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Development of a Patient Decision Aid to Help People Living with Inflammatory Bowel Disease

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ABSTRACT

BACKGROUND:
Patient decision aid (PDA) is a tool, which helps the improvement of shared decision-making and is a part of the paradigm shift from physician-centered decisions to patient-centered shared decision making. In this study, we aimed to describe the process used to develop a PDA for facilitating shared decision-making about treatment in patients with inflammatory bowel disease (IBD) who need medication (corticosteroid, azathioprine, anti-TNF, and infliximab) or surgery.

METHODS:
The development process of PDA included: 1) The development of a prototype based on literature review and interview 2) 'Alpha' testing with patients and clinicians 3) 'Beta' testing in real conditions and 4) The production of a final version. This process took about 12 months (2019-2020). The participants were adult patients with IBD, gastroenterologists, and nurses.

RESULTS:
The final PDA contains four important sections: 1) Introduction about IBD disease, the purpose of developing PDA, and emphasis on shared decision-making 2) Benefits and risks of main medicines 3) The success rate as well as the incidence of complications after surgery, and 4) The conclusion about patients' satisfaction with PDA to choose the treatment options. Besides, PDA evaluation in the real world setting showed that 100% of physicians (n=4) and 86% of patients (n=12) were completely satisfied with the content of the PDA and considered it applicable and useful.

CONCLUSION:
This PDA can help patients participate in the shared decision-making process and select the best medical and surgical treatment methods. The feedback received from clinicians and patients showed their satisfaction with using the PDA.

KEYWORDS:
Inflammatory bowel diseases, Patient participation, Decision making

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INTRODUCTION

Inflammatory bowel disease (IBD) is a general term for a set of chronic gastrointestinal disorders associated with intermittent and unpredictable periods of relapse and remission.[1] IBD is a common disorder among 0.1-0.4% of the world's population.[2] In Iran, the annual incidence of IBD, ulcerative colitis, and Crohn's disease are 3.11, 2.70, and 0.41, respectively, per 100000 people.[3]

Various medical and surgical methods are used to treat patients with IBD. Aminosalicylates, corticosteroids, immunosuppressive medicines, as well as anti-TNF-alpha monoclonal antibodies are some of the medicines used to treat such patients. The goal of medication therapy in these patients is to delay surgery, slow the progression of the disease, maintain the remission of the disease, and improve mucosal tissue.[4] Surgery is a long-term solution for ulcerative colitis treatment, but there is always a risk of disease recurrence. There are no controlled data to confirm whether the medication or the surgery is really better.[5]

Patients are often unaware that they can select among different treatment options, and their insufficient or incorrect knowledge of the benefits and risks of these treatments prevents them from making informed decisions. In this situation, the patients may make decisions such as using a drug that is not aligned with their preferences and values. In fact, it is a manifestation of decision-making conflict.[6] PDA is a tool that helps the improvement of shared decision-making and is a part of the paradigm shift from physician-centered decisions to patient-centered shared decision-making.[7] Shared decision-making is a process whereby clinicians share information about treatment options and probable outcomes with patients and empower them to make a decision based on their preferences.[8,9] Using PDA is one way to promote shared decision-making (SDM). PDA provides information about the decision, available treatment options, benefits and risks of each option, and ways to clarify patient values.[10]

The choice of the treatment process in IBD is also preferential due to the side effects of available treatments. Therefore, the existence of a PDA for this group of patients seems necessary. The results of two studies on using PDA in patients with IBD also revealed that 80% of patients wanted more information about treatment options and active participation in treatment decisions.[11,12] Nevertheless, many PDAs were developed over the past decade by researchers worldwide, including those from Ottawa Hospital Research Institute (OHRI).[9] OHRI has also developed a PDA for patients who have ulcerative colitis, who are considering surgery.[13]

In western countries, numerous PDAs were developed in support of SDM, but these PDAs are entirely based on the cultural contents, values, and preferences of patients in these communities, so the optimal option is to use them in their original context.[14] Socio-cultural barriers (language and physician paternalism), as well as lack of resources (required infrastructures and technology), are among the most important barriers, which make PDAs developed in western countries not transferable to Asian developing countries.[10] Moreover, due to the importance of using PDAs to achieve SDM and the significant impact of culture on the development and implementation of PDAs, we decided to develop a PDA based on the values and preferences of patients with IBD in Iran. The purpose of developing such a PDA is to involve the growing population of patients in deciding on the type of their treatment.

MATERIALS AND METHODS

Study design

The development process of PDA was done due to the models presented by Coulter and colleagues (2013) [15] and Shillington and co-workers (2015).[6] These models constitute four stages that will be explained in the following sections.

In this study, PDA aims to help patients with IBD make decisions and participate in choosing the treatment option. Target users are adult patients with IBD (ulcerative or Crohn's colitis) who want to choose a specific treatment from various pharmacological and surgical treatment methods.

The development process of PDA includes four stages: 1) The development of a prototype based on literature review and interview, 2) 'Alpha' testing with patients and clinicians, 3) 'Beta' testing in real conditions, and 4) The production of a final version (figure 1). This process took about 12 months.

Step 1: Development of a prototype based on literature review and interview

At first, the literature review in which the standards related to the PDA, including International Patient Decision Aid Standards (IPDAS), and relevant articles related to produced PDAs about different diseases, including IBD were examined, was done. Furthermore, semi-structured interviews were conducted with four patients, four gastroenterologists, and three nurses, and based on the results of these interviews, patients' preferences and needs for decision making were determined. Finally, based on the findings of the literature review and the interviews, the contents of the main sections of the PDA, including introduction, benefits, and side effects of the complications of the surgery, and treatment options (corticosteroid, azathioprine, anti-TNF, and infliximab), were prepared. Then, the process of drafting the outline and inserting the appropriate graphic forms was conducted. The initial draft of PDA was submitted to a multidisciplinary committee consisting of physicians and nurses, and they reviewed it for the content and compliance with PDA development standards. This review phase continued until the team members reached an agreement, and the alpha version of PDA was developed.

Step 2: 'Alpha' testing with patients and clinicians

In the second stage, two focus groups were performed, one with patients with IBD (eight patients) and the other with health care providers (two gastroenterologists, two nurses with a Bachelor of Science degree [BSN], and two Ph.D. nurses). In selecting patients to participate in the focus group, the researchers made every effort to select patients with diverse background characteristics regarding education, age, sex, location, etc. They were asked to analyze the comprehensibility and usability of the PDA. In the focus group of professionals, people were selected who either had experience working with patients with IBD or were interested in studying and developing a PDA, and they were asked to comment on the acceptability and usability of the PDA. After the focus groups were completed, the «beta» version of PDA was prepared.

Step 3: 'Beta' testing in real conditions

In the third stage, four gastroenterologists, who had no involvement in the PDA development process, reviewed and modified the beta version. Each of these physicians selected at least three patients with IBD in the PDA target group in this study and asked them to express their views and satisfaction on PDA use. Besides, the physicians themselves were asked to comment on ease of use, applicability, and other aspects of PDA.

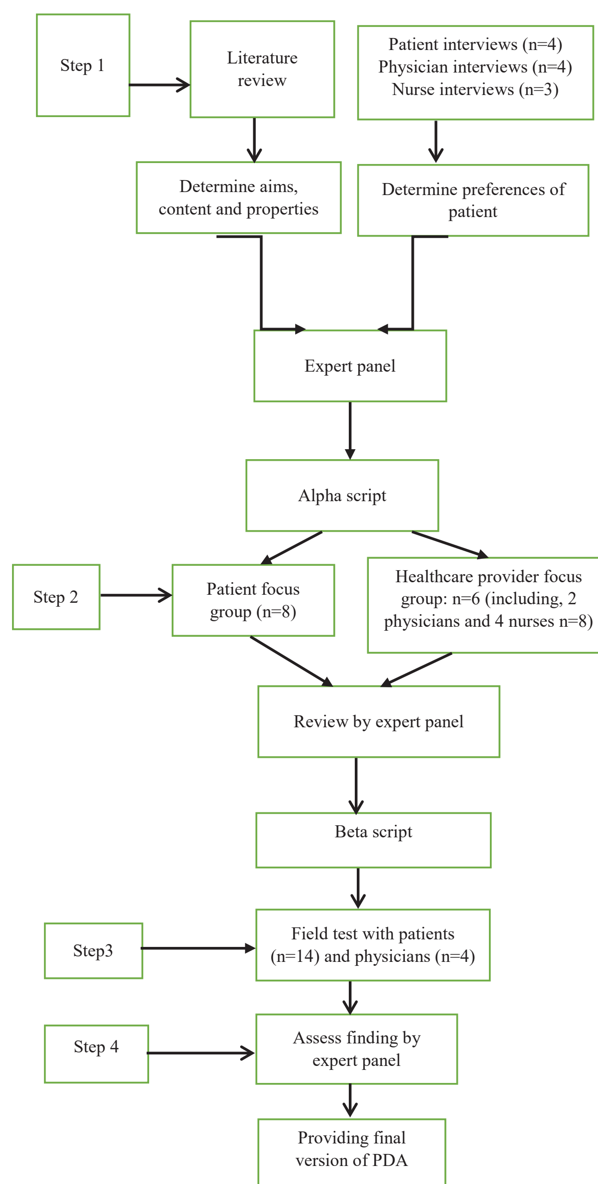

Fig. 1: Flow diagram of the development process of the patient decision aid.

Step 4: Production of a final version

Finally, the interprofessional committee reviewed the views of physicians and patients regarding the PDA and drafted the final version of the PDA.

RESULTS

The PDA for patients with IBD was developed to actively participate in the shared decision-making regarding their treatment options. The content of this PDA was compiled as follows:

1. The introduction includes brief explanations about the disease, clinical manifestations, treatment options, the purpose of developing the PDA, and emphasis on the patients' participation in decision making.
2. Benefits and risks of various medicines used in the treatment of IBD, including corticosteroids, azathioprine, infliximab, and anti-TNF.
3. Success rate (short-term and long-term) as well as the incidence of complications (such as urinary incontinence and inflammation at the incision site) after the surgery.
4. The conclusion examines patients' satisfaction with the PDA content, the effectiveness of the information expressed, especially the advantages and disadvantages of different treatment options, and it finally asks about the treatment chosen by the patient.

The PDA's final version was in the form of a booklet that was expressed in a simple and understandable language, using color-coded pictographs. The researchers did their best to use patients' and clinicians' ideas and suggestions in the iterative process at different stages of developing this product. Some examples of the PDA content are shown in figures 2 and 3.

Findings from the focus group of patients (n=8) about the alpha draft of the PDA showed that the developed product had high comprehensibility and usability. Their opinions on the order of writing the content were applied in the PDA. Besides, the comments obtained from the focus group of experts, including physicians and nurses (n=6), also showed that the developed PDA had high usability. Usability was tested by a five-item questionnaire by patients and clinicians. After applying the comments provided in the focus groups, the beta version of PDA was prepared. All physicians were satisfied with the PDA developed to help the participation of patients with IBD in shared decision-making.

From the physicians' viewpoint, involving patients in medical decisions not only gives them a feeling of satisfaction but also can increase their treatment adherence. Besides, using the PDA is very effective in informing the physicians of patients' priorities in relation to their treatment. Despite the physicians' high satisfaction from PDA application in patients with IBD, they believed that the process of using PDA would prolong the consultation time. Two of the four physicians who reviewed the beta version of the PDA gave it to three patients, and the other two gave it to four patients with IBD. Twelve patients (86%) were completely satisfied with the PDA and believed that each treatment method's advantages and disadvantages helped them make shared decisions. Two patients (14%), despite being satisfied with the participation in the decision making, believed that providing statistics about the side effects of treatments and the likelihood of recurrence can cause some fear and anxiety. All patients were satisfied with the content of the PDA for its simplicity, comprehensibility, and conciseness. The acceptability of this PDA was tested by a 5-item questionnaire about the usefulness of information, willingness to use PDA, creating preparation for shared decision-making, being understandable, and causing more benefit than harm.

One month after taking corticosteroids, 27 out of every 50 patients with ulcerative colitis improve their symptoms, 15 patients worsen their symptoms, and 8 ones do not respond to the medication.

Fig. 2: Sample of the patient decision aid.

DISCUSSION

For the first time in Iran, this study was conducted to develop a PDA for selecting a treatment option for patients with IBD. The developed PDA helps patients make the decision aligned with their preferences and values to choose their appropriate treatment by providing useful information about the types of treatment options, the success rate of each option, cases of disease recurrence after using each treatment option, and their side effects.

Nine out of every 10,000 patients with inflammatory bowel disease who use azathioprine during the remission phase of the disease develop lymphoma, while the incidence of lymphoma in patients who do not take the drug is 3 per 10,000.

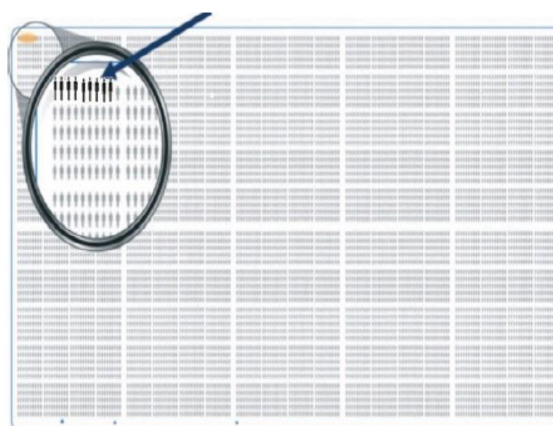

Fig. 3: Sample of the patient decision aid.

Using PDA provides the patient with sufficient information about treatment options so that the patient individualizes the information, understands the ability to participate in treatment, recognizes the individual desires, understands the potential advantages and disadvantages of the decisions made, shares values with caregivers, and acquires decision- making skills.[16] Dubois (2012) developed a PDA in Canada for patients with ulcerative colitis to help them choose between ileostomy and ileal anal-pouch reconstruction.[17] In 2020, Baker and colleagues made a PDA in England to choose between medical or surgical treatment for patients with ulcerative colitis.[8] The importance of using PDAs for shared decision making in patients with IBD has reached such a level that today, not only PDAs are used to choose the appropriate treatment method but also it is emphasized that PDAs are used for the treatment of the complications of diseases such as perianal fistulas in patients with Crohn's disease.[18]

Many of the developed PDAs have not been published, or they lack a full explanation of how they were developed. Besides, limited frameworks such as the Ottawa framework,[19] and the Dutch Institute for Healthcare Improvement [20] have been published to develop PDAs. In these frameworks, details related to the implementation of the steps have not been provided.[6] PDA development in this study is based on the model used by Coulter and colleagues,[15] and Shillington and others.[6] In this study, the PDA for patients with IBD was developed with the participation of an inter-professional team; and in all stages of PDA development, the patient's preferences and needs were considered. Despite being similar to PDAs about IBD in western countries, the authors have tried to develop a new PDA based on local culture, patients' health literacy, and healthcare system policies in Iran.

The PDA developed in this study is based on the evidence and recommendations of the IBD guidelines. The feedback received from clinicians and patients showed their satisfaction with using the PDA. But, it is important to note that all PDAs' ultimate goal is to ensure their implementation in the clinic. The results show that only 44% of the PDAs were used by clinicians in the clinic after initial trials.[21] Various studies have identified several barriers to the implementation of PDAs in clinics. One of these barriers is that the use of PDAs is time-consuming.[22-24] Lack of reimbursement system is another obstacle in using PDAs by clinicians. By providing reimbursement facilities, insurance companies can motivate physicians to use shared decision-making and PDAs.[22, 23] Clinicians' reluctance to use PDAs, fear of legal liability to use PDAs, lack of sufficient space in the office or medical center for their implementation, obsolescence of the PDAs content are other factors that prevent the implementation of these tools in clinics.[21, 22]

To address the barriers of implementing PDAs, the most important solution is applying a user-centered plan. Researchers should develop PDAs with the full participation of end-users and do an interactive consultation process with users at all development stages.[23,25] Moreover, in this study, the researchers focused their efforts on using the opinions of patients with IBD,

gastroenterologists, and nurses involved in the care of this group of patients at all stages. Finally, in the pilot implementation of this PDA, 100% of physicians and 86% of patients were satisfied with its use and implementation.

The PDA developed in this study is in the form of a booklet. If this product was provided in the form of electronic software, patients could read it on their phone or other digital devices even before visiting the doctor, and then they would be more ready to exchange views with the doctor. Besides, it was much easier to update the product. This PDA should be extensively reviewed on many patients and clinicians to ensure its usefulness, applicability, and comprehensibility. Besides, in many guidelines provided to develop PDAs, the product is eventually peer-reviewed by a number of external professional evaluators,[15] while in this study, the product was only tested in a real-world environment by patients and clinicians. Therefore, peer review was not performed by external experts. Due to the fact that this study was conducted as a pilot, more extensive studies are needed to evaluate its validity and feasibility.

CONCLUSION

The developed PDA complements the relationship between the patients and health care providers and cannot replace the health care providers. The tool developed in this study improves shared decision-making, increases patient adherence to treatment, enhances the quality of clinical interactions between the patients and clinicians, and improves the quality of care in various dimensions of IBD. Based on the benefits and side effects of different treatment methods, this PDA can help patients participate in the decision-making process and select the best treatment from various medical and surgical treatment methods.

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ETHICAL APPROVAL

The Ethics Committee of Isfahan University of Medical Sciences approved this study (IR.MUI.RESEARCH.REC.1397.322). Besides, verbal and/or written consent was obtained from all participants in this study to comply with ethical standards.

CONFLICT OF INTEREST

The authors declare no conflict of interest related to this work.

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