

# Management of Asymptomatic Hypoglycemia With Dextrose Oral Gel at 40% in Near Term at-risk Infants to Reduce Intensive Care Need and Promote Breastfeeding

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## Research Article

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# Abstract

**Background:** Neonatal hypoglycemia is a common disorder especially in at-risk infants and it can be associated with poor long-term neurological outcomes. Several therapeutic interventions are suggested, from the implementation of breastfeeding to the glucose intravenous administration. Oral dextrose gel massaged into the infant's inner cheek is a recent treatment option of asymptomatic hypoglycemia, after which oral feeding is encouraged. This approach seems to reduce the admission of infants to neonatal intensive care unit (NICU) so favouring maternal bonding and breastfeeding success at discharge.

**Methods:** In our unit we recently implemented the protocol for the management of asymptomatic hypoglycemia with the introduction of dextrose oral gel at 40%. Therefore we compared two cohorts of near term at-risk infants with asymptomatic hypoglycemia: a historical group managed with our old protocol and the second one prospectively followed after the introduction of dextrose gel at 40%.

**Results:** Primary outcome was occurrence of NICU admission and glucose intravenous needs; breastfeeding success was the secondary outcome. Infants in the dextrose oral gel group showed statistically lower need of NICU admission and higher prevalence of exclusive breastfeeding at discharge compared with infants of the historical group.

**Conclusions:** In our population the introduction of dextrose oral gel at 40% to the protocol, helped in the safe management of asymptomatic hypoglycemia in near term infants and, at the same time, implemented breastfeeding.

## Background

Hypoglycemia is the most frequent metabolic disorder in neonates, with an incidence of 5–15% in healthy term infants and up to 50% in infants with risk factors [1]. During the pregnancy the fetus receives glucose from placental circulation, but at birth this supply stops abruptly and the neonates need to become independent to produce energy. In the first two hours of life, glycemia reaches the lowest level, then the values stabilize between 4 and 6 hours of life [2].

Neonatal hypoglycemia, especially if prolonged, can be associated with brain injury and poor neurodevelopment outcomes, including cognitive impairment, sensor disability, cerebral palsy, seizures and developmental delay [3, 4]. Despite this, uncertainty persists regarding the definition of neonatal hypoglycemia and even for the correlation between the values of glycemia, the symptoms in newborns and the long-term sequelae [5, 6]. Moreover, even the inaccuracy of the measurement tools can complicate the interpretation of the data [7]. The two most recent international guidelines from the Pediatric Endocrine Society and the American Academy of Pediatrics do not help to clarify the correct values to define hypoglycemia in neonates [8, 9].

Treatment options vary according to the single case, the occurrence of symptoms and of blood glucose levels. The first intervention is early and frequent oral feeding, focused on breastfeeding, and infant

formula supplementation can be used if human milk is not available. Failing this approach, infants that remain hypoglycemic are often transferred in neonatal intensive care unit (NICU) or specialty care nursery and intravenous (IV) glucose is administered. NICU admission leads to physical separation between mothers and neonates, to a negative impact on bonding and to a delayed establishment of breastfeeding. More recently, the buccal administration of dextrose gel showed positive effects on reducing the time of mother-infant separation and increasing the likelihood of breastfeeding at discharge [10]. By the direct application to the oral mucosa, glucose can rapidly enter the systemic circulation via the lingual and internal jugular veins, even if a rate of the dose may also be swallowed and absorbed from the gastrointestinal tract [11].

For these reasons, in late 2019, we decided to implement a protocol for the management of hypoglycemia in at-risk newborns in our Neonatal Unit including a commercially sourced dextrose gel at 40% (Destrogel, Orsana ®, Italy). After this, we conducted a comparison on the impact of intensive care need (NICU admission and intravenous glucose administration) and breastfeeding success at discharge between a population of near term at-risk infants for asymptomatic hypoglycemia managed with dextrose oral gel at 40% and a historical group.

## Methods

In our Department at the beginning of November 2019, the protocol for the management of neonatal hypoglycemia was implemented with the use of a commercially sourced oral dextrose gel at 40% (Destrogel, Orsana ®, Italy).

This was a prospective cohort study with a retrospective control group. The study was approved by our local IRB and parental consents were obtained.

Two cohorts of asymptomatic near term neonates at risk for hypoglycemia, born at V. Buzzi Children's Hospital (ASST-FBF-Sacco, Milan, Italy), a tertiary level care center, were investigated: the historical group (May 2019-October 2019) (Gr1) and the prospective group (November 2019-April 2020) after the implementation of the revised protocol (Gr2).

All the infants after birth were initially maintained in skin-to-skin contact with mother and rooming-in was proposed.

For both cohorts of at-risk infants for hypoglycemia, the following inclusion criteria have been applied: mild prematurity (> 35 weeks'GA), post-term birth (> 41 + 6 weeks'GA), low birth weight (LBW; < 10<sup>o</sup> percentile), large for gestational age (LGA, > 90<sup>o</sup> percentile), intrauterine growth restriction (IUGR), birth weight under 2500 g or above 4000 g, maternal diabetes, transient mild neonatal respiratory distress, urgent cesarean section for foetal distress, maternal eclampsia and hypertension, meconium-stained amniotic fluid, foetal eritroblastosis, polycythemia, mild hypothermia, metabolic acidosis at birth, maternal pharmacological therapy during pregnancy with  $\beta$ -blockers,  $\beta$ -sympathomimetics or oral hypoglycaemic agents, congenital syndrome and twins with discordant neonatal birth more than 10%. We

excluded infants born before 35 weeks' GA, with signs and symptoms of hypoglycemia and with more than 15% of loss of weight at 48 hours of life.

A complete database with all newborn characteristics has been drafted.

**Group 1:** the protocol used in the first period indicated values for hypoglycemia < 45 mg/dl in symptomatic term or preterm neonates and < 36 mg/dl in asymptomatic at-risk neonates. In case of persistent low value of blood glycemia despite frequent oral feeding with breastfeeding, squeezed human milk or formula milk, the algorithm suggested to start intravenous infusion of glucose. Blood glucose level monitoring was made by bedside tool.

**Group 2:** in the revised protocol (Fig. 1) cut off values for hypoglycemia are different according to the life hours of the infant: < 45 mg/dl in the first 24 hours, < 50 mg/dl between 24 and 48 hours of life and < 60 mg/dl above the 48 hours of life. In case of asymptomatic hypoglycemia, the first line of treatment was the buccal administration of commercially sourced dextrose gel at 40% (Destrogel, Orsana ®,Italy) at the dose of 0,5 ml/kg, 200 mg/kg (up to six times in 48 hours) associated with breastfeeding, if available, or formula milk administration. The dextrose oral gel was massaged into the baby's inner cheek, after which feeding was encouraged. Only if control values of glycemia were under 25 or 35 mg/dl (between 0 and 4 hours of life and 4–24 hours of life, respectively) in asymptomatic newborns, it was mandatory to start intravenous glucose infusion, while in symptomatic infants intravenous treatment was started if glycemia was under 40–45 mg/dl. Blood glucose level monitoring was made by bedside tool.

Primary outcome of the study was the need of intensive care (number of newborns transferred at NICU due to hypoglycemia and the requirement to intravenous glucose therapy). Secondary outcomes: the rate of exclusive breastfeeding at discharge (defined as the newborn receiving only breast milk the last feeding before discharge) and the length of hospitalization.

A statistical analysis was performed: a t-Student test was used to analyze continuous variables, while for categorical variables like transfer to NICU, need for intravenous treatment and the rate of exclusive breastfeeding at discharge a  $\chi^2$  test was used. Statistical significance has been established for values of  $p < 0.05$ . The SPSS software was used to analyze data.

## Results

The neonatal baseline characteristics of the two groups are shown in Table 1.

Table 1  
Baseline Characteristic.

	Group 1	Group 2	P value
Number	389	308	
Males	215 (55.3%)	181 (58.8%)	0.86
Birthweight (g)	3166	3291	0.017
Gestation (wks)	38 + 5	39 + 1	0.002
Apgar score < 5 at 5 min	0	0	
Vaginal birth	277 (71.2%)	227 (73.7%)	0.53
pH at birth	7,29	7,27	0.02

We retrospectively enrolled 389 at-risk newborns (215 males, 55.3%) in the first period (Gr1). Risk factors of group 1 are listed in Table 2. Thirty-nine newborns (10%) presented asymptomatic hypoglycemia; 19/39 (48.7%) were transferred to NICU and 14/39 (35.9%) needed intravenous glucose treatment. The mean length of hospitalization was 6.43 ( $\pm$  6.36) days for a total of 248 days. Regarding the type of feeding at discharge, only 3 (7.7%) asymptomatic hypoglycemic infants were exclusively breastfed, and 1/3 received a complementary feeding during hospital stay.

Table 2  
Risk factors for hypoglycemia in Gr1.

	Number	%
Maternal diabetes	128	32.9
LBW	96	24.7
Prematurity	73	18.8
Birth weight > 4000 gr	54	13.9
LGA	36	9.2
IUGR	2	0.5
Perinatal distress	0	0
Hypothermic infants	0	0

In the second period after the introduction in clinical practice of the new protocol management for asymptomatic hypoglycemic infants, we enrolled 308 newborns (181 males, 58.8%) (Gr2). The risk

factors are listed in Table 3. A low blood glucose level was observed in 37/308 (12%) infants (25 males, 67.6%). 7/37 newborns were excluded from the data analysis due to deviations from protocol guidelines (treatment with breastfeeding or formula milk without dextrose gel). 27/30 patients (90%) had their hypoglycemia corrected with 40% dextrose oral gel while 3 hypoglycemic newborns (10%) were transferred to NICU for intravenous glucose infusion. The duration of hospitalization was of 133 days (mean  $3.73 \pm 1.53$  days). 9/30 (30%) of newborns were discharged with exclusive breastfeeding, and only 2/9 (22.2%) were complementary fed. The characteristics of asymptomatic infants in both group were similar in term of risk factors (e.g. prematurity, IUGR, LGA, etc.).

Table 3  
Risk factors for hypoglycemia in Gr2.

	Number	%
Maternal diabetes	94	30.5
LBW	79	26.7
Birth weight > 4000 gr	50	16.2
Prematurity	36	11.7
LGA	35	11.4
Perinatal distress	4	1.3
IUGR	3	1
Hypothermic infants	2	0.7
Maternal drugs	1	0.5

In Table 4 we reported outcomes of the two groups.

Table 4  
Comparison of outcomes in the two groups.

	Gr1 Newborns n = 39	Gr2 Newborns n = 30	P value
NICU admission (n,%)	19 (48.7%)	3 (10%)	0.001
Glucose intravenous therapy (n,%)	14 (35.9%)	3 (10%)	0.01
Length of hospitalization (d)	$6.43 \pm 6.36$	$3.73 \pm 1.53$	< 0.001
Exclusive Breastfeeding at discharge (n,%)	3 (7.7%)	9 (30%)	0.02

## Discussion

Neonatal hypoglycemia still remains a challenge, due to the uncertainty in its definition and in the threshold to consider intervention [12]. For asymptomatic at-risk neonates, management is focused on normalizing their blood glucose levels and preventing both short and long-term severe neurological sequelae. Secondary but relevant target is to reduce physical separation between mothers and newborns so enhancing bonding and breastfeeding success. The introduction of the administration of 40% dextrose gel in the protocols for hypoglycemia was targeted to control neonatal asymptomatic hypoglycemia until feeding was established, to reduce the need of glucose intravenous therapy and NICU admission, and to promote breastfeeding and maternal bonding.

We analyzed the data from two groups of newborns at-risk for hypoglycemia, managed with (Gr2, prospective study group) or without the administration of 40% dextrose gel (Gr1, historical control group).

In the last decades, the incidence of neonatal hypoglycemia in otherwise healthy infants is 5–15% [1, 13]; in our experience this data is respected, because we found an incidence of 10% (39/389) in the historical group (Gr1) and 12% (37/308) in the cohort of infants managed with the new protocol (Gr2).

Gr2 presented a reduced need of NICU admission, of iv therapy and a shorter length of hospitalization. Moreover, the rate of exclusively breastfed newborns at discharge, was higher in this group of infants when compared to the infants of the historical group (Gr1).

We found a significant different incidence of NICU admission for hypoglycemia: 48.7% (19/39) in the historical cohort of patients (Gr1) versus 10% (3/30) in the cohort of patients treated with dextrose gel at 40% (Gr2). This finding is similar to data reported in the literature. Rawat et al [14] demonstrated that the introduction of dextrose oral gel for the management of hypoglycemia reduced the hospitalization rate from 42–26% ( $p < 0.01$ ). Similar findings were found by Scheans et al [15], who demonstrated that in the first year of use of dextrose gel the admission at NICU due to hypoglycemia was reduced of 73%. In other two studies performed in Australia [16] and USA [17], the Authors found a reduction of admission to NICU for the treatment of hypoglycemia of 15% and 7.7%, respectively. On the contrary, two recent studies did not demonstrate the efficacy of the dextrose gel to reduce NICU admission rates. In the former study [18], the Authors found a non-significant reduction from 2.5–1.5%; they tried to explain this result suggesting that the study took place in a Baby-Friendly Hospital with a low NICU admission rates already before the introduction of dextrose gel for the management of hypoglycemia. Ponnappakkam et al [19] explained their controversial results by pointing out that despite a high compliance with dextrose gel usage, the skin-to-skin care and the early feeding are more comfortable measures for healthcare to prevent neonatal hypoglycemia.

In our study the percentage of patients who required iv treatment was significantly reduced from 35.9–10% in the cohort of newborns managed with dextrose oral gel at 40%. Similar conclusions were reached in other studies. Rawat et al [14] demonstrated a reduction of iv therapy of 15.5%, Gregory et al. [20] showed a reduction from 8.6–5.6% after the introduction of dextrose oral gel in clinical practice and, at last, even the retrospective study of Makker et al [21] emphasized the significant impact of the oral treatment on the NICU admission rate and the number of iv dextrose administration. The Cochrane review

of 2016 [10] showed no significant differences in the need of iv treatment between the group of patients treated with dextrose oral gel and placebo group, but the authors underlined the low quality of the two included studies due to inaccuracy of data collection, the presence of bias and deviations on outcomes analyzed.

Our data showed that even the length of hospital stay of asymptomatic hypoglycemic newborns managed with dextrose oral gel (Gr2) was significantly shorter than newborns in Gr1. This conclusion is, of course, linked to the reduced transfer of patients at NICU and the reduced need of iv treatment. In the same way, Rawat et al [14] and Stewart et al [22] showed a significant decrease of the length of hospital stay from  $7.3 \pm 4.3$  to  $3.1 \pm 1.1$  days and from 5.8 to 3.8 days, respectively. Conversely, Makker et al [21] found no differences in the length of hospitalization between newborns managed with dextrose oral gel and iv treatment. The authors concluded that this non-randomized and not-controlled study could have some limitations regarding especially the impact of the new protocol on healthcare routine and the maximum number of doses of dextrose oral gel fixed at 4 times instead of 6 administrations as usually made in the other studies.

Although in our study we did not directly perform a cost analysis, we observed the results of similar studies in literature [23] and we can assume that a reduced number of NICU admission, less iv treatment and a shorter length of hospitalization, make dextrose oral gel a less costly option for the management of neonatal asymptomatic hypoglycemia.

The rate of exclusive breastfeeding at discharge was the last secondary outcome evaluated in our study. Many data from the literature [24, 25] underline the crucial role of early initiation of breastfeeding and the skin-to-skin care immediately after birth. This is crucial to increase and promote maternal bonding and breastfeeding and to achieve successful exclusive breastfeeding during hospitalization and at discharge. Our results showed a significantly increased rate of newborns exclusively breastfed in group 2: 30% (9/30) in Gr2 vs 7.7% (3/39) in Gr1. This is certainly related to the fact that it was possible, in the first hours of life, to keep mothers and newborns together thanks to the use of dextrose gel. Several others studies in literature confirmed our result. Rawat et al [13] and Makker et al [21] demonstrated an increase of exclusive breastfeeding in newborns managed with dextrose oral gel from 19–28% and from 6–19%, respectively. Weston et al in 2016 [10] confirmed the increase in the percentage of exclusive breastfeeding at discharge in the group of newborns treated with dextrose oral gel during hospital stay. Two studies in literature showed different results. Stanzo et al [18] found an increase in exclusively breastfed newborns from 56.6–59.1%. This not significant result could be linked to the high rate of breastfeeding even before the introduction of management of hypoglycemia with dextrose oral gel, due to the Baby-Friendly practices. Ponnappakkam et al [19] showed an increase only of 3 percentage points in exclusive breastfed infants and they attributed this result to the critical issues related to the new protocol for healthcare personnel but also to the frequent rotation of the same staff.

In order to reduce this bias, before the application of the new protocol for the management of at-risk infants for hypoglycemia, in our department we performed several training sessions with doctors, nurses

and residents. Although we have not assessed it directly, we can say that the administration of dextrose oral gel was tolerated by newborns, and, especially, by parents and staff. Moreover, the administration of dextrose oral gel appears safe even in the long term, as indicated by the data in literature [26].

One of our concerns was the possible adverse effect of dextrose gel on breastfeeding; in fact it is reported that the administration of any supplements in the neonatal period may delay the establishment of breastfeeding, and decreased its duration [27, 28]. However, our data show that newborns managed with dextrose oral gel present higher rate of exclusive breastfeeding.

Our study has several limitations. First of all, the COVID 19 pandemic forced us to interrupt the Group 2 recruitment (due to less availability of hospital staff) and this group is less numerous. Some inhomogeneities between groups are shown in Table 1: birth weight and gestational age differences, though statistically significant, do not change the clinical definition of the neonates, who remain adequate for gestational age (AGA) and term neonates. Moreover this is a comparison between a prospective group and a historical group managed with two different protocols for the management of asymptomatic hypoglycemia. The analysis of retrospective data may limit the stringency and robustness of data quality, and it was dependent on the accuracy of documentation by clinical staff. Finally, we did not evaluate the rate of breastfeeding after discharge; this data could be interesting to confirm the relevant role of dextrose gel to improve breastfeeding during the hospital stay in hypoglycemic infants.

## Conclusions

Future large randomized control trials are needed to provide further insight into the management with dextrose gel at 40% for neonatal symptomatic hypoglycemia and to provide data about neurological outcomes. Once the effectiveness of the dextrose gel for the treatment of asymptomatic neonatal hypoglycemia has been confirmed, it would also be interesting to investigate, the role of this therapy in every single different risk factor for hypoglycemia, evaluating the short and long term outcomes.

## Abbreviations

NICU: neonatal intensive care unit; IV: intravenous; LGA: large for gestational age; IUGR: intra uterine growth restriction; GA: gestational age; SGA: small for gestational age; AGA: adequate for gestational age; LBW: low birth weight

## Declarations

### Ethics approval and consent to participate

The study was approved by our local IRB and parental consents were obtained.

### Consent for publication

Collected before patient enrollment; availability of data at V. Buzzi Children Hospital, Milan, Italy.

### **Availability of data and materials**

At V. Buzzi Children Hospital, Milan, Italy.

### **Competing interests**

The authors declare that they have no competing interests.

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### **Author Contributions**

Conceptualization, Irene Daniele, Francesca Castoldi, Francesco Cavigioli and Gianluca Lista; Data curation, Martina Manzalini; Formal analysis, Petrina Bastrenta; Investigation, Martina Manzalini and Miriam Acunzo; Methodology, Martina Manzalini, Miriam Acunzo and Gianluca Lista; Resources, Miriam Acunzo; Supervision, Gianvincenzo Zuccotti and Gianluca Lista; Validation, Irene Daniele, Francesca Castoldi and Gianluca Lista; Writing – original draft, Fabio Meneghin; Writing – review & editing, Francesca Castoldi and Gianluca Lista.

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## Figures

**Which are glycaemic targets?**  
 0 - 4 hrs of life: > 40 mg/dl  
 4 - 24 hrs of life: > 45 mg/dl  
 24 - 48 hrs of life: > 50 mg/dl  
 > 48 hrs of life: > 60 mg/dl

**Which are symptoms?**  
 - Excitement, irritability, acute crying  
 - Hypotonia  
 - Tremor, Convulsion  
 - Apnoea, cyanosis  
 - Irregular breathing patterns  
 - Sobbing > 1h, RR> 60/min

**Which are risk factors?**

MONITORING FOR 24h [ 2-4-6-8-12-18-24 ]  
 - SGA (< 10<sup>o</sup> p.le)  
 - IUGR  
 - Neonatal weight < 2500 g  
 - Preterm newborn (<37 sett)

MONITORING FOR 12h [2-4-6-8-12]  
 - LGA (>90<sup>o</sup>p.le) o > 4500 g  
 - Maternal diabetes  
 - Maternal preeclampsia/eclampsia or hypertension  
 - Drug use in pregnancy (e. g. beta blockers oral hypoglycemic agents, intrapartum maternal glucose infusion)

BLOOD SUGAR TEST IF:  
 - Perinatal stress, Asphyxia  
 - Urgent CS because of foetal distress or post-term  
 - meconium aspiration syndrome, erythroblastosis fetalis, polycythemia hypothermia, metabolic acidosis, (umbilical-cord gas analysis: pH <7,1 and/or BE < -10 mEq/L)

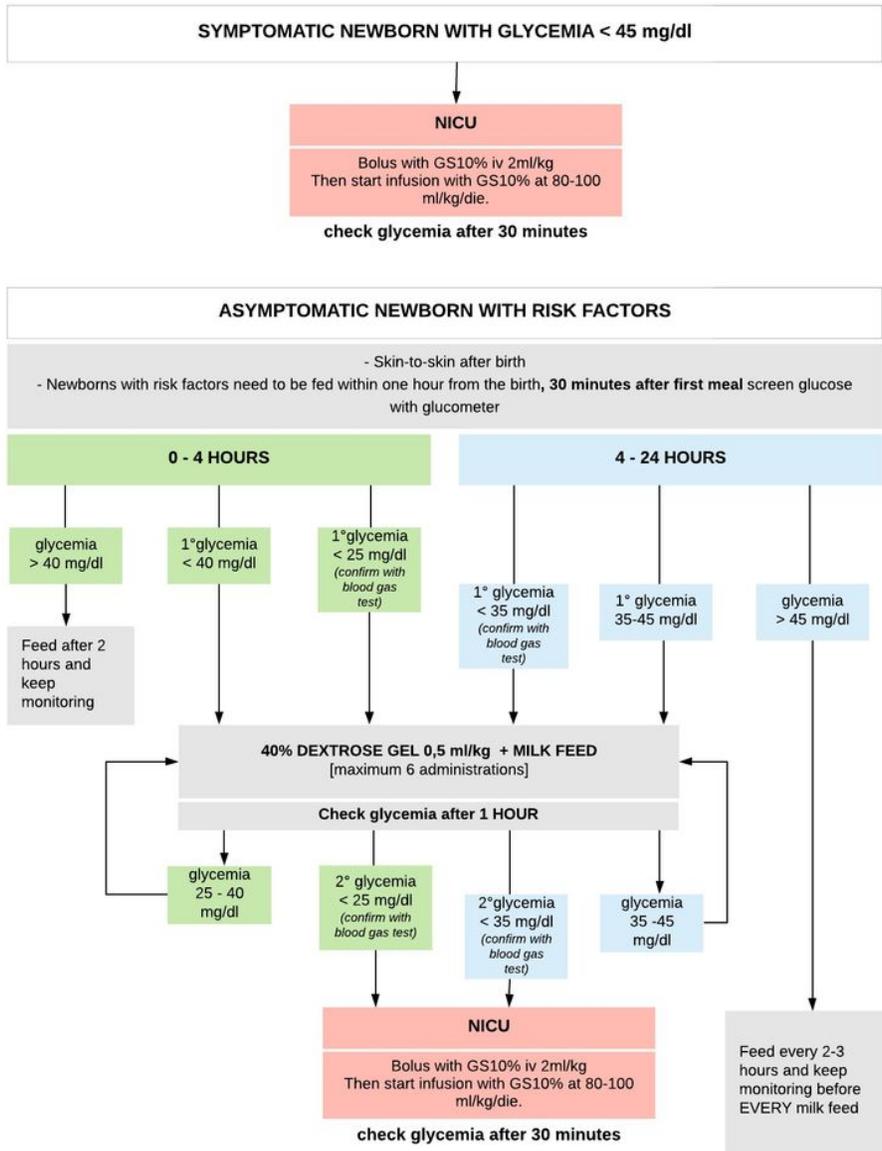


Figure 1

flow chart of new protocol for the management of hypoglycemia.