Hypoglycaemia Prevention in Children with Type 1 Diabetes by Using SmartGuard® Algorithm (SG®) in Sensor-Augmented Pump (SAP) Therapy

T. Biester[1], T. Danne[1], O. Kordonouri[1], M. Holder[2], D. Kieninger-Baum[3], K. Remus[1], T. Wadien[2], A. Thomas[4]

[1]Diabetes Centre, Kinderkrankenhaus AUF DER BULT, Hannover, Germany, [2]Olgahospital Stuttgart, Kinderklinik, Stuttgart, Germany,
[3]Universitätsmedizin Mainz, Zentrum für Kinder- und Jugendmedizin, Mainz, Germany, [4]Medtronic GmbH, Meerbusch, Germany

BACKGROUND

Experiencing a severe hypoglycaemia is a well-known barrier for achieving near-normoglycaemic control. The incidence of hypoglycaemia is particularly high in children. Sensor-augmented insulin pump (SAP) with the "MiniMed®640G"system features the PLGM algorithm (predictive low glucose management = "SmartGuard®") which stops insulin pump delivery based on predicted sensor glucose levels. This may offer advanced protection against hypoglycaemia.

AIM

User evaluation to investigate if the SG® algorithm reduces safely the frequency of hypoglycaemic episodes. Of primary interest is the frequency of SG® activations and the influence of glycaemic control under daily life conditions.

METHOD

- User evaluation over 12 weeks in 3 paediatric centres in Germany
- Patients experienced in CSII, but naive in respect of using SmartGuard®
- First phase (2 weeks): SAP without SG® (alert switched off)
- Second phase (6 weeks): patients using SG® function after appropriate education
- Settings: "suspend before low": 70 mg/dL, "hypoglycaemia alert": 70mg/dL
- Analysis:
  - Frequency of SG® activations
  - Frequency of hypoglycaemic excursions < 70 mg/dL and < 40 mg/dL
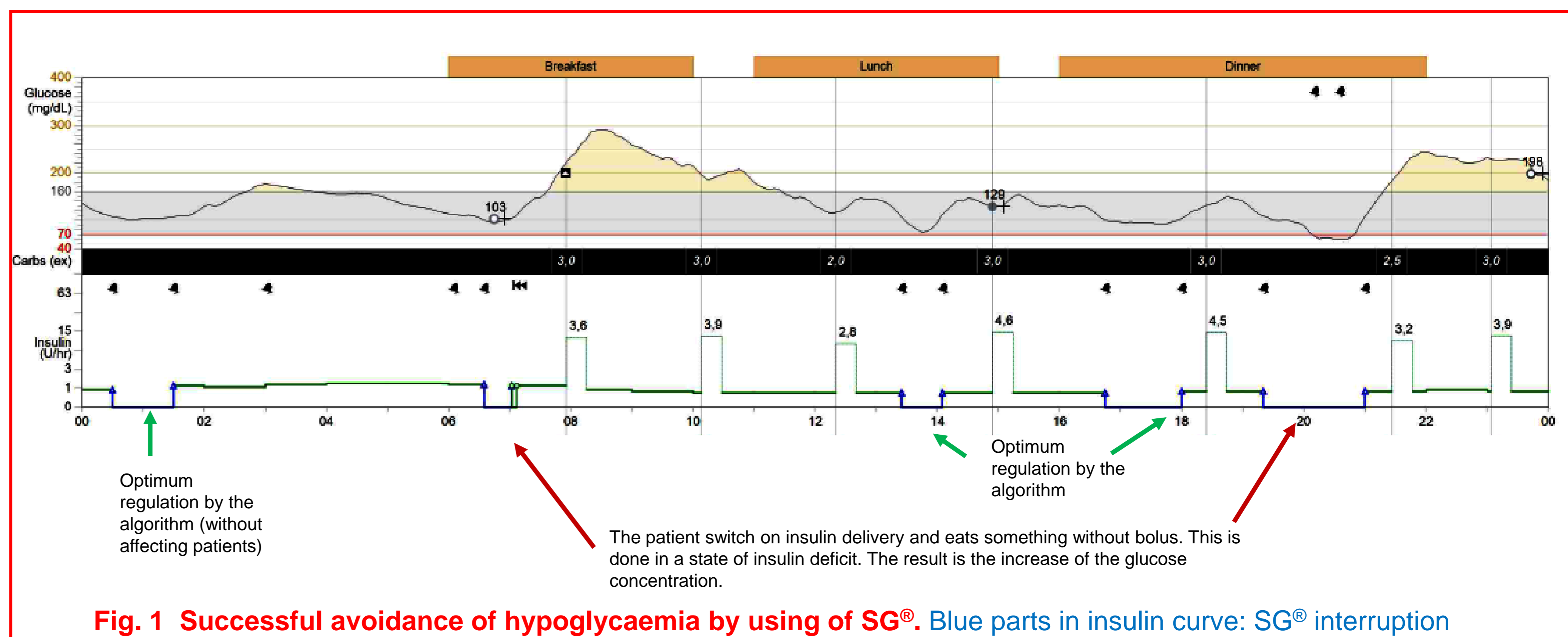 - AUC and time in hypoglycaemia

Fig. 1 Successful avoidance of hypoglycaemia by using of SG®. Blue parts in insulin curve: SG® interruption

PATIENTS

- 24 children with type 1 diabetes
- Age: 11.6 ± 5.1 years
- Diabetes duration: 7.5 ± 4.2 years
- Experience with CSII: 6.4 ± 4.4 years
- Experience with CGM: 0.9 ± 2.0 years
- Baseline HbA1c: 7.4 ± 0.7 %
- BMI: 19.3 ± 2.5 kg/m^2

RESULTS

- Evaluation of data was possible for 18 patients (one drop out, in 5 cases, patient used insulin delivery interruption in phase 1 (breach protocol)
- Frequency of SG® interruptions/patient/day: 3.15±1.03
- Average time of interruption/day: 155 ± 47 min
- In only < 10% of cases the glucose values were lower than 55 mg/dL.

Table 1 Comparison of glycaemic parameters during investigation

	Phase 1 (without SG®)	Phase 2 (with SG®)	p
Mean glucose value (mg/dL)	170.61 ± 26.16	180.17 ± 19.36	ns (0.111)
Standard deviation (mg/dL	72.00 ± 13.88	73.11 ± 12.78	ns (0.364)
Stab. Index (MW/SD)	2.42 ± 0.31	2.51 ± 0.33	ns (0.211)
AUC $_{> 160\,mg/dL}$ (mg/dL x d)	35.54 ± 18.39	40.85 ± 15.09	ns (0.175)
Excursions < 70 mg/dL / day	1.02 ± 0.52	0.72 ± 0.36	0.027
Excursions ≤ 40 mg/dL / day	0.20 ± 0.22	0.10 ± 0.10	0.038
AUC $_{< 70\,mg/dL}$ (mg/dL x d)	0.76 ± 0.73	0.38 ± 0.24	0.027
Time $_{< 70\,mg/dL}$ / day (min)	73± 56	31 ± 22	0.003
AUC x t$_{< 70\,mg/dL}$ (mg/dL x d^2)	0.063 ± 0.091	0.012 ± 0.014	0.012

Table 2: Average values at / during / after activation of SmartGuard®

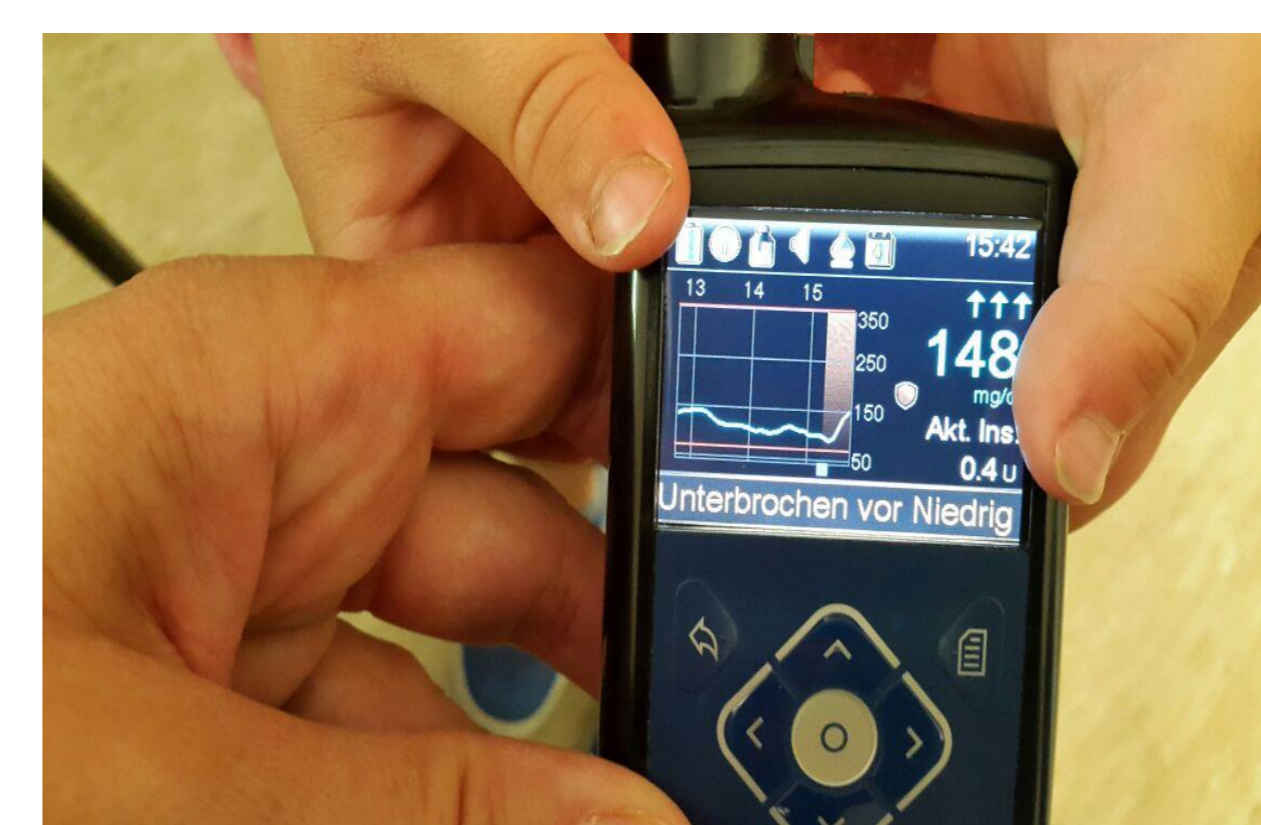|	Glucose value at shutdown insulin delivery	Glucose value when resumption insulin delivery	Minimal glucose value during interruption	Glucose value 1 hour after resumption	Duration of the switch-off
24 hour (all)	108.3 mg/dL	106.4 mg/dL	77.9 mg/dL	164.3 mg/dL	60.5 min
day time (08 am – 10 pm)	110.0 mg/dL	107.2 mg/dL	76.7 mg/dL	177.8 mg/dL	5.7 ,min
night time (10 pm – 08 am)	105.2 mg/dL	104.1 mg/dL	81.2 mg/dL	135.4 mg/dL	70.8 min
without meal during/ after interruption	107.2 mg/dL	107.9 mg/dL	79.4 mg/dL	139.7 mg/dL	67.5 min
with meal during/after interruption	109.8 mg/dL	105.9 mg/dL	75.8 mg/dL	189.6 mg/dL	55.8 min

Fig. 2a: MiniMed 640G in use

Fig. 2b: PLGM mode: Pump is "suspended before low"
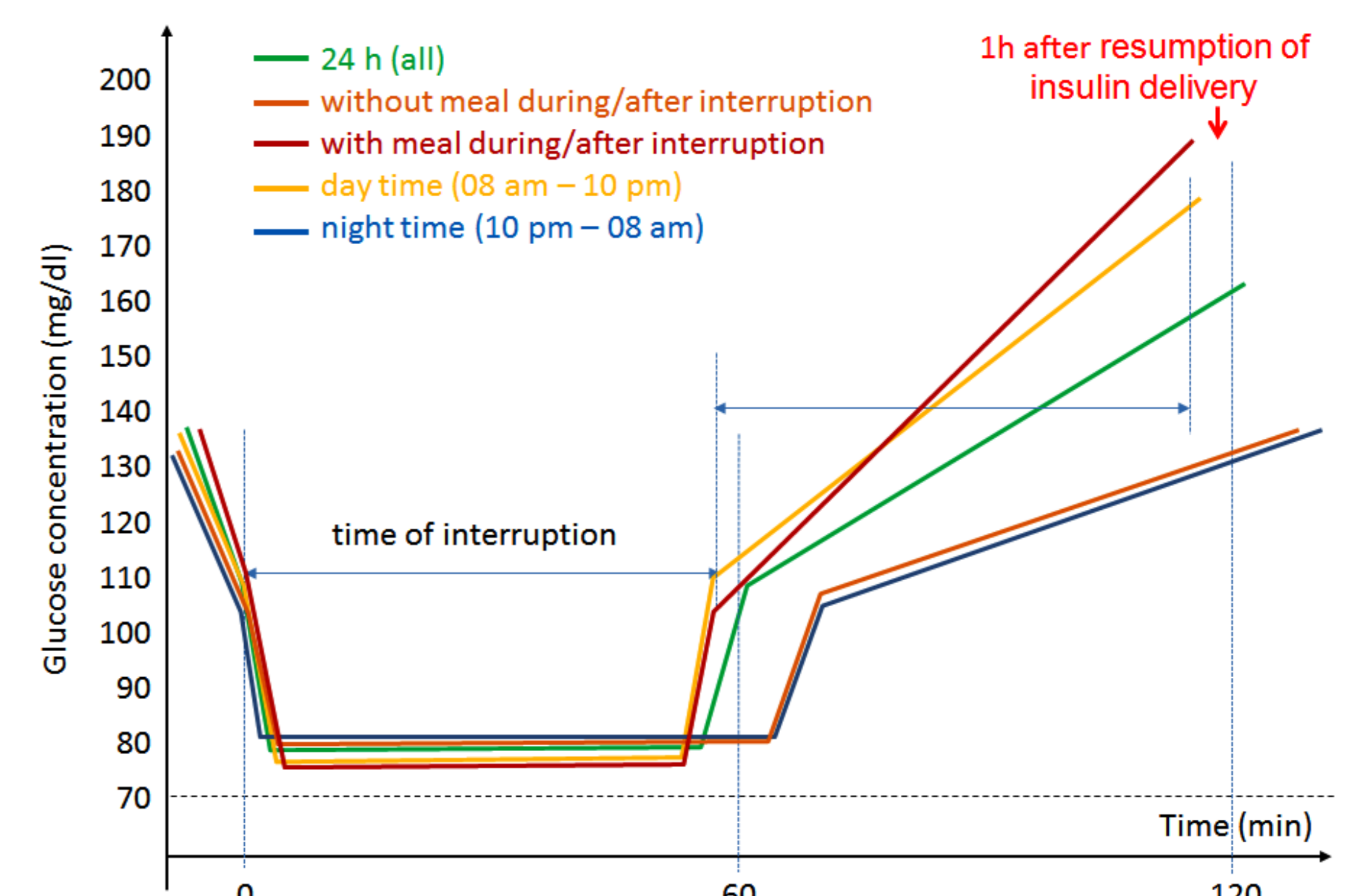
Fig. 3: schematic representation of the glucose curves (ref. Table 1)

CONCLUSION

- Clear evidence for reduction of risk for hypoglycaemia without compromising the safety of SAP therapy in children using SmartGuard®
- Severe hypoglycaemia in children can be prevented by using SAP with SmartGuard®
- "Suspend before low" level of 70 mg/dL is effective for hypoglycaemia prevention
- System performs best, if the patient does not intervene in the algorithm (e.g. at night).