

Is Transvaginal Sonography Useful in Women's Health Care Programs?

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Abstract

Objective: The role and efficacy of trans-vaginal ultra-sonography (TVS) in women's health care programs were evaluated.

Methods and materials: The subjects were 1,000 consecutive women who received a health care program with TVS. Gynecologic abnormalities detected by TVS were compared with those from a bimanual pelvic exam.

Results: 1) The incidence of Gynecologic abnormalities found by TVS was 24.5%, whereas that by pelvic exam was 13.6%. 2) The incidence of detected uterine myoma by TVS was 20.4%, whereas that by the exam was 8.3%. When compared with myoma size, myomas of <2 cm, 2-3 cm, 3-5 cm, 5-7cm and ≥ 7 cm in diameter were distributed in 26.3%, 22.0%, 27.3%, 13.2% and 11.2%, respectively. Among those found by TVS, 1.9%, 15.6%, 46.4%, 96.3% and 100% were detectable by pelvic exam, respectively. 3) Incidences of both ovaries, right ovary and left ovary visible and both ovaries invisible by TVS were 26.0%, 15.4%, 14.6% and 44.1%, respectively. When compared with the total number of ovaries, 41% of ovaries were only visualized by TVS. 4) Ovarian tumors were detected in 2.0% by TVS, whereas in 1.0% by pelvic exam.

Conclusions: TVS is more sensitive to detect Gynecologic abnormalities than pelvic exams. The high sensitivity of TVS allows it to find smaller myoma nodules and thus increases the number of gynecologically abnormal women. In contrast, ovaries are not visualized in the majority of cases.

Keywords: Trans-vaginal sonography; Pelvic exam; Health care

Introduction

Transvaginal ultrasonography (TVS) is a convenient method to detect morphological abnormalities in the Obstetric and Gynecologic fields, and may substitute for a bimanual pelvic examination. Detailed analysis of the effectiveness of TVS, however, has not yet been done, except for its role in the early detection of ovarian cancer [1-6].

The annual health care program i.e. "Ningen (Human) Dock" in Japan is nowadays a popular method for early detection of diseases, and TVS is commonly used to detect Gynecologic abnormalities in health care programs for women without concrete evidence of its usefulness. The present study evaluated the role and efficacy of TVS in a women's health care program.

Materials and Methods

Materials

The subjects were 1,029 consecutive healthy women who gave informed consent and who entered a health care program i.e. "human dock" at Shinjuku Medical Center, Meiji Yasuda Life Foundation of Health and Welfare between July 16, 2010 and May 25, 2012. Their mean age \pm SD was 48.5 ± 10.8 years old. Repeaters whose health care with TVS had been performed by the author during the period were excluded. The screening programs are based on company regulations or individual applications.

Methods

The Gynecologic aspect of the program includes history taking, a Pap smear, a bimanual pelvic examination and TVS in that order in the health care program. The pelvic exam was not repeated after TVS to avoid any effect of TVS findings. Women's history was taken by nurses in charge who had answers to previously prepared questionnaires, and the rest of the program was done by the author, who is certified an

Obstetrician and Gynecologist licensed by Japan Society of Obstetrics and Gynecology, and a Gynecologic Oncologist licensed by Japan Society of Gynecologic Oncology. Routine operating time of the program is 5 to 6 minutes excluding history taking. The results of Pap smears were excluded from this study.

- 1) Categorization of abnormalities detected and suggestions for the recipients

The results of gynecologic abnormalities found in the program were categorized, and personalized instructions and suggestions were given to the recipients of the program in the following categories:

- A: no abnormal findings
- B: minimal abnormality found, but not disturbing for daily life
- C1: re-examination in one month
- C3: follow-up and re-examination in 3 months
- C6: follow-up and re-examination in 6 months
- C12: follow-up and re-examination in 12 months
- D1: treatment needed
- D2: detailed exam needed
- E: treatment and care should be continued

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2) Transvaginal ultrasonography

A Sonovista-C 3000 (Mochida-Siemens Medical Systems Co. Ltd, Tokyo) was used for transvaginal ultrasonography, using a mechanical sector probe with a semi-spherical top edge that covered 220° fields in the 2D mode. The standard wavelength for the procedure was 7.5 MHz. Two photos were taken routinely; one measuring the widths of the uterine corpus and endometrium and one in each half of the other, either the right or left ovary (Figures 1 and 2). The area with an iliac vein in the pelvic side wall was photographed, if ovaries were not visualized.

An ovarian cystic mass was defined to be one with a diameter of 2.5 cm or greater and ovarian tumors were grouped into six types, following the criteria of the Japan Society of Ultrasonics in Medicine [7]. In brief,

Type I: cystic without echo in content

Type II: cystic with some echo

Type III: mixed pattern with central or peripheral solid echo, smooth in border

Type IV: mixed pattern, prominently cystic, with irregular solid or uneven lobular border

Type V: mixed pattern, prominently solid

Type VI: solid pattern

3) Levels of suggestions for uterine myomas and ovarian tumors

The basic instructions for women who had uterine myomas or ovarian tumors, etc. were as follows, depending on the size and type on TVS.

Uterine myoma

<3 cm: B, excluding that with < 2cm

3-5 cm: C12

5-7 cm: C6

≥ 7 cm: C3

Bigger than fist size: D2

Suggestions could be modified according to symptoms such as hypermenorrhea

Ovarian tumors

Simple cysts (Type I and II)

2.5-3 cm: B

3-5 cm: C6

5 cm: detailed exam

Type III-VI: detailed exam

Endometrial thickness ≥ 5 mm in postmenopausal woman: D2

4) Statistical analysis

Statistical analysis was performed using Excel Statistics 2010 software program for Windows® (SSRI, Tokyo). Fisher's test was used to compare the results between TVS and pelvic exam.

Results

Twenty-two and six women had undergone hysterectomy with or without salpingo-oophorectomy, and unilateral salpingo-oophorectomy, respectively. Therefore, the former were excluded from the analysis of uterine myoma and both were excluded from that of the ovary. Consequently, the total number of women without surgery was 1,001.

Comparison of abnormality incidences between TVS and the pelvic exam

The abnormal findings found by TVS were 252 out of 1,029, or 24.5%, and those by the pelvic exam were 140, or 13.6% ($p < 0.01$, Figure 3).

Incidence of uterine myoma detection

Two hundred and five women out of 1,007, or 20.4%, were found to have uterine myoma by TVS, but only 8.3% were found by the pelvic exam ($p < 0.0000$, Figure 4). Forty-one percent of those found by TVS were only detected by the pelvic exam. Women with myomas less than 2 cm, 2-3 cm, 3-5 cm (Figure 5), 5-7 cm, and 7 cm or greater in the longer diameter were 54 (26.3%), 45 (22.0%), 56 (27.3%), 27 (13.2%) and 23 (11.2%), respectively, when compared with myoma size on TVS. When compared with the pelvic exam, 1.9%, 15.6%, 46.4%, 96.3% and 100% were detected by the exam, respectively, and the findings of palpable cases depending on their sizes are listed in Table 1.

Incidences of visualization of the ovaries by TVS

Out of 1,001 women without pelvic surgery, cases with both ovaries visible were 26.0%, those with right ovaries visible were 15.4%,



Figure 1: Typical TVS findings of the uterus and the ovulatory phase of the endometrium. Slight adenomyosis is seen in the posterior wall of the corpus in a 40 year-old woman with algomenorrhea.



Figure 2: Typical TVS findings of the ovaries; right ovary in the left half and left ovary in the right half. Follicles are developing well in a 39 year-old woman.

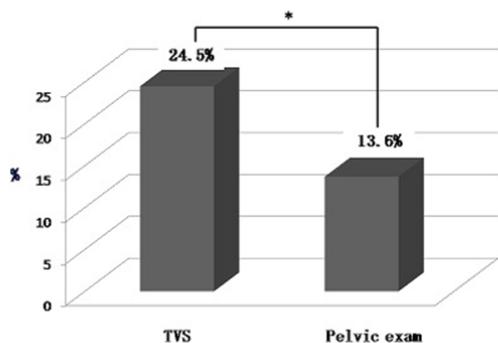


Figure 3: Incidences of detected Gynecologic abnormalities – Comparison between TVS and the bimanual pelvic exam (n=1029). TVS was more sensitive to detect abnormalities than the pelvic exam. *Fisher's exact probability test p<0.01.

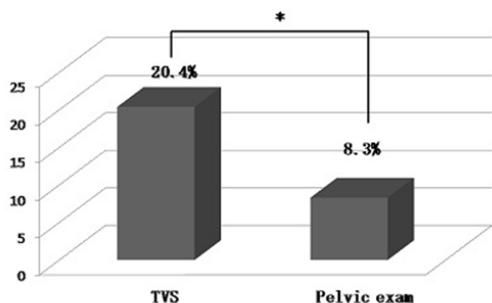


Figure 4: Incidences of detected uterine myomas – Comparison between TVS and the pelvic exam. TVS was more sensitive to detect abnormalities than the pelvic exam. *Fisher's test P<0.0000.



Figure 5: A small uterine myoma of 32.5mm in diameter in a 41 year-old woman.

those with left ovaries visible were 14.6% and those with both ovaries invisible were 44.1%.

Eight-hundred and twenty ovaries, or 41%, were visible by TVS, when counting the total number of ovaries i.e. 2,002, whereas 59% were invisible. When analyzed with coincidental uterine myoma, the incidence of invisible ovaries was 71.2% in those (n=212) with myoma \geq 3 cm in size and 73% in those (n=100) with myoma \geq 5 cm, both of

them were significantly higher than those without myoma ($p<0.0005$ and $p<0.0063$, respectively. Figure 6).

Incidence of ovarian tumor detection

Ovarian tumors by TVS were detected in 20, or 2.0%, of 1001 cases, whereas those detected by the pelvic exam were 10, or 1.0%. There was no significant difference between the two (Fisher's test). Ten women who were not detected by the pelvic exam had tumors less than 43.8 mm in diameter. Types of ovarian tumors and their categories were Type I in 11 cases (B;2, C3; 1, C6; 5, C12; 1 and D2; 2), Type II in 4 (C3; 1 and C6; 3), Type V in 1 (D2) and Type VI in 4 (C6; 2 and D2; 2, Figure 7), and no malignant tumors were detected, including the cases under research.

Miscellaneous gynecologic diseases detected

Gynecologic diseases (n=140, 147 lesions) found by history taking and pelvic exam and their categories are listed in Table 2. Miscellaneous diseases other than uterine myomas and ovarian tumors found by

Diameter of myoma	Abnormality by pelvic exam % (n)	Findings of pelvic exam
<2 cm	1.9% (54)	Irregular surface of uterus (n=1)
3-2 cm	15.6% (45)	Multiple (n=5), irregular surface (n=1)
5-3 cm	46.4% (56)	(small) goose egg size
7-5 cm	96.3% (27)	Small-large goose egg size
>7 cm	100.0% (23)	

Table1: Incidences of abnormalities found by the pelvic exam and the sizes of uterine myomas on TVS (n 205).

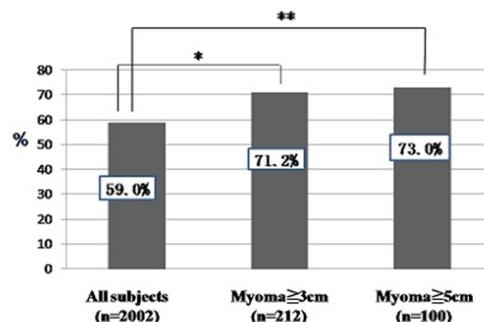


Figure 6: Incidences of invisible ovaries on TVS – Comparison between all subjects and those with coincidental uterine myoma. The incidences were higher in women with myoma than all subjects. *Fisher's test, both side $p<0.0005$, ** $p<0.0063$



Figure 7: Ovarian tumor, Type VI, of 53.7x44.3mm in a 58 year-old woman.

TVS (n=33) were fluid retention in the uterine cavity (Figure 8) in 19 cases, or 1.9% of 1,001 cases, adenomyosis (Figure 1) in 7, or 0.7%, endometrial thickness (≥ 5 mm) in postmenopausal women (Figure 9) in 4, or 0.4% and cervical cyst (Figure 10) in 3, or 0.3%. On the contrary, the endometrium was not visualized in 2.6%.

Discussion

Gynecologic abnormalities were found by pelvic exam in 13.6%,

Vulva	Adnexa
Vulvitis 1(E)	Ovarian tumor 10(C3;1, C6;4, D2;5)
Balthorin cyst 3(C12)	Functional
Condyloma 1(D2)	Algomenorrhea 2(B)
Leukoplakia 1(C12)	Abnormal Menses 4(D2; 2, B;2)
Tumor 2(C12)	Metrorrhagia 3(C3; 1, D2;2)
Vagina	Ovarian dysfunction 4(D1;1, D2;1, E;2)
Vaginitis 12(D1;9, B;3)	Others
Cervix	Deformed cervix 1(C3)
Endocervical polyp 15(B;10, D1;5)	
Portio polyp 2(B)	
Corpus	
Myoma 83(B;4, C6;22, C12;42, D1;1, D2;10, E;4)	
Myomatous uterus 1(C12)	
Descendent uterus 1(B)	

Table 2: Gynecologic diseases detected by pelvicexam and their categories for instruction.



Figure 8: Retention of fluid in the endometrial cavity, 6.0mm thick, in a 65 year-old woman.



Figure 9: Thick and irregular endometrium in a 44 year-old woman.



Figure 10: Multiple cysts located in the cervix (arrow) in a 48 year-old woman.

whereas in our previous report it was 7.9% [8]. The incidence in the present report may be due to the effect of a careful pelvic exam that conflicted with the sensitivity of TVS. In contrast, at 24.5%, the incidence by TVS was extremely high compared with that of the pelvic exam, and means one quarter of basically healthy women have gynecologic diseases from which they may suffer a disease, even though these are neglected abnormalities. The high incidence of abnormality by TVS is mainly due to the high sensitivity of detecting uterine myoma i.e. 20.4% of the program recipients. The incidence of myoma would decrease to 10.5% if we ignore myomas <3 cm in size. Therefore, it is necessary to exclude myomas <3 cm in size, if there are no symptoms. The bimanual pelvic exam did not detect uterine myomas of <3 cm with some exceptions, and approximately half of those of 3-5 cm. These small myomas have no clinical importance unless there are symptoms. Therefore, the pelvic exam is a reasonable method of detecting gynecologic abnormalities.

The majority (59%) of ovaries were not visualized by TVS in the present study. In contrast, van Negell Jr et al. [1] reported that at least one ovary was not seen in 16%, and spent a minimum time of 5 minutes to identify each ovary [2]. Spending more than ten minutes to identify ovaries, however, may be too long for healthy women. They [1,2] also defined that the ovary was regarded as negative for abnormalities, if it was not visualized. It should be defined as undetermined, since TVS is one of visual diagnostic methods. The sensitivity and specificity of TVS to define the ovaries as normal is very low. Therefore, it may not be recommended to perform TVS alone without a bimanual pelvic exam. Hiramoto et al. [9] reported that ovarian tumors were detected by TVS in 2.96-4.27%, whereas in our experience it was 2%. The ovarian tumors that were detected by TVS and not by the pelvic exam were all plain cystic masses of <4.4 cm in diameter.

Sato et al. [10] reported that using TVS for ovarian cancer screening the incidence of detected ovarian cancer was 0.04% among more than 50,000 women screened and 77.3% of them were in stage I, so the TVS screening may increase the chance for early diagnosis and reduce the mortality of ovarian cancer. Kobayashi et al. [11] reported that the ovarian cancer risk was elevated significantly among patients with ovarian endometrioma found by transabdominal and/or transvaginal ultrasound in the Cohort Study on Endometriosis and Ovarian Cancer Programme, and increased with increasing age at ovarian endometrioma diagnosis, especially in women over 50 years of age. Likewise, there is a long history of using TVS for the screening of ovarian tumors [1-5]. However, the usefulness of TVS has not yet been confirmed [6]. There are some reports [12,13] that showed the

effectiveness in multimodal trials of co-using biomarkers such as CA-125. However, there is no consensus on using the multimodal method of ovarian cancer screening for asymptomatic women [14,15]. In contrast, the evaluation of symptomatic patients who are suspected of having ovarian cancer includes TVS and serum CA-125, as well as physical examination [15]. In the present study, the incidence of detecting ovarian tumor with TVS was not significantly increased compared with that of the pelvic exam. TVS, which also has the low specificity for visualizing ovaries, may not have any benefit to screen for ovarian tumors.

Miscellaneous diseases that were found either by TVS or pelvic exam were complementary. Sznto et al. [16] reported that TVS was useful for detecting endometrial hyperplasia when postmenopausal women were screened with TVS. Alcazar [17] mentioned that the endometrium was thicker in hypertensive postmenopausal women. These results suggest that screening for endometrial cancer with TVS may be worthwhile for a selected group of women. Multiple cysts of the cervix may be good information to detect adenomatous malignancy.

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