

Claims for compensation from women with cervical cancer in Norway-
a retrospective, descriptive study of a 12-year period

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MHM and ML both work part-time at NPE as medical experts. IRKB is medical adviser in NPE.

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Abstract

Introduction In Norway, all patient-reported claims for compensation are evaluated by The Norwegian System of Patient Injury Compensation (NPE). The number of claims from women with cervical cancer is rising, and the approval rate is high. Our aim was to study claims for compensation from women with cervical cancer in order to identify the type of failures, when in the time-course of treatment medical failures occurred, and the consequences of the failures.

Material and methods A retrospective, descriptive study of claims for compensation to NPE from cervical cancer patients during a 12-year period, from 2007 through 2018. We used anonymized medical expert statements and summaries of NPE-cases.

Results In all, 161 women claimed compensation for alleged medical failure related to cervical cancer. Compensation was approved for 100 (62%) women. Mean age at the time of alleged failure was 37.5 years (SD \pm 9.9). The main reasons why women sought medical attention were routine cervical screening (56%), or vaginal bleeding or discharge (30%). In approved cases, incorrect evaluation of cytology and histology was the cause of most failures (72%). Mean delay of cervical cancer diagnosis for approved cases was 28 months (SD \pm 22). Treatment not in accordance to guidelines was the cause of failure in 2% of the cases, and failure during follow-up was the cause of failure in 12%. Consequences of the failures were: worsening of cancer prognosis (89%), treatment-induced side-effects, such as loss of fertility (43%) and/or loss of ovarian function in premenopausal women (50%), and permanent injury after chemo-radiation (27%). Seven women (7%) died, most likely as a consequence of the failure.

Conclusions The main cause of medical failure in cervical cancer patients was incorrect pathological diagnosis. The main consequences of failures were worsening of cancer prognosis and treatment-induced side-effects. Increased focus on the quality of pathological examinations, and better routines in all parts of the cervical examinations might improve patient safety for women in risk of cervical cancer.

Key Words:

Claims for compensation, cervical cancer, delayed diagnosis, medical failure

Abbreviations:

NPE: Norwegian System of Patient Injury Compensation (Norsk pasientskadeerstatning).

Key Message:

Our study indicates that incorrect pathological diagnosis is the main reason for delayed diagnosis of cervical cancer.

Introduction

Cervical cancer represents 20% of all gynecologic cancers in Norway, but are responsible for more than half of the claims for compensation due to a medical failure in this group of patients.^{1,2} Claims for compensation after alleged medical failures in Norway are evaluated by the Norwegian System of Patient Injury Compensation (NPE). The number of complaints from women with cervical cancer is increasing, and the approval rate of the claims for these cases is higher compared to complaints in other patient categories.²

The World Health Organization (WHO) aims to reduce the cervical cancer incidence to less than 4/100 000 cases each year.³ Key factors in reaching this goal are cervical screening participation higher than 70%, and more than 90% HPV- vaccination coverage among women.³ In Norway, the WHO-demands have been met with a well-established cervical screening program since 1995, and with a high HPV-vaccination coverage.⁴⁻⁶ Despite this, the incidence of cervical cancer in Norway is 10/100 000.¹

Identifying and learning from medical failures may increase patient safety.⁷⁻⁹ Medical errors in general are found to be one of the leading causes of deaths.⁷ According to WHO, “harm occurs too often and much of it is preventable”.¹⁰

In the present study, claims from cervical cancer patients to NPE were evaluated, in order to identify the types of failures, when in the time-course of treatment the failure occurred, and the consequences of the failures.

Material and methods

The study is a retrospective, descriptive study of claims for compensation to NPE from women with cervical cancer during a 12-year period, from 2007 through 2018.

In order to qualify for compensation from NPE, certain conditions have to be met.¹¹ The injury must most likely have been caused by a medical failure, the patient must have sustained a financial loss, and requirement for compensation must be submitted within three years after awareness of the harm. There are two exceptions from the basic rules, where compensation can be granted without failure: injury after hospital-acquired infections, and unexpected and severe injuries. About 20% of approved NPE-cases in gynecology are approved due to these exceptions.² Compensation from NPE is given according to the “blame-free” principle system. This means that a medical failure can be stated without looking for a scapegoat.¹² “Medical failure” in this description of method is defined as the medical failures that have been recognized by the medical expert in NPE as failures, and for which the claims have been approved.

NPE files contain all available information related to a patient's claim for compensation. The file normally includes an injury report written by the claimant, a description of the case from the defendant care institution, the medical journal, a statement from a medical expert, and a summary of the case made by the NPE-lawyer. The medical expert statement is the cornerstone of the NPE files, and is decisive for the decision of approval or denial. The NPE lawyer's summary includes a conclusion, with approval or denial of the claim. The medical expert statement and the summary together comprise the most complementary information in the NPE files, and these were our sources of information for the study. The NPE files were anonymized, thus informed consent from the included women was not necessary.

ICD10-diagnosis codes (C53, D06, N87) were used to identify all relevant claims to NPE between January 2007 and December 2018. Both approved and denied cases were included. Identification and anonymisation of files were done by the NPE staff. The medical expert statements were available as paper files, the NPE lawyer's documents as electronic files. The information and conclusions were unconditionally accepted without evaluation by the authors. A structured review of all approved and denied cases was performed by the first author (MR), and registered in an electronic case report form (eCRF). The CRF were designed by the authors for this study purpose. Complex cases were discussed in the research group to ensure correct registration.

General information was registered for all cases and included age of the applicant and if she was pregnant at time of alleged failure, defendant health institution, whether the national cervix-screening program had been followed, and stage of cervical cancer (table 1). In addition, health region, year of alleged failure and date of claim for compensation, were registered.

We categorized the reasons for seeking medical help, i.e. the symptom or situation leading to the alleged failure, as: routine cervical screening (no symptoms), vaginal bleeding or discharge, pain, routine follow-up after conization, or "other reasons" such as weight loss, anemia, routine pregnancy follow-up and urinary or intestinal symptoms (table 2).

We defined three time periods to categorise when the medical failure occurred: "Pre-treatment" was defined as the period in which the examination of the patient was performed (or neglected) before treatment was started, eg performing a cervical screening test, or ignoring bleeding as a symptom. "Treatment" was defined as the entire period with active therapy. "Follow-up" was defined as the period that included any medical action after the end of the treatment period (table 3).

For denied cases, we registered the time-period the woman claimed that the failure had occurred, although no failure was stated by the medical expert.

“Main consequences of failure” were categorized as: death, permanent injury, worsening of cancer prognosis, loss of fertility, abortion or preterm delivery, or loss of ovarian function (for pre-menopausal women) (table 4). Consequences such as “financial loss” or “psychological strain” were also included as alternatives, but not found, and therefore not included in the table. Deaths were registered if deceased before December 2018. If the woman had more than one “consequence of failure”, the most serious consequences, evaluated by the first author, were registered. “Permanent injury” included late effects of radiation and/or chemotherapy treatment necessary due to delayed diagnosis. “Worsening of cancer prognosis” was estimated by the NPE medical expert, and was documented as “number of months of delayed diagnosis”. Change in cancer stage and worsening of prognosis as a consequence, was then estimated by the medical expert and included in their statements. Only consequences *due to* the failure were registered. For example, if failure was assumed to advance the cancer stage from III to IV, loss of fertility would in either stage be the consequence of treatment, and was not registered as a consequence of failure.

A claim was denied compensation if the NPE-criteria for approval was not met, according to the medical experts and the NPE-lawyer.

Data recording and analyses

Data collection was performed using a web-based case report form (eCRF), designed by the authors, and technically developed and administered by the Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology (NTNU), Trondheim, Norway. The data were recorded and analysed using IBM SPSS Statistics for Mac, Version 25. (IBM Corp, Armonk, NY, USA).

To test differences in proportions, chi-squared test was used. A probability value of $p < 0.05$ was considered statistically significant.

Ethical approval

The Regional Committee for Medical and Health Research Ethics (REK) decided that the study did not need an approval (2019.04.29, 2019/707/REK nord). The study was approved both by the Norwegian Social Science Data Services (NSD) (2019.02.14, 40522/3/KS), and NPE’s own in-house ethical committee.

Results

In total, 161 women with cervical cancer (ICD10-diagnosis code C53) reported claims for compensation to NPE from January 2007 through December 2018. No complaints were registered from women with cervical dysplasia (ICD10-diagnosis codes D06 and N87). Compensation was approved for 100 women (62.1%).

The mean age of all women who reported claims was 37.5 (SD \pm 9.9). The mean age of women approved compensation was 36.8 (SD \pm 8.8) and of women denied compensation 38.8 (SD \pm 11.4), $p=0.23$. Further characteristics of the included women are shown in table 1.

The most common reasons for seeking medical help were routine cervical screening (56.3%) or vaginal bleeding or discharge (29.8%) (table 2). Other reasons were pain (3.8%), follow-up after conization (6.3%), and “other reasons” (weight loss, anemia, routine pregnancy follow-up and intestinal or urinary symptom) (accounting for 3.8%).

Most failures occurred during the pre-treatment period (90%), and incorrect evaluation of cytology or histology was by far the most common error (72%) (table 3). Only one woman complained because of a false positive test. Incorrect or neglected medical examinations, such as performing a cervical cytologic test instead of a biopsy from a bleeding cervical ulcer, or not performing pelvic examination when indicated, occurred in 14%. Only 2% of the cases were treatment failures, and 10% of the failures were related to incorrect follow-up.

In 93 out of 100 approved cases, the medical experts estimated the time delay of the diagnoses. The mean delay of diagnosis in these 93 cases was 28 months (SD \pm 22).

The most frequent consequence of failure was worsening of cancer prognosis (89%). Adverse effects caused by cancer treatment due to delay, were loss of ovarian function in premenopausal women (50%) and/or loss of fertility (43%), and permanent injury after treatment (37%) (table 4). Among women with permanent injury, late effects of radiation and/or chemotherapy caused the injury in 27 out of 37 cases (73%). Other permanent injuries were colostomy, urinary retention and increased future risk of premature delivery. Sixteen women were pregnant at the time of diagnosis, of whom five had an abortion due to the diagnosis. The death of seven women was considered a direct consequence of the failure. One woman died suddenly during chemotherapy necessary due to delayed diagnosis, and six women died because a false negative cytology led to cervical cancer.

Sixty-one women were denied compensation. Several categories for “reasons for denial” could be registered in the study, but only two reasons were found: “no treatment failure occurred” (49 cases, 80%) or “failure occurred, but had no consequences for the treatment or

prognosis” (12 cases, 20%). Also in denied cases, pre-treatment conditions were the most common reasons for complaint (88.5%).

Discussion

The main finding of the study is that most medical failures in women with cervical cancer were incorrect cytological and histological diagnoses. The main consequences of failure were delayed diagnosis, resulting in worsening of cancer prognosis, and/or side-effects of more extensive treatment.

The strength of the study is that the data are retrieved from the nation-based and comprehensive registry of NPE, comprising all patient claims concerning cervical cancer in Norway during a 12-year period. It is easy to forward a complaint to NPE, and patients are encouraged to claim compensation when medical failures are suspected. The blame-free principle system of NPE makes it easier for health personnel to inform patients about NPE, when suspected medical failures have occurred.

The external validity of the study is a limitation. We have no information about the women who *did not* claim compensation after possible failures. In a study from New Zealand, Bismark et al., found that only 1 out of 25 patients made a complaint after a medical failure.¹³ We do not know if this is also the case in Norway. However, patient injuries are more often registered in the NPE-system than in other incident-reporting systems.¹⁴ The NPE-criteria for approval might also be a limitation, because medical failures can be stated also in denied cases. Due to this, we evaluated also the denied cases, and found that denial most often was based on that medical failures were not identified. The “exception rules” also assure quality of conclusions, because they make up for special cases where the NPE-criteria are not met. The NPE-data might not represent all medical failures among cervical cancer patients in Norway. It is, however, the best and most comprehensive registry available.

We did not study all parts of the NPE-files, only the anonymized medical expert statements and NPE-lawyers’ summary. In a previous study of claims for compensation to the NPE, we used anonymized parts of files for the 33% who did not respond to the letter of consent.² Using the anonymized parts of files showed only a negligible loss of relevant information when compared to using the full files. Other studies on NPE-data have used only anonymized medical expert statements and summaries.^{15,16}

Incorrect evaluation of cytology or histology as main reasons for medical failures has also been reported by others.^{17,18} In Norway, re-evaluation of former pathologic specimens is performed routinely when cervical cancer is diagnosed. Failures will be uncovered and NPE-

criteria for acceptance of claims are then present. This might explain the increased number of claims for compensation from women with cervical cancer, and the high approval rate.

Norwegian pathologists' approach to improve quality is described by Alfsen et al.¹⁵ They argue that the most effective method to prevent failures is by having all specimens evaluated by two pathologists. They concluded however, that this was too expensive and not feasible. More than 400 000 routine cervical screening tests are performed each year in Norway, and the failure rate is, after all, low.¹⁸

A false-negative cervical screening test might give false security, and may lead women and health personnel to underestimate future risk of cervical cancer.^{19,20} If bleeding or vaginal discharge occurs shortly after a normal test, it might both delay women from seeking medical help, or doctors from performing a pelvic examination. Health personnel *and* women should be informed that irregular bleeding and vaginal discharge are the most common symptoms of cervical cancer. Especially in young women, ignoring symptoms are known to delay cervical cancer diagnosis.²¹

Sampling errors are believed to cause false-negative tests.²² Doctors need to be up to date about cervical examination: when and how to perform cytology and biopsy, how to interpret the test results, and having routines for follow-up. Failure to follow-up is found to be more frequent in Scandinavian countries than in other Western countries.¹⁷ It seems as though the better the cervical screening coverage is, the poorer is the follow-up.¹⁷ The National Norwegian Gynecological Guidelines, published by the Norwegian Association of Obstetrics and Gynecology, comprises guidelines concerning cervical screening and other cervical examinations. These guidelines are regularly updated and available on-line.²³

False positive results were rarely seen. From the present data, we cannot document whether this type of failure happens more often, but without being reported.

The survival rate of cervical cancer is high, mostly because the diagnoses are made at an early stage.¹ However, the consequences of delayed diagnosis can be serious even when the woman survives. Women with cervical cancer are younger than most other cancer patients.⁵ Fertility preservation is possible if cancer is diagnosed at an early stage. Hysterectomy or radiation is the treatment of choice in more advanced stages, with infertility as a consequence. Side-effects after radio-chemotherapy, such as ovarian failure, infertility, intestinal and urinary problems, abdominal pain, vaginal shortening and peripheral neuropathy are well known consequences as well.²⁴ Symptoms may be life-long, difficult to treat, and have negative impact on quality of life.²⁴ Thus, the young age of the patients and the consequences of delay, might increase the number of claims for compensation.

The number of cervical cancer cases in Norway has been rising the last decade. The increased number of HPV-infection among women is thought to be the main reason.^{4,22} The HPV-vaccination program was introduced for Norwegian girls in 2009, and for boys in 2018.²⁵ An 80% reduction in HPV-infections has been observed after vaccination.²⁶ HPV-tests have been introduced for cervical screening, and are probably better than traditional cervical screening tests for diagnosing precancerous conditions.²⁷ These initiatives are expected to reduce the incidence of dysplasia and cervical cancer. But, as our study confirms, cervical cancer may occur as a result of medical failures. In Norway, there has been increasing focus on medical failures resulting in cervical cancer, both from health personnel, public figures, celebrities, and the media. This focus is welcomed. Prevention of cervical cancer is a process involving the women, their doctors, the laboratory and the health care system.

Conclusion

According to our findings, attention to the quality of pathological examinations might be the most important step in reducing the number of cervical cancers due to medical failures.

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Tweetable abstract

Most medical failures affecting women with cervical cancer were incorrect pathological diagnoses, resulting in worsening of cancer prognosis and side-effects of treatment.

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Legends of figures and tables:

Table 1

Characteristics of women with cervical cancer who claimed compensation from NPE 2007-2018

Table 2 Reasons for seeking medical help

Tabell 3 Time-period and cause of alleged failure

Table 4 Main consequences of failure N=100