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Incidence of malignant mesothelioma and asbestos exposure in the Emilia-Romagna region, Italy

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Abstract

Background: *The aim of this study is to describe the incidence of malignant mesothelioma (MM) and asbestos exposure in an Italian region in the period 1996-June 2021.* **Methods:** *The study included cases with microscopic confirmation and those with instrumental confirmation. For each case, information on sex, age, tumour site, morphology and date of diagnosis was collected, along with details of exposure to asbestos.* **Results:** *3,097 cases of MM (2,233 males and 864 females) were registered: 90.8% with microscopic confirmation. A total of 2,840 cases involved the pleura (92%), 230 cases the peritoneum (7%), and a small number of cases the pericardium and testis (9 and 18, respectively). Most cases (78.0%) occurred after 65 years of age, while only 1.5% concerned individuals with age<45 years. The standardized incidence rate for the entire period (adjusted to the 2000 Italian standard population and calculated per 100,000 person-years) was equal to 3.9 in males and 1.4 in females, and the trend showed an increase with age in both sexes. Concerning asbestos exposure, 79.7% of cases were exposed (86.7% males and 60.1% females). In 70.3%, exposure was occupational (83.4% males and 33.2% females), while 20.7% of females and 0.8% of males had familial exposure. Building construction, rolling stock manufacture/repair and metalworking were the most prevalent economic activities associated with occupational exposure.* **Conclusions:** *This study offers an overview of MM in an Italian region characterized by high incidence and high exposure due to its particular production activities.*

1. Introduction

Malignant mesothelioma (MM) is a rare tumour of great scientific interest owing to its well-documented correlation with occupational and/or environmental exposure to asbestos and to its increased incidence in Italy and in many other industrialized countries [1-7].

Although asbestos was definitively banned in Italy in April 1994 (pursuant to Italian Law No 257/92), the lengthy latency period between exposure and the onset of disease, the increase in life expectancy, and improvements in diagnostic techniques have led to an increase in the incidence of MM in recent years [8-10]. MM remains a deadly cancer with a very poor prognosis, with a median survival period of ten months [5,9].

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Several countries have established specialized registries to monitor the incidence of MM over time, identify sources of exposure to asbestos, provide medical and legal assistance to patients and their families, evaluate survival, and forecast future trends in the incidence of MM [4, 11-13].

Italy had been using large quantities of chrysotile and amphiboles from 1945 until the 1992 ban and is currently among the countries with the highest frequency of MM worldwide [14]. In Italy, a National Mesothelioma Registry (ReNaM) has been implemented and organized as a network of regional registries [4].

The aim of this study is to describe the results of the Mesothelioma Registry (ReM) in the Emilia-Romagna region in the period 1996-2021 and the associated data on exposure to asbestos.

2. Methods

The ReM for Emilia-Romagna (Italy) covers a region of northern Italy characterized by a large population (currently about five million inhabitants) and a high rate of industrialization. A Cancer Registry specifically dedicated to the study of the incidence and etiology of MM has been active since 1 January 1996. Its task, along with performing the functions of the COR (Regional Operational Centre) for the Emilia-Romagna region, is to register all cases of MM and to acquire information to formulate the correct diagnostic definition and standardized attribution of occupational and non-occupational asbestos exposure according to the standardized rules of the ReNaM [12]. The Emilia-Romagna ReM actively and systematically collects data on all new diagnoses of MM in the region. The collection, coding and registration of cases follow standardized rules at national and international level [15-16].

All cases of MM, with morphology 90503, 90513, 90523 and 90533 [16], occurring between 1 January 1996 and 30 June 2021 in patients with the disease identified in the pleura, pericardium, peritoneum or tunica vaginalis of the testis residing in the Emilia-Romagna region at the time of diagnosis have been registered. The data on incidence are complete until 2019, but a few more months will be required to gather the data for the years 2020-2021 before a complete picture of incidence can be established. For each case, in addition to pathology reports, the medical records on significant hospitalizations in any healthcare institution have been routinely collected, whether public or private, within the region or further afield. Information on both occupational and non-occupational exposure is collected through the ReNaM's ad hoc questionnaire.

Data are collected in all public and private healthcare institutions and anatomical pathology units in the region, the hospital departments where patients with MM are cared for, and all regional public health departments. The ReNaM staff usually acquires reports of newly diagnosed cases in real time, which makes it possible to collect information on exposure to asbestos directly from the patient, when possible, or from a next-of-kin using an ad hoc questionnaire, often administered in hospital or at home and generally returned within two months of diagnosis. To verify the completeness and accuracy of incident cases, the data periodically acquired from the regional computerized archives (mortality and hospital discharge records) are linked with information from the regional population cancer registries and other COR network members.

Cases are reported by sex, age, tumour site and year of diagnosis. The distribution of exposure is reported by sex and by specific economic activity: the staff of the Mesothelioma Registry administers the questionnaires and collects information relating to the various work activities. Subsequently, the multidisciplinary team discusses and evaluates the main activity to which the exposure can be attributed. The other activities are nonetheless reported in the questionnaire.

The standardized incidence rate for the period 1996-2019 was calculated separately for males and females. Incidence rates were adjusted to the 2000 Italian standard population and calculated per 100,000 person-years. Cases were collected until mid-2021, when the region was heavily impacted by the COVID-19 pandemic.

3. Results

In Emilia-Romagna, 3,097 MM cases were registered between 1996 and 2021. The distribution by

age, diagnostic definition, sex and site is shown in Table 1. Most of the cases were diagnosed in the age groups 75+ (1,401 cases, 45.2%) and 65-74 (1,014 cases, 32.8%), and mainly affected the pleura. Few cases (47 cases, 1.5%) were recorded at a younger age (<45 years) and in this subgroup the pleura/peritoneum ratio is 2:1. Concerning diagnostic definition, 2,645 cases (85.4%) were classified as *certain*, 166 cases (5.4%) as *probable* and 286 cases (9.2%) as *possible*.

The distribution by year of diagnosis and site is shown in Table 2. A total of 2,840 cases involved the pleura (92%), 230 cases the peritoneum (7%), 9 the pericardium and 18 the testis. Over the years the number of cases has almost doubled, rising from 75 cases in the 1990s to 150 in more recent years, and

Table 1. Case Distribution by age, diagnostic definition, sex and site. Cases from 1996 to 2021 (updated to 30 June 2021).

	Males					Females				Total (%)
	Pleura	**Peritoneum**	**Pericardium**	**Testis**	**Total**	**Pleura**	**Peritoneum**	**Pericardium**	**Total**	
Age (years)										
<45	18	9	-	4	31	11	5	-	16	47 (1.5)
45-54	90	10	-	3	103	36	10	1	47	150 (4.8)
55-64	337	24	-	3	364	97	22	2	121	485 (15.7)
65-74	701	44	4	3	752	232	29	1	262	1,014 (32.8)
75+	933	44	1	5	983	385	33	-	418	1,401 (45.2)
Total	*2,079*	*131*	*5*	*18*	*2,233*	*761*	*99*	*4*	*864*	*3,097 (100)*
MM diagnostic definition										
certain*	1,793	119	3	17	1,932	619	91	3	713	2,645 (85.4)
probable**	110	9	2	1	122	37	6	1	44	166 (5.4)
possible***	176	3	-	-	179	105	2	-	107	286 (9.2)
Total	*2,079*	*131*	*5*	*18*	*2,233*	*761*	*99*	*4*	*864*	*3,097 (100)*

**Histology with well-defined and suggestive morphology of malignant mesothelioma + immunohistochemistry.*

***Histology with dubious morphology + well-defined cytology suggestive of malignant mesothelioma.*

****Absent histology + well-defined radiological and instrumental reports suggestive of malignant mesothelioma.*

Table 2. Case distribution by year of diagnosis and site.

	Site				
Year	**Pleura**	**Peritoneum**	**Pericardium**	**Testis**	**Total**
1996	63	8	-	2	73
1997	70	7	3	-	80
1998	77	4	1	1	83
1999	67	6	-	-	73
2000	76	9	-	1	86
2001	88	6	-	2	96
2002	98	15	-	1	114
2003	97	6	1	1	105

Table 2 (*Continued*)

	Site				
Year	**Pleura**	**Peritoneum**	**Pericardium**	**Testis**	**Total**
2004	110	8	2	-	120
2005	107	10	-	2	119
2006	100	7	-	-	107
2007	101	14	-	-	115
2008	122	9	-	1	132
2009	111	11	-	-	122
2010	117	12	1	-	130
2011	144	10	-	1	155
2012	142	10	1	2	155
2013	147	5	-	1	153
2014	122	11	-	1	134
2015	141	10	-	-	151
2016	150	10	-	-	160
2017	146	11	-	1	158
2018	142	14	-	-	156
2019	135	8	-	-	143
2020	119	5	-	1	125
2021*	48	4	-	-	52
Total	*2,840*	*230*	*9*	*18*	*3,097*

**At 30 June 2021.*

the increase has involved almost exclusively cases affecting the pleura. The standardized incidence rate (adjusted to the 2000 Italian standard population and calculated per 100,000 person-years) confirms this trend: this increased in males from 2.4 in 1996 to 4.4 in 2016, and in females from 0.8 in 1996 to 1.4 in 2018 (Figure 1).

As regard asbestos exposure, for 166 cases the type of exposure was not defined (patients died or it was not possible to make a classification) and for further 248 cases the information was not available since patients or family members could not be contacted or refused to provide information. The distribution by type of exposure for the 2,683 remaining cases (87% of the total) is reported in Table 3.

Occupational exposure was more frequent in males (83.4% in males vs 33.2% in females), whereas familial exposure was more frequent in females (20.7% in females vs 0.8% in males). Women also showed a higher proportion of cases exposed to environmental asbestos and of subjects for whom the type of exposure was improbable (the available data suggest that exposure to asbestos is unlikely) or unknown (the available data are insufficient to reconstruct the exposure history). By professional exposure, we mean all those sectors of economic activity in which workers have come into contact with material containing asbestos, which was used for thermo-acoustic insulation or as a protective device against fire and heat. In terms of the economic activities involved (Table 4), in Emilia-Romagna most of the males were employed in the construction sector ('construction' means building constructions and therefore bricklayers, while 'construction work completion' means sheet metal work and painting) and in the repair of railway rolling stock (the so-called "Officina Grandi Riparazioni" in Bologna).

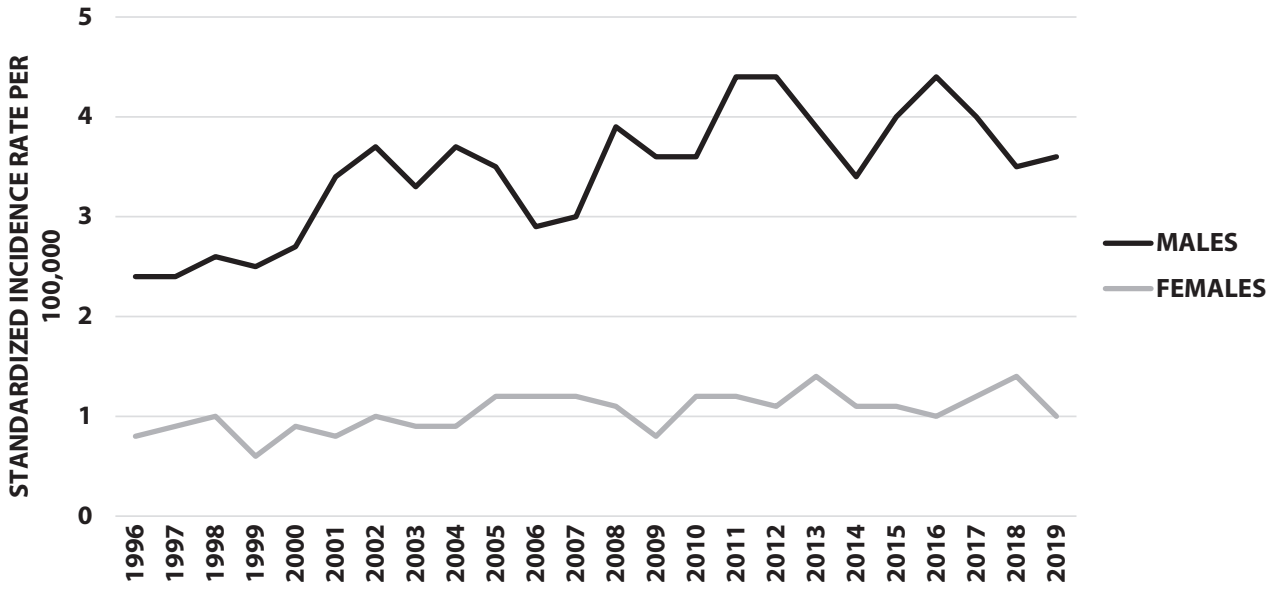

Figure 1. Standardized incidence rates (Italian population per 100,000), by sex. Years 1996-2019.

Table 3. Distribution of malignant mesothelioma by type of asbestos exposure and sex.

Type of exposure	Males		Females		Total	
	N.	%	N.	%	N.	%
Occupational	1,652	83.4	234	33.2	1,886	70.3
Familial	15	0.8	146	20.7	161	6.0
Environmental	29	1.5	28	4.0	57	2.1
Non-occupational	20	1.0	15	2.1	35	1.3
Improbable	63	3.2	87	12.4	150	5.6
Unknown	200	10.1	194	27.6	394	14.7
Total defined cases	*1,979*	*100.0*	*704*	*100.0*	*2,683*	*100.0*

Table 4. Distribution of occupational exposure to asbestos by economic activity and sex.

Economic activity	Male		Female		Total	
	N.	%	N.	%	N.	%
Construction	271	16.4	1	0.4	272	14.4
Manufacture/repair of rolling stock	190	11.5	3	1.3	193	10.2
Engineering industry	155	9.4	12	5.1	167	8.9
Sugar refineries/other food industries	113	6.8	41	17.5	154	8.2
Production of cement/asbestos products	93	5.6	32	13.7	125	6.6
Production of chemical/plastic material	100	6.1	6	2.6	106	5.6
Construction work completion	84	5.1	1	0.4	85	4.5

Table 4 (*Continued*)

Economic activity	Male		Female		Total	
	N.	%	N.	%	N.	%
Glass/ceramic/rubber manufacturing	58	3.5	20	8.6	78	4.2
Transportation	75	4.6	3	1.3	78	4.2
Production/repair of vehicles (not trains or ships)	68	4.1	4	1.7	72	3.8
Manufacturing/processing of metallic products	61	3.7	3	1.3	64	3.4
Textile industry	37	2.2	15	6.4	52	2.8
Trade	42	2.6	9	3.8	51	2.7
Production of electricity, gas and water	40	2.4	-	-	40	2.1
Social services/recreational activities/healthcare	20	1.2	18	7.7	38	2.0
National defence	37	2.2	1	0.4	38	2.0
Agriculture/animal breeding	24	1.5	12	5.1	36	1.9
Metallurgical industry	31	1.9	4	1.7	35	1.9
Other manufacturing industries	27	1.6	3	1.3	30	1.6
Other	126	7.6	46	19.7	172	9.1
Total	*1,652*	*100.0*	*234*	*100.0*	*1,886*	*100.0*

As regard women, most of the workforce was employed in sugar refineries (17.5%), followed by the production of asbestos-cement products (13.7%), which was an activity that required a great deal of patience and precision. Later, women were employed in the manufacture of glass and ceramics and to a more limited degree in the textile industry, which was not highly developed in this region.

4. Discussion

This study provides an overview across 25 years of the incidence of mesothelioma cases recorded in the Emilia-Romagna region and provides detailed information on asbestos exposure.

The study includes over 3,000 MM cases (10% of the entire national case series) recorded in a region that has implemented a widespread network for reporting new cases and a team dedicated to the correct assessment of occupational exposure, which is also valuable for compensation purposes.The incidence rate (adjusted to the 2000 Italian standard population and calculated per 100,000 person-years) for the last completed year (2019) was 3.6 in males and 1.0 in females, a figure slightly higher than the value registered in Italy in 2017 (pleura: 3.4 in males and 0.9 in females; peritoneum: 0.1 in males and 0.09 in females) [8, 15]. Given the small numbers of cases, we are not able to report the rates separately by sex and by site. The slightly higher incidence in females in our region may be due to the fact that in some provinces females were typically hired to manufacture of small products made of cement/asbestos. Since the disease can be associated with even modest exposure to asbestos, each new case must be considered a 'sentinel event' of previous exposures and should be carefully evaluated [7, 17-28].

It should be noted that the 125 cases diagnosed in 2020 could reflect a reduction in diagnoses during the COVID-19 pandemic, as has been widely demonstrated for other cancers [20]. This trend also seems to be confirmed by the 52 cases recorded in the first six months of 2021.

In our region, the average age of diagnosis is 70 years, the Male/Female ratio is 2.5, value that overlap exactly with national data [15]. The average age at diagnosis for Italy, as a whole in the period examined, was 72.0±10.7 years. A total of 78.0% of the patients in Emilia-Romagna were at least 65 years of age at the time of diagnosis, compared to the 72.0% recorded nationally [8, 15].

The primary goal of the ReNaM is to ensure that the data and information collected are complete and accurate. In a previous study, we showed that the completeness and accuracy of the information have improved [29] and that underreporting has probably

been very low in recent years. Diagnostic quality can be considered good: 90.8% of cases are accompanied by cyto-histological confirmation thanks to the widespread practice in the regional health services of performing minimally invasive biopsies, which also make it possible to examine elderly patients and/or patients with reduced performance status.

A total of 93.2% of cases in Italy are diagnosed in the pleura, while 6.3% are identified in the peritoneum. In our series, the number of peritoneal cases is slightly higher (7.4%) compared to Italian [8, 19] and international data [20,22], a situation perhaps linked to a greater involvement of gynaecologists, andrologists and abdominal surgeons in recruiting cases of peritoneal relevance.

Information on exposure has been collected in 87% of cases (the Italian average is 79%). Great efforts have been made in recent years to find healthcare personnel who can be assigned to interview patients at their hospital beds or in their homes in order to have direct information from the patient on any exposure related to his/her previous work activity. A multidisciplinary team comprising an occupational physician, an industrial hygienist and an environmental expert has been tasked with assessing exposure and then reporting any occupational disease where applicable. Occupational exposure (70.3%) is similar to that reported for Italy (69%). The familial exposure data (6%) found in our study are a little higher than the national average (5%).

It is also interesting to note that 14.4% of occupational exposures in our region are related to construction, while the second position is held by 'construction and repair of railway rolling stock', which caused a large number of MM cases in the entire period examined. For women, on the other hand, the production of asbestos cement products and food industries that employed a lot of female personnel after II World War caused a large number of cases among workers in these companies, resulting in an exposure level of almost 30%.

In addition to occupational (higher in males) and familial exposure (higher in females), it is worth mentioning the occurrence of MM without known exposure. Both improbable and unknown exposure are more frequent in women, suggesting an actual environmental exposure, in line with what is described in the literature [30].

The strengths of this work include the *completeness* of the data (the recorded cases are compared each year with the data from population cancer registries for the Emilia-Romagna region) and the *accuracy* of the diagnoses (over 90% of cases have cyto-histological confirmation, 9% have instrumental confirmation, and cases with DCO-Death Certificate Only-represent only 0.2% of the cases recorded).

Another strength is the timeliness of diagnosis and the rapid reporting of each case to the registry and direct patient interviews, when possible (1,123 patients in our series), with a specific questionnaire returned within two months from diagnosis. The availability of recent data, updated to the first half of 2021, is also an advantage for our study.

Among the limitations of this study are the lack of information on disease stage and the absence of information on treatment.

5. Conclusions

This study offers an overview of MM in an Italian region characterized by high incidence and significant exposure due to its particular production activities. The health emergency caused by the spread of the SARS-CoV-2 virus has had a considerable impact on the operational capacity of the CORs. The regional health systems have necessarily been called on to address the pandemic crisis using every available resource, and in some cases this has also led to operational difficulties for the CORs, both in the detection of incident cases and in their ability to analyze anamnestic methods of exposure to asbestos.

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Declaration of Interest: The authors declare no conflict of interest.

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