Evaluation of the Vulvar Cancer Histology Code Reported by Central Cancer Registries

Importance in Epidemiology

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• ***Context.***—**Knowing the subtype of vulvar cancer histology is important for estimating human papillomavirus–related cancer etiology. Surveillance of human papillomavirus–related vulvar cancers informs public health decisions related to vaccination against human papillomavirus.**

Objective.—**To assess the accuracy of registry classifications of vulvar cancer and determine the histologic classification of cases reported as not otherwise specified.**

Design.—**Pathology specimens were collected from Florida, Iowa, and Hawaii cancer registries. Registry diagnosis was compared with the pathology report from the medical record and a single expert study histology review of a representative histologic section from each case.**

Results.—**The study included 60 invasive vulvar squamous cell carcinoma (SCC) cases, 6 Paget disease cases, 2 basal cell carcinoma cases, and 53 in situ cases. Comparing subtypes of invasive vulvar SCC, the registry agreed with the pathology report classification in 49 of 60 cases (81.7%). Study histology review identified the same SCC subtype as the registry in 9 of 60 cases (15.0%) and the same SCC subtype as the pathology report in 11 of 60 cases (18.3%). Whereas the registry and pathology reports classified 37 and 34 cases, respectively, as being SCC not otherwise specified, the study histology review identified a more specific subtype in all cases.**

Conclusions.—**Subtypes of vulvar cancer were frequently recorded as not otherwise specified in the cancer registry primarily because the pathology report often did not specify the histologic subtype. Vulvar cancer registry data are useful for tracking broad diagnostic categories, but are less reliable for vulvar cancer subtypes.**

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Vulvar cancer is a rare malignancy that accounted for 4851 cases and 1034 deaths in the United States in 2012.[1] There are multiple histologic subtypes of vulvar cancer, and these subtypes differ by human papillomavirus (HPV) positivity prevalence, age group, and mortality.[2,3] Knowing the epidemiology of these different types is important because HPV-associated vulvar cancers could potentially be prevented by HPV vaccines.[2] Warty/basaloid vulvar squamous cell carcinomas (SCCs) are more likely to be associated with HPV, especially with types such as HPV-16 that are targeted by commercially available vaccines, and occur at a younger age than keratinizing SCC.[3–5] De Sanjosé et al[5] calculated an adjusted HPV prevalence of 69.5% in warty/basaloid vulvar SCC cases (n = 326) compared with 11.5% in keratinizing SCC cases (n = 1234).

Cancer registries have been instrumental in tracking cancer incidence and in guiding public health interventions.[6,7] The availability of detailed clinicopathologic data is particularly important for research on relatively rare cancers such as vulvar cancer.[2,8] Registry data must be accurate and comprehensive to be able to track regional, demographic, and cancer-specific trends.[9–11] Because certain subtypes (such as warty/basaloid) are more likely to be associated with HPV than other subtypes (such as keratinizing),

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knowing the epidemiology of these subtypes could help focus public health intervention and aid in identifying trends in histologic subtypes associated with HPV after HPV vaccine initiation.[2,3,12]

In their 2008 report using the National Program for Cancer Registries and the Surveillance, Epidemiology, and End Results (SEER) program, Saraiya et al[2] found that 1659 of 2266 (73.2%) of SCC cases in the registry were listed as not otherwise specified (NOS) by the International Classification of Diseases for Oncology (ICD-O) coding system. The NOS designation is applied to cases where a histology description is not reported as a specific subgroup, where the description has an adjective that does not appear elsewhere under a different code, or when only a broad, nonspecific category is documented.[13,14] The large proportion of vulvar cancer cases reported as NOS as opposed to a more specific classification in cancer registry data raises concerns about the reliability of the registry for informing public health intervention and identifying trends in histologic subtypes. It is unclear from the literature if the lack of subtype description is a result of how community pathologists describe vulvar cancer in pathology reports or if it is related to how cancer registries capture the content of clinical pathology reports. The goal of this study is to evaluate agreement among histologic classification recorded in cancer registries, pathology reports from the medical record, and a single expert review of a representative histologic section from each case and determine the histologic classification of cases reported as NOS.

MATERIALS AND METHODS

HPV Genotyping Study

Researchers working with the Centers for Disease Control and Prevention designed a study to assess baseline prevalence of HPV types in HPV-associated cancer cases from 4 population-based registries (Florida, Kentucky, Louisiana, and Michigan) and 3 registry-based residual tissue repositories (Hawaii, Iowa, and Los Angeles County). Institutional review board approval was obtained from the Centers for Disease Control and Prevention and all participating registries. The overall study, including pathology and laboratory procedures, is described in Saraiya et al,[15] and the vulvar study is described in Gargano et al.[4]

Briefly, the 7 population-based cancer registries/repositories submitted tissue samples and pathology reports to the Centers for Disease Control and Prevention containing cancer cases diagnosed from 1994 to 2005. For each vulvar cancer case, cancer registries obtained representative archived formalin-fixed, paraffin-embedded tissue blocks from local pathology laboratories or residual tissue repositories. One representative block was selected and serially sectioned, with the first and last sections being stained with hematoxylin-eosin to verify the sample was adequate for testing. The first hematoxylin-eosin section was digitized using ScanScope XT (Aperio Technologies, Vista, California). All cases were de-identified and cases were reassigned study identification numbers.[4,15] The present analysis was limited to invasive and in situ vulvar cancer cases identified by 3 of the registries (Iowa, Florida, and Hawaii) where de-identified pathology reports were available.

Study Histology Review

One study pathologist with expertise in vulvar pathology classified each invasive vulvar carcinoma case using the virtual Aperio slide without knowledge of the registry diagnosis. During this internal study histology review, samples were assigned histologic type and subtype (eg, nonkeratinizing SCC, keratinizing SCC).

Assigning ICD-O Codes

International Classification of Diseases for Oncology, 3rd edition (ICD-O-3) codes were assigned to both the study histology review and the pathology reports using the coding system published by the World Health Organization, which is the standard of coding for registrars in all US cancer registries.[13] This classification system and information regarding vulvar cancer subtypes are made available by the International Agency for Research on Cancer as part of the World Health Organization.[16,17] Coding rules were applied according to the National Cancer Institute's guidelines and the 1998 *SEER Program Code Manual*.[14] Coding per the SEER manual rules was used for all years in the study in order to keep the comparison uniform. The authors reviewed the pathology reports and used the ICD-O-3 coding system to assign a specific vulvar cancer group and subtype by ICD-O-3 code using a combination of the microscopic description and the impression/diagnosis statement.[13,14] Although the warty/verrucous (8051/3) and basaloid (8083/3) subtypes have distinct ICD-O-3 codes, for this analysis they were grouped into a combined warty/basaloid subgroup, as has been done previously.[4,5]

In Situ Cases

The in situ cases and associated pathology reports were an independent sample drawn from the same registry sources as were the invasive cases, but they were not related to the invasive cases in this study. In situ cases were not included in the histology slide review. In situ cases were classified as being vulvar intraepithelial neoplasia 3, vulvar intraepithelial neoplasia 2-3, or Bowen disease by the pathology report.

RESULTS

Histologic Diagnosis by Data Source

A total of 320 invasive vulvar cancer cases were available from the 7 registries/repositories from 1994 to 2005, which included 121 with available pathology reports. Of these cases, 68 had specimens available for study histology review and were included in the study (Table 1). Of 68 invasive cases, 33 were from Florida (48.5%), 20 were from Hawaii (29.4%), and 15 were from Iowa (22.1%). According to the registries, the 68 invasive vulvar carcinoma cases included 60 cases of invasive SCC, 6 cases of Paget disease, and 2 cases of basal cell carcinoma; there was 100% agreement among all 3 data sources regarding this general histologic diagnosis. Of 127 in situ cases, 53 had available pathology reports, which included 41 (77.4%) from Hawaii and 12 (22.6%) from Iowa.

The majority of invasive SCC cases were classified as SCC NOS in both the registry and pathology report reviews; the second most common diagnosis in both the registry and pathology report was keratinizing, NOS. In the study histology review, the most common SCC diagnosis was warty/basaloid, followed by keratinizing, NOS. Most in situ cases were classified as squamous intraepithelial neoplasia, grade III, by both the registry and the pathology report reviews.

Pathology Report Compared With Cancer Registry

The registry diagnosis agreed with the pathology report classification in 49 of 60 cancer cases (81.7%). In 30 of 60 cancer cases (50.0%), the registry and pathology reports agreed that a case's classification was SCC NOS. Table 2 illustrates the findings in the remaining 11 discrepant cases. In 7 of these discrepant cases, the registry listed the case as NOS, whereas the pathology report assigned a more specific diagnosis. In 4 cases, the registry listed a specific diagnosis, whereas the pathology report designated the case as NOS.

Table 1. Histology Classification (International Classification of Diseases for Oncology, 3rd Edition [ICD-O-3] Code) of Vulvar Cancer Cases as Identified by Registry, Pathology Report, and Study Histology Review in Iowa, Florida, and Hawaii, 1994–2005[a]

Diagnosis	Registry Report	Pathology Report	Study Histology Review
Invasive vulvar carcinoma (n = 68)			
Squamous cell carcinoma, invasive	60	60	60
Squamous cell carcinoma, NOS (8070/3)	37	34	0
Keratinizing, NOS (8071/3)	14	15	17
Nonkeratinizing, NOS (8072/3)	1	1	7
Warty (8051/3)/basaloid (8083/3)	3	4	36
Microinvasive/superficially invasive (8076/3)	3	4	0
Spindle cell (8074/3)	1	1	0
Papillary (8052/3)	1	1	0
Paget disease, extramammary (8542/3)	6	6	6
Basal cell carcinoma (8090/3)	2	2	2
In situ (n = 53)			
Squamous intraepithelial neoplasia, grade III (8077/2)	44	47	
Squamous cell carcinoma in situ, NOS (8070/2)	5	1	
Bowen disease (8081/2)	4	2	
Warty (8051/2)/basaloid (8083/2)	0	2	
Keratinizing, NOS (8071/2)	0	1	

Abbreviation: NOS, not otherwise specified.

[a] A final number of 3 in the ICD-O-3 code represents invasive cancers. A final number of 2 represents in situ cases.

In all 11 of these cases, the study histology review supplied a specific diagnosis, and this frequently disagreed with the specific diagnosis provided by the registry or pathology report. In 45 of the 53 in situ cases (84.9%), the registry listed the same in situ subtype as the pathology report.

Pathology Report Compared With Study Histology Review

The pathology report agreed with the subtype identified by the study histology review in 11 of 60 invasive SCC cases (18.3%), which included 8 keratinizing cases and 3 warty/basaloid cases. In 34 of 60 cases (56.7%), the pathology report was assigned a NOS designation when a specific subtype was identified on study review, which included 22 warty/basaloid, 8 keratinizing, and 4 nonkeratinizing cases. In 15 of 60 cases (25.0%), the study review identified a different subtype than the pathology report, as seen in Table 2.

Registry Compared With Study Histology Review

The registry record agreed with the subtype of the study histology review in 9 of 60 invasive SCC cases (15.0%), which included 7 keratinizing and 2 warty/basaloid cases. In 37 of 60 cases (61.7%), the registry applied a NOS classification when a specific subtype was identified on study review. Specifically, 23 of 37 cases (62.2%) classified SCC NOS in the registry were determined to be warty/

Table 2. Case Combinations of Invasive Vulvar Squamous Cell Carcinoma Among Registry Report, Pathology Report, and Study Histology Review, n = 60

No. of Cases	Registry Report	ICD-O-3 Code	Pathology Report	ICD-O-3 Code	Study Histology Review	ICD-O-3 Code
2	Warty/verrucous[a]	8051	Warty/verrucous[ab]	8051	Warty/basaloid[b]	8051/8083
1	Warty/verrucous[a]	8051	Warty/verrucous[a]	8051	Keratinizing	8071
1	Papillary[a]	8052	Papillary[a]	8052	Warty/basaloid	8051/8083
18	Not otherwise specified[a]	8070	Not otherwise specified[a]	8070	Warty/basaloid	8051/8083
8	Not otherwise specified[a]	8070	Not otherwise specified[a]	8070	Keratinizing	8071
4	Not otherwise specified[a]	8070	Not otherwise specified[a]	8070	Nonkeratinizing	8072
2	Not otherwise specified	8070	Keratinizing	8071	Warty/basaloid	8051/8083
1	Not otherwise specified	8070	Keratinizing[b]	8071	Keratinizing[b]	8071
1	Not otherwise specified	8070	Microinvasive	8076	Nonkeratinizing	8072
1	Not otherwise specified	8070	Microinvasive	8076	Warty/basaloid	8051/8083
1	Not otherwise specified	8070	Nonkeratinizing	8072	Warty/basaloid	8051/8083
1	Not otherwise specified	8070	Warty/verrucous[b]	8051	Warty/basaloid[b]	8051/8083
2	Keratinizing	8071	Not otherwise specified	8070	Warty/basaloid	8051/8083
7	Keratinizing[a]	8071	Keratinizing[ab]	8071	Keratinizing[b]	8071
4	Keratinizing[a]	8071	Keratinizing[a]	8071	Warty/basaloid	8051/8083
1	Keratinizing[a]	8071	Keratinizing[a]	8071	Nonkeratinizing	8072
1	Nonkeratinizing	8072	Not otherwise specified	8070	Warty/basaloid	8051/8083
1	Spindle cell[a]	8074	Spindle cell[a]	8074	Nonkeratinizing	8072
1	Microinvasive	8076	Not otherwise specified	8070	Warty/basaloid	8051/8083
2	Microinvasive[a]	8076	Microinvasive[a]	8076	Warty/basaloid	8051/8083

Abbreviation: ICD-O-3, *International Classification of Diseases for Oncology*, 3rd edition.

[a] Registry in agreement with pathology report.
[b] Study histology review in agreement with pathology report.

basaloid on study histology review; 9 (24.3%) were keratinizing, NOS; and 5 (13.5%) were nonkeratinizing, NOS. In 14 of 60 cases (23.3%), the study histology review identified a different subtype than the registry, as seen in Table 2.

DISCUSSION

This study found that registry classification closely reflected the pathology report, but a review of a representative histology section by a study pathologist frequently contradicted both. Submitting pathologists described cases without detailing histologic subtype, and therefore these cases were appropriately given NOS classifications by registrars. The observation of pathology and registry underrepresentation of the warty/basaloid subtype illustrates the degree to which the registry is less able to track this HPV-associated cancer subtype. This study suggests vulvar cancer registry data are useful for tracking broad diagnostic categories, but may be less reliable for vulvar cancer subtypes, especially warty/basaloid SCC.

The distribution of subtypes by study histology review showed that 52.9% (36 of 68) of cases were warty/basaloid, followed by 25.0% (17 of 68) keratinizing and 10.3% (7 of 68) nonkeratinizing. Results from this subset are consistent with the broader representation of registries previously reported without review of pathology reports.[4]

Comparing Pathology and Registry Reports With Study Histology Review

The study histology review did not find any NOS cases upon reviewing the pathology and, instead, found that all cases called SCC NOS by the pathology and registry reports could be categorized into one of the more specific ICD-O-3 subtypes. There are several possible reasons for the absence of histologic subtype in pathology reports. First, documentation of histologic subtype information may not be a priority for community pathologists and/or requesting physicians. The subtype often does not influence the recommended treatment, so may not be requested by the treating physician.[18] Additionally, vulvar cancer could be rare enough that pathologists may be unfamiliar with the specific ICD-O subtype.

Comparing Cancer Registry With Pathology Report

When comparing the registry designation with the pathology reports, this study found 83.8% agreement (57 of 68 invasive vulvar carcinoma cases) for invasive vulvar cancers, which is somewhat lower than previous studies reviewing cancer registry quality.[7,19] A study reviewing registry data quality for female breast cancer histology reviewed 9103 cases and found agreement in 92.6% to 99.5% of breast cancer pathology subtypes.[19] This finding may illustrate that vulvar cancer histology is less reliably reported by cancer registries; however, the study's smaller sample size could alternatively explain the lower agreement values. The classification differences between the registry and pathology reports detailed in Table 2 could represent cases where an alternative pathology report or section of the medical chart was used by the cancer registrar. However, the study histology review disagreed with the registry in all 11 of these cases, which suggests that some of the discrepancies may reflect the differences in how community pathologists report vulvar cancer when compared with the study histology review standard.

Of the in situ cases, 48 of 53 cases (90.6%) were given a specific subtype by the registry instead of a NOS classification. Of the 5 cases classified by the registry as NOS, the pathology reports agreed with 1 of these 5 cases. All 5 of the in situ cases classified by the registry as NOS, as opposed to a more specific diagnosis, were from a common state, which may indicate local variance regarding how such cases are classified.

Strengths and Limitations

The use of ICD-O-3 codes as applied to the pathology and study histology review was chosen as a way to measure the degree to which the registry and pathology reports contain information regarding the subtype of SCC. Because the ICD-O 2nd edition was transitioned to ICD-O-3 for cases diagnosed in 2001 and later, this method is limited in its ability to audit the quality of the registry data. The histology code for basaloid SCC (8083) and the adjective *warty* under code 8051 were not available for cases diagnosed through the year 2000, so the registry could only have used the SCC NOS code. However, although 11 of the 36 warty/basaloid cases were diagnosed prior to 2001, the pathology report of these cases did not contain any information that would have warranted classification as a basaloid (8083) or warty SCC (8051) using ICD-O-3 coding rules. Additionally, the ICD-O-3 code for warty SCC (8051) also contains verrucous carcinoma, which is a distinct clinical and pathologic entity.

This study was limited in its small sample size and representation from only 3 states: Florida, Iowa, and Hawaii. A study including other central cancer registries may be able to show more robustly the regional differences among specific registries and pathology laboratories. Additionally, the pathology report was the only element that was reviewed by this study from the medical chart. Although it is possible that a registrar could have gleaned a histology ICD-O diagnosis from elsewhere in the medical record or in direct, nonrecorded conversations with the physicians, it is likely that he or she would use the pathology report as the standard by which to base the specific histology diagnosis. An in situ case could have potentially been classified as invasive elsewhere in the medical record. Study histology review of pathology slides was not performed on in situ cases. Additionally, as one slide was reviewed for each case, it is possible that the representative specimen sent from the central cancer registry for study histology review was different or less well preserved than the original pathology sample. Finally, it is possible that other experts would disagree with the classifications made during this study histology review.

The newly accepted World Health Organization terminology, which uses the term *high-grade squamous intraepithelial lesions* (*vulvar intraepithelial neoplasia 2-3*) to replace the terms *vulvar intraepithelial neoplasia, dysplasia, carcinoma in situ*, and *Bowen disease*, may contribute to more consistency in the terminology and classification for these intraepithelial lesions.[17] The terminology for invasive squamous carcinomas of the vulva remains unchanged in the current World Health Organization classification. Increased documentation of histopathology code by ICD-O parameters by pathologists may be helpful in generating accurate pathology data that could be used to assess the impact of HPV vaccination on the burden of vulvar cancer in the United States.

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