Diabetic Hypoglycemia: Questions and Controversies

Presented by the
International Hypoglycaemia Study Group (IHSG)
at the
9th World Congress on Prevention of Diabetes and its Complications

December 3, 2016
Atlanta, Georgia, USA

Brought to you by members of the International Hypoglycaemia Study Group
Welcome & Introductions

Elizabeth Seaquist, MD, CDE
Professor of Medicine, Pennock Family Chair in Diabetes Research
Director, Division of Endocrinology and Diabetes
Department of Medicine, University of Minnesota
2014 President of Medicine and Science
American Diabetes Association
Minneapolis, MN, USA
WELCOME TO ATLANTA!
Formed in 2013

16 members from around the globe

Simon Heller, Chair, UK
Stephanie Amiel, UK
Pablo Aschner, Colombia
Belinda Childs, USA
Philip Cryer, USA
Bastiaan de Galan, The Netherlands

Brian Frier, UK
Linda Gonder-Frederick, USA
Tim Jones, Australia
Kamlesh Khunti, UK
Lawrence Leiter, Canada

Yingying Luo, China
Rory McRimmon, UK
Elizabeth Seaquist, USA
Robert Vigersky, USA
Sophia Zoungas, Australia

The International Hypoglycaemia Study Group (IHSG) is supported through an unrestricted education grant from Novo Nordisk A/S and is consistent with its ongoing commitment in diabetes.

Six Degrees Academy supports the IHSG with project management, logistics and supporting tactics.
WHY HYPOGLYCEMIA MATTERS

Higher incidence of hypoglycemia occurs as patients move closer to HbA1c treatment targets

Raise awareness globally across the healthcare & patient community

A better understanding can increase patient quality of life

Our goal is to improve the lives of patients with diabetes

It is an under-recognized problem that deserves increased awareness

There is a lack of understanding by both professionals and patients

Strategies & tools are needed to help physicians manage & prevent hypoglycemia
OUR OBJECTIVE THIS MORNING

To highlight important but lesser-known aspects of hypoglycemia
AGENDA

8:05 am Hypoglycemia Classification
Simon Heller

8:15 am Impaired Awareness of Hypoglycemia
Stephanie Amiel

8:30 am Fear of Hypoglycemia
Linda Gonder-Frederick

8:45 am Panel Q&A Session
All
Hypoglycemia Classification

Simon Heller, BA, MB, Bchir, DM, FRCP
Professor of Clinical Diabetes, University of Sheffield
Director of Research and Development
Honorary Consultant Physician
Sheffield Teaching Hospitals Foundation Trust
Sheffield, UK
Presenter Disclosure

- **Advisory Board Member:** Eli Lilly, Novo Nordisk, Sanofi Aventis, Takeda
- **Consultant:** Eli Lilly, Novo Nordisk, Takeda, Boeringher Ingelheim
- **Research Support:** Medtronic
- **Speaker’s Bureau:** Eli Lilly, Novo Nordisk, Sanofi Aventis, Takeda, AstraZeneca, Johnson & Johnson
What’s missing or misguided in the current classification of hypoglycemia?
Background

- June 2004 ADA Workgroup formed to advise FDA how hypoglycemia should be used as an end point in studies for diabetes
- Report in Diabetes Care 2005 recommended plasma glucose of equal or less 70mg/dl (3.9mmol/l)
- Provokes criticism in papers written by European authors
- Criticisms refuted by chairman of the workgroup who claims transatlantic differences are small
What did the ADA group actually say?

Addressed 3 questions:

1. How should hypoglycemia be defined?
2. How should hypoglycemia be reported?
3. What constitutes a meaningful reduction in hypoglycemia?
The definition should apply to:
- clinical decisions by people with diabetes and HCPs
- studies of diabetes drugs, devices, or management strategies

And should be:
- free from reporting biases
- clinically important
- applicable to all persons with diabetes
- applicable to any time of day
- measurable by practical and widely available methods,
- reportable in a standardized fashion
Hypoglycemia: An outcome critically relevant to patients

- Predicts serious morbidity and mortality
- Limitations of traditional definitions:
  - Symptoms occur at different glucose levels
  - People with impaired awareness may not have symptoms
  - Some asymptomatic hypoglycemia is clinically relevant
- Severe – often uncommon in many trials leading to insufficient statistical power to compare interventions
- Current classification doesn’t capture all significant hypoglycemia
  - Real-world prevalence is higher than clinical-trial prevalence
  - 70mg/dl (3.9mM) is not usually associated with morbidity
- *Strong* case for third agreed level denoting major-serious hypoglycemia at around 50-55mg/dl
Evidence for impaired cognitive function 3 mmol/L < 54mg/dl

- **Math Time**
  - BG level (mmol/L): <3.0, 3.0-3.8, 3.9-9.9, 10-16.6, 16.7-22.1, >22.1
  - Time (sec): 73, 70, 65, 60, 75, 80

- **Reaction Time**
  - BG level (mmol/L): <3.0, 3.0-3.8, 3.9-9.9, 10-16.6, 16.7-22.1, >22.1
  - Time (sec): 21, 18.5, 19.0, 19.5, 20.0, 22.0

Evidence that a glucose level of <54mg/dl leads to impaired awareness of hypoglycemia.

Studies inducing reduced awareness at <54mg/dl (3mmol/l)

Evidence for arrhythmias triggered by glucose levels <54 mg/dl

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incident rate ratio [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex VPB</td>
<td>0.52 [0.32; 0.86]</td>
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<tr>
<td>VPB</td>
<td>1.11 [0.90; 1.36]</td>
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<tr>
<td>Atrial ectopic</td>
<td>2.07 [1.70; 2.52]</td>
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<tr>
<td>Bradycardia</td>
<td>8.98 [7.16; 11.26]</td>
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</table>

Evidence for increased mortality associated with glucose levels <55mg/dl

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Deaths no.</th>
<th>Population no.</th>
<th>Median Time from Randomization to Hypoglycemia (IQR) days</th>
<th>Median Time from Hypoglycemia to Death (IQR) days</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
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</thead>
<tbody>
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<td>726</td>
<td>3089</td>
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<tr>
<td>Moderate hypoglycemia</td>
<td>774</td>
<td>2714</td>
<td>1 (0-2)</td>
<td>7 (2-21)</td>
<td>1.81 (1.59-2.07)</td>
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<tr>
<td>post-randomization characteristics</td>
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<td>1.41 (1.21-1.62)</td>
<td>&lt;0.001</td>
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<tr>
<td>Severe hypoglycemia</td>
<td>79</td>
<td>223</td>
<td>4 (2-9)</td>
<td>8 (3-15)</td>
<td>3.21 (2.49-4.15)</td>
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Arrows indicate decreased risk of death (→) and increased risk of death (←).
Classifying hypoglycemia in clinical trials – Level 1

- Alert value for patients and clinicians
- Usually asymptomatic
- Requires re-checking
- May require alterations in insulin dose/type

70mg/dl (3.9mM)
Alert value for patients (and clinicians)
Classifying hypoglycemia in clinical trials – Level 2

- Denotes impaired cognitive function
- Repeated episodes cause reduced awareness and predict severe episodes
- Predicts cardiac arrhythmias and mortality

<54 mg/dl (3 mmol/l)

Potential terms include:
- serious
- major
- clinically relevant
- clinically significant
Classifying hypoglycemia in clinical trials – Level 3

- Severe cognitive impairment
- requiring external assistance
- or coma/seizure
- As defined by ADA working group
Conclusions

- Hypoglycemia remains an inevitable consequence of insulin or sulphonylureas treatment.
- Current study outcomes fail to measure the true burden of hypoglycemia in people with diabetes treated with insulin or sulphonylureas.
- Hypoglycemia should be measured in more depth in clinical trials.
- An additional glucose level of 3 mmol/l (< 54 mg/dl) should be reported in clinical trials.
Impaired Awareness of Hypoglycemia

Stephanie Amiel, MD, FRCP
RD Lawrence Professor of Diabetic Medicine
Division of Diabetes and Nutritional Sciences
King’s College
London, UK
• **Advisory Board Member**: Medtronic, Novo Nordisk
The meaning of impaired awareness

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<td><strong>Friday</strong></td>
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<tr>
<td>6.9</td>
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</table>
Dictionary definitions:

Unaware (pnǎwē³)
- Not aware (of)
- Not cognizant

- Ignorant (1704)
- Blind to the consequences
- Reckless (rare) 1817

The Shorter Oxford Dictionary.
The identification of impaired awareness

“Do you know when your hypoglycemic symptoms are commencing?”

Always aware: 1, 2, 3

4, 6, 7 Never aware

<table>
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<tr>
<th></th>
<th>T1DM</th>
<th>T2DM</th>
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<tr>
<td>Events</td>
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<td>0.38</td>
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<td>Episodes per patient per month</td>
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Normal awareness of hypoglycemia
Impaired awareness of hypoglycemia

Geddes et al., 2008.
Schopman et al., 2010.
The identification of impaired awareness

Do your symptoms of hypoglycemia usually occur at a blood glucose level of:
- Greater than/equal to 3 mmol/l (54 mg/dl)
- Less than 3 mmol/l (54 mg/dl)
- Do not feel symptoms

Hopkins et al., 2012;35:1638.
Pedersen-Bjergaard et al., 2004.
The identification of impaired awareness

Do your symptoms of hypoglycemia usually occur at a blood glucose level of:
- Greater than/equal to 3 mmol/l (54 mg/dl)
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Do you have symptoms, when you have a hypo?
- ‘always’ = aware
- ‘usually’ = impaired awareness
- ‘occasionally’ or ‘never’ = unaware

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“Do you know when your hypos are commencing?”

Always aware 1 2 3 4 5 6 7 Never aware

Hopkins et al., 2012;35:1638.
Pedersen-Bjergaard et al., 2004.
The identification of impaired awareness

Step 2: Review the records

- < 3 mmol/l

Step 3: Ask the family

- < 54 mg/dl
The ADA checklist

- 15-item patient questionnaire
- Health care provider check-list

**Table 3—Hypoglycemia Provider Checklist**

<table>
<thead>
<tr>
<th>First</th>
<th>Middle</th>
<th>Last</th>
<th>Today's date</th>
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</table>

1. _Reviewed the Hypoglycemia Patient Questionnaire_
2. _Questioned the patient about circumstances surrounding severe or moderate hypoglycemia_
3. _Discussed strategies to avoid hypoglycemia with the patient_
4. _Made medication changes where clinically appropriate_
5. _Recommended carrying snack and/or glucose tablets where appropriate and provided instructions for how to use them_
6. _Prescribed glucagon if appropriate_

Seaquist et al., *Diabetes Care*, 2102.
Who is at risk?

Type 1

- Age: Preserved - 40, Impaired - 50
- Duration DM: Preserved - 20, Impaired - 30
- HbA1c: Preserved - 70, Impaired - 80

And in type 2...

**Awareness of hypoglycemia**

<table>
<thead>
<tr>
<th>Gold score</th>
<th>Episodes (SH)/patient/year</th>
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<tr>
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<td>2</td>
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**But no differences in ...**

- Age (yrs)
- Duration DM (yrs)
- Duration insulin Rx
- HbA1c (mmol/mol)
- Neuropathy (%)

Structured education in flexible intensive insulin therapy

DAFNE


HbA1c (%)

Years of follow-up

Severe hypoglycemia per 100 pt.y
40% of people coming to structured education had IAH
Structured education restores awareness to 43%
Technology can help some of the rest
‘Thinking traps’

“I’ll be ok”
“It’ll (SH) never happen to me”

“I need to avoid going high at any cost”
“I will ruin my diabetes control”

“I don’t want to make a fuss”
“I should just get on with it”

It is part of my diabetes

It can’t be fixed!
Impact of DAFNE HART on hypoglycemia

Severe Hypoglycemia Episodes Per Year

Moderate Hypoglycemia Episodes Per 6 Weeks

Summary and conclusions

- Impaired awareness of hypoglycemia identifies people at risk for severe episodes
- It is easy to diagnose
- Avoidance of exposure to < 3 mmol/l (54 mg/dl) restores awareness
- This can be achieved through a pathway of education, medications with low risk of hypoglycemia, pumps and sensors, transplantation
- For some, addressing beliefs and cognitions around hypoglycemia may be key
Fear of Hypoglycemia

Linda Gonder-Frederick, Ph.D.
Associate Professor
Department of Psychiatry and Neurobehavioral Sciences
University of Virginia, Charlottesville, Virginia
Disclosures

- Linda Gonder-Frederick has been a consultant for, received research funding/support from, and served on advisory boards for:
  - Abbot Laboratories
  - AstraZeneca plc
  - Dexcom Inc.
  - Johnson & Johnson Services, Inc.
  - Merck & Co., Inc.

- The Hypoglycemia Fear Survey (HFS) is licensed to pharmaceutical companies and other for-profit organizations. These licensing fees are used to sponsor research on the problem of hypoglycemia and fear of hypoglycemia.
Defining and Measuring Fear of Hypoglycemia

1. Hypoglycemia Fear Survey (HFS)
   - Worry Subscale
   - Behavior Subscale

2. HFS Versions
   - Adults with Type 1 and Type 2 Diabetes
   - Children/Youth with Type 1 Diabetes
   - Parents of Children/Youth with Type 1 Diabetes
   - Parents of Very Young Children (< 8 years)
   - Spouses/Partners/Caretakers
Fear of Hypoglycemia Occurs in Individuals Living with Diabetes and Their Families/Loved Ones Across Countries and Cultures
Predictors of Fear of Hypoglycemia

Hypoglycemia History
• Recurrent SH
• Frequency of hypos
• Traumatic episodes

General Anxiety
• Trait anxiety
• Anxiety sensitivity

Fear of Hypoglycemia
Hypoglycemia and fear of hypoglycemia (FoH) are the biggest barriers to optimal diabetes control for both:

Patients and Health Care Professionals

Clinical impact cannot be overstated
Impact of Fear of Hypoglycemia On Quality of Life

- Increased Anxiety and Depression
- Reduced Diabetes Self-Efficacy
- Restriction of Normal Activities (travel)
- Relationship Conflict and Tension
Willingness to Use or Prescribe Insulin

Barrier to Exercise and Physical Activity

Maintaining Higher Blood Glucose Levels to Reduce Fear
Impact of Fear of Hypoglycemia On Families/Significant Others

- **Parents of children with T1D:**
  - Generally experience more FoH than adults with diabetes
  - Especially if their child has a history of seizure or unconsciousness due to hypos

- **Non-diabetic Spouses and Partners**
  - Typically experience higher levels of FoH than their loved ones with diabetes
Consistency in findings across countries and cultures

U.S., Netherlands, U.K., China, Turkey, Iran, Norway, Germany, Slovenia, Australia, Saudi Arabia, Canada, Spain, and Sweden
Some Fear of Hypoglycemia Is Adaptive

[Diagram showing a bell curve with the term "Appropriate" in the middle, indicating a zone of moderate fear of hypoglycemia between low and high levels.]
Fear of Hypoglycemia Is Not A Linear Construct

- 32% Low risk, High concern
- 17% High risk, High concern
- 43% Low risk, Low concern
- 8% High risk, Low concern

Fear of Hypoglycemia Is Not A Linear Construct

- Low risk
  - High concern

- High risk
  - High concern

Risk of severe hypoglycemia

- Low risk
  - Low concern

- High risk
  - Low concern

Interventions For Fear of Hypoglycemia

- Medical
- Educational
- Psychobehavioral
- Technological
Clinical Implications: Patient Education

- A randomized control trial (n = 249, age 2-18 years)

- After 24 months, episodes of SH decreased from 42% to 25%
- No Δ in HbA$_{1c}$
- Cost < 10€

Clinical Implications: The “Technology Solution”

- Insulin Pump (CSII)
- Continuous Glucose Monitor (CGM)
- Sensor Augmented Pump (SAP)
- Low Glucose Suspend (LGS)
- Predictive LGS
Clinical implications

Assess the frequency and severity of episodes and

Indicators of problematic FoH
- Impact of quality of life
- Emotional implications
- The impact on diabetes self-care
Thank you!
Panel Q&A Session
QUESTIONS FOR OUR PANEL

Question?

1. Raise your hand
2. Ask your question live

OR

1. Write it down
2. Raise your hand to have it collected
Please take a moment to complete the evaluation form for today’s meeting

Coming soon...

- CME slide presentation
- Physician and patient tools
- IHSG website

Learn about these and other IHSG initiatives by signing up for our website mailing list via the evaluation form.
THANK YOU

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