

RESEARCH COMMUNICATION

Psychological Impact of Health Risk Appraisal of Korean Women at Different Levels of Breast Cancer Risk: Neglected Aspect of the Web-based Cancer Risk Assessment Tool

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Abstract

Objective: Health risk appraisal is often utilized to modify individual's health behavior, especially concerning disease prevention, and web-based health risk appraisal services are being provided to the general public in Korea. However, little is known about the psychological effect of the health risk appraisal even though poorly communicated information by the web-based service may result in unintended adverse health outcomes. This study was conducted to explore the psychological effect of health risk appraisal using epidemiological risk factor profile. **Methods:** We conducted a randomized trial comparing risk factor list type health risk appraisal and risk score type health risk appraisal. We studied 60 women aged 30 years and older who had no cancer. Anxiety level was assessed using the Spielberger State-Trait Anxiety Inventory YZ. **Results:** The results of multivariate analysis showed that risk status was the independent predictors of increase of state anxiety after health risk appraisal intervention when age, education, health risk appraisal type, numeracy, state anxiety, trait anxiety, and health risk appraisal type by risk status interaction was adjusted. Women who had higher risk status had an odd of having increased anxiety that was about 5 times greater than women who had lower risk status. **Conclusions:** Our findings indicate that communicating the risk status by individual health risk appraisal service can induce psychological sequelae, especially in women having higher risk status. Hospitals, institutes, or medical schools that are operating or planning to operate the online health risk appraisal service should take side effects such as psychological sequelae into consideration.

Key words: Risk assessment - breast cancer - risk communication - anxiety

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Introduction

Rapidly increasing investigations from basic and medical science have allowed us to understand various risk factors for many diseases. By virtue of these scientific advances, the risk notification by health risk appraisal (HRA) service is often utilized to modify individual's health behavior, especially on disease prevention (Doerr et al., 1981; Wagner et al., 1982). In recent study of systematic review reported that personalized risk communication seems to lead to increased uptake of cancer screening programmes (Edwards et al., 2003). The report suggested that further research should evaluate individual cognitive and affective outcomes of interventions using risk communication, and also suggested that it could be potentially harmful if interventions are not introduced carefully. Recent study indicated that communicating the risk status by HRA

service can have a negative effect in the promotion of health-conscious behavior (Park et al., 2010).

Even though psychological and ethical issues related to cancer risk notification have been raised by several studies (Lerman et al., 1991; Lerman et al., 1994; Lerman et al., 1995; Bowen et al., 1999; Cull et al., 1999; Cella et al., 2002), most studies have focused on genetic testing for cancer. Few studies are based on HRA using statistical models for predicting cancer risk. Moreover, most web-based HRA services are being provided to general public in spite of the fact that little is known about the psychological effect of the HRA service. Poorly communicated information by the web-based HRA services may result in unintended adverse health outcomes (Waters et al., 2009). In this study, we report the results of intervention study to explore the psychological effect of individual risk notification using epidemiological information.

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Materials and Methods

Study participants

The randomized trial was conducted between October and November 2009. We recruited study participants through advertisements in the websites for recruiting participants for panel study. A total of 75 women applied to participate in the study during the recruitment period of 30 days. Eligible women included those who age 40 and over, without a prior cancer diagnosis. All 60 women who were eligible received a call describing the study, and completed a baseline interview. Following the baseline interview, individuals were invited to participate in the trial, and 60 women who accepted were randomized to either the numerical HRA or the HRA using personal risk factor list. Participants did not know which group they had been assigned to until the intervention session began. Participants were contacted by telephone to conduct an interview for HRA according to the random assignment. Following the interview, individuals were asked whether they wanted to get the result of the HRA, and were invited to participate in the follow-up intervention study. One month after the telephone interview the original two groups of 60 women participated the meeting for the intervention sessions. The intervention sessions consist of four sessions: pre-HRA assessment for psychological status, providing HRA results, post-HRA assessment for psychological status, and counseling.

At the meeting the HRA results were provided in person attended by a preventive medicine doctor. Participants were asked to complete the questionnaire for psychological assessment before and after providing the HRA results. After completing the second assessment for psychological status after personal breast cancer risk notification by HRA, participants were guided to meet with a clinician for counseling. In addition to the disclosure of HRA results, participants were provided with medical recommendations and strategies to cope with personal risk, and referral to consultants and community resources, when appropriate. The counseling session included a cancer family history, a medical and cancer screening history, and information concerning the following: cancer and cancer predisposition, the risks, benefits, and limitations of HRA.

Types of interventions

The interventions were providing information on individualized risk for breast cancer. Firstly, personal risk factors were profiled and listed for the HRA using personal risk factor list, and general encouragement to acknowledge risks. Secondly, we used individualized lifetime risk score calculated by Gail model (Gail et al., 1989) for the numerical HRA. We explored the psychological effect of each intervention in terms of the individual risk level

Measurements

Sociodemographic variables included age, education,

and income. Breast cancer risk factors for numerical HRA included those which comprise the Gail model (Gail et al., 1989) factors (age, number of first degree relatives with breast cancer, number of previous breast biopsies, age at menarche, and age at first live birth). Breast cancer risk factors for risk factor list HRA included risk factors for breast cancer, such as height, weight, vegetable consumption, alcohol drinking, past history of benign breast disease, menstruation, and oral pill use (Colditz et al., 2000). This study was approved by the Institutional Review Board of the National Cancer Center.

The Spielberger State-Trait Anxiety Inventory YZ (STAI-KYZ Korean version) (Spielberger et al., 1970; Hahn et al., 1999), a validated self-reported questionnaire as a testing instrument, was used to assess the temporary condition of "state anxiety" and the more general and long-standing quality of "trait anxiety". The STAI-State asks respondents to indicate how they feel 'right now, at this moment' and to rate particular symptoms (for example, 'I feel strained') on a scale ranging from 'not at all' to 'very much so'. Scores range from 20 to 80.

Statistical Analysis

The analysis was conducted in three stages. First, descriptive statistics were produced to characterize the study participants in terms of the following variables: age; education; and personal risk status. Chi-square tests (for categorical variables) and t tests (for continuous variables) were conducted to compare subject in the numerical HRA group and the personal risk factor list HRA group in terms of baseline characteristics. Second, the STAI-State scores at pre-HRA and post-HRA were compared for the numerical HRA group and the personal risk factor list HRA group subjects using paired t tests. The analysis was stratified by risk status. The final step was to evaluate the independent and interacting effects of HRA type and HRA itself on state anxiety, using logistic regression modeling. Variables significant at $p < 0.1$ in the bivariate analysis were entered into the model using a stepwise selection method. All analyses were conducted using SPSS 12.0 statistical software (SPSS Inc., Chicago, IL).

Results

The Characteristics of the study population

There were no significant differences in demographic variables, numeracy, or anxiety level between study groups (Table 1). Ages ranged from 30 to 48, with a median of 38 years. The numeracy score, the number of risk factor, and the lifetime risk score were categorized into dichotomous variables based on the mean values. The average value (mean and standard deviation) for the numeracy score and the number of risk factors was 8.1 ± 2.1 and 2.5 ± 1.3 , respectively. The average estimated lifetime breast cancer risk based on the Gail model (Gail, et al., 1989) was 11.4 ± 2.5 . The average score on the measure of anxiety level using the Spielberger State-

Table 1. Characteristics of Study Participants (N=60)

| Variable | Subject sample | | P value |
|------------------------|-------------------------------------|-------------------------------|---------|
| | Risk factor list HRA group, No. (%) | Risk score HRA group, No. (%) | |
| Age | | | 1.00 |
| 30-39 | 18 (60.0) | 18 (60.0) | |
| 40-49 | 12 (40.0) | 12 (40.0) | |
| Education | | | 1.00 |
| ≤High school | 4 (13.3) | 4 (13.3) | |
| >High school | 26 (86.7) | 26 (86.7) | |
| Numeracy score | | | 0.30 |
| <9 | 17 (56.7) | 13 (43.3) | |
| ≥9 | 13 (43.3) | 17 (56.7) | |
| No. of risk factors | | | NA |
| 1-2 | 12 (40.0) | - | |
| ≥3 | 18 (60.0) | - | |
| Lifetime risk score, % | | | NA |
| <11.53 | - | 19 (63.3) | |
| ≥11.53 | - | 11 (36.7) | |
| Trait anxiety, mean±sd | 43.5±9.3 | 41.8±9.3 | 0.48 |
| State anxiety, mean±sd | 45.6±8.8 | 43.8±9.7 | 0.45 |

NA, not applicable; sd, standard deviation.

Table 2. Change in State Anxiety by HRA Type and Risk Status

| HRA type | Risk status | N (%) | Baseline Mean (SD) | Follow-up Mean (SD) | P value |
|-----------------------|---------------------|--------------|--------------------|---------------------|---------|
| Risk factor list type | All | 30 (100) | 43.5 (9.32) | 41.3 (8.33) | 0.21 |
| | No. of risk factors | | | | |
| | 1-2 | 14 (46.7) | 43.4 (7.10) | 38.9 (6.42) | 0.02 |
| ≥3 | 16 (53.3) | 43.5 (11.14) | 43.5 (9.37) | 0.75 | |
| Risk score type | All | 30 (100) | 41.8 (9.25) | 41.0 (10.57) | 0.18 |
| | Lifetime risk, % | | | | |
| | <11.53 | 25 (83.3) | 41.6 (9.53) | 39.8 (10.52) | 0.03 |
| ≥11.53 | 5 (16.7) | 42.8 (8.58) | 47.0 (9.62) | 0.23 | |

SD, standard deviation

Trait Anxiety Inventory YZ (STAI-KYZ Korean version) (Hahn, et al., 1999; Spielberg & Luschene, 1970) was 44.7±9.2 for trait anxiety and 42.6±9.2 for state anxiety.

Predictors of increase in state anxiety

As shown in Table 2, there was no overall change in state anxiety in both HRA type groups. However, there was significant decrease among women who had lower risk status in both HRA type groups. Although anxiety score increased among women who had higher risk status in risk score type HRA group, it was not statistically significant. The bivariate associations of demographic, HRA type, numeracy score, number of risk factors, lifetime risk score, and risk status with increase in state anxiety are shown in Table 3. Having higher risk status was significantly associated with increased status of state anxiety after the HRA intervention.

In order to identify the predictors of increase of state anxiety after HRA intervention, a multivariate analysis was performed (Table 4). Only risk status was the independent predictors of increase of state anxiety after HRA intervention when age, education, HRA type, numeracy, state anxiety, trait anxiety, and HRA type by

Table 3. Predictors of Increased Anxiety after HRA for Breast Cancer

| Variable | State of anxiety | | P value |
|-------------------------------|------------------------|--------------------|---------|
| | Not increased, No. (%) | Increased, No. (%) | |
| Age | | | 0.91 |
| 30-39 | 25 (69.4) | 11 (30.6) | |
| 40-49 | 17 (70.8) | 7 (29.2) | |
| Education | | | 0.25 |
| ≤High school | 7 (87.5) | 1 (12.5) | |
| >High school | 35 (67.3) | 17 (32.7) | |
| HRA type | | | 0.57 |
| Risk factor list type | 22 (73.3) | 8 (26.7) | |
| Risk score type | 20 (66.7) | 10 (33.3) | |
| Numeracy score | | | 0.57 |
| <9 | 22 (73.3) | 8 (26.7) | |
| ≥9 | 20 (66.7) | 10 (33.3) | |
| No. of risk factors (n=30) | | | 0.02 |
| 1-2 | 13 (92.9) | 1 (7.1) | |
| ≥3 | 9 (56.2) | 7 (43.8) | |
| Lifetime risk score, % (n=30) | | | 0.01 |
| <11.53 | 19 (76.0) | 6 (24.0) | |
| ≥11.53 | 1 (20.0) | 4 (80.0) | |
| Risk status | | | 0.01 |
| Lower* | 32 (82.1) | 7 (17.9) | |
| Higher† | 10 (47.6) | 11 (52.4) | |

* Either the number of risk factors was less than three or the lifetime risk was less than 11.53%; † Either the number of risk factors was greater than or equal to three or the lifetime risk was greater than or equal to 11.53%.

Table 4. Logistic Regression Analysis of Increased Anxiety after HRA for Breast Cancer

| Variable | *95% confidence interval for odds ratio | | | P value |
|-------------|---|-------|-------|---------|
| | Odds ratio | Lower | Upper | |
| Risk status | | | | |
| Lower§ | 1.00 | | | |
| Higher† | 5.03 | 1.54 | 16.43 | 0.01 |

* Adjusted for age, education, HRA type, numeracy, pre-HRA state anxiety, pre-HRA trait anxiety, and HRA type by risk status interaction.; § Either the number of risk factors was less than three or the lifetime risk was less than 11.53%; † Either the number of risk factors was greater than or equal to three or the lifetime risk was greater than or equal to 11.53%

risk status interaction was adjusted. Women who had higher risk status had an odd of having increased anxiety that was about 5 times greater than women who had lower risk status.

Discussion

In The present study showed that individualized HRA on breast cancer could lead to increased anxiety. Specifically, women who had higher risk status were more likely to have increased anxiety. Demographics, HRA type, numeracy, and pre-HRA state anxiety, and pre-HRA trait anxiety did not influence anxiety level. Although we expected some differences in the psychological effect between two HRA types, HRA type

was not a significant predictor for HRA-induced anxiety. The present study is the first to show that individual HRA using epidemiological risk factor profile instead of HRA using genetic tests.

Although it is not the cases of the epidemiological HRA, previous studies have reported psychological effect of the individual cancer risk notification using genetic tests. A preliminary examination of short-term psychological distress among women tested for the BRCA1 gene mutation associated with high risk of breast cancer showed that distress is highest among mutation carriers with no history of cancer (Croyle et al., 1997). Previously, we documented a poor association between risk perception and individual risk factor profile for breast cancer (Park et al., 2009). Since communicating individual risk is important to address the challenges associated with a gap between risk perception and real risk status, public health service such as internet based HRA could be considered as an effective tool for individual risk notification. However, our study showed that the psychological sequelae associated with cancer risk communication could occur as result of the HRA. Although internet based HRA has been emerging worldwide including Korea, because it usually omits face to face counseling or explanation by health professionals, certain kind of strategies or protocols are needed to minimize negative psychological impact.

There have been great efforts to develop communication strategies for individual cancer risk notification using genetic services (Yeomans, 1990; Vogel et al., 1993; Lerman et al., 1994; Ponder, 1994; Mahon et al., 1995; Thompson et al., 1995). However, there are few examples of communication guidelines for HRA using epidemiological risk factor profile. While there is increasing number of online cancer risk assessment services, we have the need to address the possibly harmful aspect of the services. Efforts should be made to help clients to understand the meaning of risk estimates and to be counseled properly if they want to. However, telephone counseling would be available at best in most cases when it comes to the online HRA service because of the cost and efficiency.

In interpreting the results of this randomized trial of breast cancer risk notification, one must consider several limitations of this study. Since the study population included a small sample of women who were recruited through advertisements in the websites, the population studied may not be representative of all women. Secondly, the validity of the prediction model used should be considered. Because there is no generally accepted risk prediction model for breast cancer for Asian women, we used the Gail model for risk score type HRA to calculate individual probability of developing breast cancer. However, since we used the model for the internal comparison in our intervention trial, the external validity of the Gail model may not be a serious problem. Even though this study tried to show the impact of the HRA using experimental design, this study could not explore

the long-term effect of the HRA because follow-up observation after HRA was included in the study design. Further intervention studies in this field need to include long-term follow-up and to evaluate more various psychological outcomes.

Our findings indicate that communicating the risk status by individual HRA service can induce psychological sequelae, especially in women having higher risk status. Further researches on cancer risk communication strategies for HRA service are required to explore long-term outcomes and to evaluate more various psychological outcomes. Hospitals, institutes, or medical schools that are operating or planning to operate the online HRA service should take side effects such as psychological sequelae into consideration. It will be critical to develop effective breast cancer risk communication guidelines in terms of HRA using epidemiological risk factor profile, which is being used for online based HRA services.

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