ORIGINAL ARTICLE

MALIGNANT MESOTHELIOMA IN THE ITALIAN REGION EMILIA-ROMAGNA: INCIDENCE AND ASBESTOS EXPOSURE UPDATE TO 2020

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ABSTRACT

Malignant mesothelioma (MM) is a rare disease of great interest to the scientific community and to public health due to its high lethality and to its association with asbestos exposure. The aim of this study, is to describe the incidence of MM in the period 1996-2020 with the related exposure to asbestos. The data was collected by the Regional Mesothelioma Registry (ReM) which represents one of the 21 CORs (Regional Operational Centers) in Italy. The study includes all cases of MM with a *certain* or a *probable* diagnosis (with microscopic confirmation) and *possible* cases (without microscopic confirmation). For each case, information on sex, date of birth, tumor site, morphology, date of diagnosis, follow-up and province of residence was retrieved. We collected information on previous occupational and non-occupational exposure to asbestos, by type of sector and activity. The exposure information is collected through the ReNaM (National Mesothelioma Registry) analytical questionnaire, administered to the patient or his closest relatives. The data collection is conducted by a regional survey network. Were registered, between 1996 and 2020, 3013 cases of MM classified as *certain* (85.2%), *probable* (5.4%) and *possible* cases (9.4%). The greatest number of cases are recorded for the pleura (2,763) and for the peritoneum (224) in the province of Bologna, Reggio Emilia, Parma and Modena. The most affected age groups are 65-74 and 75 +. Concerning exposure, 70.3% was defined *professional*, 6.0% *familiar*, 2.3% *environmental* and 1.3% *extra professional*.

As regards the provinces of residence, Bologna holds the primacy for cases of *professional* and *environmental* exposure, Reggio Emilia for *familiar* and Parma for *extra-professional* exposure. Most of the exposure to asbestos is recorded in the construction and in the railway sector, mainly in males.

KEY WORDS

Mesothelioma; incidence; exposure; asbestos.

IMPACT STATEMENT

This paper provides a 25-year overview of the incidence of malignant mesothelioma in Emilia-Romagna, a rare and highly interesting disease associated with asbestos exposure.

INTRODUCTION

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

In our country, asbestos was definitively banned in April 1994 (see Law 257/92); nevertheless, the long latency time between the beginning of the exposure and the onset of the disease, the lengthening of life and the improvement of diagnostic techniques have led to an increase in the incidence of MM in recent years (8-9). MM remains a deadly cancer with a very poor prognosis, with a median of approximately 10 months from diagnosis (5, 9). In Italy, the standardized incidence rates per 100,000, recorded in 2013, are equal to 4.2 for male and 1.2 for female, whereas in individuals who were exposed to asbestos the incidence is 100-1,000 times higher. The onset generally occurs after more than 40 years of exposure to asbestos, with a median of 48 ± 11.4 years (8). This pathology can also arise following modest and limited exposure to asbestos: cases have been described in workers exposed to presumably low doses and in relatives of exposed persons who took care, in a domestic environment, of the cleaning of contaminated work clothes. Cases arising from environmental exposure in residents in areas adjacent to industrial settlements where the presence or use of asbestos have also been documented (9). The ReM (Mesothelioma Registry), active since 01/01/1996, is a cancer registry specifically dedicated to the study of the incidence and etiology of MM. The objectives of the ReM, which also performs the functions of COR (Regional Operational Centers) Emilia-Romagna, are the detection of all cases of MM and the acquisition of information for a correct diagnostic definition and standardized attribution of professional or extra-work exposure to asbestos.

The aim of this study, is to report the incidence of MM in the period 1996-2020 with the related exposure to asbestos.

MATERIALS AND METHODS

All cases of MM are detected, with pleural, pericardial, peritoneal, tunica vaginalis testis localization, arising from 1 January 1996 in subjects residing in the Emilia Romagna region at the time of diagnosis. For each registered case, in addition to the reports of the pathological investigations performed, the medical records of significant hospitalizations, carried out in public and private, regional or extra-regional health institutes, are acquired. The information on exposure, both professional and non-working, is collected through the ReNaM analytical questionnaire, administered to the patient or to his closest relatives, by the panel of occupational doctors of the Public Health Departments, members of the regional survey network. Registration for diagnostic definition and exposure attribution follow the standardized rules of the ReNaM (10). The data collection is conducted by a dedicated regional survey network that integrates all public and private Institutes and Pathological Anatomy Services operating on the regional territory, the hospital departments where patients with MM electively converge and all the Departments of Territorial Public Health. The detection network tends to acquire in *real time* the reports of new cases just diagnosed, for the early collection of the information on anamnestic exposure required directly from the patient. To verify the completeness and accuracy of incident cases, link is made with the data period-

	N. CASES	DEFINITION
MM certain	2,566	Histology presents with characteristic morphological picture; characteristic/suggestive/absent immuno-histochemistry + diagnostic confirmation by imaging/clinical diagnosis of discharge.
MM probable	162	Histology presents with dubious morphological picture or cytology with characteristic picture + diagnostic confirmation by imaging/clinical diagnosis of discharge.
MM possible	285	Absent histology/cytology, indicative clinical and radiological data + diagnosis of MM CC discharge.
		DCO with wording "mesothelioma"
TOTAL	3,013	

Table I. *Case Distribution by diagnostic definition, cases from 1996 to 2020 (updated to 12/31/2020).*

YEAR	N. CASES				TOTAL
	SITE				
	PLEURA	PERITONEUM	PERICARDIUM	TESTIS	
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
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	10	-	1	133
2015	141	10	-	-	151
2016	150	10	-	-	160
2017	146	11	-	1	158
2018	138	14	-	-	152
2019	132	8	-	-	140
2020*	97	4	-	-	101
TOTAL 1996-2020	2,763	224	9	17	3,013

Table II. *Distribution of cases by site and year of diagnosis.*

* The incidence is not complete.

ically acquired from the regional computerized archives (Mortality and Hospital Discharge Records) and information exchanges with the regional population cancer registers and the COR network.

RESULTS

In Emilia Romagna 3013 MM were registered between 1996 and 2020: the distribution by type of diagnostic definition is shown in **table I**. Most of the cases (2,566) were classified as *certain* (85.2%), 162 *probable* (5.4%) and 285 (9.4%) *possible* cases and 6 cases with only the death certificate (**table I**). The distributions by year of diagnosis and localization is shown in **table II**. The cases go from less than 100 per year in the first six years of registration to an average of about 110 in 2003-2007, 130 in 2008-2010 and then reaching around 150 starting from 2011.

In the period 1996-2020 the greatest number of cases are recorded for the pleura (2,763) and for the peritoneum (224), on average 10 cases per year. Tumours in the testis are rare (17), about 1 per year. Those of the pericardium are rare.

Table 3 shows the distribution by year and residence. The provinces in which the majority of cases are recorded are: Bologna (660), followed by Reggio Emilia (463), Parma (355) and Modena (329).

An overview of the distribution of MM in the Emil-

ia-Romagna region referring to the period 2014-2018 (the most recent complete five-year period) is shown in **figure 1**. Compared with the national data for 2013 (males 4.2 and females 1.2), Emilia Romagna has a slightly lower rate in males (3.9) and higher in females (1.4). Compared with the regional data of Emilia Romagna for the period 2014-2018 (3.8 in males and 1.1 in females), it is the province of Reggio Emilia that shows the highest rates in males (5.7) and females (2.3). Following, in males, the provinces of Piacenza (4.9) and Ravenna (4.6); while in the females Piacenza (1.4), Ferrara (1.3) and Parma (1.2). As for age (**table IV**), there is a strong gradient for pleural MM in both sexes. Most of the cases are concentrated in the age of 65 +. For the peritoneum, most cases, regardless of age, are recorded at the age of 65 +; while there are no differences for testis and pericardium.

The incidence trend (**figure 2**) shows a slight increase in males but not females.

Of the 3,013 cases of MM, information on exposure to asbestos was collected in 2,605 cases, 169 not defined and 239 not classifiable. Overall, considering all those exposed to asbestos, in our region it was found that 80% of respondents were exposed (87% males and 60% females) (**figure 3**). The distribution of type of exposure is shown in **table V**: in 70.3% it was defined *professional*, 6% *familiar*, 2.3% *environmental* and 1.3% *extra professional*. Occupational exposure is much higher in males
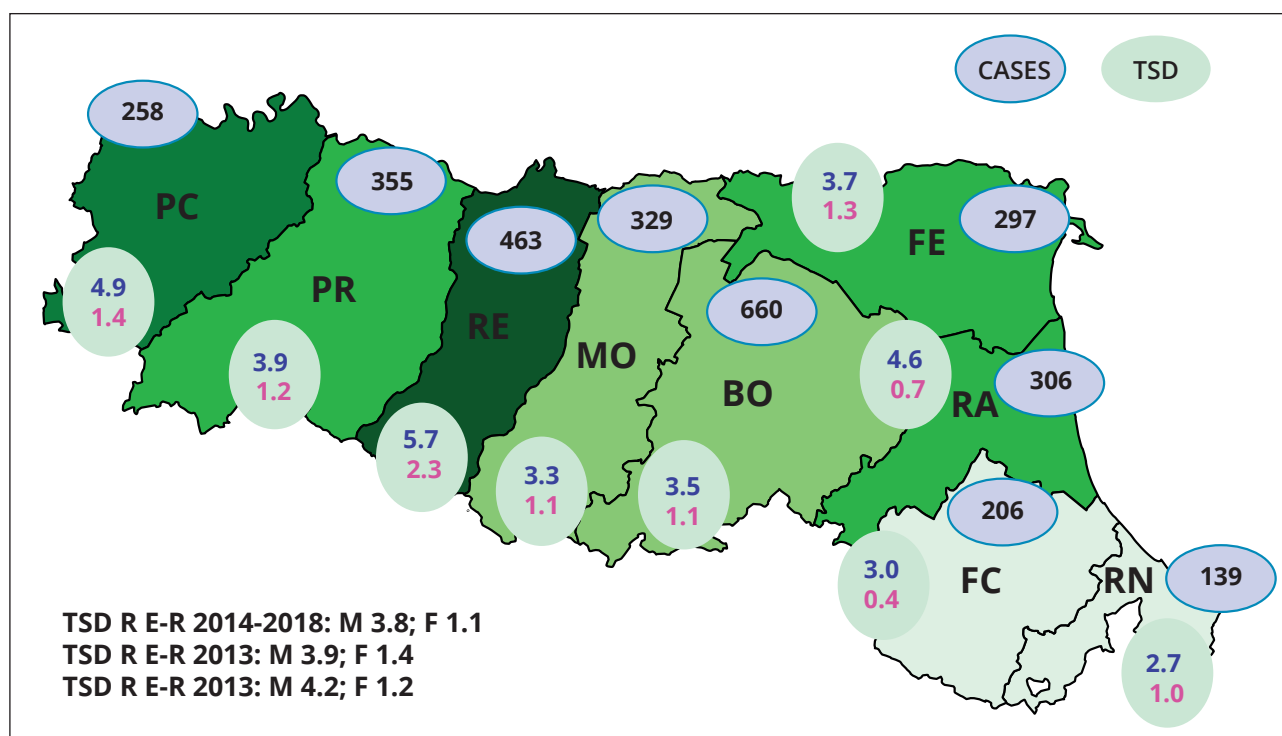

Figure 1. *ReM cases 1995-2020. DIstribution of cases and TSD by province of residence.*
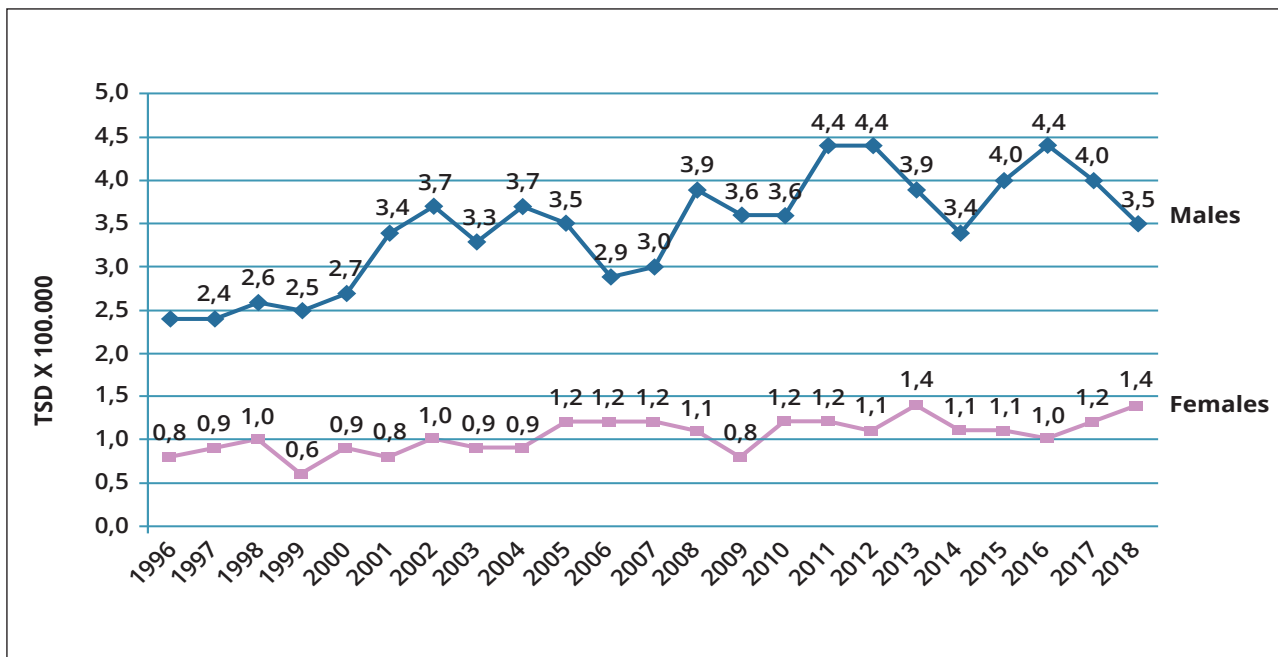
Figure 2. *Standardized incidence rates on the Italian population x 100,000. Years 1996-2018.*
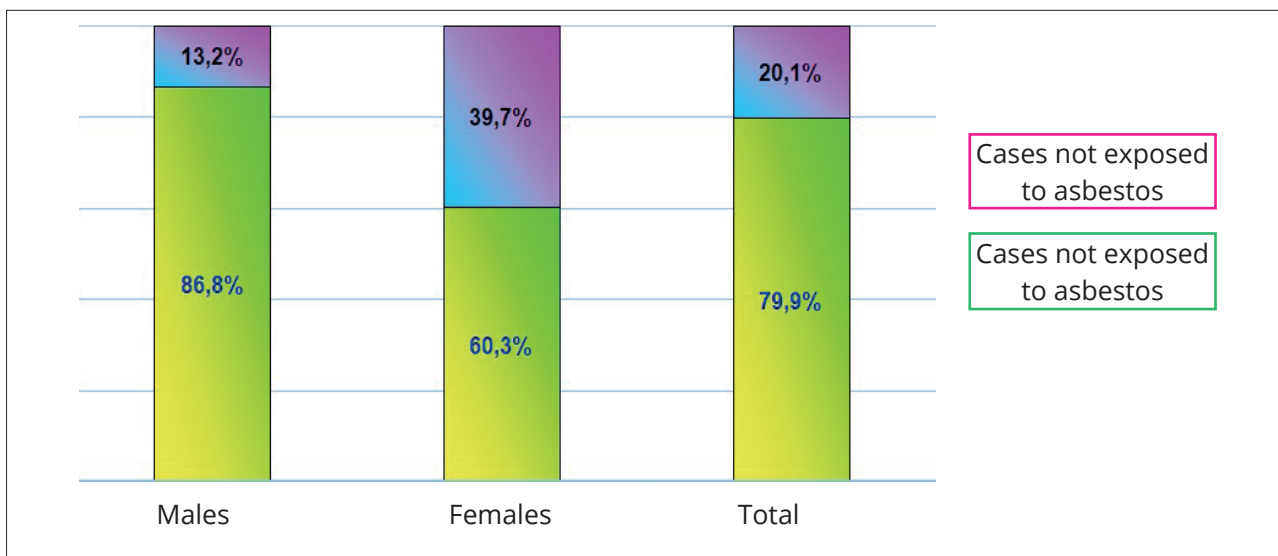

Figure 3. *Distribution by exposure to asbestos by gender in the Emilia-Romagna region.*

(83%) while the family exposure is higher in females (20.6%). As regards the provinces of residence, Bologna holds the primacy for cases of *professional* (400) and *environmental* (19) exposure, Reggio Emilia for *familiar* (38) and Parma for *extra-professional* exposure (7) (**table VI**). **Table VII** shows the working sector involved: most of the exposure to asbestos is recorded in the construction sector and in the railway sector, mainly in males. Women, in general, are less affected, but most of the cases are recorded in the sectors of sugar refineries and in production of cement.

DISCUSSION

Malignant Mesothelioma confirms its characteristics of rare tumor with an increase in the incidence in both genders, recorded up to 1996 and with the first signs of a steady trend in the following years. It should be noted that the ReM data relating to 2019 and 2020, which show a significant decrease, of -8 % and - 34% respectively, compared with the incidence rates recorded in 2018, are probably due to the detection deficit caused by the current viral

YEAR	N. CASES									
	PC	PR	RE	MO	BO	FE	RA	FC	RN	R E-R
1996	5	12	13	8	18	7	7	1	2	73
1997	9	9	10	3	24	7	5	7	6	80
1998	8	8	13	11	20	7	7	6	3	83
1999	7	6	10	6	14	9	7	8	6	73
2000	7	10	10	8	17	13	8	11	2	86
2001	9	13	12	8	22	17	5	5	5	96
2002	8	7	16	12	37	13	11	8	2	114
2003	11	7	16	11	24	10	12	7	7	105
2004	8	16	18	10	24	10	16	12	6	120
2005	13	24	16	12	22	13	9	7	3	119
2006	15	15	10	10	29	10	11	5	2	107
2007	4	19	22	15	28	6	13	6	2	115
2008	9	14	13	20	23	18	13	12	10	132
2009	7	16	10	13	26	16	19	10	5	122
2010	12	16	19	11	26	9	16	14	7	130
2011	14	14	22	22	31	15	18	10	9	155
2012	15	21	29	13	34	16	12	7	8	155
2013	15	16	25	11	35	18	18	11	4	153
2014	12	16	25	19	28	8	16	5	4	133
2015	12	13	20	20	33	23	14	8	8	151
2016	11	17	27	22	33	12	11	13	14	160
2017	17	13	27	20	35	14	15	11	6	158
2018	12	14	36	17	28	11	17	7	10	152
2019	13	22	20	15	24	11	19	10	6	140
2020	5	17	25	11	25	4	7	5	2	101
TOTAL	258	355	463	329	660	297	306	206	139	3,013

Table III. *Distribution of cases by province of residence and year of diagnosis.*

AGE	MALE				FEMALE			TOTAL
	N. CASES				N. CASES			
	Pleura	Peritoneum	Pericardium	Testis	Pleura	Peritoneum	Pericardium	
< 45	18	9	-	4	11	5	-	47
45-54	88	10	-	3	36	10	1	148
55-64	336	22	-	2	94	21	2	477
65-74	683	44	4	3	224	29	1	988
75+	904	43	1	5	369	31	-	1,353
TOTAL	2,029	128	5	17	734	96	4	3,013

Table IV. *Distribution of cases by sex, site and age at diagnosis.*

TYPE OF EXPOSURE	MALE		FEMALE		TOTAL	
	N. CASES	%	N. CASES	%	N. CASES	%
Professional	1,607	83.5	225	33.1	1,832	70.3
Familiar	15	0.8	140	20.6	155	6.0
Environmental	29	1.5	30	4.4	59	2.3
Extra Professional	20	1.0	15	2.2	35	1.3
Improbable	63	3.3	87	12.8	150	5.8
Unknown	191	9.9	183	26.9	374	14.3
TOTAL OF DEFINED CASES	1,925	100.0	680	100.0	2,605	100.0

Table V. *Distribution of malignant mesotheliomas by type of exposure and sex.*

TYPE OF EXPOSURE	N. CASES									
	PC	PR	RE	MO	BO	FE	RA	FC	RN	R E-R
Professional	147	219	314	163	400	177	215	119	78	1,832
Familiar	11	20	38	7	32	19	8	9	11	155
Environmental	4	13	7	5	19	4	3	4	-	59
Extra-professional	5	7	1	4	6	2	4	4	2	35
Improbable	12	20	8	15	41	14	24	8	8	150
Uknown	40	48	26	40	93	33	40	34	20	374
To be defined	6	10	60	42	33	4	6	7	1	169
Not classifiable	33	18	9	53	36	44	6	21	19	239
TOTAL	258	355	463	329	660	297	306	206	139	3,013

Table VI. *Distribution of cases by type of exposure and province of residence.*

pandemic, which makes it necessary to adopt ad hoc in-depth studies currently in progress at the Registry with the involvement of the ReNaM CORs. In view of its almost total lethality, however, this disease still assumes social relevance with an impact greater than that of fatal injuries. The INAIL fatal injuries data reported in 2015-2019 continue to demonstrate a lower occurrence, 610 *vs* 761, compared to the incidence of MM, recorded by the ReM in the same period (see INAIL Annual Report, June 2020).

Since the disease is almost always associated with exposures, even modest ones, to asbestos, each new case must be considered a "sentinel event" of previous exposures and carefully evaluated (7, 10-20). Based on these considerations, the primary objective of the ReM is certainly the completeness of the data and the accuracy of the information collected. These aims seem to have been achieved thanks to the capillary regional detection network which also allows a good recording of MM with extra pleural localization. The diagnostic quality can be considered of a good level: 90.5% of cases are accompanied by cyto-histological confirmation owing to the widespread practice in the regional health services of performing biopsy with minimally invasive techniques, which allow examining also elderly patients and/or patients with reduced "performance status". The involvement of Prevention Services is certainly important because it guarantees a correct anamnestic reconstruction of exposure and the drafting of good quality certifications for INAIL to guarantee the patient and his family members the recognition of the privileged public protection provided for technopathies. In all our cases, these are 249 subjects out of 2,081 with ascertained exposure to asbestos (12.0%), for which it is not possible, under current legislation, to access privileged forms of protection for damage from work.

The extension of the asbestos victims' fund to people suffering from MM due to exposure to "non-professional" asbestos tends to overcome this situation with the provision of an indemnity, albeit *una tantum*; this was introduced on an experimental basis for the three-year period 2015-2017 by the established law 2015 (see L 190/2014 and DIM 04/09/2015), validated for the following

PRODUCTION SECTOR	MALE		FEMALE		TOTAL	
	N. CASES	%	N. CASES	%	N. CASES	%
Constructions	269	16.7	1	0.4	270	14.7
Constructions/repair railway rolling stocks	186	11.6	3	1.3	189	10.3
Engineering industry	151	9.4	12	5.4	163	8.9
Sugar refineries/other food industries	112	7.0	37	16.4	149	8.1
Production of cement/asbestos products	93	5.8	32	14.2	125	6.8
Production of chemical/plastic material	98	6.1	6	2.7	104	5.7
Building completion works	80	5.0	1	0.4	81	4.4
Glass/ceramic/rubber manufacturing	56	3.5	20	8.9	76	4.2
Transportation	72	4.5	3	1.3	75	4.1
Production/repair vehicles (no trains and ships)	65	4.0	3	1.3	68	3.7
Manufacturing/processing of metallic products	60	3.7	3	1.3	63	3.5
Textile industry	35	2.2	15	6.7	50	2.7
Trade	37	2.3	8	3.6	45	2.5
Production electricity, gas, water	39	2.4	-	-	39	2.1
Social services/recreational activities/healthcare	19	1.2	17	7.6	36	2.0
National defense	35	2.2	1	0.5	36	2.0
Agriculture/animal breeding	23	1.4	12	5.4	35	1.9
Metallurgical industry	27	1.7	4	1.8	31	1.7
Other manufacturing industries	27	1.7	3	1.3	30	1.6
Other	123	7.6	44	19.6	167	9.1
TOTAL	1,607	100.0	225	100.0	1,832	100.0

Table VII. *Distribution of occupational exposure to asbestos by main sector of economic activity and sex.*

three-year period 2018-2020 and increased pursuant to art. 11 quinquies, Law 8/2020.

Significantly, the MM recorded in Emilia-Romagna show a high proportion of cases with extra pleural site: the pleura / extra pleural ratio recorded by the ReM was equal to 11.1:1, compared to 13.4:1 and 13,3:1 recorded by CORs in Italy (8, 11) and to some international reports (12, 14) which probably underestimate the data of MM with extra pleural site. Certainly, the articulation of the ReM detection network favours the exhaustiveness of the information collection both from the clinical departments, pulmonology and thoracic surgery mainly, where the MM with pleural site electively flow, and from those where cases with extra pleural site are treated: general surgery, gynaecology, cardiac surgery, urology and andrology. On the other hand, research carried out in the ISPESL/ReNaM field had highlighted some difficulties, especially in some CORs, in the systematic detection of MM with an extra pleural site and had identified possible ways to implement this detection (11).

As regards the age at diagnosis, the average was 71.9 ± 10.7 years; it is noteworthy that 77.7% of subjects were ³ 65 years of age at the time of diagnosis compared to 72.0% recorded in Italy (8). The data could be correlated to a greater tendency, in our region, to perform biopsy sampling even in older subjects, thanks to the good diffusion of minimally invasive practices (*e.g.* video-thoracoscopy) compared to more aggressive traditional methods. The regional annual incidence rates per 100,000, standardized for the 2000 Italian population, show an increasing trend. The years with a higher incidence were 2011, 2012 and 2016 for male (4.4) and 2013 and 2018 for female (1.4) (**figure 2**). The 2014-2018 regional average rates (3.8 M and 1.1 W) are lower than those recorded by the ReNaM in 2013 (4.2 M and 1.2 W). The 2014-2018 TIS show data that cannot be readily interpreted for Piacenza and Ferrara, whereas for Reggio Emilia they are mainly correlated to the significant spread in the past of companies engaged in the production of asbestos-cement products and the construction/repair

of railway rolling stock. In particular, the high value for female is certainly due to the use, peculiar in this province, of female engagement in the manufacturing of "special pieces" in cement/asbestos. The analysis of exposure to asbestos for the 2,605 cases already investigated, highlighted exposure in 79.9% of cases, whereas for the remaining 20.1% no information was found concerning exposure to asbestos, which defines the class "unlikely/unknown" asbestos exposure. This result, rather than indicating a real absence of previous exposures, even remote and episodic, is likely to be ascribed to the difficulty of recording exhaustive anamnestic, professional or extra-professional exhibition information, concerning situations that could have occurred even a few decades earlier the onset of the disease. These difficulties, more relevant for the female gender, are also linked to the reduced median survival of the MM which does not always allow to detect good quality information from the patient voice.

In most of the subjects exposed to asbestos, the origin of the exposure was traced to professional activities (88.0%), whereas exposure due to cohabitation with professionally exposed subjects or to extra-work activities occurred in 9.1% of cases. Also, among the subjects exposed to asbestos in our Region, the rate of those who developed MM because "they lived near production sites that worked or used asbestos (or materials containing asbestos)" or they have frequented environments with the presence of asbestos for non-professional reasons", the so-called environmental exposure to asbestos (see LL.GG. ReNAM) (10), is equal to 2.9%. This fraction is lower than that recorded by ReNaM in Italy, which is equal to 4.4%, and then that recorded in some Italian municipalities, subject in the past to significant environmental contamination by asbestos.

In the Emilia-Romagna Region, the production sectors most involved in the onset of MM were: building constructions (subjects distributed evenly throughout the region); construction/repair of railway rolling stock (cases mostly resident in the provinces of Bologna and Reggio Emilia); metalworking industry, sugar refineries/other food industries (118 of 149 cases, residing in the provinces of BO, FE, RA, PR, FC), production of asbestos cement products (98 of the 125 cases residing in the province of RE). National ReNaM data, on the other hand, indicate among the most involved sectors, in addition to construction (15.5%) and the engineering industry (8.6%), the textile industry (6.4) and shipbuilding (6.1%).

CONCLUSIONS

The study shows that MM is a rare but still highly lethal pathology. The early diagnosis of the neoplasm, although not able to influence the prognosis, allows to obtain more precise information directly from the patient on previous exposure to asbestos and to ensure, in due cases, the right compensation to those who have paid too high a price during his job duties.

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ETHICS

Fundings

Conflict of interests

The authors have declared no conflict of interests.

Availability of data and material

All the data supporting the findings of this study are available within the article and can be shared just before a reasonable request to the corresponding author.

Authors' contribution

LM: conceptualization, investigation, writing-original draft, visualization, supervision; CS: investigation, methodology; IB: writing - review & wediting, supervision. AR: conceptualization, supervision. All authors have read and agreed to the published version of the manuscript.

Ethical approval

N/A

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