Navigating New Treatment Options for Type 2 Diabetes Mellitus

May 2016
Michael T. McDermott MD
Director, Endocrinology and Diabetes Practice
University of Colorado Hospital
Michael.mcdermott@ucdenver.edu

Disclosure
Michael McDermott MD
No Conflict of Interest to Disclose

Diabetes Mellitus
Projection through 2033

Source: Diabetes Population Cost Model
Huang ES, Diabetes Care 2009; 32:2225-9
We Are Making Progress!


Diet

Ideal Diet for DM?
No Consensus
Mediterranean May Be Best

Main Goal
Calorie Restriction

1 lb = 3500 kcal

Deficit: 500 kcal/day
Lose 1 lb/week
Lose 52 lb/year

“Well, the Parkers are dead. You had to encourage them to take thirds, didn’t you?”

Exercise

1 Mile
2000 Steps
100 kcal

Walk 30 Minutes
130 kcal

Lose 1 lb in 27 days
Lose 14 lb in 1 year

The 100 Meter Mosey
## Personalized Diabetes Care

### Individualize

#### A1C Goal

<table>
<thead>
<tr>
<th>Medications</th>
<th>Intensive (6%)</th>
<th>Less Intensive (7%)</th>
<th>Least Intensive (8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Yrs)</td>
<td>40  45  50  55  60  65  70  72  75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM2 Duration (Yrs)</td>
<td>5</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Vascular Complications</td>
<td>None</td>
<td>Early Microvascular</td>
<td>Advanced Microvascular / Macrovascular</td>
</tr>
<tr>
<td>Comorbid Conditions</td>
<td>None</td>
<td>Few / Mild</td>
<td>Multiple / Severe</td>
</tr>
<tr>
<td>Hypoglycemia Risk</td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Psycho-Socio-Economic Issues</td>
<td>Motivated, Knowledgeable, Adherent, Good Self Care / Support</td>
<td>Less Motivated, Limited Insight, Non-Adherent, Poor Self Care / Support</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from: Ismail-Beigi F, Ann Intern Med 2011;154:554-9
Inzucchi S, Diabetes Care 2015;38:140-9
### Type 2 Diabetes Mellitus

#### Medication Development

<table>
<thead>
<tr>
<th>Year</th>
<th>Insulin</th>
<th>Sulfonylureas</th>
<th>Metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1920</td>
<td></td>
<td></td>
<td></td>
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<tr>
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<tr>
<td>2000</td>
<td></td>
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<td></td>
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<tr>
<td>2010</td>
<td></td>
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</tbody>
</table>

#### Type 2 Diabetes Mellitus

##### Pathophysiology

- **↑ Glucose Production**
- **↓ CNS Effect**
- **↑ Insulin Secretion**
- **↓ Incretin Effect**

**Hyperglycemia**

- **↑ Insulin Resistance**

- **↓ Glucose Absorption**

#### Type 2 Diabetes Mellitus

##### Pathophysiology Based Therapy

- **↓ Glucose Production**
- **↑ CNS Effect**
- **↑ Insulin Secretion**
- **↑ Incretin Effect**
- **↓ Glucose Absorption**

**Euglycemia**

- **↑ Glycosuria**

- **↓ Insulin Resistance**

- **SGLT-2 Inhibitor**
- **GLP-1 Analogs**
- **DPP4 Inhibitors**
- **Meglitinides**
- **Thiazolidinediones**
- **Basal Insulins**
- **Rapid Acting Insulins**
- **SGLT2 Inhibitors**
- **Bromocriptine**
- **Colesevelam**
- **DPP4 Inhibitors**
- **Pramlintide**
- **GLP-1 Analogs**
- **Meglitinides**
- **Glucosidase Inhibitor**
- **SGL T2 Inhibitors**
- **Bile Acid Resin**
- **Glucosidase Inhibitor**
### Metformin Use In People With CKD

<table>
<thead>
<tr>
<th>eGFR</th>
<th>Action</th>
</tr>
</thead>
</table>
| > 60 | Full Dose Metformin Appropriate  
Monitor Renal Function Annually |
| 45-59| Full Dose Metformin Appropriate  
Monitor Renal Function Q 3-6 Months |
| 30-44| Half Dose Metformin With Caution  
Monitor Renal Function Q 3 Months |
| < 30 | Stop / Avoid Metformin |

Inzucchi S, JAMA 2014; 312: 2668-75  
Inzucchi S, Diabetes Care 2015; 38: 140-9

### Incretin Physiology

- **Glucose Production**: Decreased
- **Insulin**: Increased
- **Glucagon**: Decreased
- **Gastric Emptying**: Decreased
- **L-Cells**: GLP-1 production
- **GLP-1 $T_{1/2} = 2$ min**
- **Due to DPP4**

GLP-1 = Glucagon Like Peptide-1  
DPP4 = Dipeptidyl Peptidase 4

### Incretin Based Therapy

- **GLP-1 Analog / Agonist**
  - Prolonged Duration of Analog Action
- **DPP4 Inhibitor**
  - Prolongs Duration of Native GLP-1 Action
Incretin Based Therapy
GLP-1 Analog (SQ): DPP4 Resistant
- Exenatide BID
- Liraglutide QD
- Exenatide QW Weekly
- Albiglutide Weekly
- Dulaglutide Weekly
DPP4 Inhibitor (PO): Inhibit GLP-1 Breakdown
- Sitagliptin
- Saxagliptin
- Linagliptin
- Alogliptin

Sodium Glucose Transporter 2 Inhibitors
Kidneys Filter + Reabsorb Glucose: 180 g/day
SGLT2 (proximal tubules): 90%

Normal SGLT2 Inhibitor
Glycosuria
BG > 180 mg/dL
Glycosuria
BG > 80 mg/dL

Glucose Loss
80-100 g/day
320-400 kcal/day

Blood Glucose ↓
Weight Loss
No Renal Damage
GU Infections / UTI
Diabetic Ketoacidosis

Sodium Glucose Transporter 2 Inhibitors

<table>
<thead>
<tr>
<th>Generic</th>
<th>Trade Name</th>
<th>Doses</th>
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<tbody>
<tr>
<td>Canagliflozin</td>
<td>Invokana</td>
<td>100, 300 mg</td>
</tr>
<tr>
<td>Dapagliflozin</td>
<td>Farxiga</td>
<td>5, 10 mg</td>
</tr>
<tr>
<td>Empagliflozin</td>
<td>Jardiance</td>
<td>10, 25 mg</td>
</tr>
<tr>
<td>Luseogliflozin</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Ipragliflozin</td>
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<tr>
<td>Tofogliflozin</td>
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</tr>
<tr>
<td>ISIS 388626</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>EGT 1747</td>
<td>NA</td>
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<tr>
<td>LX 4211</td>
<td>NA</td>
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</table>
Empagliﬂozin: EMPA-REG

Cardiovascular Death, Nonfatal MI, Nonfatal Stroke

RCT (7020 DM2 Patients): Empagliﬂozin 10 mg, 25 mg or Placebo x 3.1 years

**Primary Outcome**

**CVD Death**

**All Cause Death**

**CHF Hospitalization**

Conclusions

DM2 patients at high CVD risk, who took empagliﬂozin compared to placebo, had a lower rate of the primary composite CV outcome and death from any cause when the study drug was added to standard care.

**Sodium Glucose Transporter 2 Inhibitors**

SGLT2: Sodium Reabsorption

SGLT2 Inhibition:
- Reduced Na Reabsorption
- Negative Sodium Balance
- Decreased Plasma Volume
- Reduced Blood Pressure

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**Euglycemic DKA with SGLT2 Inhibitors**

Reported: 13 Episodes of Euglycemic DKA or Ketosis with SGLT2 Use. Seven had Type 1 DM, Two had Type 2 DM.

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Taylor SI, J Clin Endocrinol Metab 2015; 100:2849-52

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Peters AL. Diabetes Care 2015;38:1687-1693

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Fracture Risk
Canagliflozin (CANVAS Study)
Pooled RCT Data (10,194 DM2 Patients):
Canagliflozin 100 mg, 300 mg or Placebo

<table>
<thead>
<tr>
<th>Fractures</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Canagliflozin</td>
<td>4.0%</td>
</tr>
<tr>
<td>Non-Canagliflozin</td>
<td>2.6%</td>
</tr>
<tr>
<td>HR</td>
<td>1.51 (1.04, 2.19)</td>
</tr>
</tbody>
</table>

Falls: More Common in Canagliflozin Group
Fractures: Balanced between Upper and Lower Limbs
Cause of ↑ Fracture Risk: Unknown – Possibly due to Falls

Watts N. J Clin Endocrinol Metab 2015: epub

Personalized Diabetes Care
Considerations for Medication Choice

- Side Effects
- Side Benefits
- Cost
- Efficacy

Type 2 Diabetes: Personalized Medication Choices

<table>
<thead>
<tr>
<th>Hypoglycemia</th>
<th>Weight</th>
<th>Cost/Mo*</th>
<th>↓ A1C</th>
</tr>
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<tbody>
<tr>
<td>Metformin</td>
<td>No</td>
<td>---</td>
<td>$4</td>
</tr>
<tr>
<td>DPP4 Inhibitor</td>
<td>No</td>
<td>---</td>
<td>$320</td>
</tr>
<tr>
<td>GLP-1 Analog</td>
<td>No</td>
<td>↓ $300-600</td>
<td>0.5-1.5</td>
</tr>
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<td>SGLT-2 Inhibitor</td>
<td>No</td>
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<tr>
<td>Pramlintide</td>
<td>No</td>
<td>$300</td>
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<tr>
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<td>$200</td>
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<tr>
<td>Bile Acid Resin</td>
<td>No</td>
<td>$225</td>
<td>0.5</td>
</tr>
<tr>
<td>Bromocriptine</td>
<td>No</td>
<td>$299</td>
<td>0.4-0.6</td>
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<tr>
<td>Thiazolidinedione</td>
<td>No</td>
<td>$250</td>
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<td>Basal Insulin (vial)</td>
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<td>$245</td>
<td>15 or &gt;</td>
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<tr>
<td>Prandial Insulin (vial)</td>
<td>Yes</td>
<td>$205</td>
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* Average Retail Costs 2014-15
Individual Costs Vary with Coverage
### Type 2 Diabetes: Personalized Medication Choices

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<tr>
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<tr>
<td>Human Insulin</td>
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### Type 2 Diabetes Mellitus: Personalized Management

<table>
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<th>Lifestyle Intervention + Metformin</th>
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<tr>
<td>GLP-1 Analog</td>
</tr>
<tr>
<td>SGLT-2 Inhibitor</td>
</tr>
<tr>
<td>DPP4 Inhibitor</td>
</tr>
<tr>
<td>TZD</td>
</tr>
<tr>
<td>SU</td>
</tr>
<tr>
<td>Basal Insulin</td>
</tr>
</tbody>
</table>

| Bile Acid Resin                  |
| Glucosidase Inhibitor            |
| Bromocriptine                    |
| Pramlintide                      |
| Basal/Bolus Insulin              |

| LDL Reduction                    |
| Hypo                              |
| Wt Loss                           |
| Hypo                              |
| Wt Loss                           |
| Hypo                              |
| Wt Loss                           |
| Most                             |
| Effective                         |

MTM adapted from Inzucchi S, Diabetes Care 2015; 38:140-9

### Referral 1

HPI: 72 y.o. man with DM2 x 22 yr. Retired Engineer.

DM Complications: CAD, MI x 2, NPDR, DPN

Comorbid Conditions: HTN, HLP, CAD, CHF

Recent Severe Hypoglycemia: None

Psychosocial Economic Issues: Motivated, Knowledgeable, Adherent, Good Self Care / Support, Medicare.

DM Meds: Metformin 1000 mg BID

PE: Ht 6'0” Wt 223 lb BMI 30 BP 138/86 P 92

SMBG: FBG 108-233 A1C 8.7% eGFR 52

What is your target A1C for this patient?
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Comorbid Conditions: HTN, HLP, CAD, CHF

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DM Meds: Metformin 1000 mg BID

PE: Ht 6'0" Wt 223 lb BMI 30 BP 138/86 P 92

SMBG: FBG 108-233 A1C 8.7% eGFR 52

My Target A1C: < 8.0%

If no hypoglycemia occurs, may adjust to < 7.5% or < 7.0%

In addition to lifestyle measures, what do you recommend?

---

### Hypoglycemia Risk

- Low
- Moderate
- High

### Vascul ar Complications

- None
- Early Microvascular
- Advanced Microvascular / Macrovascular

### Comorbid Conditions

- None
- Few / Mild
- Multiple / Severe

### In addition to lifestyle measures, what do you recommend?

HPI: 72 y.o. man with DM2 x 22 yr. Retired Engineer.

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- Low
- Moderate
- High

### Vascul ar Complications

- None
- Early Microvascular
- Advanced Microvascular / Macrovascular

### Comorbid Conditions

- None
- Few / Mild
- Multiple / Severe

### In addition to lifestyle measures, what do you recommend?
Referral 2

HPI: 57 y.o. woman with DM2 x 6 yr. Elementary School Teacher.
DM Complications: None
Comorbid Conditions: Papillary Thyroid Cancer, Recurrent UTIs
Recent Severe Hypoglycemia: None
Psychosocioeconomic Issues: Motivated, Knowledgeable,
Adherent, Good Self Care / Support. Commercial Insurance.
DM Meds: Metformin 1000 mg BID, Pioglitazone 30 mg QD
PE: Ht 5’6” Wt 202 lb BMI 32.6 BP 132/82 P 82
SMBG: FBG 182-261 Afternoon 175-282 A1C 9.0% eGFR > 60

What is your target A1C for this patient?

In addition to lifestyle measures, what do you recommend?

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Comorbid Conditions: Papillary Thyroid Cancer, Recurrent UTIs
Recent Severe Hypoglycemia: None
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SMBG: FBG 182-261 Afternoon 175-282 A1C 9.0% eGFR > 60

My Target A1C: < 7.0%

In addition to lifestyle measures, what do you recommend?
Meds: Metformin, Pioglitazone  
A1C: 9.0% Target: < 7.0%

<table>
<thead>
<tr>
<th>Medication</th>
<th>Hypoglycemia</th>
<th>Weight</th>
<th>Cost/Mo*</th>
<th>↓ A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>No</td>
<td>---</td>
<td>$4</td>
<td>1.0-2.0</td>
</tr>
<tr>
<td>DPP-4 Inhibitor</td>
<td>No</td>
<td>---</td>
<td>$120</td>
<td>0.5-0.8</td>
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<tr>
<td>GLP-1 Analog</td>
<td>No</td>
<td>↓</td>
<td>$300-600</td>
<td>0.5-1.5</td>
</tr>
<tr>
<td>SGLT-2 Inhibitor</td>
<td>No</td>
<td>↓</td>
<td>$320</td>
<td>0.9-1.2</td>
</tr>
<tr>
<td>Pramlintide</td>
<td>No</td>
<td>↓</td>
<td>$300</td>
<td>0.25-0.5</td>
</tr>
<tr>
<td>Glucosidase Inhibitor</td>
<td>No</td>
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<td>$200</td>
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</tr>
<tr>
<td>Bile Acid Resin</td>
<td>No</td>
<td>---</td>
<td>$225</td>
<td>0.5</td>
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<tr>
<td>Bromocriptine</td>
<td>No</td>
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<td>$299</td>
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<td>Thiazolidinedione</td>
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<td>$250</td>
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<tr>
<td>Basal Insulin (vial)</td>
<td>Yes</td>
<td>↑</td>
<td>$245</td>
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<td>Yes</td>
<td>↑</td>
<td>$205</td>
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<td>Yes</td>
<td>↑</td>
<td>$113</td>
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</tbody>
</table>

My Preference: GLP-1 Analog  
Considerations: Weight Loss Meds

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### Obesity Treatment as DM2 Strategy

**FDA Approved for Obesity, Not Diabetes**

- Phentermine (1969): ↓ appetite
- Phentermine / Topiramate (Qsymia): ↓ appetite
- Lorcaserin (Belviq): ↓ appetite
- Bupropion / Naltrexone (Contrave): ↓ appetite
- Liraglutide (Saxenda): ↓ appetite
- Orlistat (Xenical, Alli): ↓ fat absorption

**Indications:**
- BMI > 30 kg/m²
- BMI > 27 kg/m² with obesity related disease

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### Referral 3

HPI: 52 y.o. man with DM2 x 5 yr. Mechanic. Veteran.

DM Complications: CAD
Comorbid Conditions: HTN, HLP, CAD, Pancreatitis x 2
Recent Severe Hypoglycemia: Two

DM Meds: Metformin 1000 mg BID, Linagliptin 5 mg, Glargine 80 U HS

PE: Ht 5'8" Wt 254 lb BMI 38.6 BP 136/82 P 80

SMBG: FBG 184-343 A1C 9.1% eGFR > 60

What is your target A1C for this patient?
Referral 3

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DM Complications: CAD
Comorbid Conditions: HTN, HLP, CAD, Pancreatitis x 2
Recent Severe Hypoglycemia: Two
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PE: Ht 5'8" Wt 254 lb BMI 38.6 BP 136/82 P 80
SMBG: FBG 184-343 A1C 9.1% eGFR > 60
My Target A1C: < 8.0%
If no hypoglycemia occurs, may adjust to < 7.5% or < 7.0%
In addition to lifestyle measures, what do you recommend?

<table>
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<th>Weight</th>
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<tbody>
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<td>$299</td>
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<tr>
<td>Thiazolidinedione</td>
<td>No</td>
<td>↑</td>
<td>$250</td>
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<td>Sulfonylurea</td>
<td>Yes</td>
<td>↑</td>
<td>$4</td>
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<td>Meglitinide</td>
<td>Yes</td>
<td>↑</td>
<td>$347</td>
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<tr>
<td>Basal Insulin (vial)</td>
<td>Yes</td>
<td>↑</td>
<td>$245</td>
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<tr>
<td>Prandial Insulin (vial)</td>
<td>Yes</td>
<td>↑</td>
<td>$205</td>
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<tr>
<td>Human Insulin (vial)</td>
<td>Yes</td>
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<td>$113</td>
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My Preference: SGLT2 Inhibitor Considerations: Bariatric Surgery
Summary of Type 2 Diabetes Management

- Obesity is the most important risk factor for DM2
- Lifestyle modification must be part of all DM2 prevention and management plans
- DM2 results from excess hepatic glucose production, insulin resistance and relative insulin deficiency
- Available medications address the known pathophysiological factors in DM2
- A1C ≤ 7% prevents microvascular complications
- Hypoglycemia should be carefully avoided
- Personalize glycemic goals and therapy choices
- Obesity treatment beneficial for DM2 management

Thank You