Original Investigation | LESS IS MORE

Rates of Deintensification of Blood Pressure and Glycemic Medication Treatment Based on Levels of Control and Life Expectancy in Older Patients With Diabetes Mellitus

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IMPORTANCE Older patients with diabetes mellitus receiving medical treatment whose blood pressure (BP) or blood glucose level are potentially dangerously low are rarely deintensified. Given the established risks of low blood pressure and blood glucose, this is a major opportunity to decrease medication harm.

OBJECTIVE To examine the rate of BP- and blood glucose–lowering medicine deintensification among older patients with type 1 or 2 diabetes mellitus who potentially receive overtreatment.

DESIGN, SETTING, AND PARTICIPANTS Retrospective cohort study conducted using data from the US Veterans Health Administration. Participants included 211 667 patients older than 70 years with diabetes mellitus who were receiving active treatment (defined as BP-lowering medications other than angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, or glucose-lowering medications other than metformin hydrochloride) from January 1 to December 31, 2012. Data analysis was performed December 10, 2013, to July 20, 2015.

EXPOSURES Participants were eligible for deintensification of treatment if they had low BP or a low hemoglobin A_{1c} (HbA_{1c}) level in their last measurement in 2012. We defined very low BP as less than 120/65 mm Hg, moderately low as systolic BP of 120 to 129 mm Hg or diastolic BP (DBP) less than 65 mm Hg, very low HbA_{1c} as less than 6.0%, and moderately low HbA_{1c} as 6.0% to 6.4%. All other values were not considered low.

MAIN OUTCOMES AND MEASURES Medication deintensification, defined as discontinuation or dosage decrease within 6 months after the index measurement.

RESULTS The actively treated BP cohort included 211 667 participants, more than half of whom had moderately or very low BP levels. Of 104 486 patients with BP levels that were not low, treatment in 15.1% was deintensified. Of 25 955 patients with moderately low BP levels, treatment in 16.0% was deintensified. Among 81 226 patients with very low BP levels, 18.8% underwent BP medication deintensification. Of patients with very low BP levels whose treatment was not deintensified, only 0.2% had a follow-up BP measurement that was elevated (BP ≥140/90 mm Hg). The actively treated HbA_{1c} cohort included 179 991 participants. Of 143 305 patients with HbA_{1c} levels that were not low, treatment in 17.5% was deintensified. Of 23 769 patients with moderately low HbA_{1c} levels, treatment in 20.9% was deintensified. Among 12 917 patients with very low HbA_{1c} levels, 27.0% underwent medication deintensification. Of patients with very low HbA_{1c} levels whose treatment was not deintensified, fewer than 0.8% had a follow-up HbA_{1c} measurement that was elevated (≥7.5%).

CONCLUSIONS AND RELEVANCE Among older patients whose treatment resulted in very low levels of HbA_{1c} or BP, 27% or fewer underwent deintensification, representing a lost opportunity to reduce overtreatment. Low HbA_{1c} or BP values or low life expectancy had little association with deintensification events. Practice guidelines and performance measures should place more focus on reducing overtreatment through deintensification.

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Invited Commentary

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Clinical practice guidelines and quality of care initiatives for glucose and blood pressure (BP) control have long focused on intensifying therapy to achieve target risk factor levels, such as reducing hemoglobin A_{1c} (HbA_{1c}) levels to less than 7.0% and BP levels to under 140/90 mm Hg. As a result of this focus on medication intensification, undertreatment has decreased dramatically.[1,2] Unfortunately, the same focus has also likely led to substantial overtreatment.[3-7]

Such overtreatment is not harmless. In the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study, providing treatment for patients with diabetes mellitus to achieve a target systolic BP (SBP) of less than 120 mm Hg increased the rate of serious adverse events,[6] and treating to a target HbA_{1c} level of 6.0% increased all-cause mortality.[7] Overtreatment is common even in older, medically complex patients, in whom it can be especially dangerous.[8-11] The most recent guidelines of the American Diabetes Association and the American Geriatrics Society, as well as the American Board of Internal Medicine's Choosing Wisely campaign,[12-14] have started to acknowledge the harms of overtreatment resulting in very low BP and HbA_{1c} levels. The new guidelines and the Choosing Wisely campaign specifically recommend less aggressive treatment for older patients and those with limited life expectancy, such as a target HbA_{1c} level of 7.5% or 8.0%. The report from the panel members appointed to the Eighth Joint National Committee[15] now recommends treatment in older patients to achieve an SBP level below 150 mm Hg—no longer to a level below 140 mm Hg.

To meet these new goals, many patients will need to discontinue medications within their present regimen. This process of medication deintensification may be difficult. From the patients' perspective, deintensifying treatment could mean moving away from goals that they had worked hard to reach for many years. For health care professionals, promoting deintensification means informing patients that previously recommended treatments are no longer useful; this alteration could also worsen health care professionals' performance assessments on profiles that continue to promote tight BP and glucose level control for many patients. There are no specific recommendations on deintensifying treatment.

We know little about the process of medication deintensification, including how often it happens or for whom. Therefore, we describe the frequency of treatment deintensification among older patients with diabetes mellitus who are potentially receiving overtreatment and examine whether patients with limited life expectancy (the people who are least likely to benefit) are more likely to undergo medication deintensification.

Methods

Study Population

We used the Corporate Data Warehouse from the Department of Veterans Affairs (VA) to construct 2 cohorts: one to assess blood glucose medication deintensification and the other to assess BP medication deintensification. The cohorts included all active primary care patients 70 years or older with a diagnosis of diabetes mellitus who were receiving active treatment for elevated glucose level control or BP control between January 1 and December 31, 2012.[4] Diabetes mellitus was defined using previously published methods.[4] Patients in the BP cohort had at least 1 BP measurement and primary care appointment on the same day in 2012, and those in the HbA_{1c} cohort had at least 1 HbA_{1c} measurement in 2012. The index BP or HbA_{1c} was the last measurement in 2012. We included all VA clinics in which primary care services are delivered. We excluded patients who died within 180 days of their index measurement. The Ann Arbor VA Human Studies Committee approved this study with a waiver of informed consent.

We defined a patient receiving active medical therapy for BP control as having prescriptions for hypertension medications other than low-dose angiotensin-converting enzyme inhibitors or angiotensin receptor blockers. We excluded these patients because these drugs are often appropriately prescribed for renal protection in patients with diabetes mellitus rather than exclusively for BP. Active medical therapy for blood glucose level control was defined as receiving treatment with any diabetes medication other than metformin hydrochloride. We excluded treatment with metformin alone because this drug usually does not cause hypoglycemia and may have clinical benefits apart from lowering HbA_{1c}, including possible direct cardiovascular benefits.[16]

Patients with diagnoses of congestive heart failure or cirrhosis were excluded from the low BP cohort since there are reasons for antihypertensive treatment for these conditions even in the presence of low BP. These exclusions were made to conservatively ensure that we studied individuals who would most likely benefit from deintensification.

Variable Construction and Definition

We stratified each cohort based on their index BP or HbA_{1c} level. For BP, we defined *very low* as an SBP less than 120 mm Hg or a diastolic BP (DBP) less than 65 mm Hg, *moderately low* as an SBP of 120 to 129 mm Hg or a DBP less than 65 mm Hg, *not low* as an SBP of 130 mm Hg or greater and a DBP of 65 mm Hg or greater, and *high* as an SBP of 140 mm Hg or greater or a DBP of 90 mm Hg or greater. For HbA_{1c}, we defined *very low* as less than 6.0%, *moderately low* as 6.0% to 6.4%, *not low* as 6.5% or greater, and *high* as greater than 7.5%. *Safe* was defined as all values that are neither low nor high.

The cut points chosen to define our very low BP and blood glucose level groups were based on the ACCORD randomized trial[17] of diabetes mellitus treatment as well as other studies[6,18] documenting adverse consequences of low DBP. The ACCORD trial found that treatment resulting in an SBP less than 120 mm Hg or HbA_{1c} less than 6.0% increased adverse events and all-cause mortality, respectively, in a population of patients who were substantially younger and healthier than those in our cohorts.

The cut points chosen to define our moderately low BP and blood glucose–level groups were selected because they were substantially lower than recommendations of clinical practice guidelines.[12,15,19] These cut points are within the range for which there is an absence of evidence of benefit.[15,20] Patients receiving active treatment who were experiencing very low or moderately low levels of HbA_{1c} or BP were considered to be receiving potential overtreatment. The values for high BP and HbA_{1c} were based on clinical practice guidelines of the time.

Table. Description of Cohorts

Factor	BP Cohort, No. (%)[a]			HbA_{1c} Cohort, No. (%)[b]		
	Very Low	Moderately Low	Not Low	Very Low	Moderately Low	Not Low
No. (cohort %)	81 226 (38.4)	25 955 (12.3)	104 486 (49.4)	12 917 (7.2)	23 769 (13.2)	143 305 (79.6)
Age, mean (SD), y	78.7 (5.6)	77.5 (5.5)	77.8 (5.6)	78.6 (5.7)	78.5 (5.7)	77.8 (5.6)
Charlson Comorbidity Index score,[22] mean (SD)	1.20 (1.40)	1.04 (1.33)	1.04 (1.33)	1.44 (1.69)	1.28 (1.53)	1.27 (1.50)
Life expectancy, y						
<5	12 987 (16.0)	2931 (11.3)	12 654 (12.1)	2572 (19.9)	4154 (17.5)	22 537 (15.7)
5-10	48 518 (59.7)	14 768 (56.9)	60 288 (57.7)	7516 (58.2)	13 772 (57.9)	83 392 (58.2)
>10	19 721 (24.3)	8256 (31.8)	31 544 (30.2)	2829 (21.9)	5843 (24.6)	37 376 (26.1)
Male sex	80 184 (98.7)	25 703 (99.0)	103 052 (98.6)	12 758 (98.8)	23 487 (98.8)	141 680 (98.9)
Hospice or palliative care in prior year	166 (0.2)	56 (0.2)	180 (0.2)	69 (0.5)	80 (0.3)	469 (0.3)
Dementia	1396 (1.7)	349 (1.3)	1416 (1.4)	294 (2.3)	476 (2.0)	2351 (1.6)
Metastatic carcinoma	338 (0.4)	99 (0.4)	442 (0.4)	92 (0.7)	121 (0.5)	578 (0.4)

Abbreviations: BP, blood pressure; HbA_{1c}, hemoglobin A_{1c}.

[a] Blood pressure levels were defined as follows: very low, systolic BP (SBP) less than 120 mm Hg or diastolic BP (DBP) less than 65 mm Hg; moderately low, SBP of 120 to 129 mm Hg or a DBP less than 65 mm Hg; and not low, SBP of 130 mm Hg or greater and DBP of 65 mm Hg or greater.

[b] Hemoglobin A_{1c} levels were defined as follows: very low, less than 6.0%; moderately low, 6.0% to 6.4%; and not low, 6.5% or greater.

The VA guidelines recommended an HbA_{1c} level less than 8.0%; thus, our choice of less than 7.5% was more conservative with respect to our study question.

Our primary outcome was the percentage of patients receiving potential overtreatment who underwent medication deintensification. In brief, therapy was considered to have been deintensified if the patients did not have a refill of a previously prescribed BP- or HbA_{1c}-lowering medication for 180 days after the index measurement or if their next medication refill after the index measurement was at a lower dose. Details on our definition of deintensification are available in the eAppendix and eFigure 1 in the Supplement. We did not have dosage information on insulin; therefore, an insulin deintensification event required stopping at least one type of insulin.

Comorbidity was measured with the Deyo et al adaptation[21,22] of the Charlson Comorbidity Index and derived from VA administrative data. We estimated patients' remaining life expectancy using a technique based on the patient's age and his or her Charlson-Deyo score.[23] In this technique, patients aged 70 to 79 years with a Charlson-Deyo score of 0 are recognized to have a life expectancy of more than 10 years, those aged 70 to 84 years with a Charlson-Deyo score of 1 to 3 or those aged 80 years or older with a Charlson-Deyo score of 0 have a life expectancy of 5 to 10 years, and patients aged 70 to 84 years with a Charlson-Deyo score of 4 or more or those who are 85 years or older whose score is 1 or more have a life expectancy of less than 5 years.

Statistical Analysis

After defining the cohorts, we stratified them based on the defined BP and HbA_{1c} cut points and then on whether the patients underwent deintensification of treatment. For patients who did not receive deintensification, we used the next available BP and HbA_{1c} measurements within 6 months of the index visit to describe how many patients had a follow-up value that was persistently very low or moderately low and could therefore still prompt deintensification, those whose value entered a range that could be considered to be high (conservatively defined as a BP ≥140/90 mm Hg or an HbA_{1c} level ≥7.5%), and those whose BP or HbA_{1c} level entered a safe "in-between" zone. If there were multiple values on the same date, we used the lowest one. This choice examines the risk and benefit of making no change when encountering a very low or moderately low BP or HbA_{1c} level.

We then examined whether the level of HbA_{1c} or BP or the patient's life expectancy influenced the rate of deintensification. After dividing each cohort into 9 groups for each of 3 levels of BP or HbA_{1c} and 3 levels of life expectancy, we performed a logistic regression analysis to predict deintensification for each group. We also did this in models that did not include life expectancy.

These analyses helped to differentiate between deintensification because of low BP or HbA_{1c} levels vs other reasons. Preventing potential overtreatment is unlikely the reason for deintensification in patients whose BP and HbA_{1c} levels are not low. These results were considered baseline deintensification rates representing ordinary attrition of medications, adverse reactions, patient-driven discontinuation, or medication nonadherence.[24] Rates of deintensification in the low BP and HbA_{1c} groups beyond these baseline rates were considered deintensification responses more likely to be attributable to the low HbA_{1c} or BP levels.

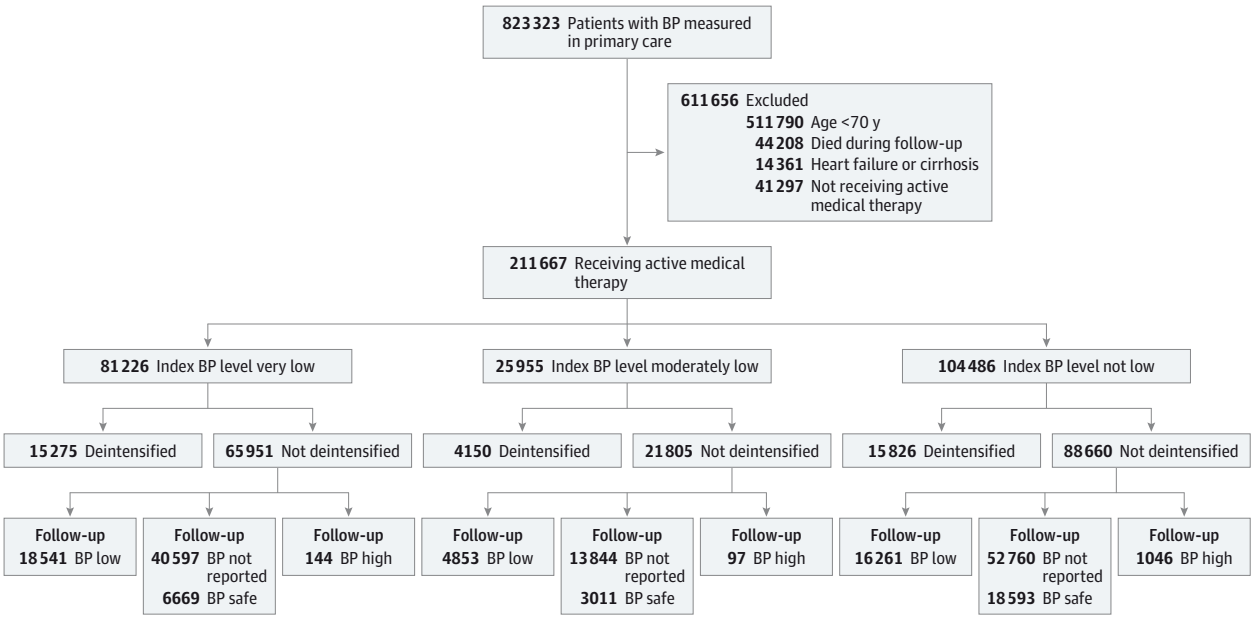
In another supplementary analysis, we compared rates of deintensification and follow-up values based on how consistently patients' BP and HbA_{1c} levels had been recorded as low. Statistical analysis was conducted using Stata, version 13 (StataCorp).

Results

Rates of Deintensification

The **Table** describes the characteristics of the cohorts. Both the low BP and low HbA_{1c} samples had advanced mean age, were almost entirely male, and had a high rate of comorbidities.

Figure 1. Flow Diagram for the Low Blood Pressure (BP) Cohort



The cohort evaluated was patients with diabetes mellitus who were older than 70 years and receiving active BP-lowering treatment. We defined *active BP-lowering treatment* as receiving treatment with medications other than low-dose angiotensin-converting enzyme inhibitors or angiotensin receptor blockers. The BP level stratification is explained in the Variable Construction and Definition subsection of the Methods section.

In the BP cohort, 25 955 of 211 667 patients (12.3%) received treatment to achieve a moderately low BP level, and 81 226 individuals (38.4%) developed a very low BP level associated with treatment (**Figure 1**). With results reported as percentage with 95% CI, patients whose BP was not low had a 15.1% (14.9%-15.4%) chance of having a BP medication deintensified, those with moderately low BP had a 16.0% (15.5%-16.4%) chance, and those with a very low BP had an 18.8% (18.5%-19.1%) chance.

In the HbA_{1c} cohort, 23 769 of 179 991 patients (13.2%) received treatment to achieve a moderately low HbA_{1c} level, and 12 917 (7.2%) received treatment resulting in a very low HbA_{1c} level (**Figure 2**). With results reported as percentage with 95% CI, patients whose HbA_{1c} was not low had a 17.5% (17.3%-17.7%) chance of having a glucose-lowering medicine deintensified; those with a moderately low HbA_{1c} had a 20.9% (20.3%-21.4%) chance, and those with a very low HbA_{1c} had a 27.0% (26.2%-27.8%) chance.

Although BP and HbA_{1c} values fluctuated between measurements, among patients who were eligible for but had not undergone deintensification, low values of BP and HbA_{1c} rarely increased to elevated levels (Figures 1 and 2). In fact, among 65 951 patients with very low index BPs whose treatment was not deintensified, during the next 6 months, 28.1% of these patients had persistently low BP levels, only 0.2% had measured values of 140/90 mm Hg or greater, and 61.6% had no measurement documented. Among 9428 individuals with very low index HbA_{1c} values whose treatment was not deintensified, during the next 6 months, 16.9% of these patients had a low follow-up HbA_{1c} level, fewer than 0.8% had an HbA_{1c} level of 7.5% or greater, and 79.8% had no measured HbA_{1c} documented.

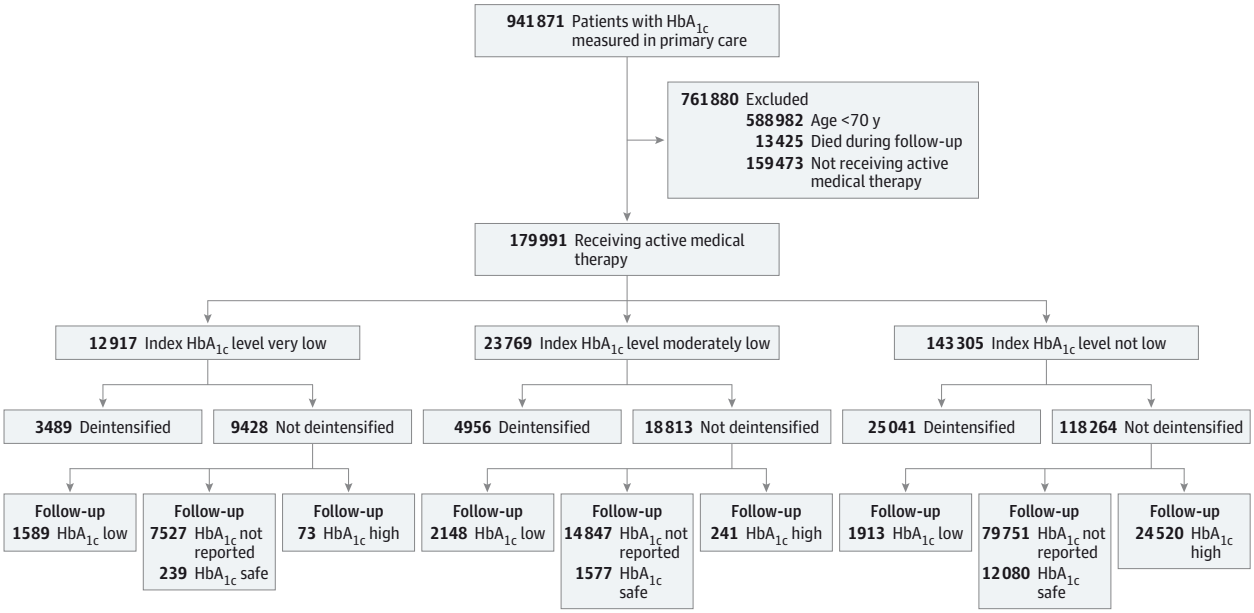
Because we were able to assess only the presence or absence of prescriptions for short- and long-acting insulin and not the insulin dosages, we repeated the analyses excluding all patients receiving only metformin (as before), receiving any insulin, or receiving both therapies. Similarly, on the possibility that some patients were receiving therapy with high-dose angiotensin agents (namely, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers) for renal protection, we repeated the analyses with all angiotensin agent use not considered active treatment. Although removing insulin from the analysis decreased the size of the cohort by 40%, neither of these exclusions had a substantial effect on the outcomes (eFigure 2 and eFigure 3 in the Supplement).

We also looked at the effect of consistency of BP and HbA_{1c} levels on deintensification (eFigure 4 and eFigure 5 in the Supplement). For both BP and HbA_{1c}, in patients with at least 1 moderately or very low measurement, we found that those with 2 or more low values and those with only 1 low value had similar rates of deintensification. Those with only 1 value measured had slightly lower rates of deintensification. After that, patients with only 1 value documented in the previous 6 months were much less likely to have any follow-up measurement. Those with 2 or more low values were more likely to have low values on follow-up than were those with only 1 low value.

Role of Life Expectancy on Deintensification

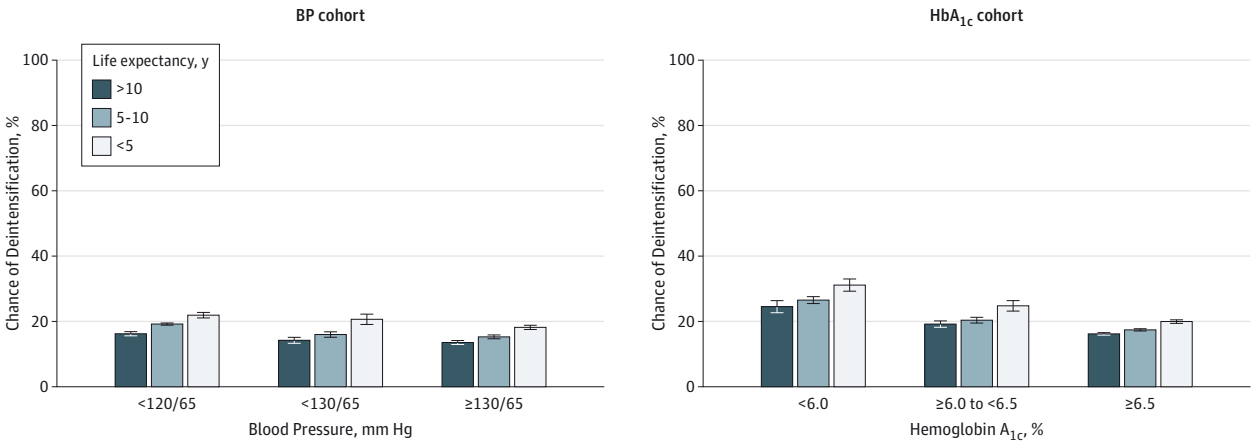
We found a weak association between a patient's estimated life expectancy and rate of deintensification (**Figure 3**). In the BP cohort, people with less than 5 years of life expectancy had a 19.8% chance of deintensification, those with 5 to 10 years had a 16.9% chance, and those with more than 10 years had a 14.7% chance.

Figure 2. Flow Diagram for the Low Hemoglobin A_{1c} (HbA_{1c}) Cohort



The cohort evaluated was patients with diabetes mellitus who were older than 70 years and receiving active blood glucose–lowering treatment. We defined *active for blood glucose–lowering treatment* as receiving any diabetes medication other than metformin hydrochloride alone. The HbA_{1c} level stratification is explained in the Variable Construction and Definition subsection of the Methods section.

Figure 3. Predicted Probability of Deintensification by Baseline Blood Pressure (BP) and Hemoglobin A_{1c} (HbA_{1c}) Levels and Life Expectancy



Error bars indicate 95% CI.

Both low life expectancy and low BP were weakly predictive of deintensification rate, but their effects were not synergistic. Only 1 of 8 possible interactions between a patient's life expectancy, BP, and the rate of deintensification was significant even before adjustment for multiple comparisons (eTables 1 and 2 in the Supplement).

In the HbA_{1c} cohort, patients with less than 5 years of life expectancy had a 21.3% chance of deintensification, those with 5 to 10 years had a 18.5% chance, and those with more than 10 years had a 17.2% chance. There were no interactions between life expectancy, HbA_{1c} levels, and the rate of deintensification.

Discussion

We found that in a cohort of older patients with diabetes mellitus receiving treatment for BP and blood glucose–level control, a patient's BP or HbA_{1c} level had only a weak association with the likelihood of deintensification. More than half of our cohort received treatment resulting in moderately low or very low BP, and more than 20% developed moderately low or very low HbA_{1c} levels. Deintensification rates for people with low BP and HbA_{1c} levels were only minimally above the rates found in people with nor-

mal BP and HbA_{1c} levels who received treatment. In fact, most patients with low values did not have a BP or HbA_{1c} measure documented in the electronic medical record in the 6 months after the low value was reported, suggesting that health care professionals did not view very low values as a problem in need of monitoring. Patients with the combination of low life expectancy and low HbA_{1c} or BP level were no more likely to have deintensification than would be expected for those with either of the risk factors alone, even though these patients have a particularly small possibility of receiving clinical benefit.

There could be several explanations for why a low BP or HbA_{1c} level has a weak association with deintensification. First, stopping a medication requires a shift in how treatment is understood by patients and explained by health care professionals; it requires a transition from a simplistic focus on "one size fits all" to the more nuanced balancing of risks and benefits. These explanations are more difficult to offer, to understand, and often to accept. Furthermore, clinical uncertainty about the reliability of a single BP and HbA_{1c} measurement[25] and unwillingness to risk undertreatment may influence decisions on whether to deintensify. Second, guidelines and performance measures remain more focused on preventing underuse than overuse. Some guidelines[12-14] have recommended more modest BP and HbA_{1c} level goals for older patients or those with multiple comorbidities; however, to our knowledge, none of the guidelines have explicitly defined circumstances for deintensification. Until guidelines and performance measures specifically call for deintensification for patients who are at risk for being harmed by overtreatment, rates are likely to remain low.

We considered patients to be eligible for deintensification if persistent intensive treatment would be unlikely to yield clinical benefit or could cause substantial adverse effects based on consultation with clinical experts and randomized evidence. For middle-aged patients with type 2 diabetes mellitus, there is evidence that an intervention that yields an HbA_{1c} level of 7.0% produces slightly better outcomes than an HbA_{1c} level of 7.9%,[26] but an intervention with a goal of less than 6.0% has greater mortality than does one with a goal of less than 8.0%.[7] Therefore, we believe that in the elderly population, achieving an HbA_{1c} value of less than 6.5% is a reasonable level of potential deintensification because it is directly between values known to be safe and those known to be dangerous. Similarly, there is strong evidence that, in middle-aged patients with diabetes mellitus, an SBP goal of 150 mm Hg is more effective than 180 mm Hg,[27] but 120 mm Hg provides no clear benefit over 140 mm Hg while increasing adverse treatment effects.[6]

Although we and others[3,4,25,28,29] have shown that overtreatment for patients with diabetes mellitus and hypertension is common, we know of no previous study that has examined rates of deintensification in these conditions. One strength of the present study is its direct relevance to current treatment choices. The Choosing Wisely campaign recommends that people "avoid using medications to achieve HbA_{1c} of less than 7.5% in most adults age 65 and older,"[13(p627)] and the American Diabetes Association guidelines say that, for older patients, "an HbA_{1c} of less than 7.5% to 8.0% may be acceptable, transitioning upward as age [and] illness burden increase."[12(p1373)] We conservatively chose cut points well below these values to strengthen the chance that many of these patients were receiving overtreatment. Our results are notable for the large sample size within the VA Healthcare System.

Our study has limitations. First, pharmacy records underestimate medication intensity for patients who obtain medications outside the VA. Therefore, we may have missed patients who were eligible for deintensification as well as those who underwent deintensification via outside pharmacies. Second, we could not calculate changes in dosing of insulin from VA Healthcare System medication data, only whether one or more insulin types was discontinued. However, results from a sensitivity analysis that examined this limitation did not differ substantially from our main results. Third, some patients with transiently low HbA_{1c} or BP levels may not require deintensification. We did find, however, that few patients whose therapy was not deintensified had significantly higher levels of HbA_{1c} or BP within 6 months after the previous value. Fourth, we lacked detailed functional status information.[30] Finally, we do not know whether deintensification resulted in better overall outcomes for the patients.

There is no data source that will indicate why therapy was and was not deintensified. We estimated a baseline deintensification rate for patients with BP and HbA_{1c} measurements that were within the normal treatment range. This rate is similar to 6-month discontinuation rates seen during active treatment in other studies[24] and presumably measures discontinuation for reasons other than overtreatment. Patients with low BP and HbA_{1c} values had treatment deintensified at a rate only slightly greater than this baseline rate.

Conclusions

Deintensification of therapy following low measurements of BP or HbA_{1c} level is uncommon, even among older patients whose treatment is well beyond recommended levels of BP and HbA_{1c}. The harms of overuse have rarely been integrated into guidelines, quality measures, and pay-for-performance efforts. The VA recently started the Hypoglycemia Safety Initiative, a national program to limit overtreatment of blood glucose in VA patients with diabetes mellitus.[31] Future performance management systems should consider how to create incentives against both overuse and underuse to motivate appropriate treatment, including deintensification of treatment that is personalized to individual needs, risks, and benefits.[32-35] In addition, health care professionals should assess the harms of intensive therapy just as they do the benefits. These changes may require new clinical decision support tools, new performance measures, and, most important, a new perspective focusing on personalized, appropriate care.

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Study concept and design: Sussman, Kerr, Saini, Hofer.

Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Sussman, Hofer.
Critical revision of the manuscript for important intellectual content: All authors.
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