TYPE 2 DIABETES MANAGEMENT

A Team Approach to Managing Hypoglycemia, Comorbidities, and Patient Challenges

Please use a dark pen and press firmly when marking responses or filling in information, and return completed form to on-site staff.

Please select the best answer(s) for the questions below:

Degree:  ○ MD/DO  ○ Nursing Professional  ○ PharmD  ○ RD  ○ Other: _____________________________

Specialty:  ○ Endocrinologist  ○ Diabetologist  ○ Diabetes Educator  ○ PCP  ○ Internist  ○ Other: ______________________

1. Please rate your confidence in integrating guidelines to individualize the management of T2DM patients:
   - Expert
   - Very confident
   - Confident
   - Slightly confident
   - Not confident

2. Please rate your confidence in managing T2DM in patients with multiple prevalent macro- and/or microvascular comorbidities:
   - Expert
   - Very confident
   - Confident
   - Slightly confident
   - Not confident

3. Please rate your confidence in using GLP-1 receptor agonists, DPP-4 inhibitors, and SGLT2 inhibitors to reduce HbA1c in your T2DM patients:
   - Expert
   - Very confident
   - Confident
   - Slightly confident
   - Not confident

4. How often do you incorporate a shared decision-making (SDM) approach to T2DM management?
   - Always
   - Frequently
   - Sometimes
   - Never
   - I do not know the definition of SDM

5. How often do you evaluate the risk of hypoglycemia in your T2DM patients and adjust management as necessary to avoid hypoglycemic episodes?
   - Always
   - Frequently
   - Sometimes
   - Never

6. Do you participate in quality reporting initiatives, such as PQRS from CMS?
   - Yes
   - No
   - I don’t know what PQRS is

1. NS is a 64-year-old man who had been taking metformin 1000 mg BID for 3 years. Four months ago, he added glyburide 10 mg QD to his treatment regimen to gain better control of his hyperglycemia. His A1c dropped from 7.9% on metformin alone to 7.4% today. However, he has noted an increase in episodes of hypoglycemia since adding glyburide. Which of the following strategies might you recommend in order to reduce his risk of hypoglycemia?
   - Discontinue glyburide and stay on metformin 1000 mg BID
   - Reduce the dose of metformin to 500 mg BID
   - Switch to metformin plus basal insulin
   - Switch to metformin plus a SGLT2 inhibitor

---CONTINUED NEXT PAGE---
2. Which of the following characteristics might prevent you from prescribing an SGLT2 inhibitor for a patient?

- Renal insufficiency, GFR 43 ml/min
- A history of recurrent UTIs
- Orthostatic hypotension
- All of the above
- None of the above

3. MK is a 60-year-old woman who was diagnosed 3 years ago with T2DM. She is currently taking metformin 1000 mg BID. Her A1c is 7.9%. She has gained 14 lbs in the past 9 months, and is very unhappy about her weight (current BMI, 28.2 kg/m²). Which of the following changes to her treatment regimen do you expect to result in the greatest reduction in body weight?

- Addition of a sulfonylurea
- Addition of a DPP-4 inhibitor
- Addition of a GLP-1 receptor agonist
- Switch to basal insulin

4. RL is a 52-year-old husband and father of 3 children aged 11 to 19 years. He was diagnosed 4 years ago with T2DM. He takes metformin, although he admits to skipping a few doses per week. His A1c is 7.6%. He is a smoker and drinks socially. He is obese (BMI, 31.4 kg/m²), and his wife and children are also overweight. Which of the following is an example of shared decision-making?

- Refer the patient to a smoking cessation program
- Involve a certified diabetes educator to coach the patient on self-management techniques
- Ask the patient to identify 3 lifestyle changes that he is willing to adopt for the next month
- Invite the patient’s family to attend a community diabetes education and screening event
TYPE 2 Diabetes Management
A TEAM APPROACH TO MANAGING HYPOGLYCEMIA, COMORBIDITIES AND PATIENT CHALLENGES

PROGRAM SYLLABUS

Presented by

Philip Raskin, MD, FACP, FACE, CDE
Gwinnett Medical Center
November 11, 2014

Jointly provided by Potomac Center for Medical Education and Rockpointe
Supported by an educational grant from Merck
CONTENTS

Program Overview/Statement of Need ........................................ Page 3
Target Audience and Learning Objectives................................ Page 3
CME Statements ........................................................................ Page 4
Disclosures ................................................................................. Page 5
Steering Committee .................................................................... Pages 6-7
Faculty ........................................................................................ Page 8

ADDITIONAL PACKET CONTENTS

Pre-activity Survey........................................................................ Front of packet
   After filling out the survey, please separate from packet and return to onsite staff

Program Slides
   Copy of presentation slides with space for note-taking

Post-activity Survey and CME Evaluation ............................... Back of packet
   After filling out the survey and evaluation, please separate from packet and return to onsite staff. The evaluation must be completed to receive CME credit.
PROGRAM OVERVIEW/STATEMENT OF NEED

The Potomac Center for Medical Education and Rockpointe welcome you to *Type 2 Diabetes Management: A Team Approach to Managing Hypoglycemia, Comorbidities, and Patient Challenges*, a CME-certified Grand Rounds program designed to give medical professionals the latest news and information on the management of T2DM patients.

The prevalence of type 2 diabetes mellitus (T2DM) continues to rise at an alarming rate, and National Committee on Quality Assurance (NCQA) data show that many patients are not reaching their HbA1c target goals. The fact that hypoglycemia often goes unrecognized or is not reported by patients has complicated treatment decisions in T2DM, increasing the risk of mortality. In addition, the national health care quality strategy stresses the need for improved communication with patients and their families to ensure optimal patient engagement and self-management to enhance outcomes.

Using a highly interactive case-based format, *Type 2 Diabetes Management* will provide participants with up-to-date information and real-world approaches for the management of complicated T2DM patients at risk of hypoglycemia and with comorbidities, while delivering practical strategies for patient engagement.

TARGET AUDIENCE

This CME-certified initiative has a target audience of endocrinologists, family practitioners, primary care physicians, internists, nurse practitioners, pharmacists, physician assistants, diabetes educators, and other health care professionals involved in the care of T2DM patients.

EDUCATIONAL OBJECTIVES

This program is designed to address the following IOM competencies: provide patient-centered care and employ evidence-based practice.

*At the conclusion of this activity, participants should be able to demonstrate the ability to:*

- Consider the risk of hypoglycemia associated with current therapeutic agents when determining treatment and re-evaluate the impact of hypoglycemia on patient outcomes throughout the ongoing management of T2DM patients
- Integrate the most recent evidence with current guidelines to provide a multifaceted, individualized approach to patients with T2DM to maintain glycemic control and reduce vascular complications
- Empower patients through individualized patient education and collaboration with the care team to address the breakdown of barriers for optimal outcomes
ACCREDITATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Potomac Center for Medical Education and Rockpointe. The Potomac Center for Medical Education is accredited by the ACCME to provide continuing medical education for physicians.

CREDIT DESIGNATION

The Potomac Center for Medical Education designates this live activity for a maximum of 1.0 AMA PRA Category 1 credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

SPECIAL SERVICES

Event staff will be glad to assist you with any special needs (e.g. physical, dietary, etc.).

FEE AND RECEIVING CME CREDIT

There is no fee for this educational activity. To receive CME credit the participant must:

- Participate in this one-hour-long program in its entirety;
- Sign in / sign out on the sheet provided by the host coordinator;
- Complete and sign the registration and evaluation forms;
- Return the registration and evaluation forms to the host coordinator.
DISCLOSURE/CONFLICT OF INTEREST STATEMENT

The Potomac Center for Medical Education (PCME) adheres to the policies and guidelines, including the Standards for Commercial Support, set forth to providers by the Accreditation Council for Continuing Medical Education (ACCME) and all other professional organizations, as applicable, stating those activities where continuing education credits are awarded must be balanced, independent, objective, and scientifically rigorous.

All persons in a position to control the content of a continuing medical education program provided by PCME are required to disclose any relevant financial relationships with any commercial interest to PCME as well as to learners. All conflicts are identified and resolved by PCME in accordance with the Standards for Commercial Support in advance of delivery of the activity to learners. Disclosures will be made known to the participants prior to the activity.

The content of this activity was vetted by an external medical reviewer to assure objectivity and that the activity is free of commercial bias.

DISCLOSURES

Faculty Speaker

The faculty reported the following relevant financial relationships that they or their spouse/partner have with commercial interests:

**Philip Raskin, MD, FACP, FACE, CDE:** Advisor: AstraZeneca, GlaxoSmithKline, Janssen Pharmaceuticals; Research: Amylin, Andromeda Biotech Ltd., Bayer HealthCare, Boehringer Ingelheim, Gilead Sciences, Intarcia Therapeutics, Eli Lilly & Company, Merck Sharp & Dohme Corp, Novo Nordisk, Pfizer; Speaker: Janssen Pharmaceuticals

Steering Committee

The steering committee reported the following relevant financial relationships that they or their spouse/partner have with commercial interests:

**Silvio E. Inzucchi, MD:** Consultant/Advisory Board: Boehringer Ingelheim, Bristol-Myers Squibb, Merck; Research: Takeda; Trial Committee Member: Boehringer Ingelheim, Eisai, Novo Nordisk

**Ellen H. Miller, MD:** Speaker: AstraZeneca

Non-faculty Content Contributors

Non-faculty content contributors and/or reviewers reported the following relevant financial relationships that they or their spouse/partner have with commercial interests:

**Carole Drexel, PhD; Blair St. Amand; Jay Katz, CCMEP; AOE Consulting:** Nothing to disclose

FDA DISCLOSURE

The contents of some CME/CE activities may contain discussions of non-approved or off-label uses of some agents mentioned. Please consult the prescribing information for full disclosure of approved uses.
A native New Yorker, Silvio E. Inzucchi, MD received his undergraduate degree from Fordham University in the Bronx and his medical doctorate from Harvard Medical School in Boston. He completed his residency in internal medicine and his post-doctoral fellowship in endocrinology and metabolism at Yale-New Haven Hospital in New Haven, CT. He is currently Professor of Medicine at the Yale University School of Medicine, where he serves as Clinical Director of the Section of Endocrinology and Program Director of the Endocrinology and Metabolism Fellowship. He is also directs the Yale Diabetes Center at Yale-New Haven Hospital.

Dr. Inzucchi has been an invited lecturer both nationally and internationally on many topics, most pertaining to clinical diabetes management. He has authored or co-authored more than 350 manuscripts, chapters, and abstracts, some published in the foremost medical journals, including the New England Journal of Medicine and JAMA. A former member of the editorial board of Diabetes Care, Dr. Inzucchi is currently an Associate Editor of the Journal of Clinical Endocrinology and Metabolism. Dr. Inzucchi co-chaired the writing group for the 2012 ADA-EASD Position Statement on Antihyperglycemic Therapy in Type 2 Diabetes.

His current research interests include diagnostic criteria for diabetes; the link between type 2 diabetes, insulin resistance, and cardiovascular complications; the evaluation of the asymptomatic diabetic patient for coronary artery disease; and the inpatient management of hyperglycemia. Dr. Inzucchi also has a large academic clinical practice involving a wide spectrum of patients with endocrine and metabolic conditions.
STEERING COMMITTEE

ELLEN H. MILLER, MD
Associate Professor of Medicine
Hofstra North Shore-LIJ School of Medicine
Uniondale, NY

Ellen H. Miller, MD is an Associate Professor of Medicine at the Hofstra North Shore-LIJ School of Medicine. She also has a private practice in internal medicine, endocrinology, and reproductive endocrinology in Hewlett, NY.

Dr. Miller received her medical doctorate from New Jersey Medical School in 1980 and completed her post-graduate work at Beth Israel Medical Center and Columbia University. She is on the Editorial Board of Postgraduate Medicine, Physician and Sports Medicine, and Hospital Practice and is a Fellow of the American Association of Clinical Endocrinologists.

Dr. Miller has conducted extensive research in the areas of endocrinology and women’s health, and has authored articles that have been published in numerous medical journals.
PHILIP RASKIN, MD, FACP, FACE, CDE
Professor of Medicine
Clifton and Betsy Robinson Chair in Biomedical Research
University of Texas Southwestern Medical Center
Dallas, TX

Philip Raskin, MD, FACP, FACE, CDE received his medical degree from the University of Pittsburgh School of Medicine, where he also completed a residency in internal medicine. He completed a fellowship in endocrinology, diabetes, and metabolism at UT Southwestern Medical Center at Dallas. He is board-certified in internal medicine and endocrinology, diabetes, and metabolism. He is a Fellow of the American College of Physicians and the American College of Endocrinology, and is a Certified Diabetes Educator.

He is a Professor of Medicine in the Department of Internal Medicine and holds the Clifton and Betsy Robinson Chair in Biomedical Research at the University of Texas Southwestern Medical Center at Dallas. He also serves as the Director of the Diabetes Clinic at Parkland Health and Hospital Systems. He is the Principal Investigator for 4 NIH-funded multicenter diabetes trials: The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC); TrialNet; The Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE Study); and Vitamin D to Prevent Type 2 Diabetes (D2d Study).

Dr. Raskin is a clinical researcher widely renowned for his work in diabetes, diabetes complications, and diabetes management. He was the Editor of the Journal of Diabetes and Its Complications from 1990 to 2011 and has served as a past Editor of Clinical Diabetes.

He is widely published in such peer-reviewed journals as the New England Journal of Medicine, Journal of Clinical Investigation, Diabetes, Diabetes Care, Annals of Internal Medicine, and Journal of Diabetes and Its Complications. He has also authored numerous chapters in clinical text books.
Educational Objectives

At the conclusion of this activity, participants should be able to demonstrate the ability to:

• Consider the risk of hypoglycemia associated with current therapeutic agents when determining treatment and re-evaluate the impact of hypoglycemia on patient outcomes throughout the ongoing management of T2DM patients

• Integrate the most recent evidence with current guidelines to provide a multifaceted, individualized approach to patients with T2DM to maintain glycemic control and reduce vascular complications

• Empower patients through individualized patient education and collaboration with the care team to address the breakdown of barriers for optimal outcomes

CASE: Introduction

• Sophie is 87 years old and has had type 2 diabetes for 15 years
  – Initially diagnosed when she had an acute MI at the age of 62
  – Managed with glipizide 10mg BID since then with fairly good HbA1C levels

• Current concerns
  – Recent episodes of confusion/dizziness
  – Occasionally forgets medication and meals
  – Home glucose monitoring shows multiple hypoglycemic episodes throughout day:
    7 mg/dL, 7 mg/dL, 7 mg/dL
  – Wrong dose of medication, 7 missing meals

• Physical examination
  – Frail appearance (BMI: 19.0 kg/m²)
  – Rales at both lung bases posteriorly
  – Bilateral + pitting pedal edema

• Laboratory evaluation
  – Random glucose: 68 mg/dL; HgbA1C: 6.1%
  – SCr 1.7; eGFR: 28 mL/min/1.73 m²
  – CXR: Mild CHF

CASE: Key Patient Features and Considerations for Individualized Therapy

• Hypoglycemia
  – Risk factors?
  – Drug classes to avoid?

• Comorbid cardiovascular disease (heart failure)
  – Drug classes to avoid?

• Renal insufficiency
  – Drug classes to avoid?
  – Required dose adjustments?

Hypoglycemia Risk Factors in Elderly Patients with T2DM

• Advanced age
• Polypharmacy
• Sulfonylurea or insulin use
• Poor nutrition or fasting
• Intercurrent illness
• Chronic renal disease
• Chronic liver disease
• Prolonged physical exercise
• Alcohol ingestion
• Endocrine deficiencies (thyroid, adrenal, pituitary)
• Loss of normal counter-regulation
• Hypoglycemic unawareness

The Association Between Medication-related Hypoglycemia and Vascular Risk


![Graph showing correlation between hypoglycemia and vascular risk](image)

ADA/EASD General Recommendations for Hyperglycemia Management


ADA/EASD Adapted Recommendations: When Goal is to Avoid Hypoglycemia


PROactive: Heart Failure Events with Pioglitazone vs Placebo in T2DM

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Pioglitazone (n=2605) No. Patients (%)</th>
<th>Placebo (n=2633) No. Patients (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any report of HF (nonadjudicated)</td>
<td>281 (11)</td>
<td>198 (8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HF leading to hospitalization</td>
<td>149 (6)</td>
<td>108 (4)</td>
<td>0.007</td>
</tr>
<tr>
<td>HF leading to death</td>
<td>25 (1)</td>
<td>22 (1)</td>
<td>0.634</td>
</tr>
</tbody>
</table>

HF = heart failure; PROactive = Prospective Pioglitazone Clinical Trial in Macrovascular Events.


Adverse Events Associated with Thiazolidinedione Treatment

- Weight gain
  - Averages 1-5 kg (2-11 lbs)
  - Correlates with improved A1C; attenuates when A1C stabilizes
  - Greatest in combination with insulin and SU
- Fluid retention
  - Rarely severe; most common when used in combination with insulin
  - In patients with heart failure, more likely peripheral than pulmonary
  - Likely PPAR-gamma effect on Na+ handling by the distal renal tubule


What About SGLT2 Inhibitors?

- Insulin-independent action (can be used regardless of DM duration)
- Complement action of other anti-diabetic agents
- Weight loss
- Decreased BP
- Low hypoglycemia rates
- Recurrent UTI
- Genital fungal infection
- Dehydration/hypotension

Specific to individuals with existing renal insufficiency, the elderly, and those receiving loop diuretics.

Significance on patient outcomes is uncertain at this time.

Dose Adjustments and Contraindications in T2DM Patients with Renal Impairment

- **Metformin**: Contraindicated when SCr ≥ 1.5 (men), ≥ 1.4 women
- **SU**: dose reduction for renal insufficiency; do not use glyburide
- **Insulin**: dose reduction for renal insufficiency
- **GLP-1 receptor agonists**
  - Exenatide: do not use if eGFR <30
  - Others: use with caution
- **DPP-4 inhibitors**
  - Sitagliptin (100 mg QD): 50 mg for eGFR <50, 25 mg for eGFR <30
  - Saxagliptin (5 mg QD): 2.5 mg QD when eGFR <50
  - Linagliptin (5 mg QD): no dose adjustment needed
  - Alogliptin (12.5 mg QD): 6.25 mg QD for CrCl <30 mL/min
- **SGLT-2 inhibitors**
  - Canagliflozin (100-300mg QD): 100 mg QD for eGFR 45-<60; discontinues when eGFR <45; contraindicated when eGFR <30
  - Dapagliflozin (10 mg QD): do not initiate when eGFR <45; discontinues when eGFR persistently <50, contraindicated in severe renal impairment, ESRD, dialysis
  - Empagliflozin (10-25 mg QD): do not initiate when eGFR <45; discontinues when eGFR persistently <45; contraindicated in severe renal impairment, ESRD, dialysis


Profiles of Antidiabetic Medications

Of the recommended options for this patient, the DPP-4i class is associated with the fewest cautions. HbA1C lowering 0.5 – 0.9%

**CASE: Key Patient Features and Considerations for Individualized Therapy**

- **Hypoglycemia**
  - Risk factors: older age, concurrent medications (SUs, insulin), comorbidities
  - Drug classes to avoid (?) SUs, insulin
- **Comorbidity: Heart Failure**
  - TZD contraindicated
  - ? New data on DPP-4 inhibitors (specifically, saxagliptin in SAVOR-TIMI)
- **Renal Insufficiency**
  - Metformin contraindicated
  - SGLT2-inhibitors not effective
  - DPP-4 inhibitors: most require dose adjustment (linagliptin exception)
  - GLP-1-RAs acceptable but use cautiously

**Clinical Tips for Preventing Hypoglycemia**

- Address at each visit
- Individualize A1C goals – avoid aggressive targets in advanced disease
- Employ flexible, physiological insulin regimens
- Avoid long-acting secretagogues when possible
- Track renal function
- Consider hypoglycemia risk factors (age, disease duration, diet changes, CKD)
- Review and apply diabetes self-management
- Request frequent SMBG – reevaluate skills periodically
- Limit alcohol intake (≤1 drink/day in women, ≤2 drinks/day in men)
- Add carbohydrate before exercising if BG <140 mg/dL
- Strict avoidance of hypoglycemia for several weeks may partly resolve hypoglycemia unawareness

**CASE: Introduction**

- George is a 54-year-old accountant admitted to the hospital with acute MI
  - In-hospital laboratory panels:
    - Morning glucose levels: 138-163 mg/dL
    - HbA1C: 8.7%
  - Current concerns
    - Is anti-hyperglycemic therapy warranted upon discharge?
  - Medical history
    - Well-controlled hypertension, dyslipidemia, gout, obesity, and OSA
    - Does not smoke; no polyuria, polydipsia, blurred vision, or non-healing wounds
    - Father has T2DM and is currently on dialysis
CASE: Key Patient Features and Considerations for Individualized Therapy

• T2DM is commonly revealed during acute cardiovascular events
  – In an AMI population: 1/3 of patients have established DM, 1/3 have newly diagnosed T2D or ‘pre-diabetes’; the remainder are euglycemic (but may have metabolic syndrome)
  – T2D therapy in the context of CVD should attempt to avoid drugs that lead to substantial risk of hypoglycemia (i.e. activates adrenergic nervous system)
  – Sulfonylureas may also decrease the body’s ability to adapt to myocardial ischemia through ischemic preconditioning
  – Heart failure when present can also affect drug choices (e.g. no TZDs, ? DPP-4 inhibitors)

Impact of Intensive Therapy for Diabetes: Summary of Major Clinical Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Microvasc</th>
<th>CVD</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>UKPDS</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
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<tr>
<td>DCCT/EDIC</td>
<td>↓</td>
<td>↓</td>
<td>↑</td>
</tr>
<tr>
<td>ACCORD</td>
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<tr>
<td>ADVANCE</td>
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<tr>
<td>VADT</td>
<td>↓</td>
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<td>↓</td>
</tr>
</tbody>
</table>

Non-Insulin T2DM Therapies

<table>
<thead>
<tr>
<th>Class</th>
<th>CV ‘Advantages’</th>
<th>CV ‘Disadvantages’</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUs</td>
<td></td>
<td>↑ T CVD events</td>
</tr>
<tr>
<td>Biguanides</td>
<td>LDL ↓, CRP ↓, insulin ↑</td>
<td>↓ Ischemic preconditioning</td>
</tr>
<tr>
<td>TZDs</td>
<td>↑ HDL, ↓ TG, ↓ insulin, ↓ l-SCR, ↓ CVD events (pc)</td>
<td>↑ HF, ↑ LDL, ↑ CVD events (mos)</td>
</tr>
<tr>
<td>GLP-1 RAs</td>
<td>↓ weight, ↓ BP, ↓ TG, ↓ CRP, ↑ direct cardiac effect</td>
<td>↑ HR</td>
</tr>
<tr>
<td>DPP-4 inhibitors</td>
<td>↑ direct cardiac effect (via GLP-1)</td>
<td>↑ HF</td>
</tr>
<tr>
<td>SGLT-2 inhibitors</td>
<td>↓ BP, ↓ weight</td>
<td>↑ LDL</td>
</tr>
</tbody>
</table>

All-cause Mortality and MACE with SU vs Metformin Monotherapy

- Retrospective analysis of patients prescribed metformin monotherapy (n=76,811) or SU monotherapy (n=15,687) as first-line glucose-lowering therapy from 2000-2012
- Median follow-up: 2.9 years with metformin; 3.1 years with SU

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Hazard Ratio (95% CI) for SU vs. Metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>1.58 (1.48-1.68)</td>
</tr>
<tr>
<td>MACE</td>
<td>1.20 (1.09-1.31)</td>
</tr>
</tbody>
</table>

MACE = major adverse cardiovascular events (MI or stroke)

© 2014 Rockpointe
UKPDS: Metformin Improves CVD Outcomes

Myocardial Infarction

Coronary Deaths

UKPDS 10-year Follow-up: MI Hazard Ratio
(fatal or non-fatal myocardial infarction or sudden death)

ProACTIVE: Time to Principal 2 Endpoint

Large CV Outcomes Trials in Diabetes

Profiles of Antidiabetic Medications

Cardiovascular safety profiles and considerations
CASE: Key Patient Features and Considerations for Individualized Therapy

- Trial of therapeutic lifestyle change
- Metformin monotherapy is ideal first-line drug so long as no CKD
  - Should reduce his A1C to <7%
  - If 2nd agent is needed, unclear which is best drug as add-on
- Consider avoiding SUs due to hypoglycemia risk and ? ischemic preconditioning
- Consider avoiding insulin due to hypoglycemia risk (but may be necessary at some point if other agents fail to control glucose)
- Don’t forget about global CVD risk reduction!
- Reasonable options: DPP-4 inhibitors, GLP-1 RAs, TZD or SGLT-2 inhibitors

What is the optimal treatment choice for this patient?

CASE: Introduction

- Ralph is a 60-year-old obese man who has had T2DM for 7 years, now treated with metformin 1000 mg BID and liraglutide 1.2 mg QD
  - He is an executive for a large global corporation and travels regularly, frequently entertaining over business dinners
- Current concerns
  - Persistent diarrhea on metformin and GI upset on liraglutide
  - While on the road, he does not follow any type of diet or exercise program and often forgets to take his medications
- Medical history: gout, HTN, HLD; no complications
- Other medications: lisinopril, atorvastatin, allopurinol
  - Physical exam: BMI: 38 kg/m², BP: 138/88 mmHg
- Laboratory results: HbA1C: 8.7 %, LDL-C: 94, eGFR >60

CASE: Key Patient Considerations for Individualized Treatment

- What are the barriers to better glycemic control?
  - Poor adherence to lifestyle advice and medications
    - Lifestyle challenges: eats out a lot; no routine for exercise
    - Medication challenges: GI symptoms with metformin and GLP-1 RA; also, reluctance to inject daily
- Other health concerns
  - Obesity
  - Hypertension, hyperlipidemia, and other CV risk factors
  - Should he be on prophylactic ASA?

Medication Adherence and Glycemic Control

- Retrospective study of 249 patients who initiated diabetes therapy with metformin (46%), SUs (39%), or TZD (12%)
- Controlling for baseline A1C and therapy, each 10% decrease in adherence was associated with a 0.1% decrease in A1C ($P = 0.0004$)

Obesity and T2D: A Common Burden

- Obesity and T2D: A Common Burden

Obesity Prevalence Among US Adults, 2013

County-Level Estimates of Diagnosed T2D Among US Adults, 2011

© 2014 Rockpointe
Complication-centric Model for Care of the Overweight/Obese Patient

SDM in Patients with T2D
- Goal of SDM: ensure that treatment decisions align with patient's preferences
  - Often includes patient education and decision-support tools
- Potential benefits of SDM in T2D
  - Increased patient knowledge and adherence
  - Less anxiety over the process of care
  - Improved health outcomes
  - Reductions in inappropriate care and costs

Lee SS et al. for the ANEC. 2013. 8: 1-4.

Decision-support Tools for SDM in T2D
Mayo Clinic “Diabetes Medication Choice” Decision Aid
- Decision-support tool for comparing T2D medications by several factors of interest to patients; available in English and Spanish


Keys to Facilitating Behavior Change

GOAL-SETTING MODEL
- Explore the problem
- Clarify feelings and meaning
- Develop a plan
- Commit to action
- Experiment with and evaluate the plan

COMMUNICATION MODEL
Ask-Listen-Emphasize-Encourage
- Ask open-ended questions
  - Reflect on areas of concern or behaviors
- Identify actions to address the problem or behavior


Beyond the Doctor
Enhancing Patient Engagement in Diabetes Care

Provide tools for making better lifestyle choices:
- Food choices when dining out
- Opportunities for physical activity while traveling

CASE: Key Patient Considerations for Individualized Treatment

- Current treatment priorities
  - HbA1C goal is <6.5% (otherwise healthy)
  - Enhance medication adherence
  - Identify medication regimen that fits with his lifestyle
  - Once weekly GLP-1RA?
  - SGLT-2 inhibitor?
  - TZD (weight gain)
  - Sulfonylurea (hypos)
  - Basal insulin (not thrilled with injections…?adherence)
  - Weight loss medications? Bariatric surgery?

What is the optimal strategy for this patient?

CASE: Key Patient Considerations for Individualized Treatment

- Involve the patient in shared decision-making
- Engage a CDE / nutritionist and diabetes care team:
  - How can he work physical activity into his daily life?
  - How can he optimize diet when traveling?
  - Identify realistic lifestyle goals the patient feels he can reach


Participant CME Evaluation

- Please take out the Participant CME Post-survey and Evaluation Form from the back of your packet.
- If you are not seeking credit, we ask that you fill out the information pertaining to your degree and specialty, as well as the few post-activity survey questions measuring the knowledge and competence you have garnered from this program. The post-survey begins on page 1 of the evaluation form.
- Your participation will help shape future CME activities.

Thank you for joining us today!
TYPE 2 DIABETES MANAGEMENT

A Team Approach to Managing Hypoglycemia, Comorbidities, and Patient Challenges

The information on this form must be completed to receive CME credit. Questions marked “optional” are not required for CME credit. Please use a dark pen and press firmly when marking responses or filling in information, and return completed form to on-site staff.

You may also mail to PCME, 8335 Guilford Rd., Suite A, Columbia, MD 21046.

Please print clearly: Name: __________________________________________________

E-mail: ___________________________________________________________________

Degree:  □ MD/DO  □ Nursing Professional  □ PharmD  □ RD  □ Other: _____________________________

Specialty:  □ Endocrinologist  □ Diabetologist  □ Diabetes Educator  □ PCP  □ Internist  □ Other: ______________

Approximately, how many total patients do you see each month? _________

Approximately, how many patients with T2DM do you see each month? _________

I have been in practice _________ years; or  □ I am retired.

Your practice type:  □ Hospital-based  □ Group Practice  □ Solo Practice  □ Managed Care  □ Academic

In the past 6 months, how many CME programs have you participated in? (optional)  □ 1-4  □ 5-10  □ 11-15  □ >15

POST-PROGRAM SURVEY QUESTIONS

1. NS is a 64-year-old man who had been taking metformin 1000 mg BID for 3 years. Four months ago, he added glyburide 10 mg QD to his treatment regimen to gain better control of his hyperglycemia. His A1c dropped from 7.9% on metformin alone to 7.4% today. However, he has noted an increase in episodes of hypoglycemia since adding glyburide. Which of the following strategies might you recommend in order to reduce his risk of hypoglycemia?
   □ Discontinue glyburide and stay on metformin 1000 mg BID
   □ Reduce the dose of metformin to 500 mg BID
   □ Switch to metformin plus basal insulin
   □ Switch to metformin plus a SGLT2 inhibitor

2. Which of the following characteristics might prevent you from prescribing an SGLT2 inhibitor for a patient?
   □ Renal insufficiency, GFR 43 ml/min
   □ A history of recurrent UTIs
   □ Orthostatic hypotension
   □ All of the above
   □ None of the above

3. MK is a 60-year-old woman who was diagnosed 3 years ago with T2DM. She is currently taking metformin 1000 mg BID. Her A1c is 7.9%. She has gained 14 lbs in the past 9 months, and is very unhappy about her weight (current BMI, 28.2 kg/m²). Which of the following changes to her treatment regimen do you expect to result in the greatest reduction in body weight?
   □ Addition of a sulfonylurea
   □ Addition of a GLP-1 receptor agonist
   □ Addition of a DPP-4 inhibitor
   □ Switch to basal insulin

4. RL is a 52-year-old father of 3 kids (aged 11-19 years). Diagnosed 4 years ago with T2DM, he takes metformin, although he admits to skipping a few doses per week. His A1c is 7.6%. He is a smoker and drinks socially. He is obese (BMI, 31.4 kg/m²), and his wife and children are overweight. Which of the following is an example of shared decision-making?
   □ Refer the patient to a smoking cessation program
   □ Involve a certified diabetes educator to coach the patient on self-management techniques
   □ Ask the patient to identify 3 lifestyle changes that he is willing to adopt for the next month
   □ Invite the patient’s family to attend a community diabetes education and screening event

---CONTINUED NEXT PAGE---
CME PROGRAM EVALUATION

Activity Assessment

For each of the following statements, please indicate your agreement.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helped me to have a better understanding of the topic(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achieved the educational objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provided me with tools/information in a unique way to improve my practice</td>
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<tr>
<td>Better prepared me to care for my patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was scientifically rigorous, fair, balanced, and free of commercial bias*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allowed me to interact with my peers and faculty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Helped me apply the information via realistic case scenarios</td>
<td></td>
<td></td>
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<tr>
<td>Facilitated the sharing of best practices (optional)</td>
<td></td>
<td></td>
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<tr>
<td>Was well-organized (optional)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allowed me to interact with my peers and faculty (optional)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provided feedback throughout the session (optional)</td>
<td></td>
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</tbody>
</table>

* If you disagree, please explain: ____________________________________________________________
______________________________________________________________________________________

Approximately, what percentage of this content was NEW to you (please select one)?

- [ ] 0%
- [ ] 25%
- [ ] 50%
- [ ] 75%
- [ ] 100%

Would you recommend this activity to your peers?  
- [ ] Yes  
- [ ] No

Did you receive information on faculty disclosures?  
- [ ] Yes  
- [ ] No

Impact Assessment

1. After this activity, please rate your confidence in integrating guidelines to individualize the management of T2DM patients:
   - [ ] Expert
   - [ ] Very confident
   - [ ] Confident
   - [ ] Slightly confident
   - [ ] Not confident

2. After this activity, please rate your confidence in managing T2DM in patients with multiple prevalent macro- and/or microvascular comorbidities:
   - [ ] Expert
   - [ ] Very confident
   - [ ] Confident
   - [ ] Slightly confident
   - [ ] Not confident

--CONTINUED NEXT PAGE--
3. After this activity, please rate your confidence in using GLP-1 receptor agonists, DPP-4 inhibitors, and SGLT2 inhibitors to reduce HbA1c in your T2DM patients:

- Expert
- Very confident
- Confident
- Slightly confident
- Not confident

4. After this activity, my incorporation of a shared decision-making (SDM) approach to T2DM management will:

- Increase
- Decrease
- Stay the same
- I need more information

5. After this activity, my evaluation of the risk of hypoglycemia in my T2DM patients and adjustment, as necessary, of management to avoid hypoglycemic episodes will:

- Increase
- Decrease
- Stay the same
- I need more information

6. After this activity, will you participate in quality reporting initiatives, such as PQRS from the Centers for Medicare & Medicaid Services?

- Yes
- No
- I don’t know what PQRS is

7. Which of the following do you perceive as being the primary barrier to optimal outcomes and implementing changes in practice? (select your top 2):

- Lack of knowledge of evidence-based strategies for the management of T2DM patients
- Lack of familiarity with new therapies
- Number of comorbidities in T2DM patients
- Low patient adherence to therapy and/or diet and lifestyle
- Low patient engagement in care
- Patient reluctance with injectables
- Other (e.g. demanding patient workloads, cost of therapies, insurance, etc.) [specify in blank below]

8. Did the activity address strategies for overcoming barriers that you encounter in practice? Yes No

9. Suggestions for future topics: ____________________________________________________________

10. Additional comments: ________________________________________________________________

In order to meet ACCME requirements, all activity participants will be contacted in 2 months to participate in a brief, follow-up outcomes survey. Please respond to the survey, as your participation will help shape future CME activities.

--END--