Tight Control in Type 2 Diabetes: More Harm than Good?

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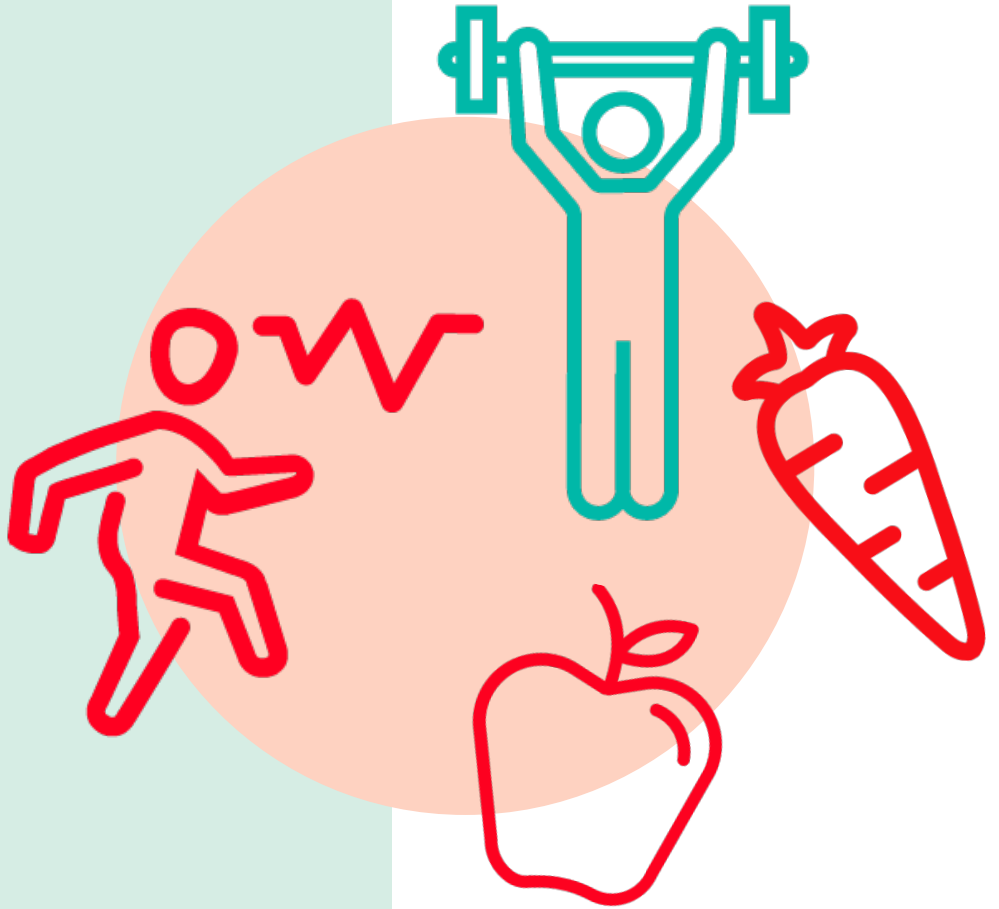

Collaborators

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More resources available at the
DC Center for Rational Prescribing

doh.dc.gov/dcrx

Course Faculty

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Conflicts of Interest Disclosure

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- **Adriane Fugh-Berman, MD** is a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical marketing practices.
- **Tom Finucane, MD** is a member of the Pharmacy and Therapeutics Committee for Anthem Inc.
- **Stephen Lippman, MD, PhD** has been a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical marketing practices.
- **Kofi Onumah, PharmD, RPh** has no conflicts of interest.
- **Leonard Pogach, MD, MBA** has no conflicts of interest.
- **Caroline Trapp, DNP, APN-BC, FAANP** has no conflicts of interest.
- **Susan Wood, PhD** has no conflicts of interest.

Important Information

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The video will progress at its own pace.

Do not attempt to speed up the video.

The post-test will only unlock after viewing the entire video.

The video can be paused and resumed later.

Course Objectives

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After completing this module, participants should be able to...

1. Discuss the risks and benefits of metformin, insulin, and other treatments for type 2 diabetes.

2. Describe the limitations of clinical evidence regarding tight control in patients with type 2 diabetes.

3. Implement new strategies for counseling patients about making lifestyle changes.

Case Study

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- A woman in her 50s
- HbA1c of 10%
- Asymptomatic
- Laboratory results are concerning

She has tried lifestyle change but hasn't succeeded in lowering her HbA1c yet.

?

What should we recommend for her treatment?

Case Study

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What risks are we worried about?

- ☑ Macrovascular events (heart attack, stroke, amputation)
- ☑ Microvascular events (blindness, renal failure, neuropathy)
- ☑ Death

The goal is to reduce these risks.

First line treatment is always healthful eating and exercise!

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- Drug treatment should be reserved for those
  - with symptomatic hyperglycemia
  - unable or unwilling to make changes in their diet and/or physical activity
- Always recommend diet and exercise as a primary part of treatment.

Lowering CVD Risks

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- Use blood pressure medicine to lower systolic blood pressure to the 120s.
- Use statins to lower cholesterol.
- Lifestyle modification can also help achieve these goals.
- Glucose control is less important.

Essential Measures

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1
Smoking cessation

2
Blood pressure control

3
Lipid reduction

4
Physical activity

5
Glycemic control

Overall, the risk for death among people with diabetes is about twice that of people of similar age but without diabetes.

—Centers for Disease Control 2011

Intensive Control

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A 2011 systematic review of 14 RCTs (n=28,614) compared intensive glycemic control with conventional glycemic control.

There was no difference in death rates.

—

The risk ratio for all-cause mortality was 1.02

Hemmingsen 2011 (BMJ), Hemmingsen 2013 (Cochrane, withdrawn)

This Cochrane review was withdrawn due to a change in Cochrane Collaboration policies because two of the co-authors were pharmaceutical company employees. Any potential bias in the paper might be expected to favor pharmaceutical intervention.

How is intensive glycemic control defined?

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Trial	Intensive Control	Standard Control
ACCORD	HbA1c < 6.0%	HbA1c of 7.0-7.9%
VADT	HbA1c < 6.0%	HbA1c < 9.0%
ADVANCE	HbA1c < 6.5%	target HbA1c levels defined by local guidelines

ACCORD Study

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The federally-funded ACCORD study of patients with type 2 diabetes and cardiovascular disease or high risk of CVD randomized patients to

- Intensive therapy, n=5,057 (target HbA1c<6%)
- Standard therapy, n=5,051 (target HbA1c of 7.0-7.9%)

Patients were followed for

5 years.

–

Intensive glucose-lowering for a mean of

3.7 years.

ACCORD Study Group 2011

ACCORD Study

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Compared with standard therapy, intensive therapy to "normalize" HbA1c levels for 3.5 years

Increased mortality

Did not reduce major cardiovascular events

These findings show an unrecognized harm of intensive glucose-lowering in high-risk patients with type 2 diabetes.

ACCORD Study Group 2011

Veterans Affairs Diabetes Treatment (VADT) Study

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- The VADT study included 1,791 military veterans (mean age 60.4 years) with type 2 diabetes.
- Patients were randomized to either intensive (n=892) or standard glucose control (n=899).
- The median follow-up was 5.6 years.

Duckworth 2009

Veterans Affairs Diabetes Treatment (VADT) Study

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Intensive glucose control in patients with poorly controlled type 2 diabetes had no significant effect on rates of:

✕ **Major cardiovascular events**

✕ **Death**

✕ **Microvascular complications**

Intensive glucose control did slow progression to albuminuria ($p = 0.01$)

Duckworth 2009

ADVANCE Study

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The ADVANCE study randomized 11,140 patients with type 2 diabetes to either standard (n=5,569) or intensive glycemic control (n=5,571).

Intensive glycemic control was aimed at achieving an HbA1c of 6.5% or less by using gliclazide plus other drugs.

The median follow-up was 5 years.

ADVANCE Collaborative Group 2008

ADVANCE Study

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Intensive glucose control to lower HbA1c levels to 6.5% yielded a 10% relative reduction in the combined outcome of major macrovascular and microvascular events.

Benefits were primarily due to a 21% relative reduction in nephropathy.

ADVANCE Collaborative Group 2008

ADVANCE Study

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No difference in:

1. Major macrovascular events
2. Deaths from cardiovascular causes
3. Deaths from any cause

ADVANCE Study: Benefit of intensive control

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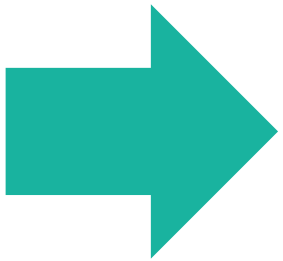
NEPHROPATHY

20% relative risk reduction;
1.1% absolute risk reduction

- 4.1% (intensive control)
- 5.2% (standard treatment)



1 in 100 people over 5 years did not develop nephropathy

Some therapies decrease glucose levels but increase CVD risk

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To establish the safety of a new antidiabetic therapy to treat type 2 diabetes, sponsors should demonstrate that the **therapy will not result in an unacceptable increase in cardiovascular risk.**

FDA Guidance for Industry 2008

The 7% solution?

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> "Treatment targets of HbA1c at 7% in the intensive glucose-lowering group have only been used in five trials, involving 542 participants. However, only three of these exclusively assessed the effects of glycaemic control and only one of these trials had a duration of more than one year."

Hemmingsen 2013 (Cochrane, withdrawn)

This Cochrane review was withdrawn due to a change in Cochrane Collaboration policies because two of the co-authors were pharmaceutical company employees. Any potential bias in the paper might be expected to favor pharmaceutical intervention.

Evidence is lacking for tight control

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"This faith [in 7% HbA1c] persists despite weak evidence from randomized controlled trials of any meaningful benefit from 'tight control' in any patient group, consistent evidence of lack of benefit for many outcomes, and an almost complete lack of evidence about elderly adults or those with extensive vascular disease."

Finucane 2012

Insulin Causes Hypoglycemia

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- Insulin-related hypoglycemia is implicated in an estimated 9.2% of emergency department (ED) visits associated with adverse drug reactions (ADRs).
- Hypoglycemia, a preventable ADR, accounts for nearly 100,000 ED visits every year.
- Patients more than 80 years old were:

2x

more likely to visit the ED

5x

more likely to be hospitalized

Geller 2014

Insulin Costs in the District of Columbia

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In 2014, DC Medicaid spent $13.4 million on insulin.

Brand Name	Established Name	Cost per Prescription	Medicaid Spending	Number of Prescriptions
Levemir	insulin determir	$326	$1,684,117	5,162
Apidra	insulin glulisine	$316	$715,941	2,263
Lantus	insulin glargine	$311	$6,306,260	20,267
Novolog	insulin aspart	$311	$3,223,267	10,365
Humalog	insulin lispro	$278	$711,220	2,560
Humulin	insulin	$175	$364,056	2,081
Novolin	insulin	$169	$366,129	2,165

Wood 2016

Survival as a function of HbA1c

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A retrospective cohort study of 48,000 patients (mean age 64) for whom oral monotherapy had not adequately lowered blood glucose

- 28,000 were prescribed an additional oral medication
- 20,000 were prescribed insulin with or without oral medication
- Patients were followed up for a median of 4 years

Currie 2010

Survival as a function of HbA1c

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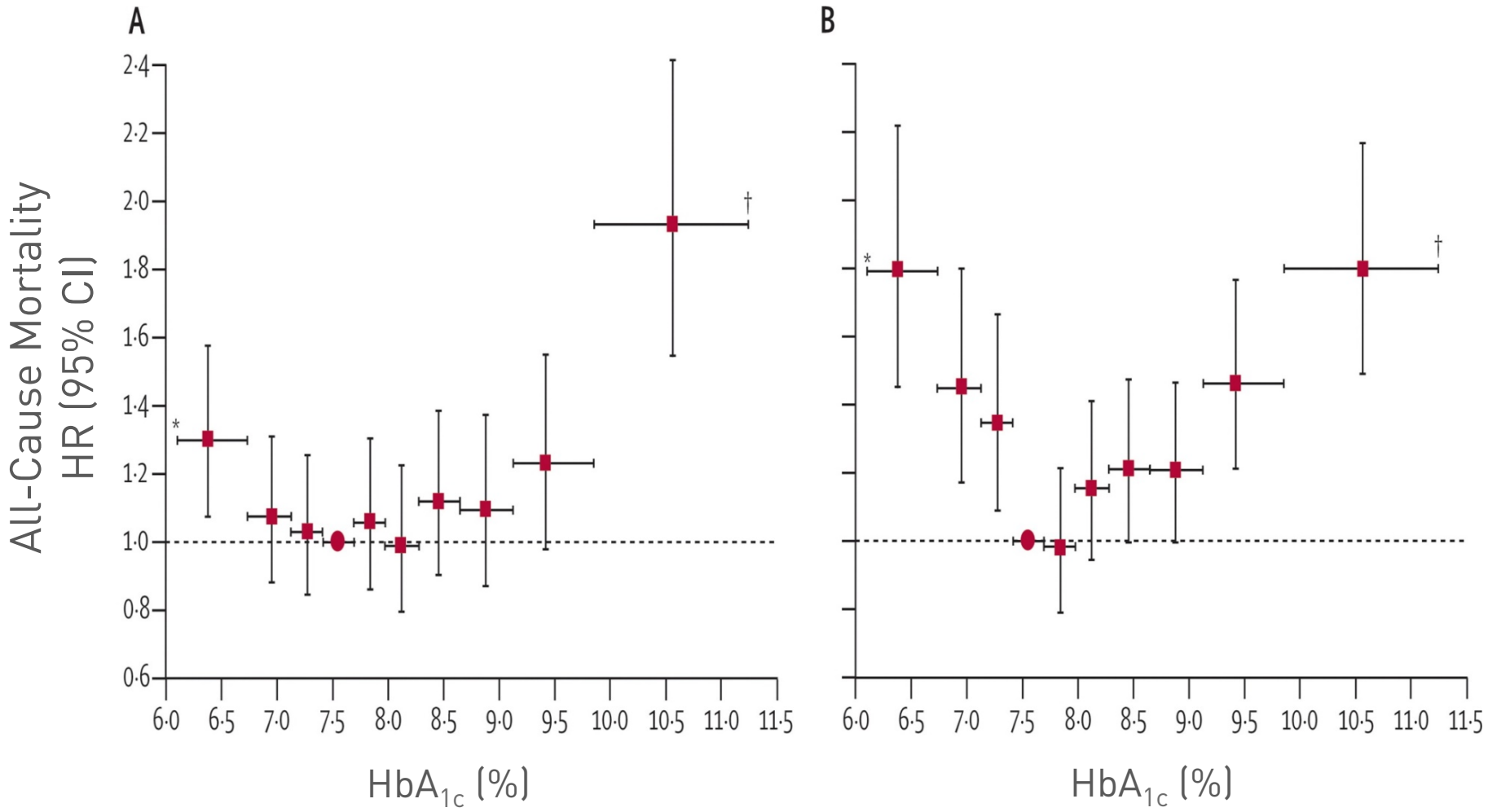
Deaths in the group prescribed insulin (2,834 deaths) were higher than those given combination oral medications (2,035 deaths).

The hazard ratio for all-cause mortality in people given insulin-based regimens, compared to those given combination oral agents was 1.49 (95% CI 1.39-1.59).

Currie 2010



Combination Oral Agents **Insulin**

Currie 2010

ADA/ACS Consensus Statement

—

"Although still limited, early evidence suggests that metformin is associated with a lower risk of cancer and that exogenous insulin is associated with an increased cancer risk."

—Giovannucci 2010

Benefits of drugs may have little to do with glycemia

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Cardiovascular outcome trials of empagliflozin, liraglutide and semaglutide demonstrated that:

"... the effects of treatment on outcomes were out of proportion to the small differences in glycemic control levels. Therefore, the effects observed were likely unrelated to differences in glucose-lowering efficacy of the evaluated drugs."

Lipska 2017

Beyond HbA1c

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- A person with type 2 diabetes usually has other cardiovascular risk factors besides hyperglycemia.
- High glycemia is associated with high rates of cardiovascular events and death, but lowering glycemia with medication doesn't reduce cardiovascular events and death.

Metformin: Drug of Choice

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There is excellent evidence that metformin should always be the first line drug treatment.

American Diabetes Association 2017, Qaseem 2017

The advantages of metformin are not explained only by glycemic control.

King 1999

Metformin is associated with a lower risk of hypoglycemia than other diabetes drugs.

Qaseem 2017

Benefits of Metformin

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Metformin benefits weight, lipids, insulinemia and diastolic blood pressure, as well as glycemic control.

Saenz 2005

Metformin lowered mortality rates in UKPDS34 (a large federally-funded trial).

King 1999

Metformin may also have other benefits.

Adverse Effects of Metformin

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- **Initially, metformin can cause gas, bloating, nausea, and other gastrointestinal symptoms.**
- **Adverse effects of metformin are mainly mild and may resolve over time.**
  - Dosing metformin after meals and slowly increasing dose may prevent gastrointestinal symptoms.
- **Metformin may decrease vitamin B_{12} levels but does not increase the rate of peripheral neuropathy.** ***de Groot-Kamphuis 2013, Ahmed 2016, Liu 2014***
  - Vitamin B_{12} levels should be monitored every two years.
  - Supplement with vitamin B_{12}

Does metformin cause lactic acidosis?

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Despite widespread belief to the contrary, metformin does not seem to cause lactic acidosis.

A Cochrane systematic review of 347 trials with 70,490 patient-years of metformin treatment (mean length 1.3 years, range 1 month to 10.7 years) found 0 cases in any trial.

A review of 94 trials that were excluded from analysis (because they lasted <1 month or were of unclear duration) also found no cases of lactic acidosis.

So, in 411 placebo-controlled or treatment-controlled trials lasting up to a decade, the number of lactic acidosis cases was ZERO.

Salpeter 2010

Why do people think metformin causes lactic acidosis?

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- Phenformin, a related biguanide, was associated with rare cases of lactic acidosis and was removed from the U.S. market in 1977.
- Phenformin has a chemical structure significantly different from metformin.
    - Phenformin can impair oxidative phosphorylation in the liver, thereby increasing lactate production by anaerobic pathways.
- Metformin inhibits hepatic gluconeogenesis without altering lactate turnover or lactate oxidation.

No RCTs of "tight control" have been done in older adults

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Hypoglycemia can occur at any age.

Risk in older adults is greater.

Intensive glycemic control in older adults leads to an increased risk for hypoglycemia.

Most trials have been done in "younger" diabetics

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Mean age at randomization:

ADVANCE	66
ACCORD	62
VADT	60
UKPDS	53
UGDP	52
Steno 2	55
UGDP	52

Insulin in Older Adults

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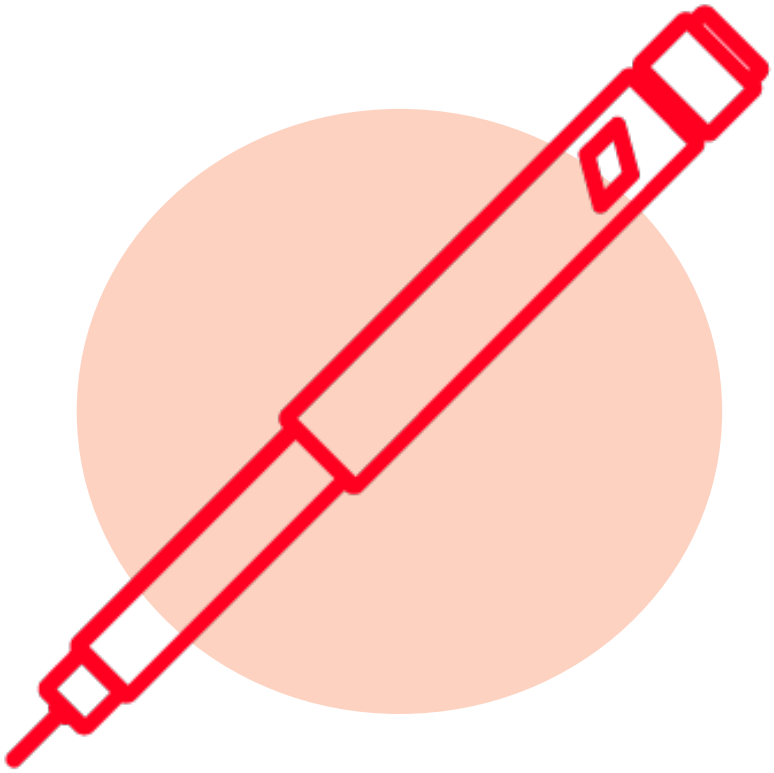
- **Insulin is associated with increased mortality.** *(Currie 2010)*
- **Insulin does not prevent complications of diabetes.**
  - No randomized controlled trial has ever shown meaningful benefit from insulin for chronic complications attributed to type 2 diabetes.



Signs of Hypoglycemia

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Mild

Shakiness, sweating, fast heartbeat, dizziness, hunger, blurred vision, difficulty paying attention, palpitations, anxiety, headache, tiredness

Moderate

Difficulty moving

Confusion

Unusual behavior

Severe

Seizures

Coma

Combative behavior

Drugs to Avoid

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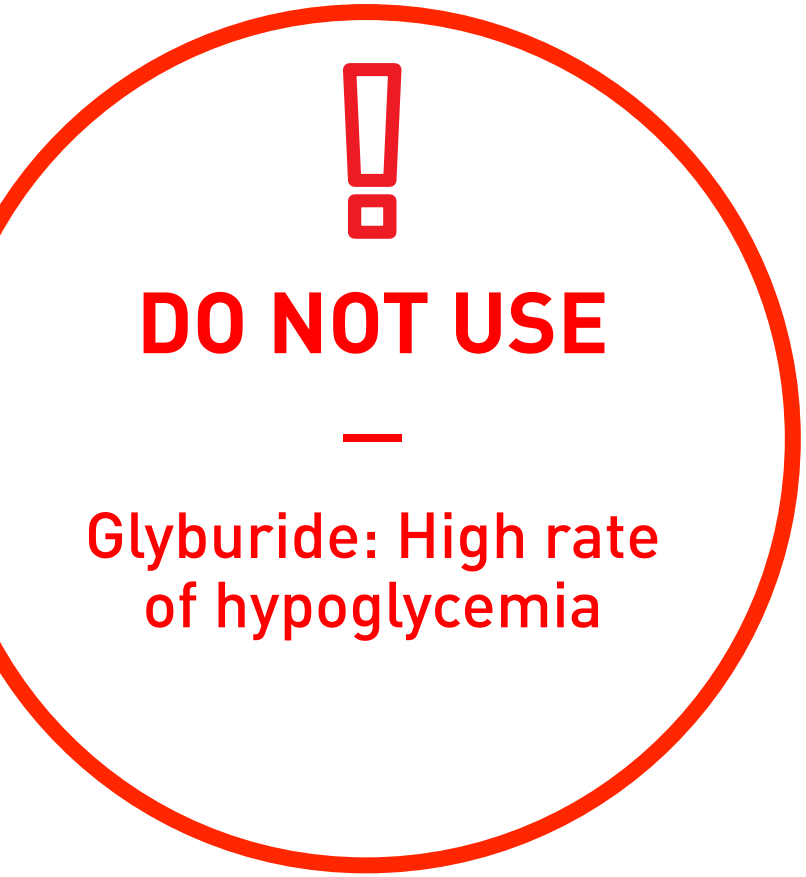

AVOID

- **Insulin**
  High rate of hypoglycemia, other adverse effects
- **Thioglitazones (thiazolidinediones: rosiglitazone and pioglitazone)**
  CHF, other adverse events
- **SGLT-2 inhibitors**
  Serious complications, especially in elders

HbA1c Target

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- Use the VA/DoD guidelines, which are not industry sponsored.
- Glycemic targets must be individualized.
- Shared decision making is important.
- Think of HbA1c targets as a range, not a single number.
- When deciding on an acceptable HbA1c range, consider age, life expectancy, ethnicity, comorbidities, and patient preferences.

Veterans Affairs/Department of Defense 2017 Guidelines

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Major Comorbidity or Physiologic Age	Microvascular Complications		
	Absent or Mild	Moderate	Advanced
Absent >10 years of life expectancy	6.0-7.0%	7.0-8.0%	7.5-8.5%
Present 5 to 10 years of life expectancy	7.0-8.0%	7.5-8.5%	7.5-8.5%
Marked <5 years of life expectancy	8.0-9.0%	8.0-9.0%	8.0-9.0%

Where did 7% come from?

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1997

nearly **2 million** Americans became diabetic when the diagnostic fasting blood sugar level was changed from 140 to 126 mg/dl.

2003

20 million people became pre-diabetic when criteria were changed.

“Far too large a section of the treatment of disease is today controlled by the big manufacturing pharmacists, who have enslaved us in a plausible pseudoscience.”

—Osler 1909

Ask Your Patient

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- "What do you typically eat?"
- "What do you like to eat?"
- "Do you eat breakfast?"
- "How often do you eat out?"
- "Do you pack meals?"

Patient Counseling

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- Avoid sounding judgmental
- Identify areas for improvement
- Recognize what patients are already doing well
- Find areas where diet could make a difference

Plant-Based Foods

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- Whole grains (including corn)
- Vegetables
- Legumes (beans, peas, lentils)
- Fruit
- Water
- Nuts and seeds

Recommended Diet

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Focus on the foods patients should be eating

Don't leave your patients hungry!

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- Patients with type 2 diabetes (n=99) were randomized to a low-fat plant-based diet (with no portion control) or the ADA diet (portion- and calorie-controlled).
- Both diets were associated with reduced HbA1c and body weight.
  - Changes were greater in the plant-based diet group.

Barnard 2006

Counseling Patients

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- Be positive! Express confidence in your patient's ability to be successful.
- Ask them what it would mean to them to be healthier
  - More self-confidence?
  - Cost savings?
  - Ability to play with grandchildren?
- Provide resources: websites, books, documentaries, local cooking classes, support groups, recreational programs, farmer's markets.

Common Objections

- “Eating healthfully is too expensive”
- “Eating healthfully is too time-consuming”
- “I hate vegetables”
- “My family won’t eat this; I don’t want to cook two meals”

"I hate vegetables"

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- Most people like certain vegetables.
  - Ask your patient, "Do you like corn? Do you like potatoes? Do you like peas?"
  - Aim for a variety of colors.
- TASTES CAN CHANGE. Encourage your patients to experiment with some new vegetables or ones they have tried before.
- Tell patients to add a little lemon juice or balsamic vinegar to steamed broccoli or greens—this brings out the sweetness.

"Eating healthy is too expensive"

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- Buy fruits and vegetables that are in season.
- Canned beans and rice are inexpensive.
- Buy frozen fruits and vegetables.
- Eat at home or pack a lunch to save money.

“My family won’t eat this; I don’t want to cook two meals.”

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- Don’t announce a big change of diet to your family.
- Incorporate fruits and vegetables into meals you already eat.
- Children love to cook! Involve your children in the cooking process.

What can patients expect?

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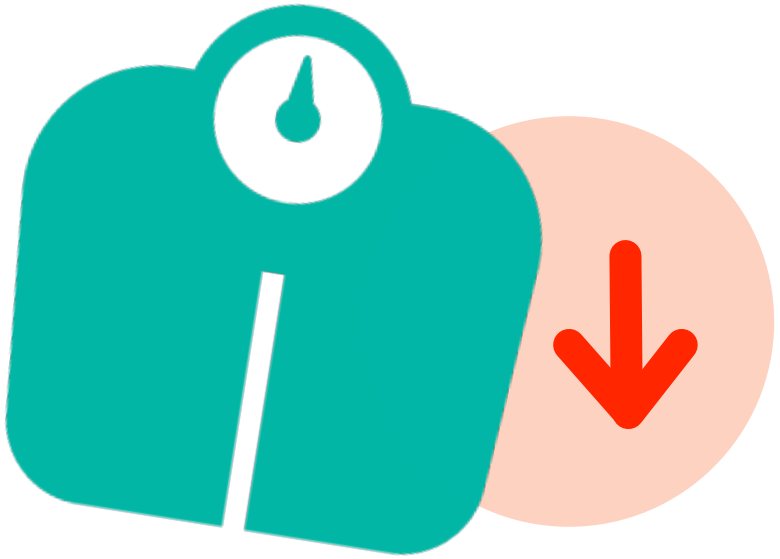
- Many will see results within a very short time
  - Blood sugars come down
  - Blood pressure improves
  - Weight may go down
- Because patients are eating more fiber, they may have some temporary GI symptoms.
- Advise patience and persistence.



Precautions

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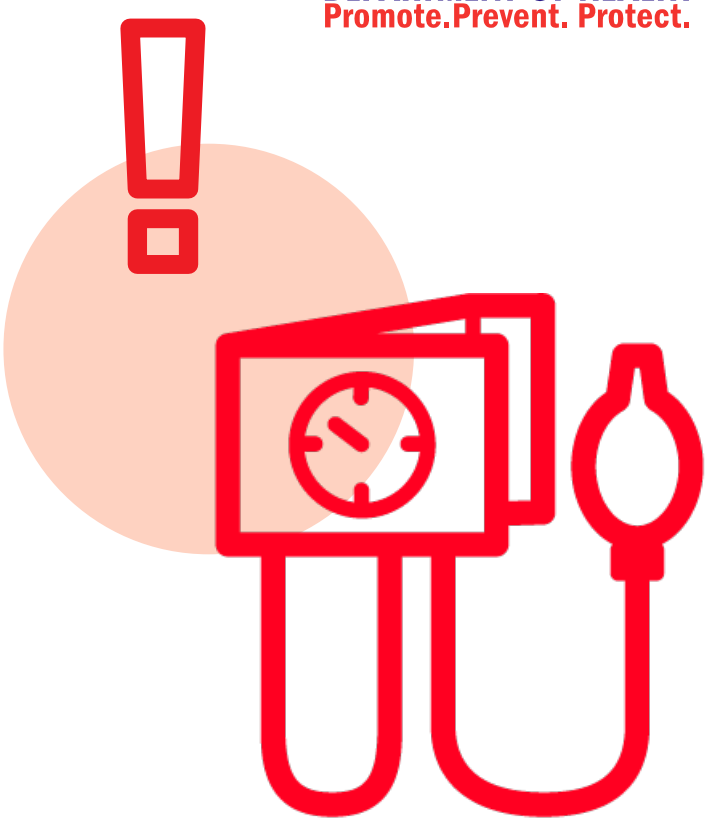
- Doses of diabetes medications may need to be reduced.
- Antihypertensive drugs may need to be reduced.
- Warfarin doses may need to be adjusted with large increase in greens. Monitor INR.
- Supplement with Vitamin B_{12} 500 mcg/d (methylcobalamin).
  - This is important for patients taking metformin and/or following a plant-based diet.
- Encourage follow up – lifestyle modifications only work if sustained.



Exercise

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- Fourteen RCTs (n=377) comparing exercise against no exercise in type 2 diabetes for 8 weeks to 12 months found that the exercise intervention significantly
  - decreased HbA1c 0.6%
  - reduced visceral adipose tissue
  - increased insulin response
  - decreased plasma triglycerides

Thomas 2006

Exercise in Type 2 Diabetics

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There was no significant difference in:

- whole body mass
- plasma cholesterol
- blood pressure

Thomas 2006

Ask:

“What activities have you enjoyed in the past?”

Walking, Bowling, Dancing, Swimming, Biking

Diabetes Exercise Precautions

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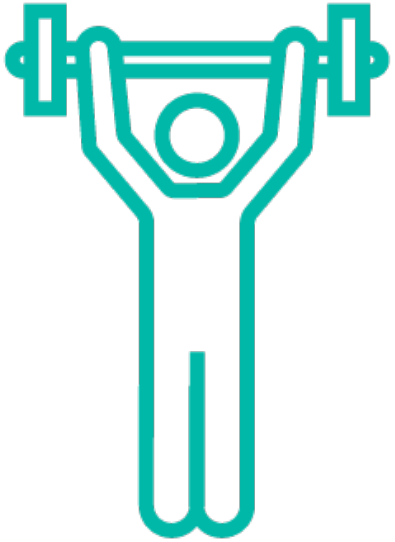
- Lifting weights is not recommended for patients with
  - Retinopathy
  - Hypertension
- Patients with neuropathy may have issues with balance and/or loss of sensation in their feet.



Resources for Patients in D.C.

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- **Free admission to Department of Parks and Recreation pools for DC residents**
- **Produce Plus Program/DC Greens**
  - Allows residents to use SNAP, Medicaid, Temporary Assistance for Needy Families, and Supplement Security Income at participating farmers markets
  - DC Department of Health sponsors this program

Park Rx America

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parkrxamerica.org

Park Rx America

Other DCRx Modules

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Taking a Sexual History to Reduce HIV Risk

Myths and Facts about Opioids

Medical Cannabis: An Introduction to the Biochemistry & Pharmacology

Medical Cannabis: Evidence on Efficacy

Medical Cannabis: Adverse Effects and Drug Interactions

Industry Influence on the Practice of Medicine

What You Need to Know about PrEP

Getting Patients Off of Opioids

Rational Prescribing in Older Adults

Drug Approval and Promotion in the United States

Generic Drugs: Myths and Facts

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