VI CONVEGNO NAZIONALE
CENTRO STUDI E RICERCHE - FONDAZIONE AMD
NAPOLI, 18-20 OTTOBRE 2012
CENTRO CONGRESSI
STAZIONE MARITTIMA

FOCUS ON: DIABETE TIPO 1 DALLA VALUTAZIONE DELLA QUALITÀ ASSISTENZIALE A UN FUTURO MOLTO PROSSIMO

LA CSII e il rtCGM nel 2012: Per Quali Pazienti?

Paolo Di Bartolo
Unità Operativa di Diabetologia
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To Pump or Not to Pump

DIABETES CARE, VOLUME 25, NUMBER 11, NOVEMBER 2002

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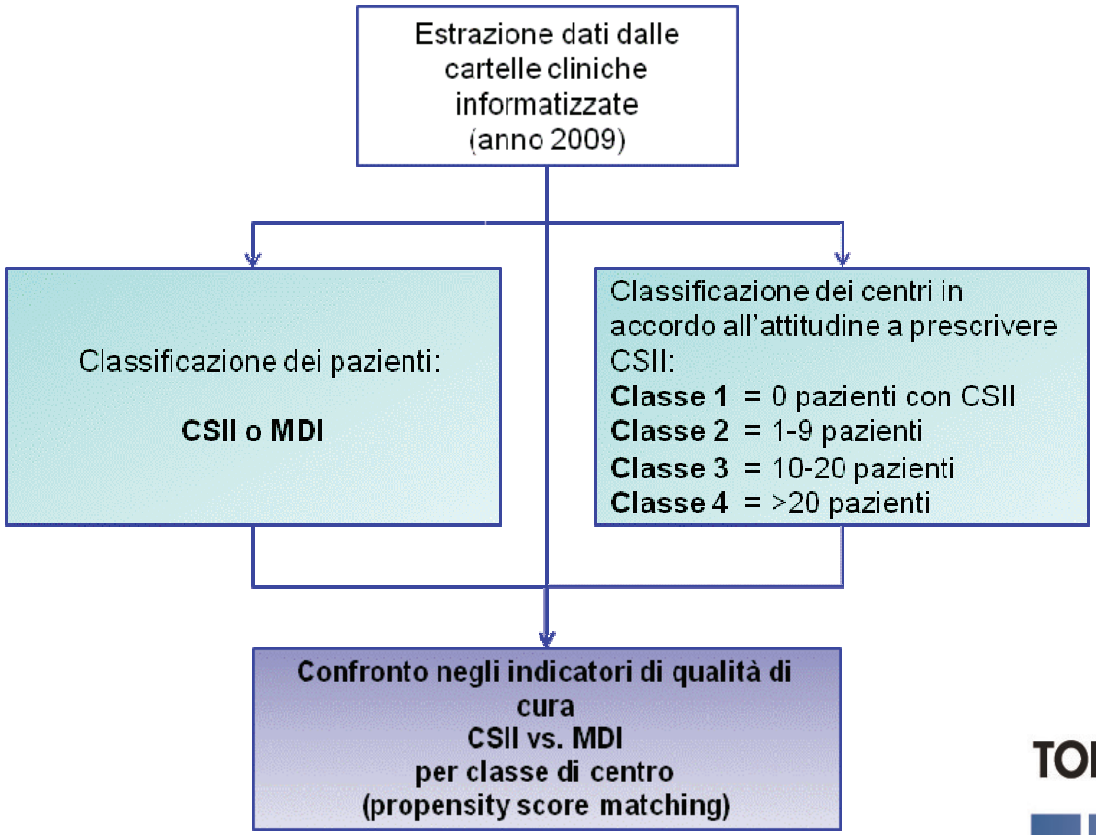
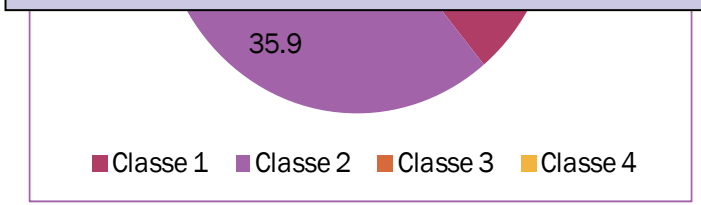
- Hsin-Chieh Yeh et al. Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus. A Systematic Review and Meta-analysis. Ann Intern Med 2012: 157: 336

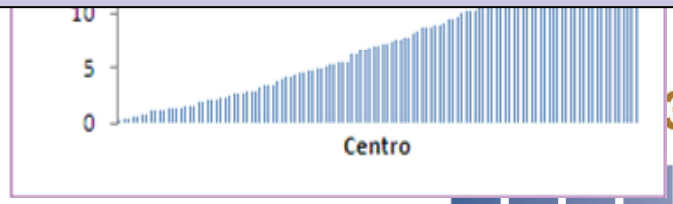
MATERIALI E METODI



RI

Variabile	Centri classe 1 (o pz con CSII)		Centri classe 2 (1-9 pz con CSII)		Centri classe 3 (10-20 pz con CSII)		Centri classe 4 (>20 pz con CSII)	
	MDI	CSII	MDI	CSII	MDI	CSII	MDI	CSII
n	4392	-	6819	219	3608	372	7561	1322
HbA1c (%)	8,0 (1,6)	-	8,2 (1,6)	8,0 (1,3)	8,2 (1,6)	8,0 (1,3)	8,0 (1,6)	8,0 (1,3)
HbA1c (%) in classi								
<=7	25,7	-	21,7	21,6	22,9	25,1	26,2	20,3
7-8	30,6	-	30,8	29,9	30,4	28,2	31,1	35,3
>8	43,8	-	47,5	48,5	46,7	46,7	42,7	44,4
HbA1c (%)	8,0 (1,6)	-	8,2 (1,6)	8,0 (1,3)	8,2 (1,6)	8,0 (1,3)	8,0 (1,6)	8,0 (1,3)





REVIEW | Annals of Internal Medicine

Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus

A Systematic Review and Meta-analysis

Hsin-Chieh Yeh, PhD; Todd T. Brown, MD, PhD; Nisa Maruthur, MD, MHS; Padmini Ranasinghe, MD, MPH; Zackary Berger, MD, PhD; Yong D. Suh, MBA, MSc; Lisa M. Wilson, ScM; Elisabeth B. Haberl, BA; Jessica Brick, MD; Eric B. Bass, MD, MPH; and Sherita Hill Golden, MD, MHS

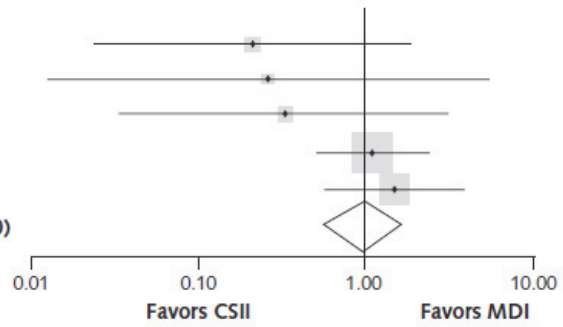
Ann Intern Med. 2012;157:336-347.

- Innovations in insulin delivery and glucose monitoring are designed to improve glycemic control and quality of life (QOL) while limiting adverse effects, such as hypoglycemia and weight gain. These advances include continuous subcutaneous insulin infusion (CSII) and real-time continuous glucose monitoring (rt-CGM).
- …….their effectiveness has not been consistently demonstrated and the populations most likely to benefit are unclear. Health professionals and their diabetic patients need objective information when making decisions about these technologies, which may be expensive or heavily marketed. Such information is important to persons who decide on reimbursement policies …..

Agency for Healthcare Research and Quality. (AHRQ)

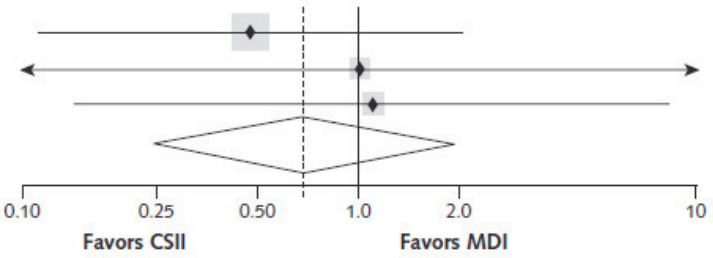
Ann Intern Med. 2012;157(5):336-347. doi:10.7326/0003-4819-157-5-201209040-00508

Figure 2. Pooled IRR for severe hypoglycemia comparing CSII with MDI among children and adolescents with T1DM.



Study, Year (Reference)	Pooled IRR for Severe Hypoglycemia, *events/person-year*	IRR (95% CI)	Total Events, *n*		Person-Years	
			CSII	MDI	CSII	MDI
Cohen et al, 2003 (31)		0.22 (0.02–1.94)	1	4	6.0	6.0
Opipari-Arrigan et al, 2007 (34)		0.27 (0.01–5.55)	0	2	3.0	4.0
Weintrob et al, 2003 (37)		0.33 (0.03–3.21)	1	3	6.7	6.7
Skogsberg et al, 2008 (36)		1.12 (0.52–2.41)	13	12	76.0	78.0
Schiaffini et al, 2007 (35)		1.50 (0.58–3.88)	11	7	38.0	34.0
Overall (I^2 = 6.5%; P = 0.370)		0.99 (0.57–1.71)	–	–	–	–

Figure 3. Pooled OR for severe hypoglycemia comparing CSII with MDI among adults with T1DM.



Study, Year (Reference)	Pooled OR for Severe Hypoglycemia	OR (95% CI)	Events, *n/N*	
			CSII	MDI
DeVries et al, 2002 (40)		0.47 (0.11–2.04)	3/39	6/40
Thomas et al, 2007 (44)		1.00 (0.10–10.17)	2/7	2/7
Bolli et al, 2009 (39)		1.09 (0.14–8.42)	2/24	2/26
Overall		0.69 (0.24–1.94)	–	–

diabetes mellitus.

Ann Intern Med. 2012;157(5):336-347. doi:10.7326/0003-4819-157-5-201209040-00508

Compar… and Glu… very

A Systematic …

Hsin-Chieh Yeh, …, PhD; Yong D. Suh, M… and Sherita Hill …

Outcome	CSII vs. MDI					
	Children and Adolescents With T1DM		Adults With T1DM		Adults With T2DM	
	Findings	Strength of Evidence	Findings	Strength of Evidence	Findings	Strength of Evidence
HbA_{1c}	No difference	Moderate	Favors CSII†	Low	No difference	Moderate
Hyperglycemia	Cannot conclude	Insufficient	No difference	Low‡§	Cannot conclude	Insufficient
Severe hypoglycemia	No difference	Low§	No difference	Low	No difference	Low§
Mild hypoglycemia	Cannot conclude	Insufficient	No difference	Low§	No difference	Moderate
Nocturnal hypoglycemia	No difference	Low§	No difference	Low§	Cannot conclude	Insufficient
Symptomatic hypoglycemia	–	–	Favors MDI	Low‖¶	–	–
Weight gain	No difference	Low§	No difference	Low§	No difference	Low**
General QOL	No difference	Low§	Favors CSII	Low‡§	Cannot conclude	Insufficient
Diabetes mellitus–specific QOL	Favors CSII	Low§	Favors CSII	Low‡§	Cannot conclude	Insufficient
Diabetes mellitus treatment–related QOL	Favors CSII	Low§¶	Cannot conclude	Insufficient	Cannot conclude	Insufficient

Ann Intern Med. 2012;157(5):336-347. doi:10.7326/0003-4819-157-5-201209040-00508

Health Technology Assessment 2010; Vol. 14: No. 11

Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation

E Cummins, P Royle, A Snaith, A Greene,
L Robertson, L McIntyre and N Waugh

RCT Summary:
Glycemic Control & Hypos

- Glycemic Control
  - RCT: CSII Vs Analogue-Based MDI
    - The studies in adults found no difference in HbA1c
    - The one study in children and adolescents reported that HbA1c was reduced by 1 %
    - The studies were of short duration (16-26 weeks)
- Hypoglycemia
  - RCT: CSII Vs Analogue-Based MDI
    - The trials in adults had too few patients, too short durations and too few SH episodes to be conclusive, but reported NS differences in the frequency of SH.
    - The trial in children reported a statistically significant drop in SH, but based on 5 episodes on MDI versus 2 on CSII

Health Technology Assessment 2010; Vol. 14: No. 11

Comparison of a Multiple Daily Insulin Injection Regimen (Basal Once-Daily Gl… Co… (Li…

A ran…

…ès Sola-Gazagnes, md[4]
…er Vitacolonna, md[5]
… Louis Selam, md[4]
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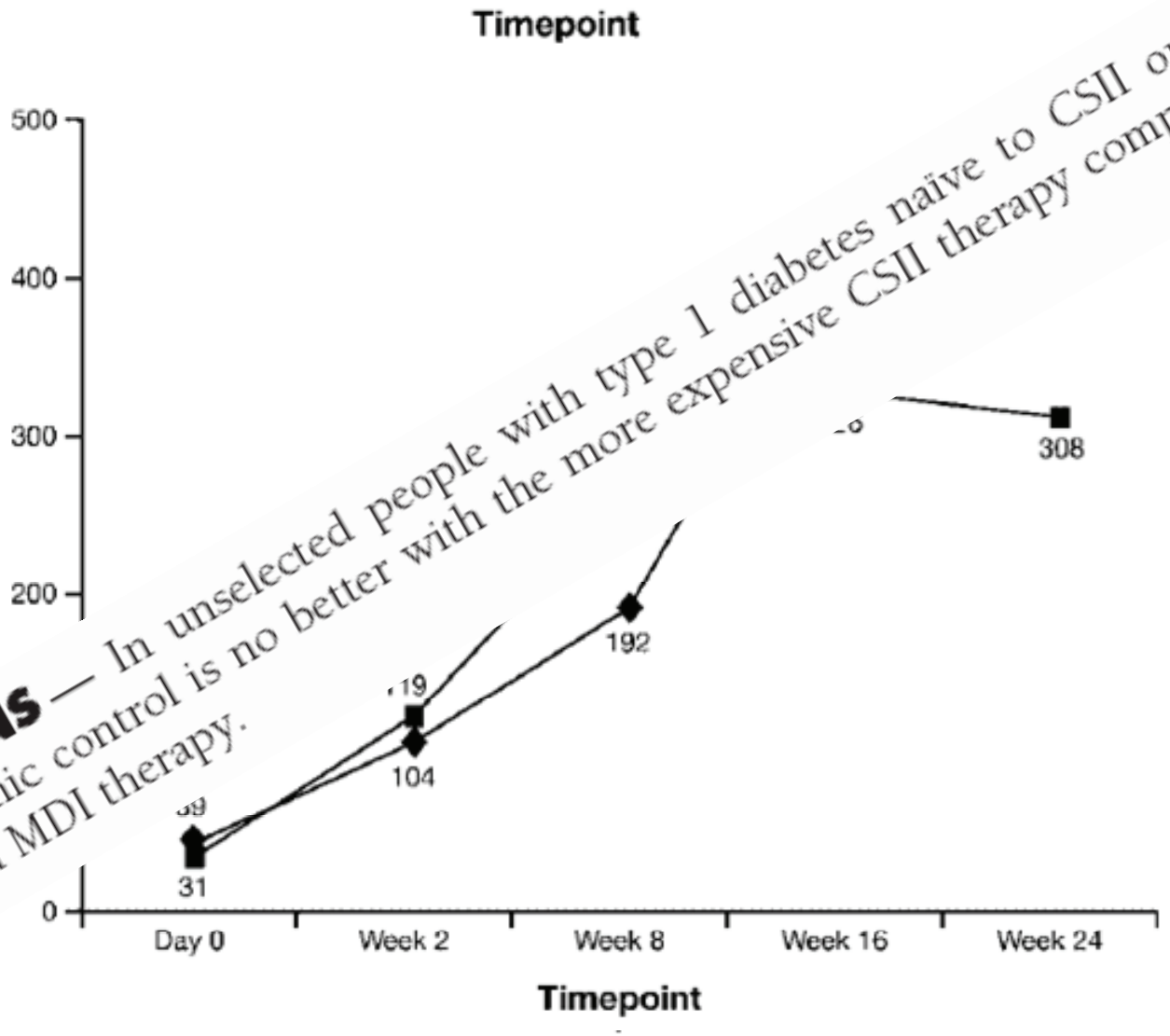
CONCLUSIONS — In unselected people with type 1 diabetes naïve to CSII or insulin glargine, glycemic control is no better with the more expensive CSII therapy compared with glargine-based MDI therapy.



Diabetes Care 32:1170–1176, 2009

Observational Study Summary: Glycemic Control & Hypos

- Observational studies: CSII Vs Analogue-Based MDI
  - They reported in general greater improvement in HbA1c than reported in the trials
  - They need to be interpreted with caution
- Observational studies: CSII Vs Analogue-Based MDI
  - These reported considerable reductions in SH.
  - This may reflect selection for CSII of people having particular problems with hypoglycaemia, but that would make them more applicable to routine care.

Health Technology Assessment 2010; Vol. 14: No. 11

Insulin Pump Therapy

Health Technology Assessment 2010; Vol. 14: No. 11

- Authors concluded that "based on the totality of evidence, using observational studies to supplement the limited data from randomised trials against best MDI, CSII provides some advantages over MDI in type 1 diabetes. For both children and adults, these are:
  - better control of glucose levels as reflected by HbA1c level, with the size of improvement depending on the level before starting CSII,
  - fewer problems with hypoglycaemia,
  - quality of life gains, such as greater flexibility of lifestyle.
  - There are benefits for families. However, the benefits of CSII come at an extra cost of about £1,700 per annum. There is no evidence that CSII is better than analogue-based MDI in type 2 diabetes, or in pregnancy..

SID- AMD
Italian Standards for Diabetes Mellitus 2009-2010

Insulin Pump Therapy Recommendations

In selected patients who despite
a modern MDI treatment,
show poor metabolic control and/or **recurrent**
hypoglycaemic episodes,
CSII should be considered as a therapeutic
option if delivered and supported
by an expert team

http://www.siditalia.it/index.php/linee-guida/488-09022011-standard-italiani-per-la-cura-del-diabete-mellito-2009-2010/download.html

NICE 2008 Guidance (1)

CSII therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

- attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia [...]
- HbA1c levels have remained high (that is, at 8.5% or above) on MDI therapy [...] despite a high level of care.

http://www.nice.org.uk/nicemedia/live/12014/41300/41300.pdf

NICE 2008 Guidance (2)

CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate…
- children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.

http://www.nice.org.uk/nicemedia/live/12014/41300/41300.pdf

NICE 2008 Guidance (3)

- It is recommended that CSII therapy be initiated only by a trained specialist team, [...].
- Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes [...].
- CSII therapy is not recommended for the treatment of people with type 2 diabetes mellitus

http://www.nice.org.uk/nicemedia/live/12014/41300/41300.pdf

Diabetes Self-Management

Evaluation and Management of Adult Hypoglycemic Disorders: An Endocrine Society Clinical Practice Guideline.
J Clin Endocrinol Metab, March 2009, 94(3):709–728

Flexible and appropriate insulin regimens

Evaluation and Management of Adult Hypoglycemic Disorders: An Endocrine Society Clinical Practice Guideline.
J Clin Endocrinol Metab, March 2009, 94(3):709–728

Frequent SMBG and… in some instances CGM

Evaluation and Management of Adult Hypoglycemic Disorders: An Endocrine Society Clinical Practice Guideline.
J Clin Endocrinol Metab, March 2009, 94(3):709–728

REVIEW | Annals of Internal Medicine

Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus

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Hsin-Chieh Yeh, PhD; Todd T. Brown, MD, PhD; Nisa Maruthur, MD, MHS; Padmini Ranasinghe, MD, MPH; Zackary Berger, MD, PhD; Yong D. Suh, MBA, MSc; Lisa M. Wilson, ScM; Elisabeth B. Haberl, BA; Jessica Brick, MD; Eric B. Bass, MD, MPH; and Sherita Hill Golden, MD, MHS

336 | 4 September 2012 | Annals of Internal Medicine | Volume 157 • Number 5

- Challenges that affect adherence to SMBG include
  - Pain
  - Costs
  - Behavioral and technical skills
  - Motivation
  - Intrusiveness.
- Systems for rt-CGM have been developed to supplement SMBG.

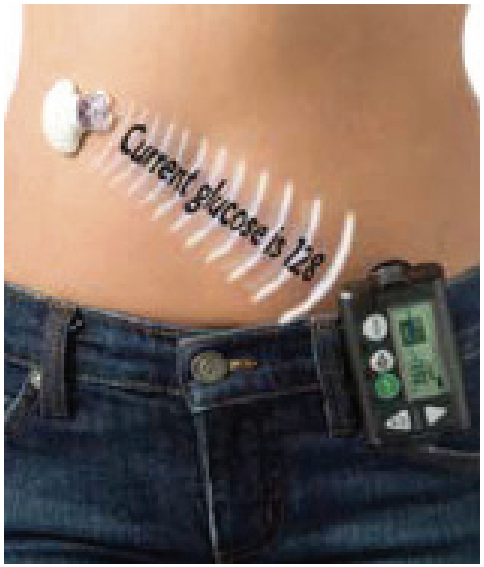
Agency for Healthcare Research and Quality (AHRQ)

Ann Intern Med. 2012;157(5):336-347. doi:10.7326/0003-4819-157-5-201209040-00508

Real Time Continuous Glucose Monitoring Systems (rtCGM)

Navigator Abbot

Guardian Medtronic



DexCom G4

Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes

The NEW ENGLAND JOURNAL of MEDICINE

Table 2. Glycemic Outcomes at 26 Weeks, According to Age.*

The use of continuous glucose monitoring averaged 6.0 or more days per week for 83% of patients 25 years of age or older, 30% of those 15 to 24 years of age, and 50% of those 8 to 14 years of age

Mean mg/dl/min — baseline/26 wk¶	0.73/0.68	0.72/0.74	0.07	0.85/0.84	0.86/0.87	0.48	0.84/0.82	0.83/0.83	0.66

The Effect of Continuous Glucose Monitoring in Well-Controlled Type 1 Diabetes

Diabetes Care 32:1378–1383, 2009

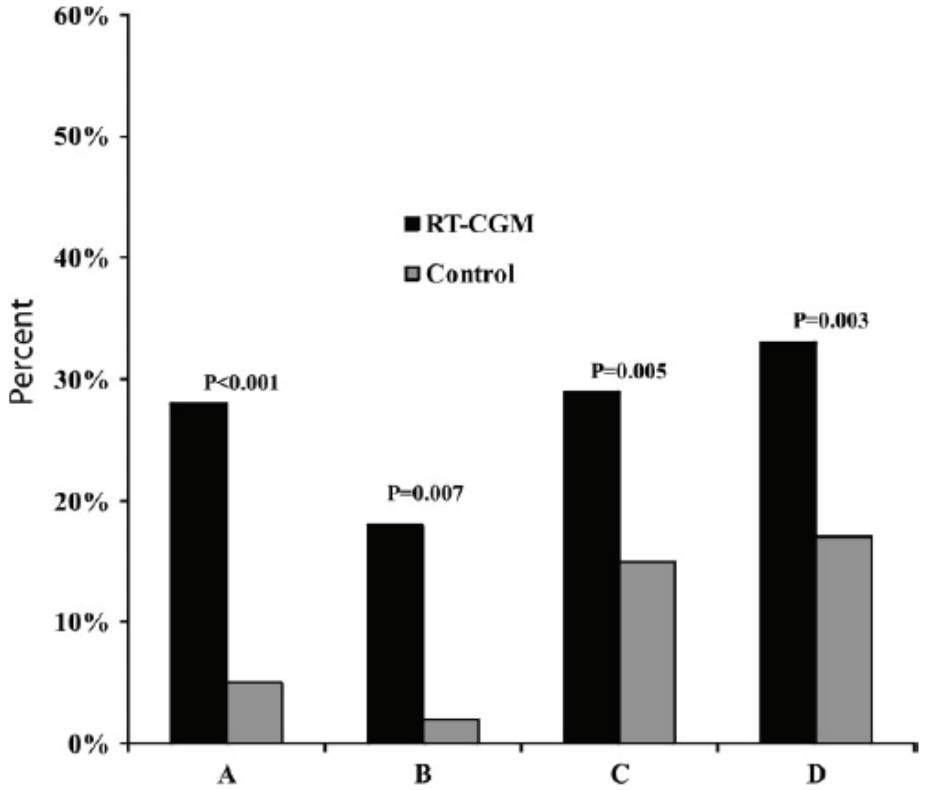


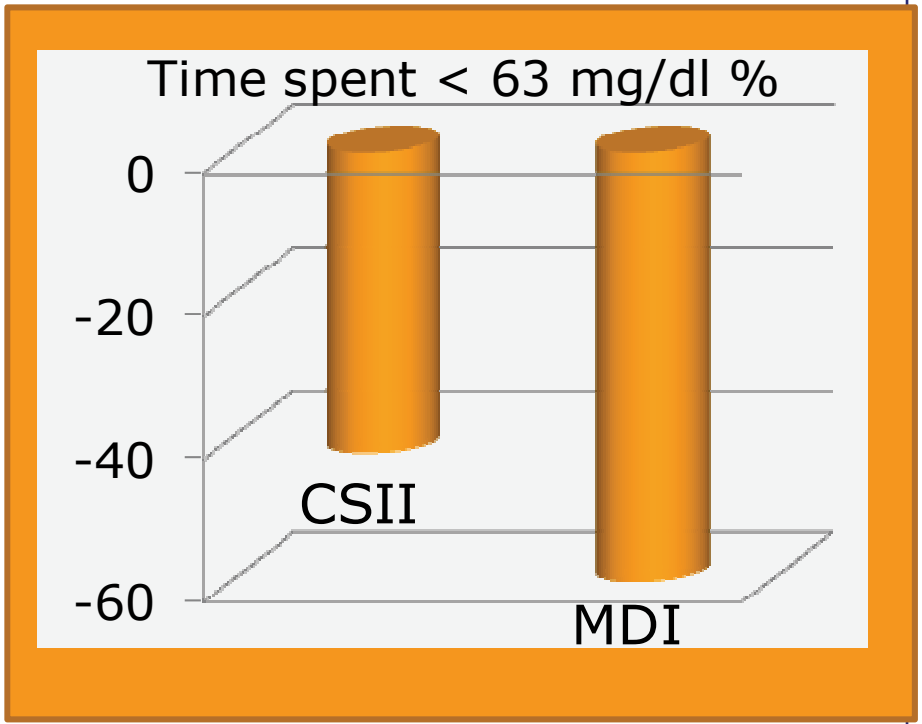
Figure 1—*Combined A1C and hypoglycemia outcomes. Four outcomes are shown: A, combined outcome of A1C improved by ≥0.3% from baseline to 26 weeks and no severe hypoglycemic events; B, combined outcome of A1C improved by ≥0.3% from baseline to 26 weeks and CGM-measured hypoglycemia (≤70 mg/dl) not increased from baseline to 26 weeks by ≥43 min/day (3% of the day); C, combined outcome of A1C not worse by ≥0.3% and CGM-measured hypoglycemia (≤70 mg/dl) decreased from baseline to 26 weeks by ≥43 min/day (3% of the day); D, combined outcome of either B or C.*

JUVENILE DIABETES RESEARCH FOUNDATION
CONTINUOUS GLUCOSE MONITORING
STUDY GROUP*

129 pts
Aged 8-69 years
HbA1c < 7 %
26 wks RCT

Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes

Tadej Battelino, MD, PhD[1]
Moshe Phillip, MD[2]
Natasa Bratina, MD, PhD[1]
Revital Nimri, MD[2]
Per Oskarsson, MD, PhD[3]
Jan Bolinder, MD, PhD[3]



Diabetes Care April 2011 34:795

RCT, multicenter study,.
-120 children and adults on intensive therapy for type 1 diabetes and HbA1c < 7.5%
-Randomly assigned to:

Control group performing conventional SMBG (5.3 ± 2.2/day) and wearing a masked CGM every 2nd week for five days

Active Group with real-time continuous glucose monitoring.

The primary outcome was the time spent in hypoglycemia (interstitial glucose concentration < 63 mg/dL) over a period of 26 weeks.

CGM Vs Fingerpricks

References	Primary Outcome	Active Group CGM	Control Group SMBG	Who Won?
D. Deis et al. Diabetes Care 2006	HbA1c	4.6 ± 1.4	5.0 ± 1.5 5.1 ± 1.8	CGM
JDRF, NEJM 2009	HbA1c	Adults: 6.5 ± 2.3 Adol: 5.6 ± 2.1 Ped: 6.7 ± 2.1	6.6 ± 2.2 6.1 ± 2.6 7.1 ± 2.5	CGM
Batalino T et al. Diabetes Care 2011	Time Spent in Hypo	5.1 ± 2.5	5.3 ± 2.2	CGM
Garg S et al. Diabetes Care 2006	Time Spent in Hypo	6+2	6+2	CGM

Sensor Augmented Pumps (SAPs)

Animas Vibe

Medtronic Veo

Accucheck Combo + Dexcom G4

Sensor Augmented Pumps (SAPs) STAR 3 (NEJM 2010: 363: 311-320)

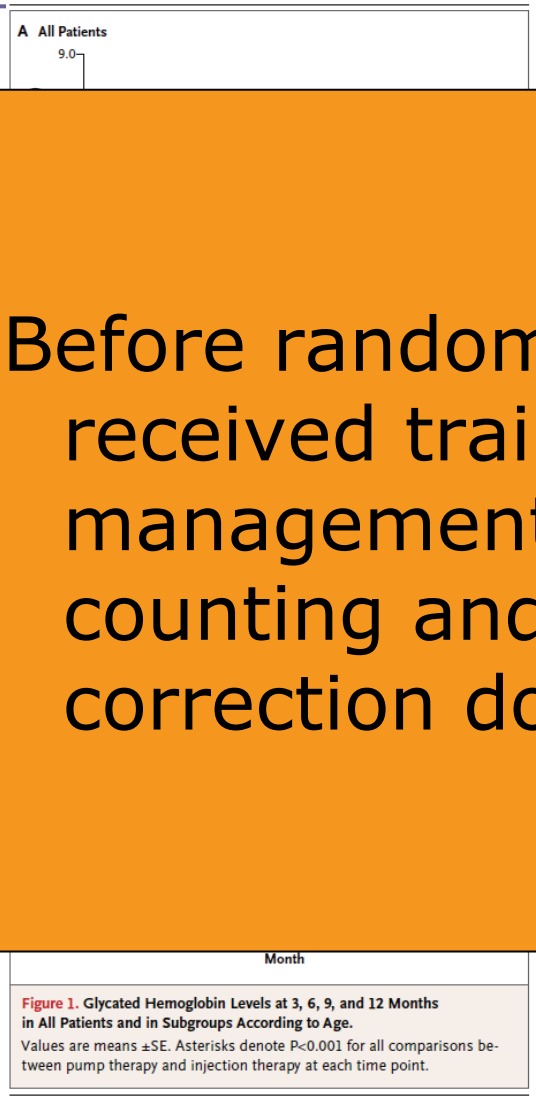


Figure 1. Glycated Hemoglobin Levels at 3, 6, 9, and 12 Months in All Patients and in Subgroups According to Age.
Values are means ±SE. Asterisks denote P<0.001 for all comparisons between pump therapy and injection therapy at each time point.

Bergenstal RM, et al.

Before randomization, all patients received training in intensive diabetes management, including carbohydrate counting and the administration of correction doses of insulin

communication with clinicians was initiated at the discretion of the patient.

Sensor-augmented pump therapy lowers HbA_{1c} in suboptimally controlled Type 1 diabetes; a randomized controlled trial

DIABETICMedicine

J. Hermanides, K. Nørgaard*, D. Bruttomesso†, C. Mathieu‡, A. Frid§, C. M. Dayan¶,
P. Diem**, C. Fermont††, J. M. F. Wentholt, J. B. L. Hoekstra and J. H. DeVries

In conclusion, these study results show that, as compared with MDI, SAP treatment in patients who are motivated but with suboptimally controlled Type 1 diabetes results in a considerable HbA1c reduction and improvement in quality of life, without increasing hypoglycaemia. The magnitude of the difference in change in HbA1c of 1.11% may be attributable to the combined effect of pump, sensor, Bolus Wizard and the process of starting sensor-augmented insulin pump therapy in this hard-to-reach population.

patient-reported outcomes were assessed.

HTA reports, HSs and systematic reviews rtCGM

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Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data

John C Pickup *professor of diabetes and metabolism*[1], Suzanne C Freeman *medical statistics student*[2 3], Alex J Sutton *professor of medical statistics*[2]

Conclusions Continuous glucose monitoring was associated with a significant reduction in HbA_{1c} percentage, which was greatest in those with the highest HbA_{1c} at baseline and who most frequently used the sensors. Exposure to hypoglycaemia was also reduced during continuous glucose monitoring. The most cost effective or appropriate use of continuous glucose monitoring is likely to be when targeted at people with type 1 diabetes who have continued poor control during intensified insulin therapy and who frequently use continuous glucose monitoring.

BMJ 2011;343:d3805 doi: 10.1136/bmj.d3805

REVIEW | Annals of Internal Medicine

Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus

A Systematic Review and Meta-analysis

Hsin-Chieh Yeh, PhD; Todd T. Brown, MD, PhD; Nisa Maruthur, MD, MHS; Padmini Ranasinghe, MD, MPH; Zackary Berger, MD, PhD; Yong D. Suh, MBA, MSc; Lisa M. Wilson, ScM; Elisabeth B. Haberl, BA; Jessica Brick, MD; Eric B. Bass, MD, MPH; and Sherita Hill Golden, MD, MHS

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Table 2. **Summary of the Subgroup Analyses in the Between-Group Change From Baseline HbA_{1c} Among Patients With T1DM Comparing rt-CGM with SMBG**

Analysis	Studies Included (Participants Included), *n* (*n*)	Mean Difference in HbA_{1c} (95% CI), %	I^2, %
All studies*	8 (1066)†	−0.26 (−0.33 to −0.19)	66.6
Adults ≥18 y‡	3 (312)§	−0.38 (−0.53 to −0.23)	77.3
Children <18 y‖	5 (434)¶	−0.13 (−0.27 to 0.01)	46.0
Adherence >60%	7 (705)**	−0.36 (−0.44 to −0.27)	40.8

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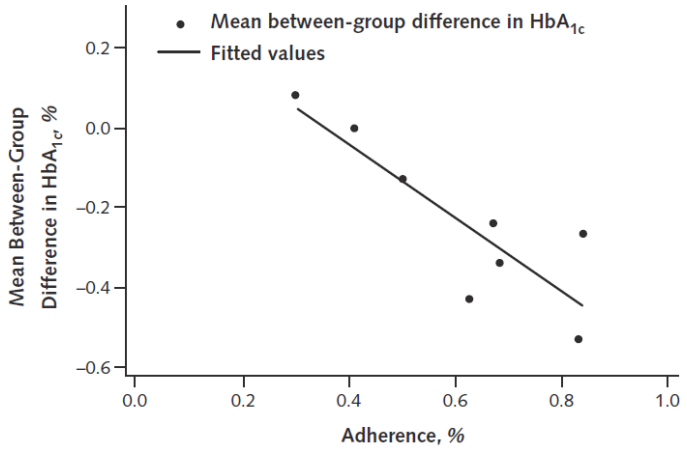
Appendix Figure 2. Adherence with sensor use and mean between-group difference between rt-CGM and SMBG in HbA_{1c} changed from baseline.



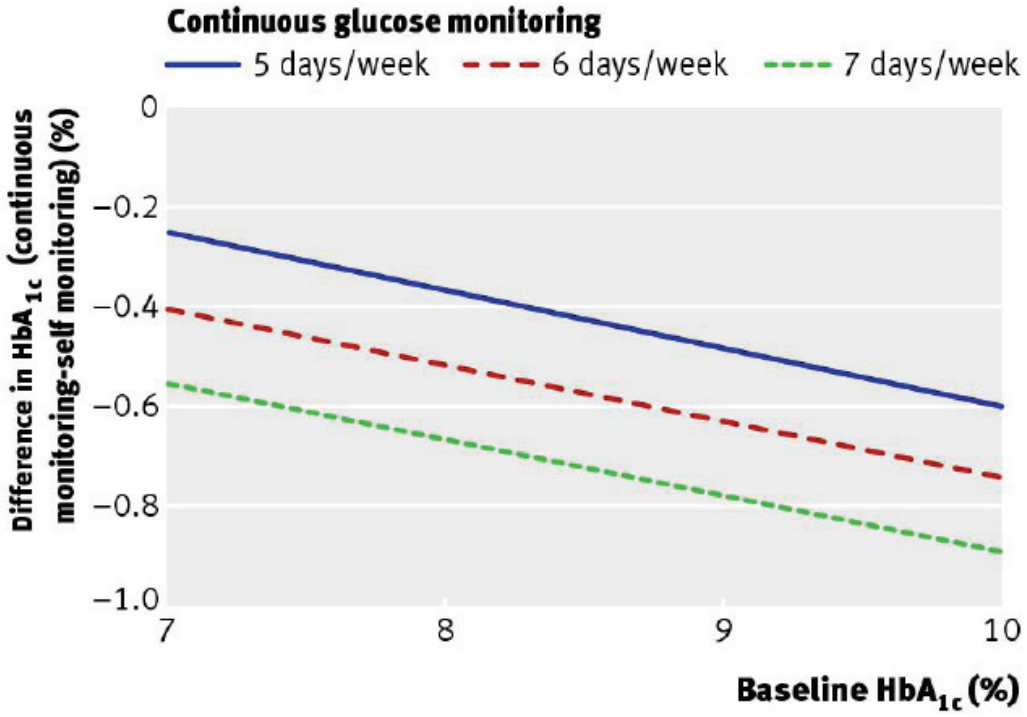
HbA_{1c} = hemoglobin A_{1c}; rt-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose.

Figure Legend:

Adherence with sensor use and mean between-group difference between rt-CGM and SMBG in HbA_{1c} changed from baseline. HbA_{1c} = hemoglobin A_{1c}; rt-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose.

Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data

John C Pickup *professor of diabetes and metabolism*[1], Suzanne C Freeman *medical statistics student*[2 3], Alex J Sutton *professor of medical statistics*[2]



BMJ 2011;343:d3805 doi: 10.1136/bmj.d3805

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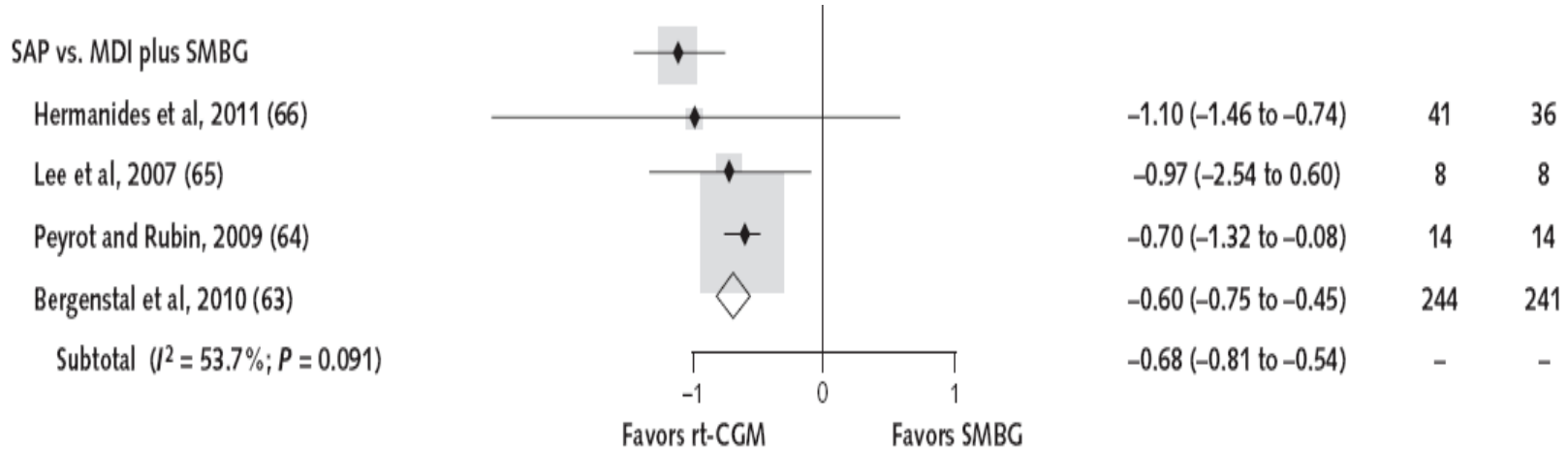
HbA1c



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	rt-CGM vs. SMBG		SAP vs. MDI	
	Adults and Children With T1DM		Adults and Children With T1DM	
	Findings	Strength of Evidence	Findings	Strength of Evidence
HbA_{1c}	Favors rt-CGM	High	Favors pump	Moderate
Hyperglycemia	Favors rt-CGM	Moderate	Favors pump	Moderate
Severe hypoglycemia	No difference	Low§	No difference	Moderate

Hypoglycaemia: From DCCT to Star3 …….Something Happened

	Star 3		DCCT
All Patients	SAP	MDI	Intesive Arm
SH rate 100 persons/year	- 80 %!!!		62
HbA1c at the end of the Study	7.5 % (p< 0.001	8.1 %	%
Children			
SH rate 100 Children/year	8.9 P = NS	5.0	85.7
HbA1c at the end of the Study	7.9 % (p< 0.001)	8.5 %	8.1 %

Conclusions

- Our findings indicate that rt-CGM is superior to SMBG in lowering HbA1c levels without increasing the risk for severe hypoglycemia in persons with type 1 diabetes mellitus, particularly those who are adherent to the monitoring device. Even though CSII and MDI without rt-CGM have similar effects on HbA1c levels, addition of rt-CGM to CSII is superior to MDI and SMBG in decreasing HbA1c levels. Thus, the addition of this monitoring method to SMBG and intensive insulin therapy can assist in achieving glycemic targets in type 1 diabetes mellitus.

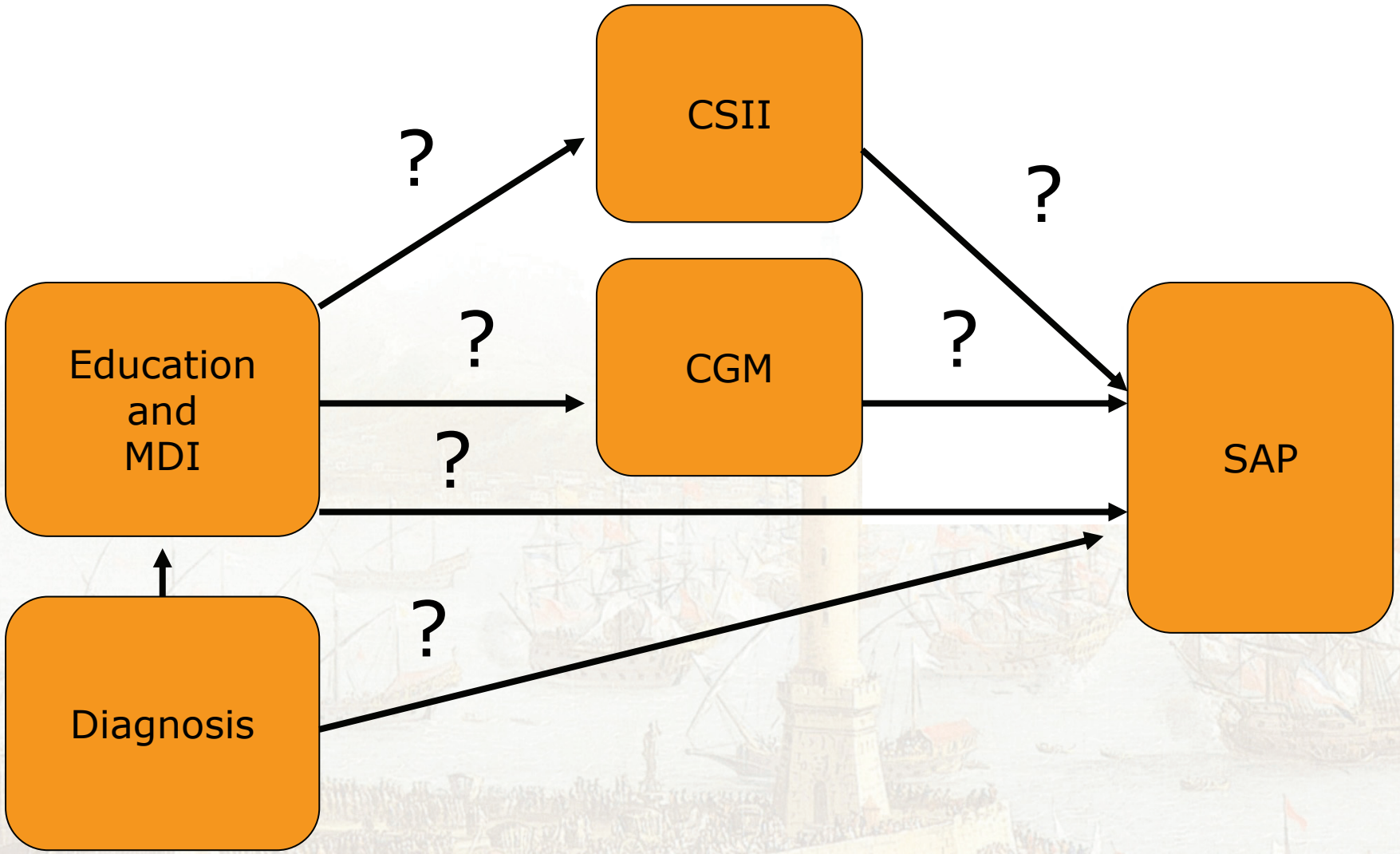
http://www.siditalia.it/documenti/2010_linee_guida.pdf

- Il monitoraggio glicemico continuo (CGM) nei diabetici di età superiore ai 25 anni in terapia insulinica intensiva è uno strumento utile per ridurre l'HbA_{1c}. (**Livello della prova I, Forza della raccomandazione B**)

- Il CGM può essere di utilità nel ridurre l'HbA_{1c} in diabetici tipo 1 in altre classi di età, in particolare nei bambini e comunque nei soggetti che dimostrano una buona aderenza all'utilizzo continuativo dello strumento. (**Livello della prova II, Forza della raccomandazione B**)

- Il CGM può contribuire a ridurre le ipoglicemie e può essere utile nel trattamento di soggetti proni all'ipoglicemica o con sindrome da ipoglicemia inavvertita. (**Livello della prova VI, Forza della raccomandazione B**)

Type 1 Diabetes Treatment Algorithm



The American Diabetes Association (ADA 2012)

- "Continuous Glucose Monitoring (CGM) used in conjunction with intensive insulin regimens can be a useful tool to lower HbA1c level in selected adults (age ≥25 years) with type 1 diabetes. (A)"
- "Although evidence for improvement of HbA1c is weaker in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)"
- "CGM may be a supplemental tool to SMBG in those patients with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)"
- ADA evidence grading system for clinical practice recommendations; level of evidence ranges from high to low where: A, Clear evidence from well-conducted, generalizable, randomized controlled trials; B, Supportive evidence from well-conducted cohort studies; C, Supportive evidence from poorly controlled or uncontrolled studies; E, Expert consensus or clinical experience.

American Diabetes Association. Standards of medical care in diabetes--2012. *Diabetes Care* 2012 January;35 Suppl .

FRANCE: Haute Autorité de Santé (HAS) opinion on Guardian® RT and Guardian® REAL-Time (2007)

- Indication: T1DM patients with HbA1c ≥ 8.1% despite well conducted intensive insulin therapy including CSII or MDI. Guardian RT should be reserved for patients having already received education and training on intensive insulin therapy.
- …
- Follow up: After 3 months utilization of Guardian® RT, it is necessary to re-evaluate each patient to check if the Guardian® RT enabled a significant reduction in HbA1c. If not, utilization of the device should be discontinued

HAS. Avis de la Commission d'évaluation des produits et prestations; GUARDIAN RT. *HAS* 2007;Available at: URL: http://www.has-sante.fr/portail/jcms/c_495944/guardian-rt.

Swedish Guidelines (2008)

- Indications
  - Hypoglycemia: 2 or more episodes of severe hypoglycemia in a year requiring help from another person.
  - HbA1c: persistently high HbA1c (>8%*(Swedish scale) in cases where optimized insulin therapy has not been effective.
  - Diabetes that is difficult to manage - Children with ≥10 medically required plasma glucose tests (SMBG)/24h which are medically justified in order to achieve acceptable HbA1c and avoid episodes of severe hypoglycemia.
- Follow-up
  - An agreement for a maximum of 3 months continuous use must always be made with the patient or family, stating the indication for treatment and the expected goal.
  - After use, there should be an evaluation of whether CGM had the desired effect in that particular individual; if not, CGM will be discontinued.
  - At clinic level, the use of CGM should be monitored and recorded via the national diabetes register (NDR) and SWEDIABKIDS.

* Swedish scale for HbA1c is approximately 1 percent-unit lower than the international scale.

Diabetolog Nytt. Riktlinjer för kontinuerlig mätning av vävnadsglukos vid diabetes mellitus. *Diabetolog Nytt* 2007;Available at: URL: http://diabetologNytt.se/extra/artikel4.html.