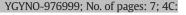
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Mean medical costs associated with vaginal and vulvar cancers for commercially insured patients in the United States and Texas

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HIGHLIGHTS

- Mean first year cost of new vaginal cancer cases in the U.S. was \$86,995.
- Mean second year cost of vaginal cancer cases in the U.S. was \$51,107.
- Mean first year cost of new vulvar cancer cases in the U.S. was \$37,657.
- Mean second year cost of vulvar cancer cases in the U.S. was \$19,139.

· Costs were associated with higher co-morbidities and pre-cancer cost.

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ABSTRACT

Objective. To estimate the average medical costs for vaginal and vulvar cancers in a commercially insured population in the U.S. and Texas.

Methods. 2011–2014 U.S. MarketScan databases were used to estimate the average medical costs associated with vaginal and vulvar cancers. Women with newly diagnosed vaginal or vulvar cancer were matched to a comparison group without cancer using propensity score. Year 1 and year 2 costs after index diagnosis date were estimated. A generalized linear model was used to estimate the cost for censored months. The differential costs between groups were defined as the net costs associated with cancer diagnosis and treatment.

Results. The analysis included 355 women with vaginal cancer and 997 with vulvar cancer in the U.S. The year 1 and year 2 costs for vaginal cancer were \$86,995 and \$51,107, respectively. The year 1 and year 2 costs for vulvar cancer were \$37,657 and \$19,139, respectively. The major factors associated with higher monthly vaginal and vulvar cancer costs were higher Charlson Comorbidity Index score and higher medical costs prior to cancer diagnosis. Monthly costs for vaginal and vulvar cancers decreased rapidly from month 1 to month 6 after diagnosis and then remained stable.

Conclusions. Seventy to 75% of all vaginal and vulvar cancers are due to HPV infections and mean medical costs associated with these cancers are substantial. These data will serve as key cost parameters in the economic evaluation of HPV vaccination dissemination and estimation of the long-term net economic benefit of promoting HPV vaccination.

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1. Introduction

https://doi.org/10.1016/j.ygyno.2017.12.019 0090-8258/© 2017 Elsevier Inc. All rights reserved. The U.S. Centers for Disease Control and Prevention estimates that about 5000 cases of vulvar cancer were diagnosed in the U.S. in 2013 and 1000 U.S. women died of the disease in the same year [1]. Vulvar cancer incidence in the U.S. ranges from 1.8 to 2.6 per 100,000 women per year and has not changed much over the past four decades [2]. The incidence is higher among white women, at 2.1 per 100,000, than in other groups, including blacks at 1.5, American Indian/Alaska Natives

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at 1.1, and Asian/Pacific Islanders at 0.4. The non-Hispanic rate is 2.1, while the Hispanic rate is 1.3. The Texas rate is 1.5, possibly reflecting the relatively large Hispanic population in the State [3].

Human papillomavirus (HPV) strains 16, 18, 31, 33, 45, 52, and 58 are risk factors for vulvar cancer, accounting for an estimated 70% of vulvar cancer cases [3]. Age is another major risk factor for vulvar cancer; less than 20% of cases are diagnosed in women younger than 50 years and over 50% are diagnosed in women older than 70 years. Invasive disease is more likely to be diagnosed in women older than 70, whereas non-invasive disease is more typically diagnosed in women aged about 50 years. Association of vulvar cancer with HPV is more common among younger women than older women [4]. Smoking is an additional risk factor for vulvar cancer, especially in woman infected with a high-risk strain of HPV.

HPV-related vulvar cancers start out as vulvar intraepithelial neoplasia (VIN). Most cases of VIN can be treated successfully and do not progress to invasive vulvar cancer. However, it is not now possible to determine which cases will advance, so careful monitoring is required. Additional risk factors include cervical precancer or cervical cancer, HIV infection and smoking. Chronic vulvar itching or burning of the vulva are early signs of vulvar dysplasia [5]. VIN can be treated topically, whereas vulvar cancer is treated, depending on the stage at detection and patient preference, with surgery, radiation therapy, and/or chemotherapy.

Vaginal cancer is relatively rare in the U.S., with 1312 cases diagnosed in 2014 and 430 women dying of the disease during the same period [6]. The age-adjusted incidence was higher among black women, at 0.9 per 100,000, than in other groups, including whites and Hispanics at 0.6 each and Asian/Pacific Islanders at 0.3 [1]. The Texas age-adjusted incidence was 0.7 in the 2010–2014 period [7]. About 75% of vaginal cancer cases are caused by HPV [8,9]. The median age at diagnosis of vaginal cancer is 67 years, with incidence monotonically increasing from near zero at age 35 years and the rate of increase rising slightly at age 65 years [10]. Additional risk factors include a history of pre-cancer of the cervix, HIV and smoking. Vaginal cancer is often asymptomatic in early stages [5]. Depending on the stage at detection and other factors, vaginal cancer may be treated with surgery, radiation therapy, and/or chemotherapy.

Healthcare cost estimates for vulvar and vaginal cancers used in leading HPV economic models, including that in a 2010 study by Elbasha and Dasbach, were taken from research by Hu and Goldie [11]. However, those cost estimates were derived from a survey of the literature and scenario analyses because of the lack of empirical studies on the lifetime costs of these cancers. These treatment cost estimates are not applicable to the current situation in the U.S. since they were based on 2003 US dollars (USD) and were rough approximations of lifetime costs. During 2013–2014, for males aged 18–59 years, prevalence of any genital HPV infection was 45.2% and that of high-risk HPV was 25.1%. During the same period, for females aged 18–59 years, prevalence of any genital HPV was 39.9% and of high-risk HPV was 20.4%. The rates were highest among non-Hispanic blacks and lowest among non-Hispanic Asians [12].

While HPV vaccination is highly effective at preventing HPV-related cancers, the U.S. immunization rate is low compared to other developed countries, where there has been a more concerted public effort to vaccinate [13]. Reagan-Steiner et al. found that, of U.S. adolescents aged 13 to 17 years, approximately 42% of females and 28% of males completed the HPV vaccination series of 3 doses; 52% and 39%, respectively, completed 2 doses [14]. Given the reluctance of most U.S. states to require HPV vaccination for schoolchildren, healthcare providers and public health agencies need to consider the economic and health consequences of expending resources to increase the HPV immunization rates. The costs associated with treatment of vaginal and vulvar cancer and other HPV-related conditions provide an important offset to immunization promotion efforts. Our purpose, therefore, was to determine the costs associated with a diagnosis of vulvar or vaginal cancer in women with commercial health insurance in the U.S. and Texas.

2. Methods

2.1. Data sources

We used the 2011–2014 U.S. Truven MarketScan Commercial Claims and Encounters (CCAE) databases to estimate the medical costs associated with vaginal and vulvar cancers. Truven MarketScan CCAE databases were part of the MarketScan databases created by Truven Health, which has created the MarketScan data warehouse to offer healthcare data on privately insured Americans. MarketScan claims databases have a very large sample size, with approximately 240 million covered lives since 1995 and 43.6 million covered lives in the most recent full year data, large enough to create a representative sample of people with the employer-provided health insurance. The databases come from approximately 350 private-sector payers each year and cover more than 90 million commercially insured populations across the U.S. in the study period. The databases are a main source for private health insurance cost studies of disease. Demographic, insurance enrollment, inpatient cost, outpatient cost, drug cost, and utilization information is available in the databases. MarketScan databases conform to the U.S. Health Insurance Portability and Accountability Act of 1996, and this study was exempted from submission for Institutional Review Board approval.

2.2. Study population

2.2.1. Cancer patient group selection

The study included all women who were newly diagnosed with vaginal or vulvar cancer during 2011 to 2014 who met our eligibility criteria; it also included a selected matched control population without cancer. To be eligible for the study, a patient had to 1) have at least one inpatient claim or two outpatient claims 30 days apart with primary or secondary diagnosis of vaginal or vulvar cancer (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9] diagnosis code: 184.0 for vaginal cancer, 184.1–184.8 for vulvar cancer); 2) have been continuously enrolled in the healthcare plan for 6 months before and 6 months after the index diagnosis date, where the index date was defined as the first date upon which the diagnosis was documented; 3) had no other cancer diagnosis before the index diagnosis date; and 4) be aged 18 years or older on the index diagnosis date. Patients with year 1 costs after the index diagnosis date greater than 1 million USD were deemed outliers and were excluded from the study.

2.2.2. Comparison group selection

The comparison group is important for estimating the cost of treating the cancers since each service component cannot be clearly identified as being utilized for treatment of the cancer. Thus, we measure total cost for the cases (all medical costs incurred during the study period) and total costs for matched controls who do not have a cancer diagnosis. The average difference is the cost attributed to the cancer diagnosis. The matched control population was selected by using a two-step matching process. First, all potential population controls in the database were randomly assigned an index date derived from those of the cancer patients. An initial control was selected if she 1) had the same index date as the cancer patient; 2) had no cancer ICD-9 diagnosis (140.0–208.9) during the 6-month period prior to the index date; 3) was of an age on the index date within 5 years of the age of the case; 4) was female; and 5) lived in the same U.S. census division (e.g., Pacific, Mountain, West North Central, etc.) as the case. Second, after the initial control group was selected, the propensity score matching method with Mahalanobis distance [15,16] was used to select a one-to-one matched control for each cancer patient. The following variables were used to calculate the distance between each cancer case and control: 1) Charlson Comorbidity Index (CCI) score in the 6-month period before the index date [17]; 2) number of psychiatric diagnosis groups in the 6-month period before the index date [18];

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