AN EVALUATION OF TRANSVAGINAL ULTRASOUND IN THE ASSESSMENT OF ENDOMETRIAL THICKNESS IN BLACK SOUTH AFRICAN PATIENTS PRESENTING WITH POSTMENOPAUSAL UTERINE BLEEDING

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TITLE: AN EVALUATION OF TRANSVAGINAL ULTRASOUND IN THE ASSESSMENT OF ENDOMETRIAL THICKNESS IN BLACK SOUTH AFRICAN PATIENTS PRESENTING WITH POSTMENOPAUSAL UTERINE BLEEDING

Dissertation submitted in full compliance with the requirements for the M. Tech in the Department of Radiography and the Durban Institute of Technology.

Except for questions specifically indicated in the text and such help as I have acknowledged, this dissertation is wholly my own work, and has not been submitted for any qualifications at any other institute.

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27/05/04

Signature Date

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Submitted on 27/05/04 at the Durban Institute of Technology of Durban.

DEDICATION

This book is gratefully dedicated to my late mum and brother for all their guidance, motivation and support and to my patients and colleagues who have so willingly helped in its preparation.

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ABSTRACT

The object of this study was to use Transvaginal ultrasound to evaluate the thickness of the endometrium to exclude endometrial abnormality in Black South African women with postmenopausal uterine bleeding. Transvaginal ultrasound is an excellent diagnostic method for assessing endometrial pathology.

The study was carried out at the Gynaecological Ultrasound Department, King Edward VIII Hospital.

The study included 76 Black women with postmenopausal uterine bleeding. The thickness of the endometrium was measured by Transvaginal ultrasound.

The measurement included both endometrial layers (double-layer technique). The Transvaginal ultrasound measurement was compared with the histopathological diagnosis of the biopsy specimens.

At the end of the investigation, findings obtained were 3.9% non-representative, 44.8% endometrial adenocarcinomas, 14.5% benign polyp, 3.9% chronic Endometritis, 17.1% benign endometrium, 5.3% endometrial hyperplasia, 9.2% atrophic endometrium, 3.9% myometrial invasion and 1.3% Malignant Mixed Mullerian Tumour.

In this study, the thickness of the endometrial echo varied from 5mm to 35mm, with a mean of 18,2mm. When the thickness of the endometrial echo was compared with the histopathological results, the mean value for non-representative was 7.83mm, much lower than the thickness of an active endometrium (13.25mm). In cases with atrophic endometrium, the thickness ranged from 6mm to 30mm with a mean of

15.86mm. The mean value obtained for cases with endometrial adenocarcinoma was 20.32mm (range 11 to 35mm). The sensitivity, specificity and accuracy of Transvaginal ultrasound for detecting endometrial malignancy were 100% if the cut-off limit of 4mm was used

In conclusion, this study using Transvaginal ultrasound demonstrated that a thickness limit greater than 8mm was considered in detecting malignancy. No malignant endometrium was thinner than 5mm. Therefore in women with postmenopausal uterine bleeding and an endometrium less than 4mm, it may be justified not to perform further investigations. Transvaginal ultrasound is a simple, well-tolerated safe and reliable method for identifying endometrial thickness in postmenopausal Black South African women.

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CHAPTER 1: INTRODUCTION

Postmenopausal uterine bleeding is a common complaint presenting for medical attention and is estimated to affect about 20% of women [Long et al., 1989)]. As part of the clinical evaluation of patients presenting with postmenopausal uterine bleeding, an assessment of the endometrial status is essential to determine the need for further evaluation. In addition to biopsy, ultrasound is used extensively to determine adnexal pathologies as well as uterine size and endometrial thickness. In terms of its diagnostic value, studies by [Karlsson et al., (1995); Maia et al., (1996) and Wolman et al., (1996)] have shown the thickness of the endometrium to be a significant clinical indicator of potential malignancy. Although available, the international standard set of cut-off values used in the assessment of endometrial thickness often differ. [Karlsson et al., (1995)]

In current practice, transabdominal ultrasound is commonly used to assess endometrial thickness. However, the reliability of the transabdominal technique in effectively determining endometrial thickness is questionable. In addition to the production of lower quality scans, underlying pathology such as fibroids and endometrial polyps are often overlooked [Kekre et al., 1997)].

A significant component in the latest design and resolution of transvaginal probes has made it possible to assess the endometrium more effectively. The use of transvaginal ultrasound may play an integral role as part of the gynaecological examination in screening for endometrial pathology. In addition,

the placement of the probe close to the region of interest and the avoidance of subcutaneous fat allows the endometrium to be evaluated more effectively and a full urinary bladder is no longer required. Transvaginal ultrasound therefore, can be performed more rapidly by avoiding unnecessary delays and proves superior in terms of patient acceptability [Maia et al., 1996)].

This study aims to use transvaginal ultrasound to investigate and demonstrate endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding and to recommend the cut-off values that may be used for early prediction of malignant lesions if present. This study aims to:

1. Evaluate endometrial thickness
2. Recommend the cut-off value in Black South Africans with postmenopausal uterine bleeding.
3. Investigate the association of malignancy with endometrial thickness.

CHAPTER 2: LITERATURE REVIEW

Postmenopausal uterine bleeding refers to bleeding from the genital tract of at least 6 months continuous amenorrhoea in a menopausal – aged woman not on hormonal replacement therapy and it is estimated to affect about 50% of women over the age of 45 [Dubskinsky et al., 1997)].

Postmenopausal bleeding may not necessarily be that of frank bleeding or spotting, as a complaint of pinkish or brownish vaginal discharge is also significant [Dubskinsky, et al., 1997)].

Patients presenting with postmenopausal symptoms often complain of hot-flushes, irritability, mood swings and night sweats which is physiologically due to estrogen deficiency. The vagina is usually dry and there is a presence of dysparenuia. [Bailie et al., (1996)].

There are various clinical and medical reasons that may cause postmenopausal bleeding such as genital tract malignancies, i.e. vulval, vaginal, cervical , uterine (endometrial / sarcoma), fallopian tube and ovarian cancer. Hormone replacement therapy, endometrial hyperplasia, atrophic endometritis / vaginitis, exogenous estrogen therapy, endogenous estrogen - tumors and obesity, polyps (endometrial / cervical) and rectal / urinary tract pathology [Bailie et al., (1996)].

However, the causes of pure uterine postmenopausal bleeding in relation to frequency are: (45%) atrophic endometritis, (15%) endometrial hyperplasia, (10%) proliferative changes, (10%) submucosal fibroids, (10%) uterine polyps, and (10%) uterine malignancy.

Anatomy of the female pelvis

The uterus lies in the pelvis between the rectum and the bladder. The components of the uterus are the cervix and the body, separated by the isthmus. The fundus defines the portion of the uterine body, cranial to the lateral horns or cornua where the fallopian tubes insert. In the longitudinal section, the uterus appears to have a relatively narrow body and a more pronounced fundus and cervix [Agur., 1997)].

The uterus appears as a thick-walled, hollow muscular shaped organ consisting of three layers:

Endometrium – this is the mucosal layer that is located in the inner layer of the uterus divided into two sub layers:

(a) Decidual layer

- Functional layer closer to the uterine cavity
- Thickness and changes in the mucosal layer appear throughout the cycle and shedding menses

(b) Basal layer

- Permanent layer that provides new decidual layer following menses.

Myometrium – muscular layer

- Forms bulk of uterine wall containing three layers of smooth muscle.

Perimetrium – serous layer

- Forms outer layer of the uterus, which is part of the visceral peritoneum.

Body – consisting of the fundus which is dome shaped.

Cervix – neck of uterus, which is rounded and conical in shape opening into vagina at 90 degrees.

Vagina – fibro-muscular tube extending from the vestibule of the vulva externally to the cavity of the uterus internally.

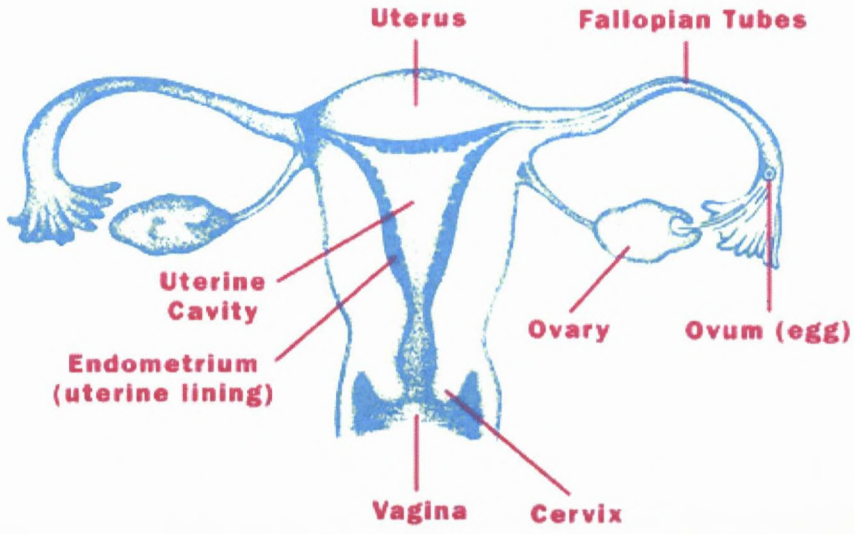


FIGURE 1: NORMAL ANATOMY OF THE FEMALE PELVIS

(Online: www.google images.anatomy of female pelvis:2003)

2.1 NORMAL ULTRASOUND ANATOMY OF THE FEMALE PELVIS

In visualizing the anatomy of the female reproductive system, two techniques may be used: ultrasonography either by transabdominal or transvaginal routes [Callen, (2000)].

The normal ultrasound features of the uterus appear pear shaped and demonstrates a homogenous to medium echogenic pattern of the myometrium.

The endometrium manifests as a highly reflective thin midline strip, termed the endometrial stripe. The hypoechoic halo, sometimes seen adjacent to the endometrium should not be included in the measurement. The cervix appears conical, homogenous with an echogenic midline stripe [Fleischer et al., (1991)].

2.1.1. Transabdominal Ultrasound

In the transabdominal approach, a full bladder is required which creates an acoustic window permitting visualization of the uterus and adnexa. Structures are imaged in more than one plane (Figure 2 A and B) i.e. transverse, longitudinal and oblique. A 3,5 to 5 MHz transducer is required. This approach is limited by obese patients, inadequate bladder filling, incontinent patients, abdominal scarring (Caesarian), and retroflexed uterus[Callen, (2000)]. The patient lies in the supine position on an examination couch, gel is applied to the pelvis and transverse-axial and sagittal scanning planes are performed through the short and long axis of the uterus. This technique assists in determining the location and anatomic relationship of pathology [Callen, (2000)].

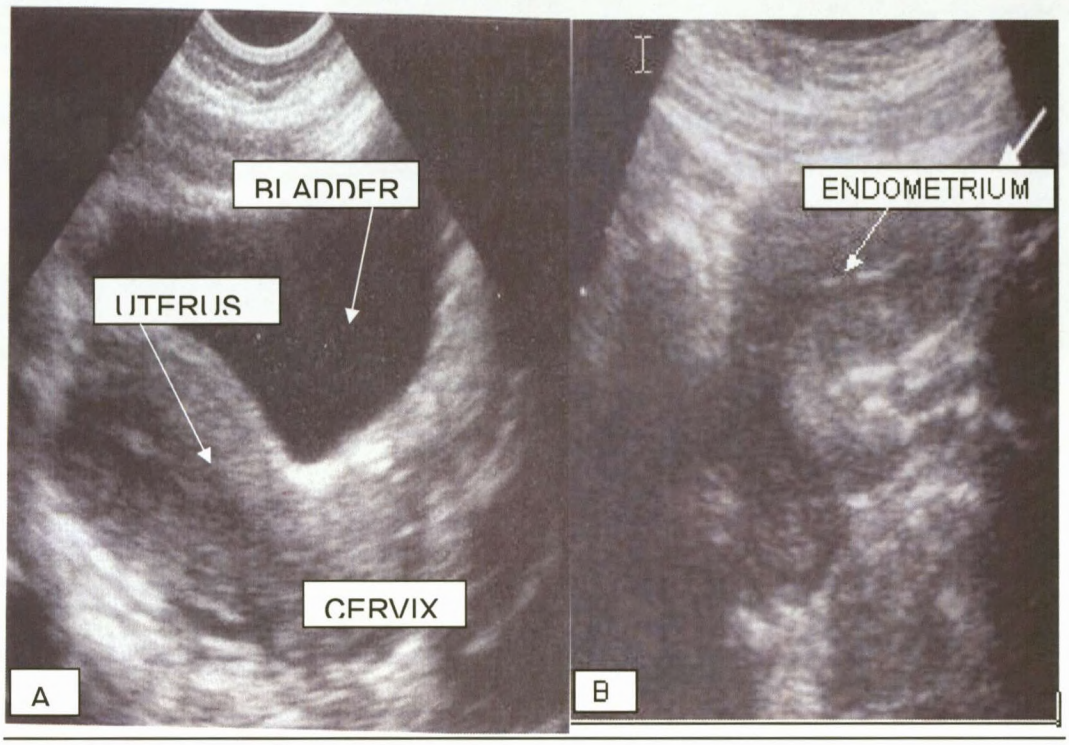


FIGURE 2: TRANSABDOMINAL ULTRASOUND SCAN OF UTERUS

A: Longitudinal Scan

B: Transverse Scan

(King Edward VIII Hospital Ultrasound Department)

2.1.2. Transvaginal Ultrasound

Transvaginal ultrasound produces a clearer image of the uterus and endometrium than transabdominal ultrasound because of the proximity of the transvaginal probe to the relevant organs [Kekre et al., (1997)].

The transvaginal approach provides more ultrasound information because of the probe - proximity to the organ of interest and the higher insonating transducers.

1. This techniques does not require a full bladder and has a high patient acceptance:
    (i) Eases stress with incontinent patients and urinary infections
    (ii) Eliminates full bladder discomfort
    (iii) Fast medical management
2. High resolution scanning with more magnification.
    (i) Ability to evaluate endometrial thickness and pathology
    (ii) Better visualization of pelvic organs in obese patients and those with excessive bowel gas.

Transvaginal ultrasound is limited in sexually inactive patients.

Development of dedicated transvaginal probes has made the study easier to perform, and much more acceptable to the patient. With the use of transvaginal ultrasound the endometrium can be visualized more accurately [Tahir et al., (1999)].

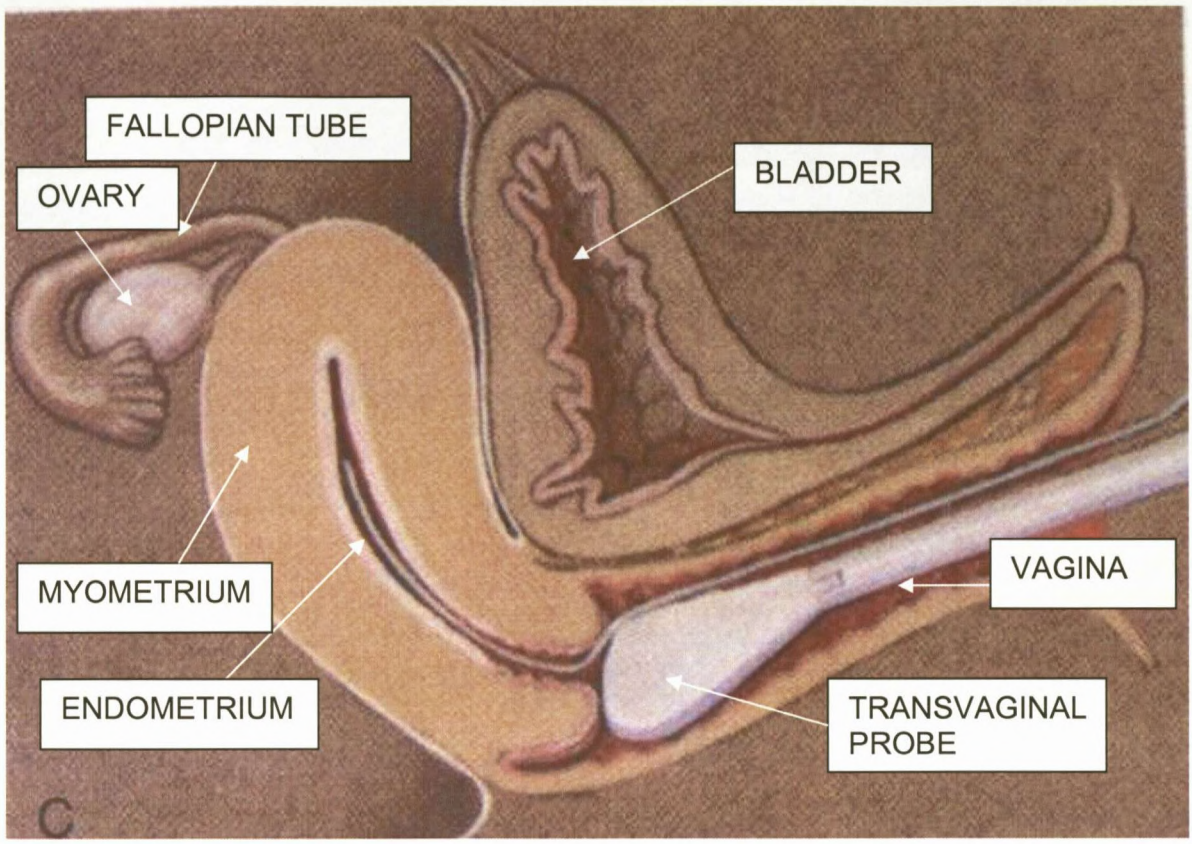


FIGURE 3: POSITION OF TRANSVAGINAL PROBE INTO VAGINA

(Adapted from: Callen. 2000)

Scanning Technique

A lubricated probe is inserted into vaginal cavity and manipulated to image longitudinal and transverse sections of the uterus and adnexa. This is done by pushing, pulling, tilting or rotating the probe.

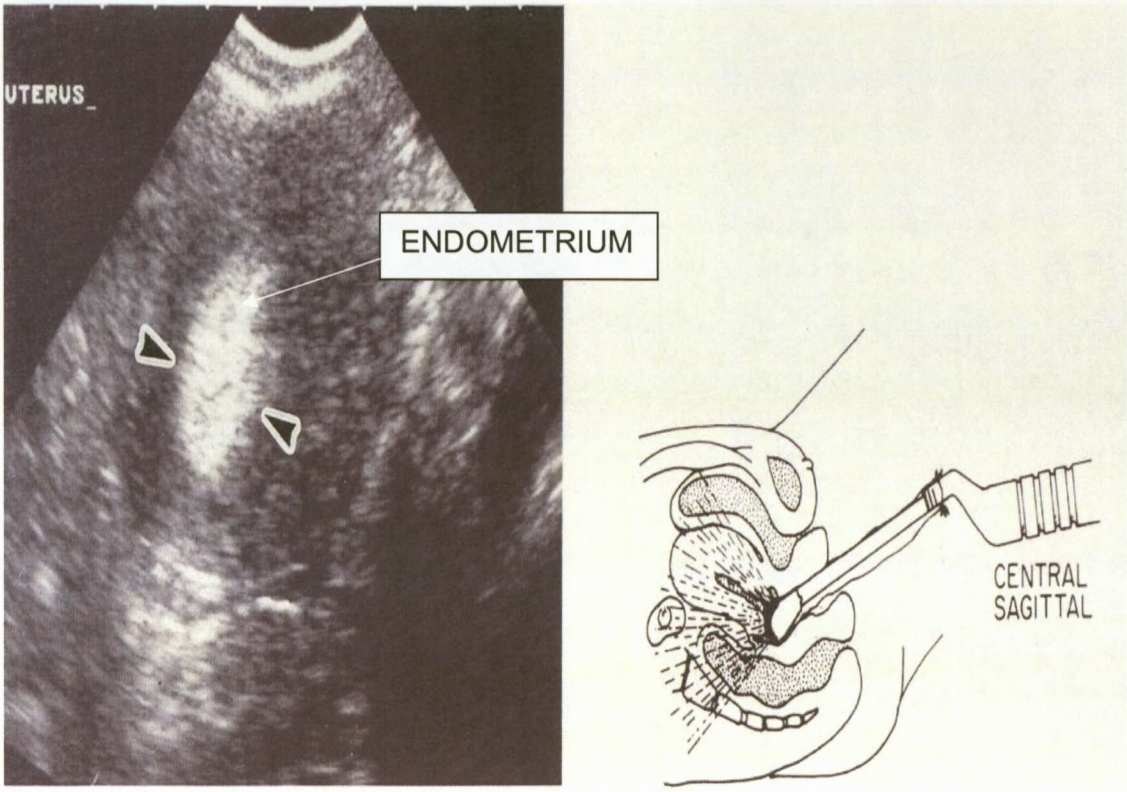


FIGURE 4: TRANSVAGINAL LONGITUDINAL VIEW OF THE UTERUS AND ENDOMETRIUM

A – Transvaginal B-Mode Image

B – Line diagram of Transvaginal Approach

(Adapted from: Fleischer et al., 1995)

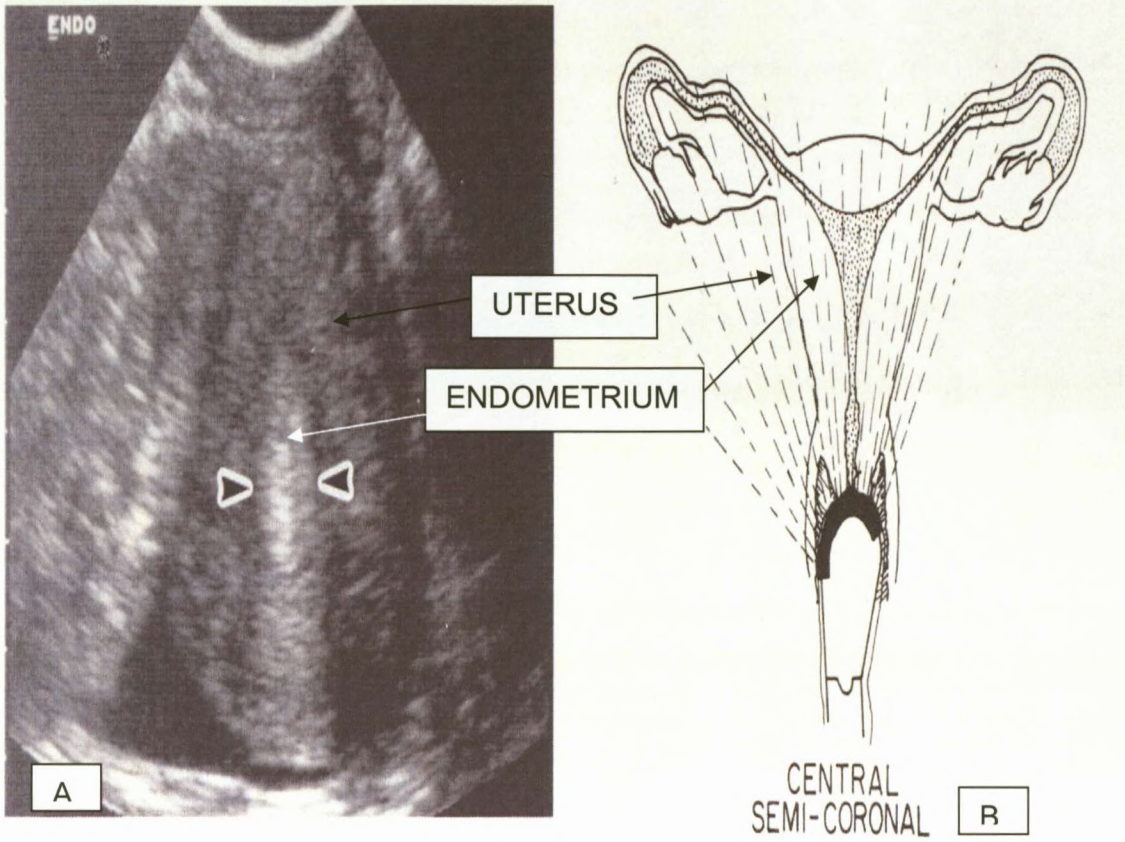


FIGURE 5: TRANSVAGINAL LONGITUDINAL VIEW OF THE UTERUS AND ENDOMETRIUM

A – Transvaginal B-Mode Image

B – Line diagram of Transvaginal Approach

(Adapted from: Fleischer et al., 1995)

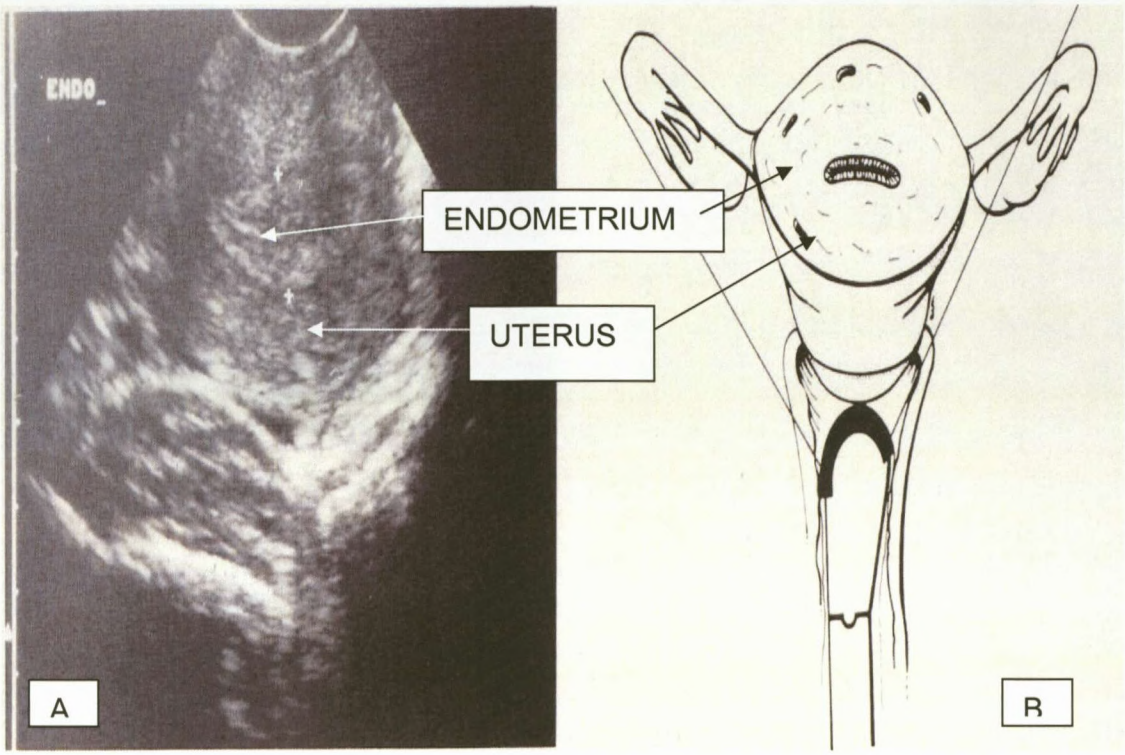


FIGURE 6: TRANSVAGINAL TRANSVERSE VIEW OF THE UTERUS AND ENDOMETRIUM

A – Transvaginal B-Mode Image

B – Line diagram of Transvaginal Approach

(Adapted from: Fleischer et al., 1991)

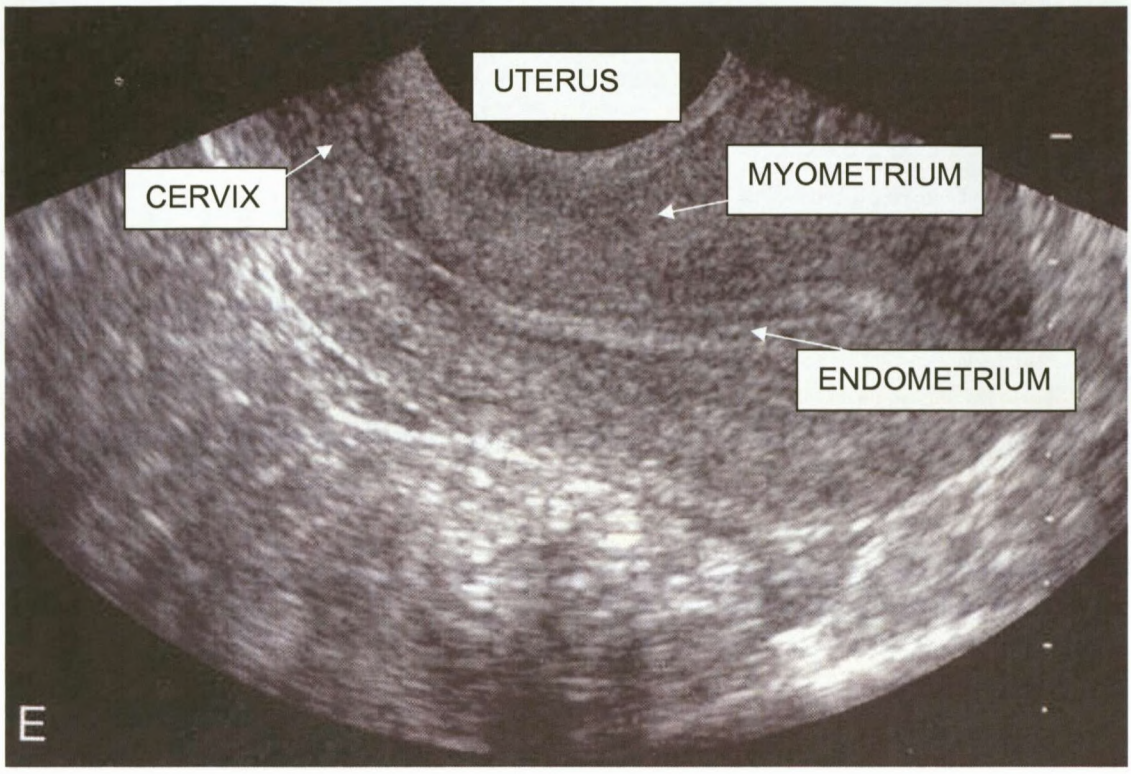


FIGURE 7: TRANSVAGINAL LONGITUDINAL SCAN OF UTERUS

(Adapted from: King Edward VIII Hospital Ultrasound Department)

2.2 EVALUATION OF THE ENDOMETRIUM

The measurement of the endometrial thickness using transvaginal ultrasound has been suggested as a screening technique to obtain an image of the endometrial lining and predict the likelihood of disease based on its thickness. Transvaginal ultrasound may be helpful in determining which patients should have a biopsy (endometrial thickness $\geq$ 4mm) and in detecting other pelvic abnormalities in patients reporting with abnormal uterine bleeding [Canavan and Doshi, (1999)].

The endometrial thickness in a premenopausal woman does not exceed 4mm on day 4 and 8mm on day 8 of the menstrual cycle. In the second half of the cycle, the endometrium is more vascular and oedematous, the echogenicity increases and the endometrial thickness measures between 7 and 12mm. The endometrial echogenic stripe should be uniform and any irregularity or variation in thickness is treated with suspicion, even if the measurement is within normal limits. The endometrium in a postmenopausal woman should be thin (< 4mm), and regular. This size may be altered by certain medications (such as estrogen prescribed for HRT). When the endometrial thickness is > 10mm thick in a postmenopausal woman with uterine bleeding, further investigation is considered. [Callen, (2000) and Fleischer et al., (1991)].

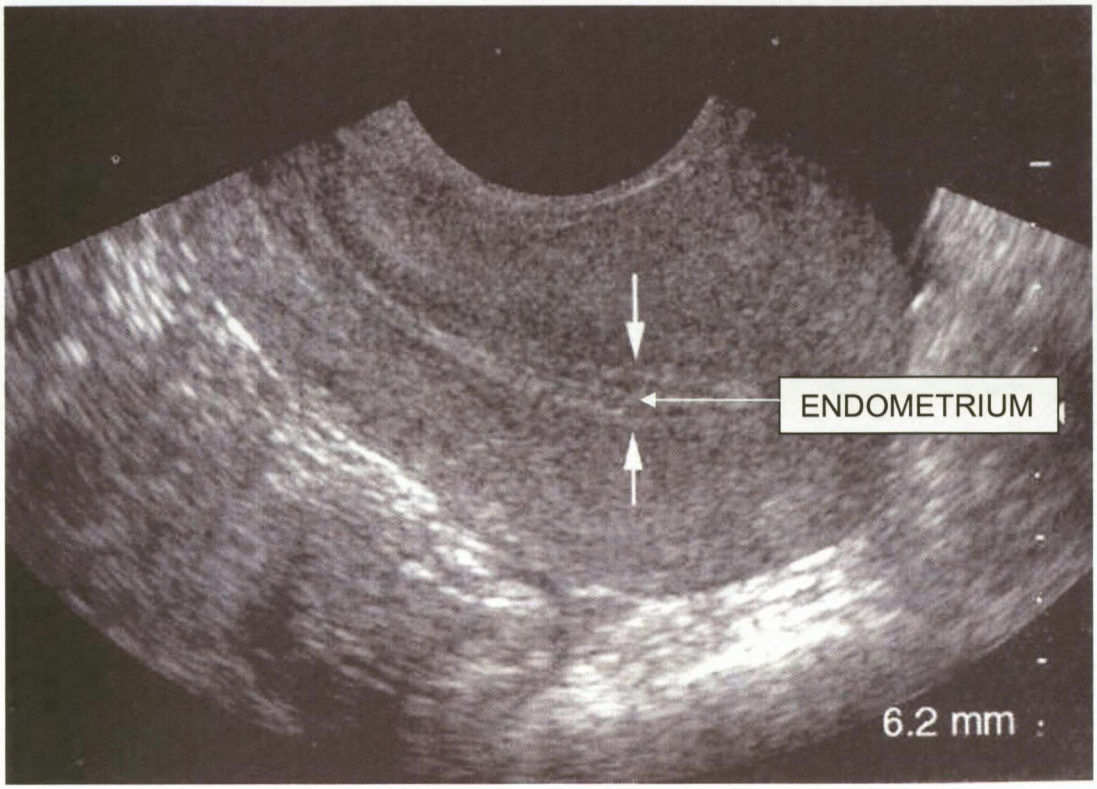


FIGURE 8: MEASUREMENT OF ENDOMETRIAL THICKNESS

(King Edward VIII Hospital Ultrasound Department)

Endometrial pathologies include endometrial hyperplasia which is a non-specific thickening of the endometrial lining caused by estrogen hyper-stimulation, common cause of vaginal bleeding and irregular thickening of the endometrium with cystic changes presenting with abnormal uterine bleeding.

The ultrasound appearance of endometrial hyperplasia is a thickened, echogenic endometrium with cystic areas [Callen, (2000)].

2.2.1 Endometrial Polyps

Endometrial polyp is a common lesion originating as local growths of endometrial tissue covered by epithelium. The lesions may be pedunculated usually arising in the fundus. The typical presentations in patients who are symptomatic are vaginal bleeding or mucous discharge.

Ultrasound appearance of endometrial polyps

- Appears as focal areas of increased endometrial thickening. The transvaginal images show focal irregularity of the endometrial stripe [Callen, (2000)].

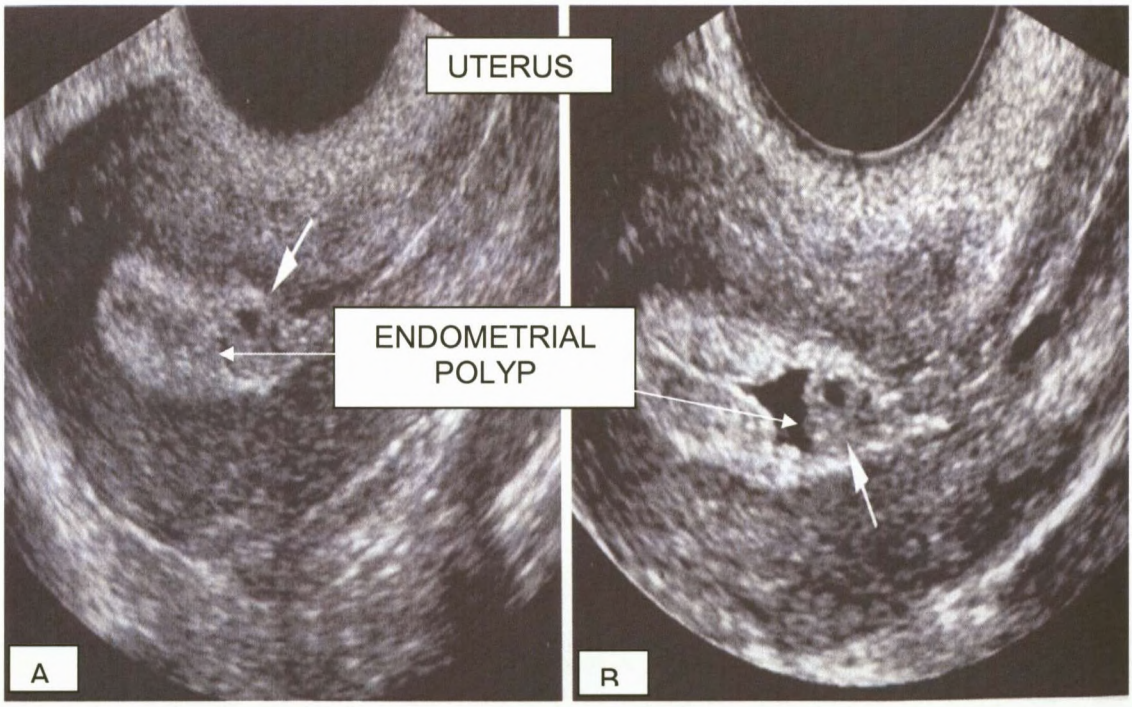


FIGURE 9: ENDOMETRIAL POLYP

A – Thickened endometrium with a small polyp

B – Polyp clearly seen after saline infusion

(Adapted from: Callen, 2000).

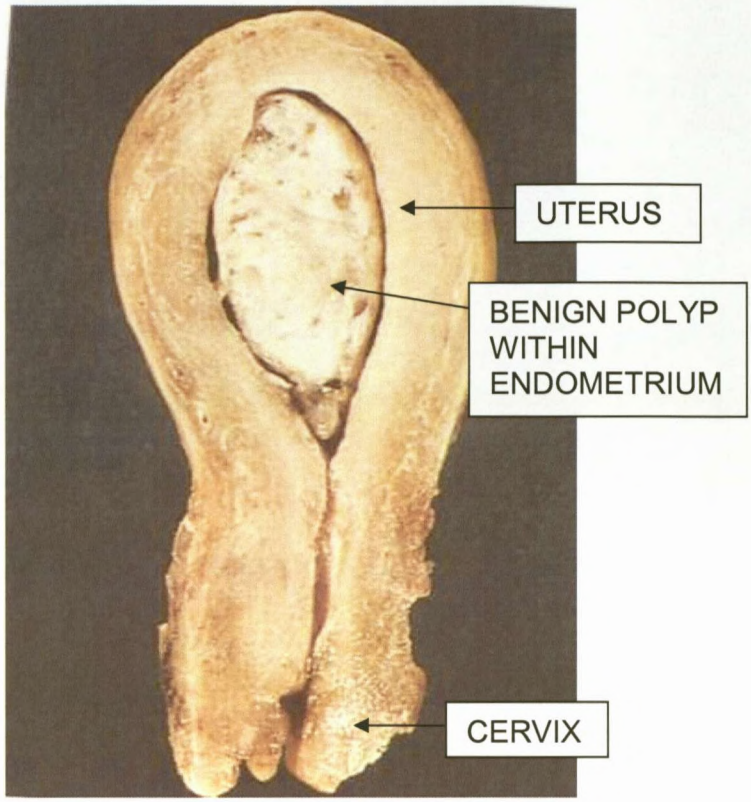


PLATE 1: BENIGN ENDOMETRIAL POLYP

(Adapted from Stevens and Lowe, 1995).

2.2.2 Submucosal Fibroids

Submucosal fibroids appear as solid masses located beneath the endometrium and protrude into the endometrial cavity. These tumours are mostly symptomatic and may cause postmenopausal bleeding.

Ultrasound appearance of submucosal fibroids may displace or distort or alter the homogenous mid-echo of the myometrium. The lesion appears as a hypoechoic solid concentric mass with relatively poor sound through-transmission. Increased echogenicity with small cystic areas confirms the degeneration process [Callen, 2000)].

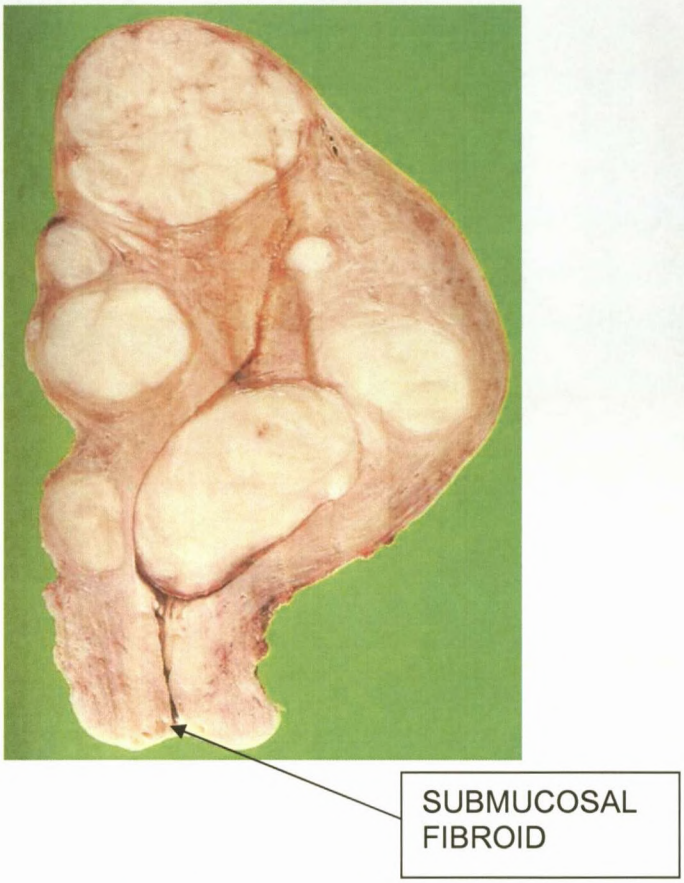


PLATE 2: SUBMUCOSAL FIBROID IN THE ENDOMETRIAL CAVITY

(Adapted from: Stevens and Lowe, 1995).

2.2.3 Endometrial Cancer

Endometrial cancer growth may be exophytic and polypoid, sometimes filling the uterine cavity. Growth towards the myometrium is superficial at first, but deep myometrial invasion may develop. Myometrial invasion with lymph node metastases is associated with poorer prognosis. Spread to the cervix is an important criterion for tumour staging. In later stages, there is transmural spread of tumour to the adnexa, fallopian tubes and

ovaries. [Callen, (2000)]. The patients often present with pain, because of uterine distension resulting from intra-cavity bleeding associated with cervical blockage.

Symptoms of postmenopausal pelvic inflammatory disease may be secondary to tumour necrosis and infection. Important diagnostic features in staging include depth of myometrial invasion, involvement of the cervix, spread to the tubes, ovaries or pelvic lymph nodes. The ultrasound appearance is a bulky uterus with a bulbous or lobulated uterine contour and an endometrium greater than 5 to 6mm. The pattern of endometrial wall may appear markedly irregular and may consist of fluid.

Ultrasound has a useful role in distinguishing endometrial cancer by excluding invasion. An echogenic mass in the adnexa is suggestive of extension to the adnexa. If the cervix appears bulky and inhomogeneous, it is suggestive of invasion [Callen, (2000)].

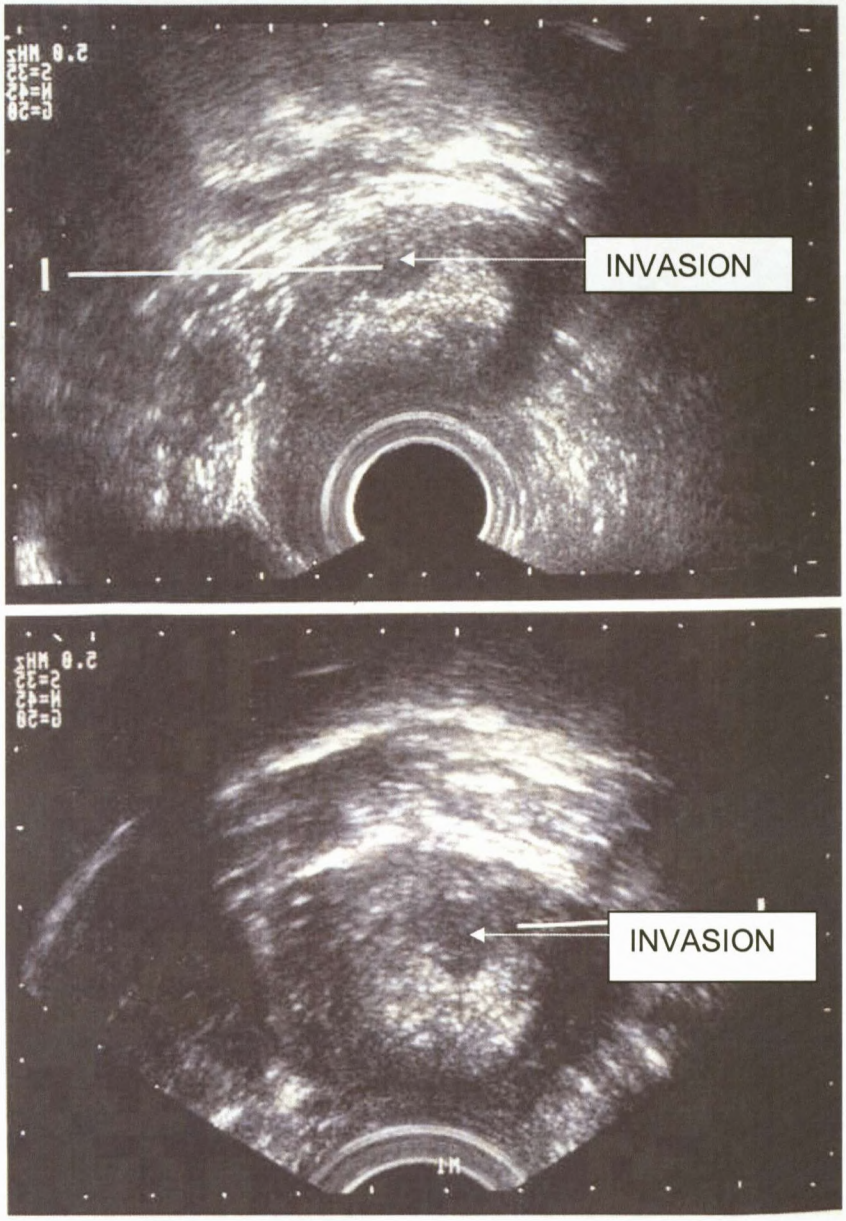


FIGURE 10: TRANSVAGINAL ULTRASOUND SHOWING ENDOMETRIAL CARCINOMA (Adapted from: Bernaschek *et al.* 1990).

A – Longitudinal scan showing widened, irregular endometrium with hypoechoic area representing invasion.

B – Transverse scan

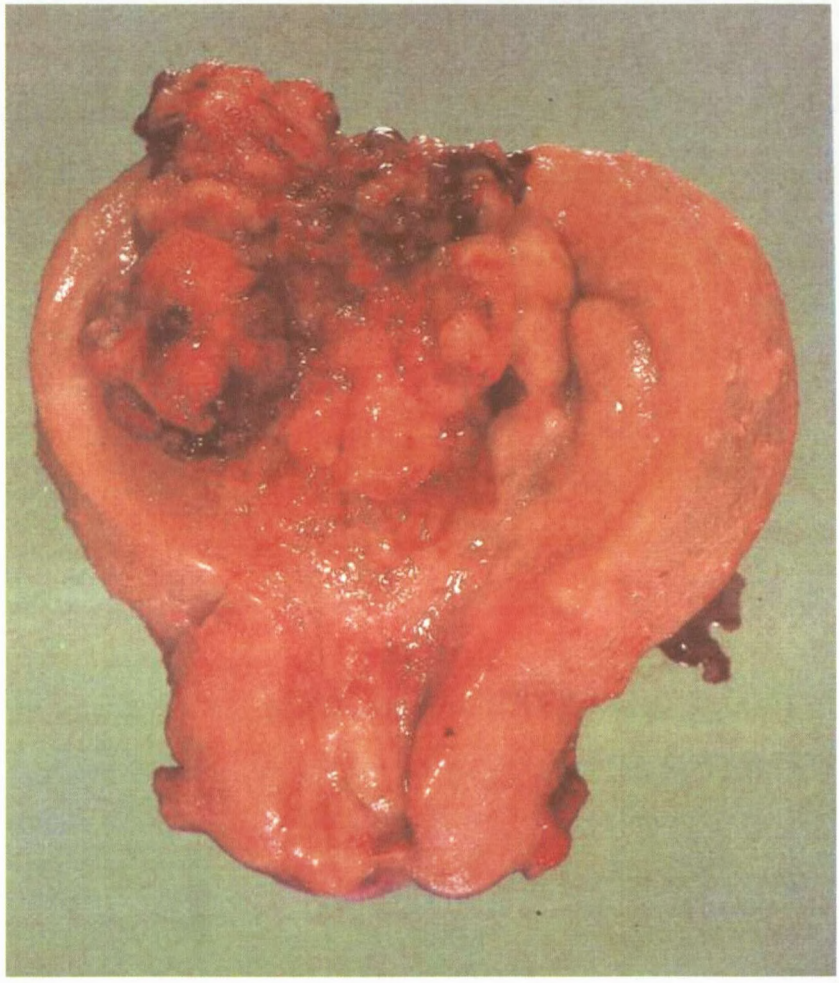


PLATE 3: ENDOMETRIAL ADENOCARCINOMA WITH MYOMETRIAL INVASION

(Adapted from: Nelson R Mandela School of Medicine – Medical Media Services Department)

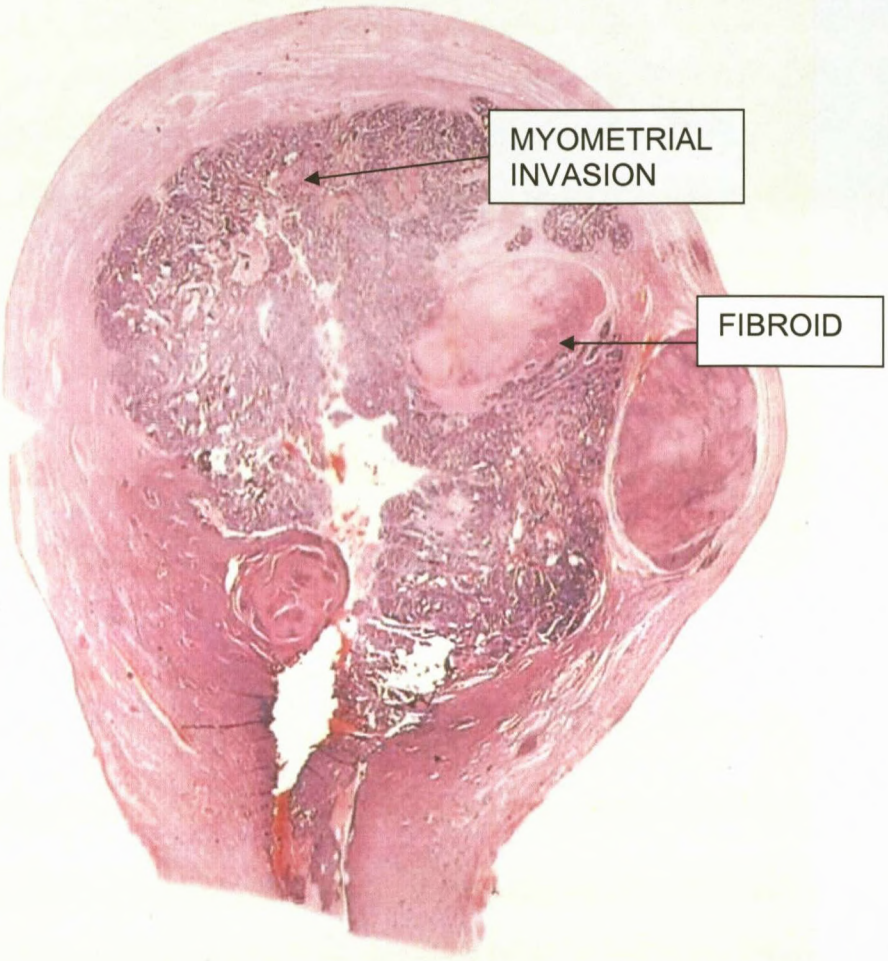


PLATE 4: HISTOLOGICAL SECTION OF UTERUS WITH ADENOCARCINOMA OF THE ENDOMETRIUM

(King Edward VIII Hospital – Histopathology Department)

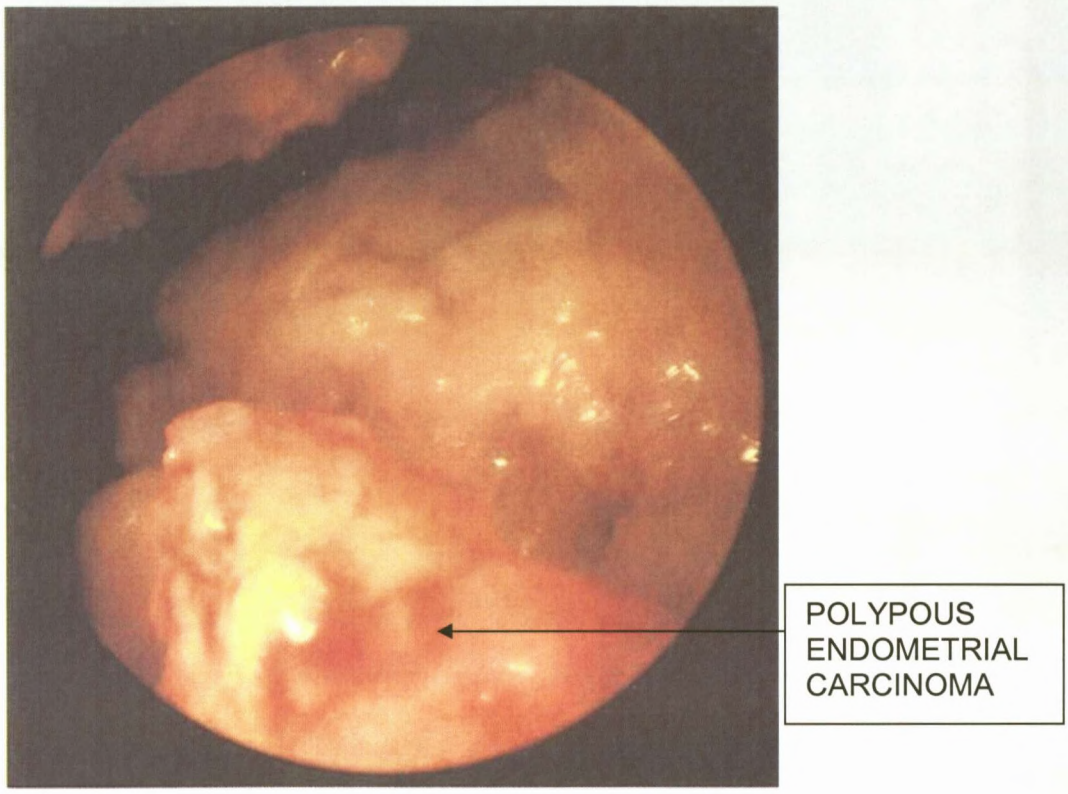


PLATE 5: HYSTEROSCOPIC VIEW OF ENDOMETRIAL CARCINOMA

(Nelson R Mandela School of Medicine – Obstetrics and Gynaecology Department).

Various studies have been performed pertaining to the measurement of endometrial thickness using transvaginal ultrasound to determine the cut-off value that could separate benign from malignant and excluding endometrial biopsy if the endometrial thickness is < 5mm [Karlsson et al., (1995); Maia et al., (1996) and Wolman et al., (1996)].

Two large studies of 930 and 1138 women reported results with transvaginal ultrasound in women with postmenopausal bleeding [Karlsson et al., (1995)]. Both used the double layer thickness of 4mm as a cut-off point. The sensitivity was 96 to 98 percent and the specificity was 36 to 68 percent [Brand et al., (2000)].

However there appears to be no documented data pertaining to cut-off values for Black patients. In general, cut-off values for endometrial thickness have been documented but studies [Karlson et al., (1995); Kekre et al., (1997); Tsuda et al., (1995)] have shown that variations between ethnic groups exist. In South Africa, the clinical impression is that there is often a lack of corroboration between values from literature and that presented upon examination of Black South African patients.

A study conducted in Japan reported that the 5 mm cut-off may not hold true for Japanese women of Asian origin, for whom a cut-off of 3mm should be used [Tsuda et al., (1995)]. It therefore appears that although the role of transvaginal ultrasound in separating pathological from non–pathological or benign from malignant causes of postmenopausal bleeding is well described, racial variations may be present, which may well influence the cut-off values for these conditions. These variations need to be taken into account if transvaginal ultrasound is to be used as a guide to decide whether endometrial biopsies are necessary to detect pathological causes of bleeding.
In the largest study that included 1168 patients conducted from 1989 to 1992, on a multi-centre co-operation amongst Nordic countries, it was found that there was no

malignancy present if an endometrial thickness of < 5mm measured on ultrasound [Karlsson et al., (1995)]. The chances of finding other pathologies was less than 5,5 % if a cut-off value or measurement < 4mm was used. Furthermore, these studies have been conducted amongst Caucasian women of European descent. The relation between the findings of endometrial thickness for the detection of uterine pathologies and ethnicity is not well documented or emphasized in the literature. In the literature reviewed, it appears that ethnicity may influence endometrial thickness in separating benign from malignant causes of postmenopausal bleeding [Tsuda et al., (1995)].

In the study conducted in India by Kekre et al., (1997), where 4mm was used as the cut -off to detect endometrial pathology, a sensitivity of 97%, specificity of 98%, positive predictive value of 97% and negative predictive value of 94% was found with the use of transvaginal ultrasound.

TABLE 1: COMPARISON OF ENDOMETRIAL THICKNESS BETWEEN ETHNIC GROUPS

Ethnic Group Author/s	Japanese Tsuda et al. 1995	Caucasian Karlson et al. 1995	Indian Kekre et al. 1997
EQUIPMENT	Aloka 650 SSD Hitachi 5-7,5 MHz	Acuson, Siemens 5 MHz	Aloka 55 D 620 5 MHz
MEASUREMENTS Average/mean Std. Deviation	3mm -	< 5mm 3.9	4mm 12.6
OTHER EXAMINATIONS	Endometrial Biopsy	Endometrial Biopsy Hysteroscopy	Endometrial Biopsy
CONFIRMED	No malignancy	No malignancy	< 4mm suggestive of
FINDINGS	<4mm for<5 yrs And <3mm ≥5 yrs Postmenopausal Bleeding.	< 5 mm	no malignancy

Table 1 shows the ultrasound findings using transvaginal ultrasound, between the different ethnic groups to assess the cut-off value for endometrial thickness.

The efficacy of transvaginal ultrasound to determine benign or malignant endometrium is recognized as it shows thickness and echopattern to establish pre-malignant and malignant causes. Whilst clinical history and physical examination are necessary in the assessment of such patients with postmenopausal bleeding, other modalities that have been described include transvaginal ultrasound, transabdominal ultrasound, outpatient hysteroscopy and endometrial biopsy and in-patient hysteroscopy and curettage [Tahir et al., (1999)].

Tahir et al., (1999) compared the efficacy of transvaginal ultrasound with in-patient hysteroscopy. It was found that a combination of transvaginal ultrasound, pipelle outpatient endometrial biopsy and outpatient hysteroscopy had similar efficacy to in-patient hysteroscopy and curettage for the investigation of abnormal uterine bleeding. This study concluded that transvaginal ultrasound and endometrial biopsy could be safely used as the initial investigative tool in the management of abnormal uterine bleeding.

Women with postmenopausal bleeding should undergo diagnostic evaluation to determine the cause of bleeding. Transvaginal ultrasound is an acceptable initial test. The critical feature of the transvaginal ultrasound scan is the maximum double-thickness width of the endometrium, measured on a sagittal image and excluding any fluid that may be present in the endometrial cavity. Until there is definitive information concerning the choice between 4mm and 5mm as the appropriate positivity criterion for endometrial thickness, Dubinsky, (1997) would recommend using 4mm because that will miss fewer cancers (i.e. has higher sensitivity) than 5mm.

In the postmenopausal patient, one of the most important uses of ultrasound involves the diagnosis and management of endometrial cancer. In general, the transvaginal ultrasound is superior to transabdominal ultrasound for visualisation of the endometrium and myometrium [Applebaum, 2002].

Sonographic signs of endometrial cancer in the postmenopausal patient include: an obstructed fluid filled canal, a thickened uterine cavity, an enlarged uterus and a lobular uterus with a mixed echopattern. Gray-scale ultrasound has accurately demonstrated the presence and extent of myometrial invasion. Cacciatore et al., (2003), using transabdominal technique, found that sonographic staging of endometrial cancer by ultrasound was accurate in 91% of cases and myometrial invasion was correctly identified in 80% of cases. In general, the data would seem to indicate that a full-thickness postmenopausal endometrium of 10mm or greater should be further evaluated either by pipelle biopsy or dilatation and curettage, to exclude either malignancy or hyperplasia [Applebaum (2003)].

Transvaginal ultrasound is useful in determining pathology without much discomfort and delay to the patient. No hospitalisation is required therefore it is affordable and cost-effective.

Due to the increasing costs of healthcare, transvaginal ultrasound is increasingly being used more than endometrial biopsy to evaluate women with postmenopausal bleeding [Davidson, 2003)].

CHAPTER 3: MATERIALS AND METHODS

The sample consisted of seventy-six Black patients presenting with postmenopausal uterine bleeding. Patients were recruited from the Outpatient Gynaecological Department of King Edward VIII Hospital, Durban, and Kwa -Zulu Natal (KZN).

Ethical clearance was obtained from the Faculty of Health Science Ethics Committee, (Appendix Section G – DIT G186).

3.1 Sample Selection:

A statistically significant sample size was calculated based on the number of Black patients with postmenopausal uterine bleeding referred as per month as per the referral pattern for Kwa -Zulu Natal (KZN).

3.2 Criteria for Inclusion of Subjects:

3.2.1 Inclusion Criteria

1. Black patients with unexplained postmenopausal bleeding above the age of 35 years with absence of menstruation for a minimum period of six months were included.

[Although menopause generally occurs from approximately 45 years of age, there are some documented cases of females below 45 years experiencing menopause. Women over the age of 35 years with a prolonged history of anovulatory bleeding are at increased risk for endometrial carcinoma, Brand, (2000)].

2. Patients who gave consent for the transvaginal procedure to be performed.

3.2.2 Exclusion Criteria

1. Patients who had been diagnosed and are already on treatment for postmenopausal bleeding.

3.3 Recruitment of Patients

A notice was placed in the Gynaecological Outpatient Department requesting registrars to refer all Black patients with abnormal postmenopausal bleeding to the researcher stationed in the Ultrasound Department.(Appendix C).

On attendance at the department, the subjects were requested to complete an information letter (Appendix A) and requested to read, understand and sign the consent form (Appendix B). Both documents were printed in English and Isizulu and a full explanation was given to the patient.

3.4 General Examination

After consent was obtained from the patient, all subjects underwent a thorough gynaecological examination conducted by a registered medical practitioner. The procedure included a full clinical examination, inspection of external genitalia to exclude bleeding, a bimanual assessment of the vagina, cervix and uterus. Following the assessment of the uterus and adnexal area, a lubricated Cusco vaginal speculum was inserted into the vagina to examine the vaults to exclude any focal lesions (Appendix D).

3.5 Transvaginal Ultrasound Examination

The transvaginal examination was performed in the Ultrasound Department in an enclosed private cubicle by the researcher.

The procedure for the transvaginal examination was as follows:

3.6 Equipment and Patient Preparation:

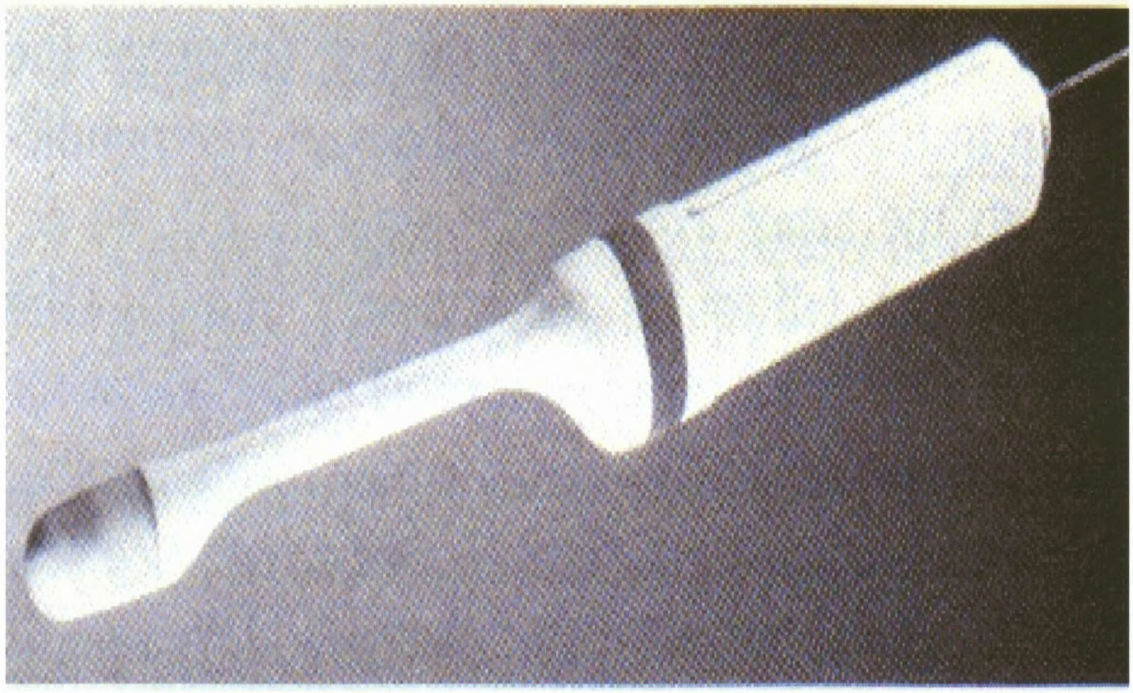


FIGURE 11: HIGH FREQUENCY (5 – 10MHz) TRANSVAGINAL PROBE

(Adapted from Fleischer and Kepple, 1995)

A General Electric 400 Ultrasound machine with a 7.5MHz high multi-frequency transvaginal probe was utilized (Figure 11). The probe was routinely disinfected between users following the examinations in the presence of the patient; thereby

assisting in assuring confidence that proper disinfections was maintained.

The transvaginal probe was covered by medium viscosity ultrasound gel to remove air bubbles and a protective latex sheath with a thin film of lubricating gel was placed over the probe before insertion into the vagina to avoid pain or discomfort to the patient while manoeuvering the probe.

Full explanation of the procedure was given to the patient to relieve any anxiety, prior to the examination. The patient was reassured that the transducer is inserted only a short distance. The patients were scanned with voided bladders. The patient was then placed in the lithotomy position and then draped with a sheet. In view of the absence of a pelvic examination table with leg and foot supports, a foam pad was placed under the patient's buttocks to elevate the hips (as shown in Figure 12).

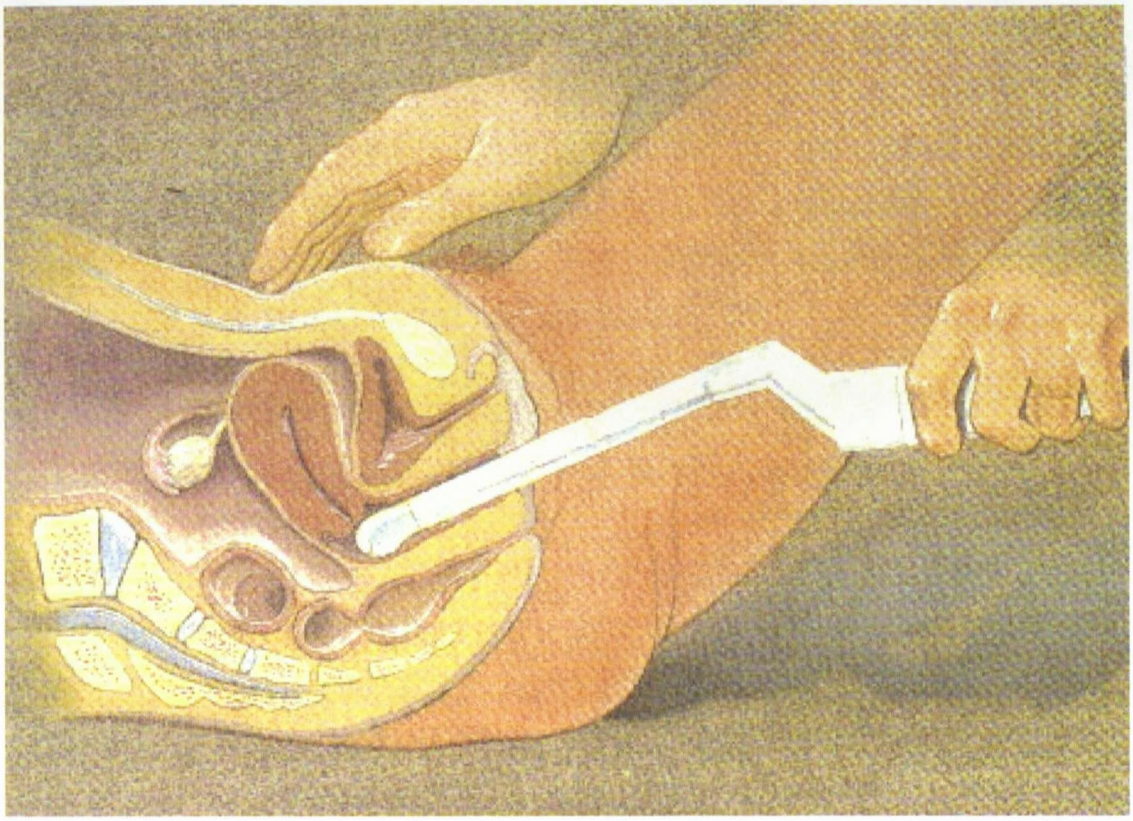


FIGURE 12: APPLICATION OF TRANSVAGINAL PROBE WITHIN VAGINA
(Adapted from Fleischer and Kepple, 1995)

3.7 The Transvaginal Technique

Side to side movements of the probe were undertaken to image the uterus in the long axis (Figure 13).

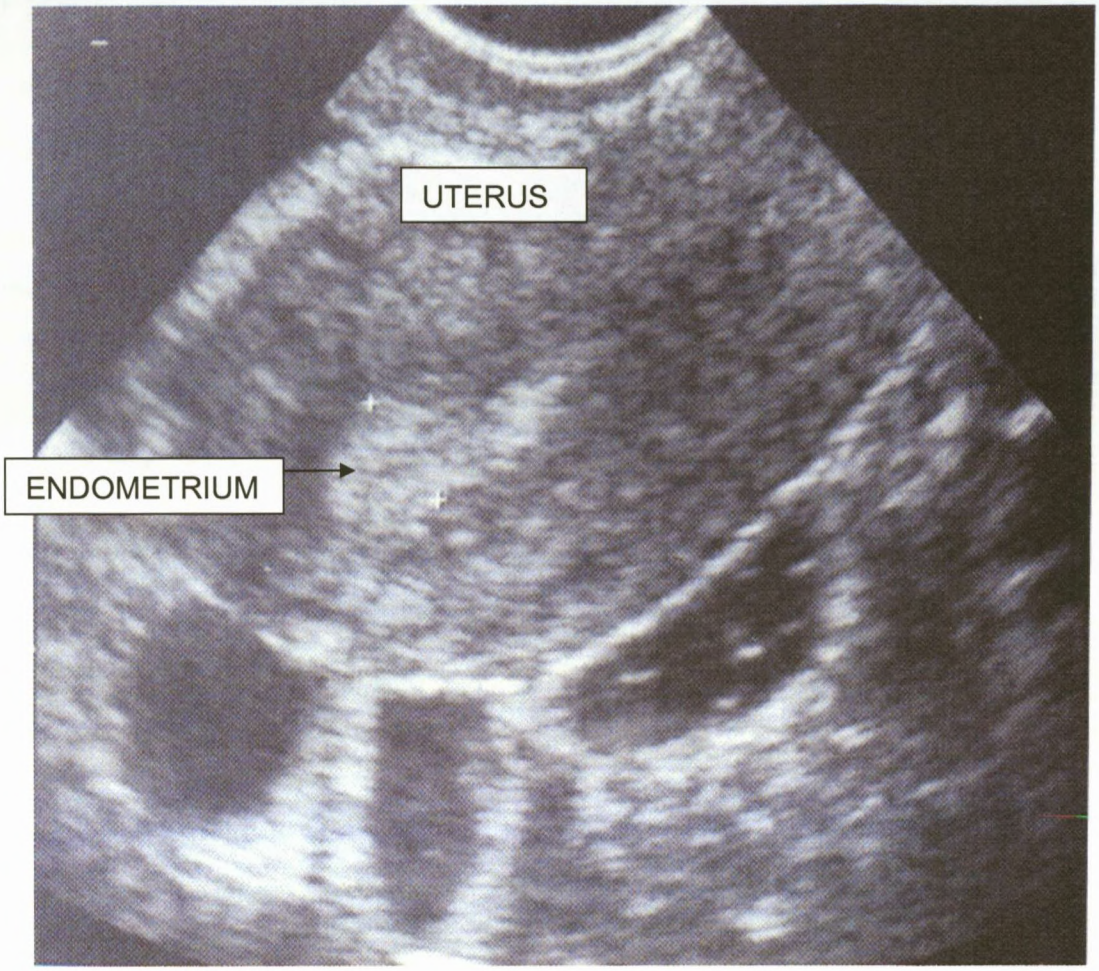


FIGURE 13: MEASUREMENT OF ENDOMETRIUM IN LONG AXIS
(King Edward VIII Hospital Ultrasound Department)

Anterior-posterior movements of the probe for optimal imaging in the short axis view were undertaken (Figure 14).

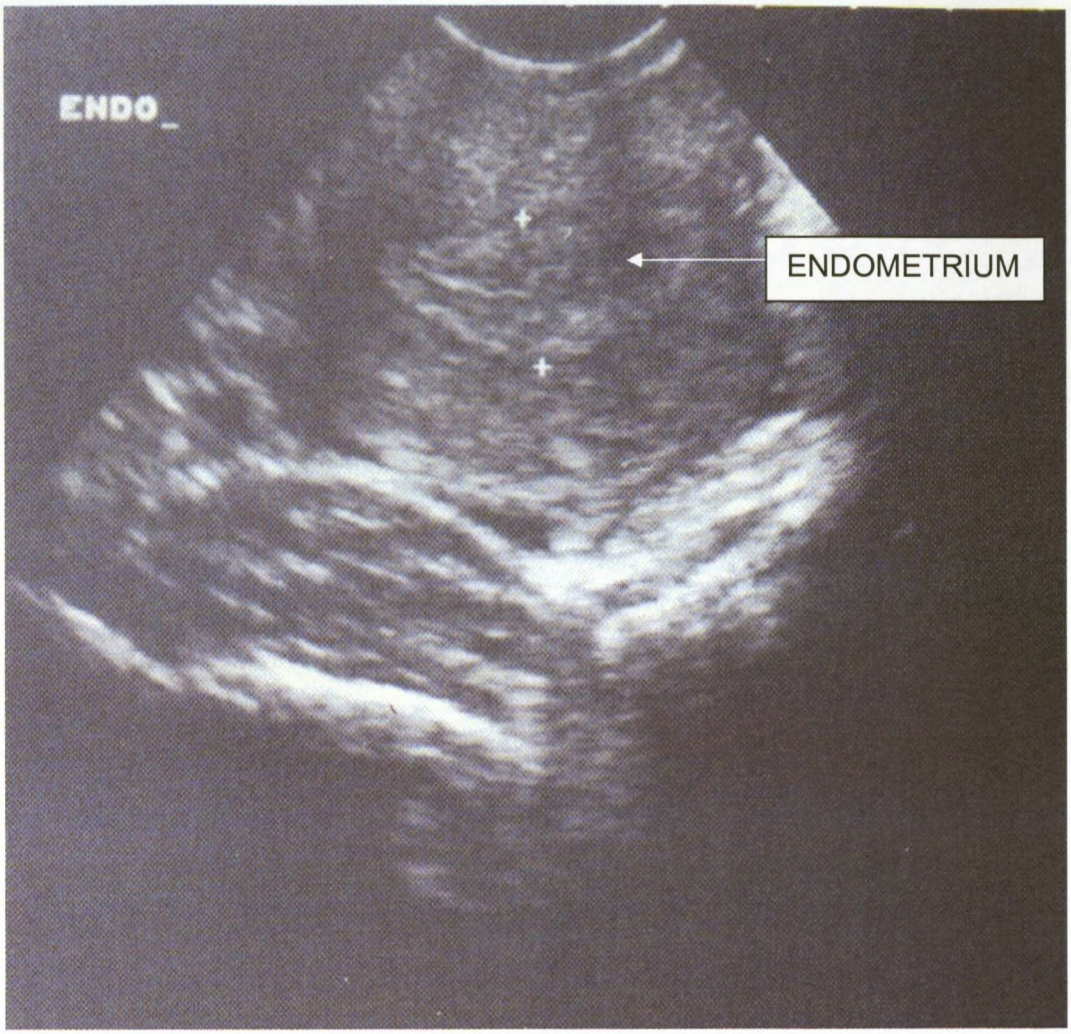


FIGURE 14: MEASUREMENT OF ENDOMETRIUM IN SHORT AXIS

(King Edward VIII Hospital Ultrasound Department)

Variation of the depth of the transducer in the long and short axis planes, the uterus, endometrium and adnexal structures were visualized.

By inserting the probe deeper, posterior structures moved upwards, and more towards the near field of the transducer. On withdrawing, the probe allowed assessment of the structures in the near field.

Endometrial thickness was measured including both endometrial layers, i.e. the measurement was performed between the two basal layers of the anterior and posterior uterine wall at the thickest point (Figures 13 & 14), and was expressed in millimetres.

An evaluation of the uterine morphology was conducted to assess for presence of submucosal fibroids, endometrial polyps, myometrial and adnexal invasion.

The data on the ultrasound report sheet was recorded as follows:

- Uterine size (mm)
- Endometrial thickness (mm)
- Adnexal pathology

3.8 Procedure for Endometrial Biopsy

Following the measurement of the endometrial thickness, a medical registrar conducted an additional clinical examination. The endometrial biopsy procedure was conducted.

This test is routinely performed in patients presenting with abnormal postmenopausal uterine bleeding to differentiate benign from malignant pathology in the endometrium.

A lubricated Cusco vaginal speculum was inserted into the vagina. An endometrial sample was taken using a Pipelle Endometrial Sampler. This device consists of a plastic outer sheath with a solid inner core.

The endometrium was biopsied and the specimen was subjected to a histopathological analysis.

The histological findings from this examination were compared with findings of the transvaginal ultrasound and hysteroscopy examination.

Data were analysed, tabulated and presented for statistical review.

Reports/data and other patient information from the examinations of selected patients, for this research are secured in a filing cabinet in the Ultrasound Department at King Edward VIII Hospital.

3.9 Data Capture

The variables of the data were tabulated under the following headings for statistical analysis.

TABLE 2: DESCRIPTIVES FOR EVALUATION

ANALYSIS	DESCRIPTION	ABBREVIATIONS
CLINICAL FINDINGS	Transvaginal Ultrasound Number	TVU
	Family History Malignancy	FHM
	Family History Malignancy Type	FHMT
	Post Menopausal	POST/MP
	Per Vaginal Bleed	PVB
	Pelvic Abdominal Mass	PAM
MEDICATION PROFILE	Medication Type	MT
GENERAL CLINICAL EXAMINATION	Abdominal Pathology	ABDO
TRANSVAGINAL SCAN EVALUATION	Uterine Size in millimetres	US (mm)
	Endometrial Thickness in millimetres	EMT (mm)
	Fluid in Endometrial Cavity	FEC
	Adnexal Pathology	AP
ULTRASOUND EVALUATION OF ENDOMETRIUM	Irregular	IRREG
	Thickness	THICK
	Echogenic	ECHOG
ENDOMETRIAL SAMPLING	Procedure	PROCED
	Cervical Stenosis	CS
HYSTEROSCOPY EVALUATION	Indication	IND
	Irregular	IRREG
	Thickness	THICK
	Invasion	INV
HISTOLOGICAL REPORT	Carcinoma	CA
	Adnexal Infiltration	ADX/IF
	Myometrial Infiltration	MYO/IF

3.10 Statistical Evaluation

The following statistical tests were applied:

1. Since there is a gold standard, the normal endometrial thickness being 4mm, the sensitivity and specificity indices were computed for comparison purposes.
2. Chi-Square Test was carried out to test whether there was any association (relationship) between the various levels of endometrial thickness and related pathology (polyp, fibroid or malignancy).
3. Kappa Statistic was computed to examine the reliability of the study.
4. One Sample Hypothesis Test was carried out to compare the average endometrial thickness with the established gold standards to see whether there is any significant difference between the two.

The SPSS Package Version was used for data analysis and the p values were used for decision-making. The level of significance was set at 5%.

CHAPTER 4: RESULTS

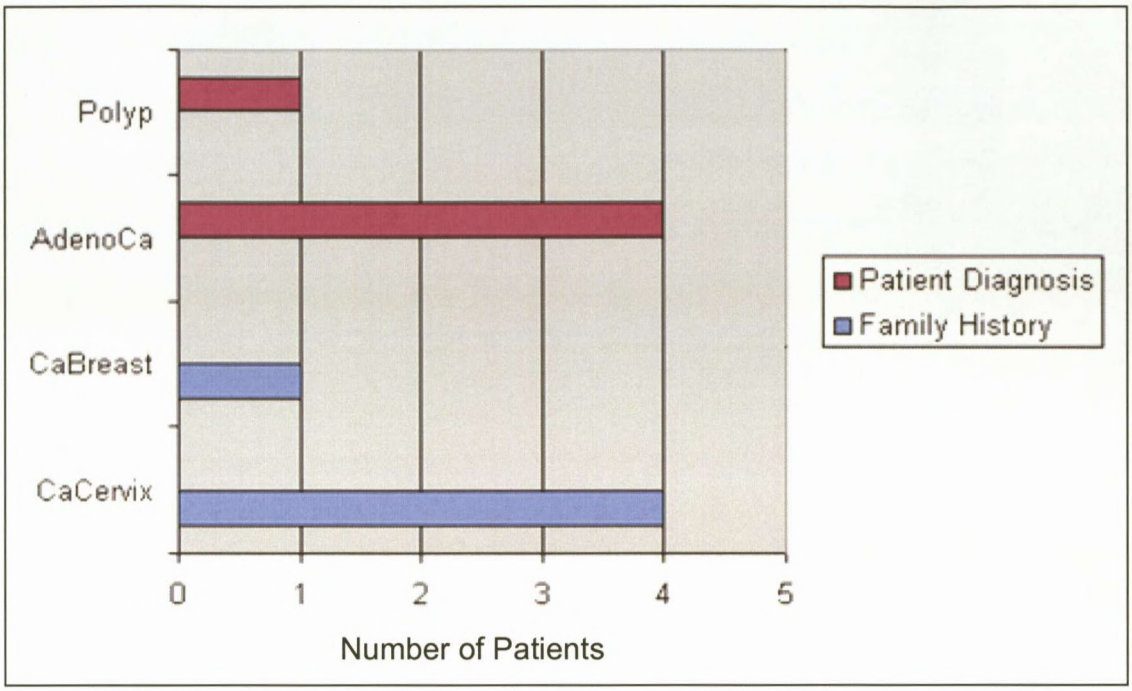
4.1 Sample Size

Seventy-six Black women, who presented with postmenopausal uterine bleeding, were evaluated. The mean age of all patients was 59,4 years (range 42 – 77 years), whilst the median parity was five (range 0 – 10).

4.2 Family History

In terms of family history for malignancy, five patients were recorded positive for malignancy. The malignancies included cervical cancer (n = 4) and breast cancer (n = 1). Of the 4 patients presenting with family history of cervical cancer, three were positively diagnosed with endometrial adenocarcinoma and one diagnosed with a benign endometrial polyp (Refer to Graph 1). The one patient that presented with a family history of breast cancer was diagnosed with endometrial adenocarcinoma. (Appendix J)

GRAPH 1: FAMILY HISTORY VERSUS PATIENT DIAGNOSIS



Majority of the women (n = 34) presented with an enlarged uterus. The mean uterine length and transverse diameter was 74mm and 51mm, respectively. The largest uterine length and transverse diameter for patient diagnosed with endometrial malignancy was 93 x 64mm.

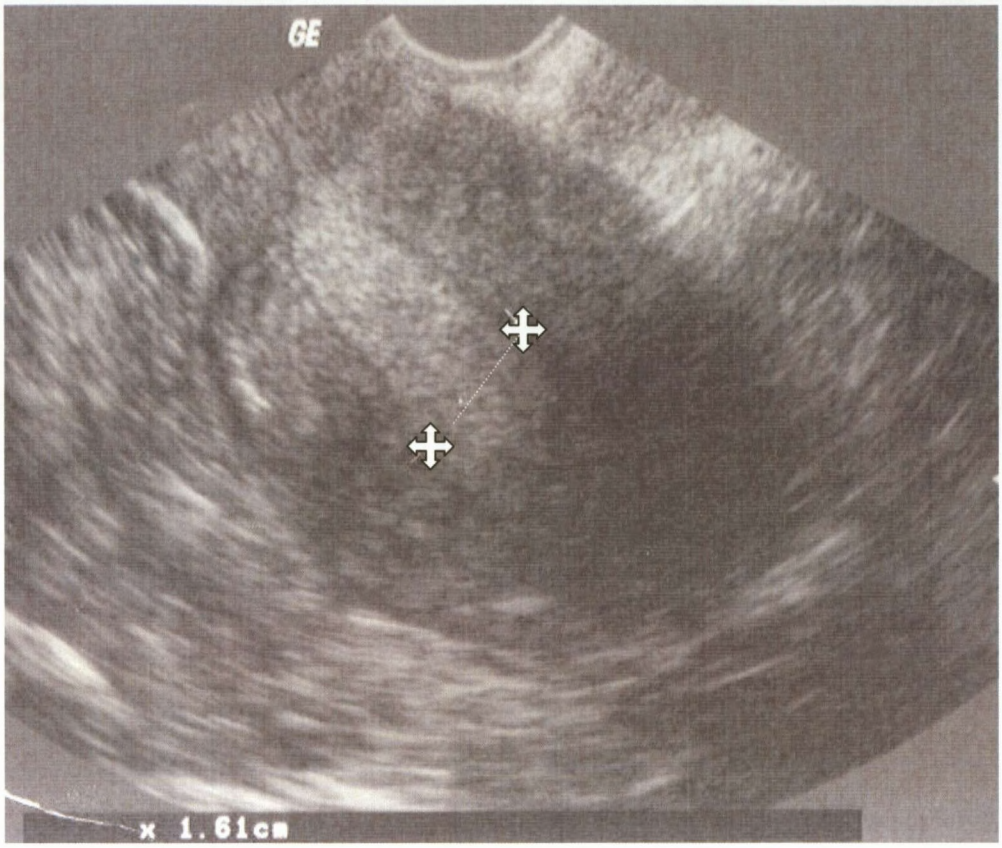


FIGURE 15: TRANSVAGINAL LONGITUDINAL SCAN OF UTERUS

(Calipers indicate endometrial thickness of 1.61 cm)

(King Edward VIII Hospital Ultrasound Department)

4.3 Uterine size and Malignancy

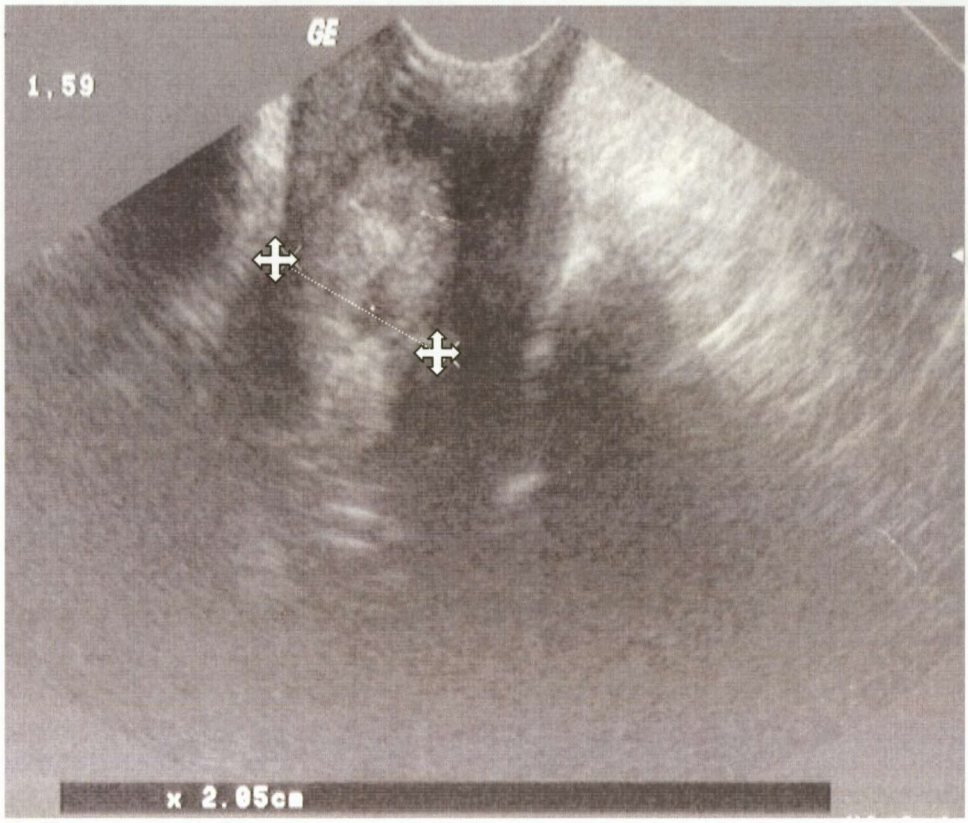


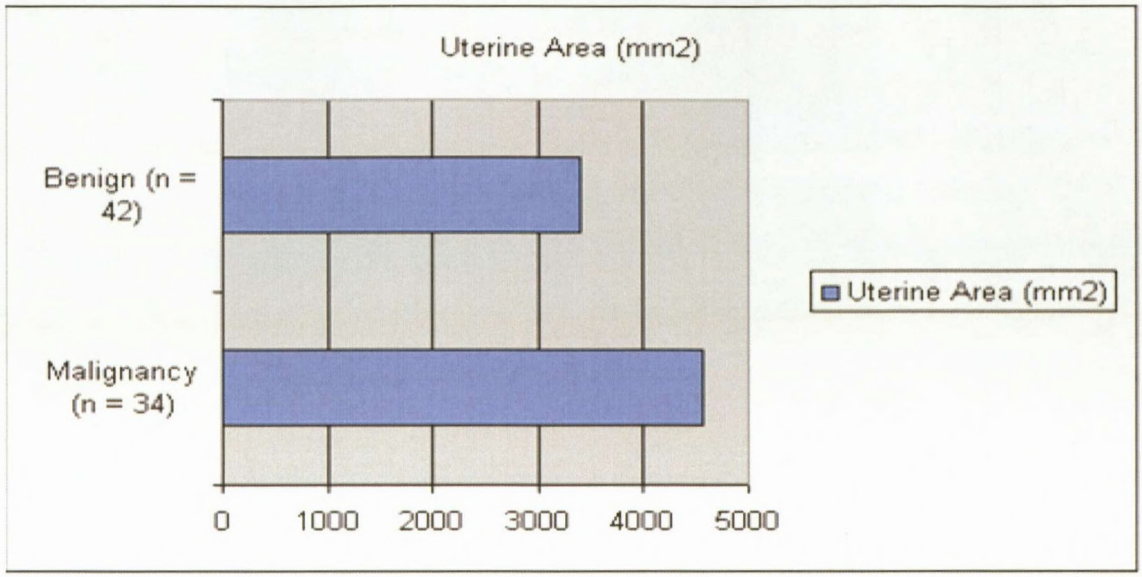
FIGURE 16: THICKENED IRREGULAR ENDOMETRIUM

(Calipers indicate endometrial thickness of 2.05 cm)

(King Edward VIII Hospital Ultrasound Department)

The mean uterine area of patients with malignancy (n = 34) was 4554mm^2 and 3405mm^2 in patients with a benign diagnosis (n = 42). The area of the uterus was significantly greater (p = 0,002) (refer to graph 2)

GRAPH 2: UTERINE AREA VERSUS MALIGNANCY



Using transvaginal ultrasound, there were only three women (3.9%) with adnexal cysts. These were benign cysts on final histology.

4.4 Fluid in Endometrial Cavity and Malignancy

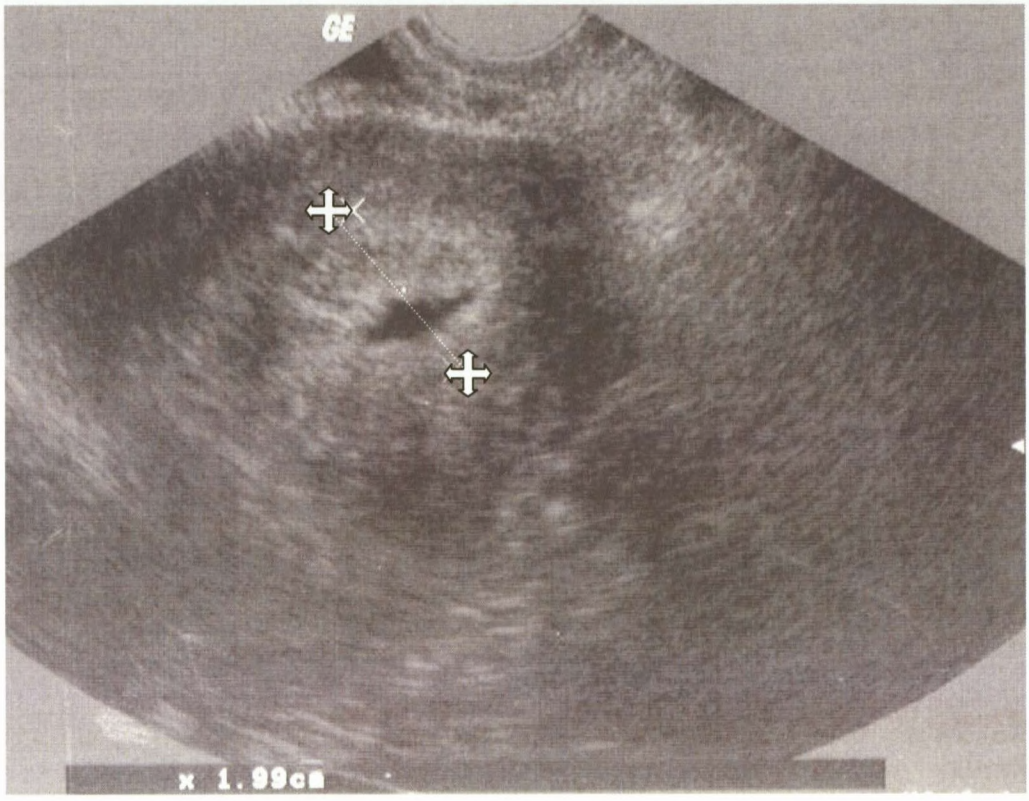


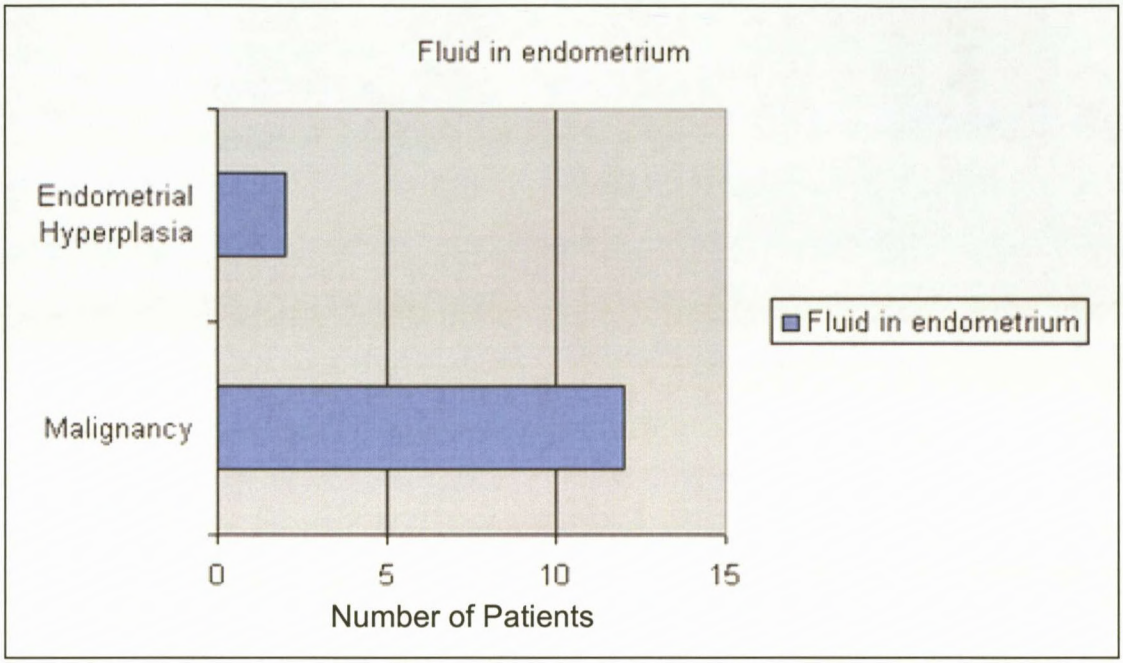
FIGURE 17: THICKENED, IRREGULAR ENDOMETRIUM WITH FLUID

(Calipers show endometrial thickness of 1.99 cm)

(King Edward VIII Hospital Ultrasound Department)

A total of 14 (18.2%) patients were recorded with fluid in the endometrial cavity as illustrated in Figure 17. Of those, 12 (86%) patients were diagnosed with malignancy ($p < 0,000$) and 2 (14.3%) were diagnosed with endometrial hyperplasia (refer to Graph 3).

GRAPH 3: FLUID IN ENDOMETRIUM VERSUS MALIGNANCY



There were only 3 (3.9%) patients with tubal-ovarian invasion. All three patients had histologically confirmed invasive endometrial adenocarcinoma.

4.5 Endometrial Irregularity and Malignancy

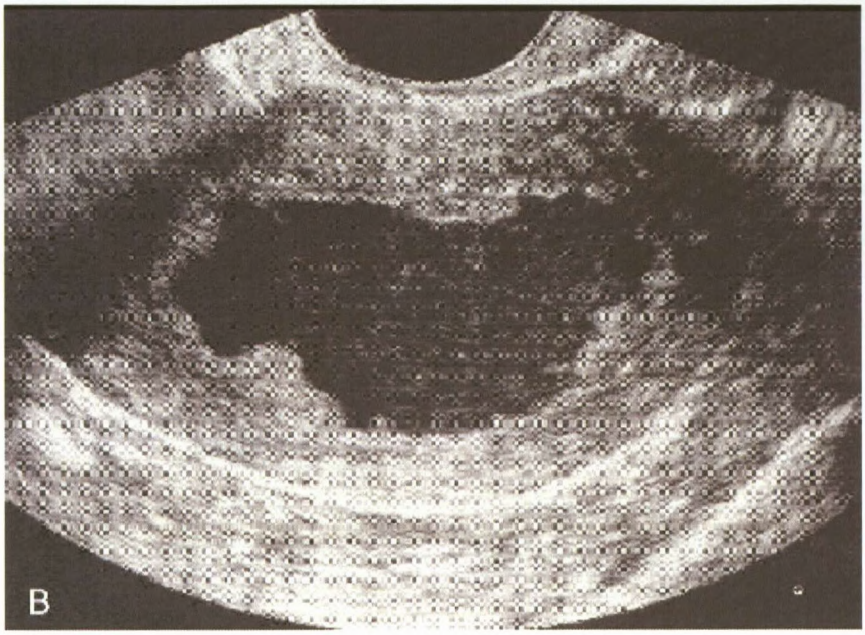
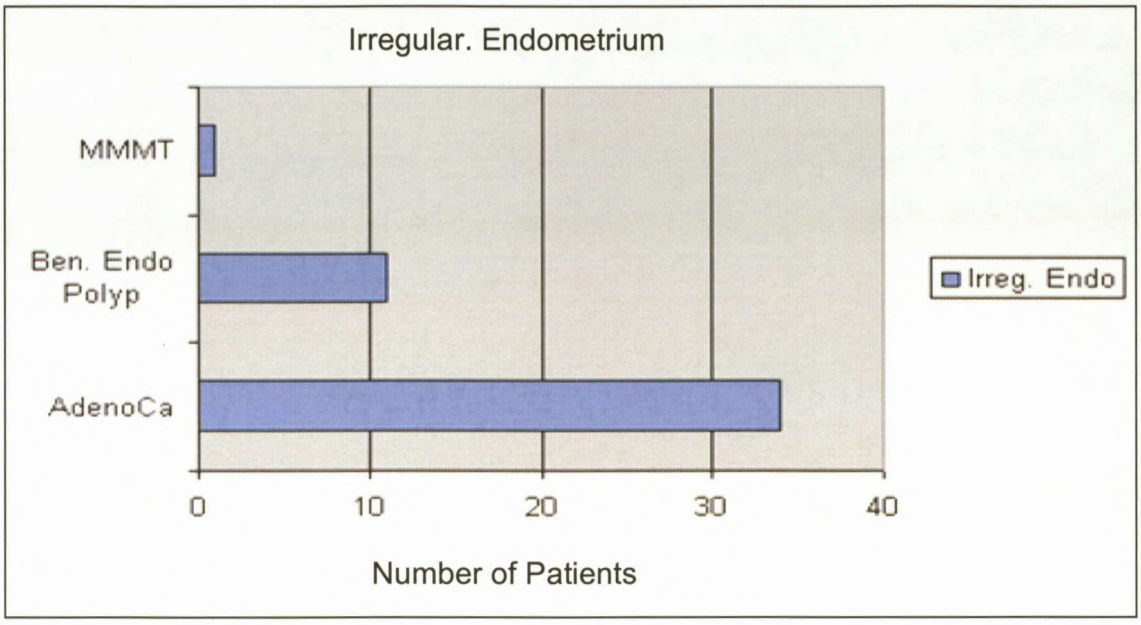


FIGURE 18: MARKEDLY IRREGULAR ENDOMETRIAL WALL WITH FLUID IN THE ENDOMETRIAL CAVITY

(King Edward VIII Hospital Ultrasound Department)

There were forty-six patients (60%) with irregular endometrial lining as illustrated in figure 18. Of this, 34 (74%) patients had endometrial adenoocarcinoma and 12 (26%) patients were diagnosed with other endometrial pathology. There was a significant association between irregular lining and endometrial carcinoma ($p < 0.001$). One patient was diagnosed with Malignant Mixed Mullerian Tumour and 11 (14.5%) patients were diagnosed with benign endometrial polyp (as shown in Graph 4).

GRAPH 4: IRREGULAR ENDOMETRIAL LINING



The mean endometrial thickness (n = 76) of all women with postmenopausal bleeding was 18,2mm (range 5 – 35mm).

4.6 The Mean Endometrial Thickness and Pathology

Table 3 illustrates the mean endometrial thickness of all women with malignancy (n = 34) was 20,32mm (range 11 – 35mm).

TABLE 3: ENDOMETRIAL THICKNESS (ET)

Diagnosis	(n)	Mean ET (mm)	Range ET (mm)
Non-representative	3	7,83	6 – 12
Adenocarcinoma	34	20,32	11 – 35
Benign Polyp	11	18,36	10 – 30
Chronic Endometritis	3	19,33	16 – 22
Benign Endometrium	13	17,3	5 - 30
Endometrial Hyperplasia	4	13,25	10 – 15
Atrophic Endometrium	7	15,86	6 – 30

Of the 34 patients with uterine malignancy, 12 (35.3%) were recorded with myometrial invasion (as shown in Figure 19) and 1 (2.9%) patient with adnexal invasion.

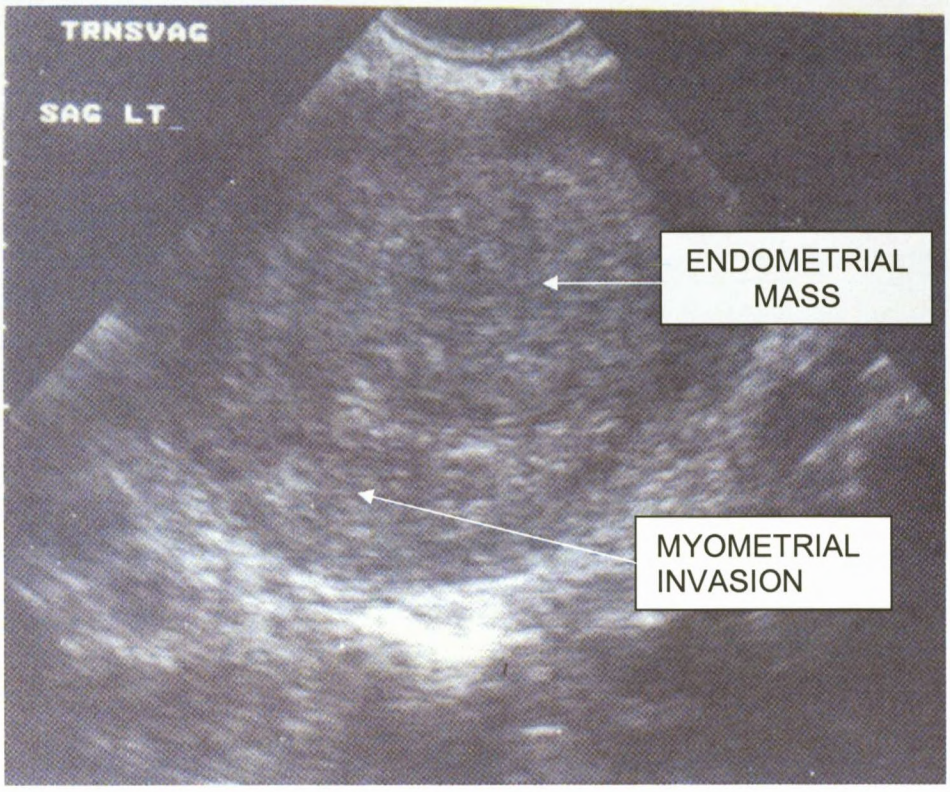


FIGURE 19: MYOMETRIAL INVASIVE ENDOMETRIAL ADENOCARCINOMA III

(King Edward VIII Hospital Ultrasound Department)

4.7 Documentation of Diagnosis

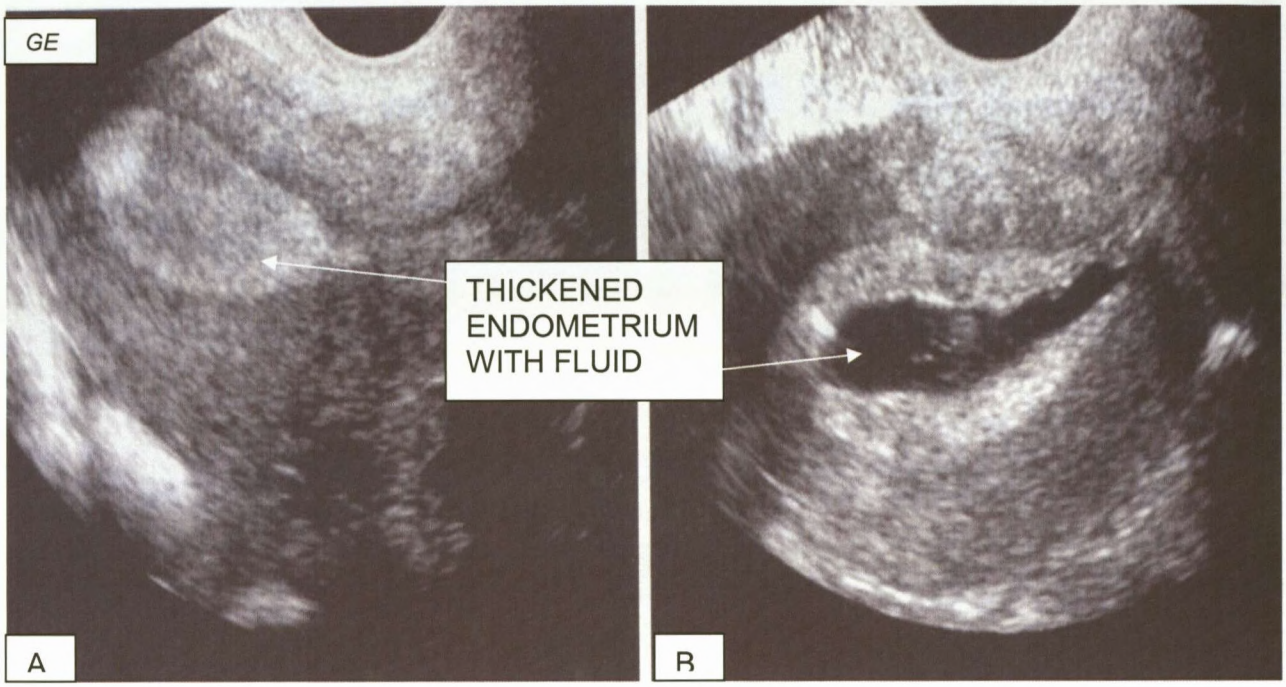


FIGURE 20: ENDOMETRIAL HYPERPLASIA

GE – General Electric Ultrasound Scanner

A – Thickened, echogenic endometrium

B – Thickened, echogenic fluid-filled endometrium

(King Edward VIII Hospital Ultrasound Department)

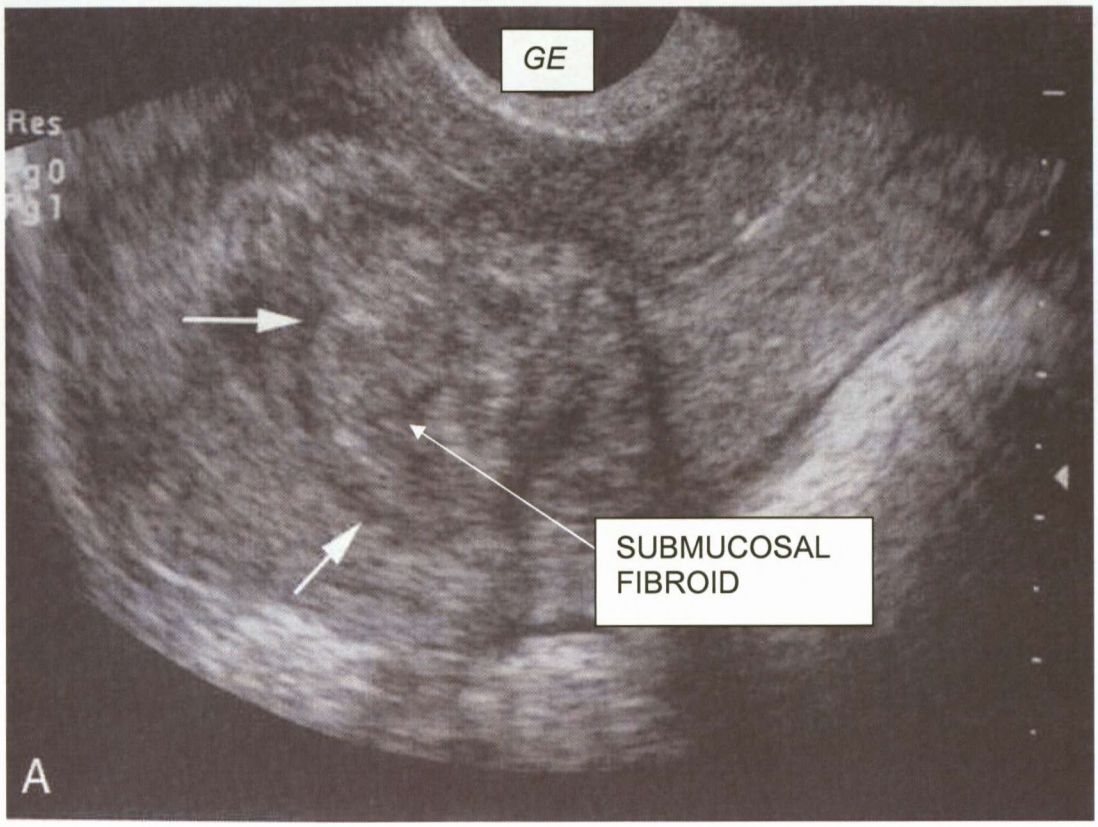


FIGURE 21: SUBMUCOSAL FIBROID

(King Edward VIII Hospital Ultrasound Department)

The diagnosis of all patients with postmenopausal bleeding, is illustrated in the table below:

TABLE 4: PERCENTAGE DIAGNOSIS

Diagnosis	Number (n=76)	Percentage (100%)
Adenocarcinoma	34	44,8
Benign Polyp	11	14,5
Chronic Endometritis	3	3,9
Benign Endometrium	13	17,1
Endometrial hyperplasia	4	5,3
Atrophic Endometrium	7	9,2
Malignant Mixed Mullerian Tumour	1	1,3
Non-Representative	3	3.9

The transvaginal scan detected 34 cases of endometrial adenocarcinoma.

CHAPTER 5: DISCUSSION

It is imperative to investigate women with postmenopausal bleeding since this is the most common clinical symptom of malignant neoplasia of the endometrium. Transvaginal ultrasound is cost-effective and practical in terms of investigating patients with postmenopausal bleeding [Tahir et al., (1999)].

5.1 Sample size

Seventy six Black women with postmenopausal uterine bleeding were evaluated. In view of a combination of methods for adequate evaluation of patients with postmenopausal bleeding, transvaginal ultrasound should be performed on all women at risk for endometrial cancer. Therefore transvaginal ultrasound showed 100 % sensitivity in this study. With advent of high-resolution multi-frequency transvaginal probes ranging from 7,5MHz to 10MHz, transvaginal sonography has been found to be superior to transabdominal ultrasound.

5.2 Family history compared to patient diagnosis

In terms of family history compared to patient diagnosis, 5.2% diagnosed with a family history of carcinoma of the cervix and 1.3% family history of breast carcinoma. The impact of these findings will assist the ultrasonographer to fully investigate the pelvic anatomy and for the gynaecologist to do further tests to rule out malignancy and this will assist in effective management of the patient.

5.3 Uterine size with malignancy

The area of the uterus was significantly greater ($p < 0,002$) with malignancy. There is a correlation between uterine size and uterine malignancy.

The diagnosis of a large uterus in a postmenopausal patient may thus serve as as indicator that further evaluation is necessary.

5.4 Fluid in the endometrial cavity

A total of 14 (18.2%) patients with fluid in the endometrial cavity were recorded, of which 12 were diagnosed with malignancy ($p = 0,000$).

The diagnosis of fluid in the endometrial cavity will enable the gynaecologist to carry out further investigations and treatment.

Transvaginal ultrasound has proved to be a quick and accurate method of evaluation to diagnose endometrial pathologies in terms of patient management [Tahir et al., (1999)].

Thus, there is a positive correlation with fluid in the endometrial cavity and irregular lining of the endometrial wall. Twelve of the fourteen patients with fluid in the endometrial cavity were diagnosed with malignancy. Of the forty-six patients with irregular endometrial lining, thirty-four (74%) were diagnosed with adenocarcinoma.

5.5 Irregular endometrial lining with malignancy

46 patients (60%) with irregular endometrial lining were diagnosed, of which 34 patients (74%) had uterine malignancy ($p = 0,000$). The endometrial contour was poorly defined and 12 (26%) were diagnosed with endometrial pathology. Irregular endometrial lining is strongly associated with endometrial malignancy.

On transvaginal ultrasound the immediate diagnosis of irregular endometrial lining will necessitate other investigations, which will aid in the appropriate patient management.

5.6 Endometrial thickness related to pathology

The related pathologies diagnosed were 34 patients with uterine malignancy. Myometrial invasion was detected in 12 (35.3%) patients and 1 (2.9%) of all patients had adnexal invasion. The evaluation of the endometrial thickness as illustrated in Table 1 describes studies conducted between ethnic groups with postmenopausal bleeding. In these studies different cut-off values for endometrial thickness (3mm, 4mm, 5mm) were used. The cut-off values of the various studies were in the Nordic study performed amongst Caucasian women, where an endometrial thickness of less than 5mm was used [Karlsson et al., (1995)]. In India women with endometrial thickness of 4mm [Kekre et al., (1997)] and in Japan the endometrial thickness of 3mm [Tsuda et al., (1995)] was used as cut-off values to decide on need for further evaluation.

TABLE 1: COMPARISON OF ENDOMETRIAL THICKNESS BETWEEN ETHNIC GROUPS

Ethnic Group	Japanese	Caucasian	Indian	Black S.A
Author/s	Tsuda et al. 1995	Karlson et al. 1995	Kekre et al. 1997	Current Study
EQUIPMENT	Aloka 650 SSD 5 MHz	Acuson, Siemens Hitachi 5-7,5 MHz	Aloka 55 D 620 5 MHz	G.E. Logic 400 5-10MHz
MEASUREMENTS **Average/mean** **Std. Deviation**	3mm -	< 5mm 3.9	4mm 12.6	≥ 4mm 18.2
OTHER EXAMINATIONS	Endometrial Biopsy	Endometrial Biopsy Hysteroscopy	Endometrial Biopsy	Endometrial Biopsy
CONFIRMED FINDINGS	No malignancy <4mm for<5 yrs And <3mm ≥5 yrs Postmenopausal Bleeding.	No malignancy < 5 mm	< 4mm of no malignancy	<4mm of no malignancy

Overall, we obtained 3.9% non-representative histological results, 44.8% endometrial adenocarcinomas, 14.5% benign polyp, 3.9% chronic endometritis, 17.1% benign endometrium, 5.3% endometrial hyperplasia, 9.2% atrophic endometrium and 1.3% Malignant Mixed Mullerian Tumour.

The endometrial echo was visualized in all patients. There was no difficulty in evaluating its thickness, since at least a tenuous line was observed even in the presence of a weaker echogenicity.

Immediate evaluation of a thick endometrium in postmenopausal Black South African patients will assist the gynaecologist in providing a faster and effective treatment for the patient. The outcome depends largely on the reason for the bleeding and endometrial thickness, thereby resulting in the patients being treated appropriately according to histological diagnosis and surgery.

Transvaginal ultrasound can also reveal the presence of heterogeneous, ill-defined, fluid-filled material as well as variations in thickness and echogenicity. The last parameter however is subjective and its interpretation varies between authors such as Tsuda et al., 1995, Karlson et al., 1995 and Kekre et al., 1997.

In this study, the thickness of the endometrial echo varied from 5 to 35mm, with a mean of 18,2mm. When the thickness of the endometrial echo was compared with the histopathological results, the mean value for non-representative was 7.83mm, much lower than the thickness of an active endometrium (13,25mm). In cases with atrophic endometrium, the thickness ranged from 6 to 30mm with a mean of 15.86mm. The mean value obtained for cases with adenocarcinoma was 20.32mm (range 11 to 35mm).

Thus there is a positive association of postmenopausal bleeding and malignancy (34 out of 76 patients = 44.7%). Patients with postmenopausal bleeding and no malignancy (41 out of 76 = 54%) were diagnosed with other benign endometrial pathologies

Furthermore, the sensitivity of transvaginal ultrasound in detecting an active endometrium was 100%, when a thickness limit of 4mm was adopted. When a thickness limit of greater than 4mm was considered, the sensitivity of transvaginal ultrasound in detecting malignancy of the uterine mucosa was 100%.

Kekre et al., 1997 showed that in all reports of postmenopausal bleeding, there seems to be an agreement that with a cut-off limit of 4mm, a benign endometrium may be found. With a thickness of less than 8mm, no malignant neoplasia was found.

To reduce any bias, the same ultrasonographer using the same ultrasound machine conducted all transvaginal scans. A gynaecology registrar conducted all pipelle biopsies and hysteroscopy was also performed with a histopathological result for comparison.

It has also been observed that submucosal fibroids alter the uterine cavity and impair visualisation of the endometrium, thus preventing precise measurement of its thickness. Transvaginal ultrasound represents a safe method for the evaluation of patients with postmenopausal uterine bleeding. Up until now dilatation and curettage has been used as a method for investigation and treatment of endometrial lesions, or when cervical stenosis prevented pipelle biopsy and hysteroscopy. Significant endometrial pathology can be excluded when the thickness of the echo is greater than 4mm. A combination of transvaginal, pipelle biopsy, hysteroscopy and histology are the various

diagnostic methods that permit the evaluation of postmenopausal bleeding and would definitely reduce the number of unnecessary curettages.

In Kwa-Zulu Natal, transvaginal screening of all Black postmenopausal patients with abnormal uterine bleeding, would be beneficial. In terms of this initial non-invasive cost-effective test, an immediate diagnosis is obtained and the patient is given optimal care resulting in effective patient management.

Immediate diagnosis prevents unnecessary expensive tests, drugs or surgery, preventing extension of malignancy to other organs. The use of transvaginal ultrasound in the evaluation of postmenopausal bleeding, will allow appropriate investigation of patients who have an endometrial thickness $\geq$4mm, whilst reducing costs and patient inconvenience if the endometrial thickness is less than 4mm. With the limited bed space and stringent health budget, this cost-effective approach appears to be more practical.

This study shows that transvaginal ultrasound, as a diagnostic method using endometrial thickness, may be accurately used to discriminate between normal and pathological endometrial conditions in patients with postmenopausal bleeding.

CHAPTER 6: CONCLUSION

The efficacy of transvaginal ultrasound in determining benign or malignant endometrium is recognised as it shows varying thicknesses and echopattern to establish pre-malignant and malignant causes.

6.1 Endometrial thickness in Black South African patients

The sensitivity of transvaginal ultrasound in detecting malignancy using a thickness of 11mm and greater was 100%. Transvaginal ultrasound is a safe method for evaluating the uterine mucosa and should be performed in all Black patients with postmenopausal uterine bleeding.

6.2 Proposed cut-off values for endometrial thickness

When the thickness of the endometrial echo is < 4mm, there is no need for additional investigations, unless there is recurrent bleeding. However, when it is ≥4mm with irregular endometrial lining, the endometrium may be active, then a combination of other diagnostic methods would permit earlier diagnosis of the cause of postmenopausal bleeding. Pipelle biopsy (outpatient) should be the next step to evaluate endometrial histology. However if there is cervical stenosis, or if the histology specimen obtained by pipelle biopsy is insufficient or non-representative, then hysteroscopy and curettage is indicated.

6.3 Association of malignancy with endometrial thickness

No malignancy was detected in this study when the endometrial thickness was less than 11mm. In addition to having achieved the above objectives, the following clinical information resulted from this investigation: endometrial polyps, endometrial hypoplasia, atrophic endometrium, benign endometrium, malignant mixed mullerian tumour and myometrial and adnexal invasion. This is in keeping with the general causes of postmenopausal bleeding described in the literature.

Transvaginal ultrasound has proved to be a quick and accurate method of examination to diagnose endometrial pathologies in terms of patient management.

Therefore, the use of transvaginal ultrasound to evaluate Black patients presenting with postmenopausal bleeding, has become increasingly popular and easily accepted. With early detection, cost -effectiveness and effective patient management maybe enhanced, reducing costs and preventing other expensive and unnecessary investigations and discomfort to the patients.

Transvaginal ultrasound is recommended as the first line of investigation in all Black South African patients with postmenopausal bleeding, as it is an easy, safe, rapid and tolerable procedure and has an excellent diagnostic accuracy of the endometrial thickness and pathology. Overall, the combination of Transvaginal ultrasound and endometrial sampling would shift the management of Black patients with postmenopausal bleeding from the traditionally in-patient assessment to the out-patient

setting, sparing hospital admission for at least 60% of women to a regional hospital which is an important factor in this age group of women where a majority of the patients are from the rural areas

REFERENCES

Agur. AMR. 1997. 9th Ed. Grant's Atlas of Anatomy. Toronto. 371 - 376

Applebaum, M. 2002. *Ultrasound and the menopause web booklet* [online]. Available from: http://www.drapplebaum.com/menopause.htm

Bailie, M. 1996. Evaluation of the Endometrial Pathology. London. 375 – 381.

Bernaschek. G, Deutinger. J and Kratochwil. 1990. Endosonography in Obstetrics and Gynaecology. Springer – Verlag. 113.

Brand, A. 2000. Diagnosis of Endometrial Cancer in Women with Abnormal Vaginal Bleeding. Journal of Obstetrics and Gynaecological Cancer. 22: 1-3.

Callen, PW. 2000. 4Th Ed. Ultrasonography in Obstetrics and Gynaecology. W.B. Saunders Company. Philadelphia. 818 – 840.

Canavan, T.P and Doshi N.R. 1999. Endometrial Cancer. America Family Physician. Available from: http://www.aafp.org/afp/990600ap/3069.html [Accessed 30/10/2003].

Cacciatore, G. and Johnson, J. 2003 Role of Transvaginal Ultrasound. 118.

Davidson, T. 2003. Postmenopausal Bleeding. The Thomson Corporation. Available from: http://www.ehendrick.net/healthy/001099.htm [Accessed 29/10/2003].

Dubinsky, TJ, Parvey HR, Maklad N. 1997. The Role of Transvaginal Sonography and Endometrial Biopsy in the Evaluation of Peri- and postmenopausal Bleed. American Journal of Roentgenology. 169: 145 – 149.

Fleischer S and Kepple A. 1995. Transvaginal Ultrasound. London. 195

Karlsson B, Granberg S, Wikland M et al. 1995.Transvaginal ultrasonography of the endometrium in women with postmenopausal bleeding – a Nordic multicenter study. American Journal of Obstetrics & Gynecology, 172: 1488 – 1494.

Kekre AN, Jose R, Seshadri L. 1997. Transvaginal sonography of the endometrium in South Indian Postmenopausal women. Australian & New Zealand Journal of Obstetrics & Gynaecology. 37: 449 – 451.

Long CA, Gast MJ. 1990. Menorrhagia. In: Chial HJ, London SN (eds).

Menstrual cycle disorders. Obstetric & Gynecology Clinics of North America. Saunders, Philadelphia. 17: 343-359.

Neis KJ, Brander P and Hepp H. 1994. Hysteroscopy Textbook and Atlas. Theime Medical. New York. 64.

Maia H Jr, Barbosa IC, Farias JP et al. 1996. Evaluation of the endometrial cavity during menopause. International Journal of Gynaecology & Obstetrics. 52:61 – 66.

Stevens A and Lowe J. 1995. Pathology. Mosby. Spain. 371 – 376.

Tahir MM, Bigrigg MA, Browning JJ et al. 1999. A randomized controlled trial comparing transvaginal ultrasound, outpatient hysteroscopy and endometrial biopsy with inpatient hysteroscopy and curettage. British Journal of Obstetrics & Gynaecology; 106: 1259 – 1264.

Tsuda H, Kawabata M. 1995. Differences between occidental and oriental postmenopausal women in cutoff level of endometrial thickness for endometrial cancer screening by vaginal scan. American Journal of Obstetrics & Gynaecology; 383 - 386.

Wolman I, Sagi J, Ginat S et al. 1996. The sensitivity and specificity of vaginal sonography in detecting endometrial abnormalities in women with postmenopausal bleeding. Journal of Clinical Ultrasound. 24:79 – 82.

APPENDICES

SECTION H – BUDGET

SECTION 1 – To be completed by student

REQUEST FOR FUNDING OF THE PROJECT (give details)

	COST

1. Consumables	R2512.18
Data sheets 100 x 2 pages @ 20cents per page = R 40.00 Information letter 150 @ 20cents per page = R 30.00 Consent form 150 @ 20cents per page = R 30.00 Notices 10 @ 20cents per page = R 2.00 4 x 5Lt. ultrasound gel @ R190.00 ea. + Vat = R866.40 2 Boxes Non-Sterile Gloves @ R32.49 per box = R 64.98 5 x Sony Thermal paper @ R250.00 ea. + Vat = R1425.00 100 condoms R53.80 per box of 100. = R 53.80	
2. Outside Specialist Services	Nil
3. Books/Documents	
Transvaginal Ultrasound book	R 2240.00
4. Library Charges	
(including literature/data bank search, inter-library loans)	R 500.00
5. Small items of equipment	R 4160.00
80 Pipelle Samplers @ R52.00 ea. + Vat = R4160.00	
6. Major items of equipment	Nil
7. Miscellaneous (specify)	R 535.00
Telephone, Faxes, e-mails =R 450.00 Stationery 4 lever arch files @ R 8-17 each =R 32.68 100 plastic sleeves @ R0.50 each =R 50.00 1 box stiffy discs R32.46 each =R 32.46	
GRAND TOTAL	R9977.32

NB: The following will **not** be supported

(1) any fees;

(2) costs of preparing dissertation/thesis including typing and printing; AND

(3) subsistence to discuss research progress or research ideas or to visit libraries

ALL APPROVED funding is ADMINISTERED by the academic department concerned.

APPENDICES

APPENDIX A Patients Information Letter.

APPENDIX B Informed Consent

APPENDIX C Patient referral Notice for Gynecology Department.

APPENDIX D Record Sheets

APPENDIX E Letter to Professor R.W. Green-Thompson requesting permission to perform the study.

APPENDIX F Letter to the Superintendent of King Edward VIII Hospital requesting permission to perform the study.

APPENDIX G Letter to Professor J. Moodley requesting permission to perform the study.

APPENDIX H Letter to Professor P. Corr requesting permission to perform the study.

APPENDIX I Letter to all medical registrars requesting that they refer all patients fulfil inclusion criteria

APPENDIX J Statistical Analysis

SECTION G - ETHICAL ISSUES CHECKLIST FOR RESEARCH APPROVAL

To be completed by all people wishing to conduct research under the auspices of Technikon Natal.

1. Use the Technikon Natals Research Ethics Policy and Guidelines to ensure that ethical issues have been identified and addressed in the most appropriate manner, before finalising and submitting your research proposal.
2. Please indicate [by a X as appropriate] which of the following ethical issues could impact on your research.
3. Please type the motivations/further explanations where required in the cell headed COMMENTS.
4. The highlighted response cells indicate those responses, which are of particular interest to the Ethics Committee

NO.	QUESTION	YES	NO	N/A
	DECEPTION			
1.	Is deception of any kind to be used? and if so provide a motivation for acceptability.		X	
	COMMENTS:			
2.	Will the research involve the use of no-treatment or placebo control conditions? If yes, explain how subjects interests will be protected.		X	
	COMMENTS			
	CONFIDENTIALITY			
3.	Does the data collection process involve access to confidential personal data (including access to data for purposes other than this particular research project) without prior consent of subjects? If yes, motivate the necessity		X	
	COMMENTS: **The data will be used to correlate ultrasound findings with other relevant information. Care will be taken to ensure confidentiality of the information used.**			
4.	Will the data be collected and disseminated in a manner that will ensure confidentiality of the data and the identity of the participants? Explain your answer	X		
	COMMENTS: **Patients will be referred to in code form. Patient identity will not be released during dissemination of the data.**			

5.	Will the materials obtained be stored and ultimately disposed of in a manner that will ensure confidentiality of the participants? If no, explain. If yes specify how long the confidential data will be retained after the study and how it will be disposed of.	X		
	COMMENTS: **The data will be stored securely in a lockable safe and disposed of 5 years after publication.**			
6.	Will the research involve access to data banks that are subject to privacy legislation? If yes, specify and explain the necessity.	X		
	COMMENTS: **The patient's clinical history will be required for documentation and discussion. The patient's consent will be obtained prior to any data being accessed. All data used will be handled confidentially.**			
	RECRUITMENT			
7	Does recruitment involve direct personal approach from the researchers to the potential subjects? Explain the recruitment process	X		
	COMMENTS: **Subjects will be referred by the referring specialist Gynaecologist at King Edward VII Hospital using notices (appendix c).**			
8	Are participants linked to the researcher in a particular relationship, for example employees, students, family? If yes, specify how.		X	
	COMMENTS			

9	If yes to 8, is there any pressure from researchers or others that might influence the potential subjects to enrol? Elaborate.			X
	COMMENTS			
10	Does recruitment involve the circulation/publication of an advertisement, circular, letter etc? Specify	X		
	COMMENTS: **Notices will be sent to the gynaecology department (Appendix C).**			
11	Will subjects receive any financial or other benefits as a result of participation? If yes, explain the nature of the reward, and safeguards		X	
	COMMENTS			
12	Is the research targeting any particular ethnic or community group? If yes, motivate why it is necessary/acceptable. If you have not consulted a representative of this group, give a reason. In addition explain any consultative processes, identifying participants. Should consultation not take place, give a motivation.			X
	COMMENTS			
	INFORMED CONSENT			
	Does the research fulfill the criteria for informed consent? [See			

13	guidelines]. If yes, no further answer is needed. If no, please specify how and why.	X		
	COMMENTS			
14	Does consent need to be obtained from special and vulnerable groups (see guidelines). If yes, describe the nature of the group and the procedures used to obtain permission.		X	
	Comments			

NO.	**QUESTION**	**YES**	**NO**	**N/A**
15	Will a Subject Information Letter be provided and a written consent be obtained? If no, explain. If yes, attach copies to proposal. In the case of subjects who are not familiar with English (e.g. it is a second language), explain what arrangements will be made to ensure comprehension of the Subject Information Letter, Informed Consent Form and other questionnaires/documents.	X		
	COMMENTS: **An additional copy in Zulu will be distributed.**			
16	**Will results of the study be made available to those interested? If no, explain why. If yes, explain how**	X		
	COMMENTS: **The results of the ultrasound will be made available to patients immediately after completion of the scan. The results of the study will be disseminated in the form of a**			

	presentation.			
	RISKS TO SUBJECTS			
17	Will participants be asked to perform any acts or make statements which might be expected to cause discomfort, compromise them, diminish self-esteem or cause them to experience embarrassment or regret? If yes, explain.	X		
	COMMENTS: **A transvaginal probe will be inserted into the vagina. The probe will be disinfected before and after use for each patient. The probe will be covered with a new condom before it is used. The condom covering the probe will be lubricated with ultrasound gel prior to insertion to allow easy insertion and minimise patient discomfort. The patient will be handled with sensitivity and care to minimise any embarrassment or discomfort.**			
18	Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability? If yes, explain.		X	
	COMMENTS			
19	Might any aspect of your study reasonably be expected to place the participant at risk of damage to their financial standing or social standing or employability? If yes, explain.		X	
	COMMENTS			
	Does the protocol require any physically invasive, or potentially			

20	harmful procedures [e.g. drug administration, needle insertion, rectal probe, pharyngeal foreign body, electrical or electromagnetic stimulation, etc?] If yes, please outline below the procedures and what safety precautions will be used.	X		
	COMMENTS: **A vaginal ultrasound probe will be inserted. The probe will be covered with a new, clean condom for each new patient that is to be scanned and it will be disinfected after each scan, as is the procedure that is currently being used at the Antenatal clinic at King Edward VII Hospital. The pipelle procedure used for tissue sampling may cause slight discomfort to the patients but care will be taken to reassure the patients. The pipelle procedure is a normal routine procedure done on all patients who present with unexplained postmenopausal bleeding.**			
21	Will any treatment be used with potentially unpleasant or harmful side effects? If yes, explain the nature of the side-effects and how they will be minimised.		X	
	COMMENTS			
22	Does the research involve any questions, stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, anxiety producing, noxious, aversive or	X		

	unpleasant during or after the research procedures? If yes, explain.			
	COMMENTS **A vaginal ultrasound probe will be inserted. The probe will be covered with a new, clean condom for each new patient that is to be scanned and it will be disinfected after each scan, as is the procedure that is currently being used at the Antenatal clinic at King Edward VII Hospital. The pipelle procedure used for tissue sampling may cause slight discomfort to the patients but care will be taken to reassure the patients. The pipelle procedure is a normal routine procedure done on all patients who present with unexplained postmenopausal bleeding.**			
23	Will any samples of body fluid or body tissues be required specifically for the research, which would not be required in the case of ordinary treatment? If yes, explain and list such procedures and techniques.		X	
	COMMENTS:			
24	Are any drugs/devices to be administered? If yes, list any drugs/devices to be used and their approved status.	X		
	COMMENTS: **ultrasound endovaginal GE probe** Medium viscosity clear ultrasound gel			
	GENETIC CONSIDERATIONS			
	Will participants be fingerprinted or DNA "fingerprinted"? If yes,			

25	motivate why necessary and state how such is to be managed and controlled.		X	
	COMMENTS			
26	Does the project involve genetic research e.g. somatic cell gene therapy, DNA techniques etc? If yes, list the procedures involved		X	
	COMMENTS			
	BENEFITS			
27	Is this research expected to benefit the subjects directly or indirectly? Explain any such benefits.	X		
	COMMENTS: **Directly – it is hoped that the procedure will assist in determining whether the patient has a benign or malignant change occurring in the endometrium. Immediate diagnosis and management can be achieved.**			
28	Does the researcher expect to obtain any direct or indirect financial or other benefits from conducting the research? If yes, explain.	X		
	COMMENTS **Masters Degree in Radiography**			
	SPONSORS: INTERESTS AND INDEMNITY			
29	Will this research be undertaken on the behalf of or at the request of a pharmaceutical company, or other commercial entity or any other sponsor? If yes, identify the entity.		X	

	COMMENTS			
30	If yes to 29, will that entity undertake in writing to abide by Durban Institute of Technology Research Committees Research Ethics Policy and Guidelines? If yes, do not explain further. If no, explain.			X
	COMMENTS			
31	If yes to 30, will that entity undertake in writing to indemnify the institution and the researchers? If yes, do not explain further. If no, explain.			X
	COMMENTS			
32	**Does permission need to be obtained in terms of the location of the study? If yes indicate how permission is to be obtained.**	X		
	COMMENTS: Letters to obtain permission will be submitted to Professor R.W. Green-Thompson, the Medical Superintendent, Professor J. Moodley (HOD Obstetrics and Gynaecology), and Professor P. Corr (Head of Radiology).			
33	Does the researcher have indemnity cover relating to research activities? If yes, specify. If no, explain why not.	X		
	COMMENTS: **Durban Institute of Technology insurance**			
34	Does the researcher have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? If		X	

	yes, specify.			
	COMMENTS			

The undersigned declare that the above questions have been answered truthfully and accurately

STUDENT NAME---------- SIGNATURE----------

DATE----------

SUPERVISOR NAME---------- SIGNATURE----------

DATE----------

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APPENDIX A

DEPARTMENT OF RADIOGRAPHY

PATIENT INFORMATION LETTER

Dear participant

You have been requested to voluntarily participate in the transvaginal ultrasound research project.

TOPIC OF RESEARCH: An evaluation of transvaginal ultrasound in the assessment of endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding.

The project aims to evaluate how accurate transvaginal ultrasound is in assisting the doctor in the examining the inner walls of the uterus (endometrium). Transvaginal ultrasound uses sound waves in order to produce images of structures in the pelvis.

PROCEDURE:

The researcher will confirm and record your clinical history. This is required to assess whether you fit into the inclusion criteria for the study. The researcher will do transvaginal ultrasound examinations of the endometrium using the ultrasound equipment in the Department of Obstetrics and Gynaecology antenatal clinic at King Edward VIII Hospital. It is necessary to measure the thickness of the endometrium. To confirm the finding of the ultrasound scan, a routine pipelle sampling of the endometrium will be done by a medical doctor. The findings obtained will be recorded on record / data sheets and filed in away. The procedure will be completed within one (1) hour.

RISKS / DISCOMFORT

Participation in the study carries no risks. The researcher will ensure that the investigative technique does not compromise your comfort. The pipelle sampling procedure may cause slight discomfort but it is the usual procedure done for all patients with postmenopausal bleeding.

BENEFITS:

1.The above mentioned study has never been performed on Black patients and results obtained will be valuable in the future treatment of patients.

2. Postmenopausal bleeding is common in Black patients and it is essential to find the cause.

3. This study will assist early diagnosis of benign/malignant lesions in Black patients.

4. With improved early diagnosis, cost – effectiveness and effective patient treatment may be achieved.

CONFIDENTIALITY:

All information obtained from you will be treated confidentially and will be used for research purposes only. Your names will be excluded from data analysis and data presentation. Please be aware that you are not compelled to be in this study and that you are free to withdraw at any stage of the project.

COST

The study will be done free of charge with no costs to you for the procedures.

PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:

Ms Premla Moodley:

Tel no.: 031 - 3603321 (Bus) 031- 208 9523 (h) Fax no.: 031 – 205 6639

E-mail address: moodleyp@dohke8.kzntl.gov.za

Ms. N. Lachman:

Tel. No.: 031 – 2042404 (w) 031-4030335 (h) E-mail address: nirushal@dit.ac.za

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APPENDIX B

INFORMED CONSENT FORM

I, ...hereby voluntarily

print name

give consent to participate in the research entitled:

An evaluation of transvaginal ultrasound in the assessment of endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding.

Name of researcher:	Premla Moodley (King Edward VIII Hospital Ultrasound Department)
Name of supervisor:	Nirusha Lachman (Department of Human Biology – DIT)
Name of co- supervisor:	Professor J. Moodley (Department of Obstetrics and Gynaecology N.R. Mandela School of Medicine)

PLEASE CIRCLE THE APPROPRIATE ANSWER:

1	Have you read and understood the research information sheet?	YES / NO
2	Have you had an opportunity to discuss the study?	YES / NO
3	Have you had an opportunity to ask questions regarding this study?	YES / NO
4	Have you received satisfactory answers to your questions?	YES / NO

5 Have you received enough information about the study? YES / NO

6 Do you understand that you are free to withdraw from?

this study: a) at any time and;

b) without having to give reason for

withdrawing? YES / NO

7 Do you agree to voluntarily participate in this study? YES / NO

If you have answered NO to any of the above questions, please obtain the appropriate information BEFORE signing.

Please print clearly in block letters:

Subject Name:_____ signature/date

Witness Name _____signature/date

PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS:

Ms Premla Moodley:

Tel no.: 031 - 3603321 (Bus) 031- 208 9523 (h) Fax no.: 031 – 205 6639

E-mail address: moodleyp@dohke8.kzntl.gov.za

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IMVUME YOKUBAMBA IQHAZA OCWANINGWENI

Mina _____-ngiyavuma

Bhala igama

ngentando yami ukubamba iqhaza ocwaningweni olusihloko sithi:

An evaluation of transvaginal ultrasound in the assessment of endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding.

Olwenziwa ngu:

Igama lomcwaningi: Premla Moodley (King Edward VIII Hospital Ultrasound Department)

Igama lombheki wocwaningo: Nirusha Lachman (Department of Human Biology – DIT)

Igama lomusekeli wombheki wocwaningo: Professor J. Moodley (Department of Obstetrics and Gynaecology N.R. Mandela School of Medicine)

UYANXUSWA UKUTHI WENZE INDILINGA EMPENDULWENI EFANELEYO

1. Ulifundile waliqonda yini iphepha elinikeza imininingwane ngalolucwaningo? YEBO /CHA
2. Ulitholile yini ithuba lokuxoxa nomcwaningi Ngocwaningo na? YEBO / CHA
3. Ingabe ulitholile yini ithuba lokubuza imibuzo mayelana nalolucwaningo na? YEBO / CHA

4. Wanelisekile yini ngezimpendulo ozitholile emibuzweni obunayo mayelana nalolocwaningo? YEBO / CHA
5. Uthole imininingwane eyanele yini ngalolucwaningo? YEBO /CHA
6. Uyaqonda yini ukuthi ukhululekile ukuyeka ukubamba iqhaza kulolucwaningo
    a. noma nini
    b. ngaphandle kokunikeza isizathu sokuyeka YEBO / CHA
7. Uyavuma ngentando yakho ukubamba iqhaza Kulolucwaningo na? YEBO /CHA

Uma uphendule wathi CHA kunoma yimuphi umubuzo kulemibuzo engenhla uyanxuswa ukuthi uthole imininingwane efaneleyo NGAPHAMBI kokuba usayine

Bhala ngokucacile ngamagama amakhulu-

Igama lobambe iqhaza ocwaningweni : - ---------- sayina/usuku- ---- -

Igama likafakazi:- ---------- sayina/usuku- --- -

Umuntu ongaxhumana naye mayelana nezinkinga kanye nemibuzo ngu :- P. Moodley

Imininingwane yokuxhumana

Inombolo yocingo: 031 – 3603321 (Bus) 031 – 2089523 (H) Inombolo yefax: 031 - 2056639

Email address: moodleyp@dohke8.kzntl.gov.za

TITLE / ISIHLOKO SOCWANINGO

An evaluation of transvaginal ultrasound in the assessment of endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding.

Ngiyakubingelela wena obambe iqhaza,

Uyenxuswa ngentando yakho ukuthi uthathe iqhaza ocwaningweni lokuhlola ngohlobo lwezithombe ze- 'ultrasound' / 'emafutheni'.

Loluhlobo lwezithombe aluthwebuli izithombe ngogesi (X-Ray – radiation) kodwa lusembenzisa uhlobo lomsindo ophakeme ongazwakali ezindlebeni zabantu futhi alunangozi.

Ucwaningo lolu luhlose ukuba nesibalo seziguli ezingamashumi ayisikhombisa nanhlanu zase Thekwini namaphethelo.

PROCEDURE / INQUBO YOCWANINGO

Umcwaningi uzoxoxa nobambe iqhaza ukuqinisekisa umlando wezempilo "clinical history."

Umcwaningi uzochaza bese eqala ucwaningo ngomshini we "ultrasound" osegunjini labakhulelwe nabezifo zabesifazane "DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY" esibhedlela i KING EDWARD VIII HOSPITAL.

Kubalulekile ukukala ububanzi bengaphakathi lesibeletho "Endometrial Thickness."

Loko okuthelwe kulolucwaningo kuyobhalwa kugcinwe ezincwadini "data sheets" futhi kuyobhekelwa ukuthi kugcineke ngendlela eyimfihlo kwabanye abantu.

Lolucwaningo luyotha imizuzu engamashumi amathathu (30 minutes) kuphela.

RISKS /DISCOMFORT / INGOZI KULOLUCWANINGO

Ukubamba iqhaza kulolucwaningo akunangozi.Umcwaningi uyoqinisekisa ukuthi ekuhloleni kwakhe ungahlukumezeki nakancane.

BENEFITS / OKUNGAZUZWA NGALOLUCWANINGO

1. Lolucwaningo olubalulwe ngenhla alukaze lwenziwe kubantu abamnyama.
2. Ukopha kwesibeletho ngemuva kwesikhathi sokuthola abantwana kuyinkinga ejwayelekile ukwenzeka kwabamnyama, ngoloko kubalulekile ukuthola imvepaphi yalesisifo.
3. Lolucwaningo luzobeka esimeni esingcono ukutholakala kolwazi ngegciwane lisasanda kuqala.
4. Igciwane lizotholakala liselisha, izindleko zokwelapha zincishiswe ngokunjalo kutholakale necebo elingcono lokubhekana nalesisifo.

CONFIDENTIALITY / IMFIHLO NGEMININGWANE

Yonke imininingwane nolwazi olofunyanwa kuwena losentshenziselwa ucwaningo kuphela futhi logcinwa ngemfihlo enkulu. Amagama angeke avezwe ekuhlaziyweni kwemiphumel nalapho sekushicilelwa. Uhlale wazi ukuthi unelungelo lokuhoxa noma nini uma ufisa ukwenza njalo.

IZINDLEKO:

Ngeke ukhokhiswe mali ngalokhukuxilongwa.

Umuntu ongaxhumana naye mayelana nezinkinga kanye nemibuzo ngu :- P. Moodley

Imininingwane yokuxhumana

Inombolo yocingo: 031 – 3603321 (Bus) 031 – 2089523 (H) Inombolo yefax: 031 - 2056639

Email address: moodleyp@dohke8.kzntl.gov.za

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APPENDIX C

ATTENTION: REGISTERED MEDICAL PRACTIONERS – OUTPATIENT GYNAECOLOGY DEPARTMENT

A STUDY IS CURRENTLY BEING DONE TO EVALUATE ENDOMETRIAL THICKNESS IN BLACK PATIENTS PRESENTING WITH ABNORMAL POSTMENOPAUSAL UTERINE BLEEDING, WHO HAVE NOT BEEN PREVIOUSLY MEDICALLY MANAGED.

PLEASE REFER ALL THESE PATIENTS FOR TRANVAGINAL ULTRASOUND EVALUATION

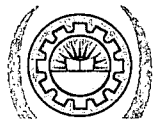
TO Ms. PREMLA MOODLEY TO BE INCLUDED IN THE RESAERCH STUDY.

ULTRASOUND DEPARTMENT – ANTENATAL CLINIC AT KING EDWARD VIII HOSPITAL

YOUR SUPPORT WILL BE APPRECIATED.

CONTACT DETAILS:Ms. P. MOODLEY

PHONE: 3603321 / 3603061



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APPENDIX D

PATIENT CODE:_____

1. NAME: _____
2. AGE: _____
3. PARITY: _____

4. CLINICAL SYMPTOMS:	YES	NO
4.1 MENOPAUSAL		
4.2 PER VAGINAL BLEED		
4.3 PELVI-ABDOMINAL MASS		
4.4 OTHER		

5. MEDICATION		
5.1 HORMONE REPLACEMENT THERAPY		
5.2 IF YES, STATE MEDICATION		

6.1 PAST / FAMILY HISTORY OF MALIGNANCY		
6.2 IF YES, STATE TYPE.		

7.GENERAL CLINICAL EXAMINATION	
7.1 ABDOMEN	

7.2 PELVIS	

8. TRANSVAGINAL SCAN	
8.1 UTERINE SIZE	
8.2 ENDOMETRIAL THICKNESS (MM)	
8.3 FLUID IN ENDOMETRIAL CAVITY	
8.4 ADNEXAL PATHOLOGY	

9. MORPHOLOGY _____

_____

_____

_____

_____

_____

_____

10. ENDOMETRIAL(PIPELLE) SAMPLING:

10.1 WAS PROCEDURE SUCCESSFUL? YES NO

10.2 IF NO, WHY: _____

_____

_____

_____

10.3 WAS HYSTEROSCOPY REQUIRED? YES NO

104. IF YES, HYSTEROSCOPY FINDINGS: _____

_____

_____

_____

11. HISTOLOGY FINDINGS

_____

_____

_____

_____

_____

_____

_____

_____

_____

DURBAN INSTITUTE of TECHNOLOGY

APPENDIX E

Secretary General of Health

Professor R.W. Green-Thompson

Department of Health

Kwa-Zulu Natal

Durban

4000

2002 : 03 : 01

Dear Professor Green-Thompson

RE: ***Permission to perform research in the Gynaecology Department***

I am currently a masters student at the Durban Institute of Technology and I am employed at the Department of Radiology – Ultrasound/Radiography at King Edward VIII Hospital. I am keen to conduct a research project towards a Masters Degree in Ultrasound.

In current practise, transabdominal ultrasound is commonly used to assess endometrial thickness. However, the reliability of the transabdominal technique in effectively determining endometrial thickness, is questionable. In addition to the production of lower quality scans, underlying pathology such as fibroids and endometrial polyps are often overlooked. This study aims to use transvaginal ultrasound to investigate and demonstrate endometrial thickness in Black South African patients presenting with postmenopausal uterine bleeding and to determine the cut – off values that may be used for early prediction of malignant lesions if present.

The protocol has been reviewed by the Department of Radiography and approved by the Faculty of Health Sciences at Durban Institute of Technology. Appropriate ethical approval has been obtained. My work will be supervised by Miss N. Lachman from Durban Institute of Technology and Professor J. Moodley from Department of Obstetrics and Gynecology (NR Mandela School of Medicine).

It is envisaged, that results from this study will enhance early diagnosis of benign/malignant lesions in Black patients and improve early diagnosis, cost-effectiveness and effective patient management.

Your support and permission in writing to perform this study at King Edward VIII Hospital will be greatly appreciated.

Yours sincerely

Ms. Premla Moodley

B. Tech. Radiography (Ultrasound)

Contact details: Department of Ultrasound, King Edward VIII Hospital

Tel.: 031- 3603321 e-mail: moodleyp@dohke8.kzntl.gov.za

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APPENDIX F

CHIEF MEDICAL SUPERINTENDENT

KING EDWARD VIII HOSPITAL

DURBAN

4000

2002 : 01 : 30

Dear Sir/Madam

RE: ***Permission to perform research in the Gynaecology Department***

I am currently a masters student at the Durban Institute of Technology and I am employed at the Department of Radiology – Ultrasound/Radiography at King Edward VIII Hospital. I am keen to conduct a research project towards a Masters Degree in Ultrasound.

In current practise, transabdominal ultrasound is commonly used to assess endometrial thickness. However, the reliability of the transabdominal technique in effectively determining endometrial thickness, is questionable. In addition to the production of lower quality scans, underlying pathology such as fibroids and endometrial polyps are often overlooked. This study aims to use transvaginal ultrasound to investigate and demonstrate endometrial thickness in

Black South African patients presenting with postmenopausal uterine bleeding and to determine the cut – off values that may be used for early prediction of malignant lesions if present.

The protocol has been reviewed by the Department of Radiography and approved by the Faculty of Health Sciences at Durban Institute of Technology. Appropriate ethical approval has been obtained. Appropriate ethical approval has been sought. My work will be supervised by Miss N. Lachman from Durban Institute of Technology and Professor J. Moodley from Department of Obstetrics and Gynecology (NR Mandela School of Medicine).

It is envisaged, that results from this study will enhance early diagnosis of benign/malignant lesions in Black patients and improve early diagnosis, cost-effectiveness and effective patient management.

Your support and permission in writing to perform this study at King Edward VIII Hospital will be greatly appreciated.

Yours sincerely

_____

Ms. Premla Moodley

B. Tech. Radiography (Ultrasound)

Contact details: Department of Ultrasound, King Edward VIII Hospital

Tel.: 031- 3603321

e-mail: moodleyp@dohke8.kzntl.gov.za

DURBAN INSTITUTE of TECHNOLOGY

APPENDIX G

PROFESSOR J. MOODLEY

HEAD OF DEPARTMENT

OBSTETRICS AND GYNECOLOGY

NR MANDELA SCHOOL OF MEDICINE

DURBAN

2002 : 01 : 30

Dear Professor Moodley

RE: ***Permission to perform research in the Gynaecology Department***

I am currently a masters student at the Durban Institute of Technology and I am employed at the Department of Radiology – Ultrasound/Radiography at King Edward VIII Hospital. I am keen to conduct a research project towards a Masters Degree in Ultrasound.

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Yours sincerely

Ms. Premla Moodley

B. Tech. Radiography (Ultrasound)

Contact details: Department of Ultrasound, King Edward VIII Hospital

Tel.: 031- 3603321 e-mail: moodleyp@dohke8.kzntl.gov.za

DURBAN INSTITUTE of TECHNOLOGY

APPENDIX H

PROFESSOR P. CORR

HEAD OF DEPARTMENT

RADIOLOGY

NR MANDELA SCHOOL OF MEDICINE

DURBAN

2002 : 01 : 30

Dear Professor Corr

RE: ***Permission to perform research in the Gynaecology Department***

I am currently a masters student at the Durban Institute of Technology and I am employed at the Department of Radiology – Ultrasound/Radiography at King Edward VIII Hospital. I am keen to conduct a research project towards a Masters Degree in Ultrasound.

In current practise, transabdominal ultrasound is commonly used to assess endometrial thickness. However, the reliability of the transabdominal technique in effectively determining endometrial thickness, is questionable. In addition to the production of lower quality scans, underlying pathology such as fibroids and endometrial polyps are often overlooked. This study aims to use transvaginal ultrasound to investigate and demonstrate endometrial thickness in

Black South African patients presenting with postmenopausal uterine bleeding and to determine the cut – off values that may be used for early prediction of malignant lesions if present.

The protocol has been reviewed by the Department of Radiography and approved by the Faculty of Health Sciences at Durban Institute of Technology. Appropriate ethical approval has been obtained. Appropriate ethical approval has been sought. My work will be supervised by Miss N. Lachman from Durban Institute of Technology and Professor J. Moodley from Department of Obstetrics and Gynecology (NR Mandela School of Medicine).

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Your support and permission in writing to perform this study at King Edward VIII Hospital will be greatly appreciated.

Yours sincerely

Ms. Premla Moodley

B. Tech. Radiography (Ultrasound)

Contact details: Department of Ultrasound, King Edward VIII Hospital

Tel.: 031- 3603321

e-mail: moodleyp@dohke8.kzntl.gov.za

The Directors
Drs Jackpersad and Partners
6/10/06

Re : Research

I am pleased to inform you that my Research Proposal had been approved by the Durban University of Technology on the 2/10/06.

The title of the research is : **An assessment of coronary artery calcification, using the calcium scoring technique, in an asymptomatic Indian population in Durban, KwaZulu Natal.**
A copy of the research proposal will be handed to Dr Kalideen who will be acting as my Supervisor in the clinical environment. The next step in the research will be the recruitment process which will be done simultaneously with the scanning of participants. The Research committee has indicated that to validate the research, ideally 100 participants should be scanned. However, this will depend on the recruitment. The Faculty of Health Sciences will fund R10 000 towards the research.

My intention is to scan the participants on the Saturday mornings when I am off duty, so that it does not affect or disrupt my normal working hours. Due consideration will also be given to the departmental CT bookings and the logistics will be discussed with Dr Kalideen.

I would also like to express my gratitute to the Directors for their continued support in my research and Dr Kalideen for his tremendous contribution thus far. I am confident that I will receive this kind of support throughout my research.

Thanking You
K.Moodley (Linda)

The protocol has been reviewed by the Department of Radiography and approved by the Faculty of Health Sciences at Durban Institute of Technology. Appropriate ethical approval has been obtained. Appropriate ethical approval has been sought. My work will be supervised by Miss N. Lachman from Durban Institute of Technology and Professor J. Moodley from Department of Obstetrics and Gynecology (NR Mandela School of Medicine).

All Black patients with unexplained postmenopausal bleeding above the age of 35 years with absence of menstruation for a minimum period of 6 months who give consent for the transvaginal ultrasound procedure to be performed will be considered for the study.

It is envisaged, that results from this study will enhance early diagnosis of benign/malignant lesions in Black patients and improve early diagnosis, cost-effectiveness and effective patient management.

Your support in referring all patients who fulfil the inclusion criteria for this study will be greatly appreciated.

Yours sincerely

Ms. Premla Moodley

B. Tech. Radiography (Ultrasound)

Contact details: Department of Ultrasound, King Edward VIII Hospital

Tel.: 031- 3603321 e-mail: moodleyp@dohke8.kzntl.gov.za

APPENDIX J

Descriptives

Descriptive Statistics

	N	Range	Minimum	Maximum	Mean	Std. Deviation
AGE	76	35	42	77	59.36	8.077
Valid N (listwise)	76					

Frequencies

Statistics
PARITY

N	Valid	76
	Missing	1
Range		10
Minimum		0
Maximum		10
Percentiles	25	3.00
	50	5.00
	75	6.00

Frequencies

Statistics

		FHM	FHMT
N	Valid	77	77
	Missing	0	0

Frequency Table

FHM

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	71	92.2	92.2	93.5
	1	5	6.5	6.5	100.0
	Total	77	100.0	100.0	

FHMT

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		72	93.5	93.5	93.5
	1	4	5.2	5.2	98.7
	2	1	1.3	1.3	100.0
	Total	77	100.0	100.0	

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
FHM * DIAGN8	5	100.0%	0	.0%	5	100.0%

FHM * DIAGN8 Crosstabulation

Count

		DIAGN8		Total
		2	3	
FHM	1	4	1	5
Total		4	1	5

Frequencies

Statistics

PVB1

N	Valid	77
	Missing	0

PVB1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	1	76	98.7	98.7	100.0
	Total	77	100.0	100.0	

Frequencies

Statistics

PAM1

N	Valid	77
	Missing	0

PAM1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	76	98.7	98.7	100.0
	Total	77	100.0	100.0	

Frequencies

Statistics

		ABDO3	PELVIS3
N	Valid	77	77
	Missing	0	0

Frequency Table

ABDO3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	66	85.7	85.7	87.0
	1	10	13.0	13.0	100.0
	Total	77	100.0	100.0	

PELVIS3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	72	93.5	93.5	94.8
	1	4	5.2	5.2	100.0
	Total	77	100.0	100.0	

Descriptives

Descriptive Statistics

	N	Range	Minimum	Maximum	Mean	Std. Deviation
LS	76	44	51	95	74.22	13.157
TS	76	57	28	85	50.95	13.846
Valid N (listwise)	76					

Frequencies

Statistics
DIAGN8

N	Valid	76
	Missing	1

DIAGN8

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	3	3.9	3.9	3.9
	2	34	44.2	44.7	48.7
	3	11	14.3	14.5	63.2
	4	3	3.9	3.9	67.1
	5	13	16.9	17.1	84.2
	6	4	5.2	5.3	89.5
	7	7	9.1	9.2	98.7
	8	1	1.3	1.3	100.0
	Total	76	98.7	100.0	
Missing	System	1	1.3		
Total		77	100.0		

T-Test

Group Statistics

	MALIGNAN	N	Mean	Std. Deviation	Std. Error Mean
AREA	0	42	3405.33	1621.498	250.203
	1	34	4553.97	1475.895	253.114

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AREA	Equal variances assumed	.577	.450	-3.195	74	.002	-1148.64	359.484	-1864.924	-432.350
	Equal variances not assumed			-3.227	72.943	.002	-1148.64	355.904	-1857.963	-439.312

Frequencies

Statistics
FEC4

N	Valid	77
	Missing	0

FEC4

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	62	80.5	80.5	81.8
	1	14	18.2	18.2	100.0
	Total	77	100.0	100.0	

Frequencies

Statistics
CA8

N	Valid	77
	Missing	0

CA8

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	41	53.2	53.2	54.5
	1	35	45.5	45.5	100.0
	Total	77	100.0	100.0	

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
MALIGNAN * CA8	76	98.7%	1	1.3%	77	100.0%

MALIGNAN * CA8 Cross tabulation
Count

		CA8		Total
		0	1	
MALIGNAN	0	41	1	42

	1		34	34
Total		41	35	76

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
FEC4 * CA8	77	100.0%	0	.0%	77	100.0%

FEC4 * CA8 Cross tabulation
Count

		CA8		Total
		0	1	
FEC4	1			1
	0	39	23	62
	1	2	12	14
Total	1	41	35	77

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	88.009(a)	4	.000
Likelihood Ratio	22.301	4	.000
N of Valid Cases	77		

a 5 cells (55.6%) have expected count less than 5. The minimum expected count is .01.

Frequencies

Statistics
AP4

N	Valid	77
	Missing	0

AP4

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	73	94.8	94.8	96.1
	1	3	3.9	3.9	100.0

	Total	77	100.0	100.0	

Frequencies

Statistics
IRREG5

N	Valid	77
	Missing	0

IRREG5

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	0	30	39.0	39.0	40.3
	1	46	59.7	59.7	100.0
	Total	77	100.0	100.0	

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
IRREG5 * MALIGNAN	76	98.7%	1	1.3%	77	100.0%

IRREG5 * MALIGNAN Cross tabulation

			MALIGNAN		Total
			0	1	
IRREG5	0	Count	30		30
		% within IRREG5	100.0%		100.0%
	1	Count	12	34	46
		% within IRREG5	26.1%	73.9%	100.0%
Total		Count	42	34	76
		% within IRREG5	55.3%	44.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	40.124(b)	1	.000		
Continuity Correction(a)	37.190	1	.000		

Likelihood Ratio	51.710	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	76				
a Computed only for a 2x2 table					
b 0 cells (.0%) have expected count less than 5. The minimum expected count is 13.42.					

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
IRREG5 * DIAGN8	76	98.7%	1	1.3%	77	100.0%

IRREG5 * DIAGN8 Cross tabulation

			DIAGN8								Total
			1	2	3	4	5	6	7	8	
IRREG5	0	Count	2		6	3	10	2	7		30
		% within IRREG5	6.7%		20.0%	10.0%	33.3%	6.7%	23.3%		100.0%
	1	Count	1	34	5		3	2		1	46
		% within IRREG5	2.2%	73.9%	10.9%		6.5%	4.3%		2.2%	100.0%
Total		Count	3	34	11	3	13	4	7	1	76
		% within IRREG5	3.9%	44.7%	14.5%	3.9%	17.1%	5.3%	9.2%	1.3%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	47.950(a)	7	.000
Likelihood Ratio	63.397	7	.000
N of Valid Cases	76		
a 11 cells (68.8%) have expected count less than 5. The minimum expected count is .39.			

Frequencies

Statistics
EMT4

N	Valid	76
	Missing	1
Mean		18.18
Range		30
Minimum		5

Maximum	35

Explore

Warnings

EMT4 is constant when DIAGN8 = 8. It will be included in any boxplots produced but other output will be omitted.

DIAGN8

Case Processing Summary

		Cases					
		Valid		Missing		Total	
	DIAGN8	N	Percent	N	Percent	N	Percent
EMT4	1	3	100.0%	0	.0%	3	100.0%
	2	34	100.0%	0	.0%	34	100.0%
	3	11	100.0%	0	.0%	11	100.0%
	4	3	100.0%	0	.0%	3	100.0%
	5	13	100.0%	0	.0%	13	100.0%
	6	4	100.0%	0	.0%	4	100.0%
	7	7	100.0%	0	.0%	7	100.0%
	8	1	100.0%	0	.0%	1	100.0%

Descriptives(a)

	DIAGN8			Statistic	Std. Error
EMT4	1	Mean		7.83	2.088
		95% Confidence Interval for Mean	Lower Bound	-1.15	
			Upper Bound	16.82	
		5% Trimmed Mean		.	
		Median		6.00	
		Variance		13.083	
		Std. Deviation		3.617	
		Minimum		6	
		Maximum		12	
		Range		7	
		Interquartile Range		.	
		Skewness		1.695	1.225
		Kurtosis		.	.
	2	Mean		20.32	1.338
		95% Confidence Interval for Mean	Lower Bound	17.60	

		Upper Bound	23.04	
	5% Trimmed Mean		20.03	
	Median		19.00	
	Variance		60.832	
	Std. Deviation		7.799	
	Minimum		11	
	Maximum		35	
	Range		24	
	Interquartile Range		15.25	
	Skewness		.544	.403
	Kurtosis		-.964	.788
3	Mean		18.36	1.955
	95% Confidence Interval for Mean	Lower Bound	14.01	
		Upper Bound	22.72	
	5% Trimmed Mean		18.18	
	Median		16.00	
	Variance		42.055	
	Std. Deviation		6.485	
	Minimum		10	
	Maximum		30	
	Range		20	
	Interquartile Range		10.00	
	Skewness		.734	.661
	Kurtosis		-.522	1.279
4	Mean		19.33	1.764
	95% Confidence Interval for Mean	Lower Bound	11.74	
		Upper Bound	26.92	
	5% Trimmed Mean		.	
	Median		20.00	
	Variance		9.333	
	Std. Deviation		3.055	
	Minimum		16	
	Maximum		22	
	Range		6	
	Interquartile Range		.	
	Skewness		-.935	1.225
	Kurtosis		.	.
5	Mean		17.31	2.092

	95% Confidence Interval for Mean	Lower Bound	12.75	
		Upper Bound	21.87	
	5% Trimmed Mean		17.29	
	Median		20.00	
	Variance		56.897	
	Std. Deviation		7.543	
	Minimum		5	
	Maximum		30	
	Range		25	
	Interquartile Range		12.00	
	Skewness		-.145	.616
	Kurtosis		-.845	1.191
6	Mean		13.25	1.181
	95% Confidence Interval for Mean	Lower Bound	9.49	
		Upper Bound	17.01	
	5% Trimmed Mean		13.33	
	Median		14.00	
	Variance		5.583	
	Std. Deviation		2.363	
	Minimum		10	
	Maximum		15	
	Range		5	
	Interquartile Range		4.25	
	Skewness		-1.194	1.014
	Kurtosis		.436	2.619
7	Mean		15.86	3.298
	95% Confidence Interval for Mean	Lower Bound	7.79	
		Upper Bound	23.93	
	5% Trimmed Mean		15.62	
	Median		16.00	
	Variance		76.143	
	Std. Deviation		8.726	
	Minimum		6	
	Maximum		30	
	Range		24	
	Interquartile Range		17.00	
	Skewness		.583	.794
	Kurtosis		-.553	1.587

a EMT4 is constant when DIAGN8 = 8. It has been omitted.

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
INV7 * DIAGN8	76	98.7%	1	1.3%	77	100.0%
INV7 * MALIGNAN	76	98.7%	1	1.3%	77	100.0%

INV7 * MALIGNAN

Crosstab

			MALIGNAN		Total
			0	1	
INV7	0	Count	42	12	54
		% within INV7	77.8%	22.2%	100.0%
	1	Count		21	21
		% within INV7		100.0%	100.0%
	N	Count		1	1
		% within INV7		100.0%	100.0%
Total		Count	42	34	76
		% within INV7	55.3%	44.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	38.248(a)	2	.000
Likelihood Ratio	47.306	2	.000
N of Valid Cases	76		

a 2 cells (33.3%) have expected count less than 5. The minimum expected count is .45.

Frequencies

Statistics

		MALIGNAN	DIAGN8
N	Valid	76	76
	Missing	1	1

Frequency Table

MALIGNAN

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	42	54.5	55.3	55.3
	1	34	44.2	44.7	100.0
	Total	76	98.7	100.0	
Missing	System	1	1.3		
Total		77	100.0		

DIAGN8

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	3	3.9	3.9	3.9
	2	34	44.2	44.7	48.7
	3	11	14.3	14.5	63.2
	4	3	3.9	3.9	67.1
	5	13	16.9	17.1	84.2
	6	4	5.2	5.3	89.5
	7	7	9.1	9.2	98.7
	8	1	1.3	1.3	100.0
	Total	76	98.7	100.0	
Missing	System	1	1.3		
Total		77	100.0		

T-Test

Group Statistics

	MALIGNAN	N	Mean	Std. Deviation	Std. Error Mean
EMT4	0	42	16.44	6.923	1.068
	1	34	20.32	7.799	1.338

Independent Samples Test

	Levene's Test for Equality of Variances	t-test for Equality of Means

		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
EMT4	Equal variances assumed	.827	.366	-2.297	74	.024	-3.88	1.690	-7.251	-.515
	Equal variances not assumed			-2.268	66.686	.027	-3.88	1.712	-7.300	-.466

Frequencies

Statistics
ECHOG5

N	Valid	77
	Missing	0

ECHOG5

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	1.3	1.3	1.3
	1	76	98.7	98.7	100.0
	Total	77	100.0	100.0	

Crosstabs

Warnings

No measures of association are computed for the crosstabulation of ECHOG5 * MALIGNAN. At least one variable in each 2-way table upon which measures of association are computed is a constant.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
ECHOG5 * MALIGNAN	76	98.7%	1	1.3%	77	100.0%

ECHOG5 * MALIGNAN Crosstabulation

			MALIGNAN		Total
			0	1	
ECHOG5	1	Count	42	34	76

	% within ECHOG5	55.3%	44.7%	100.0%
Total	Count	42	34	76
	% within ECHOG5	55.3%	44.7%	100.0%

Chi-Square Tests

	Value
Pearson Chi-Square	.(a)
N of Valid Cases	76
a No statistics are computed because ECHOG5 is a constant.	