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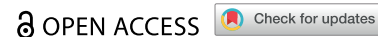


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ARTICLE



Patient-specific affect-abdominal pain interactions in endometriosis: an experience sampling method (ESM) study

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ABSTRACT

Objectives: Cross-sectional studies show that endometriosis-related pain is associated with affect. Measuring these symptoms in real-time in a longitudinal perspective yields the ability to analyze the temporal relationship between variables. The aim was to evaluate the association between affect and abdominal pain, using the Experience Sampling Method (ESM) as a real-time, randomly repeated assessment.

Methods: Thirty-four endometriosis patients and 31 healthy subjects completed up to 10 real-time self-assessments concerning abdominal pain and affective symptoms during seven consecutive days.

Results: Endometriosis patients experienced more abdominal pain and negative affective symptoms, and scored lower on positive affect compared to healthy controls. A significant association was found between abdominal pain and both positive and negative affect in endometriosis patients. For healthy controls, less strong or non-significant associations were found. When looking at abdominal pain as a predictor for affect and vice versa, we found that only in endometriosis patients, pain was subsequently accompanied by negative affect, and positive affect may alleviate pain in these patients.

Conclusions: This study confirms a concurrent and temporal relationship between affect and abdominal pain in endometriosis patients and supports the use of real-time symptom assessment to interpret potential influencers of abdominal complaints in patients with endometriosis.

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Endometriosis; momentary assessment; experience sampling method; positive affect; negative effect; pain; depression; anxiety

Introduction

Endometriosis is a gynaecological disease in which benign endometrium-like tissue is present outside the uterus causing a chronic inflammatory reaction [1]. It is estimated to affect up to 10% of women of reproductive age [1]. Endometriosis can be asymptomatic but is predominantly associated with pelvic pain, dysmenorrhea, dyspareunia, cyclical intestinal complaints, and infertility [2]. Therefore, endometriosis causes a significant social and psychological burden with a negative impact on women's quality of life [3]. Since the severity of symptoms is not directly related to the

extent of the disease, endometriosis-related symptoms may be influenced by psychological or emotional distress [4]. Currently used assessment methods for both physical and psychological symptoms are often retrospective and have important limitations, such as recall and ecological bias. In contrast, the Experience Sampling Method (ESM), a digital momentary assessment method characterized by randomly repeated momentary measurements during the day, measures pain and other symptoms in real-time, while taking into account contextual and psychological factors that might influence the severity of symptoms [5]. Collecting multiple observations within one person

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yields the ability to investigate variation over time and shows patterns of temporal covariation between different variables [6]. At the Maastricht University Medical Center (MUMC), a smartphone application for the use of ESM in endometriosis patients was developed [7]. Given that especially undetected mood and anxiety-related affect may influence the outcome in somatic conditions [8], this study aimed to evaluate the association between affect and abdominal pain in endometriosis patients compared with healthy controls, using the Experience Sampling Method (ESM) as a real-time, randomly repeated momentary assessment tool.

Methods

This prospective study was approved by the medical ethics committee of the Maastricht University Medical Center (MUMC), Maastricht, the Netherlands (Maastricht UMC; Ref. No. 2019-1261).

Study participants

Participants were recruited at the outpatient clinic of the gynecology department at MUMC or were recruited by the Dutch Endometriosis Foundation (Endometriose Stichting) between December 2019 and September 2020. Healthy controls were recruited by an advertisement flyer, which was distributed by social media (Facebook page of the MUMC). Both patients and healthy controls were non-pregnant, premenopausal women aged 18 years or older, who understand the Dutch language and understand how to utilize the ESM application.

Endometriosis was established by physical examination, imaging techniques, or laparoscopy. The patients reported endometriosis-related symptoms (dysmenorrhea, pelvic pain, or dyspareunia) on average at least one day per week in the last three months. A reason for exclusion was any organic explanation for chronic pelvic pain other than endometriosis. Healthy controls were eligible when not reporting any (present or past disorder associated with) chronic pelvic pain. All subjects gave written informed consent before participation.

Data collection

At baseline, patients were asked to fill in an electronic clinical case report form (eCRF) concerning demographic information and medical history in Castor EDC [9]. During the 7-day study period, subjects completed randomly repeated real-time questionnaires using the ESM tool.

ESM tool

At the MUMC, an endometriosis-specific ESM questionnaire was developed according to the international guidelines for the development of patient-reported outcome measures (PROMs) [7]. The development comprised 5 phases: a selection of items based on a literature review, a focus group study, expert meetings, the development of an electronic PROM using a smartphone app, and testing of the usability and feasibility with a pilot study. The tool consists of a morning questionnaire and momentary assessments with questions regarding physical, mental, sexual, and social well-being. The development and validation of this tool have been described previously [10]. All participants downloaded the smartphone application MEASuRE (Maastricht Electronic Abdominal Symptom REporting) on their smartphone, which uses this endometriosis-specific ESM questionnaire. The app sends out an auditory signal 10 times a day at random moments, so participants can complete questionnaires in real-time during their daily life. For this study, only data regarding abdominal pain and affect items were used. "Feeling dispirited (down)" and "feeling stressed" are well known and one of the most commonly investigated affective symptoms in endometriosis patients [11]. These negative affective symptoms, together with their positive counterpart "feeling cheerful" and "feeling relaxed" were selected for this study. The questions were identical between the different moments during the day and are scored on an 11-point Numeric Rating Scale (0 = *not at all* to 10 = *very severely*). All participants were instructed to complete the momentary assessments as often as possible. A questionnaire was closed and considered as missing data when not completed within 10 min following the notification. Thus variables were measured real-time, several times a day for 7 consecutive days, and symptom scores were averaged per subject before a total average score was calculated to correct for differences in compliance between subjects.

Statistical analysis

All analyses were performed in IBM SPSS Statistics 25. To compare differences for continuous outcomes, the independent *t*-test was used in the case of normal distribution. In the case of non-normal distribution, the Mann-Whitney *U* test was used. Proportions for categorical variables were tested using the Chi²-test. A Fisher's exact test was performed in case of fewer than ten cases. A *p*-value of ≤ 0.05 was considered statistically significant. Associations between affect

and abdominal pain were analyzed by using linear mixed models as ESM data are based on a hierarchical, multi-level structure with repeated measurements (level 1) nested within days (level 2) and within-subjects (level 3). Abdominal pain scores were used as the dependent variable and affective symptoms as the independent variable. To analyze whether affective symptoms at one point in time were potential provoking factors for abdominal pain later that same day, lagged scores (i.e. $t = -1$) were used. Similarly, time-lagged analyses were conducted for abdominal pain as a predictor variable for affective symptoms. All models are based on random intercept and an Autoregressive (AR(1)) covariate structure for repeated measures.

Results

Study population

In total, 38 endometriosis patients and 32 healthy controls were enrolled. Due to technical issues with their smartphones, four endometriosis patients and one healthy control were excluded from the analysis. The baseline characteristics are shown in Table 1.

Compared to healthy controls, endometriosis patients were slightly older, had a higher BMI, and were more likely to be unemployed and experienced more often unplanned childlessness. Furthermore, endometriosis patients more frequently used hormonal therapy and pain medication compared to healthy controls. Educational level, relationship status, intoxications, and traumatic life events in the past were not statistically different between groups.

Compliance

Between 19 (27%) and 63 (90%) out of 70 assessments were completed per individual. Average compliance between endometriosis patients (56.4%; 39/70) and healthy controls (53.1; 37/70) showed no statistically significant difference ($p = .151$). One healthy control did not complete retrospective questionnaires (3.2%).

ESM symptom scores

Table 2 shows the average scores for abdominal pain and the variables for negative affect and positive affect. On average, endometriosis patients experienced more abdominal pain and stress and scored higher on

Table 1. Baseline characteristics.

	Endometriosis (n = 34)	Healthy controls (n = 31)	p-value
Age (Mean [SD])	35.2 [8.7]	30.7 [8.3]	.037
BMI (Mean [SD])	25.7 [5.1]	23.2 [3.3]	.021
Educational level (n, (%))			.924
High school	2 (6)	2 (6)	
College/university	32 (94)	29 (94)	
Work status (n, (%))			.002
Student	2 (6)	12 (39)	
Unemployed	9 (26)	2 (6)	
Employed	23 (68)	17 (55)	
Relationship status (n, (%))			.831
Single	8 (24)	8 (26)	
In relationship	26 (76)	23 (74)	
Use of hormones (n, (%))	25 (74)	20 (64)	.035
Regular use of pain medication (n, (%))	26 (74)	1 (3)	<.001
Smoking (n, (%))	6 (18)	1 (3)	.061
Regular use of alcohol (n, (%))	25 (74)	28 (90)	.081
Unplanned childlessness (n, (%))	4 (12)	0 (0)	.049
Traumatic life event* (n, (%))	4 (12)	2 (6)	.460

SD: standard deviation; n: number of patients.

*Traumatic life events had different causes, such as sexual abuse or losing a parent as a child, however, in 3 out of 6 positive answers the cause was not described.

Table 2. Average symptom scores for endometriosis patients vs healthy controls, measured in real-time, several times a day.

Symptom score	Endometriosis (n = 34)	Healthy controls (n = 31)	p-value
Abdominal pain (Mean [SD])	2.79 [2.33]	0.33 [0.96]	<.001
Negative affect:			
Feeling dispirited (Mean [SD])	2.01 [2.15]	1.11 [1.82]	<.001
Feeling stressed (Mean [SD])	2.18 [2.35]	1.81 [2.23]	.037
Positive affect:			
Feeling cheerful (Mean [SD])	5.23 [1.92]	6.90 [1.50]	<.001
Feeling relaxed (Mean [SD])	5.38 [1.54]	6.41 [2.13]	<.001

SD: standard deviation.

the variable “feeling dispirited.” In addition, endometriosis patients scored lower on positive affective variables compared to healthy controls.

Association between abdominal pain and affect

Table 3 shows associations between abdominal pain and affect for endometriosis patients and healthy controls. In the endometriosis group, a significant association was found between concurrent abdominal pain and scores for positive and negative affect. I.e. on average, a 1-point increase in “feeling dispirited” was associated with 0.15 points increase in abdominal pain (SE 0.03; $p < .001$). In healthy controls, this association was also found but only 0.05 (SE 0.03; $p = .020$). In healthy controls “feeling stressed,” “feeling cheerful”

and “feeling relaxed” were not associated with abdominal pain.

Associations between abdominal pain and affective symptoms can vary highly between individuals, which is demonstrated by the individual regression coefficients for associations between “feeling dispirited” and abdominal pain, ranging from -0.44 ($p = .462$) to 2.50 ($p < .001$). This means that, in one individual, an increase in feeling dispirited does not lead to an increase or decrease in abdominal pain, whereas in another individual, a 1-point increase in feeling dispirited leads to an increase in abdominal pain of 2.50 points. Figure 1 visualizes the repeated measures for abdominal pain and dispirited mood over the 7-day study period, separately for 2 patients with endometriosis, which were selected to illustrate between-subject

Table 3. Associations between abdominal pain and affect in endometriosis patients and healthy controls.

	Endometriosis (n = 34) B [SE]	Healthy controls (n = 31) B [SE]
Negative affect:		
Feeling dispirited (down)	0.15 [0.03], $p < .001$.05 [0.02], $p = .020$
Feeling stressed	0.12 [0.03], $p < .001$	-0.02 [0.02], $p = .412$
Positive affect:		
Feeling cheerful	-0.14 [0.04], $p < .001$	-0.04 [0.02], $p = .063$
Feeling relaxed	-0.06 [0.02], $p = .012$	0.00 [0.01], $p = .805$

Regression coefficient (B) and standard error (SE) were tested using linear mixed models with abdominal pain as the dependent variable and the affective symptom as the independent variable, corrected for repeated measures (AR1 covariate structure).

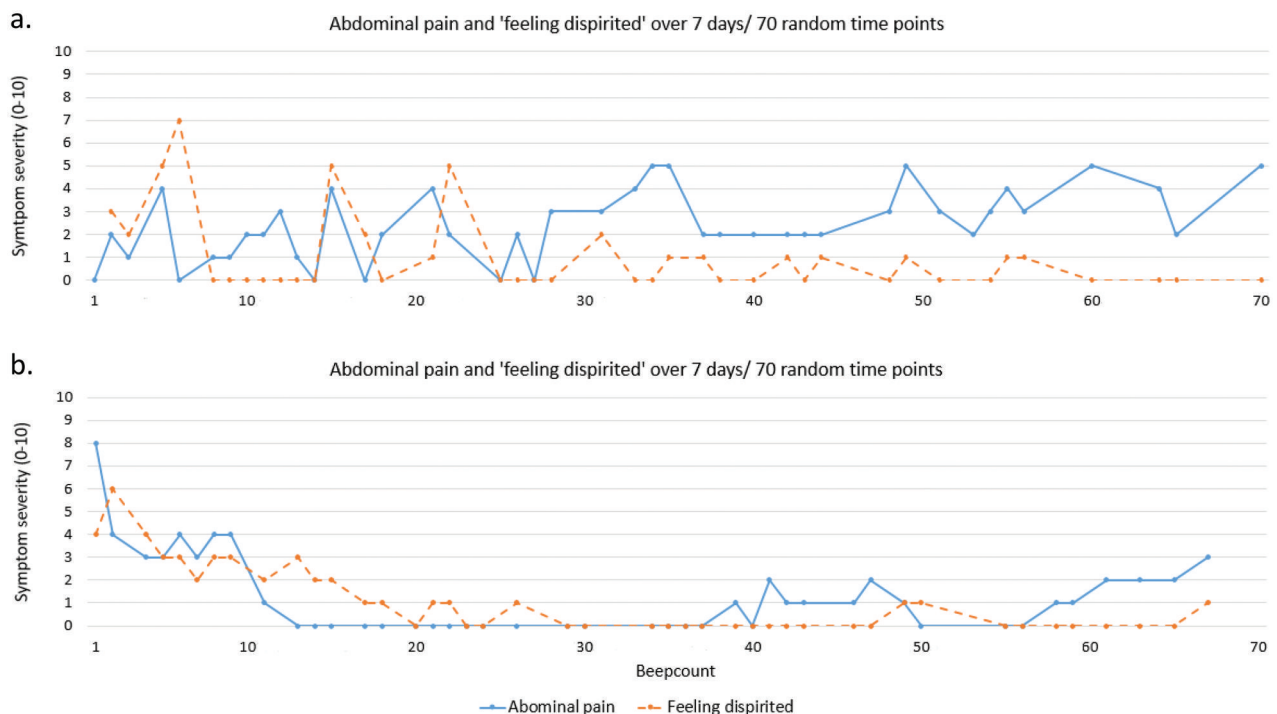


Figure 1. Longitudinal scores for abdominal pain and “feeling dispirited” for two individual patients. The x-axis represents the 70 consecutive assessments: each within a 90-minute timeframe between 7:30 AM and 10:30 PM for each day with a maximum of 10 assessments per day. The heterogeneity between subjects with endometriosis is shown by the different patterns of symptom scores; also indicated by the difference in corresponding regression coefficients for a. 0.12; b. 1.07.

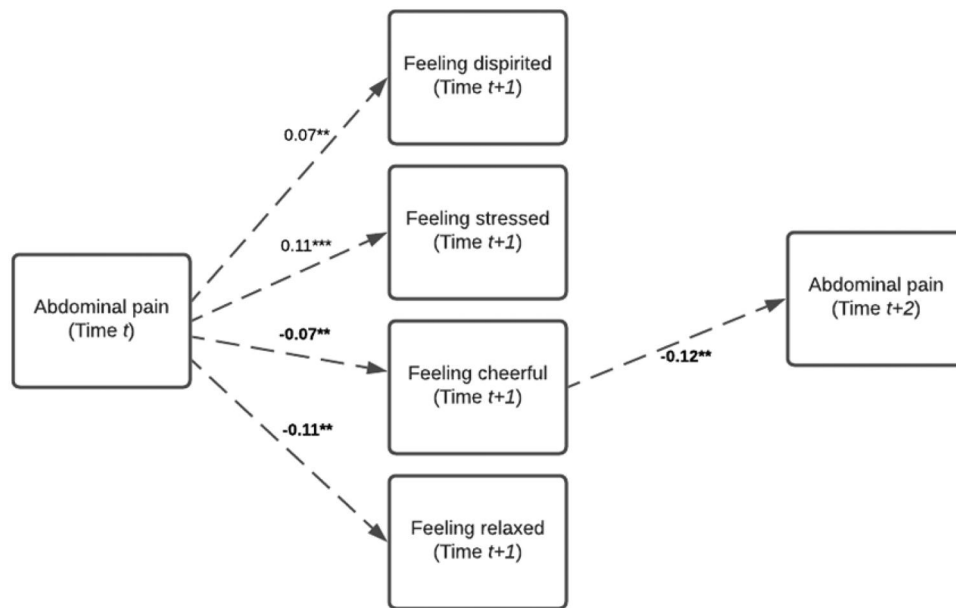


Figure 2. Temporal associations from abdominal pain at time t to the severity of positive and negative affective symptoms at $t+1$, and vice versa. The numbers represent Beta coefficients, tested using multi-level linear regression modeling on ESM data. $*P < 0.01$; $**P < 0.001$. Bold numbers represent negative predictions. Only significant associations are shown, therefore all lines represent predictions for endometriosis patients. No significant temporal associations were found for healthy controls. Questionnaires are assessed within a 90-minute timeframe. However, as patients were not obligated to fill in every questionnaire during the day, the follow-up questionnaire could be assessed later on the same day.

differences in the association between “feeling dispirited” and abdominal pain.

Abdominal pain as a predictor for affect and vice versa

Figure 2 shows the associations between abdominal pain at one point and affect on the next measurement moment and vice versa (time-lagged or temporal associations). Questionnaires are assessed within a 90-min timeframe. However, as patients were not obligated to fill in every questionnaire during the day, the follow-up questionnaire could be assessed later on the same day. On average, the time between measurements was 2 h and 22 min (with a standard deviation of 1 h and 45 min and a maximal time range of 11 h and 42 min). Abdominal pain scores at Time t were associated with higher scores for “feeling dispirited” and “feeling stressed” and lower scores for “feeling cheerful” and “feeling relaxed” at Time $t+1$ for endometriosis patients, but not for healthy controls (only significant predictions are shown in the Figure). Furthermore, Figure 2 shows the association between affective symptoms measured at one point with abdominal pain on the next. Feeling dispirited and feeling stressed at Time $t+1$ were not significant predictors for abdominal pain at Time $t+2$ in both patients with endometriosis and healthy controls.

“Feeling cheerful” was associated with less abdominal pain during the following measurement moment in endometriosis patients. A trend is also seen for “feeling relaxed,” although this result was not significant. Positive affective symptoms were not associated with consecutive abdominal pain in healthy controls.

Discussion

Summary of findings

This study aimed to evaluate the association between affect and abdominal pain in endometriosis patients, using the Experience Sampling Method (ESM) as a real-time, randomly repeated assessment tool. In addition to other cross-sectional studies [11], the current study shows that endometriosis patients with chronic pelvic pain experience more negative affective symptoms compared with healthy controls. Measuring daily life symptoms in real-time in a longitudinal perspective yields the ability to analyze the temporal relationship between variables. A significant association was found between abdominal pain and both positive and negative affect in endometriosis patients. For healthy controls, less strong or non-significant associations were found. When looking at abdominal pain as a predictor for affect and vice versa by using time-lagged (or temporal) associations, we found that only in endometriosis patients, pain was subsequently

accompanied by negative affect, and positive affect may alleviate pain in these patients. Two mechanisms might be involved in this. On the one hand, inflammation and consecutive sickness behavior might be involved in provoking negative affective complaints [12]. On the other, resilience, as portrayed by positive affect, may prevent patients from a more intensive pain perception [13]. Although the current investigation was a short-term follow-up study, with our data, causality cannot be confirmed on the revealed associations. Time-lags between predictive variables and the dependent variable varied between subjects and days, which makes it difficult to compare data. Furthermore, temporal associations are based on a relatively short time interval, on average 2 h and 22 min, and no long-term abdominal pain-affective symptom association was measured. However, the most important finding would be the individual differences in associations between abdominal pain and concurrent affect. Regression coefficients for associations between “feeling dispirited” and abdominal pain ranged from -0.44 ($p = .462$) to 2.50 ($p < .001$). This means that, in one individual, feeling dispirited is not associated with abdominal pain, whereas in another individual, a 1-point increase in feeling dispirited leads to an increase in abdominal pain of 2.50 points. This underlines the importance of providing patients with insight into individual symptom formation and could help clinicians to provide individualized treatment strategies, e.g. which patients might benefit from psychological treatment, such as cognitive behavioral therapy. Previous studies have shown that improvement of pain alone does not automatically improve depressive symptoms [14]. However, improvements in depression, anxiety, and pain catastrophizing could influence pain perception [15] and, therefore, may improve quality of life and social functioning which in turn might reduce societal relevant health care costs [16].

Strengths and limitations

For the current study, data were collected using a tool based on specific recommendations for PROM development [7]. Associations for endometriosis patients were compared to healthy controls which put extra confidence to the conclusion that the presented results are reflecting a population of women with endometriosis-related abdominal pain. However, laparoscopy was not mandatory for the diagnosis of endometriosis and HC did not undergo a laparoscopy to determine the presence or absence of endometriosis.

Therefore, it could be possible that there were asymptomatic endometriosis patients in the healthy control group. A large number of repeated measures significantly increases the power of the analyses and the criteria for power calculation as advised by Schuster *et al.* were met [17]. Each participant completed on average 39 questionnaires which generated a large dataset. Given the ESM questionnaire is available as a smartphone application, a potential limitation is that the compliance may be hindered by technical issues. However, this is accounted for as we excluded 4 patients that reported poor compliance due to technical issues, and by using advanced statistical modeling correction for repeated measures and within-subject autocorrelation. In addition, in the current study, the average compliance (55%) was considerably higher than the generally accepted compliance rates of 33% in other studies [18,19]. However, 2 individual endometriosis patients and 4 healthy controls did not meet this 33% criterion but were not excluded from the study to minimize the risk of motivational selection bias (which could also be caused by recruitment *via* advertisement). Given the advertisement was done by the MUMC, the control group contains a high number of (medical) students which explains the relatively young age. In future studies with the ESM tool, age-matching could be performed.

Suggestions for future research

Future analyses including information concerning the endometriosis stage could give additional insight into the heterogeneity of the affect-abdominal pain interaction between subjects. Furthermore, in this study, no data were analyzed concerning other endometriosis-related pain symptoms such as dyspareunia or dysmenorrhea nor the influence of the menstrual cycle on affective symptoms was taken into account. Additionally, as pain is a multifactorial symptom, many other factors could be associated with its fluctuation, such as quality of sleep, fatigue, gastrointestinal symptoms, social factors and food, medication, or use of substances. All of these variables are assessed by the endometriosis-specific ESM tool that was used during the current study. Follow-up analyses are planned concerning the gathered data.

Furthermore, the variety in pain and affective symptoms, but also gastrointestinal symptoms, makes it difficult to diagnose endometriosis as these symptoms could also be attributed to other conditions such as irritable bowel syndrome (IBS) and overactive bladder syndrome (OAB). Multifactorial pathophysiology has

been proposed for each of the syndromes and diagnosis often relies on descriptive symptom-based diagnostic criteria, giving no clue about symptom formation. We aim to compare the association between affect and abdominal symptoms in endometriosis, IBS, and OAB patients using the ESM in the future.

In conclusion

This study demonstrates that abdominal pain in endometriosis patients is concurrently and longitudinally associated with both positive and negative affective symptoms and that the magnitude of this association is highly variable between individuals. Measuring these individual associations could provide patients and caregivers with insight into symptoms and their course over time. Furthermore, using real-time and repeated measurements when interpreting contextual and psychological influencers of abdominal pain in patients with endometriosis may support treatment choices and could benefit disease management efficacy.

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