

ORIGINAL RESEARCH

Laying the Groundwork: A Pilot Study Exploring Improved Endometriosis Management Strategies in Primary Healthcare

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Objective: To evaluate if a brief educational intervention for primary health care staff regarding endometriosis gives sustainable knowledge of endometriosis symptoms and if a brief questionnaire for women seeking care for common symptoms is feasible in the Swedish primary care context.

Design: Pilot study.

Setting: 3 primary care centres (PCCs) in Sweden. Exploring knowledge among staff about endometriosis at baseline and 3 months after an information workshop. Evaluation of feasibility of a brief questionnaire for women seeking care for common symptoms For PCC personnel: knowledge about endometriosis at baseline and after 3 months. For patient questionnaire: whether adequate, understandable, acceptable, and feasible.

Participants: Females in primary care centre waiting room, and staff members at participating PCCs.

Results: The knowledge level of endometriosis was improved or sustained after 3 months compared to baseline among staff at PCCs. Over 90% of the patients stated that the questionnaire was adequate, understandable, acceptable, and feasible.

Conclusion: We found that an educational programme improved the staff's knowledge about endometriosis. The programme together with the patient questionnaire could be a way to enhance knowledge about endometriosis among PCCs. This combined effort might facilitate earlier detection and treatment of women with endometriosis.

Keywords: endometriosis, primary care, diagnosis, educational intervention

Introduction

Endometriosis is an estrogen-dependent, benign, chronic inflammatory disease, characterised by endometrial-like tissue outside of the uterus. In Sweden, the diagnosis has been used for approximately 50 years.^{1,2} Symptoms are multiple and diverse: dysmenorrhea, dyspareunia, pain in the abdomen often in the pelvic area, irregular bleeding, cystitis-like problems, bowel problems, infertility, depressive symptoms, feelings of ill health, tiredness, lack of energy and chronic pain.^{3,4} Approximately 60% of the women suffering from endometriosis have symptoms. Symptoms vary depending on the organ that is affected. The correlation between the extent of the endometriosis and the amount of pain experienced by the patient is not strong.⁴

Endometriosis has many differential diagnoses, including gynaecological problems such as myoma, polyps, infections, misplaced intra uterine device (IUD), but also lactose intolerance, Irritable Bowel Syndrome (IBS), Inflammatory Bowel Disease (IBD), chronic obstipation, colitis, depression, psychosocial problems and abuse, and musculoskeletal problems (disc hernia, fibromyalgia), thus making it difficult to diagnose.⁴

Several explanatory models exist concerning the disease, and the pathogenesis is not conclusive. There is a high risk of contracting endometriosis if a first-degree relative suffers from it, indicating a hereditary factor. One theory is that there are different mechanisms/causes depending on where the endometriosis is located.⁴

Among all women in childbearing age, about 2–10% suffer from endometriosis to a lesser or more serious extent.^{4,5} In Sweden, that corresponds to approximately 200000 women Further, 25–70% of all women with menstrual and pelvic pain and 20–50% of all infertile women suffer from endometriosis. Some women with endometriosis never experience any symptoms (~20%).⁴

Due to diagnostic difficulties, women with endometriosis usually have symptoms for many years (6–12 years) before receiving a diagnosis. ^{4,6,7} Some women with longstanding symptoms lack diagnosis. ^{4,6,7} Among younger women (<20 years), endometriosis is often underdiagnosed and time until diagnosis is longer compared to older women. ^{4,7} When the menstrual periods end at menopause, many women experience that the symptoms decrease and even disappear. ⁸

Several studies have shown that women with endometriosis have reduced quality of life, and that this is strongly associated with the amount of pain. Depression is common among patients with endometriosis and even more so among those women with both endometriosis and chronic pain. The time from debut of symptoms to diagnosis and the intensity of pain both correlate with decreased inability to work.⁹

Except for microscopic analysis of a biopsy, there are no laboratory or other diagnostic methods that with certainty can identify endometriosis. The diagnosis is frequently made on the basis of symptom constellation, clinical findings, and hormonal treatment results, ie, as an ex juvantibus diagnosis. The diagnosis can be secured only after surgery and biopsy. Because the symptoms are so unspecific and the diagnostic process tends to be extended, it is often a forgotten diagnosis. We have not identified any fully validated, symptom-based, patient-reported questionnaires for endometriosis. 11

There are several problems and challenges regarding the disease. In addition to the major problem of diagnostic difficulty, finding treatment is a challenge, and it is often difficult to ultimately retain good pain relief. Women with endometriosis cannot be cured, but only relieved from symptoms.⁴

In Sweden, primary care centres (PCCs) are the first line of health care and most patients see a general practitioner (GP) as their first encounter with health care. GPs' knowledge about endometriosis is limited, and this can be one of the reasons why they do not recognise the symptoms that may be caused by endometriosis, leading to diagnostic delay. Current electronic applications concerning endometriosis are all targeting a patient already diagnosed with endometriosis, providing them with tools such as an endometriosis pain diary. 16

Educational interventions to increase the level of knowledge among staff members regarding specific diagnoses or treatments have been studied, and the results differ. Some interventions show increase of knowledge, and some do not. ^{17,18} Perhaps the key is not only to focus on the staff, but also on the patients seeking care for several clusters of rather unspecified symptoms.

We set out to study if it is possible to enhance the general level of knowledge about endometriosis among staff at PCCs, and thereby facilitate identification of women with increased risk of having endometriosis. Our hypothesis was that this would make it possible to reach a diagnosis earlier and thus reduce suffering. To facilitate continuity in the risk identification and pedagogic process, a patient questionnaire/application targeting risk of having endometriosis was included as part of the intervention. Our hypothesis was that this could further increase staff awareness of endometriosis. Therefore, we aim to.

First: To evaluate if a brief educational intervention for primary health care staff regarding endometriosis gives sustainable knowledge of endometriosis symptoms.

Second: To evaluate if a brief questionnaire for women seeking care for common symptoms, aiming at increasing continuous awareness regarding endometriosis, is feasible in the Swedish primary care context.

Method

Study Design

This was conducted as a pilot study

Recruitment and Selection of Study Subjects

A pilot study was performed in the primary care context at three PCCs, strategically sampled regarding location (representing urban, rural and a mix between), number of patients listed and number of staff. An invitation letter explaining the different parts of the pilot study was sent to the PCCs (n=3, one public, two privately run).

The pilot study was divided into two parts. The first part explored PCC staff knowledge of endometriosis at baseline and three months after participation in a brief information workshop at the PCC to evaluate if the educational intervention for primary health care staff regarding endometriosis gave sustainable knowledge of endometriosis symptoms.

The second part evaluated if a brief questionnaire for women seeking care for common symptoms was feasible in the Swedish primary care context.

Part I, staff education: A questionnaire consisting of six short questions testing knowledge about endometriosis was developed (Appendix 1). Each question was coded as either correct (3 points), semi-correct (2 points), wrong (1point), or no answer (0 p). During a lunch meeting at the PCC, the staff were invited to fill in a written questionnaire. The questionnaire was then submitted to the study personnel before the correct answers were presented. After the questionnaire, a short lecture was given about endometriosis that took 40 minutes in total, with time for the staff to ask questions at the end. Three months after the first questionnaire and lecture, a follow up at the PCC was conducted, and the same questionnaire was distributed among the staff members in order to examine knowledge about endometriosis after 3 months, compared to baseline.

Part II, patient questionnaire and patients' perceptions of patient questionnaire: A patient questionnaire was developed consisting of 16 questions: 2 questions concerning age and number of children, and 14 questions based on known endometriosis signs/symptoms according to findings derived from a population study of women.¹⁹ Two study nurses spent a week in the waiting room at each of the PCCs to test the patient questionnaire (<u>Appendix 2</u>). The study personnel asked all female patients aged ~14-50 (in fertile age) in the waiting room if they wanted to participate. Those willing to participate received a written questionnaire to fill in. After having filled in the questionnaire, the patients also answered four questions concerning their perceptions about the adequacy, understandability, acceptability and feasibility of the questionnaire (<u>Appendix 2</u>). All questions, both those regarding endometriosis signs/symptoms and those regarding the questionnaire, had dichotomous response options (YES/NO). Some questions had extra space for the participant to write comments if needed. Our intention was to collect 10 patient questionnaires at each PCC.

Measurements

Ouestionnaire for staff members at baseline and after 3 months.

Patient questionnaire and patients' perceptions of patient questionnaire at baseline.

Outcomes and (Statistical) Analysis

Statistical significance was accepted at p<0.05. Standard statistical methods were used for descriptive statistics. Continuous variables were analysed by independent-samples t-test and categorical variables or frequencies by Pearson chi-square test. In order to more easily compare questionnaires between baseline and the 3-month follow-up, we created an index of the total scores of all the questions and used this in the analyses. To compare the total index between baseline and 3-months follow-up for the three PCCs, we created a line graph. The statistical analyses were made using statistical software SPSS, version 25.

Patient Involvement

The patients were not involved in setting the research questions or design, their contribution will help form the questionnaire to identify endometriosis in primary health care, used in the future.

Ethics

The study has been approved by the Regional Ethical Review Board in Gothenburg, Sweden (Dnr 733–18). All participants, both staff members and female patients in the waiting room, were provided with written and oral

information and signed a written informed consent. This study was performed in alignment with the Declaration of Helsinki.

Results

Three PCCs participated in this pilot study, and 43 staff members completed the knowledge questionnaire at baseline and 55 after 3 months. 106 patient participants completed the patient questionnaire.

The primary care centres consisted of 1 publicly run PCC with ~ 9000 listed patients, 1 private urban with ~ 8000 listed patients, and 1 private/urban (city) PCC with ~ 9500 listed patients with multi-ethnic origin.

The endometriosis questionnaire and lecture were conducted and completed at the PCCs with all staff available on that particular day - see Figure 1 for number of participants and Table 1 for participants' professions.

The number of participating health professionals was higher at all PCCs after three months.

The mean knowledge level about endometriosis at the three PCCs, both separately and in total, at baseline and after 3 months is presented in Figure 2. The result shows sustained and improved levels of knowledge after 3 months at all 3 sites.

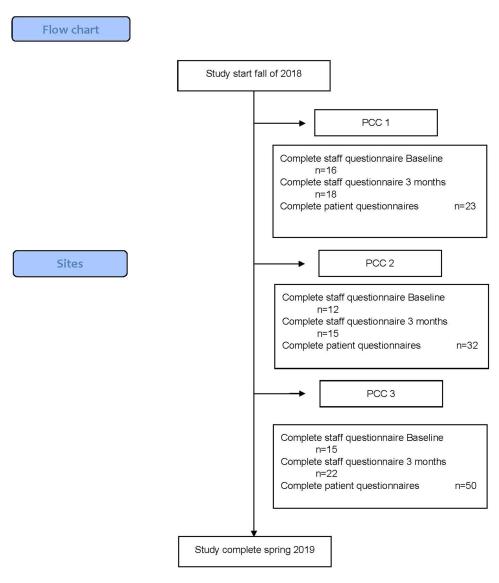


Figure I Flow chart. Data collection at three PCCs from fall 2018 to spring 2019.

Table I Staff Composition for All PCCs, Showing Number of Individuals by Profession Among Those Who Responded to the Questionnaire at Baseline and After Three Months, Respectively

Occupation	Questionnaire Baseline	Questionnaire 3 Months
General practitioner	10	15
Registered nurse	15	20
Administrator	2	6
Psychologist/Curator	2	4
Occupational therapist/Physiotherapist	5	4
Assistant nurse	3	4
Student	2	1
Total	39	54
Did not state	4	1
Total all	43	55

Patient Questionnaire

The patient questionnaire was answered by 106 patients, but one questionnaire was excluded because the patient's sex at birth was male, resulting in 105 questionnaires. Of the women, 73% had regular menstrual periods, 60% experienced pain in their stomach during their menstruation, 46% needed pain killers during menstruation, and 11% used other medicines besides pain killers for menstrual pain. Around 70% had ever been pregnant, and 5% reported infertility. The response rate for patient questions including questions concerning the construction of the questionnaire is shown in Table 2.

The mean age of the women who answered the patient questionnaire was 34.6 (range 13–58, SD 8.5) years. The majority (63%) had higher education, while 43% had middle and 5% lower education. Of the women, an overwhelming majority did not find that the questionnaire was difficult to complete, that the questions were complicated, or that the questions were perceived as being too sensitive to answer, and 91% understood all the questions (Table 3).

Discussion

In this study that evaluated the effect of a brief educational intervention to staff at PCCs regarding endometriosis and the feasibility of a patient questionnaire, a higher mean level of knowledge about endometriosis was shown among the

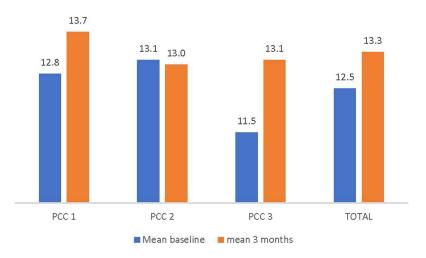


Figure 2 Mean total score on endometriosis questionnaire by staff for the three participating PCCs at baseline and after 3 months, and total scores for all three PCCs combined (right). The outcome is presented in numbers based on the entire staff's scores. There was an increase in scores at PCC I and PCC 3 at 3 months compared to baseline, but no increase at PCC 2.

Table 2 Waiting Room Survey at the 3 PCCs, Patient Questionnaire Items and Frequency of Yes and No Answers. N=105

Question	n	Yes	No	Missing %
Are your periods regular?	99	73.3%	21.0%	0
Have you ever been pregnant?	105	71.4%	28.6%	0
Infertility	105	4.8%	93.3%	1.9%
Do you feel depressed?	105	32.4%	64.8%	2.9%
Do you suffer from a general feeling of illness?	105	46.7%	52.4%	1.0%
(Fatigue, lethargy, nausea)				
Do you feel easily irritated?	105	38.1%	61.0%	1.0%
Do you suffer from pain in the body?	105	33.3%	65.7%	1.0%
Do you suffer from stomachache?	105	33.3%	64.8%	1.9%
Do you have pain in your stomach				
During menstruation?	105	60.0%	35.2%	4.8%
Do you need painkillers during				
Menstruation?	105	45.7%	49.5	4.8%
Do you have any medicine for				
Menstrual pain besides painkillers?	105	11.4%	84.8%	3.8%
Do you stay at home from work/school				
During your menstruation?	105	13.3%	83.8	2.9%
Do you have trouble defecating?	105	22.9%	76.2	1.0%
Do you have urinary tract/bladder problems?	105	16.2%	82.9%	1.0%
Do you experience pain during intercourse?	105	10.5%	85.7%	3.8%

Table 3 Evaluation of Feasibility of the Patient Waiting Room Questionnaire in the Swedish Primary Care Context. Distribution of Patients' Answers (n=105)

Questionnaire questions	n	Yes n (%)	No n (%)	Missing n (%)
Was the questionnaire difficult to complete?	105	5 (4.8)	99 (94.3)	1 (1)
Were the questions complicated?	105	1 (1)	104 (99)	0
Were the questions sensitive to answer?	105	7 (6.7)	98 (93.3)	0
Did you understand all the questions?	105	96 (91.4)	9 (8.6)	0

participating centres at follow up, indicating a remaining effect of the workshop education after 3 months. The patients' perceptions of the questionnaire indicated adequacy, understandability, acceptability, and feasibility.

Our method seems to be a successful way to enhance knowledge about endometriosis on the primary care level. Quibel¹³ showed that general practitioners' knowledge about endometriosis is limited, with possible direct consequences for the delay of the diagnosis. Further, van der Zanden¹² emphasised the need for educational programmes and awareness strategies for first-line medical professionals to be able to shorten the time to diagnosis for women with endometriosis. One of the most important ways to diagnose endometriosis is to ensure that the medical professional be on the alert for endometriosis when a woman seeks medical help for abdominal pain.²⁰

As endometriosis cannot be cured but only relieved,⁴ it is important to start available treatment according to guidelines as soon as possible. There is no need to wait for a gynaecological referral to start treatment, when the GPs, midwives and nurses in primary care suspect endometriosis in their patients. When diagnosis, treatment and relief can be made at an early onset of disease, the gap of inequity can be reduced and the concept of primary care be strengthened for all.^{21–23}

Patients perceived that the patient questionnaire was easy to complete, was not complicated, did not contain sensitive questions and was easy to understand. These findings suggest that the patient questionnaire is feasible and applicable and may potentially be offered as an electronic application in the future. This is well in line with suggestions by Field²⁴ and Fung.²⁵ Both concluded that patient questionnaires can be an important part of clinical practice and help health care professionals to make decisions for individual patients, including targeted interventions that will improve patients' care

outcome. The present study did not evaluate if the women who answered the questionnaires had endometriosis or not. However, when evaluating the answers given, we could estimate that many women had abdominal pain of a degree that affected their lives.

Strengths and Weaknesses of the Study

This study is to our knowledge the first to evaluate an educational intervention targeting the PCC staff together with a patient self-assessment questionnaire about endometriosis.

We conducted our pilot study in the primary care context at the PCCs and thus tested our intervention on the appropriate target group. Since most patients in Sweden first seek care in primary care,²¹ our findings are probably representative. Our main goal was to increase awareness about endometriosis among all staff members at the PCCs, and in order to assess that, we studied the general level of knowledge at the centres and not on the individual level.

To be able to test the applicability of the patient questionnaire, we asked all fertile women in the waiting room area to participate, and in that way, we obtained as many answers as possible. The mean age of the woman who answered the patient questionnaire was around 35 years. This shows that we probably included the relevant patients.

However, the number of staff who answered the questionnaire differed at baseline and at follow-up, and we do not know if all persons who answered the questionnaire the first time also answered it the second time. This could affect the results concerning staff knowledge. Our study acknowledges the limitations posed by the small number of GPs involved and the heterogeneity of the group. The involvement of 10 GPs in the initial phase and 15 in the subsequent phase was a result of the current staff available (In this study we focused on the primary care as a whole, rather on individuals). Despite these limitations, our findings offer preliminary insights into the diagnostic delay of endometriosis in primary care settings. We emphasize the need for further research with a larger and more homogenous sample of GPs to validate and expand upon our findings. Such studies are essential to develop more definitive strategies for reducing diagnostic delays in endometriosis, ultimately enhancing patient care outcomes. This pilot study sets the groundwork for future, more extensive research in this critical area of women's health. However, the educational intervention seems to be a time-effective, easy administered and sustainable method for raising staff awareness of endometriosis.

A possible weakness regarding the patient questionnaire was that the YES/NO response options did not provide space for intermediate answers. On the other hand, this questionnaire was intended to be used as a help to develop an electronic application, and we will be able to use the comments given by the patients to further improve the questionnaire. None of the questions are diagnostic for endometriosis, although all types of pain and staying at home during menstruation should alert the GP and personnel to include endometriosis as a differential diagnosis.

Even though our aim is to develop an application to help patients, and even if our intentions are good, we need to be careful not to be carried away by the increasing trend towards the incorporation of AI methods in patient care. In times when there is an increasing emphasis on the use of technology and the internet, the need for planned introduction and restraint is of great importance. A recent article from Liyanage et.al²⁶ concluded that:

While the use of AI in medicine should enhance healthcare delivery, we need to ensure meticulous design and evaluation of AI applications. The primary care informatics community needs to be proactive and to guide the ethical and rigorous development of AI applications so that they will be safe and effective.

We regard this as highly insightful. Therefore, we aim to develop an application that will benefit the patient as much as possible without breaking ethical principles.

Strengths and Limitations of This Study

- This study is conducted with real patients seeking treatment at primary health centres
- The methodology is easy replicated
- The study is limited to three primary health care centres
- There is a need for further development of the education and questionnaire
- This study helps to highlight and enhance the knowledge about an often forgotten diagnosis that has a large impact on women's overall health

Conclusion

The intervention with a questionnaire and lecture about endometriosis had a positive effect on general knowledge among the staff at the participating primary care centres after 3 months, albeit we do not know how long this positive effect will last. We could not see any negative effects among the participating centres. The patient questionnaire was feasible and easy to understand.

These findings could be important for the development of an educational program together with an electronic application based on the patient questionnaire, so that the staff at the primary care centres will have more knowledge about endometriosis and thus be able to identify women with the disease earlier.

Data Sharing Statement

The datasets used and/or analysed during the current study is available from the corresponding author on reasonable request.

Ethics

This study was approved by the Regional Ethical Review Board in Gothenburg, Sweden (Dnr 733-18). All participants, both staff members and female patients in the waiting room, were provided with written and oral information and signed a written informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflict of interest.

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