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ORIGINAL ARTICLE

Risk Factors for Endometrial Carcinoma in Women with Postmenopausal Bleeding

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Abstract

Objectives Most patients with postmenopausal bleeding do not have endometrial cancer. The primary objective was to evaluate risk factors for endometrial cancer among postmenopausal women with bleeding.

Methods This was a retrospective cross-sectional study. Women with postmenopausal bleeding presenting to a gynecology clinic were included in the study. Data on potential risk factors for endometrial cancer or atypical hyperplasia were collected. Univariate and multivariate analyses were performed to assess the risk factors.

Results Among 212 women studied, 24 (11.3%) women had endometrial cancer. There were 38 (17.9%) with cervical cancer and 3 (1.4%) with ovarian cancer. Women 55 or older had an odds ratio of 7.5 (95% CI 2.2 to 26.2) as compared to women below 55 years (p value = 0.002). Women with 2 or more episodes of postmenopausal bleeding had an odds ratio of 4.9 (95% CI 1.1 to 23.0) and those who had either diabetes or hypertension had an odds ratio of 3.1 (95% CI 1.3 to 7.4) of endometrial cancer as compared to those who did not.

Conclusions A third of patients with postmenopausal bleeding had a gynecological cancer. Age, frequency of bleeding, diabetes and hypertension, and increased endometrial thickness were independent risk factors for endometrial cancer.

Keywords Postmenopausal bleeding · Risk factors · Endometrial carcinoma

Introduction

Endometrial cancer is one of the commonest cancers in women. The commonest presenting complaint is postmenopausal bleeding which is defined as bleeding from the genital tract after 12 months of amenorrhea in a patient who is not on any hormone replacement therapy [1]. Vaginal bleeding occurs in 4 to 11% of postmenopausal women [2]. The risk of endometrial cancer associated with postmenopausal bleeding is 1.5–28% (average of 11%). Postmenopausal bleeding is also associated with non-endometrial cancers. The most common of these is carcinoma cervix with a reported incidence of 0.8 to 13%. In addition, they have a small risk of ovarian, breast and colorectal cancers [3].

The aim of assessment and investigation of postmenopausal bleeding is to identify a cause and exclude cancer [4]. Benign causes of postmenopausal bleeding include atrophic endometritis, atrophic vaginitis, endometrial hyperplasia, cervical and endometrial polyps, hematuria and rectal bleeding. Though only 20% of patients could have a genital malignancy, it warrants thorough evaluation [5].

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Several risk factors for endometrial cancer have been identified. A model was developed for estimating the risk of endometrial cancer in patients who presented with postmenopausal bleeding, based on clinical characteristics and not involving the results of investigations such as ultrasound and hysteroscopy. The predictors included were age of the patient above 65 years, recurrent episodes of vaginal bleeding, a history of diabetes and BMI over 31 and this was called the FAD31 score [6].

The primary objective of our study was to evaluate the risk factors for endometrial cancer among postmenopausal women with bleeding. A secondary objective was to determine the prevalence of cancer in patients with postmenopausal bleeding.

Methodology

This was a retrospective cross-sectional study at a tertiary level hospital in India. Approval was obtained from the Institutional Review Board (# 7806/18/4/12). Informed consent was waived as this was a retrospective chart review. Patients who had presented with postmenopausal bleeding, and who underwent various procedures like endometrial biopsy, cervical punch biopsy, hysteroscopy and fractional curettage during 12 calendar months were included in the study.

In order to show a prevalence of endometrial cancer of 10% among patients with postmenopausal bleeding, a precision of 4% and a desired confidence interval of 95%, 215 women with postmenopausal bleeding had to be studied.

The diagnostic procedure registers, outpatient charts and electronic medical records of these women were scrutinized to obtain information regarding the age of the patient, body mass index (BMI), past medical and gynecological history, treatment history, ultrasound finding of endometrial thickness and histopathological diagnosis. During a period of 12 months, the records of 212 women with postmenopausal bleeding were identified. Proforma for each patient was filled and then entered on an Excel spread sheet. Age $\geq$ 55 years, BMI $\geq$ 31 and endometrial thickness $>$ 4 mm were taken as risk categories. Missing data were handled by using relevant denominators and using only complete data for the modelling. Descriptive, univariate and multivariate analyses were done using SPSS version 17 (Armonk, NY; IBM Corp.). Confounding and interactions were handled with multivariate regression. The level of statistical significance was taken as $p < 0.05$. The data underlying this article will be shared on reasonable request to the corresponding author.

Results

There were 212 women with postmenopausal bleeding in this study. Their ages ranged between 42 and 80 years with a mean of 56.1 years and standard deviation (SD) of 7.3. The minimum years since menopause, to the onset of bleeding was 1 year and the maximum was 40 years with a mean of 8.2 (SD 7.1) years. The body mass index of the patients was calculated to be between 16.3 and 48 kg/m^2 (Table 1) with a mean of 28.8 (SD 7.2).

A single episode of postmenopausal bleeding occurred in 49 patients and the remaining 163 (77%) presented after several episodes or, after bleeding that lasted for more than 7 days. Of the 212 women, 8 patients were nulliparous. Some patients in the study had history of other malignancies: 3 had cancer ovary and 7 gave a history of cancer breast. One patient had a family history of endometrial carcinoma, while 3 patients had family history of breast cancer. Two patients with endometrial cancer were on thyroid replacement. Seven patients without endometrial cancer were on tamoxifen. None of the patients were on hormone replacement therapy or oral contraceptive pills.

Of the 212 patients who presented with postmenopausal bleeding, ultrasound to detect the endometrial thickness was done in 190 patients of whom 50 had an endometrial thickness of 4 mm or less and 140 (74%) had a thickness of more than 4 mm. When the endometrial thickness was $<$ 4 mm risk of endometrial cancer was 3.6% while with endometrial thickness was 4 mm or more, 23 (16.4%) had a tissue diagnosis of endometrial cancer.

Malignant causes for postmenopausal bleeding were seen in 67 (31.6%). The causes for postmenopausal bleeding were cancer cervix 38 (17.9%) and cancer endometrium in 24 (11.3%). Atypical endometrial hyperplasia was found in 4 women (1.9%) and cervical intraepithelial neoplasia (CIN) in one patient. The benign causes for PMB were endometrial polyp, secretory endometrium and endometritis.

Univariate analysis (Table 2) showed that women older than 55 years had 9 times more risk of endometrial cancer than those below 50 years ($p < 0.001$). Age-group between 51–54 years had 2.2 times more risk than the group less than 50 years which was not significant ($p = 0.53$). If the first episode of postmenopausal bleeding was 10 years or more after the menopause, the risk of endometrial cancer was 15.6 times more than those who had bleeding within 10 years ($p = 0.008$). Patients with a BMI of more than or equal to 31 had 3 times the risk of endometrial cancer than those with a BMI of less than 31 ($p = 0.007$). Those who had several episodes of bleeding had an odds ratio of 4.46 (95% CI 1.01 to 19.51) of having endometrial cancer as compared to those who had a single episode. Diabetes and

Table 1 Prevalence of endometrial cancer by characteristics of women with postmenopausal bleeding (N = 212)

Characteristics of women	Frequency *n* (%)	Endometrial carcinoma or atypical hyperplasia *n* (%)
Frequency of postmenopausal bleeding		
Single episode	49 (23.1)	2 (0.9)
Recurrent	163 (76.9)	26 (12.3)
Age (years)		
≤ 50	52 (24.5)	1 (0.4)
51–54	49 (23.1)	2 (0.9)
≥ 55	111 (62.4)	25 (11.7)
Time since menopause (years)		
< 3	54 (25.6)	1 (0.4)
3–9	78 (37.0)	7 (3.3)
≥ 10	79 (37.4)	20 (9.4)
BMI (kg/m2)		
≤ 24	72 (34.8)	4 (1.9)
25–30	83 (40.1)	11 (5.2)
≥ 31	52 (25.1)	13 (6.1)
Diabetes		
Yes	56 (26.4)	14 (6.6)
No	156 (73.6)	14 (6.6)
Parity		
Nulliparous	8 (3.8)	3 (1.4)
Parous	204 (96.2)	25 (11.8)
Hypertension		
Yes	68 (32.1)	21 (10.0)
No	144 (67.9)	7 (3.3)
Thyroid dysfunction		
Yes	11 (5.2)	2 (0.9)
No	201 (94.8)	26 (12.3)
Endometrial thickness (mm)		
≤ 4	38 (22.3)	1 (0.6)
> 4	132 (77.7)	24 (14.1)
Overall		
Atypical hyperplasia		4 (1.9)
Endometrial cancer		24 (11.3)

hypertension were also significant risk factors on univariate analysis although hypothyroidism was not. Those who had an endometrial thickness of > 4 mm had an 8.2 times increased risk of endometrial cancer ($p = 0.042$). However, this was not apparent in the multivariate analysis when controlled for frequency of bleeding and age.

Multivariate analysis (Table 3) showed that the following were independent risk factors for endometrial cancer: Model 1 ~ frequent bleeding (OR 7.5; 95% CI 1.0–59.5), age ≥ 55 (OR 7.3; 95% CI 2.0–26.0) Model 2 ~ frequent bleeding (OR 4.9; 95%CI 1.1 to 23.0), age ≥ 55 (OR 7.5; 95% CI 2.2 to 26.2) and, diabetes or hypertension (OR 3.1; 95% CI 1.3 to 7.4). Model 3 ~ frequent bleeding (OR 4.0; 95% CI 0.9–18.2), age ≥ 55 (OR 7.5; 95% CI 2.2–26.2) and, BMI ≥ 31 (OR 2.9; 95% CI 1.2–7.0).

Discussion

In developing countries like India, almost 22% of the population are below poverty line and live in rural areas where access to health care is difficult. With increasing life expectancy of women and the rising trend in the incidence of postmenopausal bleeding and endometrial cancer, the role of primary care physicians is vital for the risk evaluation and referral of these women to higher centers. A multivariable predictive model that incorporates the clinical characteristics of the patients for evaluating the risk of endometrial cancer in women with postmenopausal bleeding would empower the primary care physicians to effectively triage these patients so that those at high risk of cancer are immediately referred to a tertiary center. These patients can then access

Table 2 Univariate analysis of potential risk factors for endometrial cancer

Risk factor	Number $n=212$	Endometrial carcinoma or atypical hyperplasia	Odd's ratio (95% CI)	*p*-value
Frequency of bleeding				
One episode	49	2 (4.1)	Ref	0.047
Two or more	163	26 (16.0)	4.46 (1.02 19.51)	
Age in years				
<55	101	3 (3.0)	Ref	
≥ 55	111	25 (22.5)	9.5 (2.77–32.56)	<0.001
BMI				
<31	155	15 (9.7)	Ref	
≥ 31	52	13 (25.0)	3.11 (1.37–7.09)	0.007
Diabetes				
No	156	15 (9.6)	Ref	
Yes	56	13 (23.2)	2.84 (1.26–6.44)	0.012
Hypertension				
No	144	11 (7.6)	Ref	
Yes	68	17 (25.0)	4.03 (1.77–9.19)	0.001
Hypothyroidism				
No	201	26 (12.9)	Ref	
Yes	11	2 (18.2)	1.69 (0.34–8.41)	0.52
Endometrial thickness (mm)				
≤ 4	38	1 (2.6)	Ref	
>4	132	24 (18.2)	8.22 (1.08–62.91)	0.042

Table 3 Multivariate analyses of risk factors for endometrial cancer

Risk factor	Odds ratio (OR)	95% CI of OR	*p*-value
Model 1 ($R^2=0.283$)			
Frequent bleeding (2 or more episodes)	7.52	0.95–59.53	0.056
Age ≥ 55	7.29	2.04–26.02	0.002
Endometrial thickness >4 mm	6.59	0.83–52.64	0.075
Model 2 ($R^2=0.243$)			
Frequent bleeding (2 or more episodes)	4.92	1.05–22.96	0.043
Age ≥ 55	7.51	2.15–26.19	0.002
Diabetes or hypertension	3.07	1.26–7.44	0.013
Model 3 ($R^2=0.235$)			
Frequent bleeding (2 or more episodes)	3.95	0.86–18.24	0.078
Age ≥ 55	7.49	2.15–26.15	0.002
BMI ≥ 31	2.91	1.20–7.03	0.018

gynecologic oncologists or cancer hospitals to obtain timely, appropriate and cost-effective care.

Although the focus of investigation of postmenopausal bleeding is on the endometrium, bleeding may arise from the cervix, vagina and, urinary or gastrointestinal tracts. The clinician grapples with the possibility of an underlying malignancy, while knowing that, in most instances, the bleeding comes from a benign condition. Causes of postmenopausal bleeding in a study done on 50 patients in Pakistan showed 30% prevalence of malignancy with carcinoma cervix and endometrium in equal proportions, benign pathology in 48% cases, premalignant conditions in 14% and undetermined pathology in 8% cases [7]. In a study from India, the causes for postmenopausal bleeding were atrophic endometrium in 30%, proliferative endometrium in 27%, endometrial

carcinoma in 16%, endometrial hyperplasia in 12%, disordered endometrium in 9% and endometrial polyp in 5% [8].

Risk factors for type I endometrial cancer include early menarche, late menopause, obesity, tamoxifen use, increasing age and the metabolic syndrome. Type II cancers are seen in older women with atrophic endometritis who present with vaginal discharge or postmenopausal bleeding. Any factor related to prolonged and unopposed estrogen stimulation of the endometrium such as estrogen replacement therapy, obesity, anovulatory cycles, estrogen secreting tumors increase the risk. Hyperoestrogenic states such as fibroids, adenomyosis, endometriosis, and endometrial hyperplasia are associated with endometrial cancer. Ovulation induction with clomiphene and gonadotropins is also associated with increased risk of cancer. Decreased exposure to estrogen and increased progesterone levels due to progestogens, combined oral contraceptive pills and smoking are found to be protective. The protective effect of tobacco use such as chewing and smoking, has to be interpreted with caution as this may be an effect modification of obesity [9].

We follow a protocol of performing a cervical smear and Pipelle biopsy on all patients with postmenopausal bleeding or discharge who do not have an obvious cause for the same. A transvaginal ultrasound is also done to look for endometrial thickness and adnexal masses. If the endometrial thickness is > 4 mm, while the biopsy is negative, we do an outpatient hysteroscopy and curettage. Some have suggested that the initial evaluation should be transvaginal ultrasound and that a Pipelle biopsy is warranted only if the endometrial thickness was > 4 mm or if patient was above 60 years [10]. Dilatation and curettage in the operating room was the gold standard but now saline sonohysterography, hysteroscopy, and endometrial Pipelle biopsy have replaced it [11].

Several predictive models incorporating transvaginal ultrasound, power doppler and hysteroscopy have been developed [12, 13], but they were either underpowered or they included the reports of investigations, which was difficult to use at the primary care setting. A predictive model that does not include investigations like ultrasound, hysteroscopy and dilatation & curettage would be useful in clinics where expensive investigations are unavailable. Clear guidelines for referral would be useful and ensure that cancer is not missed. A high negative predictive value at a FAD31 score less than 4 can be used to prioritize referrals to secondary care allowing women at a low risk of endometrial cancer to be referred on a less urgent basis [6].

Burbos et al. formulated a Norwich DEFAB risk assessment tool in which recurrent episodes of vaginal bleeding were significantly associated with endometrial cancer than a single episode, considering diabetic status, age, BMI, and endometrial thickness [10]. Any factor related to prolonged and unopposed estrogen stimulation of the endometrium, e.g., hormone replacement therapy, obesity, anovulatory cycles, estrogen secreting tumors increase the risk and decreased exposure to estrogen and increased progesterone levels, e.g., OCP's and smoking are found to be protective.

A lower age-group was selected for this study as most patients with cancer endometrium were in the group of 50–59 years (16 of 28 women) and not above 65 as found in western literature. It reflects on the population of India where the life expectancy is less as compared to the western world. The incidence of cancer endometrium is also increasing in the younger age group patients and we found the risk significant after 55 years.

Body mass index (BMI) is also predictive for endometrial cancer as obesity gives rise to peripheral conversion of androstenedione to estrone. Moreover, decrease in sex hormone binding globulin (SHBG) allows an increase in free estradiol to act on estrogen receptors. In this study, 65% of endometrial cancers were seen in women with a BMI > 25 kg/m^2. Univariate analysis using BMI showed that the risk of endometrial cancer was three times in those with a BMI ≥ 31 kg/m^2 compared to those with a BMI of < 31 kg/m^2.

When a woman presents with the first episode of postmenopausal bleeding at more than or equal to 10 years, the relative risk of endometrial cancer was found to be significantly increased [14]. We did not include the time of bleeding since menopause in the multivariable model as it was correlated to age.

Diabetes was included in the FAD31 score [6] and Norwich DEFAB score [15]. Both diabetes and hypertension were found to be significantly related to endometrial cancer in univariate analysis in our study. We computed a variable where either diabetes or hypertension could be positive, but this did not reach statistical significance in our multivariate regression model.

This study aimed at assessing risk factors for endometrial cancer in women with postmenopausal bleeding, using their clinical details like age, body mass index and the frequency of bleeding. We found that age ≥ 55 years, endometrial thickness > 4 mm, frequent bleeding, BMI ≥ 31, and diabetes or hypertension were significant risk factors for endometrial cancer. Once categorized as high-risk women could have an immediate endometrial biopsy or be referred early to a specialist. Women at low risk could be counselled about the low risk of malignancy and get an ultrasonography and biopsy at their convenience.

Availability of a good quality of medical records and electronic data added to the strength of this study apart

from the fact that the desired sample size was attained. The limitations of the study were that it was a retrospective study design with its inherent flaws of selection bias and incomplete documentation. The study did not include all patients with postmenopausal bleeding, but only those who were evaluated. Not all the patients had an ultrasound examination. Moreover, a larger number of endometrial cancers would have allowed larger regression models.

Since there were only 24 cases of endometrial cancer and 4 atypical hyperplasia, multivariate models could not have more than 3 independent variables. Thus, we tried out various models with a maximum of 3 variables in each. However, all of them could explain only less than 30% of the variation. Since these women could have endometrial or cervical cancer, they should have a gynecological examination, cervical cytology or a biopsy of the cervix / endometrium.

A risk model using only patient characteristics showed fair diagnostic accuracy. However, addition of patient characteristics to endometrial thickness (ET) did not improve the diagnostic accuracy as compared to ET alone [16]. In general or family practice, when endometrial biopsy and ultrasound are not available, risk models using just clinical characteristics such as age at presentation, age at menopause, body mass index, nulliparity and recurrent vaginal bleeding may be employed. In specialized centers, all patients should have cervical cytology, human papillomavirus (HPV) testing, endometrial sampling and transvaginal ultrasound when there is no obvious cervical growth to biopsy.

Conclusion

Over a fifth of patients with postmenopausal bleeding have a gynecological cancer. Ideally, all patients with postmenopausal bleeding and profuse discharge should be referred to a gynecologic oncologist to rule out malignancy. Frequency of bleeding, age > 55 years, diabetes, hypertension, and obesity are clinical risk factors for endometrial cancer. Endometrial thickness > 4 mm on ultrasound is also suggestive for endometrial cancer.

Conflict of interest

None of the authors have a conflict of interest.

Ethical Approval

Approval was obtained from the Institutional Review Board (# 7806/18/4/12).

Informed Consent

Informed consent was waived as this was a chart review.

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Author contributions AS contributed to drafting of manuscript and approval of final manuscript. SRN collected data, drafted the manuscript, and approved the final manuscript. GR contributed to aata analysis and approval of final manuscript. LV and AR contributed to critical review and approval of final manuscript. AT contributed to study supervision, critical review, and approval of manuscript. RC contributed to interpretation and approval of final manuscript. AP contributed to conceptualization, supervision, critical review, and approval of final manuscript.

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