Review of the screening history of Alberta women with invasive cervical cancer

Evidence

Études

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Abstract

Objective: To conduct a failure analysis of cervical cancer screening among women with invasive cervical cancer in Alberta.

Design: Descriptive study. Review of demographic, staging and treatment information from cancer registry records; generation of documented screening history from Alberta Health billing records and self-reported history from subjects who agreed to be interviewed; and comparison of findings in initial cytology reports with those from subsequent review by at least 2 pathologists of all cytology slides for each patient for the 5 years before diagnosis. Cases were assigned to 1 of 6 categories of identified screening failure.

Setting: Alberta.

Subjects: All women with diagnosis of invasive cervical cancer reported to a population-based provincial cancer registry from January 1990 to December 1991.

Outcome measures: Demographic, staging and treatment information; documented and self-reported screening histories; correlation of test results in initial cytology report with those generated from slide review; category of identified screening failure.

Results: Of the 246 women identified with invasive cancer of the cervix, 37 (15.0%) had stage IA disease; 195 (79.3%) had squamous-cell carcinoma, and 35 (14.2%) had adenocarcinoma. According to the categories of screening failure, 74 women (30.1%) had never been screened, 38 (15.4%) had not been screened within 3 years before diagnosis, 42 (17.1%) had had a false-negative cytology result, and 20 (8.1%) had been managed outside of conventional protocols. Of the 23 women (9.3%) who had been screened appropriately and had true-negative results, 19 had smears that were considered technically limited. It was not possible to classify 49 (19.9%) of the cases. Agreement between the documented and the self-reported screening histories was exact for only 39 (36.1%) of the 108 women interviewed.

Conclusions: Despite widespread use of opportunistic cervical screening, many women in Alberta are still not being screened adequately. In most cases women are being screened too infrequently or not at all. Self-reported screening histories are unreliable because many women may overestimate the number of smears. An organized approach to screening, as recommended by the National Workshop on Cervical Cancer Screening, may assist in reducing the incidence of invasive cervical cancer.

Résumé

Objectif : Analyser les défaillances du dépistage du cancer du col chez les Albertaines atteintes d'un cancer du col de type envahissant.

Conception : Étude descriptive. Analyse des renseignements liés à la démographie, à la détermination du stade et au traitement tirés de dossiers du registre du cancer; production d'antécédents documentés de dépistage tirés des dossiers de facturation du ministère de la Santé de l'Alberta et antécédents déclarés par les intéressées qui ont consenti à être interviewées; comparaison des résultats des premiers rapports de cytologie à ceux d'un examen effectué ultérieurement par

au moins 2 pathologistes qui ont examiné toutes les lames de cytologie de chaque patiente pendant les 5 ans qui ont précédé le diagnostic. Les cas ont été répartis entre 6 catégories de défaillances repérées du dépistage.

Contexte : Alberta.

Sujets : Toutes les femmes chez lesquelles on a diagnostiqué un cancer du col de type envahissant qui a été signalé à un registre provincial stratifié du cancer, de janvier 1990 à décembre 1991.

Mesures des résultats : Renseignements portant sur la démographie, la détermination du stade et le traitement; antécédents de dépistage documentés et déclarés par les intéressées; corrélation entre les résultats de test signalés dans le rapport initial de cytologie et ceux qu'ont produit un examen des lames; catégorie de défaillance du dépistage définie.

Résultats : Sur les 246 femmes chez lesquelles on a diagnostiqué un cancer du col de type envahissant, 37 (15,0 %) étaient au stade IA de la maladie, 195 (79,3 %) avaient un carcinome spinocellulaire et 35 (14,2 %) avaient un adénocarcinome. Selon les catégories de défaillances du dépistage, 74 femmes (30,1 %) n'avaient jamais subi d'examen de dépistage, 38 (15,4 %) n'avaient pas subi d'examen de dépistage au cours des 3 années qui ont précédé le diagnostic, 42 (17,1 %) avaient obtenu un résultat de cytologie faussement négatif et 20 (8,1 %) avaient été traitées autrement que par des protocoles classiques. Sur les 23 femmes (9,3 %) qui avaient fait l'objet d'un test de dépistage approprié dont les résultats étaient vraiment négatifs, les frottis ont été jugés limités sur le plan technique chez 19. On n'a pu classifier 49 (19,9 %) des cas. La concordance entre les antécédents de dépistage documentés et déclarés par les intéressées n'était exacte que pour 39 (36,1 %) des 108 femmes interviewées.

Conclusions : Malgré l'utilisation généralisée du dépistage opportun du cancer du col, beaucoup d'Albertaines font toujours l'objet d'un dépistage inadéquat. Dans la plupart des cas, les femmes se soumettent trop peu fréquemment ou pas du tout à un test de dépistage. Les antécédents de dépistage déclarés par les intéressées ne sont pas fiables parce que beaucoup de femmes peuvent surestimer le nombre de frottis prélevés. Une stratégie structurée de dépistage recommandée par l'Atelier national sur le dépistage du cancer du col peut aider à réduire l'incidence du cancer du col de type envahissant.

Exfoliative cervical cytology is effective in the early detection of invasive cervical cancer. However, in most countries such testing is done on an opportunistic basis and without the benefit of an organized comprehensive screening program. Comprehensive programs have been shown to be effective in reducing the incidence and mortality of invasive cervical cancer.[1] One could consider that each death from this disease represents a failure of the screening program.

The estimated age-standardized incidence rate of cervical cancer in 1996 was 8 per 100 000 women in Canada and 9 per 100 000 women in Alberta.[2] The incidence rate in England in 1986 was 15 per 100 000 women,[3] and in Iceland in 1991 it was 10.8 per 100 000 women.[4] Although, from an international perspective, the rates in Canada are enviably low, cervical cancer is still one of the few diseases for which programmatic screening can achieve a minimum number of cases of invasive cancer.

We undertook this study to identify factors associated with the failure of screening among women in Alberta found to have invasive cervical cancer in 1990 and 1991. Acknowledging that there is currently no comprehensive screening program for cervical cancer in Alberta and that screening is conducted on an opportunistic basis, our findings may provide a focus for the subsequent development of a comprehensive program.

Methods

Case series

All cases of invasive cervical cancer registered with the Alberta Cancer Registry from January 1990 to December 1991 were identified.[5] The registry has information on at least 95% of diagnosed cases and on slightly less than 100% of cancer-related deaths in the province. Demographic, staging and treatment information was abstracted from the records, and each case was assigned a unique identifier number for confidentiality.

Of the 272 patient records identified through the reg-

istry, 26 were excluded because, upon review, invasive cancer was not present (10 cases) or because the women were not living in Alberta at the time of diagnosis (10 cases); the remaining 6 cases were excluded for other reasons, including primary disease at another site and coding errors. This left 246 patient records for the study.

As part of the routine management of newly diagnosed cases at the regional cancer centres, histopathology slides (but not necessarily the cytology slides) for the specimens of biopsy or hysterectomy, or both, that established the diagnosis were requested from the referring laboratory for review. Most (89%) of the cases were reviewed in this manner by the consultant gynecologic pathologist at 1 of the 2 regional cancer centres before treatment. The remaining 11% were managed on the basis of the submitted external histopathology report without regional review because slides were unavailable for review. All reviewed slides were categorized, as a minimal diagnosis, as either squamous-cell carcinoma (microinvasive, invasive or other) or adenocarcinoma (in situ or invasive). Any nonepithelial diagnoses were not included in this review. The criteria of the Society of Gynecologic Oncology[6] were applied to distinguish between stages IA and IB disease.

Review of cytology smears

After the cancer registry records (the Alberta Health Care Insurance Plan number is coded on registry records) were linked to billing records in the Alberta Health database, we were able to obtain a screening history for each patient by recording the laboratory and the number of cytology smears billed to Alberta Health during the 5 years before the diagnosis of cervical cancer. Through the cooperation of the cytopathology laboratories, the slides of these cytology smears were requested for review by the consultant gynecologic pathologist at the study centre. Because at least 1 of the large public laboratory does not submit an itemized bill to Alberta Health for cytology smears, this laboratory was approached separately for smears that matched the study population identifiers.

Smears were rescreened by a cytotechnologist, and any relevant clinical information was transferred to the data collection form. All slides were identified only by a randomly generated number. They were then reviewed independently by 2 of the 3 pathologists on the review panel. The 2 pathologists recorded their diagnosis using the modified Bethesda System[7] and submitted it on a specially designed data collection sheet.

Slides for which the initial diagnosis differed from that of the 2 panel members were identified and reviewed by the third member of the panel, who was the reference pathologist for the study (M.A.D.). Differences in diagnosis between the reference pathologist and the 2 review pathologists were resolved by consensus of all 3.

In addition to the study slides, negative cervical smears were included to ensure a level of quality assurance and to control for observer bias.

Structured interview

The purpose of the interview was to determine the women's self-reported screening history and correlate it with the documented Alberta Health records in order to determine whether the Alberta Health records are appropriate for identifying factors leading to screening failure. Ethical approval for the interview portion of the study was obtained from the University of Calgary Conjoint Medical Ethics Committee and the Alberta Cancer Board Research Ethics Committee.

The referring physicians of patients who were identified through the cancer registry were asked for consent to approach the patients for an interview. Only women less than 69 years of age were considered. We chose this cutoff point because it is acknowledged that in a comprehensive screening program in Canada, screening would not routinely continue beyond 69.[8] A letter was then sent to the women requesting an interview at their convenience.

The structured format for the interview had been pilot-tested on a small group of patients whose cancer had been diagnosed before 1990. Questions were included that assessed the patient's general health, attitudes and knowledge regarding cervical cytology smears, self-reported history of cervical cancer screening, history of contraception use, smoking history, residence history and social descriptors. Women were asked about their screening history in the 5 years before the diagnosis of cancer; screening episodes recalled in the year of diagnosis were excluded from the analysis because many women had several smears obtained immediately before the diagnosis.

All interviews were conducted by 1 of 3 trained interviewers from January to October 1993 and recorded on a formal data-entry sheet.

Classification of screening failures

After the cytology review data were collated with the period of coverage on the provincial health insurance plan and the interview data, the cases were classified into 1 of the following 6 categories of screening failure. Classification was done independently by 2 of the principal investigators (G.C.E.S. and S.E.M.), and any discrepancies were resolved by joint review.

- Never screened: cases in which there was no record of screening in the Alberta Health records during the study period and no history of screening in their life-

time was reported by the women during the interview.

- Underscreened: cases in which there was no record of screening in the Alberta Health records for at least 3 years before the diagnosis for women living in the province during that period and no history of screening in that period reported by the women during the interview.
- False-negative result: cases in which the cytology review panel detected at least 1 smear with an abnormality at least 2 levels greater than that recorded in the initial report; that is, the smear was recorded in the initial cytology report as being normal or benign but was subsequently diagnosed by the panel as a low-grade squamous-cell intraepithelial lesion or worse, which would have, under normal clinical circumstances, warranted intervention.
- "Off-protocol" management or follow-up: cases in which the Alberta Health records indicated an appropriate frequency of screening and consistent nonmalignant diagnoses after review but the women did not comply with or receive appropriate management or follow-up.
- True-negative result: cases in which women had been screened at least once in the 3 years before the diagnosis and had no significant abnormality recorded in either the initial cytology report or the panel's report. In this category, smears were termed "technically limited" or "technically adequate" if endocervical or squamous cells were absent or present on the slides. This may reflect a failure to sample the transformation zone adequately.
- Unable to classify: Cases in which women reported a history of screening within the 3 years before the diagnosis but the cytology records could not be confirmed through either Alberta Health records or the laboratory.

All data were then collated and entered into a computer database by a research assistant with the use of EpiInfo software (version 5.01b; US Centers for Disease Control and Prevention, Atlanta). The data were analysed with the use of SAS statistical software (SAS Institute Inc., Cary, NC).

Results

Most of the women (110 [44.7%]) were 35–49 years of age. Only 33 women (13.4%) were over 69 years old. Twenty-one patients (9.3%) were nulligravida.

At the time of diagnosis 37 (15.0%) of the women had stage IA cancer, 127 (51.6%) had stage IB disease, 46 (18.7%) had stage II disease, and 31 (12.6%) had stage III or IV disease. Four patients were diagnosed clinically as having advanced disease and 1 was diagnosed with squamous-cell carcinoma of the cervix at autopsy following a motor vehicle accident. One woman who had 2 primary lesions (stage IA squamous-cell carcinoma and stage IB adenocarcinoma) was classified as having stage IB adenocarcinoma.

In all, 198 women (80.5%) had a squamous-cell carcinoma, 36 (14.6%) had an adenocarcinoma, 9 (3.7%) had an adenosquamous carcinoma, and 3 (1.2%) had an epithelial carcinoma that was not otherwise defined. Four of the patients had an epithelial carcinoma, but the histology could not be verified.

A total of 558 slides were requested for review from 14 laboratories (range 0–10 slides per patient). One laboratory (accounting for 2 slides) was unable to participate in the review. Of the slides requested, 424 (76.0%) were received. This included 40 that were obtained either within 1 week before cancer diagnosis or after the diagnosis was established. We reviewed these slides separately because we assumed that they were probably obtained not for screening but instead for establishing the diagnosis. The results of the review are presented in Table 1.

Measurement of agreement between the diagnoses in the original cytology reports and the panel's diagnoses gave a kappa value of 0.39 (standard deviation [SD] 0.023) when the 6 categories of normal to invasive were used to classify the smears. After the categories "benign atypia" and "atypical squamous cells of uncertain significance" were collapsed (because the latter classification was not generally used over the entire period of the slide review) the kappa value was 0.42 (SD 0.026). Although both of these measures of agreement were statistically significant ($p < 0.001$), indicating agreement beyond that expected by chance, the level of agreement is considered to be fair.[9] The level of variance in this analysis is likely underestimated because multiple slides were included for some women.

Only the 204 women less than 69 years of age were considered for the structured interview. Of these, 81 were excluded for the following reasons: death (29), tracking problem (patient moved or could not be located) (22), language barrier (11), severity of illness (7), physician's refusal to give consent to contact patient (8) and other (4). Of the remaining 123 women 108 (87.8%) agreed to be interviewed. Information obtained from these interviews that was not directly relevant to our primary objective of identifying factors associated with a failure of screening will be the subject of a subsequent report. Here, we present only the responses that directly support the validity of the screening history generated by the Alberta Health records.

The Alberta Health billing records were in agreement with the self-reported screening history for 39 (36.1%) of the 108 women interviewed; 24 of the 39 women had no

record of a smear within the previous 3 years. Forty-two women (38.9%) overestimated the number of smears in the previous 5 years and 20 (18.5%) underestimated the number. Most (66%) of these 62 women had erred by only 1 number.

The premise of our review was that each patient with invasive cervical cancer represented a failure of screening that could be attributed to one of the identified categories. To categorize the women by reason of screening failure, we included the smears obtained within 3 years before the date of diagnosis and excluded those obtained 90 days immediately before diagnosis. We collated the diagnoses in the initial cytology reports, the panel's diagnoses and the combined screening history from both the interviews and the billing records. From this, we found that the most common reason for screening failure was no history of screening (74 women [30.1%]) (Table 2). The 49 women (19.9%) in the category "unable to classify" included 31 for whom slides were unavailable for review, 11 who had no record of a cervical smear but because they had lived outside Alberta during the 3 years before diagnosis the Alberta Health record was not valid, and 7 for whom it was not possible to classify for other, miscellaneous reasons.

Discussion

Our main goal was to document the factors associated with the development of invasive cancer of the cervix in the context of opportunistic screening in Alberta. The most significant factor was that 30.1% of the women had never had a cervical cytology smear. In addition, 15.4% had not been screened in the 3 years before diagnosis. That 45.5% of these women had not been adequately screened confirms that not all women are reached

Table 1: Agreement between test results in initial cytology report and those generated from subsequent review of cytology slides by panel members for Alberta women with invasive cervical cancer from 1990 to 1991

Result in initial report*	Diagnosis by panel;* no. of women								
	Normal	Benign	ASCUS	LSIL	HSIL	Invasive	No diagnosis†	Other‡	Total
Normal	50	4	29	3	11	2	2	3	104
Benign	10	9	19	0	15	9	1	1	64
ASCUS	6	0	21	5	13	5	0	2	52
LSIL	0	0	2	10	24	5	0	0	41
HSIL	0	0	8	1	81	21	0	0	111
Invasive	0	0	1	0	1	28	0	0	30
No report received§	8	0	4	1	5	1	1	0	20
Other†	0	0	0	0	1	1	0	0	2
Total	74	13	84	20	151	72	4	6	424

*Benign = benign cellular changes, ASCUS = atypical squamous cells of uncertain significance, LSIL = low-grade squamous-cell intraepithelial lesion, HSIL = high-grade squamous-cell intraepithelial lesion.
†Miscellaneous cellular changes other than those listed.
‡Slides were viewed as technically unsuitable for interpretation.
§Slides were made available but without accompanying reports.

Table 2: Category of screening failure, by histologic type of cancer and age of women

Category*	Histologic type; no. (and %) of women		Age, yr; no. (and %) of women		Total	
	Squamous-cell carcinoma	Adenocarcinoma	≤ 49	≥ 50	No. (and %)	95% CI†
Never screened	62 (31.8)	12 (23.5)	31 (19.4)	43 (50.0)	74 (30.1)	24.4–36.2
Underscreened	35 (17.9)	3 (5.7)	24 (15.0)	14 (16.3)	38 (15.4)	11.2–20.6
False-negative result	31 (15.9)	11 (21.6)	35 (21.9)	7 (8.1)	42 (17.1)	12.6–22.4
Unconventional management or follow-up	14 (7.2)	6 (11.8)	17 (10.6)	3 (3.5)	20 (8.1)	5.0–12.3
True-negative result						
Technically limited smear	11 (5.6)	8 (15.7)	11 (6.9)	8 (9.3)	19 (7.7)	4.7–11.8
Technically adequate smear	4 (2.1)	0	2 (1.2)	2 (2.3)	4 (1.6)	0.4–4.1
Unable to classify	38 (19.5)	11 (21.6)	40 (25.0)	9 (10.5)	49 (19.9)	15.1–25.5
Total	195 (79.3)	51 (20.7)	160 (65.0)	86 (35.0)	246 (100.0)	

*See Methods for definitions of categories.
†CI = confidence interval.

through opportunistic screening. A third factor was that in 17.1% of the cases the result of at least 1 cervical smear had been falsely reported as negative in the initial report but was subsequently reported as abnormal (low-grade squamous-cell intraepithelial lesion or a higher grade lesion) after review by the panel. These 3 factors accounted for over two-thirds of the women in our study.

The need for high-quality laboratory services in the context of a comprehensive cervical cancer screening program has been repeatedly emphasized.[8] Although this was not the most important finding of our study, the false-negative rate of 17.1% is more striking if it is viewed as a proportion of women who had been screened at appropriate intervals. In Table 2, by discounting the categories "never screened" and "underscreened," one would be left with 85 women known to have had a cervical cytology test in the 3 years before diagnosis. Of these women, 42 (49.4%) had significant abnormalities that were not identified in the initial cytology report. This percentage would be even higher if any of the women with smears categorized as "unable to classify" were found to have a false-negative result.

Of the 23 patients (9.3%) who had been screened at least once in the 3 years before diagnosis and who had true-negative results, 19 had "technically limited" smears and 4 had "technically adequate" smears. The former category applied to smears at the time of review that showed no evidence of neoplastic cells but that also showed no evidence that the transformation zone had been sampled. This category may have also included specimens that were compromised by less than satisfactory processing. The limited sampling of the transformation zone may explain why the true-negative rate is higher than that usually reported in the literature for effective screening programs.[10]

Twenty (8.1%) of the women had an abnormality reported in the initial cytology report but did not receive optimal management or follow-up because of poor patient compliance, or lack of communication or poor management on the part of the health care provider. The impact of this factor in a failure analysis could be minimized by an information system that would allow for automatic recall of women with a reported abnormality and linkage to a colposcopy facility for subsequent follow-up. The magnitude of this factor suggests that there is a need for consistent guidelines for the management of women with abnormal results and appropriate quality-assurance methods. Our rate of 8.1% is consistent with rates in other reviews in the literature, such as that reported by Sasieni and associates.[11] They reviewed the screening history of 348 women with cervical cancer and found that 13% of those less than 70 did not receive appropriate follow-up of abnormal smears. They concluded that, in addition to the presence of guidelines, there must be a mechanism to ensure adherence.

Our findings are similar to those previously reported in the Canadian literature.[12–14] Carmichael and associates[13] reported that 61% of women in their study had never been screened, which is similar to the 57% reported by Sweet and collaborators.[14] These figures are much higher than ours, possibly because of the longitudinal context of their studies, which included women diagnosed up to 2 decades earlier. This would reflect a time when screening rates were probably lower. Also, the women in our study were fairly young on average, representing an age group that tends to have higher screening rates. None of the previous Canadian studies included a detailed cytology review.

A validated histologic report is essential to the relevance of this study. The observation that only 10 of the 272 women registered with a diagnosis of cervical cancer did not have invasive disease reflects a relatively stringent review process in the province at the time of diagnosis.

The self-reported screening histories did not correlate with the Alberta Health records in almost two-thirds of the cases. In most cases the women overestimated the frequency of screening, which is consistent with findings in the literature.[15,16] Many of the women for whom there was a discrepancy between the self-reported and the documented histories had 2 smears taken in 1 year, and the lack of detailed questioning during the interview may have resulted in a less than complete screening history being obtained at the time of the interview. Also, we were unable to correlate billing records with smears obtained at facilities with a global budget (e.g., birth control clinics and STD clinics). Both of these factors would tend to underestimate the correlation between the self-reported and the documented screening histories. However, the level of discrepancy is not likely to change the contribution of the different factors identified in the failure analysis.

The true impact on health of each of the factors identified in our screening failure analysis may not be ascertained except through a case–control study involving control subjects who do not have invasive cancer. This would more accurately identify the magnitude of each factor in the overall assessment of opportunistic screening. Quality-assurance methodology throughout the process must be a critical prerequisite to the development of a comprehensive program for population screening while strategies to increase recruitment are implemented.

A limitation of our study was the interval between the time of diagnosis and the period of the study. It was not possible to classify almost 20% of the women, mainly because the slides were not retrievable for review, but also because residence history could not be confirmed. In addition, only 53% of the patients eligible for the structured

interview agreed to be interviewed. It is likely that an interview at the time of diagnosis would be more acceptable to the woman. Implementation of a case review and evaluation of screening failure at the time of diagnosis would permit ongoing evaluation of screening efforts and provide information about how to improve the screening process in Alberta.

Conclusions

The fact that 246 women in Alberta were found to have invasive cervical cancer in a 2-year period demonstrates that secondary prevention has not been entirely successful in eradicating this disease. Most of these women had never had a cervical cytology test. Even 1 smear obtained during a woman's lifetime may reduce the incidence of cervical cancer dramatically.[17] Self-reported screening histories are unreliable because many women may overestimate the number of smears. The high false-negative rate and the number of cases managed outside of conventional protocols emphasize the need for high-quality laboratory services and information systems, as recommended by the National Workshop on Cervical Cancer Screening. The development of a provincially based comprehensive cervical cancer screening program would ensure that all women at risk are invited to have at least 1 cytology test and become part of such a program. Recruitment of women who have never been screened or are underscreened should be a primary goal of such a program.

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