

CLINICAL **PRACTICE**

Evidence



Rebecca Anne Stewart

MBBS, FRACGP, is Senior Lecturer, Department of General Practice, James Cook University, and a general practitioner, Queensland. rebecca.stewart@jcu.edu.au

Jill Thistlethwaite

MBBS, PhD, MMEd, FRCGP. FRACGP, is Director of Research, Learning and Teaching, CIPHER, University of Sydney, New South Wales.

Routine pelvic examination for asymptomatic women

Exploring the evidence

BACKGROUND

A routine pelvic examination is often performed as part of a 'well woman' check, in combination with a Pap test, sexually transmitted infection screening, or before commencing the contraceptive pill or hormone therapy. This check is also done at the woman's request, on the understanding that it may screen for ovarian cancer and other pathology.

OBJECTIVE

This article reviews the evidence regarding the use of routine pelvic examination in asymptomatic women as a screening test, and if the examination is performed, what information should be imparted to the patient to obtain informed consent.

DISCUSSION

Review of the literature indicates that the use of routine pelvic examination as screening for ovarian malignancy (with or without serum CA-125 and ultrasound) cannot be justified due to the low prevalence of the disease and low sensitivity and specificity of the examination. Pelvic examinations may be performed at the time of routine Pap tests to aid in technical issues with the Pap test itself, but are not recommended for screening purposes. There is no evidence to support pelvic examination of asymptomatic women taking hormone therapy or attending for a sexual health check. The performance of pelvic examination at the woman's request must be preceded by thorough gynaecological, medical and family history and after obtaining informed consent from the patient.

Case example

Miss L, 26 years of age, attends for her 2 yearly Pap test. She is taking the oral contraceptive pill and does not complain of any gynaecological symptoms on routine questioning. As part of the consultation you offer her a pelvic examination. She agrees, but asks you why other doctors have not offered her this during previous Pap test examinations. She also asks what you are checking for.

'Well woman' checks are carried out by many clinicians

including general practitioners, gynaecologists and health nurses. The content of these examinations has been demonstrated to vary widely, as shown in a study by Carney et al.1 In this study, 59 primary care physicians reviewed asymptomatic women 55 years of age requesting 'check ups'. Of note, 65% of physicians provided a clinical breast examination and another 20% did so when prompted. The remaining doctors indicated they would perform the examination with the woman's next Pap test. The performance of pelvic examinations was not noted in this study.

Extensive literature review reveals little documentation into the frequency of performance of routine pelvic

examinations in asymptomatic women. Therefore, further study into this area of practice is justified, before reviewing recommendations regarding the issue.

The clinical question

The questions to ask are why are we doing pelvic examinations in asymptomatic women, and what do women believe is the purpose of such examinations? Evidence suggests that these intimate examinations may be traumatic and stressful to the patient, so we must ensure that we have sufficient reason to justify them as reliable screening tests.^{2,3} The examination may also provide false reassurance to the patient if they do not have a clear understanding of its accuracy. In our clinical experience, patients have also commented on the inconsistency with which they

are offered these examinations, giving some indication regarding differing clinician's beliefs about their value.

Many doctors perform the 'screening' pelvic examination out of 'habit' or because they were 'taught' to do so, rather than for a clear clinical indication. The method of performing a pelvic examination is relatively standard and involves 'the insertion of one or two examiner fingers into the vaginal vault with simultaneous palpation of the lower abdomen to characterise the size and shape of the uterus and adnexa'.4 The clinician should be able to palpate the uterus between their hands and, in 'normal' women, should not be able to palpate the ovaries (unless the woman is quite thin). An estimate of the size, tenderness and uniformity of the uterus and ovaries can be made.

Pelvic examination in asymptomatic women may be offered in the following circumstances:

- to detect ovarian and uterine abnormalities, more specifically as screening for ovarian carcinoma
- during a sexually transmitted infection check
- in conjunction with a routine Pap test
- before prescribing the combined oral contraceptive pill or hormone therapy.

The literature regarding each of these areas will be discussed in turn.

Pelvic examination: literature search

We searched the Cochrane database, Medline, Google, and textbooks, using the terms 'well woman check', 'routine pelvic examination', 'vaginal examination', and 'ovarian cancer screening'. Much of the information gained was in respect to the topic of ovarian cancer screening.

Screening for ovarian cancer and uterine abnormalities

A suitable screening test must detect a disease that causes significant morbidity and has a high prevalence in the population. The disease must have a preclinical phase that can be detected and is amenable to therapy. The test itself must be sensitive, specific, and cost effective and have a high positive predictive value.⁵

Although ovarian cancer has a relatively low prevalence in the community (30-50 women per 100 000), the anxiety that this illness provokes is understandably quite high. The lifetime incidence of ovarian cancer is one in 70 women.⁵ The early stages of the disease are asymptomatic but more easily treated, while most cases occur late causing high mortality. Ovarian cancer has the highest mortality of any gynaecological cancer with a 5 year survival rate of 75% if cancer is confined to the ovaries, and 17% for those women presenting with distant metastases. Twothirds of women have advanced disease at the time of diagnosis. 6 The presenting symptoms of ovarian cancer are often mild and nonspecific such as vague gastrointestinal discomfort, pelvic pressure and pelvic pain.5

Early detection of ovarian cancer has not been shown to lower mortality rates.⁶ Indirect evidence shows that this may not be correct, as mortality rates from early stage disease are significantly lower than those for late stage disease. The National Cancer Institute in America has recently embarked on a large study to explore this question. With the assumption of 100% sensitivity and 30% reduction in 5 year mortality with screening, they calculate that annual pelvic examinations in women 40 years of age would reduce the 5 year mortality from ovarian cancer by <0.0001%. Similar calculations using CA-125, with or without ultrasound screening, show an increase in life expectancy by 1 day for each woman screened.6 The UK Collaborative Trial of Ovarian Cancer screening, the NIH PLCO Screening Trial, and the European Trial of Ovarian Cancer Screening are currently also investigating the mortality reduction, if any, provided by ovarian cancer screening. To date, results of the NIH PLCO trial have identified no precursors to ovarian cancer in postmenopausal woman. The effect of screening in their study population is still unclear and requires longer follow up.7

Various methods of screening for ovarian cancer have been suggested, namely pelvic examination, transabdominal and vaginal ultrasound, and CA-125 testing. It is suggested that for ovarian cancer where the prevalence is 50 per 100 000 women, a test with 100% sensitivity and 99% specificity would result in one per 21 woman positively screened having the disease, ie. positive predictive value 4.8%. The sensitivity of the proposed methods is currently not high enough to warrant their use in screening.5 It must also be considered that laparoscopy and/ or laparotomy is the only way to definitively diagnose ovarian carcinoma, thus the implications of confirming a result is falsely positive involves significant morbidity and anxiety.8

Multiple studies have shown the inaccuracy of pelvic examinations in women, even under controlled conditions such as anaesthesia. Padilla et al⁹ conducted a study of pelvic examination findings in 140 anaesthetised women. Gynaecologists, gynaecology residents and medical students carried out the examinations. The authors found that even in ideal conditions, the overall accuracy of the examination was 70.2% for gynaecologists, 64% for residents and 57.3% for medical students. Uterine assessment proved to be more accurate than adnexal assessment and was reasonable with a sensitivity of 0.64 and specificity of 0.8. Factors such as uterine size, abdominal scarring and obesity also reduced the assessment accuracy. Gladstone¹⁰ found that other factors affecting the accuracy of bimanual examination include patient size, pelvic structure, and patient anxiety level. These must be considered also with respect to the experience of the practitioner and dimensions of the tumour itself if present.

The pelvic examination has a low sensitivity in detecting adnexal masses. The study by Padilla et al showed a sensitivity of 51% and positive predictive value of 43.8% for pelvic examination, with sensitivity being low even for masses greater than 5 cm.9 The positive predictive value for left adnexal masses was 0.5-0.69 and for right adnexal masses 0.26-0.39, thus not justifying its use as a screening test.9 One of the important issues in screening is that the disease must be detectable early. This is inherently difficult in pelvic examination where early ovarian cancers may be small. It is estimated that 10 000 pelvic examinations are required to detect one ovarian cancer and that the lesion is usually advanced.11

The deep anatomical location of the ovaries in the abdomen precludes easy examination and reduces examination sensitivity. The majority of pelvic masses found are either benign, or if malignant, advanced.6 Prevalence of adnexal masses in the general population is 0.17-5.9% in asymptomatic woman, with the higher prevalence being in premenopausal woman. It has been calculated that an adnexal mass found by pelvic examination would be surgically

confirmed 8% of the time, compared to 17% for a mass found on ultrasound.6

Grover and Quinn¹² also conducted a study to assess the accuracy of pelvic examination in healthy women; 2623 healthy asymptomatic volunteers, both pre- and post-menopausal were assessed with the aim of ovarian cancer screening. Findings were further defined with ultrasonography and CA-125 levels. Surgical intervention was performed if required. Abnormal adnexal findings occurred in 1.5% of the subjects with a positive predictive value for a benign adnexal abnormality of 22%. No ovarian malignancies were found in the screening group. The authors' comment that the use of pelvic examination as a screening test for ovarian carcinoma in a population with a low prevalence of ovarian cancer and high prevalence of benign adnexal pathology is not warranted.

Postgraduate experience improved the overall accuracy of the pelvic examination, although skills appear to plateau after a certain number of examinations have been performed.9 This begs the question that those who do not routinely perform pelvic examinations will have a lower sensitivity and specificity for disease detection and therefore even less justified at performing such examinations as part of screening.9 The importance of ongoing education and training regarding examination techniques will therefore become necessary if pelvic examination is ever used as a screening procedure, either alone or in conjunction with other modalities. The reliance of practitioners on imaging techniques in preference to examination may also impact on the proficiency with which they perform pelvic examinations.9

It is worth briefly mentioning other proposed screening tools as mentioned in the literature. Transvaginal and transabdominal ultrasound lack both the sensitivity and sensitivity to justify their use in screening. The resulting false positive rates may result in diagnostic laparoscopies for a relatively low disease yield.6 Ultrasound in combination with CA-125 testing somewhat increases this, however false positive rates are still high.^{5,10} Serum CA-125 is an antigenic determinant that is elevated in 80% of epithelial ovarian cancers, however, only 50% of patients with early ovarian disease have high levels. Therefore, its use in detecting early disease cannot be justified. 5,6

What about women at higher risk?

The lifetime risk of ovarian cancer is one in 70, but for women with one affected relative, this rate rises to 5%. Current literature suggests that the previously mentioned screening tests are still not justified, even in this high risk population. The risk with two affected relatives rises to 7% and again, screening in this group has not been justified. It is however recommended that specialist review be sought in defining hereditary ovarian cancer syndromes. For those in this group, lifetime risk of ovarian cancer is 40%. Current evidence shows no reduction in mortality by screening this group, and prophylactic oophorectomy does not guarantee that cancer will not develop.5 If screening such a high risk population is not warranted, its benefit to the general population must certainly be questioned.

Pelvic examination: sexual health checks

The performance of a pelvic examination as part of a sexual health consultation may be justified as clinical signs may be elicited that aid in diagnosis. It would be unusual however for an asymptomatic woman to present with cervical excitation on examination without complaining of dyspareunia. Schachter¹³ investigated the use of routine pelvic examinations in women presenting for sexual health checks. They concluded that delaying routine pelvic examinations and Pap tests in this group would not adversely affect outcomes.

Pelvic examinations: Pap tests

The use of pelvic examination when performing a Pap test may aid in the actual technique of performing the smear. For example, a difficult to locate cervix on speculum examination may be located after vaginal examination. It is important to note that in this instance, the pelvic examination is not being used for a 'screening' purpose. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists make no mention in their position statement on cervical cancer screening of routinely performing a pelvic examination with a Pap test.14 They do however comment that women attending for care understand that complete examination usually includes assessment of the breast and pelvis.15

It is interesting to note that if pelvic examination were recommended as ovarian cancer screening, its false positive rate would be lower in postmenopausal women due to the increased prevalence of the disease in women over 60 years of age. Current Pap test screening recommendations suggest that cervical screening be ceased at 70 years of age in otherwise healthy women with no history of previously abnormal smears. 14,16 If pelvic examinations were performed routinely in this group with smears, the patient would only have five examinations (ie. performed 2 yearly) before 'screening' ceased. Due to the natural history of ovarian cancer it is likely that the number of interval cancers would be significant.

Pelvic examination: before hormone therapy

Pelvic examination before oral contraceptive use is common in many countries and is often also done annually. Evidence to support such examinations is lacking, and false positive results may cause inconvenience and anxiety in patients.¹⁷ It must also be considered that pelvic malignancy prevalence rates in this premenopausal population are relatively low.

Although patients taking oral contraceptive or hormone therapy are generally 'well women', it is acknowledged that the effect on breast and pelvic disease by the two medication groups may be different. Oral contraception use is known to reduce the risk of ovarian cancer and fibroids, while the role of hormone therapy is unclear. The most significant factor contributing to disease incidence is the patient's age rather than the medication they are taking. This factor alone does not justify the pelvic examination as screening for well women.18

Recommendations

- The use of routine pelvic examination as screening for ovarian malignancy (with or without serum CA-125 and ultrasound) cannot be justified due to the low prevalence of the disease and low sensitivity and specificity of the examination.
- Patients at high risk of ovarian cancer due to personal or family history should be referred to specialist care for individual consideration of screening practices.
- There is no evidence to support the necessity for pelvic examination of asymptomatic women taking hormone therapy or attending for a sexual health check.

- Pelvic examinations may be performed at the time of routine Pap tests to aid in technical issues with the smear itself, but are not recommended for screening purposes.
- Pelvic examination at a woman's request must be preceded by thorough gynaecological, medical and family history and after obtaining informed consent from the patient.

Informed consent

Informed consent should involve the following:

- discussion with the patient why she is requesting the examination
- explanation that a normal pelvic examination does not exclude pathology, particularly ovarian cancer
- the necessity to follow up any abnormal examination findings and the morbidity this may involve
- recommendation that the patient seek review if she develops gynaecological symptoms, even if a recent pelvic examination has been normal.

Conclusion

Although the evidence to date recommends against routine pelvic examination as a screening procedure for ovarian cancer, it must be remembered that there is no other useful and reliable method for detection of this indolent disease which has great morbidity, mortality, financial and emotional cost to individuals and the community.8,19 Guidelines for the performance of pelvic examination in asymptomatic women are varied and often unclear. No Australian guidelines could be found. The American Cancer Society advises annual pelvic examinations. The Canadian Task Force on the Periodic Health Examination and the US Preventive Services Taskforce indicate the examination is reasonable in conjunction with other examinations (eg. Pap test collection).9

Any request for pelvic examination in an asymptomatic woman, particularly with the aim of excluding ovarian cancer, must be undertaken after thorough history and discussion regarding the perceived accuracy of the examination to exclude or confirm disease. The frequency of performance of pelvic examinations in 'well women' by doctors and the attitudes surrounding such, are the focus of a current qualitative research study by this article's authors. Women must also be informed that any abnormalities

found must be investigated, with the likelihood that the pathology is benign and intervention would not change disease outcome.

Conflict of interest: none declared.

Acknowledgment

The researchers gratefully acknowledge the RACGP Research Foundation, through the Chris Silagy Research Scholarship, for their support for this project. This project is part of a larger study regarding routine breast and pelvic examination in well women funded by the scholarship.

References

- Carney P, Dietrich A, Freeman D, Mott L. The periodic health examination provided to asymptomatic older women. Ann Intern Med 1993;119:129-35.
- Frye C, Weisberg R. Increasing the incidence of routine pelvic examinations: behavioural medicine's contribution. Women Health 1994;21:33-55.
- Gupta S, Hogan R, Kirkman RJE. Experience of the first pelvic examination. Eur J Contracept Reprod Health Care 2001:6:34-8.
- Ferrini R. Screening asymptomatic women for ovarian cancer: American College of Preventive Medicine, Practice Policy Statement. Am J Prev Med 1997;13:444-6.
- National Institute of Health. Consensus Statement Online. Ovarian cancer: screening, treatment and follow up. NIH, 1994;12:1-30.
- US Preventive Services Task Force. Recommendations on ovarian cancer screening, guide to clinical preventive services. 2nd ed. Rockville: AHRQ, 1996.
- National Cancer Institute. Ovarian Cancer Research Results from the Prostate, Lung and Ovarian (PCLO) Cancer Screening Trial: fact sheet. Bethesda: NCI, July 2005.
- Runowicz C. Ovarian cancer screening. In: New York State Department of Health, genetic susceptibility to breast and ovarian cancer: assessment, counselling and testing guidelines. Appendix VI. New York: New York State DOH, October 1999.
- Padilla L, Radosevich D, Milad M. Limitations of the pelvic examination for evaluation of the female pelvic organs. Int J Gynecol Obstet 2005;88:84-8.
- Gladstone C. Screening for ovarian cancer. In: Canadian Task Force on the Periodic Health Examination. Canadian quide to clinical preventive health care. Ottawa: Health Canada, 1994;870-80.
- NLH Primary Care Question Answering Service. Is there any guideline available regarding whether pelvic examination should be done simultaneously when women have their routine three yearly cervical smear? How useful is this type of examination as a screening tool? Available at www. clinicalanswers.nhs.uk/ [Accessed July 2006].
- Grover S, Quinn M. Is there any value in bimanual pelvic examination as a screening test? Med J Aust 1995;162:396.
- Schachter J, Schafer M, Young M, Ott M. Routine pelvic examinations in asymptomatic young women. New Engl J Med 1996;334:1847-8.
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Position statement: Screening for the prevention of cervical cancer. Melbourne: RANZCOG, 2004.
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Position statement: Guidelines for gynaecological examinations and procedures. Melbourne: RANZCOG, 2004.
- The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Position statement: Joint guidelines on Pap smears. Melbourne: RANZCOG, 2004.

- 17. Scott A, Glasier A. Are routine breast and pelvic examinations necessary for women starting combined oral contraception? Hum Reprod Update 2004;10:449-52.
- Harrison-Woolrych M, Purdie D. Breast and pelvic examination in women taking hormone replacement therapy. Br J Obstet Gynaecol 2001;108:1201-3.
- Sivanesaratnam V. Gynecological cancer screening. Ann Acad Med Singapore 1989;18:75-9.

