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ELECTROSURGICAL BI- AND MONOPOLAR ENDOMETRIAL DESTRUCTION IN PREVENTION OF RECURRENT TAMOXIFEN ASSOCIATED ENDOMETRIAL PATHOLOGY IN POSTMANOPAUSE

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Aim *To compare surgical treatments for tamoxifen associated endometrial pathology in patients in late postmenopause.*

Material and methods *The study comprised 136 postmenopausal women with breast cancer, who were taking tamoxifen, had concurrent endometrial pathology confirmed by ultrasound examination, and/or complained of genital bleeding. Patients were divided into three groups: 54 patients underwent monopolar endometrial ablation (group I), 32 patients received bipolar endometrial ablation (group II), and 50 patients had hysteroscopy, diagnostic fractional curettage, and polypectomy without endometrial ablation (group III). The results of the study were evaluated within 12 months after surgery.*

Results *The incidence of recurrent endometrial pathology in group I and group II was 1.8% and 0%, respectively. In the non-ablative group, the recurrence rate during the first year was 60%.*

Conclusion *In breast cancer patients receiving adjuvant tamoxifen therapy, endometrial ablation significantly reduces the incidence of recurrent tamoxifen-associated endometrial pathology. Our study findings suggest that the effectiveness of mono- and bipolar ablation is significantly higher than hysteroscopy, diagnostic fractional curettage and polypectomy (98.2, 100 and 40%, respectively).*

Keywords: *breast cancer, tamoxifen, endometrial pathology, hysteroscopy, mono- and bipolar endometrial ablation.*

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In recent years, life expectancy has been rising steadily in most countries globally. By 2030, every fifth person in the world will be over 65 years old [1-3]. Considering this, the importance of studying the diseases of postmenopausal women is increasing. The incidence of hyperplastic endometrial lesions in postmenopause has been estimated at 5%, and 80% of patients with endometrial cancer have a history of endometrial hyperplasia [4, 5]. An association between endometrial cancer and a history of breast cancer (BC) has been confirmed. An increased risk of endometrial cancer was observed in women receiving synthetic anti-estrogen agent tamoxifen as treatment for breast cancer. The risk of developing endometrial cancer is 2-3 cases per 100 tamoxifen-treated women and their risk of an adenomatous polyp increases from 10 to 36% [6-8].

A radical treatment for endometrial pathology in patients receiving tamoxifen adjuvant therapy for breast cancer with is a hysterectomy. However, the latter is often not feasible or undesirable because of absolute or relative contraindications [9-14].

To address these problems, searching for new alternative treatments for uterine pathology remains relevant. Technological advances in minimally-invasive surgery provide the opportunity to reconsider traditional treatments of intrauterine pathology in multimorbid elderly patients. Hysteroresectoscopic endometrial ablation is an effective treatment modality for hyperplastic endometrial lesions without concomitant tamoxifen and is an alternative to hormone therapy and radical surgery. The development of mono- and bipolar hysteroresectoscopic technologies and their application in clinical practice showed high effectiveness and safety of endometrial coagulation ablation, compared with resection in patients with endometrial atrophy and the involutive changes of the uterine walls in postmenopausal women [15-21].

Thus, treating intrauterine pathology in late postmenopause, which is associated with the involution of the reproductive system, continues to be a challenging problem of modern gynecology.

This study aimed to compare surgical treatments for tamoxifen associated endometrial pathology in patients in late postmenopause.

Material and methods

From November 2010 to September 2013 (34 months), 136 women were examined after initial treatment for breast cancer; they had an endometrial thickness of more than 5 mm detected by transvaginal ultrasound (US), and/or complained of genital bleeding. All patients were

on tamoxifen at daily dose 20 mg from 6 months to 5 years. All patients signed informed consent to take part in the study. Exclusion criteria comprised cervical cancer, tuberculosis, and contraindications to surgery.

Preoperative examination included general clinical assessment, advanced colposcopy, pelvic ultrasound, diagnostic hysteroscopy with diagnostic fractional cervical and uterine curettage, polypectomy, coagulation of the base if necessary, and morphological examination of the removed tissue. Indications for hysteroscopy were suspected endometrial pathology according to the US, and / or uterine bleeding. Morphological examination of the removed tissues was a reference test for the diagnosis of intrauterine pathology.

The first stage of the study included the assessment of baseline clinical and statistical characteristics of patients of the study sample. After that, patients were divided into three groups. Patients of group I underwent monopolar hysteroresectoscopic endometrial coagulation ablation after preliminary hysteroscopy, diagnostic fractional curettage, and polypectomy (n = 54). Indications for unipolar coagulation ablation were the endometrial pathology and the prevention of recurrent endometrial pathology.

Patients of group II underwent bipolar hysteroresectoscopic endometrial coagulation ablation after preliminary hysteroscopy, diagnostic fractional curettage and polypectomy (n = 32). Bipolar endometrial ablation was used in patients with contraindications to monopolar surgery due to a history of hip replacement surgery or implantable cardiac pacemakers.

Mono- or bipolar endometrial ablation was performed one month after hysteroscopy, diagnostic fractional curettage, and polypectomy. This time interval is optimal due to a superficial epithelization occurring during this period, which prevents increased intravascularization during electrosurgical endometrial ablation. In all cases, monopolar or bipolar endometrial destruction was performed using OLYMPUS hystero-resectoscope (Japan).

Monopolar electrosurgical endometrial destruction with a high-frequency current was conducted in a coagulation mode with a generator output power of 80-90 W. A ball point electrode was used for resection. Endometrial resection with endometrium removal to the myometrium was used for endometrial polyps, resecting the fibrous polyp pedicle to the level of the normal myometrium. A 5% glucose dielectric solution was used as an optical medium.

Bipolar electrosurgical endometrial destruction with a high-frequency current was conducted in a coagulation mode with an output power of 120-150 W. A ball point electrode was used for resection. Endometrial resection with endometrium removal to the myometrium was used for endometrial polyps, resecting the fibrous pedicle of the polyp to the level of normal myometrium with a generator output power of 280 W. As the expansion medium, 0.9% sodium chloride solution was used. In these cases, a 45° angled wire loop electrode was used for resection, which allowed the removal of even the polyp originating from the upper uterine corner.

Patients of group III (n = 50) were followed for one year after hysteroscopy, diagnostic fractional curettage and polypectomy.

Evaluation of long-term postoperative results after surgery for endometrial pathology in postmenopausal women included ultrasound examination and diagnostic hysteroscopy using a flexible or rigid office hysteroscope.

Office hysteroscopy aimed at the direct visualization of uterine cavity was performed using a single-channel fibrohysteroscope with a 3.1 mm distal end outer diameter and a 1.2 mm instrument channel. The instrument channel allows for a targeted “pinch” endometrial biopsy.

Office hysteroscopy was performed taking into account indications and contraindications for panoramic hysteroscopy, in aseptic conditions, in outpatient settings, without cervical dilation, cervical fixation, and anesthesia.

The treatment results were evaluated during a 12 month follow-up. At three, six and 12 month follow-up visits, patients had repeat ultrasound scans to monitor the changes of internal genital organs, their size, and structure associated with the surgery.

At the 12-month visit, all patients of groups I, II and III had an outpatient hysteroscopy with a targeted and aspirated endometrial biopsy.

Results

The mean age of patients was 62 ± 8.12 years (50-81 years). The mean age of menopause was 50.1 ± 4.1 years and ranged from 34 to 63 years (including one patient with premature menopause at 34 years). The duration of postmenopause in the patients averaged 10.25 ± 6.4 years and ranged from 5 to 30 years.

The most common concomitant extragenital diseases were cardiovascular diseases - 92 (67.6%), digestive diseases - 73 (54%), endocrine diseases - 41 (30.1%) and genitourinary diseases - 51 (37.5%). Forty (29.4%) women were obese.

The most common gynecological diseases were represented by uterine myoma - 37 (27%), adenomyosis - 31 (22.7%) and inflammatory diseases of the uterus, uterine appendages and vagina - 30 (22%).

Analysis of family history data showed that 55 (40.4%) patients had first line female relatives had oncological diseases.

Among the study participants, 15 (11%), 106 (78%), 12 (8.8%) and three (2.2%) women had stage I, II, III and IV breast cancer. Of them, 135 (99.3%) women underwent surgery and were taking tamoxifen as adjuvant therapy. Types of surgery included unilateral mastectomy, bilateral mastectomy and sectoral resection in 113 (83.1%), two (1.5%) and 20 (14.7%) patients, respectively. One (0.7%) patient did not undergo surgical treatment. Twelve (8.8%) and 25 (18.4%) women received radiation and chemotherapy for breast cancer, respectively. All women enrolled in the study were taking tamoxifen 20 mg/day. The duration of tamoxifen therapy at the time of detection of intrauterine pathology varied from 3 to 24 months.

Twenty six (19.1%) patients complained of genital bleeding, and the remaining 110 (80.9%) patients had no complains.

According to morphological studies after hysteroscopy, diagnostic fractional curettage and polypectomy, 64 (47.1%) patients had endometrial polyps including 55 (85.9%) and

11 (14.1%) women with concomitant endometrial atrophy and cystic atrophy, respectively. Endometrial atrophy, cystic endometrial atrophy, endometrial hyperplasia and uterine myoma were diagnosed in 37 (27.2%), 23 (16.9%), 4 (2.9%) and 7 (5.9%) patients, respectively. Histologically, cystic atrophy was characterized by periglandular condensation of stromal cells, epithelial metaplasia, and proliferative activity. Morphological findings showed no cases of malignancy; all polyps were benign. The state of the endometrium in patients after morphological verification of diagnoses is presented in the table.

Operative time of hysteroresectoscopic coagulation ablation in the mono- or bipolar mode varied from 10 to 25 min in all patients (mean 16.29 ± 3.6 min). The length of the uterine cavity ranged from 5 to 9 cm (mean 7.0 ± 0.9 cm). The speed of rolling the electrode along the inner surface of the uterus as a subjective parameter was not rigidly fixed (mean 2-3 mm/sec). Repeat rolls along the already treated surface were not applied. The choice of the speed of the active electrode was dictated by a change in the color and appearance of the endometrium. The tissues undergoing destruction acquired a characteristic yellow-brown color and were losing their structure. Also, the level of intravasation was monitored and did not exceed 500 ml in groups I and II. All patients who underwent bi-or monopolar hysteroresectoscopic endometrial ablation were followed by an anesthesiologist after surgery and received a prophylactic antibiotic. In the absence of complications, patients were discharged on the 3rd day after the operation.

On the second day after the endometrial ablation, one patient of the group I had a subfebrile temperature, caused by a hematometra. After uterine probing and antibiotic therapy, the patient was discharged on the fifth day with recovery. No cases of hematoma were observed in other patients.

The criteria for the effectiveness of endometrial ablation in the study were: the absence of genital bleeding, a linear M-echo detected by ultrasound imaging, the presence of intrauterine synechiae detected during office hysteroscopy, the absence of endometrial tissue in morphological studies.

At the three month follow-up, no patient in groups I, II and III had a pathological ultrasound echography pattern; accordingly, there were no indications for hysteroscopy and diagnostic fractional curettage. Ultrasound imaging showed a linear M-echo less than 2-3 mm in thickness with echo-positive inclusions (fibrosis).

At six months after surgery for endometrial pathology, all women of the groups I and II had endometrial atrophy according to ultrasound examination. Ultrasound imaging showed a linear M-echo less than 2-3 mm in thickness with echo-positive inclusions (fibrosis). At the same time, in five (10%) women from group III M-echo was more than 5 mm, which required a repeat hysteroscopy and diagnostic fractional curettage.

At twelve months after the surgical treatment of intrauterine pathology, only one patient (1.9%) in group I had an M-echo more than 5 mm in thickness, which required repeated hysteroscopy with diagnostic fractional curettage. In the patients of group II, ultrasound imaging showed endometrial atrophy. In the patients of group III, 30 (60%) women were found to have an increased endometrial thickening, which became an indication for repeat hysteroscopy with diagnostic fractional curettage.

Therefore, the rate of repeat hysteroscopy in group I was 1.9%, in group II no patient needed repeat hysteroscopy, and in group III 60% of patients underwent repeat hysteroscopy.

Thus, the findings of the 12 month follow-up show that in patients with breast cancer and tamoxifen associated intrauterine endometrial pathology, the effectiveness of the high-frequency electrosurgical endometrial coagulation ablation is much higher than that of hysteroscopy, diagnostic fractional curettage and polyp resection with the similar effectiveness of mono- or bipolar technology.

Analysis of the effectiveness of surgical correction of intrauterine pathology in patients receiving adjuvant therapy for breast cancer is shown in the figure.

Discussion Currently, early diagnosis and treatment of endometrial pathology in postmenopause accounting for 60-70% in the structure of gynecological diseases remain a challenging problem. The average age of patients with endometrial cancer is 60 years, and early diagnosis and treatment of intrauterine endometrial pathology are considered secondary prevention of endometrial cancer [4, 22, 23].

Current literature is lacking studies on the effectiveness of hysteroresectoscopic endometrial coagulation destruction (mono- or bipolar) against the background of the continuing impact of tamoxifen on the endometrium to prevent recurrence. The first randomized trial reported by M. Goldenberg et al. in 1998, showed that hysteroscopic polypectomy with monopolar endometrial ablation is

Table. The state of the endometrium in the study patients (n=136)

Characteristics of the endometrium	Group I (n=54)		Group II (*n*=32)		Group III (*n*=50)	
	n	%	*n*	%	*n*	%
Simple endometrial hyperplasia	1	1.85	1	3.1	2	4
Endometrial polyp with concomitant atrophy	27	50	9	28.1	19	38
Endometrial polyp with concomitant cystic atrophy	2	3.7	4	12.5	3	6
Endometrial atrophy	8	14.8	11	34.4	18	36
Cystic endometrial atrophy	13	24.1	5	15.6	5	10
Uterine myoma with concomitant endometrial atrophy	2	3.7	2	6.2	2	4
Uterine myoma with concomitant cystic atrophy	1	1.85	-	-	1	2

Note. No statistical differences between groups (p?0.05).

effective in the treatment of tamoxifen-associated endometrial polyps. In that study, 20 women were assigned to receive hysteroscopy and diagnostic fractional curettage, and ten women underwent endometrial ablation [24].

W. Gao et al., later reported a study with a similar treatment strategy. However, in this study, comparison groups were not formulated, and ablation effectiveness was assessed only regarding endometrial polyps [25].

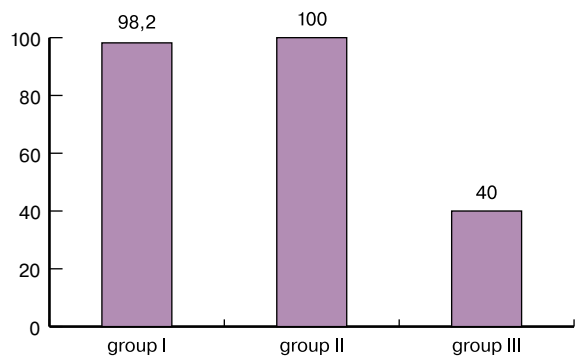
In the present study, on the second stage after hysteroscopy, diagnostic fractional curettage, polypectomy, and coagulation of the polyp base, 86 patients of groups I and II underwent hysteroresectoscopic endometrial ablation.

Endometrial ablation was performed in cases of recurrent tamoxifen-associated endometrial pathology. Monopolar hysteroresectoscopic coagulation ablation was used in 54 patients (group I), and 32 patient (group II) with contraindications to monopolar intervention underwent bipolar hysteroresectoscopic coagulation ablation.

One patient in group I, who complained of genital bleeding, and had M-echo thickness of more than 6 mm, underwent repeat hysteroscopy with diagnostic fractional curettage in an inpatient setting. A control hysteroscopy revealed synechiae seen in the upper uterine corner against the background of endometrial atrophy and hyperemia of the isthmus region. A morphological study reported endometrial atrophy. No recurrences were observed in the remaining 53 patients. At 12 months, all M-echoes were either absent or less than 3 mm in thickness, non-uniform, with fibrosis. In these patients, intrauterine synechiae were visualized during control office hysteroscopy. Other investigators reported histologically confirmed post-ablation recurrence rate of 2-10% after 1.5-3 year follow-up. In the second group, no patients needed a repeat hysteroscopy in an inpatient setting. And in the third group, 30 (60%) patients required repeat hysteroscopy in an inpatient setting for recurrent tamoxifen-associated endometrial pathology detected by ultrasound imaging and office hysteroscopy [24, 25].

Tamoxifen, causing endometrial stromal changes as early as three months after the treatment initiation, leads to a false-positive M-echo thickening on transvaginal ultrasound. Benign endometrial pathology may occur in a majority of postmenopausal women who do not have clinical manifestations and receive tamoxifen. Therefore, they need a pelvic ultrasound before administration of tamoxifen and every six months after that. For patients with endometrial thickening more than 5 mm, hysteroscopy with biopsy is recommended. For them, after ruling out malignancy, the optimal treatment option at any time of anti-estrogen therapy aimed to prevent recurrence is hysteroresectoscopic endometrial coagulation ablation (in mono- or bipolar mode).

Figure. The rate of effectiveness of surgical treatment of endometrial pathology in postmenopausal women receiving tamoxifen depending on the treatment modality, %.



Conclusion

In breast cancer patients receiving adjuvant tamoxifen therapy, endometrial ablation significantly reduces the incidence of recurrent tamoxifen-associated endometrial pathology. Our study findings suggest that the effectiveness of mono- and bipolar ablation is significantly higher than hysteroscopy, diagnostic fractional curettage and polypectomy (98.2, 100 and 40%, respectively).

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