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Effects of Demographics and OTC Analgesics on Ovarian Cancer Symptoms

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Abstract

Several independent studies have shown that ovarian cancer is not a silent disease and that many women have symptoms before diagnosis. These symptoms include abdominal/pelvic pain, feeling full quickly, and bloating. However, little information is known about what personal characteristics, medical conditions, or habits influence these symptoms or how they are reported. This report evaluates and describes factors that may be associated with how a patient reports these symptoms. We show that a small number of characteristics, include race, number of gynecologic conditions, and reason for clinic visit, may influence what symptoms are reported and the specific pattern of reporting.

Keywords

ovarian cancer; Symptoms Index; over-the-counter pain medications

INTRODUCTION

Ovarian cancer has commonly been referred to as a silent disease. It wasn't until 2004 that select symptoms were identified to be more common among women with ovarian cancer than healthy women or those with benign gynecologic conditions.¹ The results of several independent studies have shown that this select group of symptoms may be indicative of

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ovarian cancer when they present in a particular pattern.^{1–4} These symptoms, which consist of abdominal/pelvic pain, feeling full quickly/inability to eat normally, and bloating, have been used to develop a tool that can be implemented by researchers and clinicians to identify women who may benefit from undergoing traditional diagnostic tests for ovarian cancer, such as a CA125 blood test and/or transvaginal ultrasound. This tool is called the Symptom Index (SI).⁵ Based on self-reported information, the SI is designed to assess the frequency and duration of each symptom. A woman is considered to have a positive SI if one or more of the aforementioned symptoms are new to her within the past year and have occurred more than twelve times per month.⁵

The SI has shown considerable promise as an ovarian cancer screening tool. When used alone, the sensitivity appears to be approximately 56% for early-stage disease and 80% for late-stage disease.⁵ In addition, it has been demonstrated that the sensitivity of CA125 to detect early-stage disease increases from 64.5% when used alone to 80.6% when used in combination with the SI.⁶ Due to these findings, the use of symptoms as a potential screening tool for ovarian cancer has been gaining momentum. However, understanding the manner in which screening and diagnostic tools are influenced by innate personal characteristics, habits, medication use, or clinical procedures is important to ensure their utility and accuracy.⁷ Therefore, we sought to evaluate if there is an association between use of over-the-counter (OTC) analgesics and results of the SI. We then assessed if there is an association between patient characteristics and the pattern of symptoms reporting (i.e.: the frequency and duration of symptoms).

MATERIALS AND METHODS

Study Population

The study population includes the first 1,002 women to enroll in a prospective study that was designed to evaluate the feasibility of collecting information on symptoms in a women's health clinic. All study activities were reviewed and approved by the institutional review boards at the University of Washington and the Fred Hutchinson Cancer Research Center. The eligibility criteria for the study were as follows: (1) 40 years of age or older, (2) have at least one ovary, (3) not pregnant at the time of the clinic visit, (4) are able to give consent, and (5) had not participated in the study within the previous 12 months. All study participants provided informed consent prior to enrollment.

Women completed a self-administered questionnaire at the time of enrollment that included questions regarding their basic demographics, reason for clinic visit, and medical and family history. For the purposes of these analyses, women were categorized as follows for each characteristic: age (40–49 or 50), race (white, Black, Asian, other/unknown), number of children (none or 1), personal history of breast cancer (yes or no), reason for clinic visit (routine screening, routine follow-up, concerned about something), gynecologic condition (endometriosis, fibroids, ovarian cysts, other, 1 of these conditions), and general medical conditions (irritable bowel disease, urinary tract infection, interstitial cystitis, acid reflux, diabetes, hypertension, heart disease, thyroid disease, 1 of these conditions). Women were categorized as premenopausal, perimenopausal, or postmenopausal based on self report of their current menstrual periods. Premenopausal women included those who reported they

were still having periods or were pregnant or nursing and were under the age of 50. Perimenopausal women included those who reported they were still having periods or were pregnant or nursing but were over the age of 50. Perimenopausal women also included those who reported they were possibly going through menopause, regardless of their age, as well as women who were under the age of 50 but reported taking hormone replacement therapy. Postmenopausal women were included those who reported their periods had stopped naturally or due to surgery, regardless of their age. Women were also asked questions regarding their personal use of the following OTC analgesics: aspirin, non-aspirin (including: non-steroidal anti-inflammatory drugs (NSAIDS)), and pre-menstrual syndrome (PMS) medication (including: Midol). Women who reported taking any of these medications were asked to report their frequency of use (never, daily, 2–7 times/week, <5 times/month, only during PMS).

Measuring the Symptoms

The study participants completed the SI, which is a short questionnaire designed to assess the presence or absence of the following symptoms: abdominal or pelvic pain, feeling full quickly/ inability to eat normally, and abdominal bloating or increased abdominal size. Women who reported they had one or more of the above symptoms were asked to report the frequency of their symptom (0–5 days, 6–12 days, and >13 days per month) and the duration of their symptom (<1 month, 1–6 months, 7–12 months, or >1 year). Women were classified as having a positive SI if one or more of the symptoms occurred >12 times/month for less than one year.⁵ Since our objective was to closely evaluate the pattern of symptoms reporting, the remaining symptoms were categorized as follows: (1) New and Moderate Frequency (symptom occurred 12 months and 6–12 days/month), (2) New and Infrequent (symptom occurred 12 months and 1–5 days/month, (3) Chronic (symptom occurred 13 months at any frequency).

Statistical Methods

The characteristics of the study population were assessed using descriptive statistics. The association between the patient characteristics and the results of the SI was evaluated using the Fisher's exact test. STATA statistical software package [version 10.0, Stata Corporation, College State, TX] was used for all analyses. The statistical test were two-sided and considered to be statistically significant at $p<0.05$.

RESULTS

Sample Characteristics

Table 1 summarizes the patient's characteristics and the observed association between each characteristics and results of the SI. Approximately 7.6% of the total sample had a positive SI. There was no association between age, menopausal status, number of children, personal history of breast cancer or gynecologic conditions and the outcome of the SI. However, a statistically significantly higher proportion of Black women had a positive SI than white or Asian women (22% vs. 7% vs. 8%; $p=0.01$). Women who were attending the clinic because they were concerned about something were more likely to have a positive SI than women who were there for a routine follow-up or a routine screening test (14% vs. 9% vs. 4%;

$p<0.001$). Approximately 21% of the women who reported having more than one gynecologic condition had a pattern symptoms that resulted in a positive SI ($p<0.001$); however, there was no association between the individual gynecologic conditions and the SI. Similarly, women who reported having more than one medical condition had a pattern of symptoms that resulted in a positive SI ($p<0.001$), but again there was no association between the individual medical conditions and results of the SI. The single medical conditions that yielded the highest proportion of positive SI results were heart disease, irritable bowel syndrome, and acid reflux, with 22%, 13%, and 9% of the women with these conditions having a positive SI, respectively.

OTC Analgesics

Aspirin was the most commonly used OTC medication, with 20% of the sample reporting daily use. There was no association between the use of aspirin ($p=0.54$), non-aspirin analgesics ($p=0.29$), or PMS medications ($p=0.14$) and results of the SI (data not shown).

Symptoms Reporting

Table 2 summarizes the association between each personal characteristic and the pattern of symptom reporting. There was a statistically significant association between age and abdominal/pelvic pain, but not between age and feeling full/can't eat normally or bloating. Specifically, compared to women 40–49 years of age, a higher proportion of women 50 years reported abdominal/pelvic pain in a pattern that resulted in a positive SI (7% vs. 12%; $p=0.04$). In addition, 62% of the women 40–49 years of age were classified as having chronic abdominal/pelvic pain versus 53% of the women 50 years of age. A similar pattern was observed for menopausal status, which resulted in a statistically significant association with abdominal/pelvic pain, but not feeling full/can't eat normally or bloating. Compared to premenopausal or perimenopausal women, a significantly higher proportion of post-menopausal women reported abdominal/pelvic pain in a pattern that resulted in a positive SI (6% vs. 5% vs. 14%; $p=0.05$). Race was significantly associated with abdominal/pelvic pain ($p=0.03$) and bloating ($p=0.02$), but not feeling full/can't eat normally. Approximately 18% of the Black women who reported having abdominal/pelvic pain reported having that symptom in a pattern that resulted in a positive SI. This was true for only 9% of the white women and none of the Asian women. On the contrary, 21% of the Asian women who reported having bloating had that symptom in a pattern that resulted in a positive SI, compared to 12% of the white women and 13% of the Black women. The reason for the visit to the clinic was statistically associated with abdominal/pelvic pain ($p<0.001$) and bloating ($p=0.03$), but not feeling full/can't eat normally. There were no statistically significant associations between number of children, having a single gynecologic condition, or a single medical conditions and the pattern of symptoms reporting.

DISCUSSION

Ovarian cancer has the highest mortality rate of all gynecologic malignancies⁸, with a five-year survival rate of less than 30% among women who are diagnosed with late-stage disease.⁹ On the contrary, women who are diagnosed when the tumor is still confined to the ovary have a five-year survival rate of 70–90%.⁹ Therefore, there is substantial interest in

identifying new screening tools that can accurately diagnose ovarian cancer when it is in its early stages.

In our sample of 1,002 women, we found that a statistically significantly higher proportion of Black women had a positive SI than white or Asian women. Race was significantly associated with abdominal/pelvic pain and bloating, but not with feeling full/can't eat normally. The incidence rate of ovarian cancer is lower for Black women than Caucasian women (10.2 per 100,000 versus 13.5 per 100,000, respectively)¹⁰; however, Black women may have different risk factors for ovarian cancer than white women¹¹ and may experience a shorter survival than White women.¹² This may be attributed to differences in access to treatment. We also found that women who were attending the clinic because they were concerned about something were more likely to have a positive SI than women who were there for a routine follow-up or a routine screening test. The reason for the visit to the clinic was statistically associated with abdominal/pelvic pain and bloating, but not feeling full/can't eat normally. These findings may be partially explained by the known associations between cancer worry and cancer screening behaviors. Studies of ovarian cancer screening have shown that participating in a screening program may increase¹³ or decrease¹⁴ women's worry about ovarian cancer and that levels of worry among women at high-risk for ovarian cancer may subside within two years of completing the screening program.¹⁵ However, there is limited information available regarding the manner in which worry influences symptom reporting in the gynecologic setting.

We found no significant associations between any particular gynecologic or medical condition and the SI results, although women with multiple gynecological conditions were more likely to have a positive SI. The single non-gynecological medical conditions that yielded the highest proportion of positive SI results were heart disease, irritable bowel syndrome, and acid reflux, with 22%, 13%, and 9% of the women with these conditions reporting a pattern of symptoms that resulted in a positive SI, respectively. In addition, 12% of the women who reported having more than one medical condition had a positive SI. We found no association between the use of over-the-counter pain medications and results of the SI.

STUDY LIMITATIONS AND CONSIDERATIONS

Although well-trained study nurses were used to recruit women into this study, the women self-reported the symptoms they were experiencing. Self-reported data is subject to recall bias. This may be especially true among women who were visiting the doctor's office because they were concerned about something or among women with multiple medical conditions.

IMPLICATIONS FOR WOMEN'S HEALTH PRACTICE

This study has implications for nurse practitioners who are dedicated to women's health. Nurse practitioners are often tasked with completing annual health assessments of their female patients. The symptoms included in the SI are fairly nonspecific and may go unnoticed by some women. Given the importance on the frequency and duration of the symptoms included in the SI, it is the role of nurse practitioners to ensure that any symptoms

that are new or frequent to his/her patient is further investigated. This is especially true among nurse practitioners who are treating Black women, those who are visiting the clinic because they are concerned about something and those who have multiple gynecologic conditions and/or select non-gynecological medical conditions.

FUTURE RESEARCH

Additional research is needed to understand the factors that may be driving the observed differences in the SI across racial groups. Although there were no statistically significant differences in the outcome of the SI between women who did and did not have single gynecologic or medical conditions, further evaluation of this issue is warranted as additional women participate in studies of these particular symptoms.

CONCLUSIONS

To our knowledge, this is the first study that has evaluated the association between personal characteristics and the pattern of symptoms reporting with the SI. We found a small number of characteristics that may influence how women report the symptoms they are experiencing. With proper planning, information on these factors can easily be obtained when the SI is completed in the clinic and they can also be addressed when the results of the SI are analyzed, interpreted, or presented.

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Table 1

Patient characteristics and results of the Symptoms Index.

	Total (n=1002) * n (%)	Negative SI (n=926) ** n (%)	Positive SI (n=76) ** n (%)	p-value
Age				
40–49	364 (36)	329 (90)	35 (10)	0.08
50+	628 (63)	587 (93)	41 (7)	
Menopausal Status ***				
Pre	239 (24)	217 (91)	22 (9)	0.22
Peri	172 (17)	164 (95)	8 (5)	
Post	581 (58)	535 (92)	46 (8)	
Race				
White	861 (90)	802 (93)	59 (7)	0.01
Black	37 (4)	29 (78)	8 (22)	
Asian	38 (4)	35 (92)	3 (8)	
Other/Unknown	21 (2)	21 (100)	0	
Number of Children				
None	739 (74)	688 (93)	51 (7)	0.18
One or more	263 (26)	238 (90)	25 (10)	
Personal History of Breast Cancer				
No	948 (95)	874 (92)	74 (8)	0.42
Yes	52 (5)	50 (96)	2 (4)	
Reason for Visit				
Routine screen	494 (49)	476 (96)	18 (4)	<0.001
Routine follow-up	222 (22)	202 (91)	20 (9)	
I'm concerned about something	261 (26)	224 (86)	37 (14)	
Gynecologic Condition				
Endometriosis	15 (2)	15 (100)	0	0.62
Fibroids	91 (9)	82 (90)	9 (10)	0.41
Ovarian cysts	54 (5)	46 (85)	8 (15)	0.06
Other gynecologic problems	69 (7)	60 (87)	9 (13)	0.10
More than 1 of these conditions	89 (9)	71 (79)	18 (21)	<0.001
Medical Conditions				
Irritable bowel syndrome	23 (2)	20 (87)	3 (13)	0.41
Urinary tract infections	15 (1)	14 (93)	1 (7)	0.99
Interstitial cystitis	2 (<1)	2 (100)	0	0.99
Acid reflux	64 (6)	58 (91)	6 (9)	0.63
Diabetes	11 (1)	11 (100)	0	0.99
Hypertension	62 (6)	59 (95)	3 (5)	0.47
Heart disease	9 (<1)	7 (78)	2 (22)	0.51

	Total (n=1002) * n (%)	Negative SI (n=926) ** n (%)	Positive SI (n=76) ** n (%)	p-value
Thyroid disease	63 (6)	59 (94)	4 (6)	0.81
More than 1 condition	277 (28)	227 (88)	32 (12)	0.003
None of the listed conditions	259 (26)	--	--	

* Percents calculated as column totals and many not equal 100% because of missing data or rounding.

** Percents calculated as row totals.

*** Women were categorized as premenopausal, perimenopausal, or postmenopausal based on self report of their current menstrual periods. Premenopausal women included those who reported they were still having periods or were pregnant or nursing and were under the age of 50. Perimenopausal women included those who reported they were still having periods or were pregnant or nursing but were over the age of 50. Perimenopausal women also included those who reported they were possibly going through menopause, regardless of their age, as well as women who were under the age of 50 but reported taking hormone replacement therapy. Postmenopausal women were included those who reported their periods had stopped naturally or due to surgery, regardless of their age.

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Table 2

Pattern of symptom reporting . *

Symptom	Abdominal/Pelvic Pain				Feeling Full/Can't Eat Normally				Bloating/Increased Abdominal Size			
Pattern of Reporting ^a	SI+	New and Moderate Frequency	New and Infrequent	Chronic	SI+	New and Moderate Frequency	New and Infrequent	Chronic	SI+	New and Moderate Frequency	New and Infrequent	Chronic
Age ^{**}												
40–49	13 (7)	25 (13)	33 (18)	116 (62)	16 (19)	13(15)	15 (18)	40 (48)	23 (15)	14 (9)	19 (13)	94 (63)
50+	17 (12)	12 (8)	40 (27)	78 (53)	11 (13)	12 (14)	14 (16)	50 (57)	22 (12)	20 (11)	27 (15)	114 (62)
Menopausal Status ^{**, ***, ***}												
Pre	7 (6)	13 (11)	20 (17)	81 (67)	8 (16)	6 (12)	11 (22)	24 (49)	16 (16)	7 (7)	12 (12)	64 (65)
Peri	5 (5)	10 (14)	16 (22)	44 (59)	4 (15)	8 (30)	3 (11)	12 (44)	4 (6)	11 (17)	13 (20)	37 (57)
Post	19 (14)	14 (10)	37 (27)	69 (50)	15 (16)	11 (12)	16 (16)	54 (57)	25 (15)	16 (9)	21 (12)	107 (63)
Race ^{**}												
White	26 (9)	26 (9)	57 (20)	172 (61)	21 (15)	20 (15)	20 (15)	76 (55)	33 (12)	22 (8)	39 (15)	175 (65)
Black	4 (18)	3 (14)	5 (23)	10 (45)	5 (28)	2 (11)	5 (28)	6 (33)	3 (13)	6 (26)	0	14 (61)
Asian	0	2 (18)	5 (45)	4 (36)	0	1 (20)	1 (20)	3 (60)	3 (21)	1 (7)	2 (14)	8 (57)
Other/Unknown	0	3 (33)	4 (44)	2 (22)	0	2 (50)	2 (50)	0	0	3 (38)	2 (25)	3 (38)
Number of Children ^{**}												
None	20 (8)	31 (13)	57 (23)	139 (56)	18 (14)	21 (16)	25 (19)	67 (51)	27 (11)	29 (12)	34 (14)	154 (63)
One or more	10 (11)	6 (6)	18 (20)	57 (63)	9 (22)	5 (12)	4 (10)	23 (56)	18 (21)	5 (5)	12 (13)	57 (62)
Personal History of Breast Can ^{***}												
No	30 (9)	32 (10)	72 (22)	190 (59)	27 (16)	23 (14)	29 (18)	85 (52)	43 (13)	33 (10)	44 (13)	207 (63)
Yes	0	5 (39)	2 (15)	6 (46)	0	3 38)	0	5 (63)	2 (25)	0	2 (25)	4 (50)
Reason for Visit ^{**}												
Routine screen	4 (3)	3 (2)	33 (27)	83 (67)	4 (8)	7 (14)	7 (14)	33 (65)	10 (7)	14 (10)	21 (14)	100 (69)
Routine follow-up	12 (15)	11 (14)	17 (22)	38 (49)	8 (16)	8 (16)	7 (14)	27 (54)	11 (15)	7 (9)	9 (12)	47 (64)
I'm concerned about something	14 (11)	22 (17)	24 (19)	69 (53)	15 (24)	9 (15)	13 (21)	25 (40)	24 (22)	12 (11)	16 (15)	57 (52)
Gynecologic Condition ^{***}												
Endometriosis	0	1 (14)	3 (43)	3 (43)	0	0	1 (100)	0	0	1 (25)	1 (25)	2 (50)

Symptom	Abdominal/Pelvic Pain				Feeling Full/Can't Eat Normally				Bloating/Increased Abdominal Size			
Pattern of Reporting ^a	SI+	New and Moderate Frequency	New and Infrequent	Chronic	SI+	New and Moderate Frequency	New and Infrequent	Chronic	SI+	New and Moderate Frequency	New and Infrequent	Chronic
Fibroids	5 (12)	4 (9)	10 (24)	23 (55)	3 (23)	1 (8)	3 (23)	6 (46)	4 (13)	5 (17)	4 (13)	17 (57)
Ovarian cysts	2 (5)	7 (19)	9 (24)	19 (51)	5 (31)	1 (6)	4 (25)	6 (38)	6 (22)	3 (11)	4 (15)	14 (52)
Other gynecologic problems	3 (11)	7 (26)	2 (7)	15 (56)	3 (19)	4 (25)	4 (25)	5 (31)	5 (15)	2 (12)	4 (12)	20 (61)
More than 1 of these conditions	7 (13)	6 (11)	9 (17)	31 (58)	6 (23)	3 (12)	5 (19)	12 (46)	12 (27)	3 (7)	4 (9)	26 (58)
Medical Conditions ^{**}												
Irritable bowel disease	1 (6)	2 (13)	3 (19)	10 (63)	1 (14)	1 (14)	2 (29)	3 (43)	3 (67)	1 (6)	2 (11)	12 (67)
Urinary tract infections	1 (20)	0	1 (20)	3 (60)	0	1 (100)	0	0	1 (25)	0	0	3 (75)
Interstitial cystitis	0	0	0	1 (100)	0	0	0	0	0	0	0	0
Acid reflux	2 (13)	4 (25)	1 (6)	9 (56)	2 (18)	2 (18)	0	7 (63)	5 (919)	2 (8)	3 (12)	16 (62)
Diabetes	0	1 (25)	1 (25)	2 (50)	0	0	0	0	0	0	0	2 (100)
Hypertension	1 (9)	1 (9)	0	9 (82)	1 (20)	1 (20)	1 (20)	2 (40)	2 (18)	2 (18)	1 (9)	6 (55)
Heart disease	0	0	2 (100)	0	0	0	0	1 (100)	2 (100)	0	0	0
Thyroid disease	0	1 (8)	2 (23)	9 (69)	1 (13)	2 (25)	2 (25)	3 (37)	3 (21)	0	3 (21)	8 (57)
More than 1 condition	1 (2)	6 (910)	16 (26)	38 (62)	3 (11)	3 (11)	6 (22)	15 (56)	4 (5)	6 (8)	15 (21)	48 (66)
None of the listed conditions	15 (14)	4 (4)	22 (21)	63 (61)	12 (16)	6 (8)	10 (14)	45 (62)	12 (12)	12 (12)	12 (12)	62 (63)

* Associations with p 0.05 are denoted by bold, italicized font.

** Percents calculated as row totals and many not equal 100% because of rounding.

*** Women were categorized as premenopausal, perimenopausal, or postmenopausal based on self report of their current menstrual periods. Premenopausal women included those who reported they were still having periods or were pregnant or nursing and were under the age of 50. Perimenopausal women included those who reported they were still having periods or were pregnant or nursing but were over the age of 50. Perimenopausal women also included those who reported they were possibly going through menopause, regardless of their age, as well as women who were under the age of 50 but reported taking hormone replacement therapy. Postmenopausal women were included those who reported their periods had stopped naturally or due to surgery, regardless of their age.

^aSI+: symptom occurred 12 months and 13 days/month; New and Moderate Frequency: symptom occurred 12 months and 6–12 days/month; New and Infrequent: symptom occurred 12 months and 1–5 days/month; Chronic: symptom occurred 13 months at any frequency.