

Medication adherence in women with IBD of childbearing age likely associated with disease knowledge

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Abstract

Background: Medication adherence in inflammatory bowel disease (IBD) is crucial, particularly during pregnancy. Unplanned pregnancies are common; therefore, efforts to maximise adherence should not be restricted to pregnant women.

Objectives: We aimed to assess medication adherence in women with IBD of childbearing age, regardless of their reproduction plans.

Design: We performed a multi-centre pilot questionnaire study of women with IBD age 18–45 years.

Methods: Survey questions included patient demographics, disease history, and validated assessments of IBD and pregnancy knowledge, medication adherence and quality of life. The primary outcome was rates and predictors of medication adherence.

Results: In all, 72 women [58.3% Crohn's disease (CD) and 37.5% ulcerative colitis] completed the survey. The median patient age was 30 years [interquartile range (IQR): 24.8–36.0] and 37.5% had children. Medication adherence was high [84%; median Medication Adherence Report Scale: 19.0/20; IQR: 17.0–20.0]. Knowledge scores were adequate for both the Crohn's and Colitis Knowledge (CCKnow; median: 15.5/30; IQR: 12.3–18.0) and Crohn's and Colitis Pregnancy Knowledge (CCPKnow; median: 8.0/17; IQR: 4.0–11.0). Disease knowledge was predictive of high medication adherence (CCPKnow: $p=0.02$; CCKnow: $p\leq 0.01$). Higher adherence was significantly associated with a diagnosis of CD ($p=0.01$), exposure to biological agents ($p=0.03$) and immunomodulators ($p=0.04$), childbearing after diagnosis with IBD ($p=0.03$), and correctly understanding the importance of delivery modality ($p=0.02$) and IBD activity in pregnancy ($p=0.01$).

Conclusions: Following dedicated education at the IBD clinic, medication adherence, disease-specific and pregnancy-specific knowledge in women with IBD of childbearing age tends to be high. Unplanned pregnancies are frequent; therefore, we should aim to maximise medication adherence in all women of childbearing age to optimise maternofetal outcomes if unexpected pregnancies occur.

Keywords: medication adherence, inflammatory bowel disease, knowledge, pregnancy, women's healthcare

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Introduction

Inflammatory bowel disease (IBD) is a chronic illness which requires long-term medication to prevent disease flares and complications, particularly during pregnancy. It commonly affects women of childbearing age, many of whom will

reproduce at some stage. While most women with IBD are able to have uncomplicated pregnancies and produce healthy offspring, the likelihood of adverse maternofetal outcomes is greatly increased in the setting of active IBD.¹ Strict medication adherence both pre-conception and

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throughout pregnancy is therefore pertinent for optimising pregnancy outcomes in women with IBD.^{2,3} Non-adherence is also associated with increased healthcare costs,^{4,5} disability,⁶ and reduced medication efficacy and persistence.^{7,8} Reasons for non-adherence are multifactorial, including concerns about medication toxicity or necessity, forgetfulness and medication cost.^{9,10} However, disease knowledge has so far not been found to predict medication adherence.^{5,11}

While many women actively choose to start a family, nearly half (45%) of pregnancies are unintentional.¹² This suggests that we should offer preconception counselling and strive for strict medication adherence in all women of childbearing age, rather than solely those who are already pregnant or trying to conceive. To our knowledge, there have been no studies assessing medication adherence and its predictors in women with IBD of childbearing age who have not necessarily expressed a desire to reproduce. We therefore performed a pilot observational study of women with IBD of childbearing age, regardless of their childbearing intentions, to assess medication adherence and the factors contributing to this, including disease knowledge, disease-specific pregnancy knowledge, quality of life and voluntary childlessness (VC).

Materials and methods

From 2019 to 2020, we performed a multi-centre prospective pilot questionnaire study of women with IBD of childbearing age. Patients were recruited from Concord Repatriation General Hospital and from two private outpatient rooms. Criteria for inclusion in the study were female gender and aged 18–45 years. All women meeting these criteria who presented to the study sites were approached for enrolment. Exclusion criteria included male gender, aged <18 years or >45 years, and those without a diagnosis of IBD. Initial recruitment was face-to-face; however, this was transitioned to online surveys in May 2020 due to the COVID-19 pandemic. Survey questions pertained to patient demographics, disease history, IBD knowledge [measured by the Crohn's and Colitis Knowledge (CCKnow) Score], disease-specific pregnancy knowledge [measured by the Crohn's and Colitis Pregnancy Knowledge (CCPKnow) Score], quality of life [QoL; measured by the Short IBD Questionnaire (SIBDQ)] and medication adherence [measured by the

Medication Adherence Report Scale (MARS)] (Supplemental Appendix 1). Study data were collected solely from these self-completed questionnaires. The primary outcome of this study was medication adherence (MARS score and prevalence of nonadherence) and factors predictive of adherence. The reporting of this study conforms to the CROSS statement.¹³

IBD knowledge (CCKnow)

The CCKnow is a validated assessment tool for overall patient knowledge about IBD. It consists of 30 multiple choice questions covering four topics: general IBD, medication, diet and complications. Scores range from 0 to 30, with higher scores indicating greater IBD knowledge.¹⁴

Pregnancy-specific IBD knowledge (CCPKnow)

The CCPKnow is a validated assessment tool for assessing patient pregnancy-specific IBD knowledge.¹⁵ It consists of 17 multiple choice questions on seven topic domains. Scores range from 0 to 17, with scores ≥ 14 defined as 'very good' knowledge, 8 to 13 as 'at least adequate' and ≤ 7 as 'poor'.¹⁵

Quality of life (SIBDQ)

The SIBDQ consists of 10 questions from the original 32-question complete Inflammatory Bowel Disease Questionnaire, assessing health-related QoL in patients with IBD. The 10 questions assess four topics: bowel symptoms, systemic symptoms, emotional function and social function. Each question is scored from 0 (worst QoL) to 7 (best QoL). The sum of all scores is divided by the number of questions, yielding an overall score ranging from 0 (worst QoL) to 7 (best QoL).¹⁶

Medication adherence (MARS)

The MARS was developed in 1999 and validated in a range of diseases for assessing medication adherence.¹⁷ We used the MARS-4 version, consisting of four questions each with a 5-point Likert scale answer system. The total score ranges from 4 to 20, with scores ≤ 16 indicating low or non-adherence and ≥ 17 indicating high adherence.¹⁸

Statistical analysis

CCPKnow, CCPKnow and MARS were analysed as non-parametric continuous variables

using the Mann–Whitney and Kruskal–Wallis tests against categorical variables. Results were expressed as median scores with interquartile ranges and mean scores with standard deviations. MARS was also analysed as a binary variable using univariate analyses against categorical variables. Relationships between non-parametric continuous variables were analysed using Spearman's correlation. *p* Values of <0.05 were deemed to be significant. The data were analysed using SPSS version 26.0 for Windows.

Ethics approval

This study was approved by the Concord Repatriation General Hospital Ethics Committee (LNR/18/CRGH/67). Participants provided both verbal and written consent prior to participating in the study.

Results

This study recruited 72 women with IBD, 35 (48.6%) from Concord Hospital and 37 (51.4%) from private outpatient rooms. Of these participants, 58.3% suffered from Crohn's disease (CD), 37.5% from ulcerative colitis (UC) and 4.2% had IBD-unclassified. The median age of the patients was 30.0 years [interquartile range (IQR): 24.8–36.0], 37.5% of these patients had children and 10 patients (13.9%) identified as VC. The demographics and disease data are shown in Table 1.

Patient pregnancy-specific IBD knowledge and overall IBD knowledge were both only adequate, with the median CCPKnow 8.0/17 (IQR: 4.0–11.0) and the median CCKnow score 15.5/30 (IQR: 12.3–18.0) (Table 2). There was a strong positive correlation between CCPKnow and CCKnow scores ($p < 0.001$; correlation coefficient 0.52). Health-related QoL was moderate in this cohort, with a median SIBDQ score 4.7/7 (IQR: 3.9–5.4). SIBDQ scores did not correlate with either the CCKnow ($p = 0.91$) or CCPKnow scores ($p = 0.41$).

Predictors of medication adherence

Medication adherence in this cohort was high, with a median MARS score 19.0/20 (IQR: 17.0–20.0). Nonadherence (scores: $\leq 16/20$) occurred in 16% of participants. The most frequent factor driving nonadherence was forgetting to

take medications (57.4% of participants), while intentionally foregoing a medication dose was the least frequent (18.9%). When MARS was analysed as a binary variable, adherent patients had significantly higher CCPKnow [$p = 0.02$; median score: 8.0 (IQR: 4.8–11.0) *versus* 3.5 (IQR: 1.5–6.3)] and CCKnow scores [$p \leq 0.01$; median score: 16.0 (IQR: 13.8–18.0) *versus* 11.5 (IQR: 5.7–13.8)]; however, there was no difference in SIBDQ scores ($p = 0.44$). Analysed as a continuous variable, there was a trend towards a correlation between MARS and CCKnow ($p = 0.07$; $r = 0.26$); however, there was no correlation between MARS and SIBDQ scores ($p = 0.97$; $r < 0.01$). Overall pregnancy-specific IBD knowledge was not significantly predictive of MARS ($p = 0.08$; $r = 0.25$); however, correctly understanding the importance of controlling IBD activity before/during pregnancy ($p = 0.01$) and understanding the impact of IBD on delivery modality ($p = 0.02$) were associated with significantly better medication adherence.

IBD type was predictive of MARS scores, with CD patients having significantly greater scores than UC [CD: median 19.0 (IQR: 19.0–20.0); UC: median 17.0 (IQR: 13.0–20.0); $p = 0.01$]. Childbearing status overall and VC were not predictive of MARS scores; however, women who gave birth after being diagnosed with IBD had significantly higher MARS scores [median 19.0 (IQR: 18.3–20.0)] compared with women who gave birth prior to being diagnosed with IBD [median 17.0 (IQR: 9.8–18.5); $p = 0.03$]. Self-rated disease severity and prior abdominal surgery were not predictive of MARS scores; however, exposure to immunomodulators [exposed: median 19.0 (IQR: 18.0–20.0); unexposed: median 16.0 (IQR: 10.5–19.8); $p = 0.04$] and biological agents [exposed: median 19.0 (IQR: 18.0–20.0); unexposed: median 17.0 (IQR: 12.0–20.0); $p = 0.03$] was associated with significantly higher MARS scores. Corticosteroid exposure also trended towards higher MARS scores ($p = 0.05$). There were no other demographic or disease factors found to be significantly predictive of MARS scores (Table 3).

Discussion

This is the first study to identify the potential association between medication adherence and patient knowledge, including both disease-specific and pregnancy-specific IBD knowledge, in

Table 1. Participant demographics.

Demographic	Frequency number (%)
Disease subtype	
CD	42 (58.3)
UC	27 (37.5)
IBD-unclassified	3 (4.2)
Marital status	
Single	28 (38.9)
Married/separated	43 (59.7)
Ethnicity	
Caucasian	41 (56.9)
Asian/other	31 (43.1)
Employment	
Yes	56 (77.8)
No	13 (18.1)
Education level	
Primary/secondary school	1 (1.4)
University	18 (25.0)
TAFE/other	50 (69.4)
Annual household income (AUD)	
<\$17,500	18 (25.0)
\$17,500–34,999	29 (40.3)
\$35,000–84,999	3 (4.2)
>\$85,000	3 (4.2)
Parenting children	
Yes	27 (37.5)
No	45 (62.5)
If yes, child born after IBD diagnosis	
Yes	20 (74.1)
No	7 (25.9)
If yes, complications during pregnancy	
Yes	13 (59.1)
No	9 (40.9)

(Continued)

Table 1. (Continued)

Demographic	Frequency number (%)
Prior miscarriage after IBD diagnosis	
Yes	10 (13.9)
No	62 (86.1)
Prior abdominal surgery	
Yes	30 (41.7)
No	42 (58.3)
If yes, surgery within the last year	
Yes	6 (20.0)
No	24 (80.0)
IBD-related hospitalisation within the last year	
Yes	20 (27.8)
No	52 (72.2)
Exposure to biological agents	
Yes	55 (76.4)
No	17 (23.6)
Exposure to immunomodulators	
Yes	62 (86.1)
No	10 (13.9)
Exposure to corticosteroids	
Yes	64 (88.9)
No	8 (11.1)
Self-rated severity of IBD	
Mild	25 (34.7)
Moderate	43 (59.7)
Severe	2 (2.8)
Impaired QoL due to IBD	
Yes	47 (65.3)
No	24 (33.3)
Member of Crohn's and Colitis Australia	
Yes	16 (22.2)
No	51 (70.8)

AUD, Australian dollars; CD, Crohn's disease; IBD, inflammatory bowel disease; TAFE, technological and further education; UC, ulcerative colitis.

Table 2. Results of assessment scores.

Tool	Median (IQR)	Mean (SD)
MARS	19.0 (17.0–20.0)	18.0 (3.2)
CCPKnow	8.0 (4.0–11.0)	7.6 (4.2)
CCKnow	15.5 (12.3–18.0)	15.4 (5.0)
SIBDQ	4.7 (3.9–5.4)	4.7 (1.0)

CCKnow, Crohn's and Colitis Knowledge Score; CCPKnow, Crohn's and Colitis Pregnancy Knowledge Score; IQR, interquartile range; MARS, Medication Adherence Report Scale; SD, standard deviation; SIBDQ, Short IBD Questionnaire.

women with IBD of childbearing age. We found that women with good medication adherence had significantly higher CCPKnow and CCKnow scores compared with women with poor medication adherence. This finding was not corroborated by the correlation analysis, likely due to insufficient statistical power, as this pilot study was designed to identify data trends rather than definite evidence. Forgetfulness was the most frequent reason for nonadherence, rather than intentional dose omissions or alterations. Given the frequency of unplanned pregnancies within the population, and the high rate of medication nonadherence among pregnant women with IBD,¹¹ consideration should be given to provide all women of childbearing age with efforts to maximise medication adherence to optimise materno-fetal outcomes in the event of an unexpected pregnancy. The best strategy to optimise adherence has yet to be determined; however, it likely needs to be individualised for each patient and should incorporate some disease-related and pregnancy-related education strategies. Online education sessions have been shown to reduce patient concerns regarding medication safety and improve medication adherence in males and females with IBD of childbearing age.¹⁹

Exposure to biological agents and immunomodulators was associated with significantly greater medication adherence, while corticosteroid and mesalazine exposure were not. Other studies have also reported that medication adherence is lower for mesalazines compared to biological agents.^{5,20} This may reflect that patients taking biological agents or immunomodulators may have more frequent follow-up and closer rapport with their treating gastroenterologist, as they require repeat

Table 3. Factors predictive of medication adherence.

Factor	p Value
Significant	
IBD type	0.01
Exposure to immunomodulators	0.04
Exposure to biological agents	0.03
Parenting children after IBD diagnosis	0.03
Trend towards significance	
CCKnow	0.07
Exposure to corticosteroids	0.05
Not significant	
Age	0.70
Duration of IBD	0.68
Marital status	0.94
Employment status	0.68
Education level	0.52
Income	0.35
CCPKnow	0.08
SIBDQ	0.97
VC	0.11
CCA membership	0.94
Parenting children	0.46
Exposure to mesalazines	0.10
Abdominal surgery	0.42
Significantly impaired QoL	0.11
Recent hospitalisation	0.93

CCA, Crohn's and Colitis Australia; CCKnow, Crohn's and Colitis Knowledge Score; CCPKnow, Crohn's and Colitis Pregnancy Knowledge Score; IBD, inflammatory bowel disease; QoL, quality of life; SIBDQ, Short IBD Questionnaire; VC, voluntary childlessness.

prescriptions and medication monitoring. Specialist authority prescriptions are required for biological agents in Australia, which facilitates detection of nonadherence and prompting of patient reminders by the gastroenterologist. Some biological agents require infusion in a hospital or clinic setting, which adds a further layer of patient

accountability and may also improve adherence. This finding may also reflect that immunomodulators and biological agents are taken by patients with more severe disease phenotypes who may be more motivated to adhere to therapy than those with milder disease taking only mesalazines. These women with severe or active disease are also more likely to have been informed about the importance of optimising disease activity pre-conception and during pregnancy, the correct understanding of which is significantly associated with improved medication adherence. However, other markers of disease severity including surgery, recent hospitalisation and self-rated disease severity were not predictive of adherence in our study.

The rate of VC in this study was comparable to other Western cohorts,²¹ and was not predictive of medication adherence. Motherhood in general was not significantly associated with medication adherence; however, women who delivered children after being diagnosed with IBD had significantly greater medication adherence compared to women delivering children before their IBD diagnosis. This may reflect that the increased healthcare engagement during pregnancy may strengthen a woman's therapeutic relationship with her healthcare team, provide opportunities to clarify concerns about medication toxicities, and may increase her desire to positively engage in her medical care. In addition, taking regular vitamin supplements during pregnancy may help women to establish daily medication routines which can also be applied to IBD medications, subsequently reducing the likelihood of nonadherence due to forgetfulness. Conversely, women who gave birth prior to being diagnosed with IBD may have been less interested in the non-obstetric components of their healthcare as they were otherwise healthy at the time of pregnancy and were not accustomed to regularly taking medications. This suggests that pregnancy may present a unique opportunity to engage women with IBD and instigate good medication adherence and long-term disease management approaches.

CD patients were found to have significantly greater medication adherence compared with UC patients in our study. This finding has been consistent over time,^{4,5,22} and may reflect more disease complications such as fistulas or bowel

obstructions in CD, and the higher uptake of mesalazines compared with immunomodulators or biological agents in UC. A questionnaire assessing UC patient-reported barriers to mesalazine adherence identified that beliefs about medication necessity and concerns about toxicity were key driving factors for nonadherence.²³ This suggests that we should take an individualised approach to identify the patients at greater risk of nonadherence, for example patients with UC taking mesalazines, and address their specific concerns or misconceptions. This should be addressed in a therapeutic relationship with good doctor-patient rapport, rather than solely through educational attempts to increase patient knowledge.

This is the first study to assess medication adherence specifically in women with IBD of childbearing age, regardless of their desire to reproduce, in relation to validated disease knowledge and QoL scores. One of the main limitations of this study is that it relied solely on patient-reported data. Self-reports are thought to underestimate the true extent of nonadherence by up to 20%¹⁷; however the MARS score has previously been shown to achieve a 96% correlation with medication serum-level testing verification.²⁴ In addition, as this was a pilot study there was a limited sample size and did not have a comparator group; therefore, our findings need to be further analysed with larger, multi-centre cohorts with comparator groups in future studies. Future studies could also compare medication adherence before, during and after pregnancy to further understand factors that contribute to alterations in adherence over the course of gestation. It would also be of value to analyse medication adherence relative to validated disease severity scores and injectable *versus* infusion-based biological agents in future studies.

Conclusion

Following dedicated pregnancy education at the IBD clinic, medication adherence, disease-specific and pregnancy-specific knowledge in women with IBD of childbearing age tends to be high. Because unplanned pregnancies are not infrequent, maximising medication adherence in all women of childbearing age can be recommended

in order to optimise maternofetal outcomes in the event of unexpected pregnancies. Future studies should assess this relationship and ascertain whether formal education programs can further improve patient knowledge and medication adherence in this patient cohort.

Declarations

Ethics approval and consent to participate

This study was approved by the Concord Repatriation General Hospital Ethics Committee (LNR/18/CRGH/67). All patients provided verbal and written informed consent prior to participation in the study.

Consent for publication

Not applicable.

Author contribution(s)

Robyn Laube: Conceptualisation; Data curation; Investigation; Methodology; Project administration; Writing – original draft; Writing – review & editing.

Christian Selinger: Conceptualisation; Data curation; Writing – review & editing.

Rupert W. Leong: Conceptualisation; Data curation; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

The data underlying this article will be shared on reasonable request to the corresponding author.

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Supplemental material

Supplemental material for this article is available online.

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