

Take 3 – Practical Practice Pointers[©] December 17, 2018 Edition

T2D Management, Shoveling Snow, ARB Recall

From the Literature and the American Diabetes Association (ADA)

1) Management of Hyperglycemia in Type 2 Diabetes (T2D)

The ADA and the European Association for the Study of Diabetes recently released a consensus report on the management of hyperglycemia in T2D. There is more of an emphasis on the prioritization of medication selection based on co-morbidities as well as other dynamics, and in particular, medication cost. Highlights include:

Diabetes Self-Management Education and Support Programs

- Diabetes self-management education and support programs should be offered to all.
- Medication adherence should be specifically considered when glucose-lowering medications are selected.

Lifestyle Management

- All patients should be offered an individualized medical nutrition therapy program.
- Advise all overweight and obese patients on the health benefits of weight loss and encourage them to engage in an intensive lifestyle management program that may include food substitution.
- Encourage all to increase physical activity to improve glycemic control.

Metabolic Surgery

- Recommend consideration for metabolic surgery for adults with T2D and a (1) a BMI ≥ 40.0 k (BMI ≥ 37.5 in people of Asian ancestry) or (2) a BMI of 35.0–39.9 (32.5–37.4 in people of Asian ancestry) who do not achieve durable weight loss and improvement in comorbidities with reasonable non-surgical methods.

Medication Selection

- **Metformin is the preferred initial glucose-lowering medication for most people with T2D**
- The stepwise addition of glucose-lowering medication is usually preferred to initial combination therapy.
- Base the selection of medication added to metformin on patient preference and clinical features. Important clinical features include the presence of established ASCVD and other comorbidities such as heart failure or chronic kidney disease; the risk for specific adverse medication effects, particularly hypoglycemia and weight gain; safety; tolerability; and cost.
- Consideration of the impact of medication side effects on comorbidities, as well as the burden of treatment and cost, should be made when intensifying treatment beyond dual therapy to maintain glycemic targets.
- GLP-1 receptor agonists are the preferred choice to insulin for patients who need the greater glucose-lowering effect of an injectable medication. Insulin is recommended for patients with extreme and symptomatic hyperglycemia.
- Treatment should be intensified with GLP-1 receptor agonists, SGLT2 inhibitors, or prandial insulin for patients who are unable to maintain glycemic targets on basal insulin in combination with oral medications.

- A history of cardiovascular disease should be considered early in the process of treatment selection.
- Weight, hypoglycemic risk, treatment cost, and other patient-related factors that may influence treatment selection are also recommended early in the treatment selection process.
- Sodium–glucose cotransporter 2 (SGLT2) inhibitors or glucagon-like peptide 1 (GLP-1) receptor agonists with proven cardiovascular benefit are recommended as part of glycemic management if there is a history of ASCVD.
- SGLT2 inhibitors are recommended for patients who have ASCVD and HF.
- Consider the use of an SGLT2 inhibitor for patients with T2D and chronic kidney disease (CKD). If that is contraindicated or not preferred, consider the use of a GLP-1 receptor agonist.

My Comment:

See the attached article and pay particular attention to Figure 2 on page 8 of the article for a very nice one page summary of the recommendations regarding pharmaceutical treatment.

I greatly appreciate the emphasis in this recommendation on lifestyle interventions as the foundation for treatment. Unfortunately, the guideline is sparse on details as to how this can best be done. There will be more on this in future editions of Take 3. I also appreciate the guidance regarding the most cost-effective treatment. In this context, the sulfonylureas make a return to the recommendations for this patient population.

References

Davies MJ et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2018 Oct 4. [Article](#)

From the Literature and the American Heart Association

2) The Perils of Shoveling Snow

Snow shoveling is a strenuous form of physical exertion that leads to injury, hospitalization, and even death of many people each year. Snow shoveling in cold weather puts a great deal of stress on the body. The cold weather causes peripheral vasoconstriction, shunting blood to the core, causing increases in blood pressure and heart rate. Cold weather also increases blood viscosity, increases platelet activation and increases risk for clot formation. Studies have shown that even cold weather exposure without exertion increases MI rates.

Additionally, snow shoveling requires a great deal of physical exertion. It is a full body work out, requiring both upper and lower extremity exertion. Maximum recommended heart rate is often achieved in less than 2 minutes. It is difficult to prepare for this activity through traditional exercise. This physical exertion puts increased strain on the heart by increasing BP and heart rate.

The most common snow shoveling injuries are musculoskeletal strain (53%), slips and falls (20%), and being struck with snow shovel (15%). Cardiac related incidents are about 6.7%. Patients at risk are patients who are typical middle aged and older males

(>60), sedentary, have tradition cardiac risk factors (hypertension, diabetes, high cholesterol, obesity, tobacco use, family cardiac history), or have a cardiac disease history themselves.

So what can you do? Advise older patients to hire someone or ask someone to help with snow shoveling. If the individual absolutely insists on shoveling snow then follow the below advice from the American Heart Association:

"Take frequent breaks and use a small shovel while working, as lifting large amounts of snow can spike blood pressure. If at all possible, push the snow instead of shoveling it. People should also avoid eating a heavy meal beforehand, and avoid alcohol both before and after the shovel session."

My Comment:

Yes, our recent record 14" snow fall here in Roanoke served as a good reminder for me that there is really no exercise that can prepare the body for the exertion of shoveling snow except shoveling snow. And it certainly was a good workout – again, and again! My thanks to Jack Perkins, one of our Emergency Medicine faculty and husband of Karen, one of my residency faculty colleagues, for his encouragement to both publish this Pointer and to have our organization send a message to our male patients over the age of 60 bringing their attention to snow shoveling safety. It's looking to be a winter with many more opportunities to work those shoveling muscles!

Reference:

- Watson, et al. Snow shovel-related injuries and medical emergencies treat in the US EDs, 1990-2006. Am J Emerg Med. 2011 Jan;29(1):11-17. [Article](#)
- AHA News: 7 ways to keep the heart safe when shoveling snow. January 4, 2018. [Link](#)

From the US Food and Drug Administration (FDA)

3) Ongoing Recall of Valsartan-containing Drugs

In July, the FDA announced recalls of some lots of valsartan due to the presence of N-Nitrosodimethylamine (NDMA), a known animal and suspected human carcinogen. Subsequent international investigations expanded to include additional drugs in the ARB class and have resulted in additional recalls of valsartan, irbesartan, and losartan-containing products found to contain NDMA and N-Nitrosodiethylamine (NDEA) – another known animal and suspected human carcinogens.

There may be confusion regarding which products are affected by ARB recalls and which are not, especially concerning the most recent U.S. recalls of valsartan-containing products manufactured by Mylan that tested positive for unacceptable levels of NDEA. Certain ARB products have been recalled, and certain products that contain ARBs and one or more other active ingredients in a single dosage form have been recalled. It is important to note that the active pharmaceutical ingredient (API) in these products besides valsartan, irbesartan or losartan are not necessarily under a recall. As an example, valsartan/amlodipine/hydrochlorothiazide is one product that has been recalled. Neither amlodipine or hydrochlorothiazide are currently under recall. Similarly, losartan potassium and hydrochlorothiazide 100mg/25mg is a product. The FDA is encouraging the public to pay careful attention to the agency's website for the most

accurate and up-to-date information as to what products are affected. In response to ongoing concerns, Teva Pharmaceuticals recently issued the voluntary recall for “all lots of combination tablets featuring the drugs amlodipine and valsartan and another combo drug featuring amlodipine, valsartan, and hydrochlorothiazide.”

My Comment:

My thanks to Randi Earls, PharmD, who is one of our FM faculty, for her consultation on this Pointer. For patients on combination medications containing valsartan, Randi recommends splitting up the combination and switching to an alternative ARB. For example, switch valsartan 80mg/day to losartan 50mg/day; valsartan 160mg/day to losartan 100mg/day. Losartan is on the \$4 list of many pharmacies.

All these recalls are yet another incentive to try and help our patients implement lifestyle changes as a more integral part of their therapeutic regimen. I’ve yet to see any studies indicating lifestyle interventions are carcinogenic!

Reference:

FDA News Release December 11, 2018: FDA warns API manufacturer involved in valsartan recall, provides information for patients taking these medications. [Link](#)

Feel free to forward Take 3 to your colleagues. Glad to add them to the distribution list.

Mark

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