Risk of Injuries around Diagnosis of Cervical Cancer and Its Precursor Lesions: A Nationwide Cohort Study in Sweden

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ABSTRACT

Background: Highly increased risk of injuries has been noted around the time of cancer diagnosis. Whether there is a similar increase in risk around the diagnosis of cervical cancer and its precursor lesions was unknown.

Methods: We performed a cohort study including 3,016,307 Swedish women that participated in cervical screening during 2001 to 2012. We calculated the incidence rates (IR) of hospitalized iatrogenic or noniatrogenic injuries during the diagnostic workup, and the time interval from smear or punch biopsy until surgical treatment or 2 months after the last smear or biopsy, among women with invasive cervical cancer (ICC) or its precursor lesions. We calculated the IRs of injuries during the 2 months after a normal smear among the other women as reference. IR ratios (IRR) and 95% confidence intervals (CI) were calculated using Poisson regression.

Results: Compared with other women, there was an increased rate of iatrogenic injuries during the diagnostic workup of women with ICC (IR, 0.58 per 1,000 person-months; IRR, 8.55; 95% CI, 3.69–19.80) as well as of women with cervical intraepithelial neoplasia grade 3 and adenocarcinoma *in situ* (IR, 0.09 per 1,000 person-months; IRR, 3.04; 95% CI, 1.73–5.34). We also found an increased rate of noniatrogenic injuries during the diagnostic workup of women with invasive cancer (IR, 0.65 per 1,000 person-months; IRR, 2.48; 95% CI, 1.30–4.47).

Conclusions: Although rare, there was an increased risk of inpatient care for iatrogenic and noniatrogenic injuries during the diagnostic workup of women with ICC.

Impact: Women experienced burden of medical complications and psychologic distress around diagnosis of a potential cervical cancer.

Introduction

Increased risks of iatrogenic injuries, as consequences of medical intervention, and noniatrogenic injuries, accidents and intentional self-harm, have been reported among patients with cancer (1–4). The usually invasive cancer treatment and the severe psychologic distress in relation to a cancer diagnosis might be the underlying reasons for such risk increase (2, 5). Injuries, in turn, might lead to prolonged hospital stay, impaired quality of life, permanent disability, and even death among patients with cancer (4, 6). In a previous study, we found that the risk of injuries, both iatrogenic and noniatrogenic, appeared to peak immediately before and after the date of cancer diagnosis, demonstrating that cancer diagnostic workup, commonly defined as the time interval between first suspicion of cancer until the diagnosis or start of treatment, might be a high-risk time window for injuries in cancer care (7).

In contrast to common cancer types, the risk of injuries has been much less studied among patients with cervical cancer, especially during the cervical diagnostic workup (8). To this end, we aimed to assess the risk of iatrogenic and noniatrogenic injuries during the diagnostic workup of cervical cancer or its precursor lesions, among all women in Sweden that participated in cervical screening during 2001–2012.

Materials and Methods

Study population

In Sweden, until 2017, women at ages 23 to 60 were invited to participate in cytology screening for cervical cancer every 3 (at ages 23–50) or 5 (at ages 51–60) years, and the coverage of cervical screening was around 80% nationally (9). The Swedish National Cervical Screening Registry (NKCx) comprises nationwide complete information on cytology results of Pap smears, histology results of punch biopsies, and surgical treatments for cervical cancer and its precursors from 1969 onward, including both the organized and opportunistic screening (10).

From the Swedish Total Population Register, we identified 3,016,307 women that were born from 1912 to 1990 in Sweden and were 18 or above during 2001 to 2012 (11). Through the personal identity numbers uniquely assigned to all residents in Sweden, we followed these women individually from January 1, 2001 or their 18th birthday, whichever came later, until a diagnosis of cervical intraepithelial neoplasia grade 3 (CIN3), adenocarcinoma *in situ* (AIS), or invasive cervical cancer (ICC), a diagnosis of any other cancer, a total hysterectomy, emigration out of Sweden, death, or December 31, 2012,

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whichever occurred first, through cross-linkage to the NKCx, the Swedish Cancer Register (12), the Swedish Patient Register (13), and the Total Population Register.

Through the NKCx and Cancer Register, we first identified women that received a diagnosis of CIN3/AIS or ICC during follow-up. Among women without CIN3/AIS or ICC, we further identified women that received a diagnosis of CIN1–2 during follow-up. The diagnostic procedures for ICC and its precursor lesions included mainly Pap smear (cytology) and punch biopsy (histology) during the study period in Sweden. Women with symptoms could be referred directly to punch biopsy without taking a smear, whereas other patients would commonly start with smear. Among women with abnormal smear results, one or more repeated smears or biopsies might be performed during the subsequent months (10). We, therefore, defined smears and biopsies performed within 12 months as belonging to the same diagnostic workup. The diagnostic workup of women with CIN1–2, CIN3/AIS, or ICC was, therefore, defined as the time interval between the first smear or punch biopsy until surgical treatment or 2 months after the last smear or biopsy (if not treated surgically). Because it usually takes 4–6 weeks before a test result is delivered to women, we assigned a 2-month period as the waiting time for result. Approximately 76% of these women underwent a surgical treatment, including 44% of women with CIN1, 75% of women with CIN2, 80% of women with CIN3/AIS, and 49% of women with ICC, during the study period. We used the 2 months following the first normal smear of women that had only normal smear results during the study period as the reference.

We used iatrogenic injuries that required at least 2 days of hospital admission and noniatrogenic injuries that required at least 1 day of hospital admission as the outcomes of interest, according to the Swedish Patient Register, which collects nationwide information on hospital discharge records since 1987 (13). We used both the main discharge diagnosis, using the 10th Swedish revision of the International Classification of Diseases codes S00-T98, and the external causes of such diagnosis, using the Ecodes V01-Y98, to define injuries (Supplementary Table S1). Because women can be referred to outpatient and overnight inpatient care for observation after punch biopsy, we included only iatrogenic injuries with at least 2 days of hospital admission. Iatrogenic injuries were further classified as because of drug or biological substances or because of medical procedures and care, using both discharge diagnosis and Ecodes. We classified noniatrogenic injuries as unintentional injuries (mainly accidents), intentional injuries, and injuries with undetermined nature, using Ecodes. During the analysis, we took into account repeated injuries, but considered consecutive events within 1 week of each other that had the same primary diagnosis as the same event. In a sensitivity analysis, we included only the first event per woman as the outcome to assess the impact of the relatedness of outcome events on the studied associations.

We collected information on different covariates. Participation rate in cervical screening is associated with socioeconomic status and risk of cervical cancer (14). Through NKCx, we calculated screening adherence of each woman, as the percentage of the actual participation times in cervical screening divided by the recommended participation times according to the screening guideline (14). Registered smears beyond screening age were not counted in this calculation. Information on the highest education level, individualized disposable income, and marital status was retrieved from the Longitudinal integration database for health insurance and labour market studies (15).

Statistical analysis

We first compared women with a diagnosis of CIN1–2, CIN3/AIS, or ICC with women with only normal smears, in terms of age (18–40, 41–65, or >65 years), calendar period (2001–2004, 2005–2008, or 2009–2012), screening adherence (participation rate <70% as low, 70%–<80% as medium, 80%–<90% as high, or ≥90% as very high), the highest educational level (<9 years or unknown, 9–12 years, or >12 years), individualized disposable annual income (<100,800 as low, 100,800–134,900 as medium, 134,901–185,200 as high, or >185,200 as very high, in Swedish crowns), and marital status (cohabitating or non-cohabitating), using Pearson χ^2 tests.

We calculated the crude incidence rates (IR) of injuries during the diagnostic workup of women with a cervical diagnosis, as well as during the 2 months following the first normal smear among women with only normal smear results (reference). Crude IRs were calculated using counts of injuries divided by accumulated person-months at risk, discarding days spent during hospital admission. We then estimated the IR ratios (IRR) and their 95% confidence intervals (CI) by comparing the IRs of these two groups of women, using Poisson regression (16), after adjustment for age, calendar period, screening adherence, education, income, and marital status. The assumption of equal-dispersion in Poisson regression was found to hold for all analyses.

All analyses were performed using SAS 9.4 (SAS Institute) and STATA 14.1 (StataCorp LP). We considered $P < 0.05$ as the level of statistical significance. All information for participants was retrieved from nationwide registers and informed consent was waived by law in Sweden. This study was approved by the Regional Ethical Review Board in Stockholm, Sweden. The research was conducted in accordance with Declaration of Helsinki.

Data sharing statement

Data from the study are available upon reasonable request. Permission for data sharing can be provided from par.sparen@ki.se.

Results

We identified in total 1,853,510 women with normal smear, 22,435 women with CIN1, 20,692 women with CIN2, 36,542 women with CIN3/AIS, and 5,189 women with ICC during the study period (**Table 1**). Older age, earlier calendar period, lower screening adherence, less education, lower income, and non-cohabitating were all associated with a cervical diagnosis (all $P < 0.0001$).

We identified 42 iatrogenic injuries that required at least 2 days of hospital admission during the diagnostic workup of women with a cervical diagnosis (**Table 2**). Compared with the reference group, no statistically significantly increased rate of iatrogenic injuries was noted during the diagnostic workup of women with CIN1–2. There was, however, an increased rate during the diagnostic workup of women with CIN3/AIS (IRR, 3.04; 95% CI, 1.73–5.34) or ICC (IRR, 8.55; 95% CI = 3.69–19.80). The common types of iatrogenic injuries were hemorrhage or hematoma and infections. The IRs of injuries due to medical procedures and care were greater than the IRs of injuries due to drug or biological substances, among all groups of women (Supplementary Table S2). Similar results were noted when accounting only the first iatrogenic injury event per woman (Supplementary Table S3).

We identified 91 noniatrogenic injuries that required at least 1 day of hospitalization during the diagnostic workup of women with a cervical diagnosis (**Table 3**). Compared with the reference group, we did not find an increased rate of noniatrogenic injuries during the

Table 1. Characteristics of women by histology diagnosis, a nationwide cohort study during 2001–2012 in Sweden.

Characteristics	Normal smear	CIN1	CIN2	CIN3/AIS	ICC	*P*
N (%)	1,853,510 (95.62)	22,435 (1.16)	20,692 (1.07)	36,542 (1.89)	5,189 (0.27)	
If a diagnostic workup starts with a smear, *n* (%)						
Yes	1,853,510 (100.00)	21,028 (93.73)	19,745 (95.42)	35,011 (95.81)	2,759 (53.17)	
No	0 (0.00)	1,407 (6.27)	947 (4.58)	1,531 (4.19)	2,430 (46.83)	
Age in years, *n* (%)						<0.0001
18–40	994,111 (53.63)	15,783 (70.35)	16,000 (77.32)	27,886 (76.31)	1,251 (24.11)	
41–65	847,756 (45.74)	6,230 (27.77)	4,426 (21.39)	8,102 (22.17)	1,912 (36.85)	
>65	11,643 (0.63)	422 (1.89)	266 (1.29)	554 (1.51)	2,026 (39.04)	
Calendar period, *n* (%)						<0.0001
2001–2004	1,305,928 (70.46)	6,727 (29.99)	6,481 (31.32)	12,429 (34.01)	1,876 (36.15)	
2005–2008	327,802 (17.69)	6,537 (29.14)	6,279 (30.35)	12,034 (32.93)	1,679 (32.36)	
2009–2012	219,780 (11.86)	9,171 (40.88)	7,932 (38.33)	12,079 (33.06)	1,634 (31.49)	
Screening adherence, *n* (%)						<0.0001
Low	650,799 (35.11)	5,021 (22.38)	4,547 (21.97)	15,721 (43.02)	3,571 (68.82)	
Medium	410,054 (22.12)	4,087 (18.22)	3,614 (17.47)	5,639 (15.43)	563 (10.85)	
High	428,083 (23.10)	5,072 (22.61)	4,631 (22.38)	4,958 (13.57)	524 (10.10)	
Very high	364,574 (19.67)	8,255 (36.80)	7,900 (38.18)	10,224 (27.98)	531 (10.23)	
Education, *n* (%)						<0.0001
<9 years or unknown	215,299 (11.62)	2,020 (9.00)	2,035 (9.83)	4,056 (11.10)	1,769 (34.09)	
9–12 years	910,579 (49.13)	10,903 (48.60)	10,349 (50.01)	18,806 (51.46)	2,215 (42.69)	
>12 years	727,632 (39.26)	9,512 (42.40)	8,308 (40.15)	13,680 (37.44)	1,205 (23.22)	
Income, *n* (%)						<0.0001
Low	514,076 (27.74)	5,274 (23.51)	5,241 (25.33)	10,260 (28.08)	1,489 (28.70)	
Medium	515,243 (27.80)	5,635 (25.12)	5,173 (25.00)	9,342 (25.57)	1,649 (31.78)	
High	495,114 (26.71)	5,947 (26.51)	5,413 (26.16)	9,010 (24.66)	1,121 (21.60)	
Very high	329,077 (17.75)	5,579 (24.87)	4,865 (23.51)	7,930 (21.70)	930 (17.92)	
Marital status, *n* (%)						<0.0001
Not cohabitating	1,085,216 (58.55)	17,882 (79.71)	16,934 (81.84)	27,776 (76.01)	3,442 (66.33)	
Cohabitating	768,294 (41.45)	4,553 (20.29)	3,758 (18.16)	8,766 (23.99)	1,747 (33.67)	

Table 2. IRs (per 1,000 person-months) and IRRs of iatrogenic injuries during the diagnostic workup of women with cervical cancer and its precursor lesions compared with women with normal smear, a nationwide cohort study during 2001–2012 in Sweden.

	Women (*n*)	Events (*n*)	Crude IRs	IRR (95% CI)
Iatrogenic injuries that required ≥2 days of hospital admission				
Normal smear[a]	1,853,510	102	0.03	1.0
CIN1	22,435	11	0.05	2.04 (1.06–3.93)
CIN2	20,692	6	0.04	1.43 (0.62–3.33)
CIN3/AIS	36,542	17	0.09	3.04 (1.73–5.34)
Invasive cancer	5,189	8	0.58	8.55 (3.69–19.80)

[a]Normal smear: a 2-month period starting from the day of smear, for women with normal smear.

Table 3. IRs (per 1,000 person-months) and IRRs of noniatrogenic injuries during the diagnostic workup of women with cervical cancer and its precursor lesions compared with women with normal smear, a nationwide cohort study during 2001–2012 in Sweden.

	Women (*n*)	Events (*n*)	Crude IRs	IRR (95% CI)
Noniatrogenic injuries that required at least 1 day of hospital admission				
Normal smear[a]	1,853,510	458	0.12	1.0
CIN1	22,435	29	0.14	0.99 (0.62–1.58)
CIN2	20,692	25	0.15	1.11 (0.74–1.69)
CIN3/AIS	36,542	28	0.14	0.98 (0.65–1.47)
Invasive cancer	5,189	9	0.65	2.48 (1.30–4.74)

[a]Normal smear: a 2-month period starting from the day of smear, for women with normal smear.

diagnostic workup of women with CIN1–2 or CIN3/AIS, although we did find an increased rate during the diagnostic workup of women with ICC (IRR, 2.48; 95% CI, 1.30–4.74). The most common type of noniatrogenic injury was unintentional injuries (Supplementary Table S2). Similar results were noted when accounting only the first injury event per woman (Supplementary Table S4).

Discussion

In this large, nationwide cohort study, we found that inpatient care of iatrogenic and noniatrogenic injuries was rare during the diagnostic workup of cervical cancer and its precursor lesions. We found, however, increased rate of both iatrogenic and noniatrogenic injuries during the diagnostic workup of women with ICC.

Although overnight watching for temporary discomfort or bleeding is empirically expected after diagnostic procedures of cervical abnormalities, especially punch biopsy, it is uncommon for women to be hospitalized for a longer period of time for such purposes. In our study, although extremely rare, we observed increased risk of iatrogenic injuries that required at least 2 days of hospital admission during the diagnostic workup of women with ICC, and, to a smaller extent, also for women with CIN3/AIS. This result pattern was expected because women with CIN3/AIS and invasive cancer were more likely to receive invasive procedures for evaluation and possible treatment than women with normal smear. Furthermore, women with invasive cancer have commonly greater vascularity in tumor growth (17), whereas hemorrhage and hematoma were indeed the most common types of iatrogenic injuries during the diagnostic workup of women with ICC. The greater risk increase among women with ICC might also be because ICC is more common among older women and women with less active participation in cervical screening. Older age and lower compliance to screening are risk factors for cervical cancer and for adverse events after cancer treatment (14, 18–20). However, it is important to note that through studying iatrogenic injuries requiring at least 2 days of inpatient care likely only captured the most severe form of iatrogenic injuries. Because of the scant data on iatrogenic injuries, in medical practice in general (4), and the noted higher burden of such injuries among patients with cancer (7, 21–24), a systemic documentation of the burden of iatrogenic injuries among women with cervical cancer and its precursors is clearly justified.

An increased risk of noniatrogenic injuries has been shown among patients with cancer, both immediately before and after cancer diagnosis, suggesting that the psychologic distress experienced during the clinical evaluation of a suspected cancer might lead to increased risk of injuries (7). The social stigma related to cervical cancer might contribute further to a high level of psychologic distress in relation to receiving a diagnosis of cervical cancer (25). Women receiving an abnormal result when evaluated for cervical cancer, have been reported to have increased risk of anxiety, distress, sleep disturbance, and poor concentration (8, 26–29). In this study, although noniatrogenic injuries that required at least 1 day of hospital admission were rare during the diagnostic workup of women with ICC, the rate was more than two times higher compared with the reference period (waiting time for a normal smear result). In contrast, we found no elevated risk of noniatrogenic injuries during the diagnostic workup of cervical precursor lesions, which might be attributable to a lower degree of psychologic distress in relation to receiving a benign diagnosis, and the greater possibility of being cured (30). Similar to iatrogenic injuries, noniatrogenic injuries requiring at least 1 day of inpatient care were rare and likely represented the severer form of the outcome.

Cervical screening is one of the most successful cancer prevention programs and has substantially reduced the incidence and mortality of cervical cancer in developed countries (31). Compliance to the recommendations of the screening program is, however, vital to attain effectiveness (18). Although harms of cervical screening have been reported in previous studies (32), we found severe adverse events, such as injuries requiring inpatient hospital care, to be extremely rare in our study. Taken together, it is important to convey the information to the general population that participation in cervical screening is greatly beneficial and largely safe.

The nationwide population-based design and the prospectively and independently collected information on cervical abnormalities and injury outcomes minimized selection and information biases. Several limitations should also be addressed. One limitation is the lack of information on nonsurgical treatments, including palliative care, chemotherapy, and radiotherapy, for women with ICC. As a result, we had to assume 2 months after the last biopsy as the end of diagnostic workup (and start of treatment). Information on cancer stage was not available during the entire study period. As a result, we were not able to assess the contribution of cancer stage on the risk of injures among women with ICC. Finally, our results shall be generalized with caution to other populations, especially to populations with different screening protocols.

In conclusion, inpatient care of iatrogenic and noniatrogenic injuries was rare during the diagnostic workup of women with cervical cancer and its precursor lesions. The increased rate of iatrogenic and noniatrogenic injuries during the diagnostic workup of women with ICC might indicate burden of medical complications and the severe psychologic distress experienced in relation to receiving a diagnosis of cervical cancer.

Disclosure of Potential Conflicts of Interest

F. Fang reports grants from the Swedish Cancer Society; Swedish Research Council for Health, Working Life, and Welfare; and Karolinska Institutet during the conduct of the study. No potential conflicts of interest were disclosed by the other authors.

Disclaimer

The funding body had no role in the design of the study; in the collection, analysis, and interpretation of data; and in the writing of the article.

Authors' Contributions

Q. Shen: Conceptualization, formal analysis, methodology, writing–original draft, writing–review and editing. **D. Lu:** Conceptualization, writing–review and editing. **B. Andrae:** Conceptualization, investigation, writing–review and editing. **M.E.C. Schelin:** Writing–review and editing. **A. Sjölander:** Methodology, writing–review and editing. **Y. Cao:** Methodology, writing–review and editing. **P. Sparén:** Conceptualization, data curation, supervision, methodology, writing–review and editing. **F. Fang:** Conceptualization, resources, supervision, funding acquisition, writing–review and editing.

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