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RESEARCH PAPERS

Anxiety, knowledge and satisfaction in women receiving false positive results on routine prenatal screening: a randomized controlled trial

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Abstract

The majority of women receiving an abnormal result on routine prenatal screening subsequently give birth to unaffected children. Previous studies have documented high levels of anxiety in women receiving such false positive results. In an attempt to reduce this anxiety, two methods of preparing women for undergoing such testing were compared: provision of detailed written information about maternal-serum α-fetoprotein testing; and anxiety management training. Eligible women were randomly allocated to one of five groups. Eighty-five women subsequently received false positive results on routine α-fetoprotein testing. There was some evidence that completing the study questionnaires had an anxiety-reducing effect. In contrast with the results of previous studies, there was no evidence that receipt of an abnormal α-fetoprotein result resulted in raised anxiety. Neither of the interventions, alone or in combination, had an effect upon anxiety following an abnormal α-fetoprotein result. Receipt of detailed written information however, led to women having more knowledge and being more satisfied with the amount of information that they had.

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One in three of the class groups reported that the classes had influenced the way they had dealt with worries. Although the interventions did not reduce anxiety in this study, there are other reasons for considering their incorporation into routine clinical practice.

Zusammenfassung

Die Mehrheit der Frauen, die bei pränatalem Routine-Screening einen abnormalen Befund erhalten, gebären jedoch gesunde Kinder. Vorhergegangene Studien haben hohe Besorgnis bei Frauen nachgewiesen, die solch falsch positive Befunde erhielten. In einem Versuch, diese Besorgnis zu verringern, wurden zwei Methoden zur Vorbereitung der Frauen auf diese Tests verglichen: das Bereitstellen von ausführlicher schriftlicher Information über den α-Fetoproteintest anhand des mütterlichen Serums und das Angst-Management-Training. Geeignete Frauen wurden willkürlich einer von fünf Gruppen zugeteilt. 85 Frauen erhielten in der Folge bei den α-Fetoprotein-Routinetest falsch positive Befunde. Es fanden sich Anzeichen dafür, daß das Ausfüllen des Fragebogens für die Studie die Angst verringerte. Im Gegensatz zu den Ergebnissen vorhergegangener Studien wurde nicht nachgewiesen, daß der Empfang eines abnormalen α-Fetoprotein-Befundes zu erhöhter Besorgnis führte. Erhielten die Frauen jedoch detaillierte schriftliche Information, so verfügten sie über größeres Wissen und waren zufriedener mit der Menge an Information, über die sie verfügten. Ein Frau von drei aus den Schulungsgruppen meldete, daß die Schulung die Art, mit der sie mit ihren Ängsten umgegangen war, beeinflußt hatte. Obgleich die Interventionen in dieser Studie die Ängste nicht reduzierten, liegen andere Gründe dafür vor, ihre Integration in die klinische Routinearbeit zu erwägen.

Résumé

La majorité des femmes ayant reçu un résultat dans le cadre d'un dépistage prénatal systématique ont par la suite donné naissance à des enfants normaux. Des études précédentes ont documenté le haut niveau d'anxiété chez les femmes ayant reçu de tels résultats positifs faux. Pour tenter de réduire ce niveau d'anxiété, on a comparé deux méthodes de préparation des femmes à ce type d'essai: communication d'informations écrites détaillées sur l'alpha-fétoprotéine du sérum maternel (AFP) et une formation visant à apprendre aux femmes à 'discipliner' leur anxiété. Des femmes convenant à l'étude ont été affectées au hasard à un de cinq groupes. Par la suite, quatre-vingt-cinq femmes ont reçu des résultats positifs erronés dans le cadre d'examens systématiques AFP. On a constaté certaines indications que le fait d'avoir rempli les

questionnaires associés à l'étude avait réduit le niveau d'anxiété. Par contraste avec les résultats d'études précédentes, il n'a existé aucune preuve que la réception d'un résultat AFP anormal ait augmenté l'anxiété. Aucune des deux interventions, seules ou combinées, n'a exercé d'influence sur l'anxiété suivant un résultat AFP anormal. Par contre, la communication d'informations écrites détaillées a eu pour résultat que les femmes concernées possédaient des connaissances plus poussées et étaient mieux satisfaites de la quantité d'informations reçues. Un groupe sur trois ayant reçu l'information a signalé que les cours avaient influé sur leur réaction à leurs inquiétudes. Bien que les interventions n'aient pas réduit l'anxiété dans le cadre de cette étude, il existe d'autres motifs justifiant leur incorporation dans la pratique clinique courante.

Introduction

Prenatal testing for fetal abnormalities is now almost universal in obstetric care. While the potential benefits are clear, the costs in terms of patient anxiety, with its attendant risk of perinatal complications, has led to controversy about implementation. This study seeks to determine how much of this anxiety can be reduced or avoided using techniques developed in other areas of medical care.

Extremely high levels of anxiety have been found both at the time of the test result and some weeks later in women who receive an abnormal result on first, but not subsequent testing[1-4]. For some, this concern continues late into pregnancy and even after the baby is born[5]. Raised anxiety during pregnancy is of particular concern not only because it creates distress in the short-term but also because it may adversely affect the health of both the women and her baby[6-9]. There are at least two methods of dealing with anxiety: giving information to prevent any increase in anxiety occurring; and offering anxiety management training to help cope with anxiety if it does occur.

Patients' knowledge about screening tests is poor. We have found that women with least knowledge of tests are less likely to have maternal serum α-fetoprotein screening, suggesting that lack of information may lead to failure to have a test[10,11]. But even amongst those having the test, knowledge is poor. For example, in a previous study 39% of the women could not identify whether they had had blood taken to test for spina bifida[12]. Women undergoing routine antenatal care report wanting more information than is generally given about tests[13].

Health professionals, including obstetricians, frequently express reservations about giving too much information to patients, being concerned that it may cause anxiety[14]. But it is equally likely that increasing information about a test will reduce anxiety. There is good evidence showing the benefits of providing patients with detailed information about their treatment and condition[15]. There has however, been no controlled study of the effects of giving differing amounts of information on levels of anxiety in women undergoing prenatal testing.

Pregnant women's fears concerning the well-being of their unborn children are probably universal[13]. Uncertainty and anxiety can be increased by tests. High levels of anxiety have been successfully reduced using psychological techniques in patients undergoing surgery and various diagnostic procedures[15]. These techniques, which we shall refer to as Anxiety Management Training (AMT), are currently the most effective methods of reducing the anxiety associated with undergoing a wide range of medical procedures.

The study is designed to evaluate both the minimum intervention likely to be of benefit (Information booklet) and a more complex intervention likely to produce the maximum benefit (Information Booklet and Anxiety Management).

The study set out to test two hypotheses. First, that providing patients with detailed information about prenatal screening increases patient knowledge, decreases patient anxiety and increases satisfaction with information received. The second hypothesis is that training in anxiety management techniques reduces anxiety in stressful situations.

Methods

Design

The study has a two-by-two design with women receiving a booklet or not and being offered an antenatal class or not. Women were randomly allocated to one of five groups. Three of the groups received interventions: one group was allocated to receive a booklet, another group was offered an early antenatal class and the third group was offered both. The remaining two groups acted as controls; one for the intervention groups, the other for questionnaire completion. The control group for questionnaire completion had half the number of subjects of the other four study groups.

Allocation to study group was determined by randomly allocating 140 antenatal follow-up clinics for the proceeding 28 weeks to the five groups. Subjects were therefore allocated to a study group as soon as the date of their follow-up appointment was known.

The three intervention groups and one of the control groups completed four questionnaires during their pregnancy: before any intervention and before the time when α-fetoprotein testing could take place; immediately after this time, but before α-fetoprotein results are available; shortly after test results are available; and in the third trimester of pregnancy, when any tests following an abnormal result would have been completed.

Subjects

All women up to 16 weeks pregnant, presenting for antenatal care at a London teaching hospital between December 1989 and June 1990 were eligible for inclusion in the study; 896 such women presented for care during the study period. Of these, 51 women were excluded as they were not eligible for the α-fetoprotein test: 39 had a miscarriage before the time when they would

have been eligible for the α-fetoprotein test, three women terminated their pregnancies and nine women went elsewhere for their antenatal care. In addition, 40 were not sufficiently fluent in English to complete the questionnaires unaided; 69 refused to participate; and 267 failed to complete all four questionnaires.

Of the 469 women who completed all the questionnaires, 42 had an abnormal α-fetoprotein result on initial testing, 21 were raised, indicating an increased risk of the fetus having an open neural tube defect; 21 were low, indicating an increased risk of Down's syndrome in the fetus. Data from these two groups were combined as the distributions of anxiety scores were similar, both in this and a previous study[16]. On 43 occasions the α-fetoprotein test was repeated, although the initial test did not provide an abnormally low or high result. An α-fetoprotein test was repeated when the gestation of the pregnancy as estimated from the woman's last menstrual period did not agree with the estimate from an ultrasound scan. These women did not necessarily know why they were having their test repeated. The women who had their α-fetoprotein test repeated did not differ in their levels of anxiety from the group who received an abnormal α-fetoprotein result. Given the relatively small sample size of women recalled following an abnormal result, data were combined from these two groups recalled following routine α-fetoprotein screening. As the study was investigating effects over time, only women for whom complete data were available are included in the analysis.

There were no differences between women who received an abnormal α-fetoprotein result and completed some questionnaires, and women who completed all questionnaires in age, marital status, place of birth, social class, parity, trait or state anxiety. No abnormalities were detected in any of the pregnancies of the women recalled.

Measures

Knowledge of the α-fetoprotein test This was assessed using a questionnaire consisting of 12 multiple-choice items. In addition to providing a Total Knowledge Score with a range of 0–12, principal components analysis with varimax rotation resulted in three factors: basic knowledge, familiarity and sophisticated knowledge (see Appendix 1 for details). The scores for the three factors were based on the weightings given to each item loading onto it. The score for basic knowledge ranged from 0 to 3.5; for familiarity the scores ranged from 0 to 1.8; and for sophisticated knowledge the range for the scores was 0 to 2.9.

Anxiety State and trait anxiety were assessed using the Spielberger State–Trait Anxiety Inventory[17]. Scores ranged from 20 to 80. The norm for females is 35.

Satisfaction with information Satisfaction with information about the α-fetoprotein test was assessed using two questions. First, subjects rated how

satisfied they were with the information they had received about the α-fetoprotein test, and the blood test for Down's syndrome where 1 = much too little information, 2 = too little information, 3 = enough information, 4 = too much information, and 5 = much too much information. Second, satisfaction with information received from the hospital was assessed using an eight-point rating scale from 0 (not at all satisfied) to 7 (extremely satisfied).

Self-reported effects of interventions The influence of receiving a booklet on *test uptake* was assessed by a multiple-choice question. Did the booklet influence your decision about having the test? The influence of the class on how women *dealt with worries* was assessed by the question Did the class influence how you dealt with any worries or concerns during your pregnancy? Women answered by ticking yes, no or don't know.

Demographic data Information concerning women's ages, socioeconomic status, country of origin, number and outcome of pregnancies, uptake and result of α-fetoprotein screening were taken from the women's medical notes. α-Fetoprotein results were double checked using laboratory records.

The interventions

The interventions were timed to fit in with the antenatal care system at the study hospital and to minimize the number of visits a woman would have to make to the hospital. The interventions took place after the completion of the first questionnaire and before the second questionnaire was distributed.

A booklet

The purpose of this booklet was to provide information about the α-fetoprotein test. The information in the booklet, entitled *The AFP Test*, was divided into seven chapters. Three points were emphasized:

(1) The α-fetoprotein test can help reduce uncertainty about the possibility of spina bifida and Down's syndrome;

(2) It is quite common to have an abnormal result; and

(3) Being asked to come back to the hospital because the α-fetoprotein result is abnormal does not mean that the baby is abnormal: it means that further tests are needed.

Copies of the booklet are available from the authors. Two standardized formulae were used to describe how easy the text is to understand[18]. The booklet had a SMOG rating of 10, meaning that it did not require a college education to understand, and a Flesch reading ease score of 64, denoting a standard text, with an estimated 83% of the population being able to understand it.

Women allocated to this group received the booklet after they had been seen by the midwife. Women were encouraged to spend 5 min with one of

the research staff who read through the booklet and answered any questions that arose. Women were given the booklet to take away to read and keep. If a subject was unable to spend time with a member of the research team then the booklet was either given to the woman as she left the antenatal clinic when she was encouraged to read it at home, or a copy was posted to the subject's home address with a covering letter explaining the arrival of the booklet and encouraging the woman to read it.

An early antenatal class

The purpose of this class was to discuss different methods of dealing with anxieties during pregnancy, and to train women in simple anxiety management. The class was structured to help women with any worries or anxieties; it was not aimed specifically at worries about prenatal testing or α-fetoprotein screening.

The early antenatal class was led by a clinical health psychologist. It was scheduled to last 1 h. The first part of the class was spent allowing women to discuss any worries about past or future events. Four methods of coping with worries and anxiety were introduced:

(1) Clarifying the cause of the worry, enabling problem-solving;

(2) Seeking and using information, to increase accurate expectations and perceived control;

(3) Talking to someone, enabling problem-solving and social support; and

(4) Use of distraction, to take one's mind off the worry.

The final 20 min were used to teach women how to relax.

Women received a leaflet at the end of the class which summarized the methods of coping, gave detailed relaxation instructions and helpful telephone numbers. Women who did not attend the class were either given the class leaflet as they left the clinic or it was sent out to them at their home address with a covering letter.

α-Fetoprotein screening for spina bifida and Down's syndrome

This is a routine screening test offered to all women attending the study hospital. It involves taking a sample of maternal blood at between 16 and 18 weeks pregnancy, the results of which can be used to determine whether the fetus is at increased risk of an open neural tube defect (general population risk, 3/1000 in S.E. England), and, for women aged 32 and over, Down's syndrome (overall risk, 1.4/1000).

The results are known after 1–2 weeks. If the test result is positive the woman is offered a diagnostic test (such as a detailed anomaly scan or amniocentesis). If a positive diagnosis is then made, she will be offered a termination of pregnancy. About 5% of women undergoing this test will be recalled as their first result will fall outside the normal range. Use of the test in screening for

Down's syndrome results only in a revision of the age-related risk. Diagnostic amniocentesis is offered to women at the study hospital with a revised risk of Down's syndrome that is greater than 1:200. While open neural tube defects and Down's syndrome are two of the more common serious birth defects, a negative result on this screening test means that only a minority of all birth abnormalities have been excluded. The uptake rate at the study hospital is about 90%, similar to the uptake rate reported in other UK centres.

Procedure

The information routinely provided to all pregnant women varies[19], but most usually information is provided about the conditions screened, the nature of the test, and the time in pregnancy when it is conducted.

Women were invited to participate in the study by researchers who were blind to the group to which the women would be allocated.

Women in the groups completing all four questionnaires were invited to participate in the study during their first visit to the antenatal clinic. The study design and the intervention groups were explained. Women were informed that they would be randomly allocated to one of four groups and that this meant that they could not choose their group and had an equal chance of being in any of the groups. If a woman agreed to participate she was given the first questionnaire to complete. Women made their appointments for their follow-up visit at the end of their first visit to the clinic. The group to which women were allocated was therefore determined before the α-fetoprotein test was carried out.

The researchers knew which women had been allocated to the fifth study group and did not invite them to participate. The design required that these women should know nothing about the study until they were invited to complete a questionnaire when they were between 28 and 36 weeks pregnant.

Women allocated to the fifth study group were approached at the time of their 28- or 36-week follow-up visit to the antenatal clinic and asked to complete a questionnaire.

Analysis

As this is a randomized controlled trial, analyses are performed on an 'intention to treat' basis, i.e. comparisons are made between those *allocated* to the different intervention groups in contrast to comparisons between those who *received* the different interventions. As the analyses compare the groups over time, only the women for whom full data were available are included.

Results

Anxiety

Women who received abnormal α-fetoprotein results did not show any rise in anxiety either at the time of receiving their results or later (Table 1). The

Table 1 Anxiety (means ± SD) in women receiving abnormal results in the five study groups

Study group	*Time 1 (Pretest and intervention)*	*Time 2 (Post-test and intervention)*	*Time 3 (3 weeks post-test and intervention)*	*Time 4 (28–36 weeks)*
Booklet ($n = 22$)	39.9 ± 12.3	39.4 ± 11.1	37.8 ± 9.6	39.2 ± 10.3
Class ($n = 14$)	38.5 ± 6.7	39.1 ± 9.0	40.6 ± 6.6	41.5 ± 10.0
Booklet & Class ($n = 23$)	36.5 ± 10.9	34.4 ± 7.1	39.9 ± 13.8	35.8 ± 7.2
Routine ($n = 10$)	37.9 ± 12.9	36.6 ± 10.3	37.3 ± 12.3	36.0 ± 9.6
Only 1 questionnaire ($n = 15$)	—	—	—	45.0 ± 10.3

pattern of anxiety for women receiving abnormal results was the same as that for women receiving normal results.

For women receiving abnormal results, there were no differences in anxiety between the study groups shortly after receipt of their results. In the third trimester the additional study group that had received no previous questionnaires were more anxious than the other four study groups, all of whom had received questionnaires on three prior occasions ($F(4,80) = 2.6$; $p < 0.05$).

Knowledge

Women allocated to receive the booklet had significantly more detailed information about α-fetoprotein testing ($F(3,66) = 5.8$; $p < 0.001$) and tended to have more information generally about the test ($F(3,66) = 2.53$; $p < 0.065$). Knowledge was unrelated to anxiety in any of the groups.

Satisfaction

While there was no difference in overall satisfaction with information received from the hospital, women who received a booklet were more satisfied with the information they had received on the α-fetoprotein test both at the time of testing ($F(1,64) = 4.9$; $p < 0.05$) and 3 weeks later ($F(1,66) = 4.4$; $p < 0.05$).

Self-reported behavior change

Sixteen per cent of the women who received the booklet indicated that it had influenced their decision about having the test. Of the women allocated to the class groups, 38% indicated that the class influenced how they dealt with their worries.

Discussion

The results of this study provide only partial support for the two study hypotheses. The provision of detailed information about α-fetoprotein testing was associated with an increase in patient knowledge and satisfaction with this information. No evidence was found to support the hypothesis that increased knowledge or attendance at early antenatal classes before testing reduced anxiety following an abnormal α-fetoprotein test result. The most likely explanation for these findings is that anxiety was not significantly raised in women who received abnormal α-fetoprotein results. This finding differs from the results of our previous studies documenting raised levels of anxiety in women receiving abnormal α-fetoprotein results[4,10]. It also differs from results of studies conducted by other groups[1–3,20].

There are at least two main reasons why we did not find raised levels of anxiety following an abnormal α-fetoprotein result. First, anxiety was not raised in the study population, and hence this is a valid finding. Anxiety may not have been raised because clinic practice had changed since our previous studies or changed as a result of the current study. We have no evidence regarding this. It seems likely that our earlier studies had highlighted this as an area of practice needing attention. Another possible explanation for why anxiety was not raised is that completing questionnaires in itself reduced anxiety. In the third trimester, the women who had not completed questionnaires earlier in pregnancy were more anxious. This may have been mediated by knowledge – completing questionnaires posed questions that women then sought to answer. This potentially reactive effect of questionnaire completion requires further study.

Alternatively, anxiety was raised in women receiving abnormal results, but the study methods failed to detect this. Previously we have measured anxiety in women with abnormal α-fetoprotein results when they have returned to the hospital for appointments to discuss their results. In the present study, women were sent postal questionnaires. It may be therefore, that women did not complete these at the height of their concerns about their results. Another possible explanation is that the more anxious women did not complete questionnaires, and so could not be included in the data. There was however, no difference in baseline measures of anxiety between those for whom there were complete data, and those for whom the collection was incomplete. This difficulty in determining why our intervention did not produce a predicted outcome points to the importance of assessing process as well as outcome in intervention studies.

Although the interventions did not reduce anxiety, there are other reasons to consider their incorporation into routine clinical practice. The booklet was successful in increasing women's knowledge about α-fetoprotein, and their satisfaction with the amount of information that they had about the test. While increasing women's knowledge did not reduce their anxiety, conversely, it did not increase anxiety as some people predict and fear[14]. It would therefore seem that providing women with detailed information about prenatal testing in written form would be a useful adjunct to the presentation of such tests in routine consultations.

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Appendix 1

Knowledge of α-fetoprotein

The first factor had an eigen value of 4.3 and accounted for 35.9% of the variance. The following questions loaded onto this factor (loadings are in brackets); What sort of sample is used to do the α-fetoprotein test? (0.78), When is the α-fetoprotein test performed? (0.74), Have you heard of the test for spina bifida? (0.73), Who is the α-fetoprotein test (test for spina bifida) routinely offered to? (0.66) and What conditions does the α-fetoprotein test screen for in all pregnant women? (0.56). This factor was labelled 'Basic Knowledge' and had a possible range of scores from 0 to 3.5.

The second factor had an eigen value of 1.4 and accounted for 11.5% of the variance. It comprised the following questions; Did you know that the α-fetoprotein test and the test for spina bifida are the same thing? (0.91) and Have you heard of the α-fetoprotein test? (0.89) and was labelled Familiarity with α-fetoprotein test, and had a possible range of scores from 0 to 1.8. This factor was labelled 'Familiarity'.

The third factor had an eigen value of 1.1 and accounted for 9.3% of the variance. The questions that loaded onto this factor were How many women are called back after their first α-fetoprotein result for further testing? (0.73), Most women who have an abnormal α-fetoprotein result have normal healthy babies (0.68), How long does it take for the results of an α-fetoprotein test to come back? (0.58), What conditions does the α-fetoprotein test screen for in women aged 32 or more? (0.49) and If the α-fetoprotein test is normal, the mother can be certain that everything is alright with the baby (0.40). This third factor was labelled 'Sophisticated Knowledge' and had a possible range of scores from 0 to 2.9.