ORIGINAL RESEARCH & CONTRIBUTIONS

Patient Education and Pharmacist Consultation Influence on Nonbenzodiazepine Sedative Medication Deprescribing Success for Older Adults

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ABSTRACT

Introduction: Use of nonbenzodiazepine sedative hypnotics or "Z-drugs"—including eszopiclone, zolpidem, or zaleplon—is discouraged for older adults; however, these medications commonly are prescribed to treat insomnia in this population. We evaluated the impact of direct-to-patient education, with or without a pharmacist consultation, on Z-drug discontinuation among Kaiser Permanente Northwest members age 64 years and older.

Methods: We randomized 150 patients to usual care (UC), educational information only, or educational information and pharmacist consultation. Patients age 64 years and older who received 2 to 3 Z-drug fills in 2016 were included. Logistic regression was used to calculate odds of discontinuation at 6 months among patients who received either intervention, compared with those who received UC.

Results: Patients who received education only and education plus pharmacist consultation were significantly more likely to discontinue Z-drug use than those who received UC (28/50 of those who received education only and 27/49 of those who received education plus consultation vs 13/50 patients who received UC). After controlling for patient demographics, comorbidity, and antianxiety and antidepressant medication use, patients who received education only had greater odds of Z-drug discontinuation than those in the UC group (adjusted odds ratio = 4.02, 95% confidence interval = 1.66-9.77). Patients who received education and a pharmacist call also had greater odds of discontinuing use of these drugs than those in the UC group (adjusted odds ratio = 4.10, 95% confidence interval = 1.65-10.19).

Conclusion: Patients who received direct-to-patient education with or without a pharmacist consultation were significantly more likely to discontinue Z-drug use than patients receiving UC. Providing evidence-based information about Z-drug use is an effective and low-resource method to encourage drug discontinuation.

INTRODUCTION

Adults age 64 years and older routinely are prescribed nonbenzodiazepine sedative-hypnotics ("Z-drugs," which include eszopiclone, zolpidem, or zaleplon) for insomnia treatment despite a lack of evidence that demonstrates these medications improve sleep over the long term and a wealth of evidence that links long-term use with falls, daytime sedation, cognitive impairment, decreased quality of life, dependence, and hospitalization.[1-7] Contrary to this evidence and American Geriatrics Society recommendations that discourage Z-drug use, older patients continue to receive these medications for months, years, or even decades.[4]

Emerging scientific literature emphasizes the need for discontinuation, or deprescribing, of drugs when existing or potential harms outweigh existing or potential benefits.[8-13] However, the literature also acknowledges that discontinuing a medication may be just as difficult, if not more difficult, than starting a medication. One approach to deprescribing that holds great promise is direct-to-patient education, which provides information about medication use risks and empowers patients to initiate discussions with their prescribing clinician about medication discontinuation.[14-16]

Kaiser Permanente Northwest (KPNW) piloted an intervention that sought to encourage deprescribing of Z-drugs among KPNW patients 64 years of age and older. Patients were randomized to receive usual care (UC) or direct-to-patient education with or without a pharmacist consultation. We examined the impact of these interventions on Z-drug discontinuation.

METHODS

In 2017, KPNW, an integrated health care delivery system serving about 580,000 members in Northwest Oregon and Southwest Washington, conducted a pilot implementation of an intervention that used both direct-to-patient education and pharmacist counseling to encourage deprescribing of Z-drugs among older adults. The intervention was implemented by the KPNW health care system as a quality improvement initiative and delivered as part of UC; consequently, the KPNW institutional review board, which reviewed and approved this research, granted a waiver of informed consent.

Patients were eligible for the deprescribing intervention if they were at least age 64 years and received 2 or 3 prescription medication dispensings of a Z-drug—including eszopiclone, zolpidem, or zaleplon—during 2016. Members were excluded if they had less than 6 months of Health Plan enrollment or if they received a quantity ≤ 6 doses. Members also were excluded if they received palliative or hospice care or resided in an assisted-living facility during the year before randomization. Members were not eligible

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if they had active cancer, severe mental illness or current use of an antipsychotic medication, dementia, or evidence of substantial cognitive impairment (defined as current use of a cholinesterase inhibitor or memantine).

We randomized 150 total patients (50 patients per arm) to 1 of 3 study arms: 1) no intervention (UC); 2) an educational mailing and prescriber letter (Ed); or 3) an educational mailing, prescriber letter, and clinical pharmacist telephone counseling session (Ed+). Older adults randomized to the Ed or Ed+ study arms began receiving their intervention on January 1, 2017, and all follow-up was completed in September 2017.

The intervention was delivered as part of UC; however, because patients in the intervention arms received a signed letter from their Z-drug prescriber, some prescribers opted out of their patients receiving a letter with their signature. Patients whose prescribers opted out were not eligible to receive the intervention. To accomplish this, prescribers received an electronic medical record (EMR)-based message and had the option to opt out by responding within 14 days. Four prescribers declined to participate because they were on an extended leave (1 prescriber) or they preferred to not use a case management approach (3 prescribers).

The Intervention

The goal of this effort was to implement and test 2 forms of an intervention that directly provided older KPNW patients who chronically use Z-drugs with information about risks associated with Z-drug use and then engage them in shared decision making regarding discontinuation. Patients randomized to the Ed or Ed+ arms received a letter from their prescribing physician, an educational brochure, and a quiz. Educational materials were developed by a team of primary care and geriatric health care physicians, pharmacists, and researchers. Prescriber letter text explained the reason for the letter and encouraged patients to reconsider their Z-drug use. The brochure presented evidence of Z-drug-induced harms, suggestions for effective pharmacologic and nonpharmacologic alternatives to treat insomnia, and a visual tapering schedule with further instructions. The quiz reiterated messages in the educational brochure by providing a self-assessment about Z-drug use risks. A pharmacist called patients in the Ed+ study arm 2 to 4 weeks after they received the educational materials. During these telephone consultations, the pharmacist would discuss and reinforce information in the educational mailing; assess patient barriers to Z-drug discontinuation; provide personalized guidance on tapering, recommendations for care coordination opportunities available through specialty departments such as sleep medicine, mental health, and addiction medicine; and answer questions. This format also provided the opportunity to discuss Z-drug alternatives, including sleep hygiene techniques and safer medications. The pharmacist had prescriber approval and a protocol that allowed for a switch to safer sleep medications.

Outcomes

We followed patients for 6 months after their index date, defined as the educational material mailing date for patients in the Ed and Ed+ study arms or the first date of the intervention period for UC patients. The primary study outcome was discontinuation of Z-drugs during 6-month follow-up, defined as a patient not receiving a Z-drug dispensing from a KPNW pharmacy during that time.

We assessed occurrence of secondary outcomes, which included hospitalization, outpatient face-to-face encounters, and urgent care and Emergency Department visits during the 6-month follow-up. We also examined the number of Z-drug dispensings during follow-up for patients who did not discontinue use.

Statistical Methods

We used KPNW EMR data to examine baseline characteristics for patients in the UC and intervention arms. These characteristics included demographic information such as age, sex, and race; the occurrence of Charlson comorbid conditions during the year before the index date; the occurrence of insomnia or sleep disorders during the previous year; the use of psychotropic medications during the 90 days before the index date as identified through dispensings at KPNW outpatient pharmacies; and baseline health care utilization during the previous 180 days. Psychotropic drugs included antianxiety medications (including benzodiazepines), antidepressants, opioids, muscle relaxants, and anticonvulsants. We identified dispensings of medications using Medi-Span Generic Product Identifiers available in KPNW EMR pharmacy data. Baseline health care utilization included hospitalization, outpatient face-to-face visits, telephone and email encounters, and urgent care and Emergency Department visits.

We identified potential imbalance in the study groups by examining standardized differences for select baseline variables. Variables with a standardized difference exceeding 0.1 between the randomized groups were considered for inclusion as control variables. Selection of potential control variables was based on plausibility of a relationship between the characteristic and Z-drug discontinuation and the prevalence of the characteristic within the population.

We compared the occurrence of discontinuation between the Ed and Ed+ groups and the UC group. Using logistic regression, we calculated crude odds ratios (ORs) and 95% confidence intervals (CIs) for discontinuation and adjusted ORs and 95% CIs that controlled for patient baseline characteristics that were imbalanced between study groups. We then described the distribution of health care utilization outcomes among study groups.

RESULTS

Fifty patients were randomized to each study arm and completed the intervention; however, only 49 patients from the Ed+ study arm were included in the analyses because 1 patient who received the intervention had a documented request to be excluded from research activities at KPNW. This request for exclusion does not apply to inclusion in quality improvement initiatives delivered as part of UC such as the deprescribing intervention—rather, these members are excluded from the evaluation of such initiatives.

The population was, on average, age 70 years, and most patients were women (Table 1). Thirty percent, 16%, and 18% of the UC, Ed, and Ed+ participants, respectively, had 2 or more comorbid conditions, and baseline health care utilization was low (Table 1). When we examined the use of other medications, patients most commonly received antidepressants or opioids during the prior 90 days (Table 1). Fifty-four percent of UC patients, 60% of Ed

patients, and 42% of Ed+ patients had EMR documentation of insomnia. Despite randomization, there were potential imbalances among study groups with regard to age, sex, race, number of Charlson comorbid conditions, and prior antianxiety and antidepressant medication use.

Among patients randomized to UC, 13 (26%) discontinued Z-drug use during 6 months of follow-up. Among 50 patients in the Ed arm, 28 (56%) discontinued Z-drug use, and 27 of 49 patients (55%) in the Ed+ arm discontinued Z-drug use (Table 2). The crude OR for discontinuation for the Ed arm was 3.62 (95% CI = 1.56-8.42), whereas the crude OR for the Ed+ arm was 3.49 (95% CI = 1.50-8.14; Table 2). In multivariable logistic regression controlling for age, sex, race, number of Charlson comorbid conditions, and prior antianxiety or antidepressant use, the odds of discontinuation were 4.02 times higher among patients who received the Ed intervention than those who received UC (adjusted OR = 4.02, 95% CI = 1.66-9.77). Patients who received the Ed+ intervention had 4.1 times greater odds of discontinuing their Z-drug use than those who received UC (adjusted OR = 4.10, 95% CI = 1.65-10.19) after controlling for baseline patient characteristics (Table 2). Patients who received an intervention but who did not discontinue Z-drug use most commonly received only 1 additional dispensing during the follow-up period (Table 3). However, those in the UC group who continued use often received 2 or more dispensings during 6-month follow-up. Consistent with the baseline, health care utilization remained low during follow-up and did not vary across patient groups (Table 3).

DISCUSSION

In this evaluation of a pilot deprescribing intervention, we found that patients who directly received educational materials about their Z-drug use, with or without a pharmacist consultation, were much more likely to discontinue using their drug than patients who did not receive the intervention. These results suggest that this low-resource intervention has the potential to reduce potentially harmful Z-drug effects among older adults who have a history of chronic use.

Deprescribing of potentially inappropriate medications among the elderly is an emerging area of focus for health care clinicians and health care systems, but evidence that identifies the most effective deprescribing methods is lacking. In a notable exception, the Eliminating Medications through Patient Ownership of

Table 1. Baseline demographic and clinical characteristics of patients in usual care, education only, and education-plus-pharmacist call intervention arms

Characteristic	Usual care arm (N = 50)	Education only arm (N = 50)	Education-plus-pharmacist call arm (N = 49)
Demographics			
Age in years, mean (SD)	70.7 (7.3)	69.9 (6.1)	69.4 (4.1)
Age 64 to 74 years, n (%)	39 (78)	39 (78)	41 (84)
Age 75 years and older, n (%)	11 (22)	11 (22)	8 (16)
Women, n (%)	36 (72)	31 (62)	32 (66)
White race, n (%)	48 (96)	48 (96)	45 (92)
Charlson comorbid conditions (1 year before index date, prevalence > 5%), n (%)			
Peripheral vascular disease	12 (24)	8 (16)	7 (14)
Chronic pulmonary disease	10 (20)	6 (12)	7 (14)
Diabetes without chronic complications	4 (8)	6 (12)	9 (18)
Renal disease	8 (16)	2 (4)	5 (10)
Number of Charlson conditions, n (%)			
0	27 (54)	29 (58)	31 (63)
1	8 (16)	13 (26)	9 (18)
2 or more	15 (30)	8 (16)	9 (18)
Other comorbid conditions, n (%)			
Insomnia	27 (54)	30 (60)	21 (43)
Health care utilization (during the 180 days before the index date)			
Number of hospitalizations, mean (SD)	0 (0.2)	0 (0.1)	0 (0.1)
Number of face-to-face outpatient visits, mean (SD)	1 (0.2)	0.9 (0.3)	0.9 (0.4)
Number of nonface-to-face outpatient visits,[a] mean (SD)	1 (0.1)	0.9 (0.3)	0.9 (0.3)
Number of Urgent Care or Emergency Department visits, mean (SD)	0.1 (0.3)	0.1 (0.3)	0.2 (0.4)
Medication use (during the 90 days before the index date, prevalence > 5%), n (%)			
Antianxiety medication use (yes)	6 (12)	4 (8)	1(2)
Antidepressant use (yes)	24 (48)	19 (38)	19 (39)
Opioid use (yes)	21 (42)	14 (28)	9 (18)
Anticonvulsant use (yes)	3 (6)	3 (6)	6 (12)

[a] Includes telephone and email encounters with Kaiser Permanente Northwest practitioners.
SD = standard deviation.

Table 2. Logistic regression analysis of 6-month discontinuation comparing usual care to education only and education-plus-pharmacist call intervention arms

		Education only arm			Education-plus-pharmacist call arm		
Outcome	**Usual care (N = 50)**	**Patients (N = 50)**	**Crude OR (95% CI)[a]**	**Adjusted OR (95% CI)[b]**	**Patients (N = 49)**	**Crude OR (95% CI)[a]**	**Adjusted OR (95% CI)[b]**
Discontinuation (yes), n (%)	13 (26)	28 (56)	3.62 (1.56-8.42)	4.02 (1.66-9.77)	27 (55)	3.49 (1.50-8.14)	4.10 (1.65-10.19)

[a] Calculated using logistic regression; the usual care group is the reference group.
[b] Controlling for age, sex, race, number of Charlson comorbid conditions, prior antianxiety medication use, and prior antidepressant use.
CI = confidence interval; OR = odds ratio.

Table 3. Secondary outcomes among usual care, education only, and education-plus-pharmacist call intervention arms

Outcome	Usual care arm (N = 50)	Education only arm (N = 50)	Education-plus-pharmacist call arm (N = 49)
Number of Z-drug dispensings, mean (SD)	1.9 (1.6)	1 (1.5)	1 (1.6)
Number of Z-drug dispensings by category, n (%)			
0 dispensings	13 (26)	28 (56)	27 (55)
1 dispensing	10 (20)	10 (20)	11 (22)
2 dispensings	10 (20)	4 (8)	4 (8)
3 dispensings	8 (16)	4 (8)	2 (4)
4+ dispensings	9 (18)	4 (8)	5 (10)
Number of hospitalizations, mean (SD)	0.1 (0.2)	0.0 (0.2)	0.0 (0.1)
Number of face-to-face office visits, mean (SD)	0.9 (0.4)	0.8 (0.4)	0.8 (0.4)
Number of nonface-to-face[a] encounters, mean (SD)	0.9 (0.3)	0.9 (0.3)	1.0 (0.0)
Number of Urgent Care or Emergency Department visits, mean (SD)	0.3 (0.5)	0.3 (0.5)	0.3 (0.5)

[a] Includes telephone and email encounters with Kaiser Permanente Northwest practitioners.
SD = standard deviation.

End Results (EMPOWER) trial conducted by Marten et al and Tannenbaum et al[14-16] showed that direct-to-patient education led to substantial reductions in benzodiazepine use among older community-dwelling adults. A pilot study revealed that use of these educational materials was a feasible approach to initiating the deprescribing process among hospitalized individuals using sedative hypnotics.[17] KPNW based its educational materials on those developed for the EMPOWER trial but modified content to discuss Z-drugs only and tailored information to be consistent with existing KPNW educational resources and practices related to sleep and tapering of Z-drug use. Our intervention also included a pharmacist telephone call for some patients. Consistent with the EMPOWER trial, our direct-to-patient education approach led to an increased likelihood of medication discontinuation. These results suggest that pharmacist contact, however, may not significantly increase discontinuation likelihood beyond the effectiveness of educational materials only. Although our findings support education as a means to deprescribing, they also point to the need for a larger study that compares education complemented by pharmacist consultation and education without the addition of a pharmacist.

This intervention addresses common concerns related to medication deprescribing among older adults. We learned about some of these concerns when we conducted a qualitative assessment of patient and primary care clinician beliefs about Z-drug deprescribing and perceptions about educational materials in parallel with pilot implementation.[18] In that assessment, patients expressed the need for effective insomnia treatment and personalized approaches to care, and primary care clinicians cited a lack of insomnia treatment alternatives and institutional structures and resources to support nonbenzodiazepine medication deprescribing as barriers. There is a need to evaluate the ways in which deprescribing interventions directly address these expressed needs; however, our intervention's inclusion of information about effective alternatives to Z-drugs addressed these patient concerns. Our pharmacist consultation met the need for personalized care related to medication use. Both our educational materials and pharmacist availability represent resources that, if widely implemented, would support physicians' efforts to deprescribe harmful medications to older adults.

The intervention itself did not require a large amount of resources to implement. The educational materials were mailed by nonclinical Health Plan staff, and the telephone pharmacist consultations lasted 10 to 15 minutes. The intervention, whether implemented with or without pharmacist involvement, is a low-resource effort with great potential for reductions in harmful medication use and the poor outcomes that may be associated with that use. Furthermore, the pharmacist could switch patients to safer sleep medications when appropriate. This approach shifted case management from the prescriber to the pharmacist and probably reduced time and effort for prescribers. Although this study did not include a cost analysis, future studies that assess the cost of deprescribing interventions would increase understanding of their scope and feasibility.

This pilot study's findings should be interpreted with limitations in mind. First, in the spirit of a pilot study, these results are based on a small population and should be interpreted as preliminary. Although formal sample size or power calculations are not required

or recommended for pilot studies, we conducted calculations on the basis of the results of the EMPOWER trial and found that, with 50 patients in each arm, we had 80% power to detect a similar difference in discontinuation rates between each intervention group and the UC group. As a result, we could detect statistical differences; however, these results are not conclusive and point to the need for a larger trial. Furthermore, our population consisted of relatively healthy older adults who had low rates of health care utilization and a low comorbidity burden. Additional research is needed to assess the generalizability of this approach to older adults with higher comorbidity levels and more complex medical needs. In parallel, an examination of patient preference regarding potential approaches to deprescribing education such as in-person individual or group consultation would be valuable. Second, the study pharmacist was not provided with a standardized script for telephone consultations, so these interactions may not have been consistent or may be improved upon; a formalized process and additional training (eg, motivational interviewing training) may lead to improved outcomes. Third, we followed patients for 6 months, which may not be enough time to evaluate the long-term impact of the intervention on medication use. Future evaluation should examine the possibility that patients may reinitiate Z-drug use after the 6-month follow-up period. Additional assessments also should evaluate substitution effects to examine whether patients are using recommended alternatives to Z-drugs or other alternatives that may not reduce risk (eg, benzodiazepines instead of Z-drugs). In turn, an examination of substitution effects should include patient use of nonpharmacologic alternatives such as cognitive behavioral therapy for insomnia. Lastly, the intervention was not delivered to patients with evidence of cognitive decline. The use of EMR data to exclude these patients may have been imperfect and could have resulted in the inclusion of patients with milder forms of cognitive decline; future studies may include these patients and evaluate outcomes among subgroups with varying levels of cognitive function. There also may be opportunities to expand the intervention to engage patient caregivers in deprescribing efforts.

CONCLUSION

Our results provide preliminary evidence that provision of evidence-based information about Z-drug use and support for discontinuation appear to increase likelihood of drug discontinuation among older adults. There is a need for research that expands the use of educational materials tailored to Z-drug deprescribing to a larger population of older adults and studies the influence of these materials over a longer time period. Future research also should assess the role of pharmacists in deprescribing and the influence of direct-to-patient education on patient-prescriber shared decision making related to Z-drug use. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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