

Saint Paul's Hospital Millennium Medical College

MRI Measurement of Endometrial Thickness in Postmenopausal Patients in Saint Paul's Hospital Millennium Medical College.



By Mohammedseid Ahmed (MD, Radiology Resident)

Advisors:

Dr. Bekele Yadeta (MD, Assistant Professor of Radiology)

Frehiwot Worku (BSc, MPH)

A research proposal to be submitted to Department of Radiology, St. Paul's Hospital Millennium Medical College (SPHMMC) for a partial fulfillment of the requirement for post graduate degree in Radiology.

April, 2019 Addis Ababa, Ethiopia

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Summary

Background:

Female gynecologic conditions arising from the endometrium are common and depend on a women's age, her menstrual history, and use of medications such as hormone replacement. The accepted normal endometrial thickness is 5mm; lesions with endometrial thickness <5mm are considered benign, whilst those >5mm usually are considered malignant. However, recent studies suggest that asymptomatic endometrial thickness of even 8-11mm in postmenopausal women may be normal. (1)

Objective:

The objective of the study is to assess the normal endometrial thickness range in postmenopausal patients imaged in St Paul's Hospital Millennium Medical College by Magnetic resonance imaging T2-weighted sagittal images retrospectively as measured by a single radiologist.

Methodology:

A retrospective cross sectional study will be employed and data will be collected from the image pool of the Radiology department of St Paul's Hospital Millennium Medical College. The medical records for the purpose of this study will be selected by convenience sampling, a type of non-probability sampling method. with total sample size of 97. Collected data will be cleaned, edited and entered using Epi-Data version 3.1 into a computer and analyzed by SPSS version-25.

Work plan and budget:

The study will be conducted from April 1, 2019 to August 15, 2019. The estimated budget will be 26,950 ETB and source of funding will be from St Paul's Hospital Millennium Medical College.

Acronyms and abbreviations

ENT- Ear, Nose, Throat

ET- Endometrial thickness

FMOH- Federal Ministry of Health

FSE- Fast Spin Echo

HRT- Hormone Replacement Therapy

1.5-T MRI-1.5- Tesla Magnetic resonance imaging

RIS- Radiological Information System

SPHMMC- St Paul's Hospital Millennium Medical College

SPSS- Statistical Package for the Social Sciences

TVUS- Transvaginal ultrasonography

US- Ultrasonography

Chapter One

Introduction

1.1 Background

Menopause is the time at which permanent cessation of menstruation occurs following the loss of ovarian activity. Clinically, it is defined as the absence of menstruation for more than 12 months (one year) and occurs in women over 50 years of age. Post menopause is therefore by definition the time period following the final menses (2). The endometrium demonstrates a wide spectrum of normal and pathologic appearances throughout menarche as well as during the pre-pubertal and postmenopausal years and the first trimester of pregnancy. The normal endometrium is composed of 2 layers and the combined thickness of these two layers and subsequent appearance depends on many factors such as the patient's age, stage or phase in the menstrual cycle, and pregnancy status and whether she has undergone hormonal replacement therapy or tamoxifen therapy during the examination. Atrophy of the endometrium is a result of hypo-estrogenic state. (3).

The most commonly used imaging modality used for evaluating the endometrium is pelvic ultrasound with transabdominal and transvaginal techniques. Other additional imaging methods used include hysterosonography and magnetic resonance imaging (MRI). On ultrasound, with both transvaginal or transabdominal approaches, endometrial thickness is measured from echogenic border to echogenic border across the endometrial cavity on a sagittal midline image. The normal post-menopausal endometrium should be thin, homogenous, and echogenic. Intraluminal blood or sheets of sloughed endometria may be identified. When there is fluid in the endometrial canal, the two layers of endometrium are measured separately and added together. Some postmenopausal women could be on hormone replacement therapy (HRT) and receive estrogen and that induces cyclical bleeding. Therefore, in such patients the endometrium should be measured 4-5 days after the start of menses. (4)

Magnetic resonance imaging (MRI), with its superior soft-tissue contrast, multi-planar imaging capability and lack of ionizing radiation, plays a key role in the evaluation of suspected endometrial pathology. It is the current gold standard imaging modality for noninvasive assessment of uterine corpus and cervix pathologies and may be performed on either 1.5 or 3.0-T clinical scanners using phased array pelvic surface coil. T2-weighted MR images give the best images for the demonstration of the normal appearance of the endometrium because the uterus

has homogenous intermediate signal intensity with T1-weighted sequences. T2-weighted images clearly delineate the zonal anatomy of the uterus. The normal endometrium appears as uniformly high signal intensity, and the inner part of the myometrium, or the junctional zone, is of uniformly low signal intensity. (5)

1.2 Statement of the Problem

Postmenopausal bleeding is any uterine bleeding that occurs in postmenopausal women. It is the most common symptom that prompts postmenopausal patients to seek medical evaluation. It is estimated to occur globally in 4 to 11 percent of postmenopausal women. It can be caused by multiple endometrial pathologies including endometrial atrophy (making up the majority), endometrial polyp, submucosal fibroid, endometrial hyperplasia, endometrial cancer and estrogen withdrawal. The incidence of bleeding appears to correlate with time since menopause, with the likelihood of bleeding decreasing over time. (6)

Although the most common cause of postmenopausal bleeding is endometrial atrophy, all postmenopausal women with unexpected uterine bleeding should be evaluated for endometrial carcinoma as this pathology is lethal with significant morbidity and mortality if left undetected or detected at later stages of the disease. Endometrial carcinoma is the most common of the gynecological malignancies predominantly affecting postmenopausal women and is the 4th most common cancer in women globally. Postmenopausal bleeding caused by other benign causes still can cause significant morbidity in these patients (7).

The endometrial appearance is influenced by several factors, such as age, menstrual status, pregnancy and hormonal therapy. Amongst these, menstrual status is potentially the most influential factor affecting endometrial thickness. Therefore, the thickness and appearance of the endometrium is different for different patient categories.

1.3 Significance of the Study

Measurement of these endometrial abnormalities in patients with or without uterine bleeding usually poses diagnostic challenges for radiologists and gynecologists. The change in endometrial thickness with or without uterine bleeding may be an evidence of disease including endometrial carcinoma which is the most malignant endometrial pathology.

In addition, there is controversy regarding endometrial thickness with menopause. Although some authors have found that endometrial thickness decreases with age others believe there is no statistically significant change during menopause. So it is important that we have normal reference values with MRI in postmenopausal women in relation to their age and other disease entities like vaginal bleeding at SPHMMC.

Chapter Two

Literature Review

Endometrium, the inner layer of the uterus, is the most active layer that responds to cyclic ovarian hormone changes which is highly specialized and is essential to menstrual and reproductive function. On MRI, the normal postmenopausal endometrium is atrophic and appears as a homogeneous smooth endometrium, without focal thickening. In postmenopausal patients, the thickness of the endometrium varies based on the clinical setting including presence of uterine bleeding, with an upper limit of 4 mm in asymptomatic patients, 5 mm in symptomatic patients, and 8 mm in those patients who are on hormonal therapy (8),(9).

Since researches evaluating normal endometrial thickness in postmenopausal women with MRI are extremely scarce, comparison has been made with researches done with ultrasound as magnetic resonance imaging (MRI) findings often correlate with US findings. The normal postmenopausal endometrium should appear thin, homogeneous, and echogenic on ultrasound. Although the accepted normal value of endometrial thickness is < 5 mm, endometrial thickness of 5 mm or more on transvaginal ultrasonography (TVUS) imaging in a postmenopausal woman is considered as an asymptomatic endometrial thickening. On TVUS imaging, current literature suggests that asymptomatic endometrial thickness of 8 mm – 11 mm in a postmenopausal woman may be considered as normal(10).

In comparison to a study of 297 postmenopausal women by Junko Nakamura in Japan, endometrial thickness was measured using 3.0-T MRI. The endometrial thickness was measured on sagittal T2-weighted images at the thickest site between the two basal layers on the anterior and posterior uterine walls. The study describes not to use the 5 mm threshold as an indication of malignancy to avoid excessive false-positive diagnoses (10).

There is controversy regarding endometrial thickness with menopause. Although some authors have found that endometrial thickness decreases with age (11,12), others believe there is no statistically significant change during menopause(13). In general, a double-layer thickness of less than 5 mm without focal thickening excludes significant disease and is consistent with atrophy

(14). Homogeneous, smooth endometria measuring 5 mm or less are considered within the normal range with or without hormonal replacement **(15).**

It is important to understand that the appearance of the endometrium is related to multiple factors, including the patient's age, stage in the menstrual cycle, and pregnancy status, and whether the patient has undergone hormonal replacement therapy or tamoxifen therapy. Although, there is no research done evaluating these factors on MRI, a research done on factors affecting endometrial thickness with ultrasound in India by Heber S, describes that endometrial thickness in post-menopausal women may be influenced by various factors such as parity, BMI, drugs like tamoxifen, presence of myoma (fibroid), uterine volume, ovarian volume and serum estradiol. Hence, these factors have to be taken to consideration, while evaluating endometrial thickness in these women.

On the other hand, a meta-analysis of 35 published studies that included 5892 women showed that an endometrial thickness greater than 5 mm detected 96% of endometrial cancer and 92% of any endometrial disease **(16).** Using this meta-analysis, a multispecialty consensus conference sponsored by the Society of Radiologists in Ultrasound to discuss the role of sonography in women with postmenopausal bleeding concluded that an endometrial thickness of greater than 5 mm is abnormal **(17).**

Other studies have assessed the endometrium in asymptomatic postmenopausal patients and concluded that an endometrium of 8 mm or less can be considered normal. **(18,19-21).** Most of these reports have included a mixed group of patients in their study, with some patients undergoing HRT and others not. In a theoretical cohort of postmenopausal women age 50 years or older who were not bleeding or receiving HRT, Smith Bindman et al recommended that biopsy should be considered if the endometrium is greater than 11 mm in thickness, because the risk of cancer is 6.7% (which is similar to that of patients with postmenopausal bleeding and endometrial thickness >5 mm). **(22)**

Findings on clinical usefulness study show that the use of TVUS as a screening tool for endometrial pathology in asymptomatic postmenopausal women generates 93.2% false positive results. The data suggests that, in asymptomatic postmenopausal women, endometrial ultrasound evaluation is not worthwhile as a screening tool, such as it is considered in common clinical practice. **(23)**

The endometrium in a patient undergoing hormonal replacement therapy may vary up to 3mm if cyclic estrogen and progestin therapy is being used **(10)**. The endometrium will appear thickest prior to progestin exposure and thinnest after the progestin phase. Imaging should be performed at the beginning or end of a cycle of treatment, when the endometrium will be at its thinnest and any pathologic thickening will be most prominent. A patient undergoing unopposed estrogen therapy with endometrial thickening exceeding 8 mm should be considered for biopsy, whereas patients receiving progesterone in addition to estrogen can be rescanned at the beginning or end of the following cycle to determine if there has been a change in endometrial thickness **(22)**.

Any thickness greater than 5 mm in the setting of postmenopausal bleeding or any endometrial heterogeneity or focal thickening seen at transvaginal US should be investigated further with son- hystero-graphy, biopsy, or hysteroscopy.²³

Several studies have shown that in patients having a postmenopausal bleeding and consequently who have had endometrial sampling, an endometrial thickness measurement of 4 mm or less or 5 mm or less⁽²⁴⁾ can be considered normal.

In postmenopausal women not receiving hormone replacement therapy, the double-layer endometrial thickness is less than 5 mm and values above this should lead to investigation to exclude the presence of intrauterine pathology. A large multicenter study done in Italy examined endometrial thickness in 930 women with postmenopausal bleeding and who were not receiving hormone replacement therapy: an endometrial thickness of less than or equal to 4 mm had a 99% negative predictive value in the detection of malignancy(i.e endometrial carcinoma). In addition, a meta-analysis of 35 studies that evaluated transvaginal ultrasound measurements and endometrial abnormalities showed that using an endometrial thickness of 5 mm had a 92% sensitivity for detecting any endometrial disease and the 96% sensitivity for detecting cancer. These results were confirmed in those postmenopausal women taking combined estrogen and progestogen preparations as HRT **(25)**. This study had a 9% positive predictive value for serious endometrial pathology and in perimenopausal women it was suggested that the upper limit of endometrial thickness requiring further investigation should be 7mm⁽²⁶⁾. One recommendation sets the limit of endometrial thickness in perimenopausal women at 5 mm, if the transvaginal ultrasound examination is performed on the fifth day of the menstrual cycles **(27)**.

Chapter Three

Objectives of the Study

3.1 General Objectives

To measure endometrial thickness in post-menopausal patients by MRI in SPHMMC.

3.2 Specific Objectives

To assess the endometrial thickness by age and duration of post menopause in patients imaged by 1.5-Tesla MRI in St Paul's Hospital Millennium Medical College.

Chapter Four

Methodology

4.1 Study Area

The study will be conducted at St. Paul's Hospital Millennium Medical College. It is located in the northern part of Addis Ababa, Ethiopia. It is the second largest referral hospital in the nation and is under the Ethiopian Federal Ministry of Health (FMOH). Its main service includes the provision of medical care, teaching and research. The medical college conducts different undergraduate & postgraduate programs. Currently there are 448 residents in the 16 residency programs provided by the college. These are general surgery, orthopedic & traumatology surgery, neurosurgery, ophthalmic surgery, maxillofacial surgery, urology, gynecology/obstetrics, ENT, emergency medicine, anesthesiology, internal medicine, pediatrics and childhood care, radiology, pathology, forensic medicine and psychiatry.

4.2 Study Period

The study will be conducted from April 1- Aug 15/2019.

Medical records of 2 years (from August 2017 to June 2019) will be considered for this study.

4.3 Study Design

Retrospective Facility based descriptive cross-sectional study will be employed.

4.4 Source Population

The source population was all postmenopausal patients who visited radiology department of SPHMMC.

4.5 Study Population

All postmenopausal patients having pelvic MRIs at SPHMMC for various pelvic complaints or screening.

4.5.1 Inclusion criteria

All medical records of patients who are more than 50 years of age having pelvic MRI in SPHMMC.

4.5.2 Exclusion criteria

- 1) Unclear menstrual history
- 2) History of hormonal therapy, chemotherapy, radiotherapy.
- 3) History of severe gynecological disease (eg. myomatous uterus or massive endometriosis with diffuse deviation or endometrial deviation), and
- 4) Hysterectomy.

4.6 Data Sampling Technique and Procedure

4.6.1 Sample size determination:

As there is no previous study (evidence) that indicates about the endometrial evaluation status in our country and other countries with similar socio-economic status, the prevalence (P) is assumed to be 50%; as a result, single proportion population formula will be used to determine the sample size; with assumptions of, $P = 50\%$, $CI = 95\%$, margin of error = 0.05, alpha of 5%, and non response rate of 10%.

$$n = Z^2 p(1-p) / w^2$$

Where N- sample size

p- Proportion

Z- Level of confidence and W- margin of error.

Non response rate-10%

$$\frac{(1.96)^2 * 0.5(0.5) * (1.1)}{(0.05)^2} = 422$$

$$(0.05)^2$$

Hence, the total sample size for this study will be 422; as the samples will be picked up from documentations (records). But the total number of study units is 97, hence convenience sampling technique is used to include all the sampling units.

4.6.2 Sampling procedure:

As there are a total of 97 study units in the sampling frame, the medical records for the purpose of this study will be selected by a convenience sampling, a type of non-probability sampling method.

4.7 Variables

Independent variables:

Socio-demographic (age, religion, occupation, education), Vaginal bleeding, HRT

Dependent variable:

Endometrial thickness

4.8 Data collection, quality control and management

Data will be collected by radiology residents attaching to Body imaging, and supervised by the principal investigator.

Data will be collected by Radiology Residents after adequate information about the study and contents of questioner is given.

108 chart and pelvic MRI reviews will be done.

Data quality will be assured by training data collectors and incentives will be offered.

4.9 Data Analysis

Data will be checked for completeness on a daily basis. To be edited and cleaned, the collected data will be entered using Epi-Data version 3.1 and exported into SPSS version-25 for analysis. Incomplete and inconsistent data will be excluded from the analysis.

The data will be processed by using descriptive analysis, including frequency distribution, cross tabulation and summary measures.

4.10 Ethical Consideration

The proposal will be submitted to institutional review board and approved accordingly. Then official letter will be submitted to the department of radiology. Confidentiality, accountability and neutrality will be kept throughout the study.

4.11 Dissemination and Utilization of Results

The results of the study will be disseminated to SPHMMC department of radiology and other bodies who need the research accordingly

4.12 Operational Terms

Hormonal replacement therapy- Is the administration of synthetic estrogen and progesterone to replace a woman's depleting hormone levels and thus alliate menopausal symptoms.

Hysterectomy- Is the surgical removal of the uterus.

Hysteroscopy- Is direct visualization of the uterus via a hysteroscope, a thin-lighted telescope like device which is inserted through the vagina and the images are seen on a screen.

Menarche- The first occurrence of menstruation.

Myomatous uterus- A uterus affected by non-cancerous growths called myomas or otherwise known as uterine fibroids

Postmenopausal bleeding- Bleeding that occurs in the postmenopausal woman, usually after 50 years.

Puberty- The period during which adolescents reach sexual maturity and become capable of reproduction.

Severe Endometriosis- The significant implantation of endometrial tissue(gland and stroma) in places other than the endometrium eg. Myometrium, also known as adenomyosis.

Sonohysterography- Is a kind of ultrasound exam in which fluid is put into the uterus through the cervix using a thin plastic tube to for better visualization of the uterus cavity.

Chapter Five

5.1 Budget

5.1.1 Budget for Personnel cost.

Person	Quantity	Duration	Unit price		Total Cost	
			Birr	Cent	Birr	Cent
Secretary	1	20 days	100	00	2000	00
Data collectors	4	60 days	45	00	10800	00
Phone cost	4	60 days	25	00	6000	00
Total					18800	00

5.1.2 Budget for material cost.

Material	Unit	Quantity	Unit price	Total
Paper	Each	10	200.00	2000.00
Pen	Each	30	5.00	150.00
Pencil	Each	30	3.00	90.00
Eraser	Each	30	5.00	150.00
Ruler	Each	2	10.00	20.00
Sharpener	Each	30	5.00	150.00
Duplicating cost	Paper	500	1.00	500.00
Total				3600.00

Budget summary

No	Expense	Quantity
1	Personnel cost	18800.00
2	Stationary material	3600.00
3	10% contingency	2240.00
4	Grand total	24640.00

5.2 Work Plan

Activity to be performed	Responsible person	Time frame (2019)									
		J a n	Feb	Mar	Apr	May	Jun	Jul	Aug		
Draft Proposal preparation	Prime researcher										
Final Proposal submission and approval	Prime researcher, advisors										
Ethical clearance	Prime researcher, Ethical committee										
Data collection	Prime researcher										
Data analysis and write up	Prime researcher										

Draft research paper submission	Prime researcher										
Research submission and approval	Prime researcher, advisors										
Research defense and final paper submission	Prime researcher The department										

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Abstraction Tool

Saint Paul's Hospital Millennium Medical College, Department of Radiology.

1- Age of patient-_____

2- Postmenopausal duration (in years)-_____

3-Vaginal bleeding

A. Yes

B. No

C. Not recorded

4- Any previous history major illness or abdominal surgery

A. Yes (Specify-

)

B. No

C. Not recorded

5- Endometrial thickness measurement in millimeters (mm)-_____

Results

Endometrial thickness of the 97 postmenopausal women (mean age 58 years; range 50–83) was 5.11 ± 2.71 mm (mean $\pm$ standard deviation) and ranged between 2 and 20 mm. Their endometrial thickness was poorly correlated with patient age ($r = 0.026$, $p = 0.652$) and postmenopausal duration ($r = 0.031$, $p = 0.583$).

The endometrium was ≥ 5 mm in 39 of 97 (40.2%) postmenopausal women. Two (2.06%) of the 39 women had an endometrium > 10 mm. Both of which were diagnosed with endometrial carcinoma on imaging.

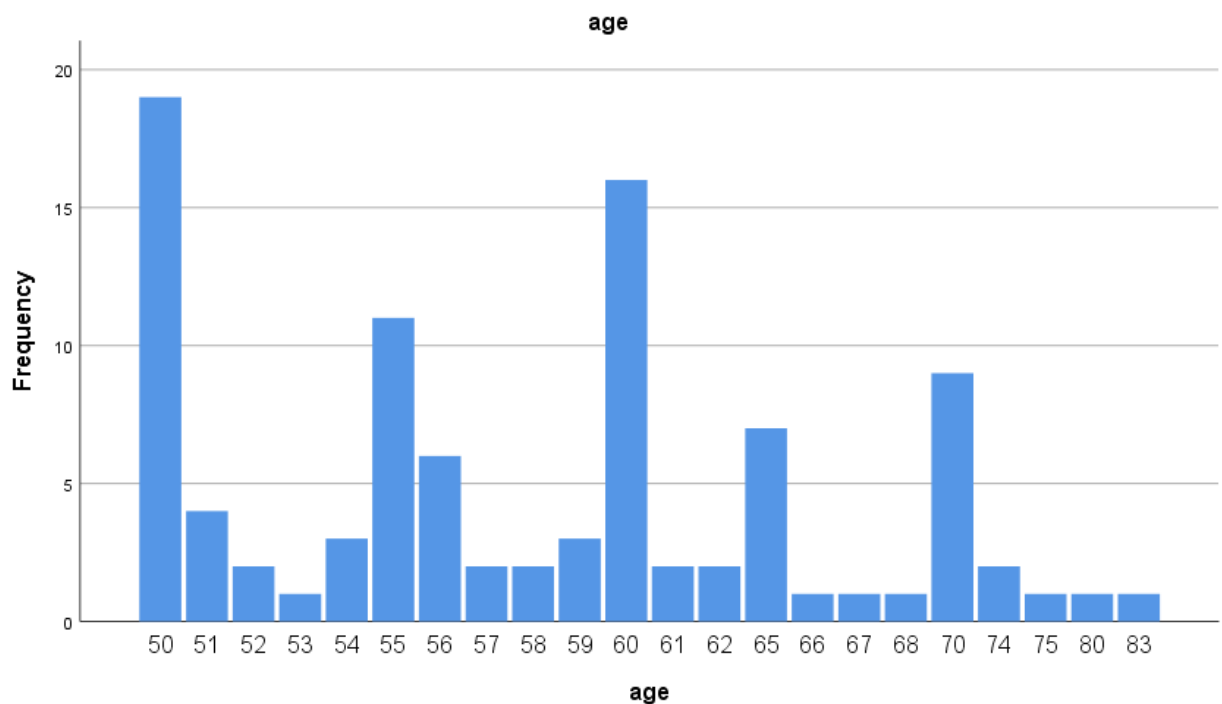


Figure 1: Endometrial thickness of 97 postmenopausal patients by age.

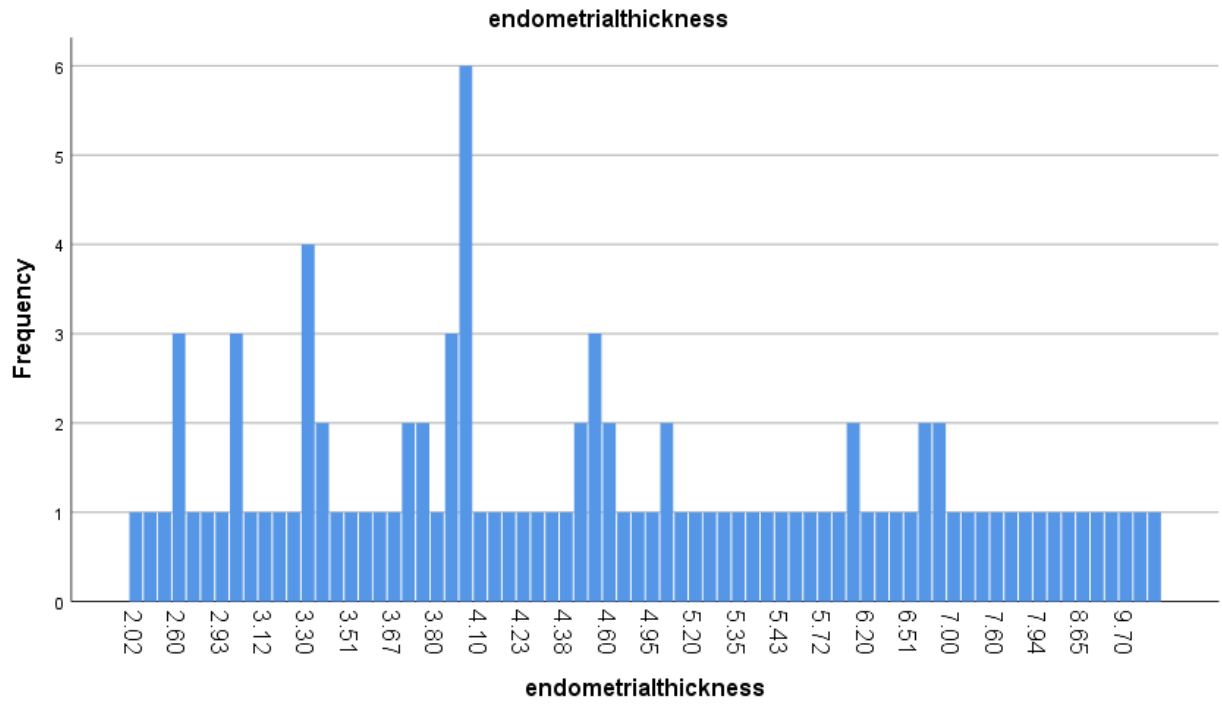


Figure 2: Endometrial thickness of 97 postmenopausal patients.

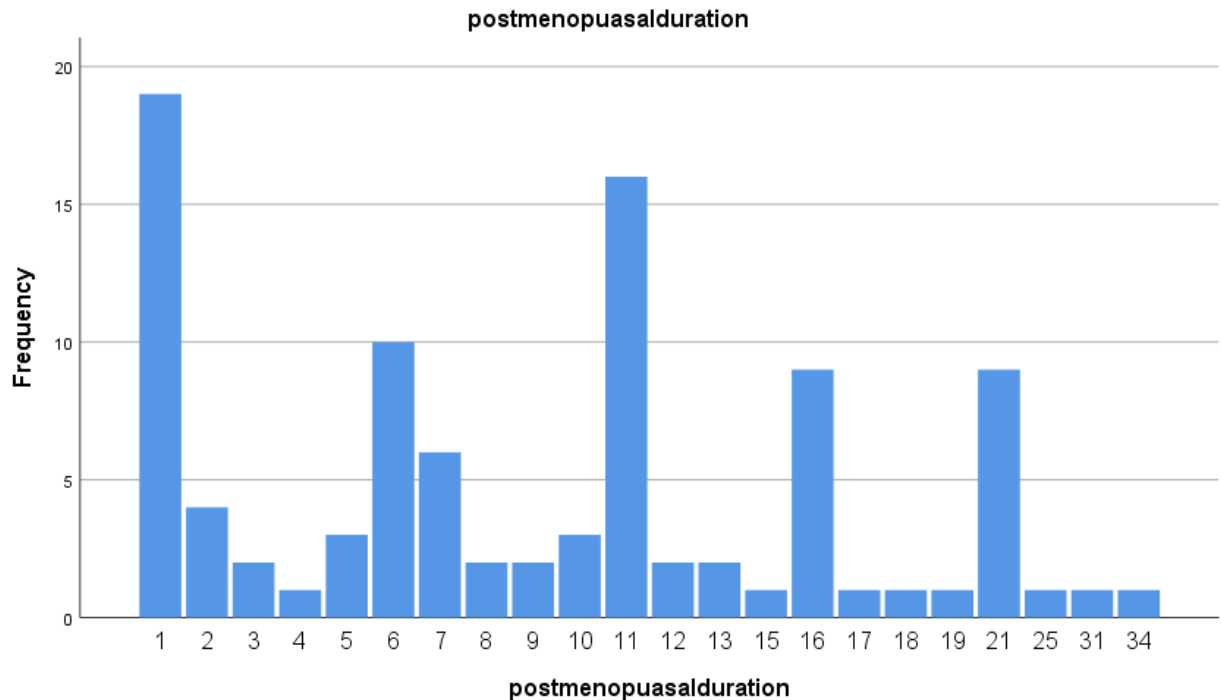


Figure 3: Relationship between endometrial thickness and time after menopause in 297 postmenopausal patients.

Discussion

The endometrial thickness was successfully measured in 97 postmenopausal women using 1.5-T MRI. US is commonly used for gynaecological examination because of its convenience and non-invasiveness; however, it has drawbacks. Because US examination depends on operator skill, examinations must be performed by experienced staff with adequate training and skills. Therefore, accurate measurement of endometrial thickness can be difficult if US image quality is suboptimal. Furthermore, US is a poorly reproducible modality, and retrospective evaluation is difficult. In comparison, MRI is highly reproducible and can be re-evaluated at any time. In the present study, MRI was not directly compared with TVUS. Further studies are required to determine whether a single T2 sagittal sequence is equivalent to TVUS for assessing endometrial thickness. The present analysis examined whether an endometrial thickness ≥ 5 mm in postmenopausal women is abnormal in a large sample population. Our findings support previous US studies stating that symptomatic endometrial thickness of 8 mm – 11 mm is most probably abnormal. In addition, the incidence of endometrial thickening (≥ 4.5 mm) in postmenopausal women ranges from 3% to 17%, while the incidence

of endometrial cancer in an unselected postmenopausal population is reportedly 1.3 to 1.7/1000 women. Some studies assert that there is no evidence supporting routine screening for asymptomatic endometrial thickening, and it remains debatable whether an endometrium ≥ 5 mm should always be considered abnormal. In 2010, Goldstein²² recommended that postmenopausal asymptomatic endometrial thickening should be evaluated on a case-by-case basis. Even in an elderly patient with endometrium ≥ 5 mm and a long postmenopausal period, it is inappropriate to consider the condition abnormal if she is asymptomatic.

The correlation between endometrial thickness, age and postmenopausal duration was also assessed. The results showed that endometrial thickness correlated poorly with postmenopausal duration and patient age. Further studies are required to determine the MRI cut-off to accurately exclude neoplasia. Future studies performing limited MRI examinations prior to endometrial biopsy in patients with endometrial hyperplasia or suspected of having endometrial carcinoma are planned.

Limitations of the study

The intra-observer error is unknown because all measurements will be performed visually by one radiologist. Furthermore, the study does not compare MR and US images in the same subject. The third limitation is that endometrial thickness may not be measured correctly on sagittal T2-weighted images owing to postmenopausal hemorrhage; in such cases, a follow-up MRI may be desirable.