

RESEARCH ARTICLE

Cost-effectiveness Analysis of Cervical Cancer Screening Strategies Based on the Papanicolaou Smear Test in Korea

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Abstract

Background: Despite the increasing number of screening examinations performed for cervical cancer utilizing the Papanicolaou smear test (Pap test), few studies have examined whether this strategy is cost-effective in Korea. **Objective:** This study was conducted to evaluate the cost-effectiveness of cervical cancer screening strategies incorporating the Pap test based on age at the start and end of screening as well as screening interval. **Materials and Methods:** We designed four alternative screening strategies based on patient age when screening was started (20 or 30 years) and discontinued (lifetime, 79 years). Each strategy was assessed at screening intervals of 1, 2, 3, or 5 years. A Markov model was developed to determine the cost-effectiveness of the 16 possible cervical cancer screening strategies, and this was evaluated from a societal perspective. The main outcome measures were average lifetime cost, incremental quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratio (ICER). **Results:** Compared with various strategies comprising younger starting age, discontinuation age, and longer screening intervals, strategies employing annual screening for cervical cancer starting at a target age of 30 years and above were the most cost-effective, with an ICER of 21,012.98 dollars per QALY gained (with a Korean threshold of 30,000,000 KRW or US\$27,272). **Conclusions:** We found that annual screening for cervical cancer beginning at a target age of 30 years and above is most cost-effective screening strategy. Considering the potential economic advantages, more intense screening policies for cervical cancer might be favorable among countries with high rates of cervical cancer and relatively low screening costs.

Keywords: Cervical cancer - cancer screening - Pap smear test - HPV infection - economic evaluation

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Introduction

The benefits of screening for cervical cancer based on Papanicolaou smear test (Pap test) are well established; routine Pap testing has led to the decline in the incidence and mortality rate of cervical cancer (Canadian Task Force on Preventive Health Care, 2013; Sripilung et al., 2014). Indeed, after implementing a Pap test-based screening program in Korea, the age-adjusted incidence rate of cervical cancer per 100,000 women decreased noticeably from 16.3 in 1999 to 9.5 in 2012 (International Agency for Research on Cancer and World Health Organization, 2014). However, cervical cancer continues to rank as the sixth most common cancer in Korea (Jung et al., 2014), with an incidence 1.4 times higher than that of the USA in 2012 (International Agency for Research on Cancer and World Health Organization, 2014; Fernandez et al., 2014) despite a 17.58% increase in the number of screening examinations performed during the previous

6 years. Therefore, Korea now faces the challenge of implementing a screening program for cervical cancer to achieve increased effectiveness in terms of economics and clinical efficiency.

Korea implemented a biannual national screening program in 1999 targeting women aged 30 years and older for cervical cancer. The costs per case of screening and incidence of cervical cancer have a significant impact on the program's economic feasibility. The majority of previous economic studies on this screening program have focused on the relative cost-effectiveness of Pap tests compared with other tests, mainly the human papillomavirus (HPV) DNA test, at different screening intervals (Voko et al., 2012; Nahvijou et al., 2014). However, the costs associated with the HPV DNA test in Korea are 7 times greater than that of Pap test. Therefore, it would be preferable to identify effective screening strategies that utilize the Pap test rather than comparing screening test methods (de Kok et al., 2012). In addition,

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only a few studies have performed cost-benefit analyses with respect to the age at which screening is started and discontinued, and the intervals at which screening incorporating the Pap test is performed (Moyer et al., 2012).

Therefore, the purpose of this study was to evaluate the cost-effectiveness of cervical cancer screening strategies based on the age at which screening is started and discontinued as well as the screening interval for Pap-based testing.

Materials and Methods

Screening alternatives

We designed four alternative screening strategies depending on the age at which screening was started (20 or 30 years old) and discontinued (life-time, 79 years old). Each alternative was assessed at 1-, 2-, 3-, and 5-year screening intervals. A summary of the corresponding 16 strategies is shown in Table 1.

The study protocol was approved by the ethics review committee of the National Evidence-based Healthcare Collaborating Agency, Seoul, Republic of Korea.

Economic Evaluation

A cohort simulation Markov model was developed to determine the cost-effectiveness of the 16 alternative cervical cancer screening strategies from a societal perspective in terms of cost and health outcomes. All analyses were conducted using Microsoft Excel 2007 and TreeAge Pro Suite (TREEAGE Software Inc.; Williamstown, MA, USA).

Model Structure

A Markov model with a one-year cycle was developed using TreeAge pro. The natural history of cervical cancer was subdivided into the following five sequential stages based on Kim et al. (2007): well, HPV infection, cervical intraepithelial neoplasia 1 (CIN1), CIN2/3, and cervical

cancer. The target cohort consisted of 20-year-old Korean women, and the course of naturally developed cervical cancers was reviewed and followed. We hypothesized that progression from well to HPV infection, HPV infection to CIN1, and CIN1 to CIN2/3 would appear at distinct intervals, which has been noted previously for progression from HPV infection to CIN1 and CIN1 to CIN2/3 (Kim et al., 2007). In our model, individuals progressed from an infected state to the next level at an age-specific rate. Likewise, individuals also progressed from CIN2/3 to invasive cancer at a specific rate, and their cancer did not regress. We simulated the natural history of HPV-induced cervical dysplasia and incorporated standard procedures used in the screening, diagnosis, and treatment of precancerous lesions of the cervix.

Model inputs

All modeling assumptions and their sources are shown in Tables 2, 3, and 4.

Most of the input parameters were taken from the report by Kim et al. (2013). Korean data on the incidence of HPV infection and age-specific HPV incidence rates were derived from Shin et al. (2010). We estimated the rate of HPV infection by calibrating the age-specific HPV prevalence, frequency of sexual activity, and HPV infection-regression rate. We used health claims data from the National Health Insurance Service (NHIS) to estimate the probabilities of transitioning from CIN1 to CIN2/3 and from CIN2/3 to cervical cancer. The International Federation of Gynecology and Obstetrics (FIGO) annual report (Quinn et al, 2006) and data obtained from a review of previous studies were used to estimate the death rate for each health state. Furthermore, although information on Korea-specific cervical cancer mortality was available, it did not differentiate the increased risk in mortality as a function of increased severity of cervical cancer (i.e., stage 1 cervical cancer vs. stage 4 cervical cancer). Therefore, we employed the mortality rates of cervical cancer by stage reported by Lee et al. (2007), which we recalibrated to provide stage-specific cervical cancer mortality rates. Lastly, we used the national cancer screening rate reported by the NHIS to estimate the rate of screening.

Diagnostic accuracy

To ascertain the accuracy of cervical cancer screening methods in Korea, we performed a systematic review and meta-analysis for cervical cancer screening among asymptomatic women. We extracted sensitivity and specificity for the detection of CIN1 and CIN2/3, with colposcopy and histology reference standards. The sensitivity and specificity of CIN1 were 0.77 and 0.86, while those of CIN2/3 were 0.97 and 0.73, respectively.

Costs

All costs were converted to 2012 US dollars (\$) and discounted at a rate of 5%. In addition to actual medical costs, we took into account societal perspectives such as costs for patient time, caregivers, and transportation. Screening costs were set as the NHIS medical fee. Physician, outpatient, and inpatient costs for other diagnostic procedures and treatments were extracted from

Table 1. Overview of Screening Strategies for Cervical Cancer Using the Papanicolaou Smear Test

No.	Pap test strategy (interval, starting age, discontinuation age)	Interval	Starting age (years old)	Discontinuation (years old)
1	1, 20- lifetime	1 year	20	Lifetime
2	1, 20-79			79
3	1, 30- lifetime	2 years	30	Lifetime
4	1, 30-79			79
5	2, 20- lifetime	3 years	20	Lifetime
6	2, 20-79			79
7	2, 30- lifetime	30	30	Lifetime
8	2, 30-79			79
9	3, 20- lifetime	20	20	Lifetime
10	3, 20-79			79
11	3, 30- lifetime	30	30	Lifetime
12	3, 30-79			79
13	5, 20- lifetime	5 years	20	Lifetime
14	5, 20-79			79
15	5, 30- lifetime	30	30	Lifetime
16	5, 30-79			79

*Pap test, Papanicolaou smear test

NHIS claims data. We calculated the cost of screening for cervical cancer based on age-specific national cancer-screening rates and private cancer-screening rates. We computed the annual medical costs per patient diagnosed with CIN or cervical cancer from NHIS claims data, and estimated unofficial medical costs based on the results of

patient surveys. We estimated the costs for transportation, time, and caregivers from NHI claims data, patient surveys, and unit costs reported by Kim et al. (Kim et al., 2013). The sum of these costs was 17,437.77, 6,297.08, and 3,416.97 for initial cancer state, follow-up 1 year after initial treatment, and follow-up 2, 3, and 4 years after

Table 2. Disease Probability Input Parameters

Parameters	Probability	Source	Range
Progression probability			
Well history → HPV infection (age [y])		Calibration	0.000-0.260
Well → HPV infection (age [y])		Calibration	0.000-0.260
HPV infection → CIN1	0.025	Debichi (2008)	
HPV undetected → CIN1	0.025	Debichi (2008)	
CIN1 → CIN2/3 treatment	0.083	Kim (2013)	
CIN1 undetected → CIN2/3 treatment	0.13	Kim (2013)	
CIN2/3 → Initial cervical cancer stage treatment	0.0174	Kim (2013)	
CIN2/3 undetected → Initial cervical cancer stage treatment	0.13	Assumption	
Initial cervical Cx undetected → symptoms	0.15	Kim (2012)	
Initial cervical Cx → Cx 1-yr follow-up (age [y])		Kim (2012)	0.701-0.877
Cx 1-yr follow-up → Cx 2-yr follow-up (age [y])		Kim (2012)	0.761-0.931
Cx 2-yr follow-up → Cx 3-yr follow-up (age [y])		Kim (2012)	0.813-0.980
Cx 3-yr follow-up → Cx 4-yr follow-up (age [y])		Kim (2012)	0.813-0.980
Cx 4-yr follow-up → Cx cured (age [y])		Kim (2012)	0.813-0.980
Recurrent/Persistent Cx → Recurrent/Persistent Cx 1-yr follow-up	0.395	Lee (2007)	
Recurrent/Persistent Cx 1-yr follow-up → Recurrent/Persistent Cx 2-yr follow-up (age [y])		FIGO report & Lee (2007)	0.813-0.980
Recurrent/Persistent Cx 2-yr follow-up → Recurrent/Persistent Cx 3-yr follow-up (age [y])		FIGO report & Lee (2007)	0.813-0.980
Recurrent/Persistent Cx 3-yr follow-up → Recurrent/Persistent Cx 4-yr follow-up (age [y])		FIGO report & Lee (2007)	0.813-0.980
Recurrent/Persistent Cx 4-yr follow-up → Post Cx state (age [y])		FIGO report & Lee (2007)	0.813-0.980
Regression probability			
HPV infection → well (age [y])		Calibration	0.670-0.752
CIN1 → HPV infection or well	0.45	Debichi (2008)	
CIN2/3 → CIN1 or well	0.23	Debichi (2008)	
Proportion			
Proportion of CIN1_well	0.1	Assumption	
Proportion of CIN2/3_well	0.5	Assumption	

*HPV, human papillomavirus; CIN, cervical intraepithelial neoplasia; Cx, invasive cervical cancer; FIGO report, The International Federation of Gynecology and Obstetrics (FIGO) annual report

Table 3. Cost Input Parameters

Parameter	Total costs	Formal medical costs	Informal medical costs	Caregiver, transportation, patient time costs	Source
CIN1	2,521.70	227.25	2,186.36	108.09	Kim et al. (2013)
Undetected CIN1	107.63	0	0	107.63	
CIN2/3	5,000.67	735.16	3,781.05	484.45	
Undetected CIN2/3	417.6	0	0	417.6	
Initial cancer	17,437.77	7,875.80	5,655.68	3,906.28	
Follow up 1 yr after initial treatment	6,297.08	1,209.54	4,511.83	575.71	
Follow up 2, 3, and 4 yr after initial treatment	3,416.97	1,005.04	2,019.55	392.38	
Recurrent/persistent cancer	28,301.58	19,431.92	1,126.71	7,742.95	
Follow up 1 yr after recurrent/persistent cancer	4,248.22	2,985.73	96.99	1,165.49	
Follow up 2, 3, and 4 yr after recurrent/persistent cancer	4,967.41	2,985.73	818.22	1,163.45	
Screening fee	28.42	6.14	0	22.28	NHIS Claims data (2012)
Pap test	6.68	6.68	0	0	
Colposcopy test	40.67	40.67	0	0	

*CIN, cervical intraepithelial neoplasia; Pap test, Papanicolaou smear test; NHIS, National Health Insurance Service; Exchange rate: \$1=1,100 KRW

treatment, respectively.

Outcomes

Quality-adjusted life years (QALYs) were used as the primary measurement for assessing cost-effectiveness between alternative screening/testing algorithms (Table 4).

Cost-effectiveness analysis

The main outcome measures of the cost-effectiveness analysis were average lifetime cost, incremental QALYs, and incremental cost-effectiveness ratios (ICERs). We defined dominant screening strategies as those that offered more effective clinical outcomes (i.e., extended life expectancy) and cost less or had a more attractive cost per QALY than the next best option. The option of cervical cancer screening was dominated through extended dominance by other screening modalities. Differentiation reflected the fact that early detection and treatment of precancerous and cancer lesions alleviated some morbidity unaccounted for in the life years gained (LYG) measure.

Sensitivity analysis

Sensitivity analysis was conducted to reflect the uncertainty of variables. To better understand the impact on the results for different levels of participants along with the purpose of determining the validity of model results, sensitivity analysis was performed for Pap test accuracy, transition probability, and discount rate. We applied the lower and upper limits of the 95% confidence interval of mean accuracy, which was drawn from Kim et al.'s review of the literature (Kim et al., 2013). To consider differences in transition probability of CIN2/3 into cervical cancer, we applied a range of 50% and 1.74% (Moyer et al., 2012). In addition, we varied the assumptions for discount rates between 0%, 3.5%, and 7%.

Results

Economic evaluation

Cost-effectiveness results are shown in Table 5, which describe the lifetime costs and clinical benefits for different screening intervals. The strategy utilizing five-year intervals with target ages of 30 to 79 years old was the least expensive, but QALY was also reduced among the 16 strategies. Although the best QALY strategy was the one performed annually with a target age of 30 years and older, the cost was relatively substantial. Cost-effectiveness was dependent on the decision-makers' choice as to whether additional health gain was worth the additional cost (e.g., US\$27,272 per additional QALY gained). Under the Korean threshold of US\$27,272, the ICER for annual PAP screening starting at 30 years of age was US\$21,012.98, which was the most cost-effective. The next best was a biannual Pap test starting at 30 years of age, which had a cost of US\$13,258.43 per QALY.

Sensitivity analysis

We evaluated the robustness of our findings with sensitivity analyses. The magnitude of the incremental cost-effectiveness ratios remained unchanged when test accuracy was varied over a wide range of transition

probabilities instead of previously reported data.

Figure 1 shows the dependence of cost-effectiveness on discount rate. Decreasing the discount rate from 7% to 0% while also increasing starting age considerably lowered the ICER. For a discount rate of 7%, screening at two-year intervals with a target age of 30 years and above, which is the current Korean guideline, was the most cost-effective strategy. Figure 1 also shows the variability of results according to PAP test accuracy. For the lower limit of test accuracy, the most cost-effective strategy consisted of two-year screening intervals with a target age of 20 to 79 years. On the other hand, for the upper limit of test accuracy, the most cost-effective strategy consisted of two-year screening intervals with a target age of 20 years and above. After applying the transition probability of CIN2/3 into cervical cancer, which ranged from 1.74% to 50%, the best strategy consisted of 1-year interval screening with a target age range of 20 to 79 years.

Table 4. Utility Input Parameters

Parameters	Probability	Source
Well history state (age [y])	0.753-0.975	Kim et al. (2013)
Well state (age [y])	0.753-0.975	
HPV infection (age [y])	0.753-0.975	0.753-0.975
HPV infection undetected (age [y])	0.753-0.975	
CIN1	0.937	0.753-0.975
CIN1 undetected (age [y])	0.753-0.975	
CIN2/3	0.933	0.753-0.975
CIN2/3 undetected (age [y])	0.753-0.975	
Initial cancer	0.835	0.898
Follow up 1, 2, 3, and 4 yr after initial treatment	0.898	
Post cancer cure (age [y])	0.753-0.975	0.778
Recurrent/persistent cancer	0.778	
Follow up 1 yr after recurrent/persistent cancer	0.805	0.778
Follow up 2, 3, and 4 yr after recurrent/persistent cancer	0.778	

Table 5. Cost-effectiveness Results of Cervical Cancer Screening Strategies

Strategy (Interval, Target age)	Cost	QALY	ICER
PAP (5, 30-79)	223.23	17.950253	-
PAP (5, 20-lifetime)	286.72	17.953058	dominated
PAP (3, 30-79)	285.08	17.95349	dominated
PAP (5, 20-79)	303.29	17.953834	dominated
PAP (5, 30-lifetime)	223.27	17.953834	11.17
PAP (2, 30-79)	348.3	17.956353	dominated
PAP (3, 20-lifetime)	399.37	17.958563	dominated
PAP (3, 20-79)	423.16	17.95953	dominated
PAP (3, 30-lifetime)	285.1	17.95953	10,853.55
PAP (1, 30-79)	507.15	17.961365	dominated
PAP (2, 20-lifetime)	515.87	17.963248	dominated
PAP (2, 20-79)	545.14	17.9643	dominated
PAP (2, 30-lifetime)	348.34	17.9643	13,258.43
PAP (1, 20-lifetime)	798.49	17.970889	dominated
PAP (1, 20-79)	835.78	17.971852	dominated
PAP (1, 30-lifetime)	507.03	17.971852	21,012.98

*Pap test, Papanicolaou Smear Test; QALYs: quality-adjusted life-years; ICER: incremental cost-effectiveness ratios; Exchange rate: \$1=1,100 KRW

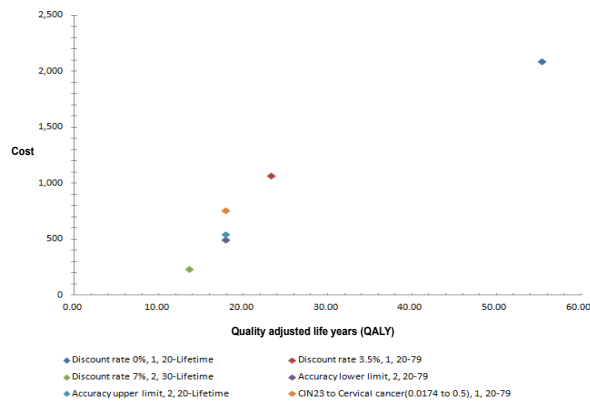


Figure 1. Sensitivity Analysis

Discussion

This study revealed 1) screening for cervical cancer with a target age of 30 years and above was the most cost-effective strategy with an ICER of US\$21,012.98 per QALY gained; and 2) annual screening was the most cost-effective strategy.

Western countries have previously recommended that annual screening for cervical cancer should start at an early age (Canadian Task Force on Preventive Health Care, 2013). In more recent years, the target age range for cervical cancer screening has narrowed, starting after 25 or 30 years of age and ending around 65 or 70 years of age based on clinical and economic aspects as well as government support (Moyer et al., 2012; Canadian Task Force on Preventive Health Care, 2013; Lee et al., 2013). However, the Korean Society of Gynecologic Oncology currently recommends that annual screening be performed for women ages 20 to 70 years based on the high incidence of cervical cancer, easy access to screening, and low medical cost in Korea (Lee et al., 2013).

The results of this study suggest that screening starting at 30 years of age is the most cost-effective approach. Specifically, there is a limited health gain for initiating screening in women under the age of 30 owing to the relatively low incidence of cervical disease. Although the overall incidence of cervical cancer in Korea was 11.7 per 100,000 in 2011, the age specific incidence for 25-29 years of age was 6.5, which is half that of the 30-34 age group (Ministry for Health and Welfare, 2011). Consistent with our findings, recommendations based on high-quality evidence suggest that routine screening for cervical cancer be performed for women 30 years of age and above (Canadian Task Force on Preventive Health Care, 2013; Netherlands Health council, 2011). Conversely, other guidelines based on moderate or weak-quality evidence recommend that screening be started between 20 and 25 years of age, and be performed at intervals of two or three years (de Kok et al., 2012; Canadian Task Force on Preventive Health Care, 2013; Australian Government, 2014).

An important result of this study was that no screening strategy with a discontinuation age of 79 years was cost-effective. Most cervical cancer screening policies suggest a discontinuation age of 65 to 70 years, under the assumption of appropriate previous screening (London,

2011; de Kok et al., 2012; Australian Government, 2014). However, there appears to be no substantial evidence to support such discontinuation, since the majority of studies we reviewed excluded this age group (Mun et al., 2011; Canadian Task Force on Preventive Health Care, 2013). In addition, protective effects of screening have been identified in women aged 65 to 70 years and above (Andrae et al., 2008). Indeed, the current consensus statement developed by US National Institutes of Health Consensus Development Conference Statement on Cervical Cancer encourages regular screening for women ages 65 and older, which is contrary to US Preventive Service Task Force guidelines (2012) (Lee et al., 2012). Moreover, Lee et al. (2013) emphasized the necessity of screening for cervical cancer among Korean women 65 years of age and older, since the incidence was double that of women under the age of 65.

With respect to the appropriate screening interval for cervical cancer, annual screening appears to be the most cost-effective strategy. Most western countries recommend an interval for cervical cancer screening of 3 or 5 years (de Kok et al., 2012; Canadian Task Force on Preventive Health Care, 2013; Lee et al., 2013). However, for countries with a high risk of cervical cancer and low screening costs, more intense guidelines may be beneficial. Specifically, such guidelines may recommend that it is necessary to begin screening at a younger age, end at an older age, and have a shorter interval between screenings (de Kok et al., 2012).

Overall, our results were susceptible to uncertainties of the model structure and input parameters, which is in line with other health economic models. Our results were also sensitive to the discount rate applied. Since the current investment will produce health benefits only after a long period of time, high discount rate devalues the benefits more than costs (Voko et al., 2012). When applying a transition probability of 1.74% rather than 50%, our results were sensitive and the ICER increased considerably.

Our study also had several limitations. First, several input parameters of the model including HPV infection rate and certain transition probabilities were estimated by calibration, since there were no available Korean data. However, in estimating the HPV infection rate, we tried to minimize this limitation by considering relevant empirical factors such as HPV prevalence, frequency of sexual activity, and HPV infection regression rate. Secondly, our analysis of cost-effectiveness was based on Korean cost data that has limited applicability to other healthcare settings. In particular, the cost related to the Pap test screening is much lower in Korea compared to other countries. However, costs were obtained from representative national data, which may be generalizable among countries with similar healthcare costs. Moreover, we considered various costs associated with patient time, caregivers, and transportation, in addition to direct medical costs. Lastly, the results of this study were sensitive to discount rate, Pap test accuracy, and transition probability.

In conclusion, the results of our study suggest that strategies employing annual screening for cervical cancer with a target age of 30 years and above are the most cost-effective in Korea. Considering the potential economic

advantages, more intense screening policies for cervical cancer may be favorable among countries with a high risk of cervical cancer and low screening costs.

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