Microinfusori: stato dell'arte e linee-guida

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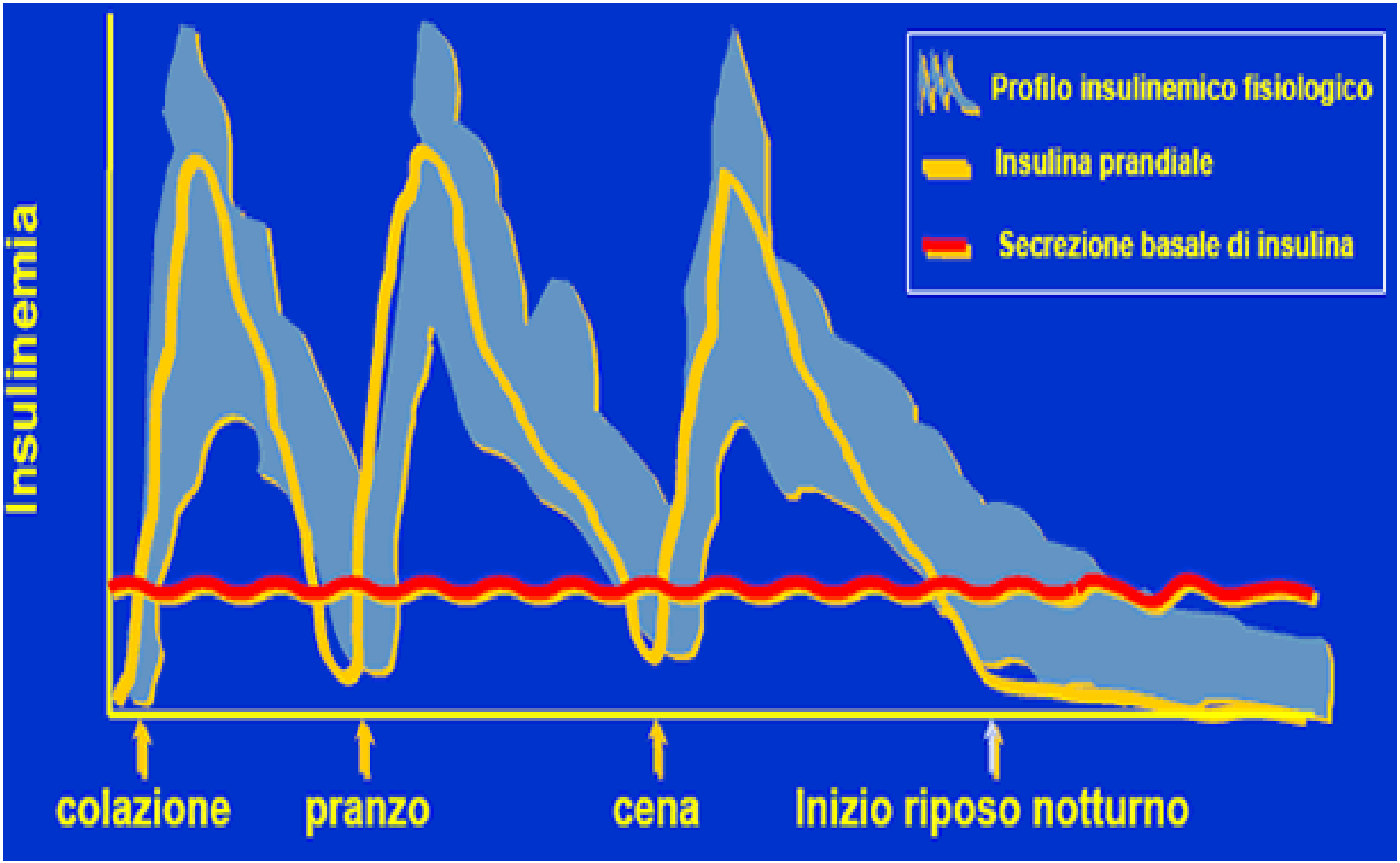
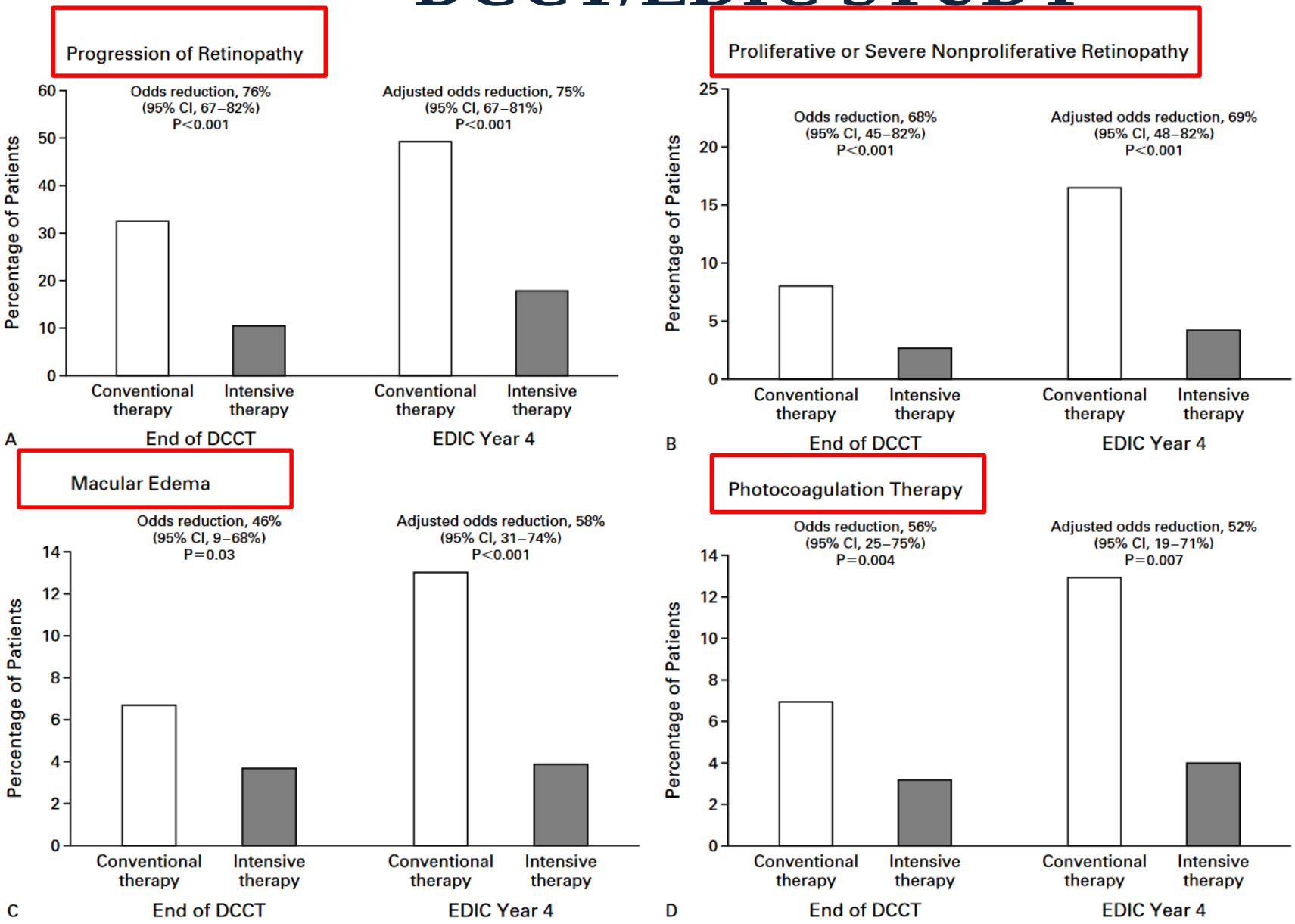
Microinfusori…….

esigenza oppure optional ???

SECREZIONE INSULINICA FISIOLOGICA

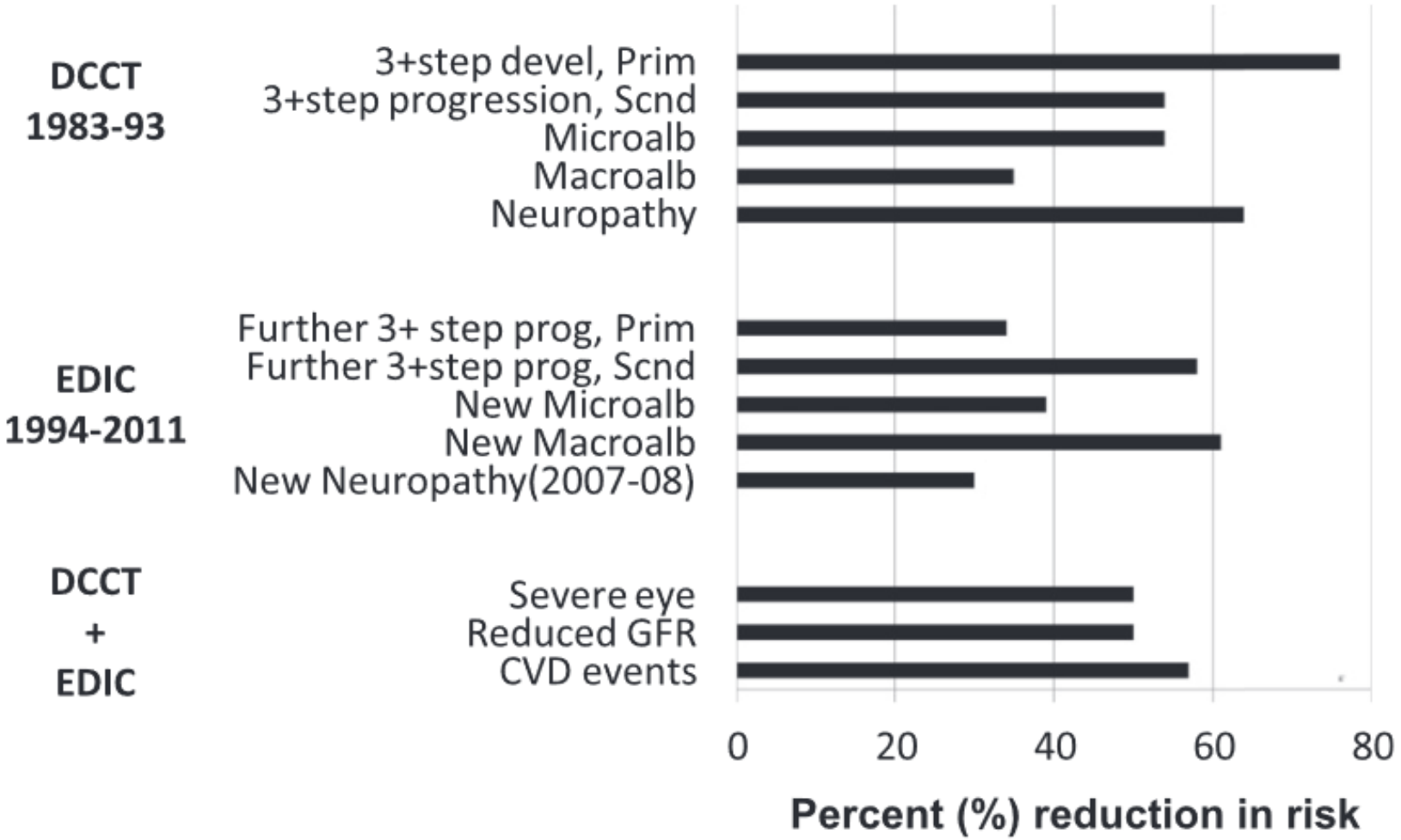


DCCT/EDIC STUDY



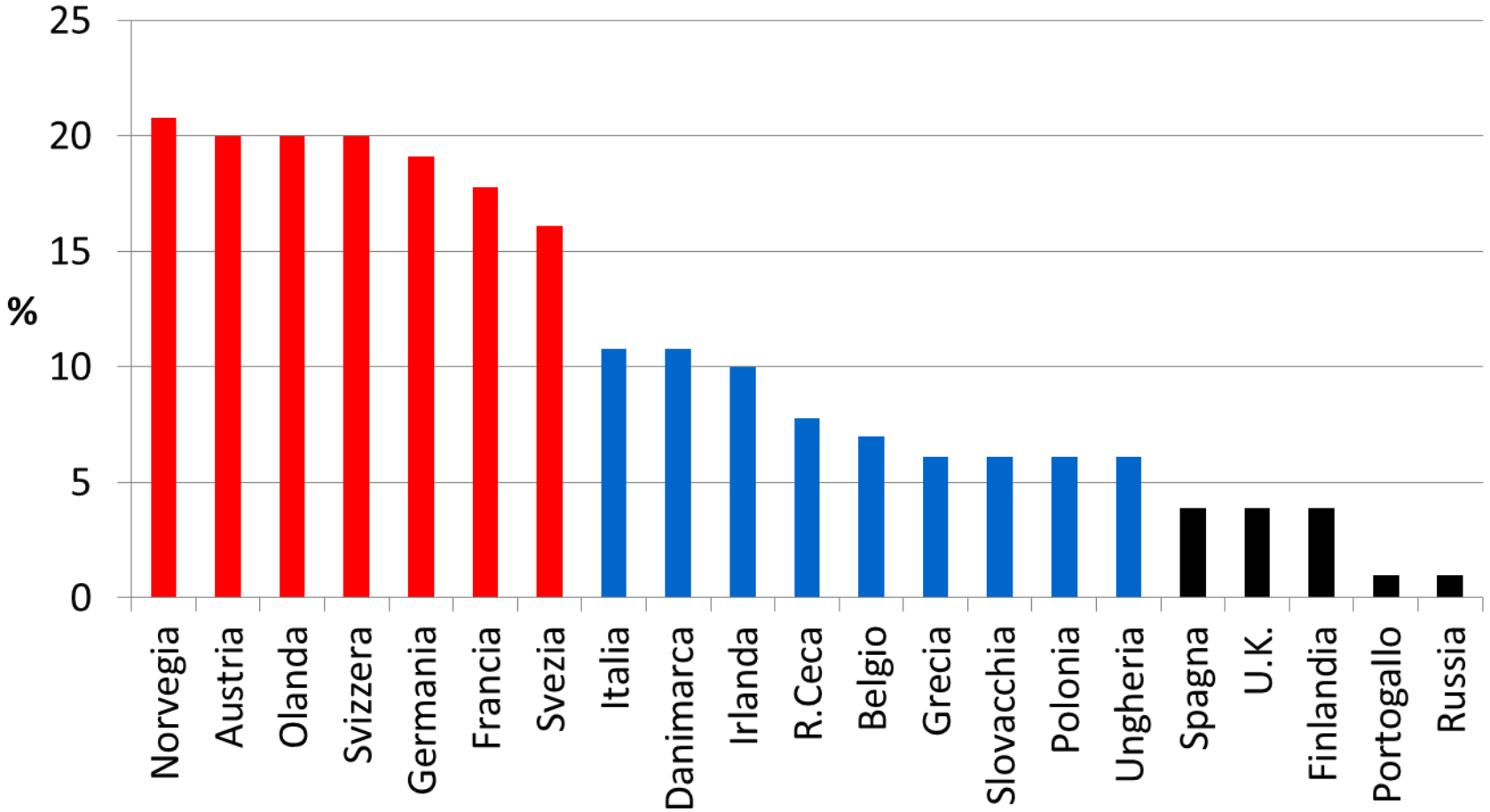
N Engl J Med 2000;342(6):381-9

DCCT/EDIC STUDY: 30 YEARS FOLLOW-UP



Nathan et al Diabetes 2013;62:3976-3986

DIFFUSIONE CSII IN EUROPA (DMT1)



E. Renard: Insulin Pump Use in Europe – Diab Techn & Ther 12 (Suppl.1), 2010

Classificazione dei medical device e requisiti per l'approvazione sul mercato

In **USA** l'FDA classifica:
microinfusori come Classe II (rischio moderato)
microinfusori in sistema integrato come Classe III (rischio alto).

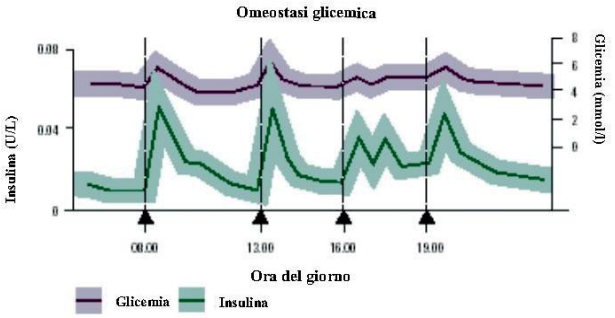
Per la Classe II non sono necessari studi clinici, occorrono solo study "human factors" che verificano che gli utilizzatori delle pompe siano in grado di comprendere ed utilizzare le caratteristiche dei micro.

Per la Classe III sono necessari studi di efficacia e sicurezza ed il superamento di un apposito processo pre-market.

In **Unione Europea** i micro sono classificati come classe IIb.
Vi sono degli Enti che rilasciano il marchio CE.

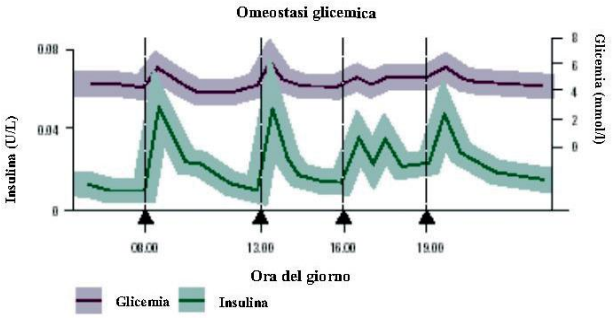
MICROINFUSORI: STATO DELL'ARTE

- I microinfusori attuali hanno diverse caratteristiche:
  - Display a colori
  - Cartucce di insulina pre-riempite
  - Diversi set di infusione
  - Diverse lunghezze di catetere
  - Assenza di catetere
  - Possibilità di interfaccia con sensori glicemici
- Aumentata accessibilità alla terapia → aumentato utilizzo del microinfusore.



CARATTERISTICHE CSII componente basale

- Modalità di insulinizzazione fisiologica
- Uso esclusivo di insulina rapida
- Assenza di depositi s.c. di insulina
- Possibilità di gestire fabbisogni insulinici molto ridotti
- Flessibilità:
  - Possibilità di variazioni temporanee
  - Disponibilità di schemi alternativi per situazioni ricorrenti



CARATTERISTICHE CSII componente bolus

- **Semplicità di erogazione in ogni situazione**
- **Facilità nella somministrazione di boli aggiuntivi**
- **Disponibilità di tipologie diverse di boli**
- **Disponibilità di diverse velocità di erogazione dei boli**

POTENZIALI VANTAGGI CSII

- Miglior controllo iperglicemia (HbA1c)
- Assorbimento più prevedibile, con minore variabilità
- Minor rischio di ipoglicemia
- Adattabilità a stili di vita diversi
- Relativa liberalizzazione alimentazione
- Complessivamente, miglioramento qualità di vita

Cochrane Library

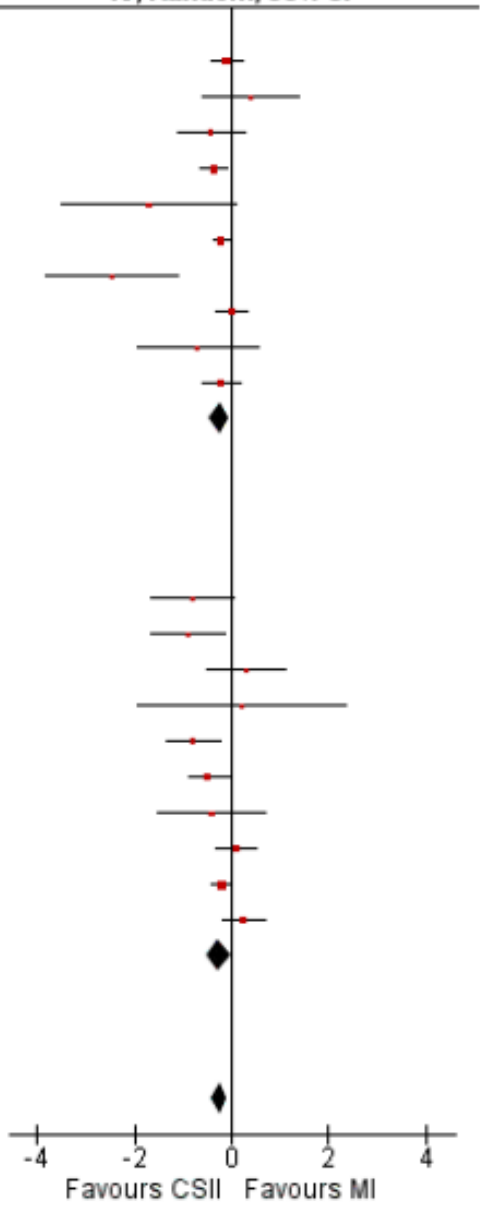
Cochrane Database of Systematic Reviews

Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus (Review)

Misso ML et al Cochrane Database Syst Rev 2010;(1):CD005103.

HbA1c

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
1.1.1 Cross-over trials				
Bruttomesso 2008	-0.1	0.168367	8.3%	-0.10 [-0.43, 0.23]
Chiasson 1984 and 1985	0.4	0.5	2.0%	0.40 [-0.58, 1.38]
Cohen 2003	-0.42	0.35	3.6%	-0.42 [-1.11, 0.27]
Hanaire-Broutin 2000	-0.35	0.14	9.4%	-0.35 [-0.62, -0.08]
Home 1982	-1.7	0.918367	0.7%	-1.70 [-3.50, 0.10]
Hoogma 2005	-0.22	0.08	11.9%	-0.22 [-0.38, -0.06]
Nathan 1982	-2.48	0.704082	1.1%	-2.48 [-3.86, -1.10]
Saurbrey 1988	0	0.16	8.6%	0.00 [-0.31, 0.31]
Schmitz 1989	-0.7	0.632653	1.3%	-0.70 [-1.94, 0.54]
Weintrob 2004	-0.2	0.2	7.1%	-0.20 [-0.59, 0.19]
Subtotal (95% CI)			**54.2%**	**-0.25 [-0.45, -0.05]**
Heterogeneity: Tau² = 0.04; Chi² = 18.61, df = 9 (P = 0.03); I² = 52%				
Test for overall effect: Z = 2.43 (P = 0.02)				
1.1.2 Parallel trials				
DeVries 2002	-0.8	0.433673	2.6%	-0.80 [-1.65, 0.05]
Doyle 2004	-0.9	0.397959	3.0%	-0.90 [-1.68, -0.12]
Lepore 2003	0.3	0.423469	2.7%	0.30 [-0.53, 1.13]
Meschi 1982	0.2	1.091837	0.5%	0.20 [-1.94, 2.34]
Nosadini 1988	-0.8	0.280612	4.9%	-0.80 [-1.35, -0.25]
Nuboer 2008	-0.48	0.214286	6.7%	-0.48 [-0.90, -0.06]
Oslo Study 1985 to 1992	-0.4	0.566327	1.6%	-0.40 [-1.51, 0.71]
Pozzilli 2003	0.1	0.209184	6.8%	0.10 [-0.31, 0.51]
Skogsberg 2008	-0.2	0.112245	10.6%	-0.20 [-0.42, 0.02]
Tsui 2001	0.25	0.221939	6.4%	0.25 [-0.18, 0.68]
Subtotal (95% CI)			**45.8%**	**-0.26 [-0.52, -0.00]**
Heterogeneity: Tau² = 0.08; Chi² = 19.06, df = 9 (P = 0.02); I² = 53%				
Test for overall effect: Z = 1.99 (P = 0.05)				
Total (95% CI)			**100.0%**	**-0.25 [-0.40, -0.10]**
Heterogeneity: Tau² = 0.04; Chi² = 37.68, df = 19 (P = 0.007); I² = 50%				
Test for overall effect: Z = 3.25 (P = 0.001)				



Cochrane Library

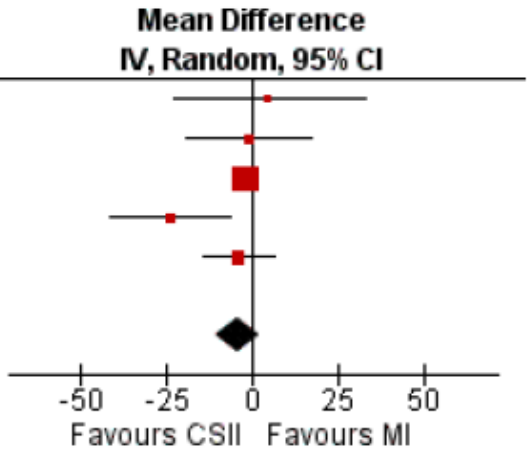
Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus (Review)

Misso ML et al Cochrane Database Syst Rev 2010;(1):CD005103.

Figure 5. Forest plot of comparison: CSII versus MI, outcome: Post prandial blood glucose (mg/dl).

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Botta 1986	4.7	14.30612	4.9%	4.70 [-23.34, 32.74]
Chiasson 1984 and 1985	-1	9.22	10.4%	-1.00 [-19.07, 17.07]
DeVries 2002	-2	1.219388	51.4%	-2.00 [-4.39, 0.39]
Hirsch 2005	-24	8.9	11.0%	-24.00 [-41.44, -6.56]
Weintrob 2004	-4	5.4	22.3%	-4.00 [-14.58, 6.58]
Total (95% CI)			**100.0%**	**-4.44 [-10.91, 2.03]**

Heterogeneity: Tau² = 19.69; Chi² = 6.35, df = 4 (P = 0.17); I² = 37%
Test for overall effect: Z = 1.35 (P = 0.18)



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Cochrane Database of Systematic Reviews

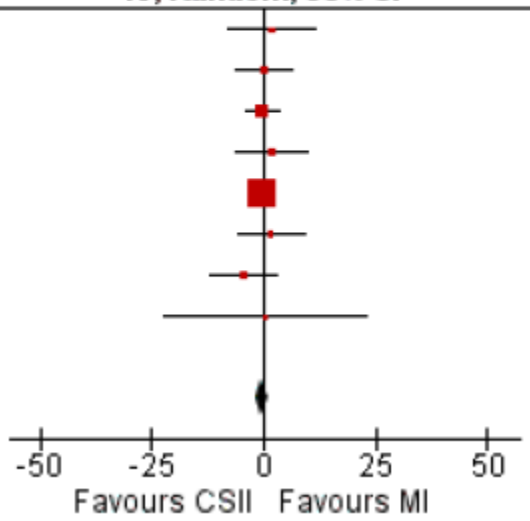
Misso ML et al Cochrane Database Syst Rev 2010;(1):CD005103.

Figure 6. Forest plot of comparison: CSII versus MI, outcome: Weight (kg).

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Bak 1987 and Husted 1989	1.8	4.98	2.7%	1.80 [-7.96, 11.56]
DeVries 2002	0	3.229592	6.5%	0.00 [-6.33, 6.33]
Hanaire-Broutin 2000	-0.3	1.82	20.5%	-0.30 [-3.87, 3.27]
Home 1982	1.9	4.1	4.0%	1.90 [-6.14, 9.94]
Hoogma 2005	-0.5	1.1	56.1%	-0.50 [-2.66, 1.66]
Lepore 2003	1.6	3.821429	4.6%	1.60 [-5.89, 9.09]
Oslo Study 1985 to 1992	-4.6	3.693878	5.0%	-4.60 [-11.84, 2.64]
Schmitz 1989	0.2	11.45	0.5%	0.20 [-22.24, 22.64]
Total (95% CI)			**100.0%**	**-0.37 [-1.98, 1.25]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.10$, $df = 7$ ($P = 0.95$); $I^2 = 0\%$

Test for overall effect: $Z = 0.45$ ($P = 0.65$)



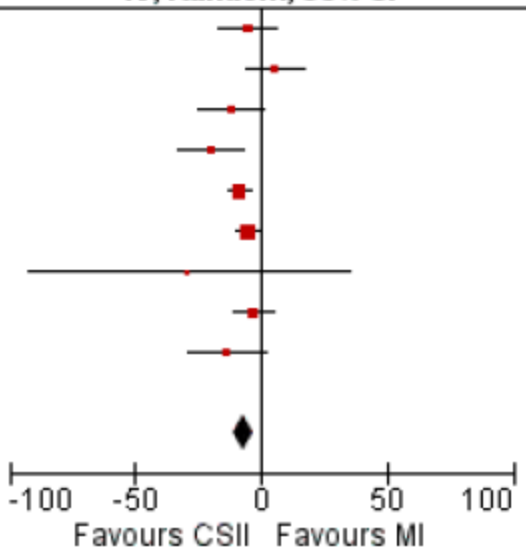
Cochrane Library
Cochrane Database of Systematic Reviews

Misso ML et al Cochrane Database Syst Rev 2010;(1):CD005103.

Figure 7. Forest plot of comparison: CSII versus MI, outcome: Daily insulin requirement (U).

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95% CI
Bak 1987 and Husted 1989	-5.3	5.77	8.7%	-5.30 [-16.61, 6.01]
Botta 1986	5.4	6.05102	8.1%	5.40 [-6.46, 17.26]
Chiasson 1984 and 1985	-12.2	6.57	7.1%	-12.20 [-25.08, 0.68]
DeVries 2002	-19.8	6.596939	7.1%	-19.80 [-32.73, -6.87]
Hanaire-Broutin 2000	-8.8	2.4	24.6%	-8.80 [-13.50, -4.10]
Hirsch 2005	-5.2	2.3	25.3%	-5.20 [-9.71, -0.69]
Home 1982	-29	32.59	0.3%	-29.00 [-92.88, 34.88]
Lepore 2003	-3	4.290816	13.4%	-3.00 [-11.41, 5.41]
Nathan 1982	-13.4	7.831633	5.3%	-13.40 [-28.75, 1.95]
Total (95% CI)			**100.0%**	**-6.98 [-10.77, -3.19]**

Heterogeneity: Tau² = 9.47; Chi² = 11.83, df = 8 (P = 0.16); I² = 32%
Test for overall effect: Z = 3.61 (P = 0.0003)



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Cochrane Database of Systematic Reviews

Misso ML et al Cochrane Database Syst Rev 2010;(1):CD005103.

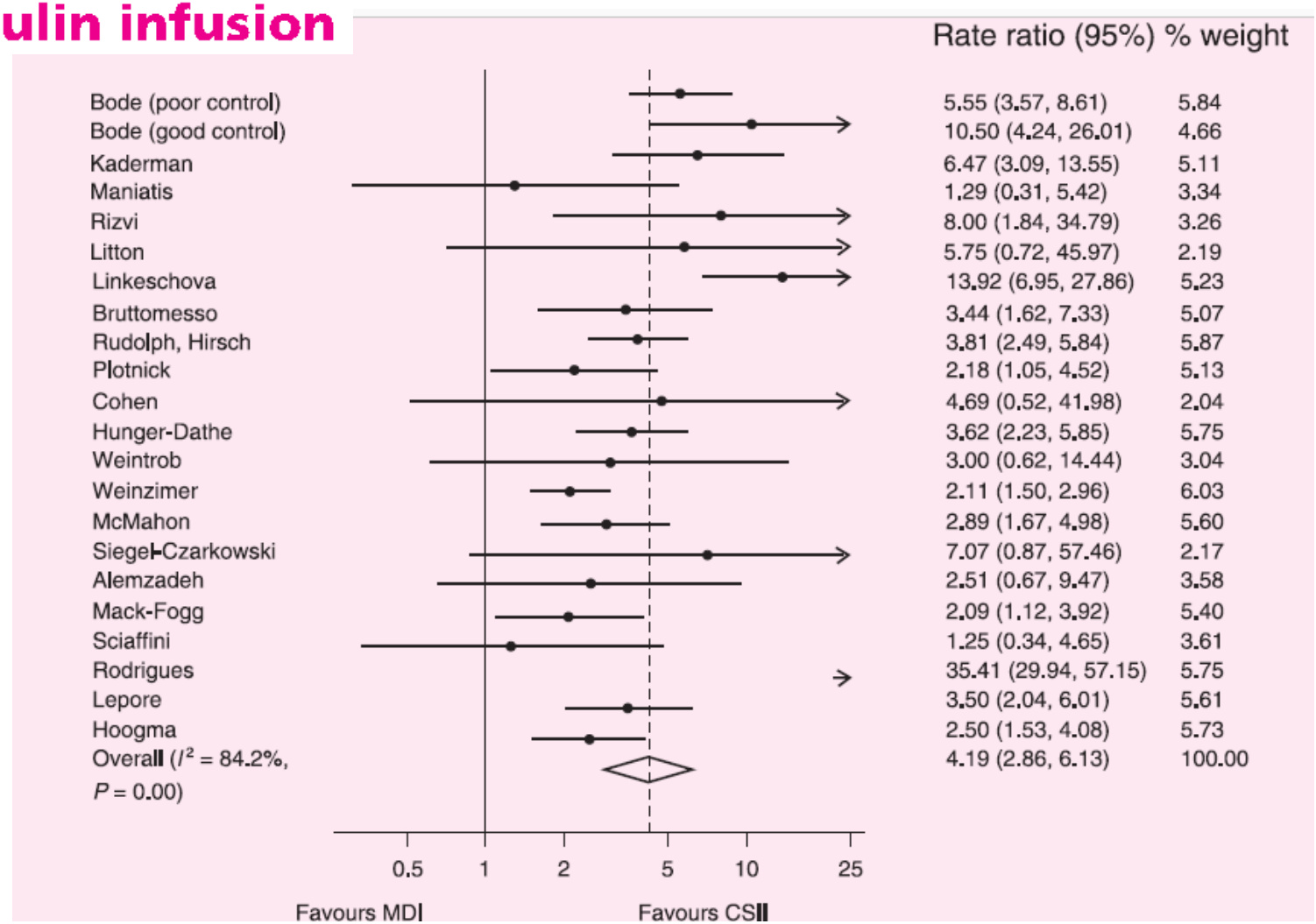
CSII versus multiple insulin injections for type 1 diabetes mellitus

THE COCHRANE COLLABORATION®

Main results

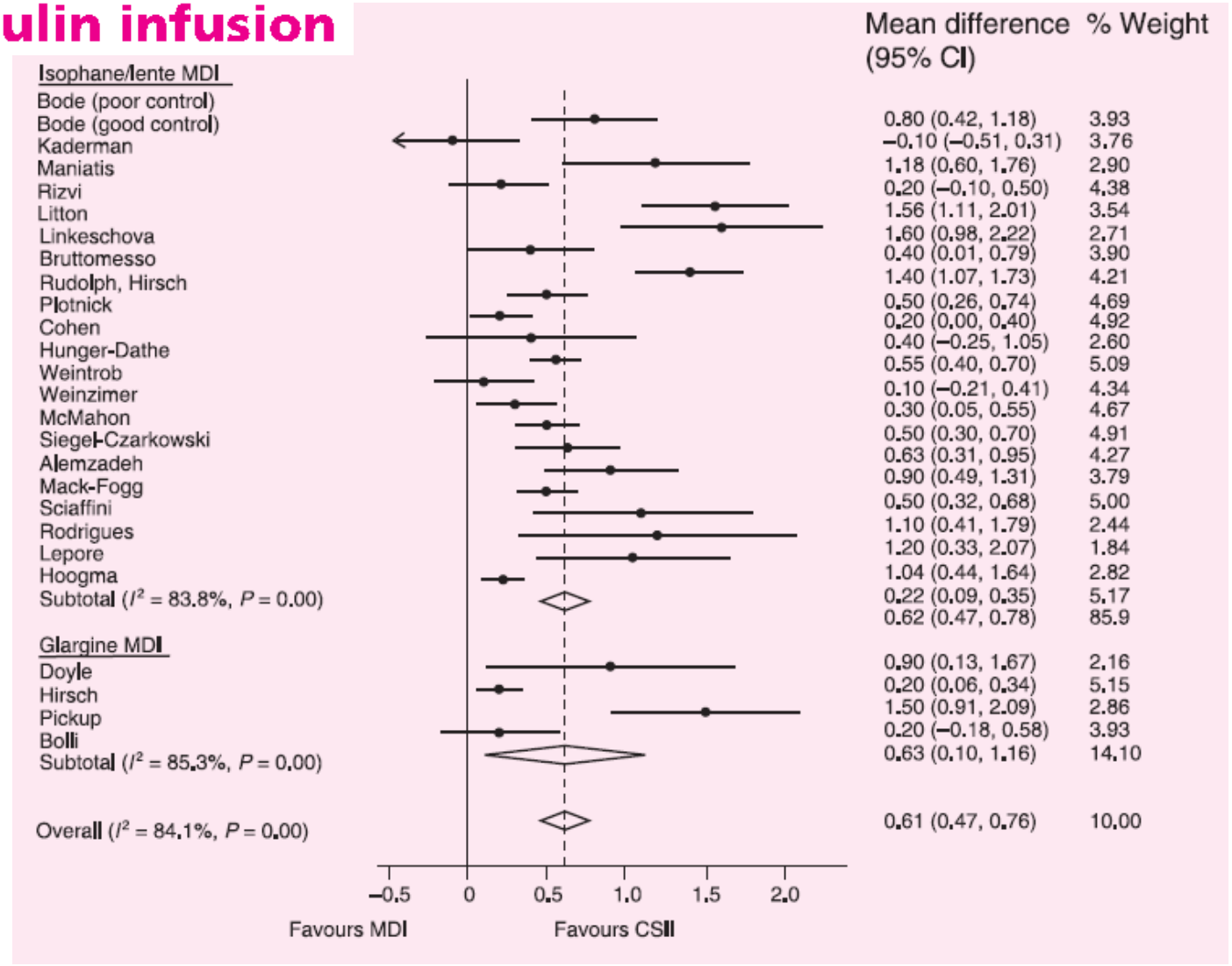
- Twenty three studies randomised 976 participants with type 1 diabetes to either intervention.
- Statistically significant difference in HbA1c favouring CSII (weighted mean difference -0.3%).
- No obvious differences between the interventions for non-severe hypoglycaemia, but severe hypoglycaemia appeared to be reduced in those using CSII.
- Quality of life measures suggest that CSII is preferred over MI.
- No significant difference was found for weight.

Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion



Pickup JC Diabet Med 2008;25(7):765-74

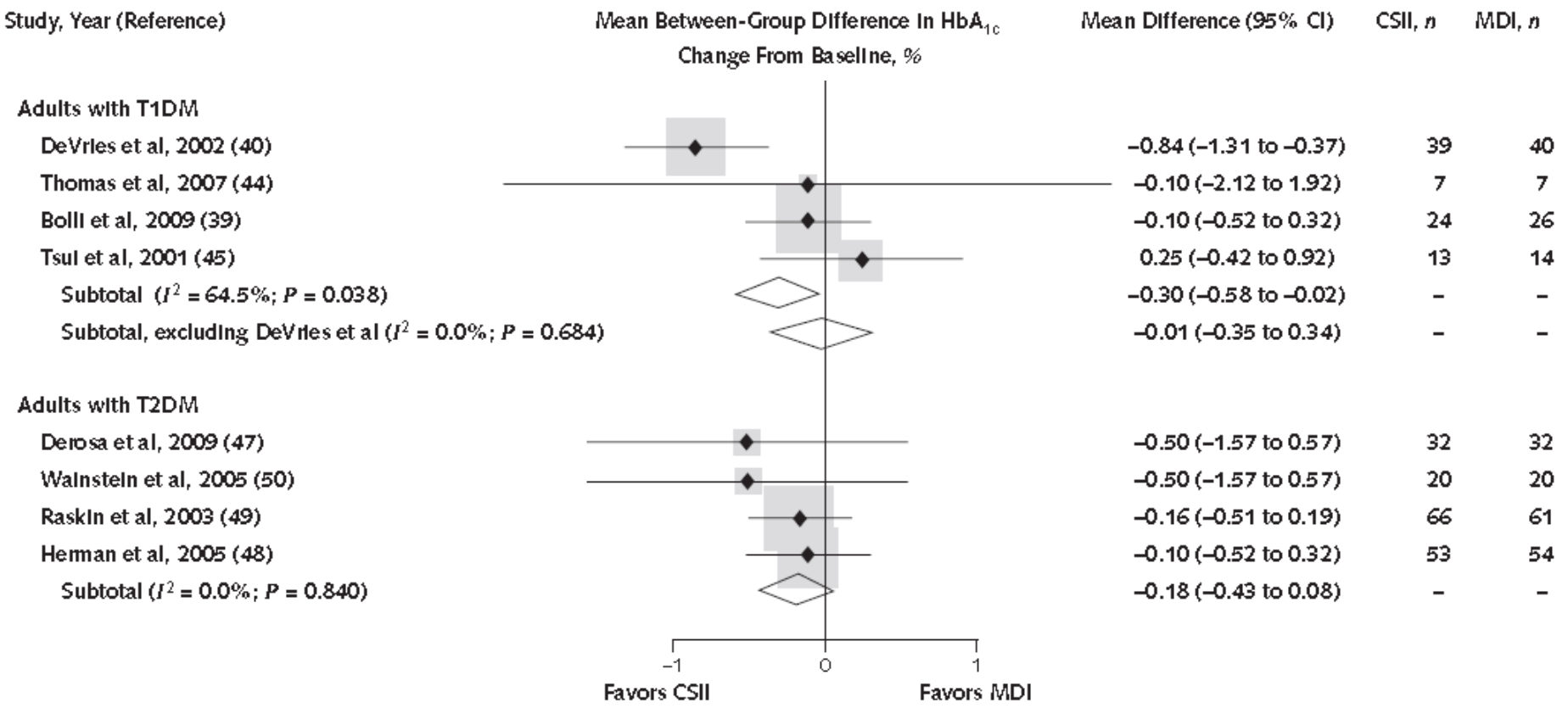
Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion



Pickup JC Diabet Med 2008;25(7):765-74

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

A Systematic Review and Meta-analysis



Yeh HC et al Ann Intern Med 2012;157(5):336-47

Cosa ci dicono le Linee Guida

Standard italiani per la cura del diabete mellito 2016

Una questione di evidenza

Livelli di prova / Prove di tipo	Livello delle raccomandazioni / Forza
I Prove ottenute da più studi clinici controllati randomizzati e/o da revisioni sistematiche di studi randomizzati **II** Prove ottenute da un solo studio randomizzato di disegno adeguato **III** Prove ottenute da studi di coorte non randomizzati con controlli concorrenti o storici o loro metanalisi **IV** Prove ottenute da studi retrospettivi tipo caso-controllo o loro metanalisi **V** Prove ottenute da studi di casistica ("serie di casi") senza gruppo di controllo **VI** Prove basate sull'opinione di esperti autorevoli o di comitati di esperti come indicato in linee-guida o *consensus* conference, o basate su opinioni dei membri del gruppo di lavoro responsabile di queste linee-guida	**A** L'esecuzione di quella particolare procedura o test diagnostico è fortemente raccomandata. Indica una particolare raccomandazione sostenuta da prove scientifiche di buona qualità, anche se non necessariamente di tipo I o II **B** Si nutrono dei dubbi sul fatto che quella particolare procedura o intervento debba sempre essere raccomandata, ma si ritiene che la sua esecuzione debba essere attentamente considerata **C** Esiste una sostanziale incertezza a favore o contro la raccomandazione di eseguire la procedura o l'intervento **D** L'esecuzione della procedura non è raccomandata **E** Si sconsiglia fortemente l'esecuzione della procedura

Standard italiani per la cura del diabete mellito 2016

In soggetti selezionati che, malgrado un regime basal-bolus ottimale, presentino scarso controllo glicemico e/o ipoglicemie ricorrenti, può essere considerata l'indicazione all'uso del microinfusore che deve essere prescritto da parte di un team esperto nel suo utilizzo.
(Livello della prova III, Forza della raccomandazione B)

Nei pazienti già in trattamento con microinfusore (CSII) può essere utile proseguire tale modalità di somministrazione della terapia anche durante il ricovero ospedaliero, purché ne sia possibile la corretta gestione nella specifica situazione clinica.
(Livello della prova VI, Forza della raccomandazione B)

Clinical recommendations in the management of the patient with type 1 diabetes on insulin pump therapy in the perioperative period: a primer for the anaesthetist

Pre-operative Preparation for CSII Patients

Topics for discussion with patient

- Choice of continuation with pump therapy during theatre
- Supply of adequate pump consumables required for entire in-patient stay
- Re-siting of infusion set on the day before surgery and monitor blood glucose
- Position of infusion site (eg. thigh -away from operative field, diathermy and accessibility for anaesthetist)
- Overnight basal assessment before to surgery
- Notification of the diabetes pump team (may not be the local diabetes team)
  - to confirm self-management competencies
  - to optimise basal rates, and glucose control before to surgery
  - to supply plastic infusion sets

Partridge H et al Br J Anaesth 2016;116(1):18-26

Clinical recommendations in the management of the patient with type 1 diabetes on insulin pump therapy in the perioperative period: a primer for the anaesthetist

Perioperative management for CSII

- Assess glucose hourly
- If blood glucose uncontrolled perioperatively-change to an i.v. insulin infusion
- If blood glucose falls to below 4mmol, treat as hypoglycaemia according to local policy
- If hypoglycaemia is recurrent – stop/disconnect the pump and commence an i.v. insulin infusion
- The pump should be disconnected in emergency surgery, if possible with a 30 min overlap with i.v. insulin
- The pump should not be used if screening radiology is required

Post-operative Management for CSII Patients

- Check capillary glucose hourly until the patient is conscious and able to manage the pump themselves
- Advise patients to increase frequency of testing for one to two days after surgery

Partridge H et al Br J Anaesth 2016;116(1):18-26

NICE National Institute for Health and Care Excellence

NICE guidance

Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus

Technology appraisal guidance
Published: 23 July 2008
nice.org.uk/guidance/ta151

Use of CSII restricted to patients who have experienced poor glycaemic control or ‘disabling’ hypoglycaemia when using MDI.

Position Statement

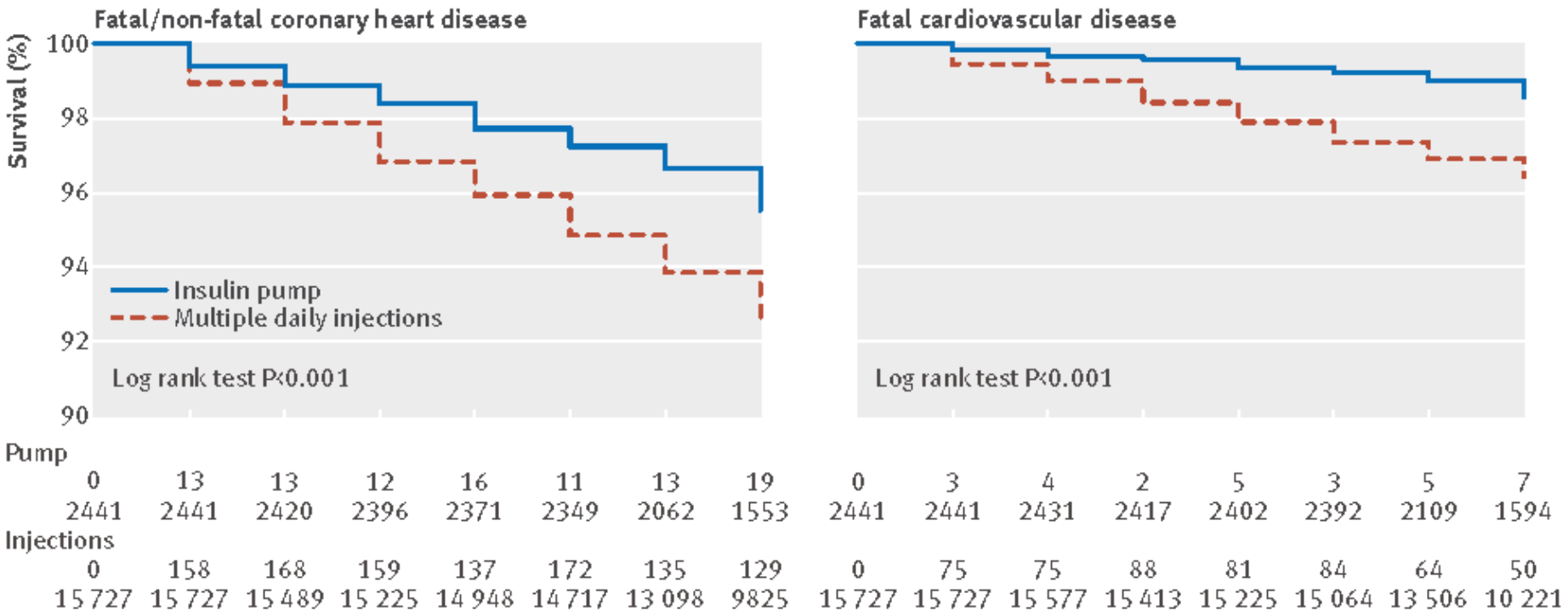
When to treat a diabetic patient using an external insulin pump. Expert consensus. Société francophone du diabète (ex ALFEDIAM) 2009

V. Lassmann-Vague [a,*], S. Clavel [b], B. Guerci [c], H. Hanaire [d], R. Leroy [e], G.A. Loeuille [f], I. Mantovani [g], M. Pinget [h], E. Renard [i], N. Tubiana-Rufi [j]

CSII should be considered in patients who have:

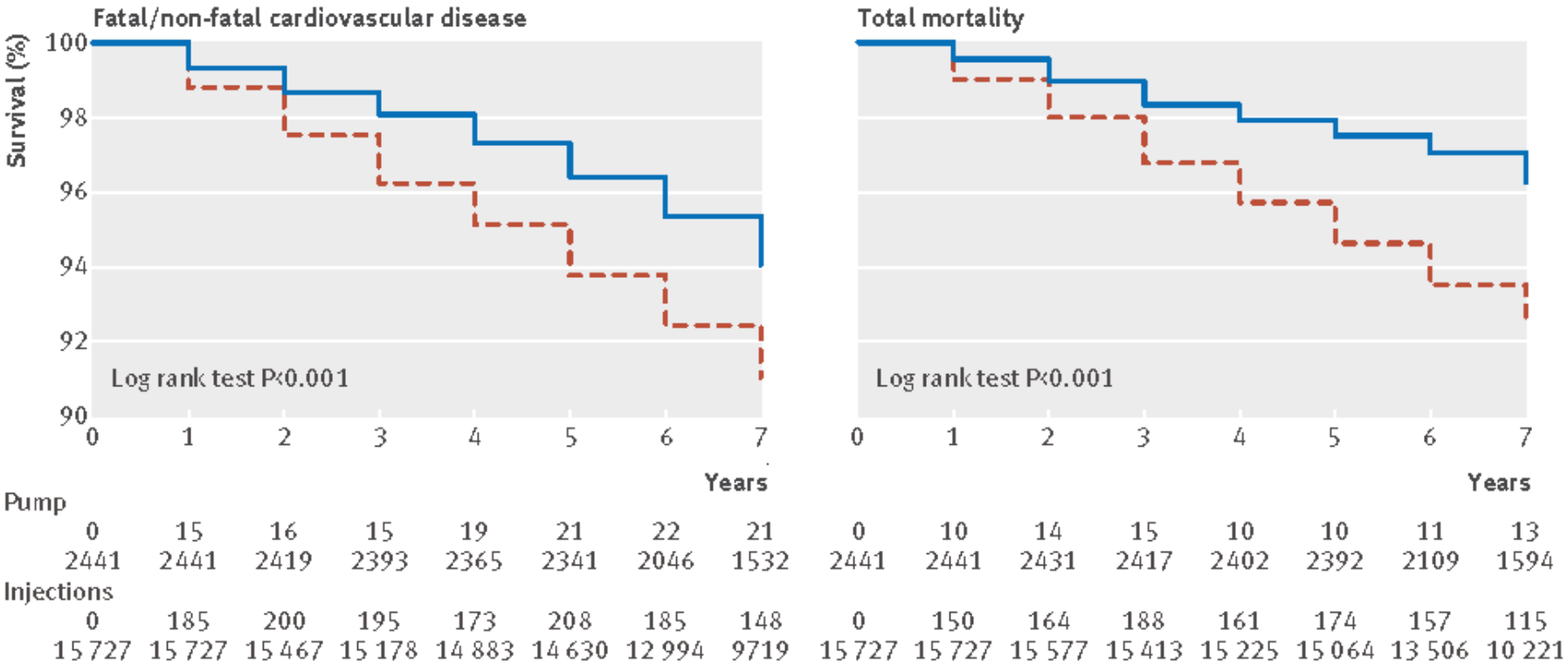
- persistently elevated HbA1c despite intensified MDI
- recurrent hypoglycaemia
- marked glycaemic variability
- variable insulin requirements
- insulin allergy
- experienced a negative impact of MDI on their social or professional life

Insulin pump therapy, multiple daily injections, and cardiovascular mortality in 18 168 people with type 1 diabetes: observational study



Steineck I et al BMJ 2015;350:h3234

Insulin pump therapy, multiple daily injections, and cardiovascular mortality in 18 168 people with type 1 diabetes: observational study



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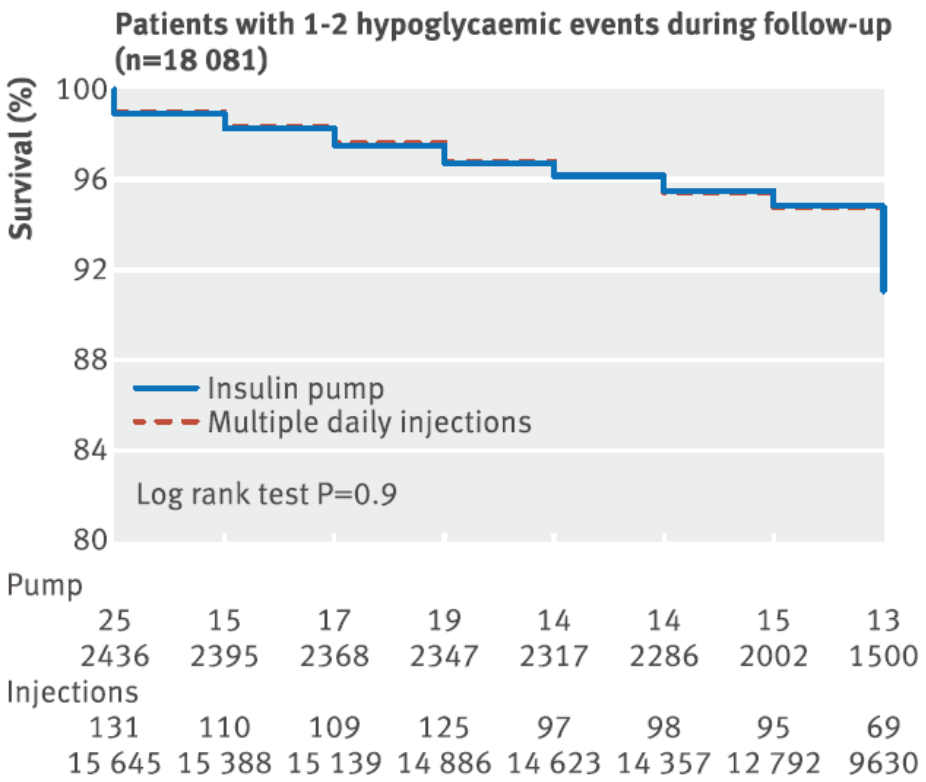
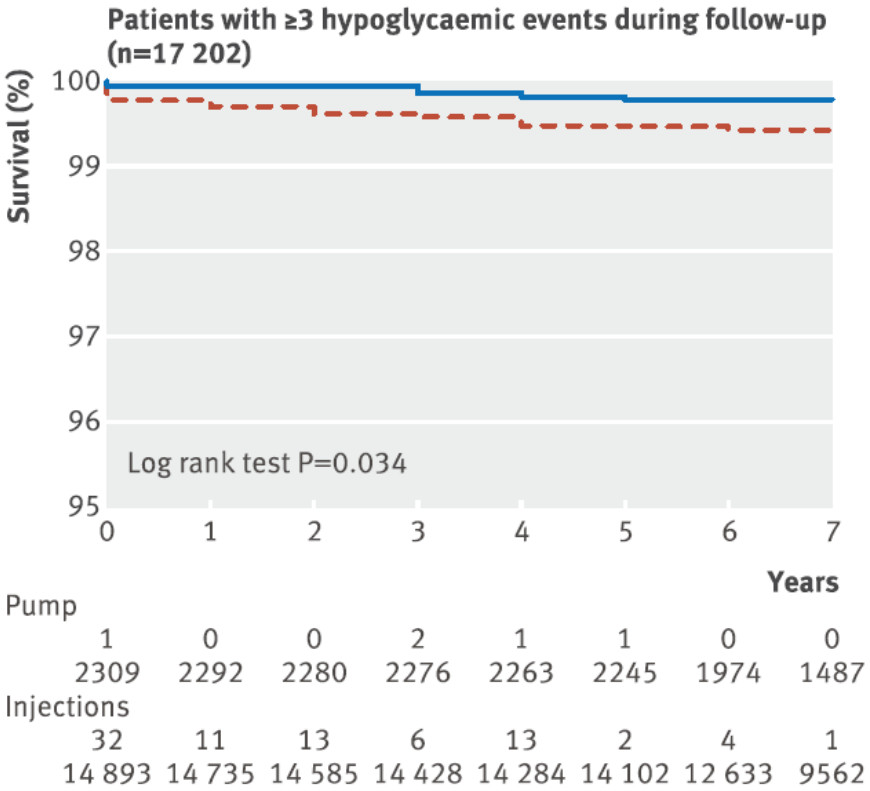
Insulin pump therapy, multiple daily injections, and cardiovascular mortality in 18 168 people with type 1 diabetes: observational study

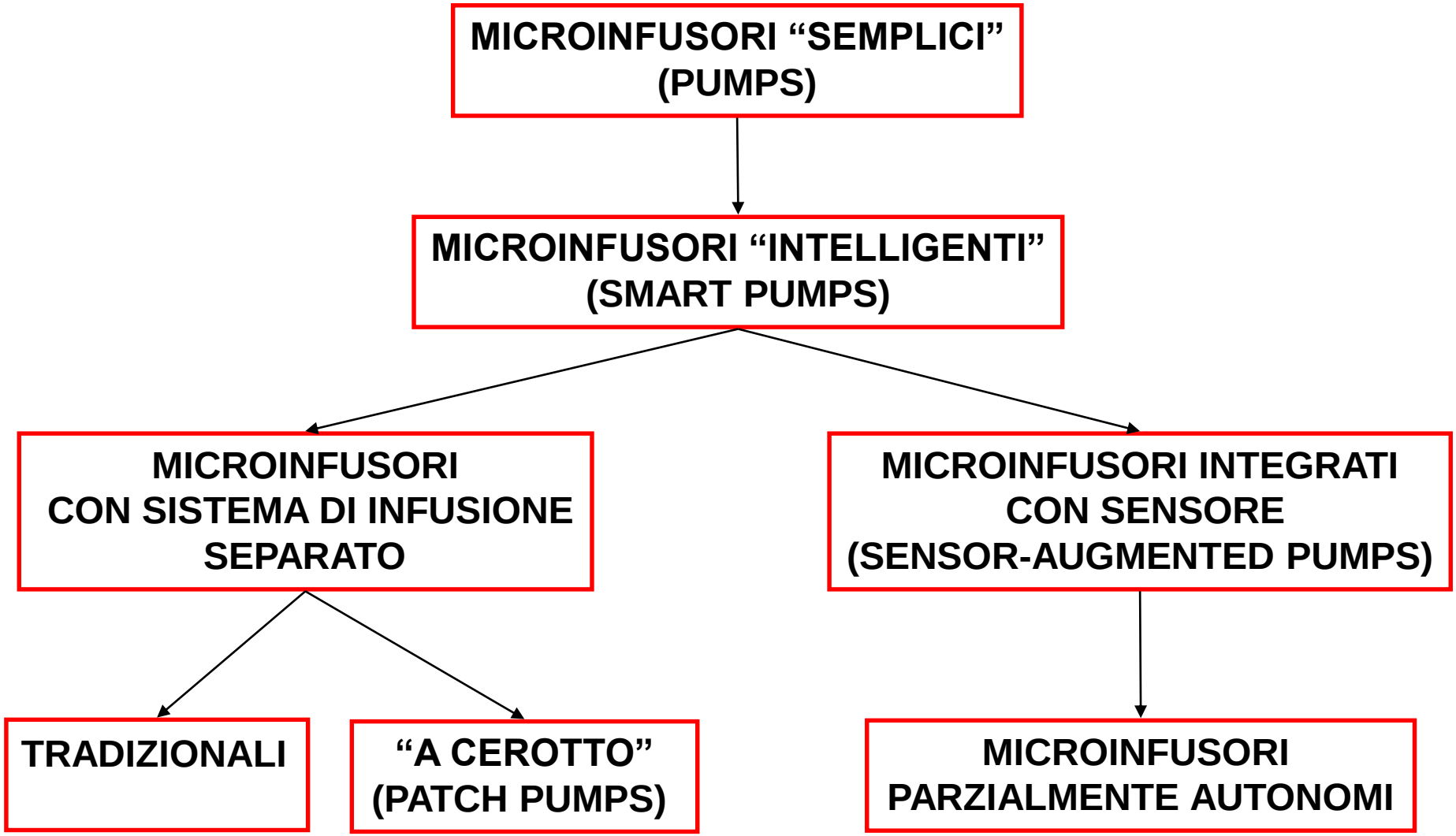




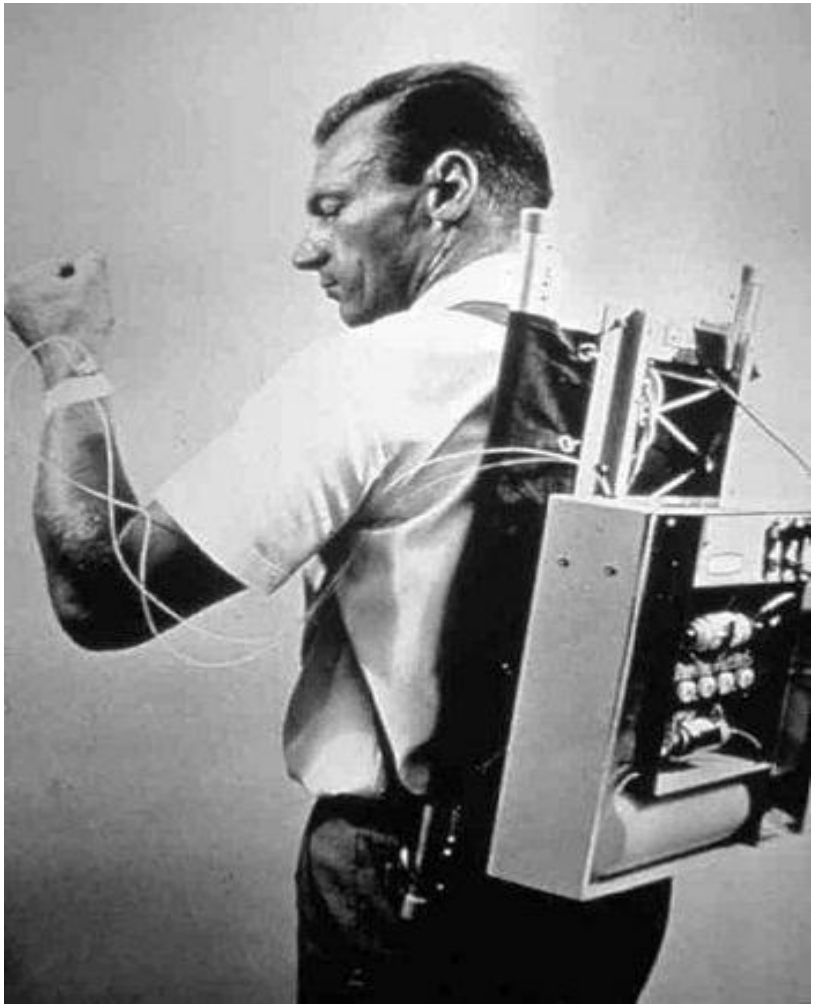
Steineck I et al BMJ 2015;350:h3234

MICROINFUSORI: L'EVOLUZIONE DELLA SPECIE

MICROINFUSORI: L'EVOLUZIONE DELLA SPECIE



Il microinfusore ieri (1960)



anni ‘80

POMPE INTELLIGENTI ("SMART PUMPS")

- **Reminders**
  - Test glicemia (dopo Ipo/Iper - Dopo Bolo insulinico…..)
- **Storia del microinfusore**
  - Boli Insulinici
  - Glicemie
  - Carboidrati Introdotti,…
- **Supporto decisionale** (previa programmazione)
  - Obbiettivi glicemici nelle differenti fasi giornaliere
  - FS personale nelle diverse fasi giornaliere
  - I/CHO personale nelle differenti fasi giornaliere.
  - Suggerimento bolo in base a:
    - glicemia riscontrata all'autocontrollo
    - quantitativo di CHO introdotti con il pasto
    - attività insulinica residua

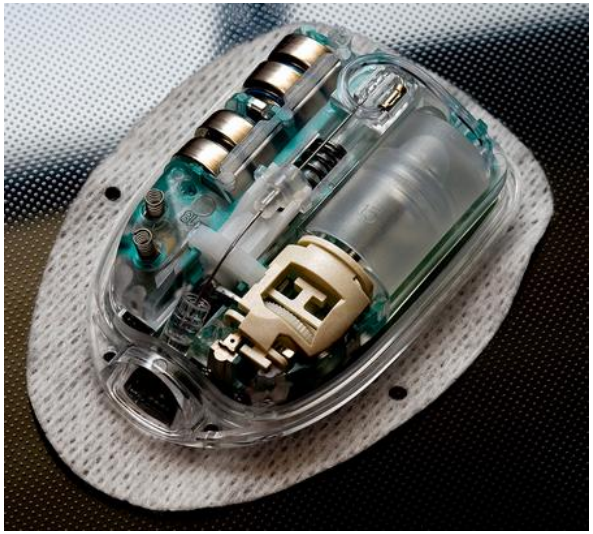
SMART PUMPS


ONETOUCH
ping
10:37am
Last BG
Jun 4-08
7:16pm
109
Alt Bnft
Avg.
7 days
113
OK
10:37AM
Basal Rate
0.025U/Hr
Insulin:177U
Status
OK


ACCU-CHEK®
Aviva Combo
10:02
2 Feb 06
bG Test
Bolus Advice
Pump
My Data
Settings
ACCU-CHEK® Spirit Combo


CONTOUR LINK
05.04
11:45 AM
93
Medtronic
M
10:52
10:52A
24 Hour
93
ACT

PATCH PUMP OMNIPOD



Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Insulet Corp. **OmniPod** 	**Pod:** 1.53 x 2.05 x 0.57 in. 0.88 oz. with empty reservoir **Personal Diabetes Manager (PDM):** 2.4 x 4.4 x 0.98 in. 4.4 oz. with batteries	**Pod:** battery integrated **PDM:** 2 AAA	Pod includes built-in reservoir that holds 200 units.	Does not use tubing. Pod comes with a built-in cannula and automated inserter.	From 0.05 to 30 units per hour in 0.05-unit increments

Insulet Corp.
OmniPod

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.05 to 30 units in increments of 0.05, 0.1, 0.5, or 1 unit. Insulin-to-carb ratio in whole units only.	Yes, PDM contains more than 1,000 common foods (with nutrition information) and stores up to 36 preset carb values.	Yes, a FreeStyle blood glucose meter is built into the PDM.	No	No tubing required: System includes a pod that's worn for up to 72 hours and a PDM that controls the pod's functions (you can't control the pod without the PDM). Pod is waterproof for up to 25 feet deep for 60 minutes, so there's no need to disconnect while swimming or bathing. Seven "skins" are available for PDM personalization. Works with Abbott's CoPilot data management software. Software is compatible with Windows (except Windows 8), but is not Mac compatible.

Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Animas Corp. **Vibe** ew! 	2 x 3.25 x 0.85 in. 3.9 oz. without batteries and with empty reservoir	(1) 1.5-volt lithium AA or 1 AA	200-unit cartridge	Compatible with all standard Luer-lock infusion sets	From 0.025 to 25 units per hour in 0.025-unit increments

Animas Corp.
Vibe

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.05 to 35 units in 0.05-unit increments. Insulin-to-carb ratio in whole units only.	Yes, pump stores up to 500 foods and their nutrition information.	No	Yes, works as an all-in-one pump/CGM.	The Vibe is a pump with built-in CGM technology that uses a sensor to wirelessly transmit continuous glucose readings. (More on its CGM functions on p. 56.) Pump is waterproof for up to 12 feet deep for 24 hours, so there's no need to disconnect while swimming or bathing. Eight pump "skins" are available to customize. Works with Diasend Web-based data management software, which is compatible with Windows and Mac operating systems.

Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Medtronic Diabetes **MiniMed Paradigm Real-Time Revel** 	**Model 523:** 2 x 3.3 x 0.82 in. 3.4 oz. with battery and empty reservoir **Model 723:** 2 x 3.7 x 0.84 in. 3.6 oz. with battery and empty reservoir	1 AAA	**Model 523:** 180-unit reservoir **Model 723:** 300-unit reservoir	Compatible with Medtronic infusion sets only	From 0.025 to 35 units per hour in 0.025-unit increments for up to 0.975 units. Increments of 0.05 units for between 1 and 9.95 units. Increments of 0.1 units for 10 units or more.

Medtronic Diabetes

MiniMed Paradigm Real-Time Revel

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.025 to 25 units. Increments of 0.025 units up to 0.975 units. Increments of 0.05 units for 0.975 units or more. Insulin-to-carb ratio allows for fractions of grams.	No	Yes, Contour Next Link meter wirelessly sends blood glucose results to pump.	Yes, available as a stand-alone pump or an all-in-one pump/CGM.	The Real-Time Revel is a pump with built-in CGM technology that uses a sensor to wirelessly transmit continuous glucose readings. (More on its CGM functions on p. 56.) Remote-control capabilities. Remove pump body before bathing, swimming, or other water activities. Pump comes in five different colors, and "skins" are available to customize. Works with CareLink Personal software to upload and manage pump and CGM data. Compatible with Windows (except Windows 8) and Mac operating systems.

Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Medtronic Diabetes **MiniMed 530G With Enlite** 	**Model 551:** 2 x 3.3 x 0.81 in. 3.4 oz. with battery and empty reservoir **Model 751:** 2 x 3.7 x 0.82 in. 3.7 oz. with battery and empty reservoir	1 AAA	**Model 551:** 180-unit reservoir **Model 751:** 300-unit reservoir	Compatible with Medtronic infusion sets only	From 0.025 to 35 units per hour in 0.025-unit increments for up to 0.975 units. Increments of 0.05 units for between 1 and 9.95 units. Increments of 0.1 units for 10 units or more.

Medtronic Diabetes

MiniMed 530G With Enlite

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.025 to 25 units. Increments of 0.025 units up to 0.975 units. Increments of 0.05 units for 0.975 units or more. Insulin-to-carb ratio allows for fractions of grams.	No	Yes, Contour Next Link meter wirelessly sends blood glucose results to pump.	Yes, works as an all-in-one pump/CGM.	The MiniMed 530G is the first FDA-approved device with Threshold Suspend. This feature stops insulin delivery for up to 2 hours if the blood glucose level reaches a preset low limit and the user doesn't react to a low-glucose alarm. (More on its CGM functions on p. 56.) Remove pump body before bathing, swimming, or other water activities. Works with CareLink Personal software to upload and manage pump and CGM data. Compatible with Windows (except Windows 8) and Mac operating systems. Not approved for use in children.

Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Roche Insulin Delivery Systems **Accu-Chek Combo** 	**Pump:** 3.2 x 2.2 x 0.8 in. 3.9 oz. with battery and full reservoir **Meter remote:** 3.7 x 2.2 x 1.0 in. 3.6 oz. with batteries	**Pump:** (1) AA lithium, alkaline, or rechargeable **Meter remote:** (3) AAA alkaline	315-unit cartridge	Compatible with all standard Luer-lock infusion sets	From 0.05 to 25 units per hour. Delivers in 0.01-unit increments for up to 1 unit per hour, in 0.05-unit increments for up to 10 units per hour, and in 0.1-unit increments for up to 25 units per hour.

Roche Insulin Delivery Systems

Accu-Chek Combo

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.1 to 25 units in increments of 0.1, 0.2, 0.5, 1, and 2 units for standard boluses. Extended and Multiwave boluses are adjustable in increments of 0.1 units. Insulin-to-carb ratio allows for fractions of grams.	No	Yes, Accu-Chek Aviva Combo meter remote sends results wirelessly to pump.	No	Meter remote and pump can each control nearly all pump functions, including delivering a bolus, monitoring pump stats, and confirming alarms and warnings. Meter screen displays graphs and data in full color. Meter remote works from about 6 feet away. Pump is watertight for up to 8 feet for 1 hour, though disconnecting is recommended for bathing, swimming, and other water activities. Works with Accu-Chek 360° software, insulin pump configuration software, and Smart Pix device reader for data management. Software and reader are compatible with Windows (except Windows 8; only 360° software works with Windows 7) but are not Mac compatible.

Company Insulin Pump	Size and Weight	Battery	Reservoir	Infusion Set	Basal Range
Sooil Development **Dana Diabecare IIS** 	2.95 x 1.77 x 0.75 in. 1.8 oz. without battery	(1) 3.6-volt DC lithium	300-unit cartridge	Compatible with Sooil infusion sets only	From 0.1 to 16 units per hour in 0.1-unit increments

Sooil Development
Dana Diabecare IIS

Bolus Range	Food Database?	Meter Interaction?	CGM Interaction?	Details
From 0.1 to 10 units in 0.1-unit increments. From 10 to 87 units in 1-unit increments. Insulin-to-carb ratio in whole units only.	No	No	No	Menu uses icons instead of words. Available in a choice of five colors. Does not work with data management software.

PATCH PUMP “IBRIDA” CELLNOVO

Accu-Chek INSIGHT

- **Dimensions**:
  - 72 x 52 x 16 mm without adapter
  - 84 x 52 x 19 mm with adapter
- **Weight:** Approx. 115 g (including battery, full cartridge, Infusion Set)
- **Display Size:** 38 x 15 mm without zoom button, 220 x 80 pixel
- **Pump casing:**
  - Shock/scratch-resistant plastic
  - Backside metal
  - Resistant to pharmaceuticals
  - All edges rounded
- **Temperature ranges:**
  - Operation: +5 °C to +37 °C (+41°F to +99 °F)
  - Storage in shipping: +5 °C to +45 °C (+41 °F to +113 °F)
  - Transport: –20 °C to +50 °C (–4 °F to +122 °F)
- **Air humidity (Relative Humidity):**
  - Operation: 20% to 90%
  - Storage in shipping: 20% to 85%
  - Transport: 5% to 95%
- **Barometric pressure:**
  - Operation: 50 to 106 kPa (500 to 1060 mbar)
  - During storage in shipping: 70 to 106 kPa (700 to 1060 mbar)
  - During transport: 50 to 106 kPa (500 to 1060 mbar)

- **Basal rate: Minimum = 0.02 U/h , Maximum = 25 U/h** E.g. Below 0.19 U/h, delivery is close dependent. 0.19 U/h and above delivery every 3 mins
- **Bolus:**
  - Maximum bolus amount per delivery is 25 U
  - Standard, Extended and Multiwave Boluses, are adjustable in increments of:
  - 0.05 U (up to 2.0 U)
  - 0.1 U (2-5 U)
  - 0.2 U (5-10 U)
  - 0.5 U (10-20 U)
  - 1.0 U (20-25 U)
  - Duration of Extended and Multiwave Boluses are adjustable in intervals of 15 minutes up to 24 hours
  - Multiple boluses can run in parallel

- **Temporary basal rate:**
  - Adjustable in 10% increments, from 0 - 250%
  - Duration is adjustable in 15 minute intervals, up to a maximum of 24 hours
  - Last duration programmed is the default setting for the next Temporary Basal Rate

- **Bolus delivery rate:**
  - Very slow = 3 U/min
  - Slow = 6 U/min
  - Moderate = 9 U/min
  - Standard = 12 U/min

MEDTRONIC 640G

Basal delivery

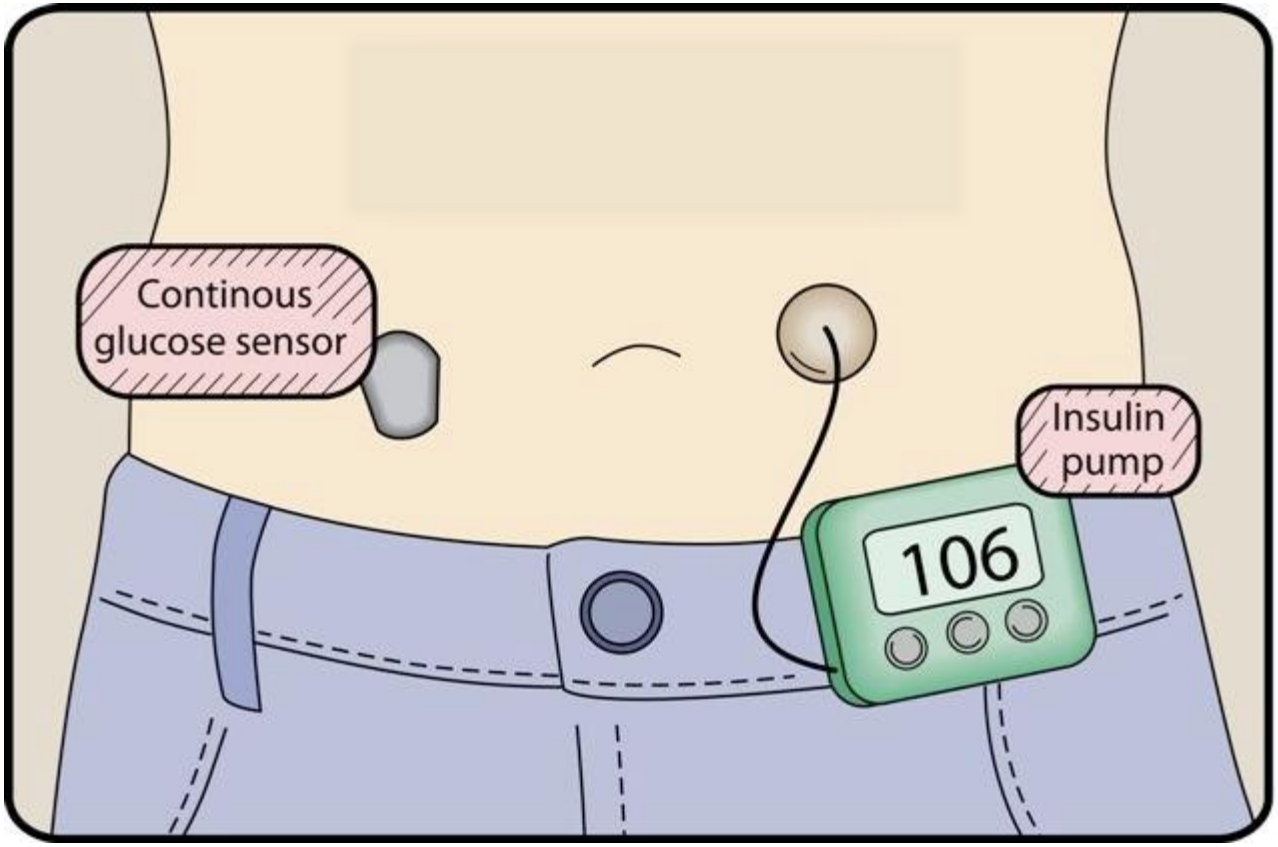
Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower.
Max Basal Rate default	2 units per hour

Basal patterns	Maximum of 8 patterns. Each pattern covers a 24 hour period and can have up to 48 rates. Rates are set in 30 minute increments.
Basal pattern names	Fixed names: Basal 1, Basal 2, Basal 3, Basal 4, Basal 5, Workday, Day Off, Sick Day
Increments	• 0.025 units per hour for basal amounts in the range 0 to 0.975 units • 0.05 units per hour for basal amounts in the range 1 to 9.95 units • 0.1 units per hour for basal amounts of 10 to 35 units

Bolus delivery

Bolus Speed options	• Standard: 1.5 units/minute • Quick: 15 units/minute
Bolus programming increments	• 0.025 units • 0.05 units • 0.1 units

IL SISTEMA INTEGRATO INFUSORE/SENSORE



INTEGRATED SYSTEMS (SAP)

POTENTIAL ADVANTAGES

- Possible more aggressive therapeutical approach
- Pursuit of more physiological glucose targets
- Greater psychological confidence

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Threshold-Based Insulin-Pump Interruption for Reduction of Hypoglycemia

Richard M. Bergenstal, M.D., David C. Klonoff, M.D., Satish K. Garg, M.D., Bruce W. Bode, M.D., Melissa Meredith, M.D., Robert H. Slover, M.D., Andrew J. Ahmann, M.D., John B. Welsh, M.D., Ph.D., Scott W. Lee, M.D., and Francine R. Kaufman, M.D., for the ASPIRE In-Home Study Group*

Bergenstal RM et al NEJM 2013;18:224-32

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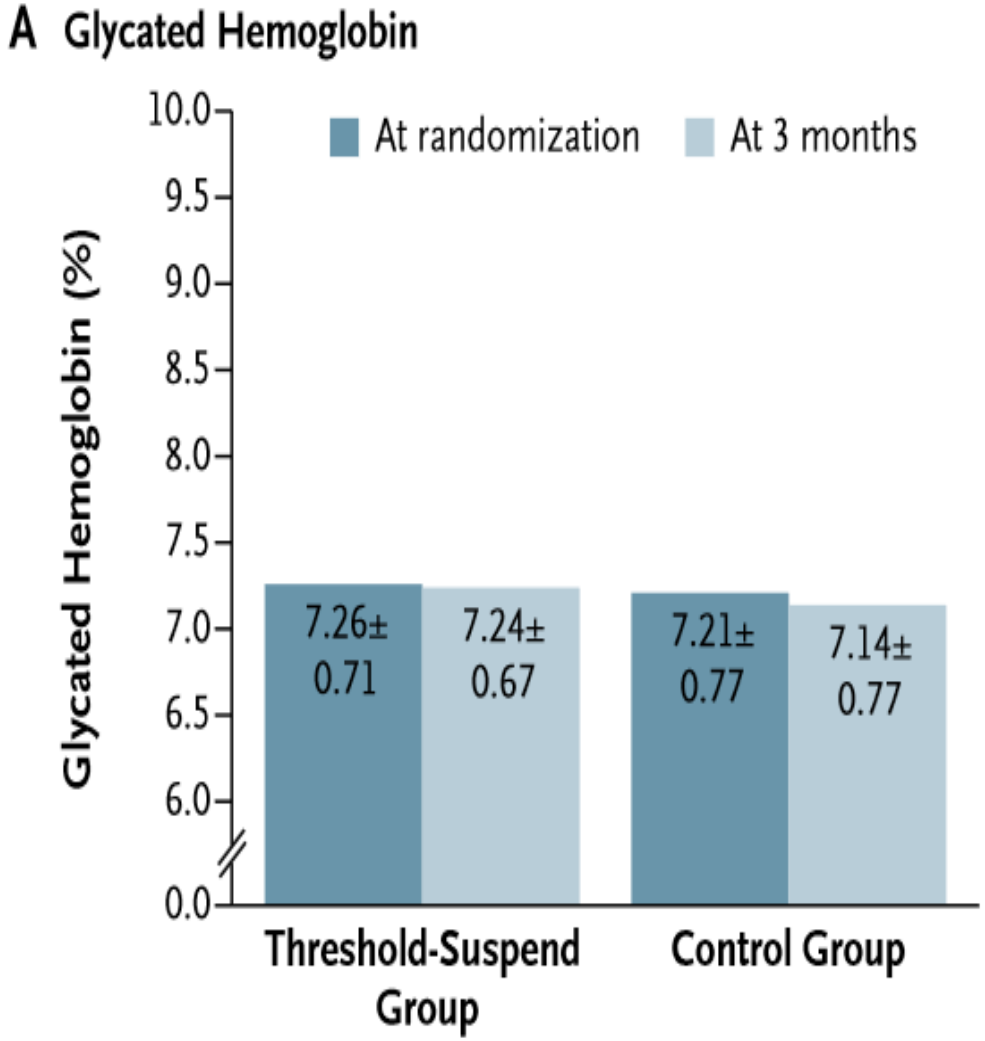

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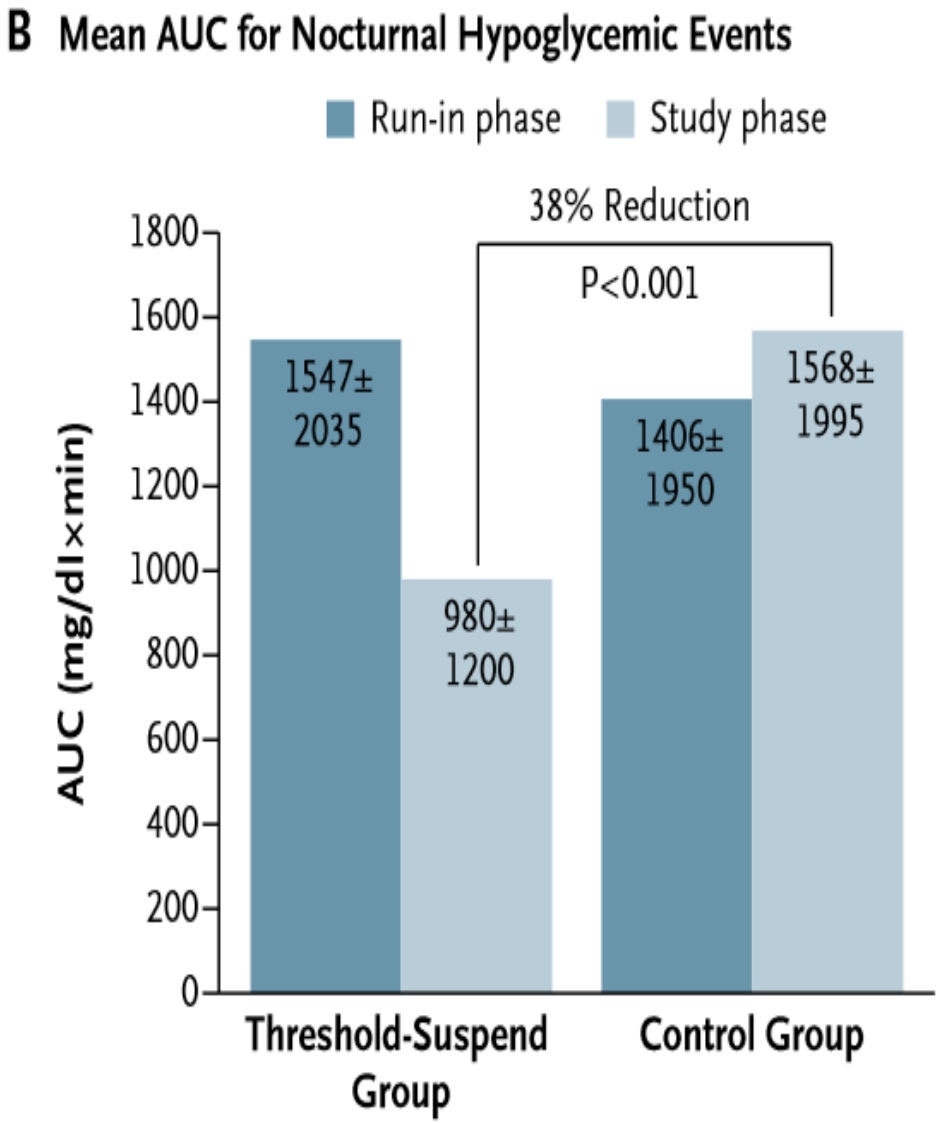

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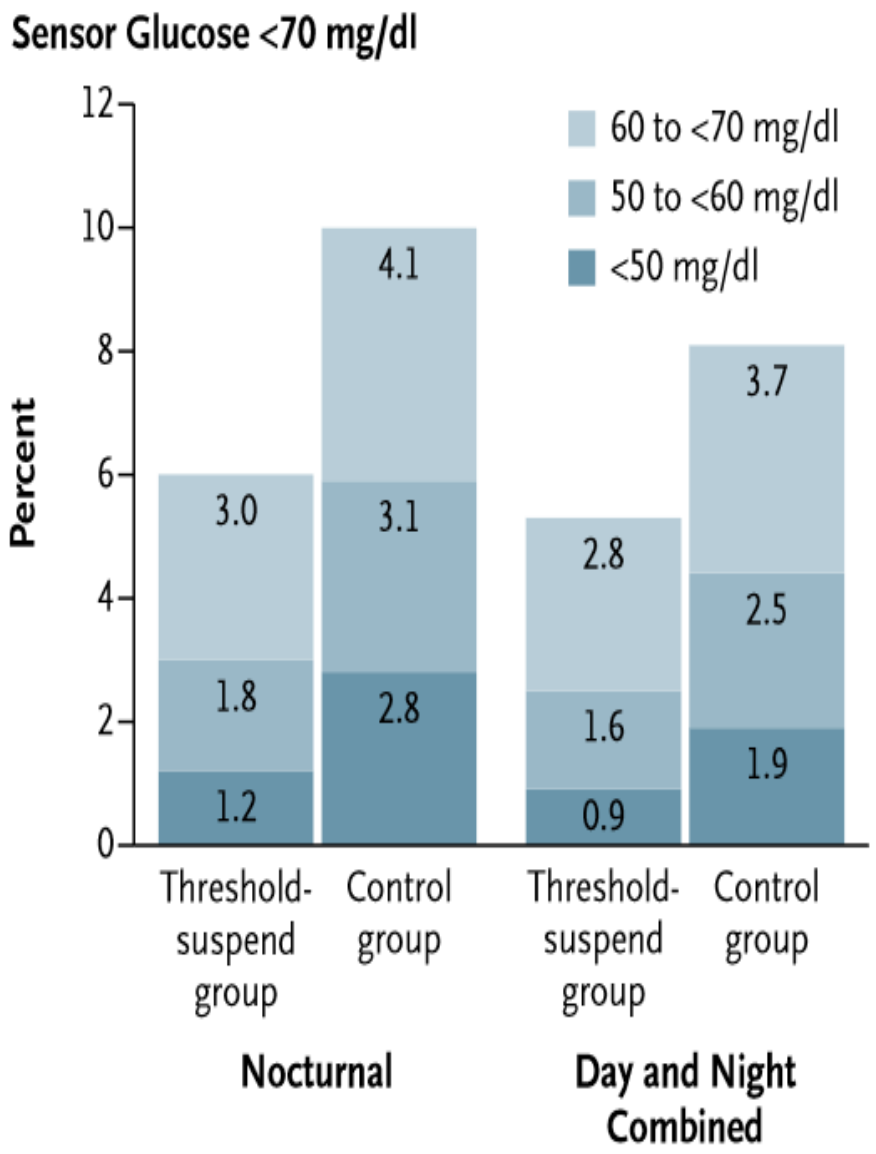


Bergenstal RM et al NEJM 2013;18:224-32

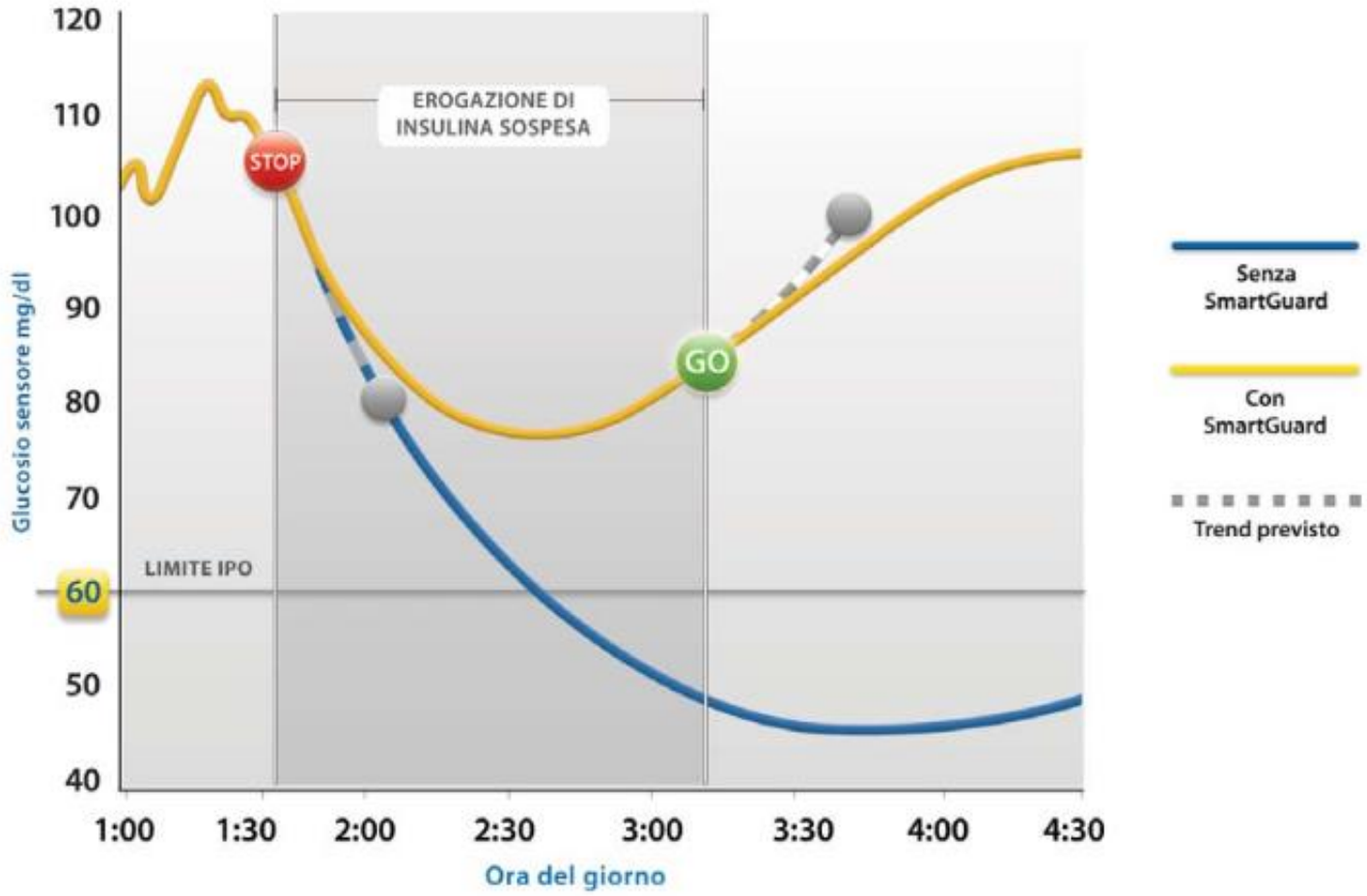
Effect of Sensor-Augmented Insulin Pump Therapy and Automated Insulin Suspension vs Standard Insulin Pump Therapy on Hypoglycemia in Patients With Type 1 Diabetes

A Randomized Clinical Trial

	Insulin Pump (n = 49)	Sensor-Augmented Pump With Low-Glucose Suspension (n = 46)
Sum of Severe and Moderate Hypoglycemia		
Baseline		
Rate per 100 patient-months (95% CI)[a]	20.7 (13.8 to 30)	129.6 (111.1 to 150.3)
No. of events (total No. of patients)	28 (45)	175 (45)
End point		
6-Month rate per 100 patient-months (95% CI)[a]	11.9 (6.8 to 19.3)	28.4 (19.8 to 39.6)
No. of events (total No. of patients)	13 (45)	35 (41)
Incidence rate per 100 patient-months (95% CI)[b]	34.2 (22.0 to 53.3)	9.5 (5.2 to 17.4)
Patients modeled	45	41
Incidence rate ratio per 100 patient-months (95% CI)[b]		3.6 (1.7 to 7.5)
P value		<.001

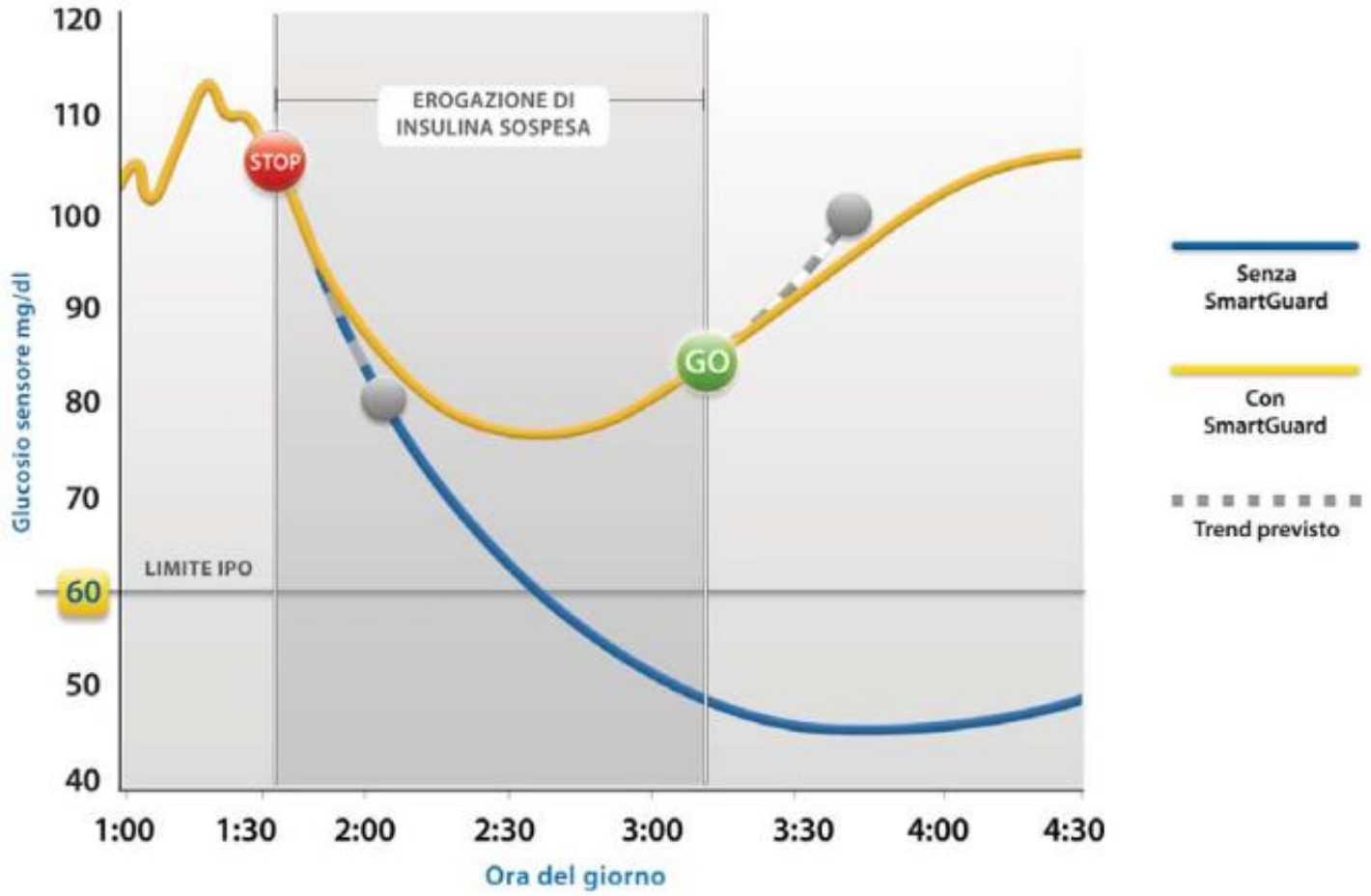
Ly TT et al JAMA 2013;310:1240-1247

640G SMARTGUARD



Criteri di sospensione: il glucosio del sensore deve trovarsi a non più di 70 mg/dL dal limite di glucosio basso e l'algoritmo deve stimare che il valore del glucosio del sensore possa trovarsi entro 30 minuti a non più di 20 mg/dL sopra il limite di glucosio basso.

640G SMARTGUARD



Criteri di riavvio: il glucosio del sensore deve essere almeno 20 mg/dL sopra il limite di glucosio basso e l'algoritmo deve stimare che il valore del glucosio del sensore possa trovarsi entro 30 minuti ad almeno 40 mg/dL al di sopra del limite di glucosio basso.

La sospensione dell'erogazione di insulina deve essere avvenuta per almeno 30'.

LA CHIUSURA DELL'ANSA

Breaking News: FDA Approves the MiniMed 670G System, World's First Hybrid Closed Loop System

Posted by **Karrie Hawbaker** On September 28, 2016 In **Featured Posts**, **Innovation**

Microinfusori…….

esigenza oppure optional ???

Microinfusori…….

esigenza ed opportunità

GRAZIE PER L'ATTENZIONE