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Appropriate Application of Evidence to the Care of Elderly Patients with Diabetes

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Abstract

Modern diabetes care may benefit a significant proportion of adults living with diabetes; however, these benefits may not be consistently realized among the heterogeneous subpopulation of elderly patients over 65 years of age. There are three clinical constraints that have been proposed as important considerations for individualizing diabetes care among elderly patients. Life expectancy should be an important determinant of the intensity of glucose control because intensive control has been found to prevent complications only after extended periods of treatment. Therefore, patients with limited life expectancy may not benefit from intensive glucose control. The time and attention of health care providers should also be considered a constrained resource that can be optimally allocated to care for elderly diabetes patients. In the face of multiple chronic conditions and symptomatic complaints, patients and their providers should prioritize diabetes care within the context of a patient's overall health care plan. The complexity of chronic medications or polypharmacy is the final clinical constraint. Polypharmacy may increase the probability of adverse drug events and represent a significant burden on quality of life. More direct clinical investigation of elderly diabetes patients will be needed if we are to truly improve the quality of life of this growing subpopulation.

Keywords

Diabetes; Geriatrics; Polypharmacy; Falls; Hypoglycemia

INTRODUCTION

Significant advances in diabetes care have been made in the past decade. Major clinical trials such as the Diabetes Control and Complication Trial [1], the United Kingdom Prospective Diabetes Study (UKPDS) [2], the Kumamoto Study [3], the Steno 2 Study [4], and the subgroup analyses of larger blood pressure and cholesterol lowering studies [5,6] have all contributed to our current conception of modern comprehensive diabetes care. These trials have helped to illustrate the benefits of intensifying control of glucose, blood pressure, and cholesterol control and influenced the setting of treatment goals for each of these risk factors (i.e., glycosylated hemoglobin $A_{1C} < 7\%$, blood pressure <130/80 mm Hg, and LDL cholesterol <100 mg/dl) [7].

While striving for the standard treatment goals of diabetes care may benefit a significant proportion of adults living with diabetes, there are concerns about the appropriateness of applying these goals to the care of all diabetes patients over 65 years of age. These concerns have been summarized in multiple thought pieces [8,9] and codified in a recent geriatric diabetes care guideline endorsed by multiple medical organizations including the American

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Diabetes Association [10]. Elderly diabetes patients are highly heterogeneous across a variety of characteristics such as diabetes duration, diabetes complications, functional status, and comorbid illnesses and clinical trial populations, whose data form the basis for current goals of diabetes care, have typically not reflected this heterogeneity. In the past, clinical trials of diabetes therapies such as the UKPDS systematically excluded patients above the age of 65 years of age [2]. While age restrictions are slowly being raised in current clinical trials, ongoing clinical trials such as the Action to Control Cardiovascular Risk in Diabetes continue to exclude elderly patients with significant functional impairment or comorbid illnesses. The major question for an elderly patient and his/her health care providers is whether or not the treatment goals set forth in clinical guidelines should be the diabetes care goals for an individual patient.

This review outlines the current understanding of the constraints that should influence the application of evidence to the care of elderly patients with diabetes and identifies areas for future investigation.

CONSTRAINTS OF CARING FOR ELDERLY DIABETES PATIENTS

The Constraint of Limited Life Expectancy of Elderly Patients

Life expectancy is considered to be a primary method for distinguishing between elderly diabetes patients who will or will not benefit from the intensive risk factor control targets of modern diabetes care. This is clearly an important consideration for intensive glucose control but less so for blood pressure and cholesterol control. For intensive glucose control, the UKPDS illustrated that at least 9 years of ongoing intensive glucose control was required before evidence of treatment benefit was achieved in middle-aged patients with new-onset diabetes [2]. This time to treatment effect was most likely due to the fact that the microvascular complications of diabetes take many years to develop. Because UKPDS began with patients with new-onset diabetes, the development of complications was prolonged and hence the observed benefits of intensive glucose control were delayed. Based on this result, it is suspected that elderly patients should have at least 5 years of life expectancy in order to benefit from intensive lowering of glucose levels. On the other hand, this same concern for limited life expectancy does not exist when treating hypertension [11], using HMG-CoA reductase inhibitors (statins) [12], or using ACE inhibitors [13] where the benefits of treatments have been accrued as early as 2-3 years in clinical trials. Many of these trials have in fact been conducted in elderly populations who were at high risk of developing cardiovascular complications.

There are several key clinical variables for determining life expectancy in elderly patients. Age is, in and of itself, the most powerful predictor of life expectancy and should be an important first factor to consider. From disease simulation studies, we know that the benefits of intensive glucose control steadily decline as the age of onset increases because of changing background mortality [14,15]. Within age groups, we can differentiate between patients with and without significant comorbid illness. We know from studies of comorbidity indices that they have predictive power for mortality [16]. In addition to comorbidity, functional status is known as an independent predictor of mortality among elderly patients [17]. Very recently, a prognostic index for 4-year mortality that combines age, comorbidity, and functional status has been developed and may be of use in stratifying diabetes patients [18].

Whether or not any of these clinical characteristics can be practically used for making treatment decisions in elderly diabetes patients is unknown. The last major effort to evaluate the value of providing prognostic information to providers took place during the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) trial [19]. During this trial, prognostic information was given to health care providers regarding elderly hospitalized patients in order to align decisions regarding code status and intensity of care with

prognosis and patient preferences. The intervention did not bring about changes in processes or outcomes of hospitalized elders and the potential reasons for this lack of success have been previously described [20].

In the setting of diabetes care in the elderly, there has been no attempt like the SUPPORT trial to evaluate the benefits of prognostic stratification of elderly diabetes patients. Our research of current clinical practice suggests that some physicians are already beginning to account for life expectancy in their diabetes treatment decisions but the same data indicate that there is currently no clear distinction between the treatment of elderly patients with limited life expectancy and that of healthier older patients. When physicians are asked about their glucose control goals for their elderly patients, they are more likely to identify higher glucose control goals for their patients with limited life expectancy [21]. At the same time, when we have compared the risk factor levels of elderly patients of varying clinical characteristics, we have found almost no difference in the degree of glucose control or in the number of medications used to treatment glucose levels [22]. This combination of results suggests that physicians may have the intention to treat distinct groups of elderly diabetes patients differently but the ability to implement distinct treatment plans may be difficult for a variety of practical and ethical reasons that have yet to be delineated.

The Constraint of Care Time: Priorities of Care

The time that health care providers have with elderly patients is limited, given the number of health care issues that must be addressed. As a result, prioritizing the care time spent with patients is an important clinical task for the care and health of elderly patients. We know from studies of the clinical visit that time spent with patients is increasing [23]; however, the number of medical issues addressed during clinical visits is increasing at a corresponding rate [24]. The pace of clinical work during a visit is most rapid among the oldest patients. This finding reinforces concerns about whether the quality patient-provider interactions can be maintained as the number of preventive care recommendations continue to increase [25].

It is important for patients and providers to be reminded of the fact that the risk factor goals of diabetes care exist within the overall health care context of an elderly patient. Diabetes care may in fact be only one of many conditions of importance to an elderly patient. Failing to recognize that there is a hierarchy of health care conditions for an individual patient can lead one to focus almost entirely on the care of an individual condition that may not contribute to a patient's ability to improve his/her general health. For most providers and public health officials, the traditional goal of health care has been the prevention of morbidity and mortality. In the fields of aging and geriatrics research, the proposed goal of health care for elderly patients has been more specifically conceived as achieving compressed morbidity [26]. When asked about their health care goals, elderly patients, including those living with diabetes, have been found to focus almost entirely on their functional status and their independence [27,28]. The language of patients is distinct from the biomedical language of health care providers but in meaning, the goals of patients are highly related to the ideas of compressed morbidity as well as the idea of enhanced quality of life.

The geriatric diabetes care guidelines [10], alluded to earlier, have proposed an approach to care prioritization that may help elderly patients avoid the complications of diabetes that are most likely to occur for the individual and to minimize the daily burden and side effects of medications. The guidelines also have a broader intention of refocusing the attention of the provider from purely focusing on risk factor control of diabetes to also considering the presence of geriatric syndromes. The term, geriatric syndromes, refers to one symptom or a complex of symptoms with high prevalence in frail elderly patients, resulting from multiple diseases and multiple risk factors. Geriatric syndromes can have a devastating effect on quality of life of elderly patients. Specific syndromes such as falls [29] and polypharmacy [30] have some direct

implications for how intensely providers may actually manage diabetes-related risk factors. Other geriatric syndromes, such as depression [31], cognitive impairment [32], urinary incontinence [33], and chronic pain [34] are more common among elderly patients with diabetes and may be of great importance to the patient. Reminding providers to screen for these syndromes may ultimately help patients address complaints that significantly affect their quality of life. Addressing these geriatric syndromes in addition to reconsidering the risk factor goals of diabetes care will, in effect, move the attention of providers from diabetes specific goals to the overall health care goals of patients. All of these considerations encourage a holistic approach to care for an elderly patient for whom diabetes may in fact not be his/her most important concern.

The Constraints of Medication Harms: Polypharmacy and Adverse Drug Events

Another way to distinguish among elderly patients is to identify those elderly patients who will be at greatest risk for suffering from the adverse effects of treatments such as hypoglycemia as well as classic geriatric syndromes such as falls. Many of the same characteristics that will likely limit the benefits of intensive risk factor control are also the characteristics that increase the risk for side effects and geriatric syndromes. The risk of hypoglycemia is highest among patients who are over the age of 80 (relative risk (RR) 1.8, 95% confidence interval (CI) 1.4-2.3), and use five or more concomitant medications (RR 2.0, 95% CI, 1.7-2.4) [35]. The risk of falls in elderly patients is highest among patients with orthostasis, depressive symptoms, impairments in cognition, vision, balance, gait or muscle strength, and the use of four or more prescription medications [29]. Polypharmacy itself is recognized as a geriatric syndrome. Polypharmacy can not only increase the risk of hypoglycemia and falls but is also associated with cognitive deficits and depression. Unfortunately, comprehensive diabetes care is intimately linked to a standard form of polypharmacy that worsens as the duration of diabetes progresses [36]. The average number of prescribed medications related to diabetes has now risen to four [37]. Concerns regarding polypharmacy raise questions regarding the possible harms of routinely prescribing drugs such as statins or aspirin that may be reducing the risk of cardiovascular disease but adding to the complexity of a patient's medication regimen.

Concerns regarding polypharmacy are particularly relevant for some elderly patient who live with sentinel conditions that may dictate whether or not intensive risk factor control can be practically pursued. Dementia or cognitive impairment is a sentinel condition for diabetes because it not only affects background mortality but alters the ability of patients to fully participate in the self-care [38]. Patients who have already developed end-stage complications of diabetes such as blindness or end-stage renal disease also pose unique challenges for providers. Like the demented, blind patients may have particular difficulties in adhering to complex treatments without special assistance. Patients with end-stage renal disease will typically require wholesale revision of their glucose lowering regimens because their inability to clear insulin.

Polypharmacy is also important to consider as a quality of life issue for elderly patients. The burden of everyday medications is generally an underappreciated issue in part because the quality of life effects of treatments have been assessed in clinical trial populations who may have systematically different perceptions than the general population and because instruments used to measure the burden of everyday medications on quality of life have been relatively insensitive [39-41]. In our work assessing the quality of life effects of individual medications and comprehensive diabetes care, we have found that there is significant heterogeneity in patients' perceptions of treatment burden [42,43]. On average, the burden of comprehensive diabetes care is rated similarly to that of intermediate complications (0.64 on a utility scale from 0 to 1). However, when examining the distributions of quality of life ratings we have found that the majority of patients actually rated life with treatments as being close to perfect

health indicating that treatments were not burdensome. At the same time, an important minority of patients (10-18%) give ratings that indicate that they perceived life with treatments as being a significant burden on quality of life.

DISCUSSION

The concerns that have been recently raised about the appropriateness of applying care recommendations developed for the general population of diabetes patients to the care of elderly diabetes patients are significant, especially given the fact that the proportion and number of patients over 65 living with diabetes is expected to continue to rise in the coming decades. The central challenge is that clinical trial populations have not reflected the heterogeneity of the general population of elderly diabetes patients. This requires that clinicians extrapolate findings from healthier, compliant trial patients to the care of elderly patients. The clinical constraints described in this review should clearly be considered in this extrapolation process in the formulation of day-to-day management for individual elderly patients. Since 2004, the American Diabetes Association has formally acknowledged the importance of these constraints in the care of elderly diabetes patients [44].

Despite these recent recommendations, the diabetes care literature and the discussions of quality of care incentives have generally ignored the heterogeneity of elderly diabetes patients [45,46]. Pilot studies of diabetes disease management programs [47] have been undertaken in elderly Medicare populations, largely without consideration for patient heterogeneity. Recent changes in diabetes care performance measures that now encourage uniform achievement of intensive glucose control levels ignore issues of patient heterogeneity [48,49]. Measures that promote intensive glucose control for all elderly patients could actually cause some patients harm by either promoting intensification in patients who are not likely to benefit from such treatments or by promoting perverse incentives such as dropping patients with poor control from practices.

While there is a clear need to focus greater attention on the unique needs of elderly diabetes patients, it is less clear how to implement many of the new recommendations related to individualizing care in elderly diabetes patients. There is particular uncertainty around how to identify patients who will benefit or be harmed by intensive risk factor control related to diabetes. The clinical characteristics that have been promoted as criteria for stratifying patients have face validity and may provide clear decisions for some elderly patients. However, it is very likely that many elderly patients will have clinical characteristics that are predictive of both increased risk of complications related to diabetes as well as increased risk of adverse events related to diabetes therapies.

Another important unresolved aspect of individualizing care for elderly diabetes patients is how to respond to dynamic changes in the health status of elderly patients. Elderly patients may move into and out of states of illness and functional impairment on a regular basis. We now know that the functional impairment in elderly patients actually comes and goes and is not fixed [50]. The problem with dynamic health states is that we may begin with goals consistent with intensive diabetes care in a given patient but be forced to modify treatment goals as illnesses develop. Lessons from clinical trials would suggest that we should continue intensive treatments for a series of years to ensure that their benefits are realized. On the other hand, data on comorbidities and functional status would tell us that the benefits of continuing intensive treatments are minimal. These issues related to altering therapies in the midst of an elderly patient's history with diabetes are complex and should be studied in greater depth.

It is clear that significant clinical research is needed to confirm or deny the many concerns that clinicians have when caring for elderly diabetes patients. This research will also help to define

the optimal approach to caring for elderly diabetes patients. The approach must somehow acknowledge the clinical constraints of caring for elderly patients while also accommodating patient preferences for treatments. The lessons learned in diabetes care may be applicable to other forms of chronic disease management in the elderly.

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