean duration of diabetes  $5.0 \pm 3.9$  years) with T1DM from 184 centres in Germany and Austria from 1995–December 2006 were available for analysis. The most recent year of observation was evaluated.

**Results:** Out of 31 341 patients 17 031 patients (54%) have been screened at least once for CD antibodies in the observation period. Positive antibodies (EMA and/or transglutaminase antibodies) for CD were found in 11.3% of the screened patients. Patients with positive antibodies were significantly younger at diabetes onset, had a significantly longer duration of diabetes and had a significantly higher HbA1c (p < 0.001). The screening frequency has increased over the observation years. In 1995, 44.0% of the patients have been screened at least once for CD compared to 68.2% in 2006. The annual screening for CD has also increased over time (11.9% in 1995 compared to 43.4% in 2006). Compared to screening for CD, screening for thyroid antibodies was more frequent (72.9% at least once). Annual screening for thyroid antibodies also increased over time (15.9% in 1995 compared to 48.9% in 2006).

**Conclusion:** In this multicenter analysis we found that out of 31 341 T1DM children 54% have been at least once screened for CD. 11.3% of them had positive antibodies. Furthermore screening for associated autoimmune diseases has increased over time. Screening for thyroid antibodies is more frequent than screening for CD.