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Comparison between Endometrial Volume Assessed by VOCAL versus Office Hysteroscope for Diagnosis of Endometrial Polyps

Thesis

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By

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To

Spirit of my father

My mother

My sisters Mai & Heba Eisa

My husband Mohamed Naguib & my son Ascer

My brothers Ehab, Abdallah & Mohamed

And Jodi, Mohamed Ehab Eisa

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Introduction

Endometrial polyps are localized hyperplastic overgrowths of endometrium that contain both endometrial glands and stroma. The majority of these lesions are benign. Polyps have variable presentations. They can occur as individual or multiple lesions, ranging in size from millimeters to centimeters, and can be sessile or pedunculated. Although endometrial polyps may be identified during evaluation of abnormal bleeding, many polyps are asymptomatic and discovered accidently during screening for another disease ***(Rackow et al., 2011).***

Evaluation of the endometrium as a cause of abnormal uterine bleeding is mainly along three modes:

1- Imaging patterns of the endometrium by transvaginal ultrasound, hystero-sonography (SHG) and to some extent a magnetic resonance imaging (MRI).

2- Visual assessment by hysteroscope.

3- Cellular assessment by microscopic evaluation of endometrial samples ***(Kotdawala et al., 2013).***

Transvaginal ultrasound: is an inexpensive, non-invasive and a convenient way to indirectly visualize the endometrial cavity. Therefore, it is recommended as a first line diagnostic tool for assessing uterine pathology in reproductive age women presenting with abnormal uterine bleeding ***(Kotdawala et al., 2013).***

Hysteroscopic evaluation of the endometrial cavity and visually directed biopsy for histo-pathological evaluation is considered the gold standard for assessing the endometrium. Many complications are uterine perforation when either the hysteroscope itself or one of its operative instruments breaches the wall of the uterus. This can lead to bleeding and damage to other organs. If other organs such as bowel are injured during a perforation, the resulting peritonitis can be fatal.

Furthermore, cervical laceration, intrauterine infection (especially in prolonged procedures), electrical and laser injuries, and complications caused by the distention media can be encountered. The use of insufflation media can lead to serious and even fatal complications due to embolism or fluid overload with electrolyte imbalances **(Kotdawala et al., 2013).** Blind dilation and curettage used to be a gold standerd procedure for all women with abnormal uterine bleeding over the age of 40 years old. However, dilation and curettage may miss an existing endometrial pathology in 25%, perforation of uterus in .6-1.3 % of cases, infection 0.3-0.5% and hemorrhage in 0.4% of cases ***(Kotdawala et al., 2013).***

Thus, endometrial volume measured by VOCAL (Virtual Organ Computer-aided AnaLysis) may be a useful method for diagnosis of endometrial polyp, compared to hysteroscope which is the gold standard that allows direct visualization of endometrial lesions.

Aim of the Work

The aim of the work is to determine the overall accuracy of measuring endometrial volume by VOCAL compared to office hysteroscope for diagnosis of endometrial polyps in premenopausal women.

Research Question:

Is measuring endometrial volume by VOCAL comparable to office hysteroscope for detection of intrauterine polyps in cases of premenopausal bleeding?

Research Hypothesis:

Endometrial volume measured by VOCAL is a good method to diagnosis endometrial polyps and as accurate as office hysteroscope.

Population of study:

Premenopausal women with abnormal uterine bleeding.

Intervention:

All participiant will have 3D transvaginal ultrasound and hysteroscope to assess endometrium.We will compare the accuracy of measuring endometrial volume by VOCAL versus hysteroscope in the diagnosis of polyps as a cause of premenopausal bleeding.

Outcome:

The primary outcome will be comparing accuracy of VOCAL versus office hysteroscope in diagnosis of polyp as a cause of premenopausal bleeding and to reach a cut off level which can predict endometrial polyps.

The secondary outcome will be presence of other endometrial pathology after correlation with histopathological diagnosis.

Patient and Methods

Location:

This study will be done at Ain-Shams Maternity Hospital in the period from March 2015 to December 2015.

Study design: prospective study

Study population:

One hundred nine premenopausal women attending clinic at Ain Shams Maternity Hospital complaining of abnormal uterine bleeding.

Sample Size calculation:

The required sample size has been estimated using the Power Analysis and Sample Size software version 11.0.10 (PASS; NCSS, LLC, Kaysville, Utah).

The current study will include a cohort of women presenting with perimenopausal bleeding who will be subjected to 3D-transvaginal ultrasound (3D-TVUS) examination and the findings will be confirmed with hysteroscopy. Hysteroscopy will be regarded as the reference diagnostic tool against which 3D-TVUS is contrasted.

A previous study by **Leone at al. (2011)** reported that 3D-TVUS had a sensitivity of 74% and a specificity of 99% for identification of endometrial polyps. Another study reported that the prevalence of endometrial polyps in women presenting with premenopausal bleeding was 32% **(Dreisler et al., 2009).**

Thus, sample size of 109 patients would achieve a power of 82% (type II error, 0.18) to detect a statistically significant difference of 24% between An expected sensitivity of 74% and a null sensitivity of 50% for

identification of endometrial polyps using 3D TVUS.

The same sample size of 109 patients would have a power of 100% to detect a statistically significant difference of 49% between an expected specificity of 99% and a null specificity of 50% for exclusion of endometrial polyps using 3D-TVUS.

These calculations used a two-sided binomial test with a confidence level of 95% (type I error, 0.05) and assumed a prevalence of endometrial polyps of the order of 32% in the study population.

Statistical methods

Data will be collected, tabulated, then analyzed on a personal commuter using IBM© SPSS© Statistics version 21 (IBM© Corp., Armonk, NY).

Normally distributed numerical data will be presented as mean and SD, and skewed data as median and interquartile range. Qualitative data will be presented as number and percentage.

The diagnostic value of 3D-TVUS will be assessed by calculation of the following indices, sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios, correct classification rate (accuracy), and diagnostic odds ratio, along with the 95% CI of the estimates.

Inclusion criteria:

- Age ≥ 20
- Irregular uterine bleeding which is defined as a bleeding pattern that differs in frequency, duration and amount from a pattern observed during a normal menstrual cycle.

Exclusion criteria:

- Age > 50.
- Postmenopausal (amenorrhea for one year or FSH > 20 IU/mL).
- Other causes of bleeding e.g. general and systemic causes, drug use, other local lesions like fibroid.
- Patients on hormonal contraception, steroids and anticoagulants.

For every patient the following will be done:

1- Obtaining approval by the hospital's research committee.

2-History taking in details:

- Personal history: including name of the patient, her age, address, occupation.

- History of present illiness: when the condition starts, improved or worsened by time.

- Obstetric history including: parity, mode of delivery vaginal or ceserian section and year of last delivery.

- Menstrual history: including age of menarche, menstrual cycle regularity, last menstrual period, duration of the menstrual cycle.

We shall ask about amount and duration of bleeding and if it affects the general condition of the patient and causing anemia.

- Surgical history: we shall ask about previous dilatation and curettage or any uterine operation.

- Contraceptive history: recent use of any hormonal contraception.

3- Physical examination to exclude any associated medical disorder e.g.

diabetes mellitus, hypertention, liver disorders and blood diseases.

4- All patients will have endometrial volume assessment sing VOCAL imaging programe and hysteroscope to detect if there is an intrauterine lesion.

VOCAL imaging programe: it will be done for all patients using **Voluson E6 (GE USA)** 3D system with a S-VDW 5-8 MHz transvaginal probe. Volume estimation will be based on three-dimensional sonography using the more recently introduced rotational method through the VOCAL-imaging programe (Virtual Organ Computer-aided AnaLysisThe patient should™), be in a supine position with knees flexed and hips abducted. A longitudinal view of the uterus will be obtained and the volume mode entered. The resultant truncated sector defining the area of interest will be moved and adjusted and the sweep angle set to 30^{o} to ensure that the complete endometrial cavity obtained.

The patient will be asked to remain as still as possible and every effort made by the ultrasonographer to limit inappropriate movements of the transducer. The 3D dataset will be acquired using the slow sweep mode. The resultant multiplanar display will be examined to ensure that the complete endometrial cavity has been captured with particular attention being given to the coronal image in plane C. If the volume is complete and considered to be of sufficient quality, the dataset then will be stored to a magnetic optical disk.

The vaginal probe will not be removed and replaced for every volume obtained; the probe program will be reloaded after each dataset had been stored such that it is necessary to relocate the uterus before subsequent acquisitions. Standardization of the ultrasound settings will be assured by using the same predefined probe program without adjustment once the program had been loaded. At the end of the scan

session, the acquired volumes will be reloaded from the magnetic optical disk and transferred to a personal computer. The junction between the myometrium and endometrium now will be traced in a clockwise fashion using a standard computer mouse until completion of $180^{o}$of rotation and the generation of a calculated volume. In all cases of rotational measurement,

We will rotate plane C (coronal image) about plane A (longitudinal image) with all measurements being conducted in plane C. We shall use this plane because it is considered to give more information about the coronal aspects of the endometrial cavity and because the upper and lower aspects of the endocervical canal are more readily identified. The number of steps taken is not predefinable and the actual number will be decided by conducting a repeat measurement, when it is subjectively felt that the area has changed significantly.

All the TV U/S will be carried by a single experienced sonographer.

Office hysteroscopy technique, a 5 mm office hysteroscope with a 30^{o} fore lens and a continous flow migration using normal saline will be used Karl Storz™ (Germany). Vaginoscopic entery will be utilized while the patient is in the lithotomy position to assess the ectocevix, cervical canal and uterine cavity for the presence of polps and other abnormalities. polps will be removed. Scissors and graper together with hysteroscpically used for endometrial sampling.

All the hysteroscope procedures will be carried by the same experienced hysteroscopist who will be blinded to the results of TV U/S.

References

Albers, J.R.; Hull, S.K.and Wesley, M.A. Abnormal uterine bleeding. Am Fam Phys. 2004;69:1915–26.

Biewenga, P.; de Blok, S.and Birnie, E. Does diagnostic hysteroscopy in patients with stage I endometrial carcinoma cause positive peritoneal washings? GynecolOncol. 2004;93:194–8.

Bonilla-Musoles, F.; Raga, F.; Osborne, N.G.; Blanes, J. and Coelho, F. Three-dimensional hysterosonography for the study of endometrial tumors: Comparison with conventional transvaginal sonography, hysteron-salpingography, and hysteroscopy. Gynecol Oncol.1997; 65:245–252.

Bree, R.L.; Bowerman, R.A.; Bohm-Velez, M.; Benson, C.B.; Doubilet, P.M. and DeDreu, S. et al. US evaluation of the uterus in patients with postmenopausal bleeding: A positive effect on diagnostic decision making. Radiology. 2000;216:260–264.

Chapple, A. Menorrhagia: women'sconditionperceptionandits treatment. J AdvNurs. 1999;29:1500–6.

de Sa Rosa e de Silva, A.C.; Rosa e Silva, J.C.; Candido dos Reis FJ, Nogueira AA, Ferriani RA. Routine office hysteroscopy in the investigation of infertile couples before assisted reproduction. J Reprod Med. 2005;50:501–6.

Ely, J.W.; Kennedy, C.M.; Clark, E.C. and Bowdler, N.C. Abnormal Uterine Bleeding: A Management Algorithm. J Am Board Fam Med. 2006;19:590–602.

Epstein, E.; Ramirez, A.; Skoog, L. and Valentin, L. Transvaginal sonography, saline contrast sonohysterography and hysteroscopy for the investigation of women with postmenopausal bleeding and endometrium >5 mm. Ultrasound Obstet Gynecol. 2001;18:157–

62.

Grimes, D.A. Diagnostic dilation and curettage: A reappraisal. Am J Obstet Gynecol. 1982;142:1–6.

Johnson, C.A. Making sense of dysfunctional uterine bleeding. Am Fam Phys. 1991;44:149–57.

Kim, M.R.; Kim, Y.A.; Jo, M.Y.; Hwang, K.J. and Ryu, H.S. High frequency of endometrial polyps in endometriosis. J Am AssocGynecolLaparosc. 2003;10:46–8.

Kupfer, M.C.; Schiller, V.L.;Hansen, G.C. and Tessler, F.N. Transvaginal sonographic evaluation of endometrial polyps. J Ultrasound Med. 1994;13:535–9.

Litta, P.; Merlin, F.; Saccardi, C.; Pozzan, C.; Sacco, G. and Fracas M, et al. Role of hysteroscopy with endometrial biopsy to rule out endometrial cancer in postmenopausal women with abnormal uterine bleeding. Maturitas. 2005;50:117–23.

Munro, M.G.; Critchley, H.O.; Broder, M.S. and Fraser, I.S. FIGO Working Group on Menstrual Disorders.FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age.Int J Gynaecol Obstet. 2011;113:3–13.

Revel, A.; Tsafrir, A.; Anteby, S.O. and Shushan, A. Does hysteroscopy produce intraperitoneal spread of endometrial cancer cells? Obstet Gynecol Surv. 2004;59:280.

Seamark, C.J. The demise of the D and C. J R Soc Med. 1998;91:76–9.

Shapley, M.; Jordan, K. and Croft, P.R. An epidemiological survey of symptoms of menstrual loss in the community. BJGP.2004; 54:359–63.