Evaluation of Type 2 Diabetes Mellitus Medication Management and Control in Older Adults

Angela Thompson, Joseph P. Vande Griend, Sunny A. Linnebur, Joseph J. Saseen

OBJECTIVES: The primary aims of this study were to characterize glycemic control and pharmacologic management in older patients and to compare glycemic control and pharmacological management in patients 65 to 79 years of age ("young-old") with those 80 to 89 years of age ("old-old"). We hypothesized that patients 80 to 89 years of age would be prescribed fewer medications and would have higher A1c values compared with younger patients.

DESIGN: Retrospective medical record review.

SETTING: This study was conducted in outpatient clinics within a university hospital setting.

PATIENTS, PARTICIPANTS: This study included 400 adults 65 to 89 years of age with a diagnosis of type 2 diabetes mellitus and at least one A1c measurement over 12 months.

MAIN OUTCOME MEASURES: A1c measurements and diabetes mellitus medications were assessed in these patients.

RESULTS: The overall mean A1c was similar in the young-old compared with the old-old (7.1 ± 1.1% vs. 7.0 ± 1.1%; P = NS). There was no difference between groups for any of the A1c ranges studied. Fewer diabetes medications were prescribed in the old-old compared with the young-old (P = 0.003). In the young-old compared with the old-old, metformin (51.0% vs. 33.0%; P < 0.01), glucagon-like peptide-1 agonists (6.7% vs. 0%; P < 0.01), insulin glargine/detemir (24.7% vs. 13.0%; P < 0.05), and short-acting insulin (15.0% vs. 7.0%; P < 0.05) were more frequently prescribed.

CONCLUSION: Our results indicate that glycemic control was similar between the young-old and old-old. However, the old-old required fewer diabetic medications for this same level of glycemic control.

KEYWORDS: Aged, Diabetes mellitus, Geriatrics, Type 2 diabetes mellitus.

ABBREVIATIONS: ADA = American Diabetes Association, Clcr = Creatinine clearance, DM = Diabetes mellitus, DPP-IV = Dipeptidyl peptidase IV, EASD = European Association for the Study of Diabetes, GLP = Glucagon-like peptide, NPH = Neutral protamine Hagedorn, SCr = Serum creatinine, T2DM = Type 2 diabetes mellitus, TZD = Thiazolidinedione, UCH = University of Colorado Hospital.


Background

In the United States, it is estimated that 26.9% of patients older than 65 years of age have type 2 diabetes mellitus (T2DM). As a result of increased life expectancy, increases in screening for diabetes mellitus (DM), and more stringent changes in the DM diagnostic criteria, it is predicted that the prevalence of T2DM in patients 75 years of age and older will increase from approximately 700,000 patients in 2000 to 3.1 million patients by the year 2050. Medical expenditures in patients with T2DM are estimated to be 2.3 times higher than medical expenditures in patients without DM; thus, the growing number of older adults with T2DM is likely to produce a large economic burden to society.

Diabetes is associated with macro- and microvascular complications, including cardiovascular (CV) disease, nephropathy, retinopathy, and neuropathy, but these typically occur as a result of disease over many years. Landmark trials have shown that intensive glycemic control reduces these complications, but approximately eight years are needed before a reduction in microvascular complications is seen with intensive glycemic control. Even more time may be needed to see the potential benefits of glycemic control on macrovascular complications. The evidence of macrovascular benefits with intensive glycemic control has not been consistent as demonstrated in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study, which found increases in mortality, with rapid lowering of glucose levels. There are few long-term studies demonstrating the benefits of intensive glycemic control in older adults. Intensive glycemic control is often also associated with increased rates of hypoglycemia. Among older adults, hypoglycemia may lead to serious consequences such as falls and hip fractures. Complicating matters even more,
Type 2 Diabetes Medication Management in Older Adults

Age-associated abnormalities in counter-regulation can impair the ability to recognize and respond to hypoglycemia.\(^4\) Given the time it takes for glycemic control to reduce DM complications, the lack of studies in this patient population, and the risks of intensive glycemic control, older adults may not receive the same benefit from tight glycemic control as younger patients.\(^4\) Finally, polypharmacy, drug-drug, and drug-disease interactions make it important to carefully prescribe and monitor pharmacologic therapy in older adults.\(^5\)

There are several guidelines available recommending varying glycemic goals for older adults; however, the majority of these recommendations are based on expert opinion rather than trial data.\(^3\) The current American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists guidelines do not provide specialized goals for the treatment of DM in the geriatric population, but both guidelines do recommend less stringent goals in certain patient populations, including those with life-limiting comorbid conditions and substantial cognitive or functional impairment.\(^3,4\) The California Healthcare Foundation/American Geriatrics Society Guideline also recommends a less stringent A1c goal of < 8% in certain geriatric populations including frail older adults, those with a life expectancy of less than five years, and when the risk of strict glycemic control outweighs the benefit.\(^4\) Although each agency recommends slightly different glycemic targets, each guideline stresses glycemic targets should be individualized.\(^3\)

The recently published ADA/European Association for the Study of Diabetes (EASD) position statement further emphasizes that glycemic goals should be individualized in the older adult and that patient preferences should play a role in establishing glycemic targets.\(^6\) This patient-centered approach advocates that several patient-specific characteristics should be taken into account when determining glycemic targets in older adults.\(^6,7\) These patient-specific characteristics include psychosocioeconomic considerations, such as the motivation of the patient and the patient's support system, risk for hypoglycemia, patient age, duration of diabetes, other comorbid conditions, and established vascular complications.\(^6,7\) Even in those older adults who meet requirements for individualized, less intensive goals because of the above factors, glycemic goals should be set to avoid acute consequences of poorly controlled diabetes such as dehydration, poor wound healing, and hyperglycemic hyperosmolar coma.\(^5\)

Glucose variability plays a role in overall A1c in all patients, but because of hypoglycemic unawareness, it may be more important in older adults. A1c values can be misleading in patients who have large excursions in blood glucose values. For example, if a patient has a consistently elevated blood glucose level, but experiences several episodes of hypoglycemia per week, the A1c may indicate better glucose control than the patient truly has.\(^8\) Thus, A1c may not always accurately describe the glucose control of patients, especially older adults.

Pharmacologic therapy for DM must be used carefully in older adults by weighing risks against potential benefits for individual patients. Older adults in good health may benefit more from tight glycemic control and may tolerate a variety of pharmacologic agents; whereas, in frail older adults with a limited life expectancy, the risk of stringent glycemic control and certain pharmacologic medications may outweigh the benefit. For example, insulin and sulfonylureas are very effective agents; however, both are associated with hypoglycemia. Metformin is also very effective but concerns about lactic acidosis with decreases in renal function may be problematic, especially in the older adult population. Even though the glucagon-like peptide (GLP) agonists and dipeptidyl peptidase IV (DPP-IV) inhibitors are relatively safe medications, they may be economically harmful to older adults with limited incomes. Although the management of DM may be determined based on specific patient characteristics, prescribing patterns and overall management of T2DM in older adults are not well described. We hypothesized that patients 80 to 89 years of age would be prescribed fewer medications and would have higher A1c values compared with younger patients.

This study aimed to characterize glycemic control and pharmacologic management in older patients,
and to compare glycemic control and pharmacological management in patients 65 to 79 years of age (“young-old”) with those 80 to 89 years of age (“old-old”) within the University of Colorado Hospital (UCH) Outpatient Clinics of the University of Colorado Health.

**Methods**

This study was approved by the Colorado Multiple Institution Review Board and conducted within the UCH Outpatient Clinics (UCH-affiliated Family Medicine Clinics, the UCH Seniors Clinic, the UCH Endocrinology Clinic, and UCH-affiliated Internal Medicine Clinics). Adults 65 to 89 years of age with a diagnosis of T2DM based on an ICD-9 code of 250.X and at least one A1c measurement in an outpatient clinic from October 1, 2010-September 30, 2011, were included. Primary data parameters included A1c measurements and type of DM medications. Data were identified through an individual retrospective chart review of identified patients using electronic health records (EPIC and TouchWorks [Allscripts Healthcare Solutions]). The last A1c measured during October 1, 2010, to September 30, 2011, was used and recorded as the index date. All demographic data, laboratory values, medications, and disease states were recorded from this date. If data were unavailable at the index date, data were collected from the most recent available date prior to the index date but within one year of the index date. Renal function was estimated according to the Cockcroft-Gault equation. Adjusted body weight was used for patients 30% over their ideal body weight; otherwise renal function was calculated with actual body weight. Patients were excluded if they had a diagnosis of type 1 DM, an A1c measurement only during a hospitalization, or an A1c measurement from an outside clinic. Within the identified UCH clinics, 2,028 patients meeting inclusion criteria were identified. Data were collected from a random sample of patients until a target inclusion of 100 patients in the “old-old” 80 to 89 years of age group and 300 patients in the “young-old” 65 to 79 years of age group (1:3 ratio) was achieved.

**Statistical Analysis**

Assessment of the primary and secondary objectives was completed using descriptive statistics. Student t-tests were used to evaluate whether there were between group differences in these measures for normally distributed data. Standard deviation was used as a measure of variability. When the data were not normally distributed, median with range was used, and the Wilcoxon Mann-Whitney test was used to determine if there were between-group differences. Median with range was also used to describe nominal data. The Fisher’s exact test was used to compare differences between groups for nominal data, such as the use of certain DM medications and presence of contraindications to currently prescribed DM medications. Statistical significance was set at $P < 0.05$ for all statistical analyses.

**Results**

Baseline characteristics of the 300 young-old patients and the 100 old-old patients included in this study are shown in Table 1. The average age of patients was 71.5 years and 83.5 years in the young-old and old-old groups, respectively ($P < 0.05$). Compared with the young-old group, the old-old group had a higher

**Table 1. Baseline Characteristics of the Study Population**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Young-Old 65-79 Years (n = 300)</th>
<th>Old-Old 80-89 Years (n = 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>71.5 ± 4.1</td>
<td>83.5 ± 2.7</td>
</tr>
<tr>
<td>Gender (% female)*</td>
<td>51.7</td>
<td>64.0</td>
</tr>
<tr>
<td>Height (cm)*</td>
<td>167.3 ± 17.4</td>
<td>161.3 ± 25.8</td>
</tr>
<tr>
<td>Weight (kg)*</td>
<td>86.8 ± 20.1</td>
<td>76 ± 16.8</td>
</tr>
<tr>
<td>Serum creatinine (mg/dL)</td>
<td>1.2 ± 0.8</td>
<td>1.2 ± 0.4</td>
</tr>
<tr>
<td>Creatinine clearance (mL/min)*</td>
<td>61 ± 20</td>
<td>45 ± 14</td>
</tr>
</tbody>
</table>

Note: Data presented a mean ± standard deviation or percentage.
*Statistically significant between-group differences.
Type 2 Diabetes Medication Management in Older Adults

Mean A1c values and the breakdown of A1c attained are displayed in Figure 1. There was no difference in mean A1c values between the two groups. (7.1 ± 1.1% in the young-old vs. 7.0 ± 1.1% in the old-old; P = NS). More than 50% of patients in each group achieved an A1c less than 7%, and more than 80% of patients in each group achieved an A1c less than 8%, with no difference between groups. Seven patients in the young-old had an A1c greater than 10%, and one old-old patient had an A1c greater than 10%. There was no difference between groups for any of the A1c ranges studied. The median number of A1cs measured during the one-year collection period was two measurements for both age groups.

The number of DM agents used in each age group is displayed in Figure 2. Overall, fewer DM medications were prescribed for the old-old compared with the young-old (P = 0.003). Of the young-old, the majority of patients (64%) were prescribed one or two DM medications. Approximately 19% of the young-old were on no DM medications, and 17.2% of patients in this age group required three or more DM medications. Of the 100 old-old patients, the majority (69.0%) of patients required zero or one DM medication. Only 23.0% of this population required two DM medications, and rarely were any patients on three or more DM medications.

The classes of DM medications that were most commonly prescribed in all patients include the biguanides, sulfonylureas, and long-acting insulin (Table 2). A significantly higher percentage of the young-old were prescribed metformin compared with the old-old. Additionally, a significantly higher percentage of patients in the young-old group received GLP-1 agonists, insulin glargine or detemir, and rapid-acting insulin.

Potentially inappropriate use of DM medications is shown in Table 3. Of patients prescribed metformin, few patients had a serum creatinine prohibiting its use;
however, a small number of patients overall had a creatinine clearance (Clcr) of less than 30 mL/min (4.7% in the young-old and 11.0% in the old-old), for which use is not recommended. Glyburide use occurred equally between the two groups. Significantly more patients in the young-old group had hypoglycemia reported in their medical record when compared with the old-old (16.3% vs. 6.0%; \( P = 0.03 \)). The number of patients with hypoglycemia who were prescribed a glucagon pen for the treatment of hypoglycemia is described in Figure 3. All patients who were prescribed a glucagon pen were receiving either sulfonylureas or insulin therapy. Of those patients prescribed glucagon, a total of 2 patients were receiving sulfonylureas and 10 patients were receiving insulin.

**Discussion**

This study examined the likelihood of reaching glycemic targets in clinical practice. Results of this study indicate that although there are barriers to achieving optimal glycemic control in older adults, it is possible to reach these targets, as the majority of patients achieved A1cs less than 8%. This study also revealed that young-old and old-old patients are equally likely to achieve these glycemic targets. Moreover, the old-old required fewer medications to achieve glycemic targets than the young-old, as young-old patients were prescribed more DM agents, and a large number of the old-old were controlled on diet alone. Overall, there was a wide variety of DM medications prescribed, revealing that DM regimens are individualized for the older adult.

Metformin must be used cautiously in patients with renal insufficiency; however, there is controversy surrounding what values to use for metformin dosing in renal insufficiency. According to the package insert, the use of metformin is contraindicated in males with a serum creatinine (SCr) \( \geq 1.5 \) mg/dL and in females...
Lipska and colleagues’ proposed metformin can be used safely in mild-to-moderate renal insufficiency with proper monitoring and dose adjustments until the GFR falls below 30 mL/min/1.73 m² at which point its use is contraindicated. In the current study, a large number of patients received metformin. Overall, metformin was used appropriately with low use in patients who had severe renal insufficiency. Only one patient on metformin had a Clcr < 30 mL/min, and that patient’s Clcr was approximately 29 mL/min. Fewer than 4% of patients in the entire study were prescribed metformin with SCr levels greater than the recommendations in the package insert.

The 2012 American Geriatric Society Beers criteria strongly recommends avoiding glyburide in older adults because of high-quality evidence demonstrating an increased risk of severe prolonged hypoglycemia; thus, if sulfonylureas are prescribed in older adults, it is recommended to use an alternative sulfonylurea, such as glipizide or glimepiride. Despite this recommended restriction on glyburide use in the elderly, there were a significant number of patients in this study who were prescribed glyburide. In 2011, the effect of glyburide discontinuation in older adults was examined by Aspinall and colleagues and demonstrated that A1c levels did not significantly increase when compared with older adults who remained on glyburide. There was not a significant difference in the rate of severe hypoglycemia in those patients in which glyburide was discontinued; however, this was a secondary outcome, and the study was not powered to detect this difference. Of note, hypoglycemia in patients with severe renal impairment (SCr > 3 mg/dL) occurred significantly less in patients who had stopped taking glyburide compared with patients remaining...
Approximately 12% of our study population was prescribed a thiazolidinedione (TZD), and TZDs are associated with several adverse effects that are of concern for the older adult. TZDs are associated with an increased risk of congestive heart failure and peripheral edema and are contraindicated in patients with New York Heart Association class III-IV heart failure. Increased age has been shown as one risk factor for developing heart failure on a TZD. A 2007 meta-analysis found an increase in acute myocardial infarction with rosiglitazone use. In a subsequent analysis of both rosiglitazone and pioglitazone use in older adults, rosiglitazone was associated with an increased risk of stroke, heart failure, and death when compared with pioglitazone. Further evidence for increased myocardial infarction risk with rosiglitazone use has now led to limited use of this agent as a result of CV risks. Several studies have demonstrated decreased bone

### Table 2. Distribution of DM Medications Prescribed in the Study Population

<table>
<thead>
<tr>
<th>DM Class/Medication</th>
<th>Young-Old, 65-79 Years (n = 300) % of patients</th>
<th>Old-Old, 80-89 Years (n = 100) % of patients</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biguanide&lt;sup&gt;a&lt;/sup&gt;</td>
<td>51.0</td>
<td>33.0</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Secretagogue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sulfonylureas</td>
<td>30.3</td>
<td>35.0</td>
<td>0.39</td>
</tr>
<tr>
<td>• Glipizide</td>
<td>29.0</td>
<td>33.0</td>
<td>0.45</td>
</tr>
<tr>
<td>• Glyburide</td>
<td>17.0</td>
<td>21.0</td>
<td>0.37</td>
</tr>
<tr>
<td>• Glimepiride</td>
<td>10.0</td>
<td>8.0</td>
<td>0.69</td>
</tr>
<tr>
<td>• Meglitinides</td>
<td>2.0</td>
<td>4.0</td>
<td>0.28</td>
</tr>
<tr>
<td>Long-acting insulin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Glargine/detemir&lt;sup&gt;a&lt;/sup&gt;</td>
<td>26.0</td>
<td>4.0</td>
<td>0.08</td>
</tr>
<tr>
<td>• NPH</td>
<td>13.0</td>
<td>2.0</td>
<td>0.64</td>
</tr>
<tr>
<td>Rapid-acting insulin&lt;sup&gt;a&lt;/sup&gt;</td>
<td>15.0</td>
<td>7.0</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>TZDs</td>
<td>12.0</td>
<td>12.0</td>
<td>1.00</td>
</tr>
<tr>
<td>DPP-IV inhibitors</td>
<td>11.3</td>
<td>10.0</td>
<td>0.85</td>
</tr>
<tr>
<td>GLP-1 agonists&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.7</td>
<td>0.0</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>• Exenatide</td>
<td>3.0</td>
<td>0.0</td>
<td>0.12</td>
</tr>
<tr>
<td>• Liraglutide</td>
<td>3.7</td>
<td>0.0</td>
<td>0.07</td>
</tr>
<tr>
<td>Insulin 70/30</td>
<td>1.7</td>
<td>0.0</td>
<td>0.34</td>
</tr>
<tr>
<td>Alpha–glucosidase inhibitors</td>
<td>0.6</td>
<td>0.0</td>
<td>0.44</td>
</tr>
</tbody>
</table>

<sup>a</sup>Statistical significance.

**Abbreviations:** DM = Diabetes mellitus, DPP-IV = Dipeptidyl peptidase-IV, GLP = Glucagon-like peptide, NPH = Neutral protamine Hagedorn, TZD = Thiazolidinedione.
density and increased fracture risk with the use of TZDs. As bone density decreases with age, TZDs should be used cautiously in older adults. Additional concerns for the use of TZDs in older adults include the increased risk of bladder cancer, macular edema, and hepatic failure.

Although neutral protamine Hagedorn (NPH) was prescribed infrequently in our study population, insulin analogs such as insulin glargine and insulin detemir are preferred over NPH because of the variable onset, suboptimal duration of action, and increased risk of hypoglycemia that are seen with NPH. While the American Association of Clinical Endocrinologists and American College of Endocrinology no longer recommend the use of NPH, the ADA/EASD position statement recognizes the increased risk of hypoglycemia with NPH but includes its use in their recommendations. Risk of hypoglycemia is also less with a basal insulin regimen compared with a basal/bolus or premixed insulin regimen. Although only a small percentage of patients in our study were prescribed insulin 70/30, a significant proportion of our patients received a basal/bolus regimen. Although patients well-controlled on glyburide, NPH, insulin 70/30, and basal/bolus insulin may continue these regimens, if tolerated, focusing on the avoidance of glyburide, NPH, insulin 70/30, and basal/bolus regimens could potentially reduce hypoglycemia in older adults at the UCH.

In this study we found very few patients had an active prescription for glucagon. Even more concerning is the small number of patients with documented hypoglycemia and a prescription for glucagon. As previously discussed, intensive glycemic control is often also associated with increased rates of hypoglycemia, and age-associated

<table>
<thead>
<tr>
<th>Prescribing Information/Expert Consensus</th>
<th>Young-Old 65-79 Years n/N (%)</th>
<th>Old-Old 80-89 Years n/N (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin use in patients with creatinine clearance &lt; 30 mL/min&lt;sup&gt;21&lt;/sup&gt;</td>
<td>0/153 (0.0)</td>
<td>1/33 (3.0)</td>
<td>0.18</td>
</tr>
<tr>
<td>Metformin use in males with serum creatinine &gt; 1.5 mg/dL&lt;sup&gt;20&lt;/sup&gt;</td>
<td>3/77 (3.9)</td>
<td>0/12 (0.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Metformin use in females with serum creatinine &gt; 1.4 mg/dL&lt;sup&gt;20&lt;/sup&gt;</td>
<td>4/76 (5.3)</td>
<td>0/21 (0.0)</td>
<td>0.57</td>
</tr>
<tr>
<td><strong>Beers Criteria&lt;sup&gt;22&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glyburide use</td>
<td>30/300 (10.0)</td>
<td>8/100 (8.0)</td>
<td>0.69</td>
</tr>
<tr>
<td>TZD use with heart failure</td>
<td>1/36 (2.8)</td>
<td>0/12 (0.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>TZD use with edema</td>
<td>4/36 (11.1)</td>
<td>2/12 (16.7)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

**Abbreviation:** n = Number of patients meeting criteria, N = Number of patients on specific pharmacologic therapy, TZD = Thiazolidinedione.

**Source:** References: 20-22.
abnormalities in counter-regulation can impair the ability of older adults to recognize and respond to hypoglycemia. Budnitz and colleagues found when presenting to the emergency department for medication adverse events, almost 95% of hospitalizations resulting from endocrine agents were for hypoglycemia. Thus, it is important to ensure patients on pharmacologic agents that cause hypoglycemia and patients with previous episodes of hypoglycemia have proper education on the identification and treatment of hypoglycemia.

Limitations of this study include the inability to include patients older than 89 years of age and its retrospective nature. The retrospective nature of data collection may have led to an under-representation of certain medications and/or disease states, and potentially under-reporting of hypoglycemia. Data regarding hospitalizations for hypoglycemia were not collected as the inability to ensure use of the UCH inpatient system would have led to inaccurate results. The retrospective nature of this study also limits the ability to collect information on the amount of glucagon used as well as if patients prescribed glucagon were adequately educated on its proper administration. All patients included in this study were ambulatory patients seen in outpatient clinics; therefore, the majority of the patients are living independently and are in better health than patients requiring long-term care. Data may not apply to all long-term care and assisted living patients, especially those patients who are nonambulatory. Baseline characteristics between the two groups were significantly different; however, this was expected because of the difference in age between the two groups. A larger than expected number of the sample population was controlled with diet and exercise alone, and perhaps many of these patients were newly diagnosed. Unfortunately, as a result of difficulty finding such information, the duration of DM was not included in data collection. Therefore, some patients may have been diagnosed with DM many years prior to the collection period while others may have been diagnosed with the A1c used to define the index date. Not controlling for these data may have affected the results of the study.

**Conclusion**

Within the UCH Outpatient Clinics, glycemic control in older adults with T2DM is similar between patients 65 to 79 years of age and 80 to 89 years of age. There is also greater use of metformin, GLP-1 agonists, long-acting insulin, and rapid-acting insulin in the young-old compared with the old-old. However, fewer medications for diabetes are needed in the old-old to achieve this similar degree of glycemic control. These findings support a tailored approach to implementing DM medication management in older adults.

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Type 2 Diabetes Medication Management in Older Adults

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