A New Method for Diagnosing and Follow up the Treatment of Uterine Fibroids: Uterine Endoscope: a Review Article

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Abstract:
Fibroids which are common and benign monoclonal neoplasms of the smooth muscle cells of the myometrium are of major concerns in the process of women’s health care. Pelvic examination and ultrasound have long been known as the first step to assess the uterus which has got limitations beside low sensitivity. On the other hand, due to the invasive and expensive other methods, the researchers of the current study set out to invent and make a new device called uterine endoscope, a kind of device which has got high sensitivity and accuracy in diagnosing uterine fibroids. At the same time, it is cheap and its use does not require a lot of knowledge and patients don’t feel uncomfortable with.

Introduction:
Fibroids are great concerns of women’s health care process since they are the most common indication for hysterectomy. According to reports, they are the cause of almost 240000 hysterectomies annually in the United States (1). Fibroids are common and benign monoclonal neoplasms of the smooth muscle cells of the myometrium within which there are large gatherings of extracellular matrix (1, 2). Some fibroids were discovered in 77% of delicate levels of uterine serial of 100 women who underwent hysterectomy. Some of these fibroids were as small as 2mm. In a random sampling from women of 13-49 years old screened from self-report, review of medical records and ultrasound, it was found that the incidence of fibroid in African-American women are 60% by 35 and 80% by 50 years old. Among white women, the outbreak rate of fibroid are 40% and 70%
by 35 and 50 years old respectively (1). The incidence of these tumors during pregnancy is probably about 2% and depends on the intended population characteristics (2). Although the exact cause of fibroid incidence is unknown, some progress has been made in understanding the molecular biology of these tumors, growth factors and their hormonal and genetic factors. Fibroids almost never cause death but they may cause morbidity and impact the quality of life significantly. Sub mucous fibroids decrease fertility and their removal results in pregnancy raise. (1)

**Current Methods of Diagnosis**

**A: Pelvic Examination**

Pelvic examination has long been used as the first attempt to assess the uterus, ovaries, fallopian tubes and diagnosis of adnexal masses. Books of a hundred years ago considered manual examination as a reliable diagnostic device for the assessment of women-oriented diseases (3). Currently, the role and status of this method is questionable in the clinical diagnosis of women’s diseases and disorders. A limited number of studies consider manual examination as an acceptable method in the assessment of location, size and shape of the uterus (4, 5). This method has lots of limitations such as: different experiences and the definition of the examiner, patient’s obesity, patient’s stress and restlessness, muscle contraction in examination and low accuracy and sensitivity of diagnosis. In many studies, lack of knowledge of experience in vaginal examination considers to be as a confounding factor. (6-8).

In 2000, Padilla and et al attending physicians, resident and medical students performed manual examination on 140 unconscious patients before laparotomy and laparoscopy and then compared examination results with the surgical ones. Examiners often estimated tumors’ size less than the real and pelvic examination sensitivity for the diagnosis of left tumors was 0.23-0.36 and 0.15-0.28 for right tumors. The positive predictive value of the pelvic examination was very low in left tumors (0.50-0.69) and right ones (0.26-0.36).

In this study, obesity had affected the outcomes (9). In another study in 2005, Padilla and et al, placed 84 women under general anesthesia before laparotomy and laparoscopy and all of them were examined by women’s attending physician, resident and medical students. None of the examiners were aware of the other’s assessment result. The results of this study suggested that even in the most ideal conditions, pelvic examination cannot be a useful method for diagnosing and evaluating the women’s reproductive system. 70% of attending’s examinations consisted with laparotomy’s results. However, consistency percentage of residents’ examination and medical students was 64% and 57% respectively. Diagnosis sensitivity of adnexal masses was less than the assessment of uterine size and shape (10). Also, in other studies, the diagnosis of uterine and adnexal masses by pelvic examination alone was extremely difficult (5, 11, and 12) and patients’ obesity was one of the confounding factors of examination results (10). So when a doctor gains experience over many years, it only helps diagnosis accuracy increase, whereas the sensitivity of the adnexal mass assessment is still low among them (10 and 12).

According to Nicolas and et al, pelvic examination used for measuring uterine size by attending physician is consistent with ultrasound results in 92% whereas only 75% of residents were able to assess correctly (13).
In Clouse and et al study, two non-ladies physicians examined 186 women in hospital’s emergency room. The consistency of two physicians’ examinations was 17%-33% resulting from their definition and experience of the issue (14). Avery and et al (2011) realized that inexperienced examiners diagnose normal cases and the experienced ones diagnose abnormal ones. Examinations were concordant in 75% of cases (15). Another disadvantage of manual examination is its low accuracy and sensitivity as the first test in women’s health care centers. Grover and et al examined 2623 healthy women without symptoms in order to diagnose ovarian cancer. They used pelvic examination, ultrasound, CA125 measurement, and in case necessity, laparoscopy and laparotomy. Predictive value of the benign tumors’ diagnosis by means of pelvic examination was only 22%. Researchers drew this conclusion that pelvic examination cannot be a good screening factor for diagnosing masses (16).

In a review article, Stewart found that vaginal examination cannot be a good way to screen ovarian cancer due to low sensitivity and accuracy. Moreover, there is no evidence proving the efficiency of this examination prior to hormone therapy or as a routine checkup for women visiting health care clinics (17). It should be noted that the desired result of vaginal examination might give false reassurance to both the patient and his/her doctor and discourage them from pursuing diagnosis and treatment process (18) which in turn can be an alarming call for the of the women. Studies suggest that 5 cm masses are not often diagnosed in pelvic examination (9). Patient’s obesity and anxiety can also affect pelvic examinations’ results (19).

In some studies, pelvic examination’s results have been compared with ultrasound observations. Inconsistency between the results of manual examination and ultrasound is ranging from 9% to 54% which is different in various studies. (14) Toyal’s study dealt with the comparison between common manual examination and ultrasound manual examination. They realized that ultrasound method does better in diagnosing the position of cervix, uterus size and shape, uterine tenderness, ovaries’ size and tenderness and diagnosing adnexal masses than vaginal examination (p<0.05) (20). In the study of Carter and his colleagues only 20% of the examined cases consisted with each other (12). According to the aforementioned statements, it is safe to say that pelvic examination is not a detailed assessment method for uterine adnexal masses. Even if it is seen as a diagnostic method, it must certainly be used with ultrasound or other diagnostic methods. Otherwise manual examination cannot closely diagnose the masses single-handedly. In Hudelist’s study (2009) done on 200 women in order to diagnose endometritis, they found out that vaginal examination can be considered as a useful diagnostic method for pelvic endometritis when it is used along with trans-vaginal ultrasound (21).

B: Ultrasound

Trans-vaginal ultrasound has got high sensitivity on diagnosing myoma in uteruses greater than 10 weeks. Using high-power probes, one can diagnose micro fibroids but it’s very difficult to locate exactly where they are in the uterus using ultrasound. There are some limitations facing this method in locating myomas within bigger uteruses or a larger number of tumors (22). It is also unable to diagnose micro-fibroids and serous. Various studies have presented varying degrees of accuracy and sensitivity of trans-vaginal ultrasound (table 1).
C: Other Methods
Sonohystrography (SHG): in this method saline is injected into the uterine cavity and then ultrasound is administered. It is more expensive and invasive than ultrasound method. According to Medicare Allowable Pricing, each time’s trans-vaginal ultrasound price is less than half the cost of Sonohystrography (23). However, this method’s accuracy and sensitivity in diagnosing serous myomas and focal endometrial lesion is high (table 1).

Hysteroscopy: this method is very reliable (table 1), but is more aggressive than SHG. One study dealt with the hysteroscopy and SHG operation in diagnosing uterine fibroids on 117 women. The results showed that the error rate of SGH was much higher than hysteroscopy (22% vs. 6%), but the pain is less (1.6% vs. 3.%). SHG error was rooted in the cervical stenosis (24).

MRI: in a double-blind study on pre-menopausal women undergone hysterectomy for benign cases, ultrasound and MRI had diagnosed myomas equally accurate (table 1). It seems that MRI shall be used in cases where myoma’s exact location is significant; myoma is located in bigger uterus or in case of multi-myomas (22). Each time’s MRI use is twice as expensive as diagnostic Sonohystrography and hysteroscopy (23).

Table 1: Evaluation of Diagnostic Methods of Uterine Myomas

<table>
<thead>
<tr>
<th>Study</th>
<th>Pasrija (27)</th>
<th>Bonnamy (26)</th>
<th>Dueholm (22)</th>
<th>Farquhar (25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>56 marked patients, comparing TVS with SHG</td>
<td>84.4</td>
<td>79</td>
<td>65</td>
<td>21-100</td>
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<tr>
<td>Sensitivity</td>
<td>94</td>
<td>91</td>
<td>99</td>
<td>53-100</td>
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<tr>
<td>Accuracy</td>
<td>82.4</td>
<td>91</td>
<td>91</td>
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<tr>
<td>Positive predictive value</td>
<td>82</td>
<td>96</td>
<td>96</td>
<td></td>
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<tr>
<td>Negative predictive value</td>
<td></td>
<td>97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trans-vaginal ultrasound (TVS)</td>
<td></td>
<td></td>
<td>Systematic review study with 19 heterogeneous studies</td>
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<tr>
<td>Sonohystrography (SHG)</td>
<td>94.1</td>
<td>91</td>
<td>7 studies</td>
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<tr>
<td>Sensitivity</td>
<td>88.5</td>
<td>91</td>
<td></td>
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<tr>
<td>Accuracy</td>
<td>91.4</td>
<td>94</td>
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<tr>
<td>Positive predictive value</td>
<td>92</td>
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<td>57-100</td>
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<tr>
<td>Negative predictive value</td>
<td></td>
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<td>96-100</td>
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<tr>
<td>Hysteroscopy</td>
<td>88</td>
<td>94</td>
<td>4 studies</td>
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<tr>
<td>Sensitivity</td>
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<tr>
<td>Accuracy</td>
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<td>97-100</td>
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<tr>
<td>MRI Sensitivity</td>
<td>Accuracy</td>
<td>Positive predictive value</td>
<td>Negative predictive value</td>
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<td>86</td>
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Conclusion:
Considering low accuracy and sensitivity of pelvic examination in diagnosis of masses and the fact that factors like varying definitions and experience of the examiner, obesity and anxiety distort the examination’s results and, more importantly given that ultrasound is unable to diagnose mini-myomas or find it difficult to diagnose big myomas in large uteruses or multi-myomas, on the other hand, considering the high cost of other methods, researcher of the study attempted to invent and make a new device called uterine endoscope. This is a device with high accuracy and sensitivity in diagnosis of uterine fibroids, with low cost and does not require lots of knowledge to be used. Also, it is less painful. This device can be employed in gynecologist’s office and health care centers and clinics. Therefore, in the initial examination of the patient, the inner uterine cavity is completely visible using this device. So, the patient’s problem is diagnosable within the first visit and with low cost. Using this device, diagnosis of uterine fibroids and malformations is possible in healthcare centers by trained midwives. Thus, the diagnosis process is reduced which, in turn, results in less time and cost. This device’s system is similar to that of endoscope consisting of a bundle of narrow tube equipped with a camera. The tube’s structure is quite flexible and can be connected to a monitor via a wire so uterine images are visible on the screen. Inserting speculum, the device’s tube is transferred through cervical opening with direct vision and enters the uterus. Thus, the examiner examines endocervical status, its possible injuries such as cervical polyps and uterine cavity through observing the screen.

The benefits of the invention:
Implementing this new initiative pattern, the following results would emerge:
1. Proper and definitive diagnosis of cervical polyps.
2. Proper and definitive diagnosis of uterine fibroids.
5. The time and cost savings for patients.
6. It doesn’t take a lot of money to make the device, so a large amount of money is not imposed on the treatment system. And it is quite reasonable considering the high functionality of the device in diagnosis of uterine disorders.

References:


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