Pregnancy-Related Beliefs and Concerns of Inflammatory Bowel Disease Patients Modified After Accessing e-Health Portal

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ABSTRACT

Objective: Poor inflammatory bowel disease (IBD)-specific reproductive knowledge is associated with concerns and medication noncompliance. Having shown an educational portal can improve knowledge, we evaluated its effectiveness for addressing IBD patients’ reproductive and medication concerns.

Methods: Adult IBD participants (aged 18 to 45 years) were invited to access an e-health portal providing information on heritability, fertility, surgery, pregnancy outcomes, delivery, postpartum, and breastfeeding in the context of IBD and IBD medications. At pre-, post-, and 6+-month postintervention, participants completed a questionnaire on IBD-specific pregnancy concerns, medication concerns from the Beliefs About Medicines Questionnaire (BMQ), and medication adherence via the Medication Adherence Rating Scale (MARS). The Wilcoxon signed-rank test was used to compare median differences between scores (95% confidence).

Results: Demographics for 78 (70.3%) participants completing postintervention questionnaires: median age 29.3 (interquartile range: 25.6 to 32.9) years; 54 (69.2%) Crohn’s disease; 21 (26.9%) ulcerative colitis; 63 (80.3%) females, 5 (7.9%) pregnant; and 19 (30.2%) previously pregnant. Postintervention, the median number of reproductive concerns decreased from 3 to 1, and remained stable 6+ months later (P < 0.001*). The median BMQ score decreased from 28 to 25, and remained stable 6+ months later (P = 0.032*). Participants adherent to medications increased from 82.4% to 87.8% postintervention (P = 0.099).

Conclusion: Using an e-health portal may potentially reduce IBD-specific reproductive and medication concerns. An e-health portal is feasible as one component of managing IBD patient’s reproductive and medication concerns during preconception and pregnancy.

Keywords: Beliefs about medications; BMQ; Canada; Concerns; CCPKnow; Inflammatory bowel disease; Maternal and child health; Medications; Medication adherence; MARS; Pregnancy; Sexual and reproductive health
BACKGROUND AND SIGNIFICANCE

Pregnancy adds additional complexity to inflammatory bowel disease (IBD), due to the interaction between the mother’s changing physiology, her IBD status and medications. Almost 50% of women with IBD have been identified to have poor disease-related reproductive knowledge (1). It is thought that educational programs and decision aids aimed at improving disease knowledge in IBD patients have the potential to reduce patient concerns and fears, in addition to improving adherence to medications (2). However, there has been conflicting evidence, especially concerning medication adherence. Selinger et al. found no association between adherence and anxiety, depression, or IBD-related patient knowledge (3). Even less is known about medication adherence of pregnant women (4). Some studies show interventions targeting pregnancy-specific beliefs improve adherence; active preconception counselling has been associated with both increased adherence and decreased risk of disease relapse (5–7).

The internet has become one of the most used sources for all kinds of health information. More than half of IBD patients seek the internet to gather IBD-specific information (8). IBD patients aged 26 to 35 years tend to use the internet more frequently, and almost two thirds of patients under the age of 40 report using the internet to seek IBD specific information (9). This result is consistent with results from a 2014 University of Alberta Preconception and Pregnancy in IBD clinic survey of 248 women with IBD (10). The survey identified five topics of concern, which became the focus for the development of a novel educational e-health portal (https://pregnancy.ibdclinic.ca) (10,11).

We have demonstrated that this portal improves IBD-specific reproductive knowledge and is sustained months later (11). However, it is not known how the web portal affects concerns regarding pregnancy and IBD medications, or medication adherence (11). The primary aim of this study was to evaluate the effect of an educational e-health portal on the IBD-specific reproductive concerns and medication beliefs of women and men with IBD. The secondary aim was to evaluate if the portal was able to influence self-reported medication adherence.

MATERIALS AND METHODS

Study Design

A pre-post-intervention study, assessing the effectiveness of an e-health portal in eliciting within-subject change of pregnancy-related concerns, medication beliefs, and medication adherence among women and men with IBD. This study’s methods have been partially described in a previous publication (Wierstra et al. (11)).

Intervention: Access to e-health Portal

The intervention consisted of unlimited access to the e-health portal for 60 days. Participants accessing the portal went through each of five modules (development process described previously (10,11)). The modules comprised text with references, 5-minute informational videos, slide decks, and self-quizzes. Content and usability was pilot tested prior to the study by 11 individuals (including 3 trainees, 3 research coordinators, and 5 IBD patients) and their feedback was utilized in the portal design.

Setting and Population

Adult (aged 18 to 45 years) men and women with IBD were invited to participate in the study directly (in-person) from the IBD clinic (University of Alberta Hospital, Edmonton, AB, Canada) between June 2015 and May 2016. Those not attending clinic in a reasonable time period were mailed a study invitation pamphlet. If not responding to the first mail, a reminder was sent 2 months later. Posters were placed around the University of Alberta Hospital and campus, as well as online advertising through Canadian Digestive Health Foundation and Crohn’s and Colitis Canada websites. Pregnancy was not an exclusion criterion; the study was meant to be pragmatic and applicable, by including any potential patients of the IBD preconception and pregnancy clinic.

Study Procedures

Upon consent, participants were asked to complete the preintervention questionnaire, consisting of demographic and medical information, IBD history and medications, reproductive history, patient reproductive concerns, the Medication Adherence Report Scale (MARS-5) (12), the Beliefs about Medicines Questionnaire (BMQ-IBD-S18) (13), and the Crohn’s and Colitis Pregnancy Knowledge (CCPKnow) score (1). Afterwards, participants were given access to the portal for 60 days with unique login and password. At any time in this 60-day window, participants could complete the modules. Postintervention, they repeated the baseline questionnaires (concerns, MARS-5, BMQ, CCPKnow) and feedback questions. Demographic and baseline information from preintervention questionnaire is available in Appendix A (Supplementary File 1), repeated measures from all study time points are available in Appendix B (Supplementary File 2).

Once enrolled, participants were sent regular email reminders indicating their time remaining to access the portal. If the time passed and participants had not completed the post questionnaire, they were offered the option to extend the time for 14 days. Participants who completed the postintervention questionnaire were invited to repeat it again 6 months later.

Data Sources and Variable Definitions

Patient Reproductive Concerns

Six ‘yes/no’ IBD-specific reproductive concern questions were asked (adapted from Marri et al. [2007]) (10,14). These were analyzed individually and cumulatively.
Self-reported 5 statement Likert questionnaire evaluating nonadherent medication taking behaviours (12). Scores were analyzed individually or summed to reach a total out of 25; higher scores indicating higher self-reported adherence. A total of greater than 20 was considered adherent (12).

**BMQ IBD S18**

An IBD-specific version of the validated BMQ questionnaire, measures beliefs that influenced adherence to medications. Specific questions from this BMQ version are subdivided into necessity and concerns scales (13). Participants rank statements from the Likert scale (strongly disagree -> strongly agree). Sores are summed to obtain a total for each scale.

**CCPKnow**

Measures IBD-specific reproductive knowledge. Correct answers to the 17 CCPKnow questions are summed to form a total score, and this score was also categorized into levels consisting of poor (0 to 7), adequate (8 to 10), good (11 to 13), and very good (14 to 17).

**Statistical Analysis**

To characterize within-subject reduction in the total number of IBD-specific reproductive concerns at each experimental stage (pre-, post-, and 6+ months postintervention), nonparametric Wilcoxon signed-rank test was used. IBD-specific reproductive concerns were also compared individually, using McNemar’s test, to compare proportions of patients with each concern.

To characterize medication adherence and medication beliefs as functions of the intervention and of other modifiable factors, total MARS-5 scores, BMQ-necessity, BMQ-concerns, reproductive concerns, and CCPKnow scores were tabulated. Medians at each stage were compared using Wilcoxon. Each MARS-5 item was analyzed individually. Pearson chi-squared analysis (Fischer’s test when cell n < 5) was done for categorical demographic variables. Frequency distributions of categories were tabulated and differences in distributions were compared across subgroups. P-values were reported using the null hypothesis of no difference in frequency distribution.

IBM SPSS Statistics 23.0 software was used for statistical analysis with 95% confidence levels. Minor variations in sample size among some analyses were caused by attrition due to small amounts of missing data/question answers.

**Ethical Considerations**

Study protocols and materials, including an online electronic version of the consent form, were approved by the Health Research Ethics Board of the University of Alberta.

**RESULTS**

**Participants**

The total number of potentially eligible patients (between age 18 and 45 years) attending IBD clinic was approximately 1010, identified from the Division’s IBD Electronic Database. This population has been described previously by Wierstra et al., with a flowchart of the recruitment process to the sample analyzed post- and 6+ months postintervention (Figure, Supplementary File 3) (11). Basic demographic information for all participants invited to participate is presented in Supplementary Table S1 (Supplementary File 4) (11). Of 169 patients invited in clinic, in-person, 111 registered for the e-portal, and 101 completed the preintervention questionnaires. Of these, 78 (70.9% completion rate) completed the postintervention questionnaire, and comprise the primary study population. Their demographics are displayed in Table 1.

The demographics were not statistically different between those who completed the pre- and postintervention questionnaire and those who only completed the preintervention questionnaires (Supplementary Table S2, Supplementary File 5) (11). The exception was pregnancy status, where the proportion of patients who were pregnant and completed the postintervention questionnaire was lower than those who were pregnant and only completed the preintervention questionnaire (6.4% versus 26.1%, P = 0.008*). Of the 11 participants who were pregnant during the pre-intervention assessment, 10 (90.9%) had an adequate knowledge level. In contrast, 37 (47.4%) of the study population had poor knowledge (CCPKnow < 8) at preintervention (Table 1). As previously shown, this web portal improved participants’ knowledge significantly, with only four (5.1%) having poor knowledge at postintervention (11).

**e-Health Portal Usage**

Usage data were collected on the time spent on each module of the portal. The mean, standard deviation, median and interquartile ranges (in minutes) are presented (see Supplementary Table S3, Supplementary File 6). Usage data were also collected on viewership of the videos available within each module. In total, 47.5% of the participants watched at least one full video, and 60% watched at least part of one video. Exactly 25% of the participants watched three or more videos (out of five total) to completion. Of note, the videos were considered supplementary to the text shown on the pages.

**Reduction of IBD-Specific Reproductive Concerns Postintervention**

At preintervention, 69 of 78 (88.5%) patients identified at least one IBD-specific reproductive concern, and 60 of 78 (76.9%) had two or more. Postintervention, 56 of 78 (71.8%) had at least one concern, and 34 of 78 (43.6%) had two or more concerns. At 6+ months postintervention, 18 of 37 (48.6%) had two or more concerns.
Table 2 shows the median number of reproductive concerns preintervention to be 3.0 (interquartile range [IQR]: 2.0 to 4.0), compared to postintervention median of 1.0 (IQR: 0.0 to 2.0). The median within-subject decrease in number of concerns was 1.0 (z = −5.833, \( P < 0.001^* \), Wilcoxon). In total, 50 participants decreased, 6 increased, and 22 experienced no change in number of concerns from pre- to postintervention. This effect remained at 6+ months with a median number of reproductive concerns equal to 1.0 (IQR: 0.5 to 2.0), and a median decrease from preintervention of 1.0 (z = −4.037, \( P < 0.001^* \)). In total, 26 participants decreased, 3 increased, and 8 experienced no change in number of concerns from pre- to 6+ months postintervention.

On an individual level, Figure 1 shows the percentage of patients who identified having each of the six IBD-specific reproductive concerns, at preintervention, postintervention,
Reduction of IBD-Specific Medication Concerns Postintervention

As shown in Table 2, the median total BMQ-concern scores decreased postintervention. The median within-subject decrease in total score was 1.0 ($z = -3.998, P < 0.001^*$$)$. In total, 49 participants decreased, 20 increased, and 8 experienced no change in number of concerns from pre- to postintervention. The effect remained at 6+ months with a median decrease from preintervention of 1.0 ($z = -2.144, P = 0.032^*$). In total, 26 participants decreased, 8 increased, and 2 experienced no change in number of concerns from pre- to 6+ months postintervention.

The most common individual medication concern at preintervention was: “I am concerned about future long-term side effects of these medicines” (BMQ C8, Supplementary Appendix B), with 73.5% agreeing or strongly agreeing. This decreased postintervention to 70.1% ($P = 0.036^*$) and remained at 60% ($P = 0.175$) 6+ months postintervention.

The second most common medication concern was: “Having to take these medicines worries me” (BMQ C1, Supplementary Appendix B), with 70.5% agreeing or strongly agreeing. It decreased postintervention to 61.8% ($P = 0.006^*$) and remained at 60% ($P = 0.175$) 6+ months postintervention. Concern for being dependent on IBD medications decreased from 46.2 to 41.6% postintervention ($P = 0.041^*$), and to 28.6% 6+ months later ($P = 0.463$). Other individual concerns showed trends towards improvement postintervention but without significance.

Changes in Medication Adherence Postintervention

There were 74 participants who completed postintervention and had complete MARS-5 data. The majority of these participants were adherent to their medications at preintervention, with 61 of 74 (82.4%) having a total MARS-5 score of greater than 20/25. Preintervention scores ranged from 7 to 25, and were skewed towards higher adherence. Postintervention, the number of adherent individuals increased to 65 of 74 (87.8%). The change was the result of eight individuals remaining as low adherers, one individual moving from high to low adherence,
and five individuals improving from low to high adherence. The median and mean MARS totals are shown in Table 2.

Figure 2 shows proportions who selected ‘always’, ‘often’, or ‘sometimes’ for each individual item of the MARS-5, pre- and postintervention. The most common identified nonadherent behaviour was unintentional; ‘I forget to take them’. With the exception of ‘I stop taking them for a while’, all five nonadherent behaviours exhibited a percentage decrease. Of note, ‘I decide to miss out a dose’ and ‘I take less than instructed’ were almost cut in half. With the exception of ‘I decide to miss out a dose’, where four of nine nonadherent participants became adherent (P = 0.046*, Wilcoxon), the statements did not reach statistical significance.

**DISCUSSION AND CONCLUSION**

**Discussion**

*Reduction of Patient Reproductive Concerns Postintervention*

Study findings support our hypothesis that the e-health portal reduces the concerns of participants on an individual and aggregate level for 6 months or more. Two reproductive concerns were unaffected by the online education regarding the stress of raising a child affecting one’s IBD, and IBD affecting one’s ability to care for a child. These were not specifically addressed by content in the e-health portal’s modules, and their inclusion established a pseudo-control.

The concern reported by the largest proportion of female participants regarded ‘flaring due to pregnancy’. This is an understandable concern as the risk of disease activity during pregnancy is elevated for those women who enter pregnancy with active disease (15,16). However, particularly for CD, the risk of flaring for patients in remission is not substantially greater than for nonpregnant women, which is something patients can receive education about (11,15,17). It is also likely that some of the women who flare in pregnancy do so because of discontinuing their medication (18). This may be for a plethora of reasons, however, we know that women with IBD have a stronger inclination to discontinue their IBD medications during pregnancy due to concerns regarding safety and teratogenicity (18).

Some studies have reported that patients remain skeptical about taking drug treatments during pregnancy in spite of physician-oriented pregnancy-specific guidelines (19). This communication gap was not reflected in this study as most IBD-specific reproductive concerns were limited to 30% or less postintervention.
The results provide evidence that the e-health portal resolved IBD-specific medication concerns. Overall, the median total concerns scores on the BMQ were lower postintervention and 6+ months postintervention. The percentage of patient’s agreeing or strongly agreeing with three most common individual concerns was also shown to decrease postintervention, with significance. Although the percentages were still lower, the results were not significant at 6 months (likely due to the lower sample size). Nonetheless, these findings are important because, to date, there has been little research showing that interventions can reduce concerns about medication (BMQ scores) in IBD or pregnancy in IBD. An in-person pharmacy intervention was unable to produce changes in BMQ concerns or necessity at follow-up, even though they improved adherence in nonadherent patients (20). We have shown improvements in BMQ using only a web-intervention, which can be easily implemented in other IBD clinics.

**Changes in Medication Adherence Postintervention**

Previous research has shown that IBD (UC) patients adherent to their medications had an almost 90% chance of maintaining remission in pregnancy, compared with 39% for those nonadherent (21). Medication noncompliance during preconception and pregnancy still remains pervasive in many chronic disorders, although less so in IBD patients (5). Our study findings are consistent with previous findings in that IBD participants had high rates of self-reported adherence, at over 80% (>20 MARS-5 score). It should be noted that we used a more stringent MARS cutoff, as some studies use >19 MARS for ‘adherent’ (22). Postintervention, we were able to improve adherence rates to 87.8%, and showed an increase in mean total MARS scores. However, these were not significant. It has proven difficult to change medication adherence beliefs with a single intervention. In IBD, the most convincing results come from an in-person Pharmacist counselling intervention targeting nonadherent patients, where it was primarily the patients with severe nonadherence (<14/20 MARS-4) who improved (20). Our study population on the other hand, did not have as much room for improvement (median baseline MARS-5 of 24/25). Self-selection bias may explain some of this difference.

The most common reason for nonadherence, ‘I forget to take them’, is consistent with previous research of adherence both in general IBD and IBD in pregnancy (23). One of the most frequently reported reasons for medication nonadherence is disease quiescence (6,23). This is interesting, as we would typically want patients to view disease remission as effectiveness of their medication, and not as a reason to discontinue it. Investigating this viewpoint was not a part of this study, but is an important implication for future studies of medication adherence in IBD in pregnancy.

**Limitations**

This study has several limitations described in our previous publication, including a smaller sample size, attrition rate, and technology or internet availability selection bias (11). There is mixed evidence that patients who search the internet are more willing to accept prescribed therapies (24,25), which may partially account for our population’s high baseline adherence. Self-reported adherence is also likely to overestimate (26), and adherence in preconception or pregnant IBD patients assessed by pharmacy data has shown much lower adherence (27).

Another limitation is self-selection bias combined with the only 11% response rate and moderate attrition rate (particularly for 6-month follow-up). However; as mentioned, the study utilized multiple recruitment methods, and the response rate for in-person invitations was quite good. Meanwhile, it is known that online survey response rates can be quite low, and the true effect of nonresponse bias is quite contested (28). Nonetheless, we cannot exclude the possibility that this reflects on the acceptability of our web portal.

The pre-post-intervention design limits what conclusions we can make. The study serves as a preliminary validation of an e-health portal; a larger RCT or cluster randomized multicenter study is warranted. The IBD clinic at the University of Alberta is specialized and known for its care and knowledgeable providers. In this specialized follow-up setting, patients may be more likely to have active disease, or have more positive beliefs about the medical system, both of which could influence adherence. The MARS-5 is also known to have low variance and skew towards high adherence (29), which might have contributed to our highly adherent study population, and influenced our effect sizes. Other scales with greater variance, such as the new ProMAS or the MMAS-8, could be considered in future medication adherence focused studies (29), although the MMAS-8 is engulfed in controversial legal and financial expectations of its creator (30). A fine line is required between comprehensively answering questions in surveys, and survey fatigue, whereby patients may drop out of studies due to the lengthy questionnaires. In addition, we chose these shorter surveys in order to envision that successful completion of the study may allow or suggest these to be used in clinical practice.

**CONCLUSION**

In summary, our data show that access to a well-designed e-health portal has the potential to reduce IBD-specific reproductive and medication concerns for patients, with a sustained effect months later. Therefore, it is important to refer family planning IBD patients to a reliable and readable educational resource. This is especially true for patients who are not available to be educated at length, in person, by an expert.
SUPPLEMENTARY DATA
Supplementary data are available at Journal of the Canadian Association of Gastroenterology online.

DATA STATEMENT
Research data for this article
The data for this article and for Wierstra et al. study (11) has been described in a publication in Data in Brief (31), and the raw data is hosted on Mendeley data: (http://dx.doi.org/10.17632/g223h3p8gy.1).

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AUTHOR CONTRIBUTIONS
R.T.S.: Study coordinator, patient recruitment, statistical analysis, manuscript drafting, revision and finalization. K.W.: Study coordinator, patient recruitment, literature search, portal text content drafting and manuscript revision. J.B.: patient recruitment, literature search, portal content drafting. K.P.I.: literature search, portal text content revision, multimedia content creation, manuscript revision. L.A.D.: patient recruitment, manuscript revision. B.H.: patient recruitment, manuscript revision. K.I.K.: patient recruitment, manuscript revision. R.N.E.: Primary co-investigator, study conception and design feedback, patient recruitment. K.B.: study design feedback, manuscript revision. V.W.H.: Primary investigator, study conception and design, patient recruitment, literature search, portal text content drafting and revision, multimedia content creation, manuscript drafting, revision and finalization.

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