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Withdrawal from familial ovarian cancer screening for surgery: Findings from a psychological evaluation study (PsyFOCS)

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ABSTRACT

Objective. A prospective psychological evaluation study of familial ovarian cancer screening (PsyFOCS) is underway in partnership with the UK Familial Ovarian Cancer Screening Study (UK FOCSS Phase 2). One of the aims of PsyFOCS is to examine factors associated with withdrawal from the UK FOCSS prior to the onset of 4-monthly screening.

Method. 1999 of 3224 women completed a baseline questionnaire. 110 (5.5%) women withdrew from screening prior to their first routine Phase 2 screen, of which 73 (66.4% of withdrawals) had withdrawn because they had undergone removal of their ovaries and fallopian tubes (withdrawn group). The comparison group consisted of 1868 women who remained on screening. The baseline questionnaire included measures of cancer-specific distress, anxiety, depression and illness perceptions.

Results. Logistic regression analysis indicated that having had prior annual (Phase 1) screening (OR = 13.34, $p < .01$), past experience of further tests (OR = 2.37, $p < .01$) and greater cancer-specific distress (OR = 1.38, $p < .01$) were associated with withdrawal for surgery. Belief in ageing as a cause of ovarian cancer was also associated with withdrawal (OR = 1.32, $p = .05$).

Conclusion. These cross-sectional data suggest that withdrawal from familial ovarian cancer screening may be influenced by both clinical and psychological factors. These may reflect women's experience of the drawbacks of screening and increased concern about ovarian cancer risk, as well as having opportunities to consider surgery as an alternative risk management strategy whilst using screening as an interim measure.

Introduction

Familial ovarian cancer (OC) accounts for approximately 10% of all OCs [1,2]. Currently the only risk management option known to effectively reduce risk of OC for these women is surgery to remove their ovaries and fallopian tubes [3]. This procedure is known as risk-reducing bilateral salpingo-oophorectomy (RRSO). RRSO may not be acceptable to some women because of the risks associated with surgery and anaesthesia as well as the resulting loss of fertility and immediate onset of the menopause if undertaken pre-menopausally. The UK Familial Ovarian Cancer Screening Study (UK FOCSS) is assessing the clinical effectiveness of familial ovarian cancer screening (OCS) using the tumour marker CA125 and ultrasound scans (UKCRN ID 1069; ISRCTN32794457). Phase 1 (P1) of UK FOCSS comprised an annual ultrasound scan and CA125 blood test. However in Phase 2 (P2), the frequency of CA125 blood tests was increased to 4-monthly following meta-analysis evidence suggesting that annual screening might not be frequent enough to identify early stage familial OC [4,5]. A psychological evaluation (the Psychological evaluation of Familial Ovarian Cancer Screening; PsyFOCS) is being conducted alongside UK FOCSS P2 to examine the emotional outcomes of screening. Given that a high participation rate is necessary for a clinically

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successful screening programme, a further important outcome of familial OCS is withdrawal from screening.

Psychological factors such as increased distress, anxiety and negative perceptions of OC risk may influence some women to withdraw from screening. Increased levels of distress and depression have been reported in women at high risk of OC [6,7]. Increases in anxiety have also been found in women following recalls for repeat OCS tests in intermediate and high risk groups [8–10]. Not only this, cancer-related anxiety has been shown to be associated with consideration of risk-reducing surgery in women who are at high genetic risk [11,12]. High perceived risk of OC has also been associated with non-adherence (unexplained absences) to OCS [13].

Demographic and clinical factors such as age and gene mutation status may also be associated with withdrawal from screening for surgery. For example, advancing age may be a factor in women's decisions to undergo surgery, since there are potentially fewer drawbacks to surgery as age increases. Indeed a number of studies have shown age to be associated with RRSO [14]. Previous studies have also shown an association between *BRCA1/2* mutation status and RRSO [14]. Testing positive for an OC predisposing gene may be associated with withdrawing from screening for surgery because it confirms high-risk status and women may therefore decide to opt for the greater security offered by RRSO, rather than the uncertainty of an experimental screening programme.

The Self-Regulatory Model (SRM) [15,16] provides a theoretical model for understanding the range of women's responses to their risk of OC. According to the SRM, once a health risk has been identified, individuals form a cognitive representation of the health threat (e.g. OC risk) and an emotional response to the threat. These thoughts (cognitive representations) and feelings (emotional responses) then influence how individuals cope with that health threat. Withdrawing from screening can be conceptualised as a strategy for coping with the risk of OC, and thoughts and feelings about OC risk may therefore be associated with withdrawal. As women may withdraw from screening to reduce their anxiety, we would expect that representations of OC risk and emotional responses to OC risk that are associated with increased anxiety would also be associated with withdrawal from screening. Indeed, Lancastle and colleagues [17] found that stronger negative feelings about OC risk and a greater belief that OCS can prevent the negative effects of OC or control the risk of getting OC are associated with greater cancer-specific distress in this cohort.

The present study examines factors associated with withdrawing from familial OCS before the first P2 blood test result in order to have surgery (removal of ovaries and fallopian tubes) using cross-sectional baseline data from the PsyFOCS study. It was hypothesised that withdrawal from screening would be associated with higher anxiety and cancer-specific distress, less belief in the effectiveness of screening, feeling that OC has more negative consequences, stronger negative feelings about OC risk, a clearer understanding of OC risk, past experience of further tests following OCS, testing positive for an OC predisposing gene mutation and increased age.

Methods

Sample

Women who had been recruited to UK FOCSS P2 were also invited to take part in PsyFOCS. The eligibility criteria for UK FOCSS included a significant family history of OC or breast cancer, being over the age of 35 and having at least one ovary or fallopian tube (see ukfocss.org.uk for full eligibility criteria). Women were all at increased genetic risk for OC (estimated ≥10% life time risk). Fig. 1 shows the recruitment into PsyFOCS and the exclusions made for the present analyses. The final sample consisted of 73 women who had withdrawn from screening for surgery before their first P2 blood test result (withdrawn group) and 1868 who continued with screening at least until after the result of their first P2 blood test (screening group).

Procedure

Having consented to UK FOCSS P2 women were sent a PsyFOCS invitation pack (including an invitation letter, information sheet, consent and non-consent form, questionnaire and pre-paid envelope). They completed the consent form and questionnaire if they wished to take part and the non-consent form if they did not. Reminder packs were sent 2 weeks after the invitation pack. Consent was sought for PsyFOCS participation and access to clinical information from UK FOCSS. The UK FOCSS research team notified the PsyFOCS research team when and why women withdrew from screening. The Eastern Multi Centre Research Ethics Committee approved the study (reference: 97/5/007).

Measures

Demographic and clinical information

Women were asked their marital status, highest level of education, ethnic group and whether they had been recalled for further tests following previous ovarian screening. Age at the time of first P2 blood test (screening group) or surgery/withdrawal (whichever event came first; withdrawn group) was calculated. Information on prior involvement in P1 of UK FOCSS and gene mutation status (along with the date of the laboratory result report) was gathered from the UK FOCSS database. The laboratory report date was used to estimate awareness of their gene mutation status at the time of starting screening, or withdrawal from screening. Four weeks on from the laboratory report date was used as the cut-off before which it was assumed that women would not have been aware of their gene status. This was chosen as the minimum time likely between the laboratory result report and the consultation to convey this information to women.[3] The interval between consenting to UK FOCSS P2 and starting the screening (being sent the first blood test pack) or withdrawal/surgery (if this was before the first blood test pack was sent) was derived from the UK FOCSS database. For some women this was a considerable interval of time (median = 12 weeks, maximum = 3 years) and as this might be associated with their withdrawal from P2 screening it was included in the analyses.

General distress

The Hospital Anxiety and Depression Scale (HADS) [18] measured general anxiety and depression (see Table 2 for example items). Each sub-scale of the measure includes 7 items on a 0 to 3 scale, anchored to how participants felt in the last week.

Cancer-specific distress

The Impact of Event Scale (IES) [19] measured the extent of unwanted intrusive thoughts and avoidance of such thoughts about risk of OC. This 15-item scale asked women to indicate the frequency of these in the last week and these items load onto a global IES distress score [19].

Beliefs about OC risk

Participants' beliefs about their OC risk were measured using an adapted version of the Illness Perception Questionnaire—Revised (IPQ-R) [20,17]. The measure included 10 sub-scales [17] which included elements of the SRM: perceived non-specific consequences of OC, perceived specific consequences of OC risk, personal control over OC risk, prevention/control over OC risk, understanding of OC risk, emotional representations of OC risk, detection of OC,

[3] Because the cut-off of 4 weeks was an estimate, the analyses were re-run using alternative cut-off points of 3 and 6 months. The results were unchanged.