

Aspects on computing CSII-therapy

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Background

From the “Diab-Care” movement based on the St Vincent Declaration (WHO), it is easy to believe that the register and the process of benchmarking are the primary goals while computing diabetes care. In the 80-ties I was participating in this movement delivering data from a medical record system today called Journalia. Below is a text I wrote for Diab-Care in 1995.

From the Journalia medical record system it is possible to export data from the Diab-Base branch according to the DiabCare format. With this technical achievement we want to show that a participation in the DiabCare project can be independent of platform and be a natural part of daily work. The users of the system can thus participate in benchmarking of quality indicators within the DiabCare Quality network in Europe. Journalia also have the ambition to make it possible for the users to participate in other activities that stimulates better care of diabetic patients. There are functions within the system that supports export of data to the national diabetes register in Sweden. Statistical work and different research activities are also supported. Furthermore Journalia is working on translation of the system to other languages. There are plans to cooperate with Telenor Infomedica AS in Norway, which probably will result in integration with other existing medical record systems. The benefit of the use of the Journalia medical system is that data collection is made as a natural part of patient education and the production of the medical record. The quality of data of the patient document can easily be checked at the visit.

The first version of Diab-Base was used in 1984. The software was gradually improved and spread to other clinics and primary care units in Sweden. In 1993 there were about 50 users of Diab-Base in the country. The number of patient documents was approximately 18000. In 1995 Journalia Inc was created and a Windows version of the system was launched. After a suggestion from SPRI (The Swedish Health Institute for Health Services Development) data was caught from 4000 patient documents at nine medical clinics using the new version. Data from the different clinics has been published by SPRI. An abstract in English had the following text:

The architecture of a medical information system will reflect our attitudes toward the patient. We should ask how our diabetic patient is involved by our system. When economical labels are put into care the medical record system is forced into a certain form pushing doctors to work more with laboratory investigations and less with education. Inevitable a focus on cash flow will result in more non-value activities. To reverse this process we have to show that we can handle details. This will simplify a move from abstract finances to concrete activities like education. A basic information sheet with codes is carried by the patient and is the starting point while we write the medical record together. Free text is integrated with structured

information in the medical record. The codes are saved to the system and used for production of readable records and statistics. Results from educational activities and the content of education can thus be demonstrated. Evaluation is educational for the tutors as well as for the patient. The information sheet can be used as an integration link between primary care units and the hospital. In a future a patient card or a diskette could also be used for information flow. We have shown that it is possible to handle well-structured and detailed information from a management system and make comparisons between clinics and primary care units. Diabetes is very expensive and care is patchy as far as priorities and results. That is why we need to collect large materials and establish shared care, continuously monitoring risks and our results.

Today I am more prone to stress that the computer is a tool for the daily work of the profession rather than a tool solely for evaluation of care. I strongly believe that management of diabetes should and can be computerized in a comprehensive fashion well integrated with other systems in the hospital avoiding double work. Such an effort can prevent hospitalisations as well as development of complications of diabetes. With good software for diabetes management quality assurance and quality improvement will be performed more easily. The patient, doctor and nurse will share information and a true teamwork can be created. Patient empowerment can reach a new level. In front of the screen of the PC education will be individualized (Fig1 and Fig2). Written plans can be given to the patient at the visit (Fig3).

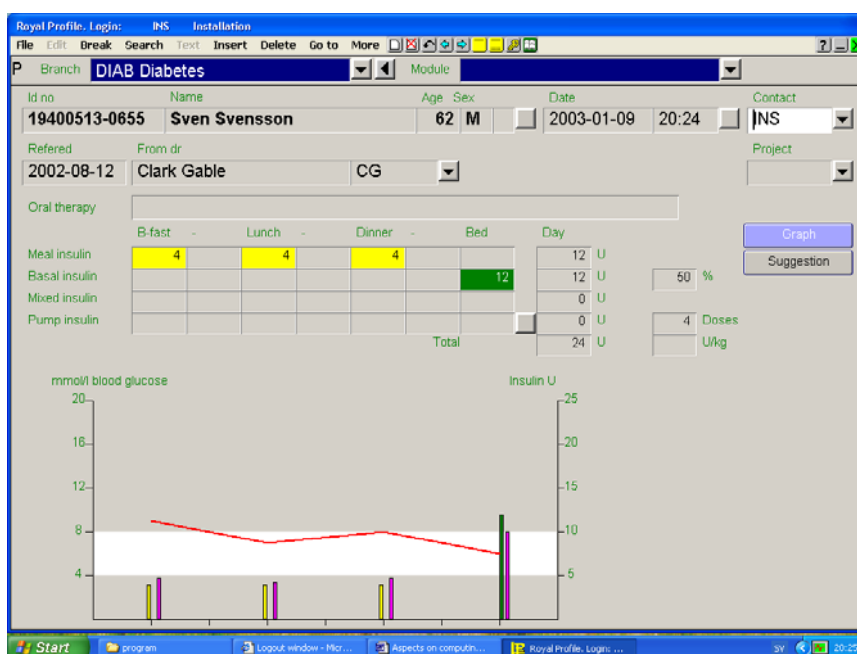


Fig1. Dosage of insulin and blood glucose together with suggestions can be discussed with the patient.

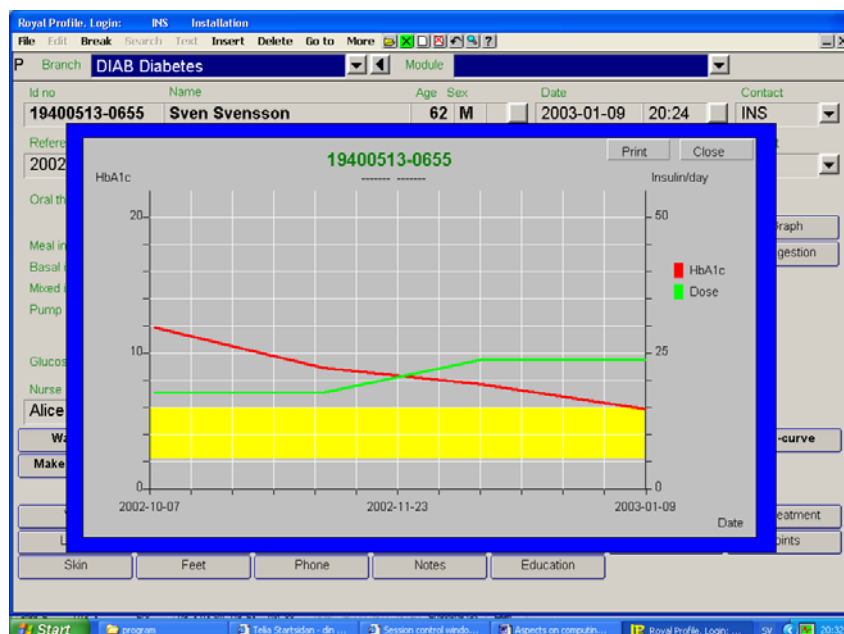


Fig2. Individualised goals of HbA1c together with daily dosage and HbA1c.

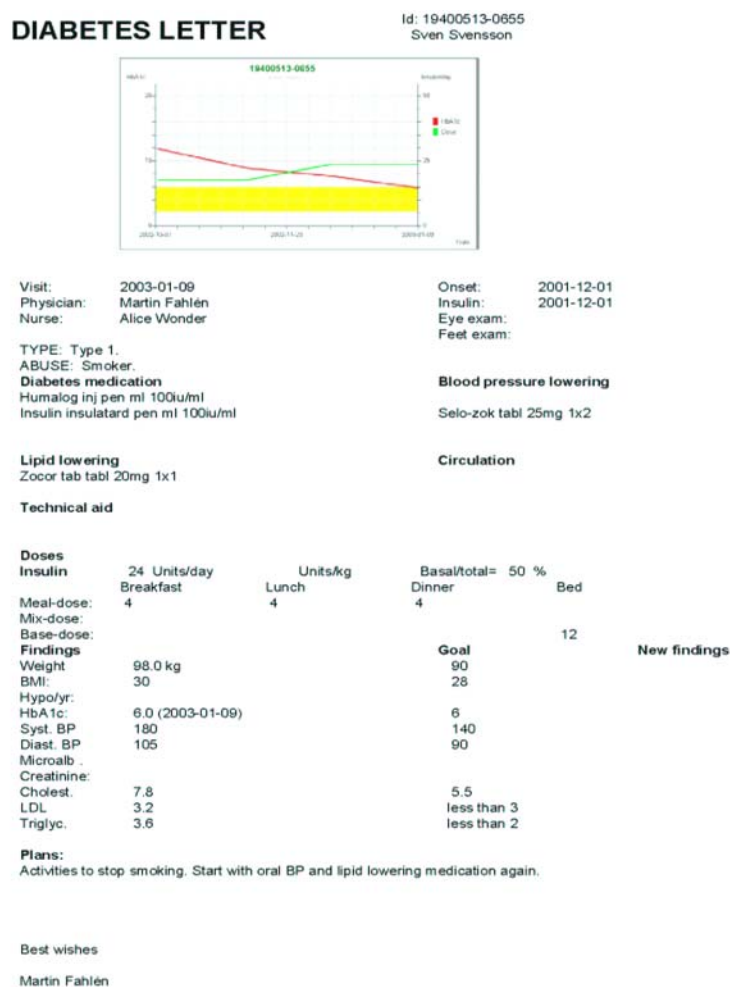


Fig 3. Written individualised plans including a graph showing HbA1c. The nurse will become more proficient in her work. She will also enjoy her work as otherwise difficult tasks can be facilitated. Such a task is for example nursing for patients using CSII. A

special informative letter about CSII can be used. Her medical record will be highly advanced and have the same design as the one used by the diabetologists (Fig4).

2003-01-09 Visit	Vist together with a relative. Eva (wife) is here today.					
Diagnoses	E109 Type 1 diabetes without complications					
Onset	Diabetes 2001-12-01. Insulin 2001-12-01. TYPE: Type 1.					
Social	FAMILY: Married. WORK: Physically light work. ABUSE: Smoker.					
Control	BMI: 30. Height: 180.0 cm. Weight: 98.0 kg.					
Eyes	Eye examination 2003-01-09. GENERAL: No problems with vision. RIGHT: Small changes. LEFT: Small changes.					
BP	Hypertension 2001-12-01. Betablocker. BT-dia:105. BT-sys:180.					
Lipids	Hyperlipidemia 2002-04. Reductase inhibitor. HDL:4.0. Kol: 7.8. LDL: 3.2. Tg: 3.6.					
Nerves	RIGHT: Normal vibration sensitivity. LEFT: Normal vibration sensitivity.					
Insulin		B-fast	Lunch	Dinner	Bed	Day
	Meal	4	4	4		12 U
	Basal				12	12 U
	Blood	9	7	8	6	7.5 mmol/l
	Basal/Meal dose 50%					
Medication	Humalog inj pen ml 100iu/ml, Insulin insulatard pen ml 100iu/ml, Selo-zok depottab tabl 25mg 1x2, Zocor tab tabl 20mg 1x1					
Plans	Activities to stop smoking. Start with oral BP and lipid lowering medication again.					

Fig 4. A medical record where plans includes the same text as in the Diabetes letter.

Computing stimulates goal consciousness and the use of CSII will increase. Data can be monitored and collected for research (see copy of the manuscript “Blood pressure in Type 1-diabetes with multiple daily insulin injections or continuous subcutaneous insulin infusion therapy; a medical record study” by Martin Fahlén and Anders Odén. The manuscript has been submitted to Diabetic Medicine for publication). More will thus be known about the role of CSII in treatment.

All of this is excellent but difficult to achieve. There are several obstacles. Among doctors there are reluctance to computing and change of habits in daily work. Medical professors are not comfortable with computing and are not aware of the necessity to follow information in the medical record systems and use data in their own research work. Teamwork with nurses is difficult. There are barriers including monopolised professional language used by doctors, different status and income compared to the nurse. Furthermore, the main medical record system of the hospital is seldom compatible with specialist systems. The architecture of the different systems and mode of information use varies. Technicians lack knowledge about clinical needs and dominate in planning computerization of health care. Efforts are technique

oriented with a focus on standardization rather than problem oriented. Specialist systems are not welcome in a world where chaos is anticipated if all type of such systems would be introduced. Continuous support and education from the vendor is needed, but this is cut out from the budget, as there are economical problems.

Medical physics versus the cascade and the use of enCapture

In the demo version of enCapture it is presented on the front cover as an “Advanced patient management system”. It would be more realistic to call it an “Advanced system for clinical evaluation of well defined problems”. The software is user-friendly for certain isolated problems. Below I suggest how it can be used within the field of diabetes and pump-treatment. However, the big question is what we absolutely need to evaluate when we use CSII. Any diabetologist or politician would immediately answer “health economy”. This number one question will imply evaluation of complications, which are the economical burden of diabetes. However, this question can only be studied on very large materials and for a very long time. We need a control group and a huge amount of data. The system enCapture touches a narrower world and evaluates today problems from the world of medical physics. When electricity is turned on pain is gone or to be more precise; during spinal cord stimulation for chronic intractable angina pectoris the number of angina attacks can be counted and the therapy can be evaluated with the support of enCapture. Diabetes belongs to the world of chemistry and must be analysed with other tools suitable for a cascade of events. It is more difficult to follow a metabolic disturbance without immediate pain. Several factors are involved when we look at outcome. However, it is possible to quit the cascade view and study certain isolated aspects of the cascade and within a limited period of time. Below a list problems that might be suitable for enCapture and on the following pages some of the codes (ICD10 and ATC excluded) used in Diab-Base needed for the huge cascade:

1. **The influence of CSII on pain in patients with neuropathy.**
2. **Optimising insulin therapy with CSII using algorithms and glucose sensor.**
3. **The use of CSII in the intensive care unit.**
4. **The use of CSII in diabetes and myocardial infarction.**
5. **The use of CSII in severe insulin resistance.**
6. **Evaluation of patients not responding to CSII.**
7. **The use of CSII from onset of type1 diabetes. Eye photo.**
8. **The use of CSII from onset of type1 diabetes. Microalbumin.**
9. **Blood pressure after start of CSII.**
10. **Tool for patient empowerment. CSII-letter.**

Lab

804	BP-syst	
932	Syst. BP goal	mm Hg
802	BP-diast	
933	BP diast. goal	mm Hg
808	Weight	kg
936	Weight goal	kg
806	Height	cm
801	Body mass index	
934	BMI goal	
6005	HbA1c	%
931	HbA1c goal	%
6003	Blood glucose	
6002	Blood glucose non fa	
6007	Cholesterol	mmol/l
935	Cholesterol goal	mmol/l
6009	Triglycerides	mmol/l
6006	HDL	mmol/l
6008	LDL	mmol/l
6011	Chol/HDL	
6013	Sensibility index	
809	Visual aquity right	
810	Visual aquity left	
6034	BG meas./week	
6012	Blood glucose	mmol/l
6035	UG meas./week	
850	K-cal	
6030	Hypo/year	
6031	Hyper/year	
813	No of cig/day	
6004	C-peptide	
6036	ICA	JDF enhet
6037	GAD-ak	ak-index
7003	Micro albumine	mg/l
7002	Creatinine	Ámol/l
7006	Creatinine clearance	ml/min
6014	Alb/creat	mg/mmol
7004	Urea	
7001	Glomerulus filtratioml/min	
930	Interval of visits	
824	BP-syst. standing	
822	BP-diast. standing	
803	BP-mean	
910	Normal pregnancies	
911	Misscarriages	
912	Perinatal death	
913	Major malformation	
914	Partus week	
915	Birth weight	kg

Events

DIAB	Diabetes
HYP	Hypertension
HYPERLIP	Hyperlipidemia
HYPO	Severe hypoglycemia
INSCOMA	Insulin coma
HYPTRAF	Hypoclycemia in traffic
HYPERG	Severe hyperglycemia
KETO	Keto acidosis
KETOSJH	Keto acidosis hospitalized
KOST	Only diet
BIGU	Biguanide
SULF	Sulphonylurea
ACARBOS	Glucosidase inhibitor
INSULIN	Insulin
PUMP	Insulin pump
DTABL	Oral treatment
ÖGASUS	Eye examination
LASERH	Photocoagulation of right
LASERV	Photocoagulation of left
VITRECTH	Vitrectomy of right eye
VITRECTV	Vitrectomy of left eye
BLINDHÍ	Blind in right eye
BLINDV-	Blind in left eye
FOTSUS	Foot examination
DEBF	Onset of foot problems
GIPS	Treated with plaster
FOTS+RH	Ulcer on right foot
FOTS+RV	Ulcer on left foot
FOTAMPHÍ	Amputation below right
FOTAMPV-	Amputation below left ankle
BENAMPHÍ	Amputation above right
BENAMPV-	Amputation above left ankle
HJUNS	Stroke
HJEMB	Cerebral embolus
HJBLÍ	Cerebral hemorrhage
SUBAR	Subarachnoid hemorrhage
TIA	TIA
ANGINAP	Angina pectoris
INF	Myocardial infarction
PTCA	PTCA
ACB	ACB
ACBK	ACB+valv. surg.
CLAUDI	Claudicatio
CARSTE	Carotid stenosis
CAROP	Carotid surgery
FOTPTAH	PTA right leg
FOTPTAV	PTA left leg
BPASSHÍ	Bypass on right foot

- BPASSVÄ Bypass on left foot
MICROA Microalbuminuria
PROTUR Proteinuria
DIALYS Dialysis
NJURTRPL Kidney transplantation
AUNEVRO Autonomous neurop
NERVMOT Motoric neuropathy
SENEURO Sensorisc neuropathy
SJUKP Disablement pension
FIMPA Quited smoking
PARTUS Partus
ABORT Misscarriage
- Visit 1:1
A Vist together with a relative.
B *
- Type, TYPE: 200:1
A Type 1.
B Type 2.
C Other type.
- Type, OTHER TYPE: 200:2
A Chronic pancreatitis.
B Pancreatectomi.
C Hemochromatosis.
D Cystic fibrosis.
E Part of a metabolic disorder.
F Drug induced diabetes.
G Genetic syndrome.
- Type, HER.: 200:3
A Type 1 in family.
B Type 2 in family.
C Twin with diabetes.
D One sibling with diabetes.
E Two siblings with diabetes.
F Several siblings with diabetes.
G Father with diabetes.
H Mother with diabetes.
I Hypertension in family.
J Hyperlipidemia in family.
K Coronary heart disease before 60 years of age.
- Type, RELATED DISORDER: 200:4
A Coeliac disease.
B Hypothyreosis.
C Hyperthyreosis.
D Morbus Addison.
E Pernicious anemia.
F Vitiligo.
- Social, LIVING: 43:1
A Lives in an apartment.
B Lives in a house.
C Nursing home.
- Social, FAMILY: 43:2
A Lives with mother.
B Lives with father.
C Lives with parents.
D Lives with stepparents.
E The only child.
F Siblings at home.
G Lives alone.
H Married.
I Divorced.
J Has children.
K Adopted child.
L Children lives at home.
M Children lives close.
N Spouse is ill.
O Widow.
P Widower.
- Social, WORK: 43:3
A Physically light work.
B Physically heavy work.
C Stressful work.
D Have more than one job.
E Satisfied with work.
F Problems at work.
G Military service.
H Unemployed.
I Pension.
J Sick-listed.
K Partly sick-listed.
L Been sick listed more than 3 months.
- Social, SCHOOL: 43:4
A High school.
B University.
C Satisfied with school work.
D Problems in school.
E Problems in participation due to disease.
- Social, EXERCISE: 43:5
A Physically inactive.
B Physically active.
C Exercises seldom.
D Exercises regularly.
E Participates in contests.
- Social, LOCUS OF CONTROL: 43:6
A Mostly external.

B Mostly internal.
Social, ABUSE: 43:7

- A Nonsmoker.
- B Smoked earlier.
- C Smoker.
- D Passive smoker.
- E Takes snuff.
- F Total abstainere.
- G Seldom alcohol.
- H Alcohol regularly.
- I Moderate drinking.
- J Earlier abuse of alcohol.
- K Abuse of alcohol.
- L Earlier abuse of narcotics.
- M Abuse of narcotics.

Pregnancy 215:1

- A Is pregnant.
- B Abortion after onset of diabetes.
- C Delivered one child after onset of diabetes.
- D Delivered two children after onset of diabetes.
- E Delivered more than two children after onset of diabetes.
- F Used insulin pump during the last pregnancy.
- G Cesearean section.
- H Normal labour.
- I Congenital malformation has been present.
- J Stillbirth has occured after onset of diabetes.

Control, MEAL: 209:1

- A Loss of appetite.
- B Anorexia nervosa.
- C Can not cook.
- D Consumes mostly fast food.
- E Irregular meal times.
- F Snacks before bed.
- G Attends a wheightwatcher club.
- H Has been successful in reducing wheight.
- I Difficulties in controlling foodintake.
- J Increased sugar thrive.
- K Increased caloric intake.
- L Takes repeated snacks.
- M Sometimes intense hunger.
- N Bulumia.

O Vegetarian.

Control, TABL.: 209:2

- A Sulfonylurea withdrawn due to side effects.
- B Biguanide withdrawn due to side effects.
- C Acarbose withdrawn due to side effects.
- D Improved control after dose adjustment of therapy.
- E Improved control after combination therapy.
- F Offered insulin but do not comply.
- G Practical difficulties are a hindrance for using insulin.

Control, INJECTION: 209:3

- A Skips doses.
- B Injection in arm.
- C Injection in abdomen.
- D Injection in buttoc.
- E Injection in leg.
- F Risk for intramuscular injection.
- G Lipohypertrophy is present.

Control, PUMP: 209:4

- A Uses pump.
- B Want to test pump treatment.
- C Could not adjust to pump treatment.
- D Better long-term control during pump treatment.
- E Metabolic control not better.
- F Problems with local infection.
- G Problems with canula.
- H Irritation of skin.
- I Technical problems has occured.
- J Developed ketoacidosis.
- K Hospitalized due to problems.

Control, HYPO: 209:5

- A Frequent episodes of hypglycemia.
- B Night sweat.
- C Headache related to hypglycemia.
- D Episodes of muscle fatigue.
- E Prickling sensation.
- F Episodes with lack of concentration.
- G Emotionally unstable.
- H Car accident due to hypoglycemia.

- I Extreme fear for hypoglycemia.
- J Extreme desire to have low glucose value.
- K Has glucagon.
- L Has been treated at home with glucagon.
- Control, HYPER: 209:6
- A Fatigue due to high glucose values.
- B Increased thirst.
- C Deficient healing of wounds.
- D Repeated infections.
- E Dental problems due to diabetes.
- F Genital infection.
- Control, PROTOCOL: 209:7
- A Daily blood glucose self-monitoring.
- B Measures blood glucose several times a week.
- C Measures blood glucose a few times a month.
- D Sporadic blood glucose self-monitoring.
- E No blood glucose monitoring.
- F Finds urine glucose self-monitoring useful.
- G Uses protocol.
- H No protocol.
- I Active making adjustment of doses.
- J Noticed better values during recent year.
- K Better after reduction of doses.
- L Measures blood glucose at 3AM
- Control, RELATION: 209:8
- A Internal locus of control.
- B External locus of control.
- C Can talk with others about diabetes.
- D Non-compliant.
- E Anxiety.
- F Depression.
- G Membership in the Diabetic Association.
- BP-treatment 51:1
- A ACE-inhibitor.
- B Angiotensin II-inhibitor.
- C Betablocker.
- D Calciumantagonist.
- E Furosemide.
- F Thiazide.
- Lipids 50:1
- A Nicotinic acid.
- B Cholestyramine.
- C Reductase inhibitor.
- D Fibrate.
- Cardiovasc., GENERAL: 48:1
- A *
- Cardiovasc., HEART FUNCTION: 48:2
- A Heart enlargement.
- B Atrial enlargement.
- C Hypertrophy of left ventricle.
- D Reduced ejection fraction.
- E Diastolic dysfunction.
- F Heart failure.
- G Earlier cardiogenic chock.
- H Earlier pulmonary edema.
- I NYHA I.
- J NYHA II.
- K NYHA IIIA.
- L NYHA IIIB.
- M NYHA IV.
- Cardiovasc., ANGINA: 48:3
- A No angina.
- B Stable angina.
- C Unstable angina grade 1.
- D Unstable angina grade 2.
- E Unstable angina grade 3.
- F CCS I.
- G CCS II.
- H CCS III.
- I CCS IV.
- Cardiovasc., HEART SURGERY: 48:4
- A No heart surgery.
- B Earliier CABG.
- C Mechanical aortic prothesis.
- D Biological aortic prothesis.
- E Mechanical mitral prothesis.
- F Biological mitral prothesis.
- G Refused reoperation.
- H Heart transplantation.
- I Heart-lung transplantation.
- Cardiovasc., PTCA: 48:5
- A No PTCA.
- B PTCA performed.
- C Stent is installed.

- Cardiovasc., CVS: 48:6
- A No symptoms after stroke.
 - B Some symptoms after stroke.
 - C Paresis after stroke.
 - D Paralysis after stroke.
- Cardiovasc., ARTERIES: 48:7
- A Carotid stenosis.
 - B Renal artery stenosis.
 - C Pain from claudicatio.
- ECG, RYTHM 46:1
- A Sinus rythm.
 - B Pacemaker rythm.
 - C Bradycardia.
 - D SVES.
 - E VES.
 - F Atrial tachycardia.
 - G Nodal tachycardia.
 - H Ventricular tachycardia.
 - I Atrial fibrillation.
- ECG, QRS: 46:2
- A Normal.
 - B Not normal.
 - C S in V1 plus R in V5-V6 is >35 mm (hypertrophy).
 - D Aberrent conduction.
 - E Delta wave.
 - F Left bundle branch block.
 - G Right bundle branch block.
 - H Pacemaker complex.
 - I New Q-wave.
 - J Older Q-wave.
- EKG, STT: 46:3
- A Normal.
 - B Not normal.
 - C Secondary ST-T changes due to wide QRS.
 - D Unchanged compared to earlier
- ECG
- E ST-elevation.
 - F ST-reduction.
 - G T-inversion.
- ECG, BLOCK: 46:4
- A SA-block.
 - B AV-block I.
 - C AV-block II type I.
 - D AV-block II type II.
 - E AV-blocke III.
- Eyes, GENERAL: 204:1
- A Eyes examination not carried out.
 - B No progress.
 - C Progress of changes since last examination.
 - D No problems with vision.
 - E Certain problems with vision.
 - F Partially sighted.
 - G No driving due to visual loss.
 - H Special equipment due to visual loss.
- Eyes, RIGHT: 204:2
- A No retinopathy.
 - B Retina not seen.
 - C Small changes.
 - D Preproliferative retinopathy.
 - E Proliferative retinopathy.
 - F Photocoagulated.
 - G Vitrectomy.
 - H Venous changes.
 - I Maculopathy.
 - J Macular edema.
 - K Retinal detachment.
 - L Catarakt.
 - M Glaukoma.
 - N Advanced diabetes eye disease.
 - O Blind due to diabetes.
 - P Blind not due to diabetes.
- Eyes, LEFT: 204:3
- A No retinopathy.
 - B Retina not seen.
 - C Small changes.
 - D Preproliferative retinopathy.
 - E Proliferative retinopathy.
 - F Photocoagulated.
 - G Vitrectomy.
 - H Venous changes.
 - I Maculopathy.
 - J Macular edema.
 - K Retinal detachment.
 - L Catarakt.
 - M Glaukoma.
 - N Advanced diabetes eye disease.
 - O Blind due to diabetes.
 - P Blind not due to diabetes.
- Neuropathy, GENERAL: 207:1
- A Postural hypotension.
 - B Neuropathic bladder.
 - C Erectile impotence.
 - D Autonomic neuropathy.
 - E Mononeuropathy.

F Loss of "warning" signs of hypoglycemia.

Neuropathy, GI: 207:2

- A Heartburn.
- B Reflux symptoms.
- C Difficulties in swallowing.
- D Loss of appetite.
- E Early sensation of fullness.
- F Abdominal fullness.
- G Nausea.
- H Vomiting.
- I Symptoms aggravated by meals.
- J Low blood glucose after meals.
- K Diarrhoea.
- L Obstipation.
- M Fecal incontinence.

Neuropathy, RIGHT: 207:3

- A Normal vibration sensitivity.
- B Reduced vibration sensitivity.
- C Normal pin prick sensitivity.
- D Reduced pin prick sensitivity.
- E Ankle reflex present.
- F Ankle reflex absent.
- G Amyotrophy.
- H EMG is pathological.
- I Osteopathy.

Neuropathy, LEFT: 207:4

- A Normal vibration sensitivity.
- B Reduced vibration sensitivity.
- C Normal pin prick sensitivity.
- D Reduced pin prick sensitivity.
- E Ankle reflex present.
- F Ankle reflex absent.
- G Amyotrophy.
- H EMG is pathological.
- I Osteopathy.

Kidneys 203:1

- A No proteinuria.
- B Episodic proteinuria.
- C Constant proteinuria.
- D Proteinuria with nephrosis.
- E Microalbuminuria not tested.
- F No microalbuminuria with test-strip.
- G Microalbuminuria with teststrip.
- H No microalbuminuria.
- I Microalbuminuria.
- J Plasma creatinine is normal.
- K Plasma creatinine is high.

L Glomerular filtration rate is not examined.

M Glomerular filtration rate is decreased.

N Referred to nephrologist.

O Dialysis.

P Renal transplant.

Joints 206:1

A Limited joint mobility.

B Flexortenosynovitis.

C Dupuytren's contracture.

D Underwent surgery of Dupuytren's contracture.

E Carpal tunnel syndrome.

F Underwent surgery for carpal tunnel syndrome.

G Painful shoulder.

H Painful hip.

Skin 208:1

A Atrophy.

B Dry skin.

C Loss of hair.

D Pigmentation.

E Fungal infection.

F Bacterial infection.

G Healed ulcers.

H Skin breaks.

I Deep fissures.

J Claw toes.

K Thick callus.

L Verrucae.

M Damage of skin at pressure areas.

N Purpura.

O Diabetic dermopathy.

P Necrobiosis.

Q Xantomata.

Feet, GENERAL: 205:1

A Seen by chiropodist.

B Has attended the foot clinic.

Feet, RIGHT: 205:2

A Normal skin.

B Skin problems.

C Foot pulses present.

D Foot pulses absent.

E Edema.

F Present ulcer.

G Healed ulcer.

- H Insoles.
 - I Specialist foot wear.
 - J Treated with plaster.
 - K Rest pain.
 - L Pain while walking.
- Feet, LEFT: 205:3
- A Normal skin.
 - B Skin problems.
 - C Foot pulses present.
 - D Foot pulses absent.
 - E Edema.
 - F Present ulcer.
 - G Heald ulcer.
 - H Insoles.
 - I Specialist foot wear.
 - J Treated with plaster.
 - K Rest pain.
 - L Pain while walking.
- Education, CAUSE: 216:1
- A Regular visit.
 - B Referral.
 - C Acute visit.
 - D Visit with the team.
 - E Visit as inpatient.
 - F New onset of diabetes.
 - G Introducing tools.
 - H Start of pump treatment.
 - I Complication as the dominating problem.
 - J Pregnancy.
- Education, EDUCATION: 216:2
- A Presentation of booklet.
 - B Questionnaire.
 - C Interactive training.
 - D Self-monitoring.
 - E HbA1c.
 - F Injection.
 - G Changing doses.
 - H Pump.
 - I Diet.
 - J Foot care.
 - K Complications.
 - L Exercise.
 - M Hypoglycemia.
 - N Glucagon.
 - O Driving.
 - P Sex.
 - Q Pregnancy.

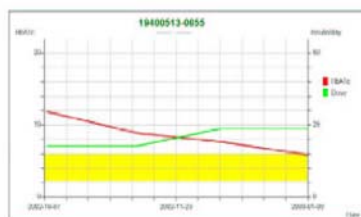
- R Sick days.
 - S About Diabetic Association.
- Education, PLANS: 216:3
- A No changes.
 - B More frequent visits.
 - C More frequent tests of HbA1c.
 - D Increased dose needed.
 - E Decreased dose needed.
 - F Dose-adjustment.
 - G Change of insulin.
 - H Combination therapy introduced.
 - I Treatment of complication.
 - J Activities to stop smoking.
 - K Referred to foot clinic.
 - L To the ward.
 - M Referred to another physician.
 - N Referred to primary care.

The patient marketing CSII

Of course enCapture is one part of marketing. If we stress this and if we are looking for a general tool we have to exclude no 1-9 of my suggestions. Medtronic sells a product and the user will be happy if they get more value than just the product. The added value is the CD that contains knowledge, education and possibilities for evaluation. The patient, doctor and nurse want to participate in evaluation of their therapy and get feedback from the system. There is also a need for support when they face a new technology like the CSII. For the doctor it is difficult to know a priori which patient that will benefit most from using CSII. The patient will experience a change in their life. If they lack information in front of this unknown change they hesitate. If they are told that a test with CSII will broaden their experience and that it is just an experiment rather than a prescription from the doctor, they will be interested. This experiment needs documentation and the final evaluation is educational. An important tool is the “CSII-letter” to the patient produced from enCapture. The “report function” can be tailored to deliver a global view of risks and plans. It might look like the one used in Diab-Base.

CSII LETTER

Id: 19400513-0655
Sven Svensson



Visit: 2003-01-09
Physician: Martin Fahlén
Nurse: Alice Wonder

Onset: 2001-12-01
Insulin pump: 2002-12-01
Eye exam: 2003-01-09
Feet exam:

PUMP: Better long-term control during pump treatment.

TYPE: Type 1.
ABUSE: Smoker.
Diabetes medication
Humalog inj 10 100 ie/ml

Blood pressure lowering

Selo-zok depottab tabl 25mg 1x2

Lipid lowering
Zocor tab tabl 20mg 1x1

Circulation

Technical aid
Minimed.508, blå, Accutrend-glucose cross pharma.

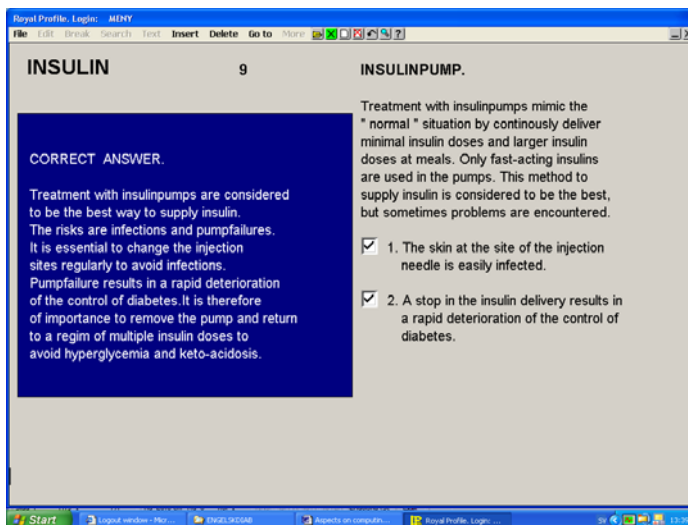
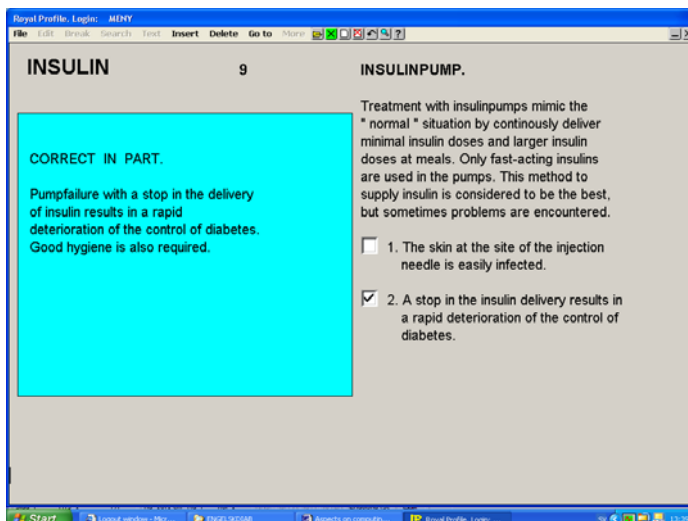
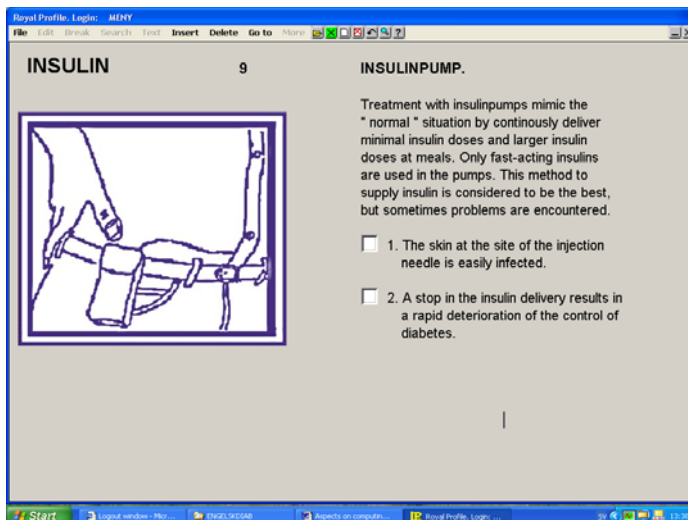
Insulin	46 Units/day	0.5 Units/kg	Basal/total= 57 %
Breakfast	Lunch	Dinner	Bed
8	6	6	26
Basal profiles			
00:00-04:00	1.0 E	04:00-08:00 1.4 E	08:00-24:00 1.0 E

Findings		Goal	New findings
Weight	98,0 kg	90	
BMI:	30	28	
Hypo/yr:			
HbA1c:	6.0 (2003-01-09)	6.0	
Syst. BP	180	140	
Diast. BP	105	90	
Microalb .			
Creatinine:		6	
Cholesterol	7.8	less than 3	
LDL	3.2	less than 2	
Triglycerid	3.6		

Plans :
Activities to stop smoking. Start with oral BP and lipid lowering medication again.

Interactive education

Besides the CSII-letter I suggest the use of multimedia or an interactive course about CSII on the Internet or on the CD. Screens from Journalia education below.



**Blood pressure in Type 1-diabetes with multiple daily insulin
injections or continuous subcutaneous
insulin infusion therapy; a medical
record study.**

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Abstract

Aims: To study blood pressure and the need of antihypertensive medication in Type 1 diabetes mellitus with multiple daily insulin injections (MDI) or continuous subcutaneous insulin infusion (CSII) therapy.

Methods: Data was obtained from 16 Swedish and Norwegian clinics with computerised medical records of 6075 patients with type 1 diabetes mellitus. Of these 564 were on CSII therapy and 5511 on MDI therapy. Median duration of CSII treatment was 2.4 years. Logistic regression analysis and multiple regression analysis were used.

Results: Systolic blood pressure was significantly lower ($p < 0.05$) and antihypertensive therapy was less common ($p < 0.05$) in the CSII group. In women the multiple regression analysis showed that the estimated difference of systolic blood pressure was 2-4 mm Hg within a wide region of age and duration. The corresponding difference for men was 1-3 mm. The increase in blood pressure depending on age and duration of diabetes could be estimated with great accuracy. The annual increase in men with MDI was 0.62 mm Hg (95% CI : 0.57-0.67) and for women 0.66 mm Hg (95% CI: 0.60-0.71).

Conclusions: Patients with CSII have lower systolic blood pressure. The findings are in accordance with earlier studies on implantable insulin infusion. A possible role of the relative exogenous hyperinsulinemia seen among patients with MDI is discussed. The difference in systolic blood pressure is small but may be an indicator of general beneficial effects of CSII.

Introduction

Treatment with continuous insulin infusion (CSII) was introduced in 1978[1]. In a recent meta-analysis including 302 patients from 12 randomised studies [2] it was found that CSII was better than multiple daily insulin injections. Metabolic control was improved and the insulin dosage could be decreased. There were also beneficial effects on ketotic events, levels of FFA and growth hormone [3]. The severity of hypoglycaemia was decreased and the quality of life increased[4,5]. There are few studies on the influence of CSII on health economics, morbidity, mortality and on important risk factors like blood pressure. In comparison with normal subjects blood pressure is higher in Type 1-diabetes [6] and the prevalence of hypertension is increased[7]. There have been no reports whether these elevations in blood pressure would be modified during CSII therapy, but in one study on the use of the implantable insulin pump, systolic blood pressure as well as the need for antihypertensive therapy, decreased [8]. We have used a large population of CSII-users from a computerised medical record system to study a possible influence of CSII on blood pressure.

Patients and methods

Data was obtained from 16 hospital based diabetes clinics in Sweden and Norway using a diabetes management system developed by Journalia Inc. Baseline demographic data, clinical history, diabetes therapy, other medication and laboratory results were continuously recorded in this system. Structured information together with free text was compiled in producing the medical record. Statistics were regularly made for local purposes and data was annually collected for evaluation within a national diabetes register (NDR).

Included were 6075 patients with Type-1 diabetes mellitus. Of these 564 (9.3%) were CSII users and 5511 used multiple daily insulin injections (MDI). The number of daily doses in the MDI group was 4,1 (± 0.9). Among CSII- patients, median duration of treatment with pump was 2.4 years and mean duration of diabetes was 22.8 years (± 11). HbA1c, weight, BMI, insulin/day, systolic blood and systolic blood pressure was obtained from all individuals. Microalbumin in urine and serum creatinine was recorded in 74% of all CSII-users. In the group treated with MDI data on microalbumin was recorded in 68% and creatinine in 75%. A common reason for patients starting with CSII was the difficulty in achieving good control with multiple injections. HbA1c values prior to pump treatment was obtained from 244 patients. Among these individuals there was a significant fall of HbA1c from 7.69 (± 1.6) to 7.03 (± 1.3) during CSII -treatment ($p < 0.001$, T-test for pair comparison).

Comparisons between MDI and CSII were performed by logistic regression analyses including the current variable in Table 1 and sex and age. This method was chosen, as there were differences between the groups in respect to sex and age. The systolic blood pressure

was estimated by multiple linear regression as a function of age and duration of diabetes for men and women separately.

Results

In Table 1 mean and standard deviation of studied variables are unadjusted with regard to sex and age; however, the p-values are adjusted with respect to these variables. An over-representation of women was noted among CSII-users, 58% were women compared to 43% among MDI-users ($p < 0.0001$). Mean age was 40.1 years (range 18-78) in CSII and 44.6 years (range 17-92) in MDI ($p < 0.05$). Units of insulin per day during CSII therapy, was 42.2 (± 18) which was 19% lower ($p < 0.0001$) compared to MDI. Antihypertensive therapy was given to 20% of patients treated with CSII and to 25% of those on MDI ($p < 0.05$). Systolic blood pressure was 126 ± 15 mm Hg in the CSII-group and 132 ± 18 mm Hg in the MDI-group. In the logistic regression model the beta coefficient of systolic blood pressure was -0.0022 ($p < 0.05$). This is approximately equal to the difference in systolic blood pressure divided by the variance. When also the daily insulin dosage was included in the regression analysis, the beta coefficient was -0.0017 (n.s.), thus, the difference between the two groups was somewhat reduced when insulin was taken in consideration.

By multiple regression analysis the mean increase of blood pressure depending on age and duration of diabetes, could be estimated with great accuracy (Table 2). The annual increase in men with MDI after onset of diabetes, was 0.62 mm Hg (95% CI : 0.57-0.67) and for women 0.66 mm Hg (95% CI: 0.60-0.71). While using data from the multiple regression analysis, the estimated difference for women in the two groups was 2-4 mm within a wide range of age and duration (Figure 1). Within a limited region of age and duration the difference was significant. The corresponding difference for men was 1-3 mm, but not significant.

Discussion

In Type 1-diabetes mellitus patients with CSII have lower systolic blood pressure than patients treated with MDI and the need of antihypertensive treatment is reduced. The findings may be an indicator of general beneficial effects of CSII and are in accordance with earlier studies on implantable insulin infusion[8]. As blood pressure was not measured from the start of CSII-therapy we cannot exclude that there may have been a selection of more patients with low blood pressure from the start; however, we have had no reports of such a selection from previous studies. Development of the annual rise of systolic blood pressure from the start of CSII therapy should, however be analysed in the future and the size of material for assessing the efficacy can be estimated. In such a study it is also of interest to follow concomitant hormonal and renal changes. It is then of special interest to make such studies from the onset of disease. When regular tracking of blood pressure was done in young diabetic patients it was suggested that an increase of intraglomerular and/or systemic blood pressure preceded the appearance of and could be responsible for microalbuminuria[9]. We could not demonstrate any lowering effect on microalbuminuria during CSII-treatment, but onset of CSII was late, given after 20 years of duration. The frequency of microalbuminuria was 26% which is in accordance with earlier reports [10].

It is a well-known observation that the level of insulin needed can be reduced when the patient shifts from MDI to CSII-treatment. This might have a beneficial effect on blood pressure and explain different results between men and women. When insulin was included in the logistic regression analysis the difference in systolic blood pressure was not significant. This possibly supports the role of the level of insulin given. Hyperinsulinemia is concomitant with hypertension in man and sex differences exist in the effects of insulin on the

endothelium. Short-term hyperinsulinaemia in women is associated with a decline in levels of immunoreactive endothelin, and possibly with a rise in the production of nitric oxide and prostacyclin[11]. Studies on rats suggest that insulin cause high blood pressure due to sodium retention and activation of endogenous norepinephrine[12]. Exogenous insulin aggravates hypertension in spontaneously hypertensive rats[13]. Besides a role of insulin there are other multifactorial influences, i.e. the role of quality of life.

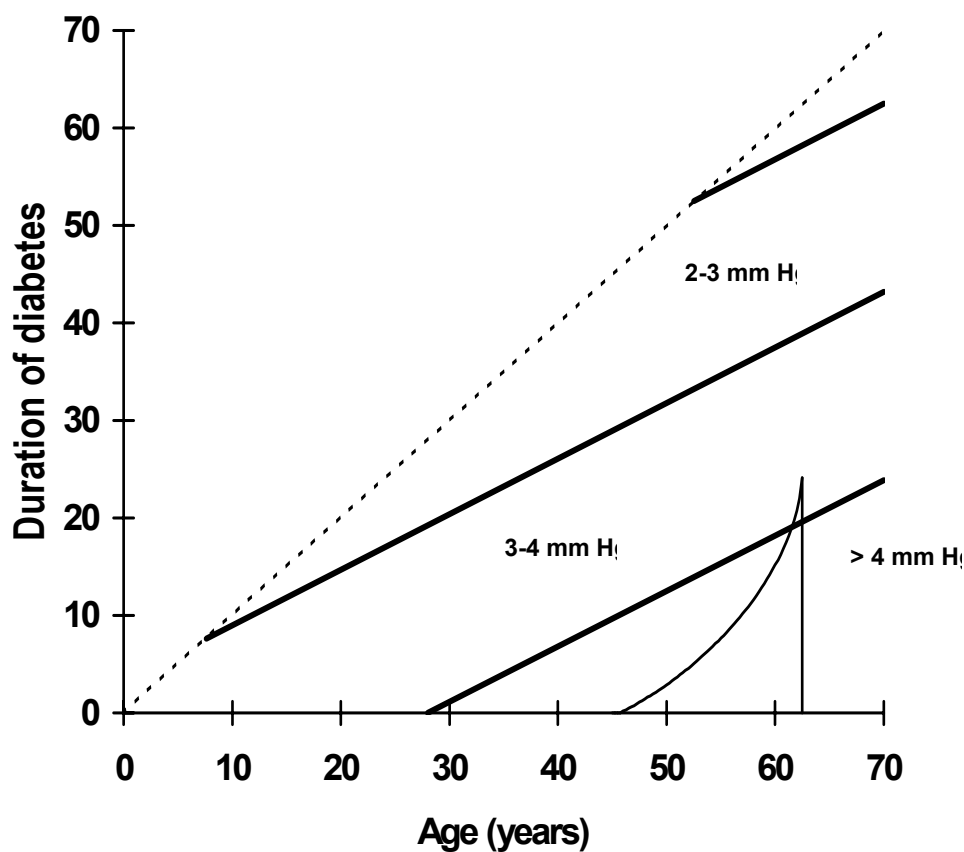


Figure 1. Difference between patients with and without CSII with respect to expected systolic blood pressure in women.

Variable	CSII	MDI	P-value
Number, n	564	5511	
Age, years	40.1 ± 12	44.6 ± 15	0.0166 *
Diabetes duration, years	22.8 ± 11	22.3 ± 14	1.1299
Women, %	58	43	0.0000 ***
HbA _{1c}	7.17 ± 1.3	7.31 ± 1.5	0.1062
Weight, kg	73.0 ± 12	75.5 ± 13	0.5667
BMI, kg/m ²	24.9 ± 3.4	25.2 ± 3.7	0.3197
Insulin/day, units	42.2 ± 18	51.9 ± 22	0.0000 ***
Creatinine, μmol/l	87 ± 31 (n=415)	89 ± 31 (n=4185)	0.4577
U-Albumin >30 mg/liter, %	24 (n=416)	28 (n=3773)	0.6968
BP-systolic, mm Hg	126 ± 15	132 ± 18	0.0358*
BP-diastolic, mm Hg	73 ± 8.4	74 ± 9.3	0.7179
BP-therapy, %	20	25	0.0249*

Table 1. Data (mean±SD or %) from patients with Type 1-diabetes with CSII and MDI. P-values were obtained from logistic regression analysis including sex, age and the current variable.

Type of therapy	n	c	b1 (age)	95% CI (b1)	b2 (duration)	95% CI (b2)
Men MDI	2606	107	0.48	0.44-0,53	0.14	0.09-0.19
Women MDI	1880	103	0.54	0.49-0,59	0.12	0.06-0.17
Men CSII	202	111	0.36	0.17-0,56	0.15	-0.05-0.36
Women CSII	274	100	0.51	0.36-0,66	0.19	0.04-0.35

Table 2. After multiple regression analysis systolic blood pressure (SBP) can be predicted from the equation: $SBP=c+b1*age+b2*duration$ where c is the constant and b1 and b2 are regression coefficients for age and duration.

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