Continuation or deprescribing of proton pump inhibitors: A consult patient decision aid

Wade Thompson, BScPhm, PharmD, MSc; Barbara Farrell, BScPhm, PharmD; Vivian Welch, PhD; Peter Tugwell, MD, MSc; Cynthia Way, BScPhm, ACPR; Lisa Richardson, BScPhm, ACPR; Lise M. Bjerre, MD, PhD

Introduction

Many patients continue on long-term proton pump inhibitor (PPI) therapy unnecessarily.[1] Evidence-based guidance suggests attempting to reduce or stop PPIs in patients whose symptoms abate and have no indication for long-term use.[2] Patients may therefore be faced with the decision to continue or reduce PPI use. Deprescribing is the planned, supervised dose reduction or stopping of a medication (for PPIs: lower dose or use "on demand" [as needed]). Patients are generally open to discussing ongoing PPI use; however, the decision to continue or reduce PPI use depends on preferences and values.[3] Patients would like to be part of such discussions and planning surrounding ongoing PPI use.[3,4] Thus, a structured tool to guide such a discussion would be helpful in clinical practice.

Patient decision aids (PtDAs) are tools that facilitate shared decision-making between patients and clinicians.[5] They educate patients on the decision being made, as well as the benefits and harms of treatment options, and allow patients to clarify which outcomes matter most to them, thereby incorporating values and preferences into decisions.[6] Traditional PtDAs are typically reviewed by a patient on their own prior to a consultation with a health care provider. Consult PtDAs are specifically designed to be used during a health care visit, where the patient and health care provider would go through the consult PtDA together.[5] Consult PtDAs may be preferred over traditional PtDAs because they encourage discussion and decision-making in real time.[5] Pharmacists are accessible drug therapy experts and are well suited to have discussions surrounding ongoing medication use with patients. The aim of our study was to develop and pilot test a consult PtDA aimed at continuation or deprescribing of PPIs.

Methods

We conducted a before-after study. This study design is suggested for piloting of PtDAs by the Ottawa Hospital Research Institute PtDA group.[7] The trial protocol was registered at clinicaltrials.gov (NCT02558049) and the methods have been previously described.[8] We used a published template and established methods[5] to develop our consult PtDA, available at http://deprescribing.org/resources/deprescribing-patient-decision-aids/.

The study was conducted in 2 family medicine clinics and 1 geriatric outpatient clinic in Ottawa, Ontario. Patients were ≥18 years of age, taking PPIs for ≥4 weeks, asymptomatic and had no indication for continued use (history of gastrointestinal [GI] bleed, current ulcer, Barrett's esophagus, severe esophagitis, moderate-high GI bleeding risk). The consult PtDA was delivered by a clinical pharmacist during a 15-minute appointment. If a decision was reached following the consult, the pharmacist developed a plan with the patient (with the physician's previous approval) or the patient could discuss with his or her physician. Our primary outcome was change in decision preference (continue/unsure vs deprescribing) before and after the consult

© The Author(s) 2018
Article reuse guidelines:
sagepub.com/journals-permissions
DOI:10.1177/1715163518816719

TABLE 1 Decision preference

Before	After: Continue PPI or unsure	After: Have PPI deprescribed (lower dose or on-demand)	Total
Continue PPI or unsure	3	1	4
Have PPI deprescribed (lower dose or on-demand)	0	8	8
Total	3	9	12

PPI, proton pump inhibitor.

PtDA, evaluated using McNemar's test (5% significance level). The target sample size based on the primary outcome was 54 patients.

We measured patient knowledge about the decision before and after the consultation using an 11-question quiz. The quiz score (as a %) after the consult was compared to the quiz score before. We also evaluated whether patients had realistic expectations of symptoms returning for the different options (continue PPI vs deprescribe). Both before and after the consult, we gave patients a 4-question quiz about the probability of symptoms returning (correct answer = patient provides the probability of event within 25% of the true value). We compared the quiz score (as a %) after the consult to the score before. When we asked patients their decision preference before and after the consultation, we also asked them how confident they felt in their choice. We measured confidence using a 4-item questionnaire (SURE: Sure of myself; Understand information; Risk-benefit ratio; Encouragement); a score of 4 indicates confidence in the decision whereas <4 indicates decisional conflict.[9] The questionnaire and quizzes were administered immediately before and immediately after the consultation. Change in knowledge, realistic expectations and decisional confidence were all evaluated using the Wilcoxon sign rank test (5% significance level). We originally planned to use paired *t* tests to evaluate these outcomes but owing to a small sample size, we used the nonparametric equivalent. We followed up by phone at 8 weeks to assess symptom control (no, mild, moderate or severe symptoms). Patients and pharmacists separately and blindly rated their perception of shared decision-making during the encounter on a scale of 1 (patient made decision alone) to 5 (pharmacist made decision alone), where 3 reflects a shared decision.[10] Agreement was measured using a weighted kappa statistic.

The trial was approved by the Ottawa Health Science Network and Bruyère Research Ethics Boards.

Results

We recruited subjects between March and December 2016. Clinic pharmacists screened 338 patients for eligibility. Reasons for exclusion were not completely reported, but the most common reasons for ineligibility were that patients had a valid indication for continued PPI use or there was not enough information in the electronic medical record to assess the indication. Twelve eligible patients consented to participate (mean age 71 [SD 8.6], mean duration of PPI use 7.3 years [SD 4.3], 75% female, 83% using for upper GI symptoms and 17% for diagnosed gastroesophageal reflux disease).

Decision preference results are in Table 1. There was no significant difference in the proportion of patients whose preference changed after the PtDA ($p = 0.32$). Decision-making parameters are shown in Table 2; the consult PtDA improved patient knowledge, realistic expectations and decisional confidence. The weighted kappa for pharmacist/patient rating of shared decision-making was 0.50 (95% confidence interval, 0.15 to 0.85). Pharmacists and patients agreed on the extent of shared decision-making in 7 out of 12 interactions. In 3 out of 12 interactions, patients felt that they had made the decision, while in 2 out of 12, the patient felt a shared decision had been made but the pharmacist felt the patient made the decision. Eleven out of 12 patients enacted their plan during the pharmacist visit. Follow-up data were available for 10 patients at 8 weeks (Table 2).

Discussion

In our study of pharmacist and patient use of a consult PtDA, we found no difference in the

TABLE 2 Decision-making parameters and clinical follow-up

	Median (IQR)		
	Before	**After**	**Difference**
Knowledge (%)	50.0 (29.5)	72.7 (20.5)	36.4 (36.4), $p = 0.0010$
Decisional conflict (SURE) (out of 4)	3.0 (1.3)	4.0 (0)	1.0 (1.5), $p = 0.014$
Realistic expectations (%)	12.5 (50)	50 (6.25)	37.5 (50), $p = 0.016$
	Symptoms at 8 weeks?		
PPI status at 8 weeks	**Yes**	**No**	**Total**
Continued PPI	0	3	3
On-demand	0	2	2
Lower dose	1*	4	5

IQR, interquartile range; PPI, proton pump inhibitor; SURE, sure of myself—understand information—risk-benefit ratio—encouragement.

*Mild symptoms.

proportion of patients who changed their preference after the consultation compared to before. Our results do suggest that use of the consult PtDA may increase patient knowledge, realistic expectations and decisional confidence around the decision. The consult PtDA led to decisions being made in real time, which is a noted strength of consult PtDAs[5] and is particularly suited to primary care. We aimed to address common barriers to implementing PtDAs in primary care (such as lack of physician time, disruption in workflow)[11] by having a clinical pharmacist deliver the consult PtDA in 15 minutes. Our tool was successful in this respect, as the pharmacists were able to complete the consultations during 15-minute appointments, and decisions were made and implemented during 11 out of 12 clinical encounters.

There was moderate agreement on the extent of shared decision-making during the consultation. While a higher level of agreement related to shared decision-making would be desired, it is encouraging that even in the disagreements, patients felt the decision was shared (2/12) or that they made the decision (3/12). This suggests our tool empowered and engaged all patients in the decision-making process.

This study has a number of limitations. Recruitment was low and we did not meet our target sample size of 54. Therefore, the study was underpowered to detect a difference for the primary outcome. The major barrier was identifying eligible patients, a difficulty previously reported in studies addressing inappropriate PPI use.[12] Pharmacists found it time-consuming to screen patients due to lack of information on indication in the electronic medical record. This highlights a major barrier to addressing potentially inappropriate PPI use in primary care. Documenting an indication and intended duration of therapy when a PPI is originally prescribed will enhance the ability to discuss continued PPI use once the intended duration is over.

Our study was conducted with pharmacists working in multidisciplinary clinics (family health teams and an outpatient geriatric clinic). Pharmacists working in different practice settings may face different environmental constraints that could limit the ability to use our tool. For example, community pharmacists may have time constraints, limited staffing and limited access to information. While our consult PtDA can be used across practice settings, its feasibility and effectiveness for pharmacists in other practice settings requires further study.

Another challenge with implementation of our tool in other practice settings may be that patients would rather discuss deprescribing decisions with a physician than a pharmacist. For example, in a Canadian survey ($n = 129$), 75% of older persons would pursue deprescribing if their physician thought it was a good idea, but only 51% felt pharmacists should lead the process.[13]

In the clinics in our study, pharmacists and physicians collaborate closely (i.e., discussing suitability for having a discussion with the patient about deprescribing prior to the visit). Having prior physician buy-in to discuss continuation vs deprescribing may have facilitated use of the tool in our study. However, it is unclear how patients would perceive deprescribing decision-making with pharmacists in other settings. Use of consult PtDAs by pharmacists with independent prescribing authority would be an interesting area for future study. Regardless of the setting, collaboration with physicians when using the consult PtDA (discussing planned use of the consult PtDA) may be one approach to facilitate uptake.

We originally planned to use paired *t* tests for continuous outcomes but because of our small sample size, we used nonparametric testing. We attempted to conduct logistic regression analysis on values-choice congruence but have not reported these results owing to our small sample size and concern for the validity of the model. Given the lack of a control group and a small sample size, our results can only be considered preliminary and larger studies with a control group would be needed to provide more definitive evidence on the effects of using this tool. While lack of a comparison group was a limitation of our study, the pre-post design is a recommended design for pilot testing of PtDAs and has been widely used for this purpose.[7] Further, while our sample size was small, the aim of pilot testing a PtDA is to assess the utility of the tool and to gain insight on how to revise and improve it. A sample size of 12 patients allowed us to achieve this aim and to understand the applicability of the tool in clinical practice.

A final limitation is that patients in our study were motivated to try deprescribing at baseline (67% preferred this); therefore, the results may not be generalizable to all patients on PPIs.

Conclusion

In our study of pharmacist and patient use of a consult PtDA for proton pump inhibitors, we saw no difference in the proportion of patients who changed their decision preference after using our tool. Our results suggest that use of the consult PtDA with a clinical pharmacist may improve patient knowledge, realistic expectations and decisional confidence around the decision, as well as engage patients in the decision-making process. Our consult PtDA allowed for real-time decisions surrounding continued PPI use during a 15-minute visit with a clinical pharmacist in a group of patients who were open to discussing options. The consult PtDA led to 75% of patients reducing PPI use after their visit. Given lack of a control group and a small sample size, these results can only be considered preliminary. Our findings suggest that it may be feasible for pharmacists to take the lead on shared decision-making surrounding continuation or deprescribing of PPIs in primary care clinics. However, a major barrier to the process was identifying eligible patients. Documenting an indication and the intended duration of therapy when a PPI is prescribed will enhance the ability to discuss continued PPI use in clinical practice. ■

From the School of Epidemiology, Public Health and Preventive Medicine (Thompson, Welch, Tugwell, Bjerre), University of Ottawa; the Bruyère Research Institute (Thompson, Farrell, Welch, Tugwell, Bjerre); the Department of Family Medicine (Farrell, Bjerre), University of Ottawa; the Centre for Global Health (Welch, Tugwell); the Ottawa Hospital Research Institute (Tugwell); the Ottawa Hospital Academic Family Health Team (Way); and the Rideau Family Health Team (Richardson), Ottawa, Ontario. Contact wthomp01@gmail.com.

Author Contributions: *W. Thompson conceived and designed the study, collected and analyzed data and drafted the manuscript. V. Welch, B. Farrell, P. Tugwell, L. M. Bjerre conceived the study, supervised the study, interpreted results and provided critical revisions for the manuscript. C. Way and L. Richardson collected data, recruited patients, conducted study visits and provided critical revisions for the manuscript. All authors provided approval for the manuscript.*

Funding: *This research did not receive any financial support.*

Statement of Conflicting Interests: *Dr. Thompson reports an MSc stipend from the Government of Ontario; Dr. Bjerre reports personal fees and nonfinancial support from the Department of Family Medicine, University of Ottawa; nonfinancial support from Bruyère Research Institute; grants from the Canadian Institutes for Health Research; and grants from the Ministry of Health and Long-Term Care of Ontario, outside the submitted work.*

References

1. Heidelbaugh JJ, Kim AH, Chang R, Walker PC. Overutilization of proton-pump inhibitors: what the clinician needs to know. *Ther Adv Gastroenterol* 2012;5(4):219-32.
2. Freedberg DE, Kim LS, Yang Y-X. The risks and benefits of long-term use of proton pump inhibitors: expert review and best practice advice from the American Gastroenterological Association. *Gastroenterology* 2017;152(4):706-15.
3. Thompson W, Black C, Welch V, et al. Patient values and preferences surrounding proton pump inhibitor use: a scoping review. *Patient* 2018;11(1):17-28.
4. Reeve E, To J, Hendrix I, et al. Patient barriers to and enablers of deprescribing: a systematic review. *Drugs Aging* 2013;30(10):793-807.
5. Stacey D, Légaré F, Lyddiatt A, et al. Translating evidence to facilitate shared decision making: development and usability of a consult decision aid prototype. *Patient* 2016;9(6):571-82.
6. Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014;(1):CD001431.
7. O'Connor A, Jacobsen M. Workbook on developing and evaluating patient decision aids. 2003; Available: https://decisionaid.ohri.ca/docs/develop/develop_da.pdf (accessed Oct. 14, 2016).
8. Thompson W, Farrell B, Welch V, et al. Should I continue taking my acid reflux medication? Design of a pilot before/after study evaluating a patient decision aid. *Can Pharm J (Ott)* 2017;150(1):19-21.
9. O'Connor A. User Manual—Decisional Conflict Scale [Internet]. 2010. p. 1-16. Available: https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_decisional_conflict.pdf (accessed April 7, 2016).
10. Sepucha KR, Borkhoff CM, Lally J, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. *BMC Med Inform Decis Mak* 2013;13(Suppl 2):S12.
11. Shultz CG, Jimbo M. Decision aid use in primary care: an overview and theory-based framework. *Fam Med* 2015;47(9):679-92.
12. Reeve E, Andrews JM, Wiese MD, et al. Feasibility of a patient-centered deprescribing process to reduce inappropriate use of proton pump inhibitors. *Ann Pharmacother* 2015;49(1):29-38.
13. Sirois C, Ouellet N, Reeve E. Community-dwelling older people's attitudes towards deprescribing in Canada. *Res Soc Adm Pharm* 2017;13(4):864-70.