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Acceptance of transvaginal sonography by postmenopausal women participating in the United Kingdom Collaborative Trial of Ovarian Cancer Screening

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KEYWORDS: acceptability; discomfort; pain; patient experience; transvaginal scan; UKCTOCS

ABSTRACT

Objective *To assess pain and overall experience of transvaginal sonography (TVS) in asymptomatic postmenopausal women.*

Methods *In the United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS), 50 639 postmenopausal women were randomized to undergo annual TVS at 13 trial centers in England, Wales and Northern Ireland. Together with the appointment letter for their annual scan, a random sample of 150 women per center was sent a detailed 48-item postal questionnaire regarding the screening experience. It included a specific question about pain using a score of 0–5, where 5 was severe pain and 3 was discomfort. To assess factors that might affect a woman's reported pain experience, the pain score was regressed on age, hormone replacement therapy use, body mass index, a history of hysterectomy, prolonged scanning time, ovarian visualization, scan result, sonographer's visualization rates and opinion of the women regarding the sonographer who performed the scan.*

Results *Between 7 July and 9 September 2009, 1950 randomly chosen women (150 per regional center) were sent the questionnaire. Of the 800 (41.0%) who returned the questionnaire, 651 could be linked to their TVS appointment. One-hundred and fifty-two (23.3%) women reported pain/discomfort (score 3–5) during TVS and 473 (72.7%) reported no discomfort (score 0–2). Only 23 (3.5%) women reported experiencing moderate/severe pain. Increasing discomfort/pain was independently associated with a history of hysterectomy and participant's reporting of prolonged scan time. Women who experienced pain on TVS were less compliant (odds ratio = 0.87) with the following year's scan compared with those who did not experience pain.*

Conclusions *The majority of postmenopausal women found TVS acceptable. Pain influenced compliance and correlated with women's perception of increased scanning time and previous hysterectomy.* *Copyright © 2012 ISUOG. Published by John Wiley & Sons, Ltd.*

INTRODUCTION

Transvaginal sonography (TVS) is key to ovarian cancer screening. It is universally used either as the primary screening modality or as a second-line test following primary screening with serum CA 125[1–4]. Although TVS is a relatively invasive procedure and potentially embarrassing for the woman, it is increasingly the routine investigation for assessment of pelvic conditions both in younger and in older patients[5,6]. It is preferred over transabdominal sonography (TAS) as the pelvic organs are better visualized and, unlike TAS, women are not required to fill their bladder. Previous studies looking at the acceptability of TVS have shown that most women find it acceptable[6]. However, these studies were mainly in younger premenopausal women in an early

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pregnancy/obstetrics setting. To our knowledge, there are currently no published studies specifically exploring the experience of TVS in postmenopausal women, the population who will need to undergo annual scanning if ovarian cancer screening is found to have a mortality impact[4], or in women with postmenopausal bleeding for whom TVS is the primary line of investigation. In this older population, it is likely that women may experience increased discomfort because of atrophic changes resulting from a hypo-estrogenic status and find it more intrusive.

We report on pain, acceptability and overall satisfaction with TVS in postmenopausal women from the general population participating in the United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS).

METHODS

In total, 202 638 postmenopausal women were recruited to the UKCTOCS through 13 regional trial centers located in National Health Service (NHS) Trusts in England, Wales and Northern Ireland. The design of the trial has been reported previously[4,7]. Briefly, between April 2001 and October 2005 the women were randomized to a control group (no screening), a multimodal group (annual screening with CA 125 as a primary test and TVS as a secondary test) and an ultrasound group (annual screening with TVS), in a 2:1:1 ratio; 50 639 women were randomized to annual screening with ultrasound.

Women were offered TVS as the screening modality as it offers a superior view of the pelvic organs. However, when this was not acceptable, TAS was performed. The scans were undertaken by certified sonographers, trained midwives, doctors in the NHS trained in gynecological scanning or experienced certified gynecologists/radiologists. All scans were performed using the same model of ultrasound machine and vaginal probe (Medison Accuvix; Medison, Seoul, South Korea)[4].

A 48-item volunteer-satisfaction questionnaire was developed by the UKCTOCS Ultrasound Subcommittee. It included questions on waiting times for the scan, information regarding the scan, experience of undergoing the scan, pain/discomfort at the scan, interaction with the sonographer and access to/facilities at the center. The majority of the questions were dichotomous, with few questions being open-ended or using a Likert scale. The key question on discomfort/pain was 'In your opinion please grade the pain/discomfort you experienced during the scan, with '0' being no pain, '3' being discomfort and '5' being severe pain'.

In 2009, the questionnaire was posted to a random sample of 150 women per center, along with their appointment letter. It was sent 6 weeks before their scan appointment. Women were asked to complete the questionnaire following the scan and to return it in the enclosed freepost envelope. Women were able to complete the form anonymously if they so wished.

Annual screening continued in the UKCTOCS until 31 December 2011. The trial management system was queried to ascertain attendance at future annual screening appointments for women who returned the completed questionnaire.

The UKCTOCS study was approved by the UK North West Multicentre Research Ethics Committees (North West MREC 00/8/34). It is registered as an International Standard Randomized Controlled Trial (no. ISRCTN22488978).

Statistical analysis

Descriptive statistical analysis, including a frequency table, was undertaken. Based on their reported experience of pain, women were grouped into two categories: 'no pain or discomfort', which included scores ranging from 0 to 2; and 'discomfort to severe pain', which included scores ranging from 3 to 5. For the model, the reported experience of pain was imputed as an ordinal variable.

To assess factors that might affect a woman's reported pain experience, the pain score (with scores 4 and 5 merged) was regressed on the following: body mass index (BMI) recorded at recruitment to the trial; hysterectomy status, obtained by combining data captured at recruitment and at scan; age at scan; hormone replacement therapy (HRT) use at scan; perceived time taken scanning ('too long' or not); visualization of ovaries[4]; scan result of ovarian assessment (classified as normal, unsatisfactory or abnormal), both captured on the scan report; and opinion of the woman regarding the sonographer who performed the scan, using an ordinal logistic regression (or proportional odds) model with backward stepwise selection, with probability of removal = 0.05. The proportional odds model assumes that the relationship between an explanatory variable and the dichotomization of the ordinal dependent variable, for example, pain = 0 *vs* pain =1, 2, 3 or 4, is the same as that when using any other ordered dichotomization such as pain = 0 or 1 *vs* pain = 2, 3 or 4. Hence, only one odds ratio (OR) is estimated for each explanatory variable.

The competence of the sonographer was assessed (as per the UKCTOCS quality-assessment measure) by looking at their visualizing rates, calculated as the percentage of the right ovary seen (the rates for the right ovary and the left ovary are proportionally similar) out of all scans they performed during the trial. The visualization rates for the right ovary only are reported. We compared the visualization rates between those who scanned the women who experienced any discomfort/pain (score 3–5) and those who did not experience discomfort/pain (score 0–2) to explore whether competence affected the scores. An ordinal logistic model was used to assess if visualization rates could be used as a predictor of discomfort/pain.

RESULTS

A random sample of 1950 women (150 per regional center), selected from 6645 women sent appointment letters for their annual ultrasound screen between 7

July and 9 September 2009, were also sent the 48-item questionnaire. Eight-hundred (41.0%) women returned the questionnaires, and none was discarded because of inadequate completion. Of the 697 women who could be identified, 46 had an abdominal scan only and were therefore excluded from further analyses. The remaining 651 had a transvaginal scan. The contribution of responses from each center ranged from 5.1% to 9.7%.

The baseline characteristics of the 651 women included in the analysis are reported in Table 1. All were postmenopausal with a median age of 60.8 (interquartile range (IQR), 56.1–65.5) years. Most women had undergone a median of six (range, four to eight) annual scans previously. The median time from menopause was 10.5 (IQR, 5.3–16.5) years. Although, at recruitment, 126 (19.4%) women were using HRT, when questioned before the TVS, only 20 (3.1%) reported that they were still using HRT. Both ovaries were visualized in 423 (65.0%) scans, of which 403 were normal and 20 had complex morphology requiring a repeat scan as per the UKCTOCS protocol. In 55 women one or both ovaries were not visualized, with sonographers obtaining a good view of the pelvic sidewall in 46 and a poor view, mainly as a result of bowel gas, in nine.

Four-hundred and seventy-three (72.7%) women reported experiencing no pain/discomfort during the scan (score 0–2), and 23 (3.5%) reported moderate/severe pain (score 4–5) (Table 2). Overall, 152 (23.3%) women reported some discomfort/pain (score 3–5) but only 64 (42.1%) of these mentioned it to the sonographer.

Six-hundred and thirty-two (97.1%) women were scanned by a female sonographer, and 596 (91.6%) felt that they received clear and understandable information on what to expect at the scan. Six-hundred and thirty-six (97.7%) women reported that the sonographer behaved professionally, 607 (93.2%) that they were sensitive and 608 (93.4%) that they were reassuring, and 630 (96.8%) women reported that they were treated with dignity. Six-hundred and twenty-seven (96.3%) women felt that they had enough privacy during the scan. Only 34 (5.2%) women reported feeling embarrassed during the scan (Table 3). Only 80 (12.3%) women were shown the ultrasound monitor screen during the scan, although 317 (48.7%) reported that they would have liked to see the monitor during the examination (Table 3). In addition, only 10 (1.5%) women reported waiting over 30 min for their scan. The majority of the women, 584 (89.7%), lived within 30 miles of the center, and 561 (86.2%) had travelled for less than an hour (Table 4). Overall, the volunteers reported favorably on the facilities at the local screening center.

Using an ordinal logistic regression model incorporating discomfort/pain, age, BMI, history of hysterectomy, HRT use reported at scan and time taken scanning, we found that hysterectomy significantly increased the odds of each upwards pain-score transition (going from one ordered group dichotomization to the next) by 2.42-fold (95% CI, 1.68–3.50), whilst volunteer-reported 'prolonged scanning time' increased the odds by 5.81 times (95% CI, 1.92–17.62). The variables that showed evidence of being related to pain score when modeled individually included prior HRT use (OR = 1.36), hysterectomy (OR = 2.51), prolonged scanning time (OR = 6.78), abnormal (OR = 2.27) or unsatisfactory (OR = 1.69) scan result, concern about the scan results (OR = 1.55) or embarrassment (OR = 1.66). However, only hysterectomy (OR = 2.42) and prolonged scanning time (OR = 5.81) were retained in the backward selection model (Table 5). In an ordinal logistic model using visualization rates as a predictor of pain, the OR was 1.47 (95% CI, 0.38–5.80; $P = 0.574$), suggesting that the visualization rates (as a surrogate for the competence of the sonographer) did not affect the discomfort/pain experienced by the women.

Compliance with the following year's scan in women who experienced pain on TVS was lower (OR = 0.87; 95% CI, 0.58–1.23; $P = 0.379$) compared with those who did not experience pain.

DISCUSSION

Our study shows that TVS is well accepted by the majority of asymptomatic postmenopausal women (median age 60.8 (IQR, 56.1–65.5) years), with 23.3% reporting some discomfort/pain during the procedure but only 23 (3.5%) reporting moderate/severe pain. Increased reporting of pain was associated with previous hysterectomy and women's perception of prolonged scanning time. Pain decreased the likelihood of future attendance for TVS screening.

For a screening strategy to impact on mortality, in addition to high sensitivity and specificity, the test needs to be acceptable to those undergoing screening. Given that TVS is core to all ovarian cancer-screening strategies[8,9], assessing the acceptability of this modality by older postmenopausal women is important. Our reported rates of moderate/severe pain of 3.5% are somewhat higher than the 1.9% reported for young women undergoing TVS for vaginal bleeding in an early-pregnancy setting[5]. While women in both groups may share apprehensions about the intrusive nature of the test, higher rates in our cohort probably relate to the age and the postmenopausal hypo-estrogenic status of women. In addition, some of the women may not be sexually active. Data related to sexual activity, collected as part of the Sussex Health Outcomes Research & Education in Cancer (SHORE-C), are currently being analyzed[10]. The rates of discomfort/pain are much lower in the present study compared with breast screening, where over 70% of women described mammography as mild to severely painful[11]. Additionally, there may be some selection bias in the present study as a result of a response rate of only 40% to the questionnaire.

Although some factors showed evidence of being related to an increased pain score when modeled individually (previous HRT use, hysterectomy, prolonged scanning time, abnormal or unsatisfactory scan result, concern about the scan results or embarrassment), only women's

Table 1 Baseline characteristics of women invited to participate in survey on experience of transvaginal sonography (TVS) *vs* those who responded

Characteristic	*All women invited (n = 1950)*	*Responders who had TVS (n = 651)*
Age (years) at randomization	60.3 (55.9–65.5)	60.8 (56.1–65.5)
Years since last period at randomization	10.5 (5.2–17.4)	10.5 (5.3–16.5)
Duration (years) of HRT use in those on HRT at randomization	8.3 (4.6–12.5)	7.6 (4.9–11.4)
Duration (years) of OCP use in those who had used it	5 (2–10)	5 (2–10)
Age at menarche (years)	13 (12–14)	13 (12–14)
Miscarriages (pregnancies < 6 months)	0 (0–1)	0 (0–1)
No. of pregnancies > 6 months	2 (2–3)	2 (2–3)
Height (cm)	162.6 (157.5–165.1)	162.6 (157.5–167.6)
Weight (kg)	67.1 (60.3–76.2)	66.7 (60.3–75.0)
Ethnicity		
White	1877 (96.3)	639 (98.2)
Black	27 (1.4)	6 (0.9)
Asian	18 (0.9)	1 (0.2)
Other	18 (0.9)	3 (0.5)
Missing	10 (0.5)	2 (0.3)
Hysterectomy	358 (18.4)	134 (20.6)
Tubal ligation	409 (21.0)	122 (18.7)
Infertility	55 (2.8)	17 (2.6)
Use of OCP (at any point)	1180 (60.5)	393 (60.4)
Use of HRT at recruitment	363 (18.6)	126 (19.4)
Personal history of cancer*	112 (5.7)	33 (5.1)
Personal history of breast cancer	74 (3.8)	25 (3.8)
Maternal history of ovarian cancer	29 (1.5)	7 (1.1)
Maternal history of breast cancer	136 (7.0)	39 (6.0)

Results are given as median (25^{th}–75^{th} centile) or *n* (%). *Includes those with a personal history of breast cancer. HRT, hormone replacement therapy; OCP, oral contraceptive pill.

Table 2 Degree of discomfort/pain experienced during transvaginal ultrasound

Discomfort/pain score	n	%
0	247	37.9
1	131	20.1
2	95	14.6
3	129	19.8
4	21	3.2
5	2	0.3
Grouped scores		
0–2	473	72.7
3–5	152	23.3
Missing data	26	4.0

perception of 'prolonged' scanning time and previous hysterectomy influenced pain in the final model. It needs to be noted that duration of scanning time was based on the women's perception, and the actual scanning time might be a better measure in future surveys as women's reporting could have been affected by the pain response itself. Factors influencing pain, in women of similar age to those in the present study, in the screening mammography study from the Netherlands included sensitive breasts, a family history of breast cancer, expected pain based on former mammography, higher education, anxiety and insufficient attention of the technologist[11].

Pain influenced compliance with the following year's scan. This is in keeping with the findings from breast screening that one of the major factors influencing future non-participation is a painful mammography experience[12]. In a survey of women regarding factors affecting colorectal cancer screening compliance, fear about screening-related pain was the strongest obstacle to screening[13]. It is essential in any screening using TVS that the scanning protocol includes clear recommendations on steps to reduce pain if any is experienced during screening. Given the importance of compliance for a successful and effective screening program, a detailed analysis of factors affecting it in both the multimodal (venepuncture for CA 125) and TVS screening study arms is now underway.

As the competence/skill of the sonographer is a factor that could influence women's reporting of discomfort or pain, we analyzed the sonographer's visualization rates. There was no difference between those who scanned women who reported no pain *vs* those who scanned women who reported some level of discomfort/pain (75.2%; IQR, 64.1–82.6% *vs* 74.9%; IQR, 65.8–83.1%) (data not shown). We found that the visualization rates did not affect the reporting of pain (OR = 1.47, $P = 0.574$).

A variety of other factors are likely to influence continued participation in annual screening. In our study, the majority of women had a positive opinion regarding the sonographer who scanned them. In addition to adequate privacy, the attitude of the staff administering the test is crucial in intimate examinations, such as TVS. It is important that women feel that the sonographer is sensitive and reassuring, and treats them with dignity. Ninety-seven per cent of the women were scanned by

Table 3 Women's view of their experience with the sonographer during transvaginal ultrasound examination

	Women (n *(%))*		
Factor assessed	*Yes*	*No*	*Missing data*
Scanned by a female sonographer	632 (97.1)	8 (1.2)	11 (1.7)
Sonographer behaved professionally	636 (97.7)	2 (0.3)	13 (2.0)
Sonographer sensitive to situation	607 (93.2)	18 (2.8)	26 (4.0)
Sonographer reassuring	608 (93.4)	22 (3.4)	21 (3.2)
Received adequate information on what to expect at scan	602 (92.5)	41 (6.3)	8 (1.2)
Received information that was clear and understandable*	596 (91.6)	3 (0.5)	35 (5.4)
Felt had enough privacy	627 (96.3)	13 (2.0)	11 (1.7)
Felt embarrassed during the scan	34 (5.2)	602 (92.5)	15 (2.3)
Treated with dignity	630 (96.8)	5 (0.8)	16 (2.5)
Shown ultrasound monitor screen during scan	80 (12.3)	558 (85.7)	13 (2.0)
Would have liked to be shown screen during scan	317 (48.7)	220 (33.8)	114 (17.5)

*17 women were excluded as they felt this was not applicable in view of previous scans in the trial.

Table 4 Screening-center facilities

Variable	n *(%)*
Distance from center (miles)	
1–10 miles	324 (49.8)
11–20 miles	201 (30.9)
21–30 miles	59 (9.1)
>30 miles	49 (7.5)
Missing data	18 (2.8)
Travel time to center (min)	
1–30 min	260 (39.9)
31–45 min	200 (30.7)
46–60 min	101 (15.5)
>60 min	80 (12.3)
Missing data	10 (1.5)
Waiting time (min)	
None (seen prior to appointment)	154 (23.7)
None (seen at time of appointment)	239 (36.7)
< 15 min	173 (26.6)
15–30 min	60 (9.2)
31–45 min	9 (1.4)
46–60 min	0 (0.0)
> 60 min	1 (0.2)
Missing data	15 (2.3)
Changing area deemed private	
Yes	563 (86.5)
No	37 (5.7)
Missing data	51 (7.8)
Changing area deemed clean	
Yes	582 (89.4)
No	4 (0.6)
Missing data	65 (10.0)
Changing area close to scanning room	
Yes	534 (82.0)
No	3 (0.5)
Missing data	114 (17.5)

a female sonographer. In an earlier UKCTOCS survey, 83.3% of women had expressed a preference for a female sonographer[14]. The general consensus is that same-gender staff are preferred in such situations. This includes obstetrics settings, with 62% of 1002 pregnant women (25–40 years of age) preferring a female sonographer[15]. In obstetric scanning it is now routine for women to be shown the monitor. Nearly half of the women reported that they would have liked to see the monitor during the examination. In reality, only 12.3% were shown the ultrasound monitor screen. Inclusion of such issues in training sessions of staff providing screening is important.

Other factors affecting continued participation with screening include distance from the woman's home to the center. In the Kentucky Ovarian Cancer Screening Trial, greater compliance was reported in those living close to the screening center compared with those living more than 51 miles from the screening center[16]. In our study, 89.7% of those sampled lived within 30 miles of the center, with 86.2% having to travel for less than an hour. A comfortable and acceptable environment is probably an equally important issue, with the majority of the women reporting satisfaction with the facilities provided at the center.

Only 34 (5.2%) women reported feeling embarrassed during the scan. An older study on sigmoidoscopy suggested using relaxation training ahead of the procedure to minimize embarrassment[17]. Providing a calm and relaxed environment ahead of the scan is probably a strategy that is likely to reduce embarrassment in postmenopausal women.

One of the limitations of the study was the relatively low response rate of 40%. It is possible that as the questionnaire was sent 6 weeks in advance of the scan appointment, some women may have misplaced or forgotten about it. As the women surveyed had attended four to eight scans previously in the trial and had a long-term relationship with the center, it is conceivable that they did not feel the need to respond to such a survey. In addition, the survey contained 48 items and some women may have found it too long and therefore not been inclined to fill it in. Another limitation of our study was that our analysis of 'time taken scanning' was based on the women's impression ('Did you feel the scan took too long?') rather than on an actual value, and this might have been biased by her experience of pain. In similar studies in the future it would be best to capture the exact time taken to perform the scan.

In conclusion, postmenopausal women find TVS an acceptable screening test with only a minority experiencing significant pain. The reporting of pain was increased in those who had a previous hysterectomy or experienced

Table 5 Results of ordinal logistic regression model fitted to pain response using various potential explanatory baseline variables and survey items

Factor	*Odds ratio*	*95% CI*	P
Age	1.00	0.97–1.02	0.798
Hormone replacement therapy	1.36	0.61–3.03	0.460
Body mass index	1.02	0.99–1.06	0.150
Hysterectomy	2.51	1.75–3.60	< 0.001
Scan took too long ('prolonged' scanning time)	6.78	2.34–19.56	< 0.001
Ovary seen (left)	0.81	0.59–1.13	0.224
Ovary seen (right)	0.72	0.50–1.03	0.074
Scan result			
Normal	1.00		
Abnormal	2.27	1.08–4.80	0.031
Unsatisfactory	1.69	0.71–4.02	0.233
Sonographer's visualization rate	1.47	0.38–5.80	0.574
Sonographer reassuring	0.43	0.19–0.97	0.043
Sonographer sensitive to situation	0.36	0.14–0.93	0.036
Sonographer behaved professionally	0.24	0.00–13.68	0.491
Sonographer gave explanation of procedure	0.47	0.23–0.94	0.034
Sonographer gave explanation of findings	0.70	0.50–0.96	0.028
Sonographer discussed findings after scan	0.68	0.49–0.93	0.017
Sonographer discussed what would happen after scan	0.67	0.44–1.01	0.056
Sonographer told woman that she would return to annual screening	0.59	0.43–0.80	0.001
Woman concerned about results of scan	1.55	0.98–2.46	0.061
Woman felt she had enough privacy	0.62	0.22–1.70	0.349
Woman felt the scan had caused embarrassment	1.66	0.89–3.08	0.108
Woman was shown ultrasound monitor screen	0.57	0.37–0.89	0.014
Woman would have liked to be shown the screen	1.14	0.83–1.57	0.408
Seating deemed adequate	0.51	0.19–1.36	0.178
Woman felt toilet was close by	0.34	0.10–1.19	0.092
Woman felt toilet was clean	0.21	0.06–0.69	0.011
Changing area deemed private	0.88	0.47–1.66	0.691
Changing area deemed clean	0.13	0.02–0.92	0.041
Changing area deemed close to scan room	0.61	0.08–4.53	0.630
Hysterectomy*	2.42	1.67–3.50	< 0.001
Prolonged scanning time*	5.81	1.92–17.62	0.002

*Retained in backward selection model.

a 'prolonged' scanning time, and it influenced future compliance. These data are of value, not only to screening strategies that may incorporate TVS, but also to older women undergoing ultrasound scanning in the clinical setting.

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DISCLOSURES

Ian Jacobs has a consultancy arrangement with Becton Dickinson in the field of tumor markers and ovarian

cancer. Ian Jacobs and Usha Menon have a financial interest through UCL Business and Abcodia, Ltd., in the third-party exploitation of clinical trials biobanks, which have been developed through the research at UCL. There are no other declarations. None of the other authors has any conflict of interest.

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