MODERN EVALUATION OF THE ENDOMETRIUM

Steven R. Goldstein, M.D., FACOG, NCMP, CCD, FRCOG(H)
Professor of Obstetrics & Gynecology
New York University School of Medicine
Director of Gynecologic Ultrasound
Co-Director of Bone Densitometry
New York University Medical Center

THE STANDARD OF CARE HAS CHANGED!!!!

BUT HOW MANY CLINICIANS ARE AWARE OF IT?


● Used to say...“endometrial assessment to exclude cancer is indicated in any woman older than 35 years who is suspected of having anovulatory uterine bleeding”

HIGHLIGHTS OF NEWEST ACOG BULLETIN (7/12)

“DIAGNOSIS OF AUB IN REPRODUCTIVE AGED WOMEN”

ACOG PRACTICE BULLETIN JULY 2012

“One third of outpatient visits to the gynecologist are for AUB and it accounts for more than 70% of GYN consults in the perimenopausal and postmenopausal years”
AUB most frequently occurs in women 19-39 as a result of pregnancy, structural lesions (polyps, myoma), anovulatory cycles (e.g. PCOS), hormonal contraception and endometrial hyperplasia. EM carcinoma is less common but may occur in this age group.

In women aged 40 to menopause AUB may be due to anovulatory bleeding which represents normal physiology in response to declining ovarian function. It may also be due to EM carcinoma or hypeplasia, EM atrophy or leiomyomas.

The endometrium consists of a basalis and a functionalis.

Estrogen causes the functionalis to proliferate.

Progestrone (or in sequential hormone therapy the use of a progestin) will convert an estrogen primed endometrial functionalis to a secretory phase.

Hormonal status obviously affects endometrial thickness.

Mitoses

Note amount (or height) of tissue.
SECRETORY EM

• AFTER SHEDDING OF THE FUNCTIONALIS THE BASAL ENDOMETRIUM THAT REMAINS IS INITIALLY QUITE THIN AND HAS A PENCIL LINE APPEARANCE ON TV U/S

POST MENSTRUAL EM

• IN MENOPAUSE THERE IS NO ESTROGENIC STIMULATION OF THE FUNCTIONALIS AND THE ENDOMETRIUM IS ATROPHIC

ATROPHIC EM

• Simple tubular glands
• Lacks mitotic activity
• Fibrotic stroma with increased collagen fibers

• SINCE THERE IS NO "NORMAL" WIDTH OF ENDOMETRIAL THICKNESS... WHAT IS THE PROPER USE OF THE ENDOMETRIAL ECHO CLINICALLY?
ANSWER

- **THE HIGH NEGATIVE PREDICTIVE VALUE OF A THIN DISTINCT ECHO IN PATIENTS WITH BLEEDING**

ENDOMETRIAL CANCER

- American cancer society (2013): 41,520 new cases, 8,145 deaths
- Vaginal bleeding will be the presenting sign in almost all
- Most women with PM bleeding actually bleed secondary to atrophic changes of vagina or EM
- Incidence of EM cancer in women with PMB ranges from 1-14%

POSTMENOPAUSAL BLEEDING NOT SO EASILY DEFINED

- Menopause “The Final Menstrual Period”
- Retrospective diagnosis
- Classic definition: “No bleeding for 12 months due to a depletion of ovarian follicles”
- Serum measurements of FSH and estradiol notoriously unreliable – snapshot of ovarian function at that time.

CLINICAL REALITY

- Postmenopausal bleeding is “endometrial cancer until proven otherwise” Mandates evaluation
- ACOG Practice Bulletin July 2012 mandates that endometrial assessment to exclude cancer is indicated in any woman older than 40 years who is suspected of having abnormal uterine bleeding

ENDOMETRIAL ASSESSMENT

- Erratic function of the ovaries in late perimenopause often makes it difficult to label bleeding as definitively postmenopausal
**HISTORICAL BACKGROUND**

- **D&C (Dilatation & Curettage)**
  - 1st described in 1843
  - Most common operation performed on women in hospital through much of the 20th Century
  - Prehysterectomy studies showed that when done blindly much of the uterine cavity goes unsampled

**VABRA ASPIRATOR**

- Re-usable metal cannula attached to suction machine for in office EM sampling with little or no anesthesia
- High level of patient discomfort
- 86% accurate in diagnosing cancer

**SUCTION PISTON BIOPSY INSTRUMENTS**

- Smaller, cheaper, disposable plastic catheters with an internal piston to generate suction
- Marketing success of Pipelle brand (“Xerox, Kleenex”)
- Similar efficacy but better patient acceptance when compared to Vabra

**PIPELLE SUCTION PISTON BIOPSY**

- 1st described by Cornier in an article in the Gray journal in 1984
- Of next 8 papers (1988-1991) 7 dealt with EM dating as part of infertility W/U (no longer utilized)
- One paper dealt with AMOUNT of tissue obtained with Pipelle compared to Vabra
- Next paper (1991) was WIDELY publicized

**PIPELLE AND EM CARCINOMA**

**PIPELLE**
**PIPELLE ENDOMETRIAL SAMPLING**

65 pts with known carcinoma of EM
Pipelle under anesthesia prior to TAH
- missed 11/65 cancers of which
  3 were < 5% EM area
  4 were 6-25% EM area
  4 were 26-50% EM area
  5/11 had tumor in polyps that were missed

Concluded “Pipelle is excellent for detecting global processes in the endometrium”

**FALSE NEGATIVE RATE OF PIPELLE IN PATIENTS WITH KNOWN CARCINOMA (OTHER STUDIES)**

- 7% (missed 2/26)
- 17% (missed 14/80)
- 33% (missed 12/37)
- Not nearly as reliable as the original work by Stovall

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**TV U/S IN PMB: HISTORICAL PERSPECTIVE**

In the early 1990’s, it was utilized in women with postmenopausal bleeding to see if it could predict which patients lacked significant tissue and could avoid D&C or endometrial biopsy and its discomfort, expense, and risk.

**TRANSVAGINAL ULTRASOUND**

- Consistently, the finding of a thin distinct endometrial echo \( < 4 \) to 5mm was shown to effectively exclude significant tissue in postmenopausal women with bleeding.

**AUTHOR** | **YEAR** | **THINNEST EM IN A CASE OF CANCER** | **THICKEST EM ASSOCIATED WITH INACTIVE HISTOLOGY**
--- | --- | --- | ---
Goldstein | 90 | 7 | 6
Varner | 91 | 5 | 5
Granberg | 91 | 9 | 15
### Transvaginal U/S Validation of Early Studies

#### EndometrialThickness and Cancer Findings in Postmenopausal Women With Bleeding

<table>
<thead>
<tr>
<th>Reference</th>
<th>Endometrial thickness*</th>
<th>Number of women</th>
<th>Number of cancers</th>
<th>Negative Predictive Value</th>
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<tr>
<td>Karlsson 1995</td>
<td>≤ 4 mm</td>
<td>1,168</td>
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<td>100%</td>
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<tr>
<td>Ferrazzi 1996</td>
<td>≤ 4 mm</td>
<td>930</td>
<td>2</td>
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<td></td>
<td>&lt; 5 mm</td>
<td></td>
<td>4</td>
<td>99.6%</td>
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<tr>
<td>Gull 2000</td>
<td>≤ 4 mm</td>
<td>163</td>
<td>1</td>
<td>99.4%</td>
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<td>Epstein 2001</td>
<td>&lt; 5 mm</td>
<td>97</td>
<td>0</td>
<td>100%</td>
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<tr>
<td>Gull 2003</td>
<td>≤ 4 mm</td>
<td>394</td>
<td>0</td>
<td>100%</td>
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</table>

### Transvaginal U/S Validation of Early Studies

- For EM ≤ 4mm incidence of malignancy 1 in 917

### Is Endometrial Biopsy Still Necessary?

- False negative rate of TV U/S ≤ 4mm significantly less than a negative suction piston biopsy
- EM biopsy on patients with EM < 5mm: only 82% successfully performed, and of those only 27% gave a sample adequate for diagnosis

### Is Endometrial Biopsy Still Necessary? (Con’t)

- ACOG Committee Opinion (2/09) “When transvaginal ultrasound is performed for patients with postmenopausal bleeding and an EM thickness ≤ 4mm is found EM sampling is *not* required”
GENERAL PRINCIPLES

- Use the highest frequency transducer that still yields adequate penetration
- Once EM echo well visualized use as much magnification as feasible
- Obtain multiple images in the Long Axis plane... midline as well as to the right and left of midline
- Measurements should be on a long axis view of the thickest point

IMPORTANCE OF “EM NOT WELL VISUALIZED”

- Not all uteri lend themselves to a meaningful U/S examination (Axial uterus, marked obesity, coexisting fibroids, previous surgery, etc.)
- Just because you can produce something that is “linear and white” Doesn’T mean you should!!!
- When an EM echo is not TOTALLY distinct, do NOT be afraid to indicate “EM echo not well visualized”

ENDOMETRIAL TEXTURE

- Heterogeneity or irregularity may be important in addition to simply measured thickness

ENDOMETRIAL ABNORMALITIES ARE NOT ALWAYS GLOBAL

IMPORTANCE OF 3D RECONSTRUCTION

Realize that any single frozen ultrasound image is a two dimensional “snapshot” e.g. a single long axis view of a seemingly normal endometrium does not rule out pathology. The entire structure must be observed and three dimensional anatomy reconstructed.

BUT WHAT ABOUT NON BLEEDING PATIENTS?
CLINICAL CASE

65 y/o woman,
- 14 years since menopause
- Excellent overall health
- On no medications
- Presents to ER with lower abdominal pain

CLINICAL CASE

- Afebrile
- Normal labs (blood and urine)
- ER physician orders CT scan with Dx: “R/O diverticular disease”

CLINICAL CASE

- CT of pelvis and abdomen: “totally unremarkable except region of decreased attenuation centrally located within the uterus. Recommend transvaginal ultrasound”
- Patient has a rather large bowel movement with total resolution of her symptoms.

CLINICAL CASE

- TV U/S performed: “thickened endometrial echo measuring 11.2mm with some heterogenous echoes. Suggest clinical correlation”
- Patient back to usual routine of 1-2 hours of tennis per day (singles, no less)

CLINICAL CASE

- Patient referred to her gynecologist who attempts suction piston endometrial biopsy in office. She is unable to get into endometrial cavity secondary to a stenotic os

CLINICAL CASE

- Patient is in excellent health
- Patient has no risk factors for endometrial cancer (no diabetes, hypertension or obesity)
CLINICAL CASE

- Patient is parous but had 2 C/S, the last one 31 years ago.
- Because of inability to get tissue, patient is referred to another clinician in a teaching institution in a metropolitan area for a D&C, hysteroscopy under anesthesia.

CLINICAL CASE

- Despite using fine lacrimal probes and ultrasound guidance the cavity is not successfully entered.
- In fact, it was the impression of the operator that a false channel had been created.

CLINICAL CASE

- Patient sees gyn oncologist in consultation.
- Patient undergoes hysterectomy.
- Final pathology report: “Submucous myoma, inactive.”

CLINICAL CASE

What is the point of this case?

In discussing this case with a friend who is a gynecologic oncologist, I remarked how interesting it was that these clinicians felt so obliged to get a tissue sampling on the basis of what they perceived to be an abnormal finding on an imaging study and an incidental finding, at that!

He said he probably also would have wanted endometrial tissue sampling! I found this quite perplexing. I said to him, “Doesn’t the gynecologic oncology community recommend that tamoxifen patients not undergo endometrial sampling unless they have bled?” (ACOG Committee Opinion 232, April 2000)
He responded, “Yes that’s correct.” I pointed out that the woman we were discussing was 1) not on a drug that has cancer producing potential (tamoxifen), 2) has had no bleeding in 14 years, 3) has never had breast cancer, and 4) plays tennis 2 hours a day.

I asked, why did he feel so obliged to sample HER endometrium since he felt Tamoxifen pts should be left alone UNLESS they bleed? A look of realization slowly came over his face and he said “I guess I see your point.”

**How did this come to be?**

**TRANSVAGINAL ULTRASOUND**

- Introduced in the mid 1980’s, the vaginal probe utilizes higher frequency transducers in close proximity to the structure being studied. It yields a degree of image magnification that has been dubbed “sonomicroscopy”.


**TRANSVAGINAL ULTRASOUND**

- In the early 1990’s, it was utilized in women with postmenopausal bleeding to see if it could predict which patients lacked significant tissue and could avoid D&C or endometrial biopsy and its discomfort, expense, and risk.

Consistently, the finding of a thin distinct endometrial echo ≤ 4 to 5mm has been shown to effectively exclude significant tissue in postmenopausal women with bleeding.

What have health care practitioners HEARD and DONE ?!?

If ≤5mm is good then >5mm must be bad.

But remember this was all done in women WITH BLEEDING

So without any validation women with EM > 5mm ABSENT BLEEDING have been and often still are routinely biopsied.
The endometrial echo revisited: Have we created a monster?

Steven R. Goldstein, MD

Department of Obstetrics and Gynecology, New York University School of Medicine, New York, NY

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The problem is not with the imaging...

It is the INTERPRETATION of the imaging

So: 1) how COMMON is a thick EM echo in non bleeding patients?

2) when present what is its significance?

Few prospective studies exist but consider this...

10% of postmenopausal women trying to enroll in the Raloxifene uterine safety studies had asymptomatic endometrial polyps on sonohysterography

A. Parsons (verbal communication)
17% of 550 newly diagnosed postmenopausal breast cancer patients in Brussels had unsuspected ASYMPTOMATIC polyps prior to initiating tamoxifen therapy


A randomly selected Danish population aged 20-74 underwent TV U/S and SIS

Prevalence of uterine polyps overall= 7.8%

Prevalence increased with age

In PM women (n=169) prevalence of Asx polyps was 13.0% (n=22)

Dreisler et al Ultrasound Obstet Gyencol 2009:33-102

WHAT IS THE RISK OF MALIGNANCY IN SUCH POLYPS?


- Removed 117 polyps in PM women without bleeding
- NONE were malignant
- Discussed importance of distinguishing EM carcinoma with polypoid growth from carcinoma arising in a polyp (base and surrounding EM must be benign)

Shushon et al, Gynecol Obstet Invest, 2004;58:212-215

- 300 consecutive women with polyps who underwent hysteroscopic removal
- Combined peri and PM patients
- 73 (24.3%) were asx and polyps were discovered incidentally
- ALL asx polyps were benign


- 1152 Asx PM women diagnosed with a polyp by SIS underwent hysteroscopic removal
- 1 EM cancer in a polyp (<0.1%),
- Mean diameter 40 mm
- 3 perforations, 7 cervical tears, 3 false passages
- 3 cancers (0.3%) occurred in Asx PM women that were not in polyps but were polypoid appearing on imaging and not global
Lev-Sagie A et al, BJOG 2005;112:379-382

- 82 postmenopausal women with incidental sonographic findings of EM "thickening"
- Operative hysteroscopy
- 67 (82%) inactive polyps, 7 submucosal myomas, 6 atrophic EM, 1 proliferative EM, 1 polyp with simple hyperplasia
- NO complex hyperplasia or carcinoma
- 3.6% total complication rate (2 perforations, 1 difficult intubation)


- U/S detection of Asx EM cancer in screened PM women offers no prognostic advantage over symptomatic disease that had uterine bleeding for less than 8 weeks
- Thus for the negligible risk that an Asx polyp MIGHT harbor a cancer (<1 in a 1000) there is no therapeutic advantage over waiting until it results in bleeding; and such an approach would spare the other 999 out of a 1000 any intervention and its risks, discomfort and expense

SO...FOR AN INCIDENTAL FINDING OF EM THICKENING...

- There is NO validation whatsoever that these patients need AUTOMATIC EM sampling
- The incidence of thick EM echo is probably 10-17% and is much like "simple" cyst of the post menopausal ovary was 20 years ago
- Still appropriate (and always was) to use clinical JUDGEMENT if high risk (obese, diabetic, hypertensive, nulliparous)

BUT IN POST MENOPAUSAL BLEEDING...

- “CANCER UNTIL PROVEN OTHERWISE”
- ROLE OF HIGH NEGATIVE PREDICTIVE VALUE OF A THIN DISTINCT EM ECHO
- PERFORM TV U/S FIRST, SONOHYSTEROGRAFY IF NECESSARY, TO TRIAGE PTS TO 1) NO PATHOLOGY 2) GLOBAL PROCESS (BLIND BX) 3) FOCAL PROCESS (DIRECT VISION)

SALINE INFUSION SONOHYSTEROGRAPHY

- REMEMBER FLUID ENHANCES SOUND TRANSMISSION
SONOHYSTEROGRAM

- Fluid instillation to enhance U/S detail of the endometrium
- Among the easiest TV U/S scans you will ever perform!
- Technical aspects simple for GYNs, slightly more daunting for radiologists

SONOHYSTEROGRAM: Technique

- Pelvic scan, unenhanced (baseline appearance)
- Palpatory bimanual (anteverted, retroverted)
- Insert speculum
- Cleanse cervix
- Thread catheter (flush air first)

SONOHYSTEROGRAM: Technique

- Remove speculum (carefully)
- Insert vaginal probe
- Instill sterile saline (10cc syringe), slowly, watch the screen
- Scan from cornua to cornua
- “Reload”, turn 90° and scan from fundus to cervix

UNSCHEDULED UTERINE BLEEDING IN PERIMENOPAUSAL WOMEN

- May be annovulatory, dysfunctional
- Heightened concerns about anatomic pathology (hyperplasia, polyps, submucous myomas, carcinoma)
- Invasive diagnostic procedures commonplace
Pilot Study

- 21 perimenopausal women (age range 40-52)
- Clinical history of irregular vaginal bleeding
- Studied on day 4-6
- 5.3Fr Soules IUI catheter inserted
- Sterile saline infused under real-time vaginal ultrasound video taping

Results

- 8 patients with obvious polyps, triaged for hysteroscopic removal
- 3 patients with submucous myomas (2 offered wire loop resectoscopic surgery, 1 with extension to serosa treated expectantly)
- 9 patients with no anatomic lesion and surrounding endometrium < 3.2mm, all showed proliferative endometrium on biopsy. DX: DUB. Subsequently treated with progestin
- 1 patient with 8mm endometrium, path revealed simple hyperplasia without atypia: subsequently treated with progestin

CONCLUSION

- Broad based endometrial masses can be distinguished from those on a stalk or pedunculated
- Allows appropriate triage for operative hysteroscopy when needed
- Eliminates the need for diagnostic hysteroscopy in patients whose bleeding is dysfunctional

Of note 9/21 patients had clinical and sonographic evidence of myomas but only 3/21 had a submucous component on sonohysterogram. Thus 6/21 had dysfunctional uterine bleeding co-existing with intramural/subserosal myomas.

Ultrasonography-based triage for perimenopausal patients with abnormal uterine bleeding

Steven R. Goldstein, MD, Ilana Zeltser, BS, Camile K. Horan, RDMS, Jon R. Snyder, MD, and Lisa B. Schwartz, MD. Am J Obstet Gynecol 1997;177:102-8

Ultrasound based triage uses vaginal ultrasound screening of all patients and selected SIS when the unenhanced TV U/S is not thin or reliable.
MATERIALS AND METHODS

- 433 patients
- Perimenopausal (average age 47.4, range 37-54 years)
- Abnormal uterine bleeding (menorrhagia, metrorrhagia, or both)

ABNORMAL PERIMENOPAUSAL BLEEDING:

433 patients
Unenhanced Vaginal Ultrasound
280 patients ≤ 5mm (day 4-6)
153 patients > 5mm or nonvisualization of EM

SALINE INFUSION SONOHYSTEROGRAPHY:

153 patients
44 (29%) for nonvisualization of EM
109 (71%) for EM > 5mm

THUS OF 433 PATIENTS:

- 342 (78.9%) had dysfunctional bleeding
- 23 (5.3%) had submucous myomas
- 58 (13.4%) had polyps of which 3 were endocervical
- 15 (3.5%) had hyperplasia (of which 5 were symmetrical, 4 were focal, and 6 were in polyps)

OF 15 PATIENTS WITH HYPERPLASIA

- 5 were symmetrically thick (4 simple, 1 complex)
- 4 were focally thick (1 simple, 3 complex)
- 6 were in polyps (3 simple, 3 complex)
Pipelle biopsy alone could have missed up to 79 lesions (18%) in patients with polyps, submucous myomas, focal hyperplasia.

The study algorithm allows:
- 65% to have ultrasound exam done
- 17% to have ultrasound and SIS only
- 2.3% to have U/S, SIS pipelle bx only
- 15.9% to have U/S, SIS D&C hysteroscopy

In my opinion…

No longer appropriate to do a blind office biopsy procedure unless you first verify that whatever the endometrial process it is indeed global and not focal.

I wrote that slide 20 years ago!!!!

So back to the ACOG Practice Bulletin of July 2012…

“The primary imaging test of the uterus for the evaluation of AUB is transvaginal ultrasonography.”
“If transvaginal ultrasonographic images are not adequate or further evaluation of the cavity is necessary, then sonohysterography (also called saline infusion sonohysterography) or hysteroscopy (preferably in the office setting is recommended).”

“An office endometrial biopsy is the first-line procedure of tissue sampling in the evaluation of patients with AUB.”

“Endometrial biopsy has high overall accuracy in diagnosing endometrial cancer when an adequate specimen is obtained and when the endometrial process is global.”

“If the cancer occupies less than 50% of the surface area of the endometrial cavity, the cancer can be missed by a blind endometrial biopsy sample.”

“A positive test result is more accurate for ruling in disease than a negative test result is for ruling it out.”

“These tests are only an endpoint when they reveal cancer or atypical complex hyperplasia.”
• NOW THE STANDARD OF CARE CORROBORATES THAT A NEGATIVE BLIND BIOPSY IS NOT A STOPPING POINT. CLINICIANS CAN STILL BEGIN WITH A BX BUT UNLESS IT IS MALIGNANT (OR COMPLEX ATYPICAL HYPERPLASIA) THE ENDOMETRIAL EVALUATION IS NOT COMPLETE!

I ACKNOWLEDGE...

- Ultrasound does NOT give you a tissue diagnosis

The value of U/S and Sonohysterogram is to TRIAGE patients to...
  - NO anatomic pathology
  - GLOBAL EM process (blind biopsy)
  - FOCAL process (direct vision)

PUTTING IT ALL TOGETHER

A thin distinct homogenous EM echo ≤ 4-5mm with a hypoechoic zone surrounding it reliably predicts lack of SIGNIFICANT tissue.

In all other scenarios fluid instillation coupled with high resolution endovaginal probes can offer tremendous diagnostic enhancement as a simple inexpensive well tolerated office procedure.

This algorithm of U/S as the first step in the evaluation of AUB works in ALL CASES – as long as you understand the difference between patients who cycle vs. those who do not.
IMPORTANT CAVEAT

- procedure is VERY time sensitive. It must be done on the last days of staining or the first days after the bleeding cycle ends when the endometrium will be as thin and uniform as possible
- as endometrium proliferates and thickens it is not always perfectly symmetrical (BEWARE “moguls” or small irregularities)

CYCLING VS. NON CYCLING

- In NON CYCLING patients – everyday is the same.
- In patients WHO ARE CYCLING, timing is crucial.
- Ultrasound evaluation should be performed at a time when the EM will be as thin as it will all month long (just as the bleeding ends).
- This prevents misinterpretation of EM “moguls” later in the cycle as being pathologic.

...ANOTHER EXAMPLE

WHILE WE'RE AT IT...

AVOID SONOHYSTEROGRAPHY WITH ACTIVE BLEEDING !!!

AVOID GETTING AIR INTO THE CATHETER OR THE SYRINGE (AIR IS VERY ECHOGENIC !!)
In Summary

- THE MAIN USE OF ENDOMETRIAL THICKNESS MEASURED ON TV U/S IS THE HIGH NEGATIVE PREDICTIVE VALUE OF A THIN DISTINCT ECHO (LOSE THE WORD "STRIPE")

In Summary

- IN WOMEN WITH POSTMENOPAUSAL BLEEDING EM< 4 MM HAS A RISK OF MALIGNANCY OF 1 IN 917 AND DOES NOT REQUIRE ENDOMETRIAL SAMPLING

In Summary

- IN POSTMENOPAUSAL WOMEN WITHOUT BLEEDING THE INCIDENCE OF “THICK” ENDOMETRIAL ECHO (MOSTLY POLYPS) IS 10-17% AND NO ROUTINE INTERVENTION IN SUCH NON BLEEDING IS INDICATED

In Summary

- THE RISK OF MALIGNANCY IN SUCH PATIENTS IS LOW (<4/1000) WHILE THE RISK OF SERIOUS COMPLICATIONS FROM OPERATIVE HYSTEROSCOPY APPROACHES 3.6%

In Summary

- IN PRE MENOPAUSAL PATIENTS WITH AUB AN EM ECHO <5MM EARLY IN THE CYCLE EXCLUDES SIGNIFICANT PATHOLOGY
- OTHERWISE SALINE INFUSION SONOHYSTEROGRAPHY WILL DISTINGUISH GLOBAL FROM FOCAL PROCESSES AND ALLOW APPROPRIATE TRIAGE