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Research Article

Contributions and Limitations of National Cervical Cancer Screening Program in Korea: A Retrospective Observational Study

Jung Hyun Lee, MPH, [1] Hyeongsu Kim, M.D., PhD, [1,*,☆] Heejung Choi, RN, Ph.D., [2] Hyoseon Jeong, Ph.D., [1] Young Ko, RN, Ph.D., [3] Seung-Hyuk Shim, M.D., [4] Eunjoo Lee, Ph.D., [5] Su Hyun Chae, M.D. [4]

[1] Department of Preventive Medicine, School of Medicine, Konkuk University, Seoul, Republic of Korea
[2] Department of Nursing, College of Nursing, Konkuk University, Seoul, Republic of Korea
[3] Department of Nursing, College of Nursing, Gachon University, Incheon, Republic of Korea
[4] Department of Obstetrics and Gynecology, School of Medicine, Konkuk University, Seoul, Republic of Korea
[5] Bigdata Steering Department, National Health Insurance Service, Wonju, Republic of Korea

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SUMMARY

Purpose: The purpose of this study was to evaluate the contributions and limitations of the cervical cancer screening test with accuracy in Korea.
Methods: This was a retrospective observational study. The study population consisted of all participants who underwent cervical cancer screening test from 2009 to 2014. The data were obtained from National Health Information Database (NHID) which represents medical use records of most Koreans. As the indices for contributions and limitations of the screening test, crude detection rate, incidence rate of interval cancer, sensitivity, specificity, and positive predictive value were used.
Results: The crude detection rate of screening test per 100,000 participants increased from 100.7 in 2009 to 102.1 in 2014. The incidence rate of interval cancer per 100,000 negatives decreased from 13.0 in 2009 to 10.2 in 2014. The sensitivities of screening test were 88.7% in 2009 and 91.2% in 2014, and the specificities were 98.5% in 2009 and 97.7% in 2014. The positive predictive value of screening decreased from 6.2% in 2009 to 4.3% in 2014.
Conclusion: The Korean national cervical cancer screening program has improved in accuracy and has contributed to detection of early stage of cervical cancer over the years. Along with efforts to promote participation in cancer screening programs, quality control over the screening program should be enhanced.

Introduction

Cervical cancer had been one of the three major cancers affecting women in Korea until 2000. As its incidence has been on a continuous decline in recent years, the age-adjusted incidence per 100,000 women has decreased from 18.6 in 1999 to 10.7 in 2014 [1], but the age-adjusted prevalence was still high 121.3 in 2014, and the age-adjusted mortality has increased from 6.6 in 2006 to 9.6 in 2016 [1,2]. The recent ranking of incidence, prevalence, and mortality of cervical cancer is sixth, fifth, and sixth highest, respectively, in cancers that affect women.

To ensure early detection of cervical cancer, a screening test with Papanicolaou (Pap) smear was introduced for recipients of Medical Aid in 1999 and was later expanded to include National Health Insurance beneficiaries [3]. The program has been run by the National Health Insurance Service (NHIS), and it was initially accessible biennially, for free of charge, and to all women aged ≥30 years. In 2016, the age limit was expanded to 20 years.

Although the actual participation rate of the screening test for cervical cancer has continuously increased, from 40.2% in 2010 to 52.0% in 2014 [4], it is still lower than that in Europe and North America, where screening programs for cervical cancer are well established; the 2012 participation rate was 73.4% in Canada, 73.6% in France, 78.1% in the United States, and 79.7% in Sweden [5].

To increase the participation rate, Korean health professionals still make efforts to make more specific health education contents including the accuracy and effectiveness of the screening test. The

* Correspondence to: Hyeongsu Kim, M.D., Ph.D., Department of Preventive Medicine, School of Medicine, Konkuk University, 120 Neungdong-ro, Gwangjin-gu, Seoul, 05029, Republic of Korea
E-mail address: mubul@kku.ac.kr
☆ ORCID: https://orcid.org/0000-0002-5379-134X

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reason is that the more accurate the screening test, the higher the participation rate can be expected. Some studies showed that health education about cervical cancer screening could increase screening participation through lower the perceived barriers and higher the perceived benefit to the screening test [6,7]. Information on the accuracy of the screening test can increase women's perceived benefit and ultimately increase participation in screening.

The accuracy of the screening test could be evaluated through the presentation of sensitivity and specificity, positive predictive value, and negative predictive value [8]. Furthermore, the clinical utility of the screening test would be assessed through the disease prevention and mortality rate [9]. Therefore, to evaluate the effectiveness of large-scale cervical cancer screening, research has been conducted on various aspects of screening tests such as the diagnostic accuracy [10–12], trends in cervical cancer incidence, mortality rates due to cervical cancer [13], the psychological side effects [14], and various other effects of screening test [15,16] in many other countries. However, no study has yet addressed the effectiveness and limitations of the screening test including the accuracy of this test since its introduction in Korea. Only factors influencing program participation including cognitive and behavioral parameters [17,18] have been explored. The effect of the screening test on early detection and prevention of cervical cancer should be reported to encourage more women to participate in the national cancer screening program. Because many Korean women, especially young adults, are not confident in the effect of the screening test [19], it is important to evaluate the effectiveness including diagnostic accuracy of the screening test to educate the necessity of participation in the screening test.

The purpose of this study was to evaluate the contributions and limitations of the screening test through the crude detection rate, the incidence rate of interval cancer, and the diagnostic accuracy such as the sensitivity, specificity, and positive predictive value.

Methods

Study design

This was a retrospective observational study. We obtained data of the screening test for cervical cancer collected from 2009 to 2014, combined with health insurance data for medical claim on cervical cancer treatment from January 2002 to August 2015, which were extracted from the National Health Information Database (NHID), with the consent of the NHIS (Approval no. NHIS-2017-1-038). The NHID is a public database on health-care utilization, health screening, sociodemographic variables, and mortality for the whole population of South Korea, formed by the National Health Insurance Service [20]. We utilized cervical cancer screening database (medical check-up DB) and the health insurance claim database (treatment DB) of NHID material to check the cervical cancer screening and the presence of cancer.

Setting and sampling

The target population consisted of women who participated in the screening test for cervical cancer from 2009 to 2014. Using the health claim data from 2002 to 2014, we excluded those who had been treated for cervical cancer before the screening date. The final numbers of study population included in the analyses were 2,680,984 in 2009, 2,694,573 in 2010, 3,356,852 in 2011, 3,454,471 in 2012, 3,514,542 in 2013, and 3,877,774 in 2014. The incidence of cervical cancer in this study was also limited to those who received a cervical cancer screening test.

Ethical consideration

This study was reviewed and approved by the Institutional Review Board of Konkuk University Hospital (Approval no. KUH1040057).

Data collection

The subjects were selected from combined data set which is a merge of the cervical cancer screening database and the health insurance claim database. Subject identification (ID), age, screening date, and results were retrieved from cervical cancer screening database, and subject ID, age, disease code (from 1st to 5th diagnose), treatment methods, special case registration, and the dates of visits to medical institutions were retrieved from the health insurance claim database. Then these two DBs were merged by same subject ID. Through this combined data set, we have checked the cervical cancer screening and the presence of cancer. The screening results were divided into as “normal,” “inflammatory disease,” “epithelial cell abnormalities,” “suspected cervical cancer,” and “other”. Of them, we classified “normal,” “inflammatory disease,” and “other” as “negative” and “epithelial cell abnormalities” and “suspected cervical cancer” as “positive”.

“Cervical cancer incidence” refers to the first detection of cancer. We measured this incidence based on the codes used in the health insurance claim data set, which employs the Korean Standard Classification of Diseases (C53: malignant neoplasm; D06: carcinoma *in situ* (CIS); and V193: special case registration for cancer). The date of first treatment (within 6 months from the screening date) was defined as the detection date; the absence of such treatment within 6 months was considered to reflect no cancer. Special case registration ensures that the economic burden imposed on patients diagnosed with cerebrovascular and heart diseases, cancer, intractable diseases, or severe burns is decreased by reducing the copayment for treatment by NHIS for 5 years. This system was introduced in July 2001 with the copayment of 20%, and it decreased to 10% in 2005 and to 5% in 2009. Malignant neoplasm and CIS of the cervix are included in the criteria for special case registration.

Measurements

We evaluated the contribution and the limitations of cervical cancer screening using the parameters of a previous study [21]. Positive rate of the screening test was calculated as basic information. Next, we calculated the crude detection rate and the incidence rate of interval cancer. Lastly, sensitivity, specificity, and positive predictive value of the screening test were calculated. Sensitivity and specificity are important indices for the accuracy of a screening test, but they do not have practical use when the clinicians estimate the probability of specific disease of an individual. So, predictive value can be used to evaluate probability of disease, and it depends on disease prevalence as well as sensitivity and specificity. The ability to understand and apply the value of validity indices of a screening test is very important for the experts including nurses who work in public health area or clinical setting. The definition and formula of each indices were as follows (Figure 1A) [8]: (1) positive rate of the screening test was the percentage of participants with positive screening results; (2) the crude detection rate of the screening test was defined as the number of subjects per 100,000 screening positive for cervical cancer; (3) the incidence rate of interval cancer was defined as the number of cervical cancer cases detected among 100,000 people with negative cervical cancer screening results; (4) the sensitivity of the test reflects the probability that the screening test will be