SENSITIVITY AND SPECIFICITY OF THE REPORTING OF MALIGNANT MESOTHELIOMA1

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ABSTRACT

Objective: To measure the sensitivity and specificity of the reporting of malignant mesothelioma in the Population-Based Cancer Registry in Curitiba, PA, Brazil. Method: Retrospective, cross-sectional study conducted in the Population-Based Cancer Registry in Curitiba and 11 reporting institutions, from January to December 2017. The final sample was composed of 92 medical records of adult patients, with diagnoses and reporting of cancer, with topographical codes C38 (pleura, heart, and mediastinum) and C48 (peritoneum and retroperitoneum). Stata 14 was used to analyze sensitivity and specificity, and internal consistency. Each medical record (considered the gold standard) provided by the reporting institutions was compared to those in the registry. Results: The registry sensitivity in reporting mesothelioma (ICD-10: C45) and pleural cancer (ICD-10: C38.4) was 100% (8/8) and 50% (1/2), respectively. Specificity was 90.2% (74/82), as eight cases were wrongly classified as pleural cancer. Conclusions: the registry presented high sensitivity in the reporting of malignant mesothelioma, with no underreporting, and overestimated pleural cancer reporting (nine instead of one) due to erroneous and misleading reporting.

Keywords: Mesothelioma. Asbestos. Public health. Epidemiology. Information Systems.

INTRODUCTION

Malignant mesothelioma (MM) is a rare type of cancer that is lethal in most of the individuals affected. The primary types include pleural mesothelioma (>90%), peritoneal mesothelioma (<10%), and verv rarely paratesticular mesothelioma. This cancer resembles adenocarcinoma of other organs, making it difficult to determine an accurate diagnosis early, a situation that has not improved in recent years⁽¹⁾. Prognosis is generally poor, with a low survival rate (<10% survive five years after the restricted diagnosis), with therapeutic management and limited quality of life⁽²⁾. The diagnosis triggers a range of emotions among patients and families, such as fear, anguish, and even denial(3).

Asbestos exposure is the primary cause of MM. Authors⁽⁴⁾ note that MM can be considered fingerprint of asbestos exposure. Occupational exposure accounts for 80% to 85% of the cases, and environmental and nonoccupational exposure accounts for 4.2% and 1.65, respectively. All the different types of (amphiboles and chrysotile) are considered carcinogenic, though with potential differences in terms of fiber potency; the latency between exposure and the emergence of cancer may take many decades⁽⁵⁾.

The fiber used in Brazil, banned in 2017, was all virtually in the chrysotile form. Even though its commercialization is legal in other countries, it causes many diseases, especially in the respiratory system, known as Asbestos Related Diseases (ARD). They include pulmonary

1/Article extracted from the Master's thesis titled "Análise da qualidade de um registro de base populacional ao notificar casos de câncer potencialmente relacionados ao amianto" [Quality *RN. Ph.D. Student at the Federal University of Paraná. Erasto GaertnerHospital. Curitiba, PR, Brazil. E-mail: marcondes.lari@gmail.com ORCID ID: https://orcid.org/0000-0002-8745-6486 Analysis of a population-based cancer registry in reporting posturing. Student at the Federal University of Paraná. Erasto Gaerther-Hospital. Curitiba, PR, Brazil. E-mail: marcondes.lari@gmail.com URCID ID: https://orcid.org/0000-0001-9572-3989
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fibrosis (asbestosis), benign pleural effusions, lung cancer, pleural plaques, atelectasis, diffuse pleural thickening, and MM; the latter is the asbestos-related primary pathology^(4,5). However, it is worth noting that up to 2017, fiber-cement productionplants using asbestos as raw material were concentrated in Curitiba and its metropolitan region. For this reason, there is a need to monitor and record MM cases among those working in this industry.

Even though reporting is mandatory, MM incidence rates are low. Of the 28 incidences reported by the last issue of the Brazilian Population-Based Cancer Registry (RCBP), 12 were not related to MM. Among the RCBPs reporting cases, the one located in the Southeast, represented by São Paulo, stands out. São Paulo housed the largest fiber cement production plant in Brazil, using asbestos as raw material. This plant closed in the 1990s, but incident rates were 0.16/100,000 men and 0.08/100,000 women between 2001 and 2005. In the Northeast, represented by Recife, the rates between 2000 and 2003 were 0.19/100,000 men and 0.06/100,000 women. In the Mid-West, the incident rates in Goiania from 2001 to 2005 were 0.11 and 0.20 for every 100,000 men and women, respectively, while in Curitiba, in the same period, the rates were 0.07/100,000 women and 0.10/100,000 men. Note that the North did not report any MM case⁽⁶⁾.

Incidence rates are calculated according to the reports of asbestos-related diseases and deaths. MM's reporting in the Notifiable Diseases Information System (SINAN) is mandatory, and cases are monitored by the Unified Health System (SUS) in the hospitals providing care to cancer patients. Health workers are responsible for reporting and collecting information that is then included in the Cancer Hospital Registries (RHC) of the hospitals providing care to this population and later sent to the Population-Based Cancer Registries (RCBP) available in all Brazilian capitals. However, the quality of RHC and RCBP information is not uniform throughout the country, as they often report duplicated, missing, or incomplete data⁽⁷⁾.

According to the Centers for DiseaseControlandPrevention (CDC), one way to assess the quality of data available in a system or registry is by calculating its sensitivity (Se) and specificity (Sp), which refer to the ability to

report data concerning the proportion of cases of a given disease detected in the system⁽⁸⁾.

Data from Brazil diverge from the MM incidence and mortality rates reported by other According to the Mortality Information System (SIM), the number of MM reports between 2000 and 2010 in Brazil, a country with 209.5 million inhabitants, totaled 2,123⁽⁹⁾. A study conducted in Italy, a country with 60.36 million people, reports that the number of cases in 12 years (2000 to 2012) was 4,442; Italy banned asbestos in 1992⁽¹⁰⁾. The authors of a study conducted in Argentina⁽¹¹⁾ report 3,259 deaths caused by MM between 1980 and 2013. Additionally, there are reports of pleural cancer without histological assessment and possibly erroneous reports of mediastinal cancer⁽¹⁰⁾. Thus, the following guiding question emerged: Is the low occurrence of MM in Curitiba due, at least in part, to the low sensitivity and specificity of data provided by the RCBP for this type of cancer?

Hence, this study's objective was to measure the sensitivity and specificity of MM reports provided by the Population-Based Cancer Registry in Curitiba, PR, Brazil.

METHOD

Retrospective and cross-sectional study conducted in the RCBPin Curitiba-PR, located in the South of Brazil, from January to December 2017

Inclusion criteria were: cases reported by the RCBP in Curitiba, according to the International Classification of Diseases for Oncology, version 3.0 (ICD-O-3), with topographical codes C38 and C48, and morphology M____/3 (malignant tumor) or absent, from 1998 to 2012. This topography refers to primary malignant heart tumors (C38.0), mediastinum (C38.1, C38.2, C38.3), pleura (C38.4), retroperitoneum (C48.0), and peritoneum (C48.1, C48.2), which may hide asbestos-related cancers. The timeframe was established according to the year the RCBP started reporting, and complete information was stored in the database. Note that the RCBP report system's structure is based on the ICD-O, requiring that reporting institutions convert data from the International Statistics of Diseases and Health-Related Problems – 10th revision (ICD-10) into ICD-O.

Exclusion criteria were: reports of patients younger than 18 years old at the time of the diagnosis, reports not authorized by the institution of origin and reports not found by the reporting sources.

Data were initially extracted from the reporting system (SisBasepop) of the RCBP in Curitiba, the coding of which is based on the ICD-O. The following variables were included: identification (ID card, patient's full name, mother's full name, medical recordnumber); demographic variables (sex, birth date, age at the time of the diagnosis, race, marital status, education level, occupation/profession); data concerning the tumor (complete address/origin, examination number, topographical code,

morphology, diagnostic test, disease extension, laterality, staging, classification of malignant tumors (TNM), distant metastasis, date of the diagnosis); information (year, reporting source, date of collection); and follow-up (date of death, type of death, vital status, date of the last contact).

All the reporting sources (hospitals, outpatient clinics, institutes, laboratories of pathology, mortality information system – SIM) were contacted after filtering and applying exclusion criteria to access the physical and/or electronic medical records to complement and better explore patients' data. The steps followed to select the sample are described in Figure 1.

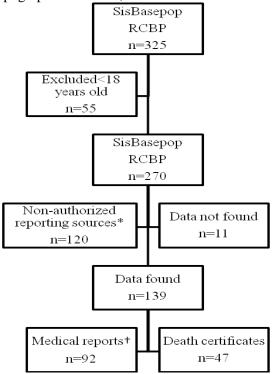


Figure 1. Flowchart concerning the inclusion of data collected from the diagnosed and reported medical records from 1998 to 2012

*Non-authorized reporting sources are facilities that did not release data to the study. †Final sample considered in the analysis

Data were tabulated in Microsoft Excel® 2010, and descriptive statistics were used and expressed in simple and absolute (%) frequency. Sensitivity and specificity describe the proportion of positive or negative results among those known to be ill or those not ill. Internal consistency was verified by comparing information in the system to the original sources'

information; the reported cases' veracity depend on the original documents. Hence, a table was organized to compare the morphology and diagnosis found in the RCBP to the anatomopathological (AP) assessment and/or immunohistochemistry (IHQ) results in the patients' medical records; the latter was considered the gold standard. Data from the medical records concerned the disease progression and examinations. Then. the diagnoses were coded according to the guidelines provided by ICD-O-3 and ICD-10. In the end, all the codes (RCBP and verification) were converted into ICD-10, i.e., cases with mesothelioma morphology ICD-O-3: 90503, 90513, 90523, 90533) were reclassified as C45 (ICD-10).

The number of true positive cases described sensitivity data, while specificity data reflected false-positive cases. The following formula was used to obtain the specificity rate:—n of reported cases/n of cases verified -1 x 100. Spearman's coefficient of correlation was verified using Stata 14®.

This study was approved by the Institutional Review Board at the Federal University of Sciences Paraná, Health Sector (No.1,669,226),and by co-participating institutions, the Health Department Curitiba(Opinion No. 2,027,730), report Hospital de Clínicasat the Federal University of Paraná(No. 1.732.999)and Erasto GaertnerHospital(No. Ethical 1.653.835).

guidelines concerning research involving human subjects were complied with according to Resolution 466/2012.

RESULTS

RCBP data comprised 325 cases of cancer with topographical codes C38 and/or C48 reported by 11 co-participating institutions. After applying the exclusion criteria, 139 reports remained: 92 with medical records and 47 death certificates. The medical records that corresponded to the 47 death certificates were not recovered; hence, they were not included in the subsequent analyses.

Analysis of all the diagnoses available in the medical records (n=92) resulted in 35 (38%) cases of retroperitoneal cancer, 22 (23.9%) of(Hodgkin and non-Hodgkin)lymphoma, 13 (14.1%) cases of mediastinal cancer, eight (8.7%) ofmalignant mesothelioma, five (5.4%) cases of lung cancer, four of peritoneal cancer (4.3%), three (3.3%) metastatic pleural cancer, two (2.2%)pleural cancer, and one (1.1%) prostate cancer (Table 1).

Table 1. Verification of diagnostic data found in Population-Based Cancer Registry using clinical records. Curitiba, PR, Brazil 1998-2012

Verification										
RCBP	C38.1/2/3	C38.4	C45	C48.0	C48.1/2	C34	C61	C782	C81-C86	Total
C38.1/2/3 Mediastinum	13*	0	0	0	0	0	0	0	0	13
C38.4 Pleura	0	1*	0	0	0	4^{\dagger}	1 [†]	3 [†]	0	9
C45 MM	0	1^{\dagger}	8*	0	0	0	0	0	0	9
C48.0 Retroperitoneum	0	0	0	34*	0	1 [†]	0	0	0	35
C48.1/2 Peritoneum	0	0	0	1 [†]	3*	0	0	0	0	4
C81-C86 Lymphoma	0	0	0	0	0	0	0	0	22*	22
Total	13	2	8	35	3	5	1	3	22	92

RCBP - Population-Based Cancer Registry; * Concordant cases; †Non-concordant cases

Most patients (70%) with MM or pleural cancer (n=10) were men (seven); five were married (50%); aged 66.3 years old on average, ranging from 42 to 89. The RCBP did not report race, nor was it included in the medical files of ten (100%) cases; the occupations were not reported in nine cases (90%). Three cases lacked schooling information (30%); while the

remaining reported that three (30%) had completed high school, one (10%) had some medical studies, one (10%) had complete high school, and one (10%) had some undergraduate studies.

When comparing ICD-10 with C38.1-3, mediastinal cancer, no discrepancies were found between the anatomopathological and

immunohistochemical results reported in the patients' medical records and the RCBP reporting (13 cases). All 22 cases of lymphoma (C81-C86) reported by the RCBP were confirmed.

Table2refers to the synthetic verification of the Se and Sp when diagnosing MM and pleural cancer reported by the RCBP.

Table2. Sensitivity and specificity of diagnostic data reported by the Population-Based Cancer Registry. Curitiba/PR, 1998-2012

Type of cancer	True positive – Se* n(%)	False positive – Sp [†] n(%)	Total n=18
C45 – MM	8 (100)	1 (50)	9
C38.4 – Pleura	1 (50)	8 (9.8)	9

MM – Malignant mesothelioma; *Se: sensitivity; †Sp: Specificity

The **Se** of the RCBP for MM (C45) was8/8=100%(95% Confidence Interval - CI): 63-100%); and 1/2=50% (95% CI: 1-98%) for pleural cancer (C38.4), with one case wrongly classified as C45. This case lacked confirmatory morphological examination and should have been classified as C38.4; hence, it is considered a false positive (FP) for mesothelioma.

The following was found for Sp: 74/82=90.2% (95%CI: 82-96%); 8/82 (9.8%) cases were wrongly reported (false positive) as C38.4 (primary pleural tumor), while they referred to four cases of lung cancer, one prostate cancer, and three metastatic pleural tumors. The medical records did not contain information regarding the cancer of origin in these cases of metastatic pleural tumor (Table 1).

The results concerning specificity show MM was overestimated by 12.5% and pleural cancer by 350%. Eight of the nine MM records reported by the RCBPwere correct, while two of the nine records of pleural cancer reported by the RCBPwere correct.

DISCUSSION

The percentage of sensitivity and specificity of MM reports (ICD-10, C45) found in this study was high in both analyses (>90%). However, even though there were few cases, wrong diagnoses of pleural cancer (C38.4) were found with approximately 10% of false-positive cases. Consequently, if these results were applied to all the cases between 1998-2012, the rates reported by RCBP in Curitiba for C45 and C38.4 would be respectively slightly and significantly overestimated.

Historically, cancer control programs use various registries to generate incidence and mortality rates. RCBPs play an essential role in supporting this action as the information they provide is used in research and the planning and implementation of specific services to prevent and control cancer.

The various Brazilian health information systems are growing and increasing the dissemination of information, enabling specific analyses. However, analyses are more reliable and of greater quality when follow-up is performed by an MM-specific cancer registry system. Authors⁽¹²⁾ note that it is essential to monitor the effects of different types of cancer on health and the extension of occupational exposure or environmental contamination over the years.

To better clarify the outcomes and analyze data sensitivity and specificity in this study, physical and/or electronic medical records were considered the gold standard. Authors highlight the need to improve the completion of medical files in hospitals because these are essential tools to improve understanding of cancer causes⁽¹³⁾.

There is a lack of data from epidemiological studies addressing MM in Brazil, and cases of pleural MM and cancer are underreported⁽¹⁴⁾. This may due to the low reporting of these types of cancer in Brazilian information systems (13). Authors (15) note that current statistics on MM in Brazil and worldwide are affected by a lack of appropriate data on its mortality and incidence, lack of records, and wrong coding. The incidence of these types of cancer is likely to increase in the coming decades⁽¹⁶⁾, suggesting the need registries forcancer toimplement efficient

epidemiological monitoring to improve the prevention, quality of life, and prognoses of these patients.

Not all cancer registries produce quality data to enable accurate estimates and impartial incidence rates, especially data related to rare cancer types. However, the Cancer Incidence in Five Continents (CI5) monograph, published by the International Agency for Research on Cancer, provides quality peer-reviewed data⁽¹⁷⁾. Thus far, the RCBP in Curitiba does not have incidence information published by CI5; however, the quality of data is improving to meet publication criteria.

Regarding CI5 vol. X, data concerning 2003 to 2007 show that the six Brazilian RCBPs. whose data are included, reported 82 cases of MM and 59 cases of pleural cancer; 74.4% of these were reported by the RCBP in São Paulo, the largest city in Brazil. Annual rates for both cancers do not surpass 2/million inhabitants. This is well below the incidence found in Italy, for instance, where asbestos was banned in 1992, and the incidence of MM is 18.4 for men and 5.1 for women for every 100,000 inhabitants, and 2.3 for men and 0.9 for women for every 100,000 inhabitantsfor primary pleural cancer(13,17).

The MM specificity in this study reached 100% as no false-negative cases were found. This finding diverges from a study⁽¹⁸⁾ conducted in France, which reports that 86% of pleural cancer cases were actually mesothelioma. This discrepancy may be related to the diagnostic method used by the European population. European countries relate clinical the examination to the patients' occupational history. In Brazil, reporting is made after an anatomopathological or immunohistochemical examination, which decreases the number of MM false-negative cases.

One study⁽¹⁹⁾ conducted in the United Kingdom reports that data from 1971 to 2005 revealed an improvement in the global determination for mesothelioma (C45) after ICD-10 was implemented, when the specific code for mesothelioma was created. The study's high sensitivity is explained by the fact that data were collected after 1995 when the ICD-9 was replaced by the ICD-10 and a specific code for mesothelioma cancer was created.

European studies such as the one conducted in France⁽¹⁸⁾ report the incidence of asbestos-related cancer considering ICD-10 C38.4 and C45 together. However, these codes cannot be assessed together in the RCBP in Curitiba because 9.8% of pleural cancer cases are false positive, suggesting an overestimation of 350%. In Brazil, we should consider that other registries might incur the same error. Thus, caution is needed when considering C38.4 and C45 together to calculate the incidence of asbestos-related cancer.

No divergences were found for mediastinal cancer (ICD-10 C38.1-3) between the medical records and the RCBP; that is, analysis of the medical records, anatomopathological and immunohistochemistry, revealed no underreporting of C45 in this study. Argentinian authors, (7) however, state that the number of mediastinal tumors in Brazil is high compared to European countries. Considering that the mediastinum is quite close to the pleura, these cases possibly include inaccurate MM and pleural cancer reporting.

However, it is possible that the RCBP sensitivity and specificity are different from those of RCBPs located in other Brazilian regions or registries, as it happens in other reporting systems. The study conducted in Recife-PE, reports the poor quality of RHC records that result from delays in the collection, processing, and sending of data and the insufficient number of qualified human resources, which compromise cancer reporting's sensitivity and specificity. Another study conducted in a cancer hospital in Paraná verified that the specificity of RHC in diagnosing MM was 81%, which is below the one found in this study; the difficulty reported was incorrect topography. Considering that RCBP data originate from information provided by RHCs, converting it to ICD-10 is unfeasible when the topographical codes are wrong, which leads to missing data and underreporting of cases^(19,20).

Weaknesses were found in a study addressing pleural cancer, which presented 50% of sensitivity due to the small number of cases. However, this weakness may motivate strategies to search and monitor patients actively. Another limitation is that some institutions that report to the RCBP did not authorize crosschecking information with MM confirmatory exams.

There may be underreported MM and pleural cancer cases in Curitiba, as these may have been reported under other types of cancer, considering that lung cancer was not included in this study. For this reason, workers with occupational asbestos exposure should be monitored appropriately, similar to what happens in other countries, to avoid underreporting.

CONCLUSION

This study's findings show that the Population-Based Cancer Registry presented high sensitivity for MM reports as all the MM cases were correctly identified, recorded, and reported, without any false negatives. However, the result presented false positives for pleural cancer, in which C38.4 rates were highly overestimated.

Creating a specific registry for MM could improve the reporting of cases and favor the storage of complete data, improving the quality of reporting and follow-up of cases.

SENSIBILIDADE E ESPECIFICIDADE DOS REGISTROS DE CÂNCER NAS NOTIFICAÇÕES DO MESOTELIOMA MALIGNO

RESUMO

Objetivo: Mensurar a sensibilidade e especificidade das notificações de mesotelioma maligno do Registro de Câncer Base Populacional de Curitiba/Paraná. **Método:** Estudo retrospectivo, transversal, realizado no registro de câncer de base populacional de Curitiba e em 11 fontes notificadoras, de janeiro a dezembro de 2017. A amostra final foi composta por 92 prontuários de pacientes adultos, com diagnóstico e notificação de registrados com câncer de topografia C38 (pleura, coração e mediastino) e C48 (peritônio e retroperitônio). Para análise da sensibilidade e especificidade utilizou-se o *software Stata 14*, com análise da consistência interna; para cada caso notificado pelo registro foi examinado o prontuário da fonte notificadora correspondente, considerando-o como padrão ouro. **Resultados:** A sensibilidade do registro em notificar mesotelioma (CID-10: C45) e câncer de pleura (CID-10: C38.4) foi de 100% (8/8) e 50% (1/2), respectivamente. A especificidade foi 90,2% (74/82), tendooito casos de outros cânceres classificados como câncer de pleura. **Conclusões:** O registro apresentoualta sensibilidade para notificar mesotelioma maligno, não havendosubnotificação para essescasos, e uma sobreestimativa para as notificações de câncer de pleura (nove ao invés de um) devido ànotificação errônea e equívoca.

Palavras-chave: Mesotelioma. Asbestos. Saúde pública. Epidemiologia. Sistemas de informação.

SENSIBILIDAD Y ESPECIFICIDAD DE LOS REGISTROS DE CÁNCER EN LAS NOTIFICACIONES DEL MESOTELIOMA MALIGNO RESUMEN

Objetivo: determinar la sensibilidad y especificidad de las notificaciones de mesotelioma maligno del Registro de Cáncer Base Poblacional de Curitiba/Paraná/Brasil. **Método:** estudio retrospectivo, transversal, realizado en elregistro de cáncer de base poblacional de Curitiba y en 11 fuentes notificantes, de enero a diciembre de 2017. La muestra final fue compuesta por 92 registros médicos de pacientes adultos, con el diagnóstico y la notificación de registrados con cáncer de topografía C38 (pleura, corazóny mediastino) y C48 (peritoneo y retroperitoneo). Para el análisis de la sensibilidad y especificidad se utilizó el*software Stata 14*, con análisis de la consistencia interna. Para cada caso notificado por el registro, fue examinado elregistro médico de la fuente que ha notificado, considerándolo como estándarde oro. **Resultados:** la sensibilidad del registro para notificar mesotelioma (CID-10: C45) y cáncer de pleura (CID-10: C38.4) fue de 100% (8/8) y 50% (1/2), respectivamente. La especificidad fueel90,2% (74/82), con ocho casos de otros cánceres clasificados como cáncer de pleura. **Conclusiones:** el registro presentóalta sensibilidad para notificar mesotelioma maligno, no existiendo subnotificación para estos casos, y unincremento para las notificaciones de cáncer de pleura (nueve al revés de uno) debido a la notificación incorrecta y equivocada.

Palabras clave: : Mesotelioma. Asbestos. Salud pública. Epidemiología. Sistemas de información.

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