

DIABELOOP CLOSED-LOOP DOES BETTER THAN SENSOR-AUGMENTED PUMP ON BLOOD GLUCOSE CONTROL DURING 3 DAYS WITH EITHER INTENSIVE PHYSICAL EXERCISES, GASTRONOMIC DINNERS OR REST IN T1D

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BACKGROUND AND AIMS

Variability of way of life is an issue for good BG control in type 1 diabetes(T1D). Diabeloop is a Closed-loop (CL) system with a MPC algorithm reinforced by a decisional matrix, uploaded on an android smartphone linked to Dexcom CGM and a Cellnovo insulin patch-pump [1]. The primary aim of the study was to compare BG control with Diabeloop CL versus sensor-augmented insulin pump therapy (SAP), in well-educated patients practicing intensive physical exercises repeatedly, or gastronomic dinners or rest, during 3 days.

PATIENTS AND METHODS

Thirty-eight T1D patients on insulin pump therapy were recruited from 9 centers in a randomized crossover study including two 72-hour periods under conditions of sedentarity for the 1st group, gastronomic dinners for the 2nd group, and physical activity bouts for the 3<sup>rd</sup> group, either with SAP or CL. Meals and exercises were announced during the CL periods.

Demographics and metabolic variables	Gr1 sedentary (N=14)	Gr 2 Gastronomic dinners (N=10)	Gr 3 Physical activity bouts (N=14)	All (N=38)
Age (yrs)	53.7 (±16.0)	46.4 (±16.1)	48.7 (±11.8)	49.9 (±14.5)
Duration of diabetes (yrs)	30.4 (±15.5)	23.6 (±13.1)	20.9 (±10.6)	25.1 (±13.6)
BMI ( Kg/m2)	26.2 (±5.0)	24.5 (±4.0)	24.5 (±3.1)	25.2 (±4.1)
HbA1c ( %)	7.6 (±0.7)	7.7 (±0.8)	8.0 (±0.5)	7.8 (±0.7)
serum C-peptide [ng/mL]	0.2 (±0.2)	0.1 (±NA)	0.0 (±0.0)	0.1 (±0.1)
Non severe hypoglycemia frequency during the week preceding the experiments	4.6 (±3.8)	3.2 (±2.4)	3.1 (±3.9)	3.7 (±3.5)

Study design

Randomized nine-centers cross-over study, 4 subjets/center  
Rest (Caen, Nantes, Strasbourg) ; Gastronomic dinners (Toulouse, Grenoble, Montpellier); Intensive physical exercises (CHSF, Besançon, Marseille)

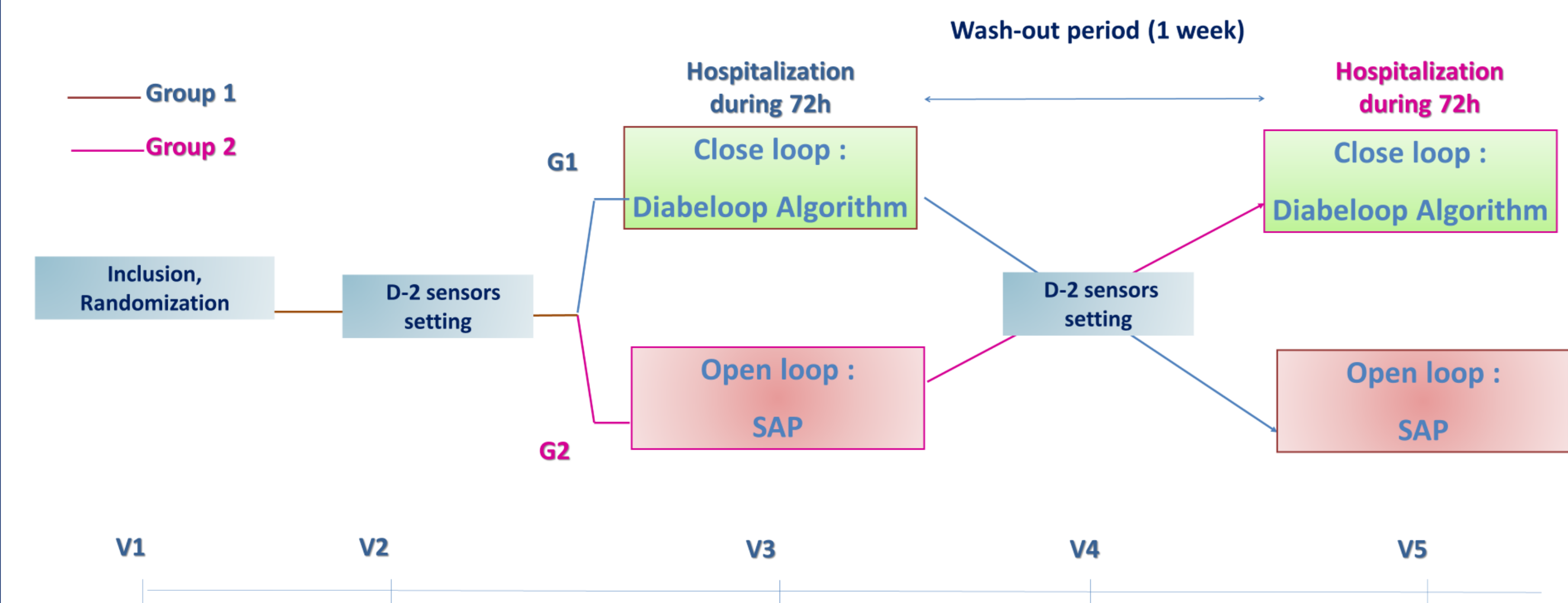


Figure 1 : Study Design Diabeloop SP6.2

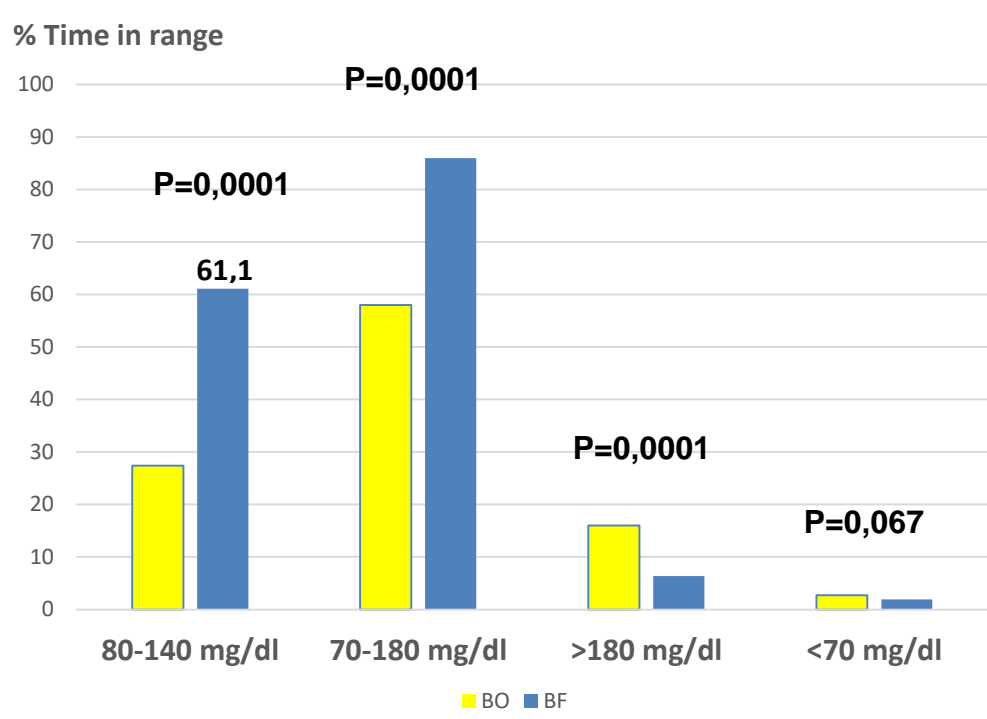
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RESULTS

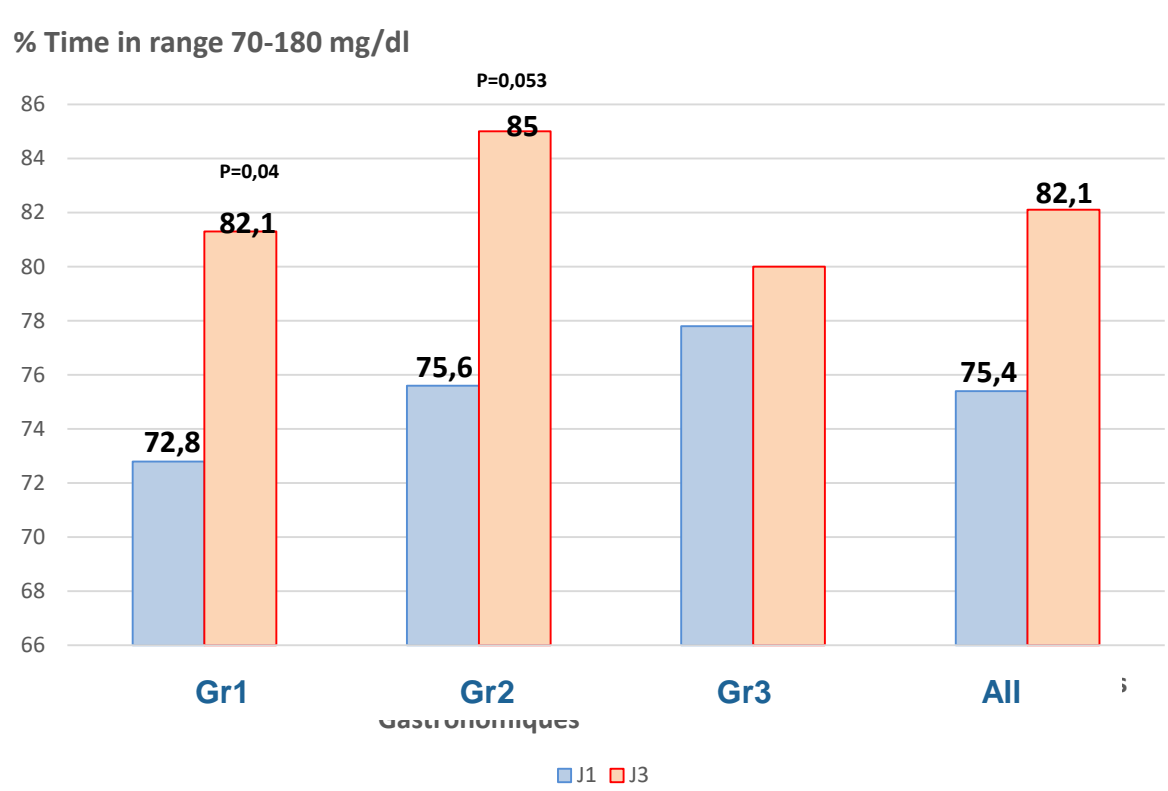
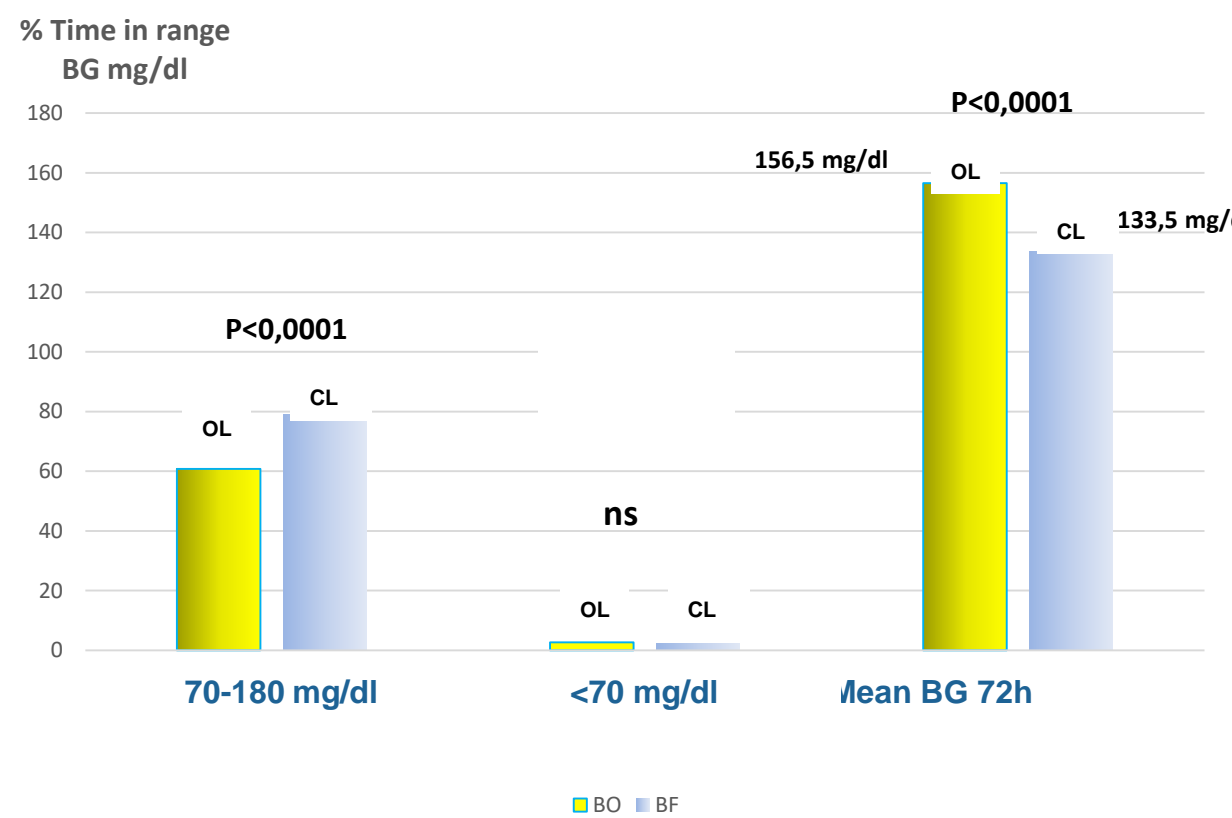
Primary Endpoint :

3-day nocturnal Time-in-range significantly increased in CL vs OL  
3-day nocturnal Time-in-Hyperglycemia significantly decreased in CL vs OL  
3-day Time-in-hypoglycemia remained low in both CL and OL

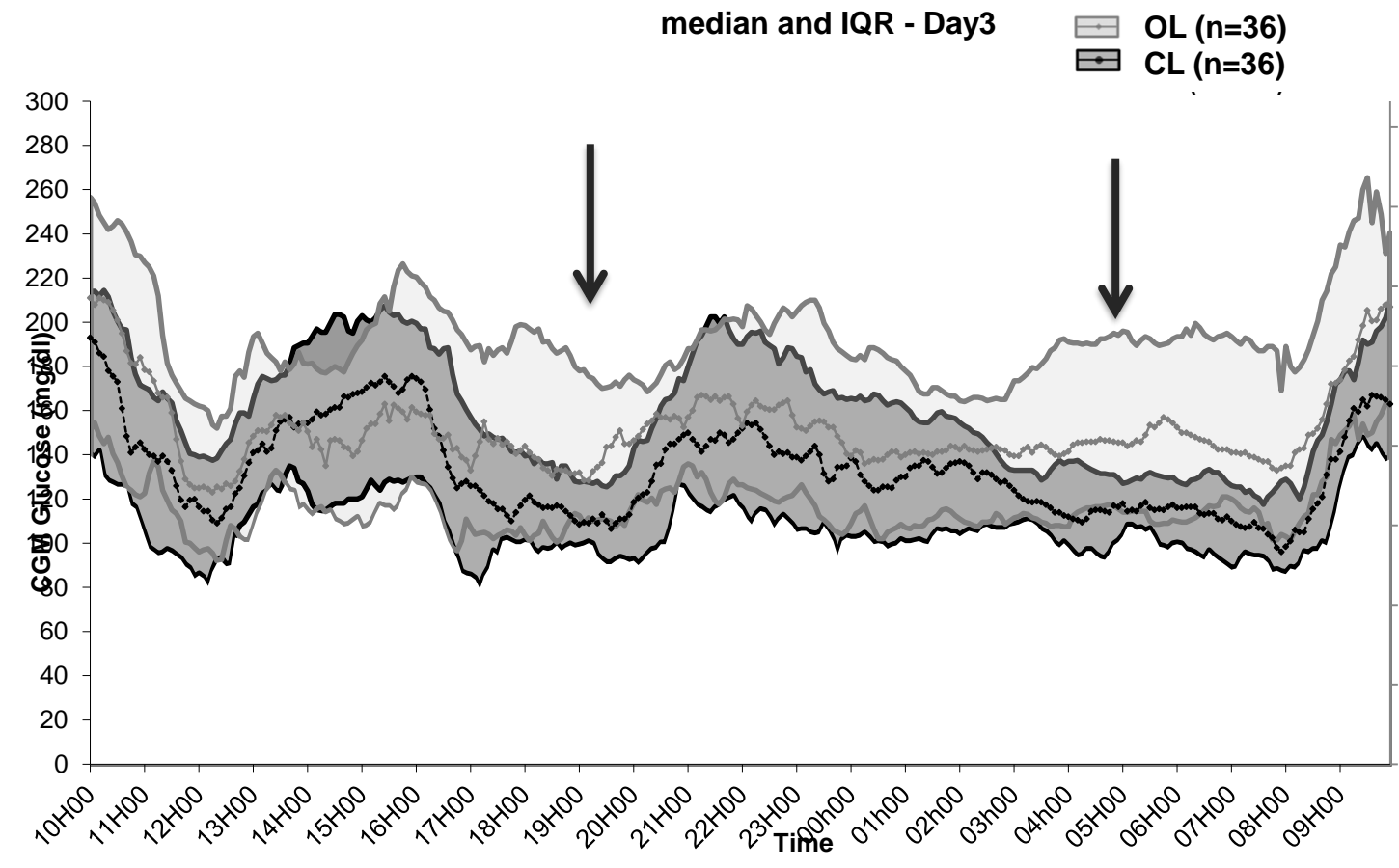


Secondary Endpoints :

72h Time-in-range significantly increased in CL vs OL  
72h mean BG decreased significantly in CL vs OL  
Comparison between Day 1 and Day 3 of CL experiments : % Time-in-range had a trend toward increasing with CL



Twenty-four-hour glucose profiles during in-hospital use of closed loop (CL) and SAP (OL): Evening and overnight superiority of CL



Quality of Life : DTSQ score increased with CL compared to OL

DTSQs Score (n=36) OL	DTSQs Score (n=36) CL	DTSQs OL-CL (C95%)
26.0 (±5.5)	31.0 (±5.5)	-4.83 [-7.28; -2.38] P=0.0003

CONCLUSIONS

In various situations such as intensive exercise, gastronomic dinners or resting, Diabeloop increased by 2-fold the overnight % time spent in 80-140mg/dl BG range, reduced the time in hypoglycemia and decreased average BG level in comparison with SAP. Quality of life index (DTSQ) was increased when using Diabeloop vs SAP.

REFERENCES

[1] Querais, Doron et al, JDST 2014 Nov;8(6):1177-84

ACKNOWLEDGEMENT

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