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Prof. Marcello Imbriani (1951-2022)

Il prof. Marcello Imbriani ci ha lasciato prematuramente all'età di 70 anni. Tutta la Redazione del Giornale Italiano di Medicina del Lavoro ed Ergonomia, e più in generale i colleghi che lo hanno conosciuto e con cui ha collaborato, lo ricordano con commozione come professionista preparato e studioso solido.

La sua carriera è stata equamente divisa tra il costante impegno di ricerca e insegnamento presso l'Università degli Studi di Pavia dove è stato professore ordinario di Medicina del lavoro e Direttore del Dipartimento di Sanità Pubblica, Medicina Sperimentale e Forense, e la pratica clinica svolta con attenzione e cura presso la Fondazione Maugeri IRCCS, di cui diresse l'Unità Operativa Ospedaliera di Medicina del Lavoro e di cui è stato Direttore scientifico.

E proprio l'attività scientifica, praticata con rigore, gli ha consentito di pubblicare oltre 350 lavori a stampa, tra articoli, libri e materiale didattico, lavori che hanno affrontato in modo particolare le problematiche respiratorie, cardio-metaboliche ed ergonomiche connesse all'attività lavorativa, fino a occuparsi, nell'ultima parte del suo percorso di studioso, delle potenzialità della rigenerazione tissutale anche in ottica riabilitativa.

Non possiamo poi non ricordare il lungo, proficuo e costante impegno nella redazione e successivamente nella direzione di questo giornale scientifico, mantenendo e valorizzando un'eredità preziosa per tutti i collaboratori e, ci auguriamo, per i lettori di questa pubblicazione.

Chiunque sia stato vicino a Marcello Imbriani ne ha conosciuto le qualità umane, l'ironia, e lo spirito antiretorico, cui non vorremmo fare torto dilungandoci troppo in questo ricordo, per quanto sincero e sentito.

Insieme al ringraziamento per quanto Marcello Imbriani ci ha insegnato, rivolgiamo le nostre più affettuose condoglianze alla moglie Marialuisa, alle figlie Chiara e Paola, e ai famigliari più stretti che come e più di noi hanno avuto la fortuna di condividere con lui una parte del cammino.

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MEDICINA DEL LAVORO

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Thyroid parameters variations in healthcare workers and students exposed to low-dose ionizing radiations

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ABSTRACT. **Background.** ***Ionizing Radiations (IR) are an important occupational risk factor for the potential damage that can cause to workers' health and for their presence in numerous professional settings. Health care workers (HCW) can be exposed to IR from various sources, in particular from x-rays using radiological equipment, and represent the largest group of workers occupationally at risk, despite increased regulation and protection which caused exposure to low dose radiations. The thyroid gland is one of the most sensitive organs to damage and an important target of IR, leading to functional and organic diseases. The aim of this study is to assess the variations in thyroid hormones, in a population of HCW exposed to low-dose IR.***
Methods. ***121 individuals of the Teaching Hospital Policlinico Umberto I in Rome exposed to low-dose of IR (78 HCW, 17 Residents and 26 Radiology Technicians Students) were observed assessing serum levels of different thyroid function parameters as free triiodothyronine, free thyroxine and thyroid stimulating hormone at T1, T2 and DeltaT. Age, gender, history of thyroid diseases, BMI and smoke were analyzed as possible influencing factors using linear and multiple logistic regression analysis.***
Results. ***Analyzing TSH, fT3 and fT4 serum levels, in two different measurement (T1 and T2) and considering Delta between them, adjusting for different confounding factors, data showed no variation of TSH levels related to occupational exposure, a decrease of fT3 hormone values in HCW and residents, and an increase of fT4 in HCW.***
Discussion. ***The analysis of our results revealed that hospital occupation has an impact on thyroid hormones variations, with an increase of fT4 and a decrease of fT3 and no variations of TSH.***
These results are in conflict with previous studies evidences, in which both free hormones decreased with a concomitant increase of TSH.
Conclusion. ***Exposure to low dose IR influences levels of free thyroid hormones, with no variation in TSH, which could result in a functional or organic disease. For this reason it is recommended continuous surveillance through a periodic check of all the thyroid hormones for an overall view of each HCW. However, further studies are necessary to confirm hormones trend and assess any related thyroid diseases.***

Key words: *TSH, fT3, fT4, healthcare workers, ionizing radiation.*

Background

Radiation in physics is defined as the emission or transmission of energy in the form of waves or particles through space or through a material medium including humans and animal models. Radiation can be classified into ionizing and non-ionizing energy, based on the damaging effect on living tissues (Alawneh, 2018). Ionizing radiation (IR) is a form of energy that causes tissue disorders by removing electrons from atoms and molecules and can travel unseen and pass through materials that include air, water, and living tissue. A familiar example of ionizing radiation is x-rays, which can penetrate our body and alter molecules within the cells of our body (CDC, 2021). Harmful effects of ionizing radiation vary based on dose, exposure time, type of proliferation, and degree of cell differentiation (Luna-Sánchez, 2019).

The thyroid gland is one of the most sensitive human organs to the damaging action caused by ionizing radiations (IR). Usually IR are considered at high doses when exposures higher than 1 Gy occur, whereas for exposures lower than 0.1-0.5 Gy it is deemed at low doses. Adverse effects induced by IR high doses have been extensively studied especially investigating the health consequences of the explosion of the atomic bombs on Hiroshima and Nagasaki, or the Chernobyl nuclear accident. Literature reports an increased incidence of thyroid cancer and nodules, but also a significant growing of thyroid autoimmunity due to high doses of IR and reported the possible role played by IR high doses in the etiopathogenesis of hypothyroidism, Hashimoto disease and Graves hyperthyroidism (Cioffi, 2020). In general the development of thyroid nodules is a common problem and most of them are benign, only 0,3% turn into malignancy and the most frequent form is the papillary or papillary-follicular adenocarcinoma. The incidence of thyroid cancer had grown from 10 to 100 times due to Chernobyl disaster in high dose IR exposed zones (Epicentro ISS, 2019).

Over recent decades there has been an increased use of IR in medical procedures followed by a significant exposure reduction in general due to more regulation, more workers shifts, use of individual and collective protection devices, but health care workers are still a risk group (Volzke, 2005).

Currently, the attention is focused on the effects on thyroid function and other pathologies related to occupational exposure to low-dose IR, to which health care workers are more easily exposed and considering that IR are an extremely important occupational risk factor (about 30 million workers are professionally exposed to IR) both for the potential damage that can cause to workers' health and for their presence in numerous professional settings like healthcare workers, radiology technicians students and residents.

Most of the available studies have focused on the potential relationship between IR and the development of nodules and malignancy, on the other hand little is known about the possible pathological effects on thyroid function because very few studies investigated hypothyroidism caused by occupational exposure to IR low or very low doses (Alawneh, 2018; Luna-Sánchez, 2019; Chaker, 2017; De Leo, 2016; Antonelli, 1995; De Sio 2016; Caciari, 2014). Furthermore, these studies findings do not allow to extrapolate definite conclusions because of the limited and quite fragmented data.

The aim of our study is to assess the variations in thyroid hormones, such as thyroid stimulating hormone (TSH), free thyroxine (fT4) and free triiodothyronine (fT3), in a population of health care workers, radiology technician students and residents exposed to low-dose of IR, seen in two different medical examinations.

Methods

This retrospective cohort study reviewed data on 121 hospital workers employed in Teaching Hospital Policlinico Umberto I in Rome, Italy who have a history of occupational IR exposure and subdivided into three categories according to hospital occupation.

The category of exposition wasn't considered as a variable but and so to low-dose IR levels. In Italy the ordinance which provides the safety rules relating to protection against ionizing radiations and divides into categories based on the exposure levels is the Legislative Decree 101/2020, hosting the European Atomic Energy Community Directive 2013/59/Euratom, setting the general population limit to 1 mSv.

The employers of Umberto I are subjected to an annual or biannual health examination which includes a complete hematological profile, a physical examination and the evaluation of thyroid hormones, in order to keep a close eye on radiations exposure and for health surveillance in general (according to the Legislative Decree 81/08). Through this medical surveillance all employers data are collected, including socio-demographic data like age, gender and education, anamnestic data like some of the reported in this study, which are:

- Gender;
- Place and date of birth;
- Residential address;
- Name of the agency (Policlinico Umberto I, teaching center in Rome and Sant'Andrea hospital);
- Functional Unit (health care workers, residents and students radiology technicians);
- Years of visits;
- Risk factors (Chemical, physical, biological and night risk and stress);
- Family history for neoplastic, autoimmune and thyroid diseases;
- Weight and height;
- Serum levels of TSH, fT3, fT4 and their variations;
- Previous diagnosis or thyroid diagnosis;
- Any treatment in case of detection of thyroid diseases;
- Smoke;
- Pregnancy.

All of the information collected were reported in a database to be analyzed using SPSS 27.0 statistical program, whereby it was possible to calculate data reported into tables to draw conclusions.

Statistical analysis has allowed the processing of frequency tables as shown. The univariate analysis was carried out using unpaired data Mann-Whitney test and Kruskal-Wallis test for multiple samples. The multivariate analysis included full and backward linear regression models, with dependent variables like TSH, fT3 and fT4; age, gender, role (HCW, residents, students radiology technicians), smoke, BMI and thyroid diseases were independent variables.

The significance level was set on $p < 0.05$.

Results

General characteristics

In Table I the absolute frequency, the percentage and, for age and BMI, the mean and standard deviation of variables of the population assessed are represented. The population consists of a large number of health care workers (78), students radiology technicians (26) and residents (17). The mean age results in 43 years old with a standard deviation of 15,55 years, due to larger sample of health care workers who work for a long time in hospital compared to the residents and student radiology technicians. Regarding the gender instead, females are moderately

Table I. *Characteristics of the population*

	N (%); Mean (SD)
Age	42,98 (SD 15,55)
Sex	
Male	53 (43,8%)
Female	68 (56,2%)
BMI	20,59 (SD 3,76)
Smoke	
No	90 (74,4%)
Yes	31 (25,6%)
Role	
Students Radiology Technicians	26 (21,5%)
HCW	78 (64,5%)
Residents	17 (14,0%)

more frequent (56,2%); the percentage of smokers is 25,6%, compared to 74,4% of non-smokers; the BMI has shown a mean of 20,59 with a standard deviation of 3,76, describing a healthy population according to dietary habits.

Univariate analysis

Considering all the population, Table II shows a reduction of the median value of TSH between the two measurements (from 2,06 to 1,80) and concurrently a raise of fT4 (from 1,19 to 2,80) and a reduction of fT3 (from 3,30 to 1,36).

Looking at gender results, the hormones follow the same trend, except for TSH, which decreases in women and is stable in men. TSH measurements in T1 and fT3 in T2 are the only ones with a significant association, in fact, women have higher values of thyroid stimulating hormone and lower free-triiodothyronin, in first and second measurement respectively.

There is the same trend of population hormones values for smoke variable. In recent measurements there is an association with smokers lower levels of TSH and fT4 and higher of fT3.

Once again, analyzing roles we have: a decrease of TSH and fT3 and an increase of fT4 in Health Care Workers; this setting is similar in Residents and Students, with the only difference of a decrease of fT4 in the first one and a stable values of fT3 in the second one. Kruskal-Wallis analysis showed an association only in free hormones in both T1 and T2, with higher levels of fT4 in residents and even higher in HCW than Students Radiology Technicians, with a different trend of fT3 which is lower in HCW and higher in Residents.

Finally, focusing on the diagnosis of thyroid disease and comparing values in the two measurements, subjects without any disease have the same thyroid hormones trend of the entire observed population.

After Mann-Whitney analysis significant association has been observed only in free thyroid hormones in both T. In particular, there are mixed results regarding fT4, which is a little higher in T1 and very low in T2 in subjects with diseases, while fT3 had a different behavior, because

Table II. ***Median with Min and Max values for every hormone in the two measurement (T1 and T2) and univariate analysis (Mann-Whitney and Kruskal-Wallis) in each variable considered***

	TSH 1 Median (range)	**TSH2 Median (range)**	**fT4 1 Median (range)**	**fT4 2 Median (range)**	**fT3 1 Median (range)**	**fT3 2 Median (range)**
Entire Population	2,06 (0,03-11.28)	1,80 (0,01-11,10)	1,19 (0,67-1,83)	2,80 (0,87-6,20)	3,30 (2,30-5,80)	1,36 0,87-5,13)
Gender						
Males	1,82 (0,14-1,40)	1,80 (0,01-5,10)	1,18 (0,67-1,83)	3,00 (0,87-6,20)	3,40 (2,60-5,40)	1,36 (0,88-5,13)
Females	2,42 (0,03-11,28)	1,81 (0,01-11,10)	1,19 (0,78-1,76)	2,70 (0,90-4,00)	3,28 (2,30-5,80)	1,33 (0,87-4,60)
p	0,012	0,871	0,514	0,347	0,064	0,509
Smoke						
No	2,13 (0,03-11,28)	1,91 (0,01-11,10)	1,22 (0,67-1,83)	2,82 (0,87-4,00)	3,30 (2,30-5,80)	1,31 (0,87-5,13)
Yes	1,97 (0,21-4,92)	1,76 (0,05-5,10)	1,14 (0,78-1,70)	1,71 (0,87-6,20)	3,30 (2,30-5,40)	2,60 (0,90-4,20)
p	0,201	0,088	0,103	0,088	0,562	0,073
Role						
Students Radiology Technicians	2,15 (0,63-11,28)	1,84 (0,01-11,10)	1,03 (0,78-1,54)	1,14 (0,87-1,72)	3,48 (2,72-5,40)	3,45 (2,60-4,60)
HCW	2,05 (0,03-5,10)	1,88 (0,01-8,05)	1,17 (0,67-1,83)	3,10 (1,06-6,20)	3,20 (2,30-4,40)	1,19 (0,87-1,85)
Residents	2,04 (0,21-4,92)	1,48 (0,05-3,36)	1,46 (1,12-1,76)	1,32 (0,90-1,71)	3,90 (2,30-5,80)	3,50 (2,20-4,60)
p	0,932	0,196	<0,001	<0,001	<0,001	<0,001
Thyroid Diagnosis						
No diseases	2,05 (0,03-5,35)	1,83 (0,39-11,10)	1,17 (0,67-1,83)	2,84 (0,87-4,00)	3,29 (2,30-5,40)	1,29 (0,87-4,60)
Thyroid diseases	2,30 (0,05-11,28)	1,41 (0,01-3,36)	1,37 (0,79-1,76)	1,34 (0,95-6,20)	3,69 (2,90-5,80)	3,43 (1,08-5,13)
p	0,936	0,075	0,018	0,044	0,008	<0,001

remained higher in both T in subjects with a diagnosed disease.

In Table III are represented variations of thyroid hormones in correlation with Age and BMI variables, wherein age is the only significant, while BMI is not correlated to thyroid changes. Looking at results with a p<0,05, the age increase corresponds to an increase of fT4 only in the recent measurement while there is a decrease of fT3 in both T. So, the older subjects have more thyroxine but less triiodothyronine compared to younger people.

Multivariate analysis

In Table IV it is considered the association between thyroid stimulating hormone and the variables assessed (Age, Gender, BMI, Smoke, HCW, Residents and Thyroid diagnosis) using a regression model which shows only statistically significant variables after the removal of confounding factors, in former and recent measure (labelled as T1 and T2), and Delta between them (T1 – T2).

According to Table IV, there is not a statistically significant variable associated in T1, while in backward analysis the female gender has a positive association (0,193) with a p=0,033, therefore a higher TSH value in first measurement in females and no association neither in full analysis nor in backward one in T2.

Thirdly, focusing on Delta T measures the only significant result is the thyroid diagnosis, both in full and backward analysis, with a beta value of 0,306 (p=0,005) and 0,292 (p<0,001) respectively, showing that thyroid diseases are linked to higher values of TSH in former measure and so to a decrease in the recent one.

Finally, the evaluation of R2 shows that we have a low reliability of results in all measurements, with a R2 not exceeding 0,106 (in T1 full analysis).

In Table V has been evaluated the trend of fT4 hormone and its correlation with the same variables assessed in the previous one, in the same measurement times.

In T1 there is a positive correlation between BMI, HCW and residents (with the following values: BMI= 0,201; HCW= 0,318; Residents= 0,610), thus showing higher levels of the hormone consequently to professional exposure and higher BMI score in latest measurement.

In T2, in both analyses, unmodifiable variable like age and female gender has a negative correlation (age= -0,181; female gender= -0,123) while HCW and Thyroid diagnosis has a positive one (HCW= 1,104; Thyroid diagnosis= 0,185), confirming once again higher level of ft4 in this workers and showing that thyroid disease may involve an increase of the hormone.

Thirdly, variables with a significant result in Delta T measure are HCW and thyroid diagnosis, with a negative result in the difference between T1 and T2, which means higher values in recent measures and so an increase of the hormone. On the other hand age and female gender, which show a higher Delta with a decrease of the hormone.

Focusing on professional exposure, HCW have higher levels of fT4 in both measurements and Residents have higher levels only in the first one.

Finally, the R2 values in T2 and Delta T seem to be highly reliable with measures near 1, while in T1 we have low values (0,286 in full and 0,272 in backward).

In Table VI there is a negative correlation in T1 for female gender and age, showing lower levels of fT3 in older people and women. Regarding roles, HCW has a negative correlation in T2 and a positive Delta (beta=0,896), while Residents have a positive correlation in T1 and Delta (beta=0,118). The results show that HCW have lower levels in last measurement and a decrease of fT3, whereas residents have higher levels in T1 and an increase compared to Students Radiology Technicians. In contrast with fT4 analysis, where the trend of the hormone was the same in both categories examined, there is an opposite trend.

Lastly, based on R2 values there is a high reliability in T2 and Delta measures and a low in T1.

The comparative analysis of the last three tables shows some important correlations.

Concerning TSH, the only significant correlation is in Delta measure and only with thyroid diagnosis, clearly demonstrating that the trend of this hormone is influenced exclusively by thyroid diseases.

Regarding the two free thyroid hormones it is clear that, in addition to individual characteristics like age, gender, BMI and the presence of a thyroid diagnosis, roles have an important impact on each hormone, causing, as concerns HCW, higher levels of fT4 and lower of fT3.

According to follow-up variable, the univariate analysis (Appendix, Table VII) showed a significant correlation only with the Delta T, while in a later multivariate analysis in which it has been assessed the follow-up in association with all previous variables there is no more statistical significance, like is shown in Tables VIII, IX and X in Appendix. Therefore, it is not proved any important difference between the results of the regression model with and without the variable of follow-up.

Table III. ***Bivariate analysis using Spearman's Correlation coefficient between the Age and BMI variables and variation of thyroid hormones in T1 and T2 measurements***

	TSH 1	TSH2	fT4 1	fT4 2	fT3 1	fT3 2
Age	-0,093 (p=0,311)	0,028 (p=0,760)	0,046 (p=0,619)	0,611 (p<0,001)	-0,324 (p<0,001)	-0,649 (p<0,001)
BMI	-0,137 (p=0,133)	-0,019 (p=0,836)	0,016 (p=0,863)	0,106 (p=0,249)	0,090 (p=0,325)	0,035 (p=0,700)

Table IV. *TSH regression models with standardized coefficients in former measure (T1), recent measure (T2) and Delta between them (T1 – T2), considering all variables in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2*

TSH ß (p)			
	T1	**T2**	**DeltaT**
Age			
Full	-0,175 (p=0,305)	-0,075 (p=0,664)	-0,104 (p=0,545)
Backward			
Female Gender			
Full	0,168 (p=0,134)	0,096 (p=0,397)	0,075 (p=0,504)
Backward	**0,193 (p=0,033)**		
BMI			
Full	-0,053 (p=0,63)	-0,022 (p=0,846)	-0,033 (p=0,769)
Backward			
Smoke			
Full	-0,177 (p=0,061)	-0,170 (p=0,078)	-0,010 (p=0,915)
Backward			
HCW			
Full	-0,022 (p=0,91)	-0,099 (p=0,607)	0,079 (p=0,681)
Backward			
Residents			
Full	-0,217 (p=0,085)	-0,183 (p=0,153)	-0,038 (p=0,764)
Backward			
Thyroid Diagnosis			
Full	0,164 (p=0,131)	-0,136 (p=0,214)	**0,306 (p=0,005)**
Backward			**0,292 (p<0,001)**
R^2			
Full	0,106	0,081	0,100
Backward	0,037	<0,001	0,085

Discussion

The low-dose IR exposition has an impact on the thyroid gland. An overall assessment, focusing only on values frequencies in professional categories considered in this study, shows an increase of fT4 and a decrease of TSH and fT3 in HCW.

There was a significant association only with free hormones in univariate analysis, confirmed by the linear regression which established higher values of fT4 and lower values of fT3 in health care workers compared to students radiology technicians, with no association in the variation of TSH.

The lack of a long observation, the little variations observed in general in thyroid hormones in hospital workers exposed to low-dose IR and the research of a specific disease as main purpose, have resulted in a limited number of studies available about this issue.

For example, in a recent study, Cioffi et al. (Cioffi, 2020) focused, with only one measurement, on assessing alterations of thyroid hormonal status in exposed and non-exposed workers, finding an increase in TSH values and a decrease in fT3 and fT4, establishing a condition of hypothyroidism based on specific cut-off values.

Similarly, the retrospective cohort study performed by Wong et al. (Wong, 2019) tried to correlate the low-dose IR exposure with alterations in thyroid hormones, assessing

Table V. *fT4 hormone regression models with standardized coefficients in former measure (T1), recent measure (T2) and Delta between them (T1 – T2), considering all variables in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2*

fT4 ß (p)			
	T1	**T2**	**DeltaT**
Age			
Full	-0,168 (p=0,272)	**-0,200** **(p=0,009)**	**0,162** **(p=0,043)**
Backward		**-0,181** **(p=0,011)**	**0,203** **(p=0,008)**
Female Gender			
Full	0,066 (p=0,51)	**-0,104** **(p=0,036)**	**0,118** **(p=0,025)**
Backward		**-0,123** **(p=0,003)**	**0,131** **(p=0,002)**
BMI			
Full	**0,251** **(p=0,012)**	0,048 (p=0,323)	0,007 (p=0,896)
Backward	**0,201** **(p=0,013)**		
Smoke			
Full	-0,068 (p=0,422)	0,027 (p=0,518)	-0,041 (p=0,347)
Backward			
HCW			
Full	**0,443** **(p=0,010)**	**1,143** **(p<0,001)**	**-1,038** **(p<0,001)**
Backward	**0,318** **(p<0,001)**	**1,104** **(p<0,001)**	**-1,095** **(p<0,001)**
Residents			
Full	**0,603** **(p<0,001)**	0,056 (p=0,316)	0,076 (p=0,193)
Backward	**0,610** **(p<0,001)**		
Thyroid Diagnosis			
Full	0,023 (p=0,808)	**0,166** **(p<0,001)**	**-0,160** **(p=0,002)**
Backward		**0,185** **(p<0,001)**	**-0,135** **(p=0,004)**
R^2			
Full	0,286	0,826	0,806
Backward	0,272	0,823	0,801

326 health care workers and showing a critical decrease of fT3 and fT4 hormones, with a concurrent correlated increase of TSH and a condition of overt hypothyroidism.

Furthermore, Luna-Sanchez et al. (Luna-Sanchez, 2019) evaluated thyroid hormones alterations in a small sample of 46 health care workers belonging to category A, assessing an increase of TSH values in 1 and 5 years with no modification in serum levels of fT3 and fT4, and showing a condition of subclinical hypothyroidism.

In another study, Alawneh et al. (Alawneh, 2018) evaluated TSH, fT4 and fT3 levels in 50 exposed health care workers and 50 non-exposed, concluding that alterations in serum concentration levels of thyroid hormones are associated to occupational radiation exposure especially among men, in particular with variations in TSH and fT4 with no modifications in fT3, just as the other cited studies with an increase of TSH and a decrease of fT4.

Compared to all the scientific scene studies, one of our stronger benefits was the presence of two measurements, which gave us the opportunity to assess the trend over years in an exposed population of hospital workers, even after several years in some cases. The two times, T1 and T2, allow us to have a follow-up period, which was a considered variable, even if it was rejected after a linear re-

Table VI. *fT3 regression models with standardized coefficients in former measure (T1), recent measure (T2) and Delta between them (T1 – T2), considering all variables in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2*

fT3 ß (p)			
	T1	**T2**	**DeltaT**
Age			
Full	-0,143 (p=0,357)	-0,032 (p=0,562)	-0,042 (p=0,663)
Backward	**-0,223 (p=0,009)**		
Female Gender			
Full	**-0,246 (p=0,017)**	-0,052 (p=0,155)	-0,077 (p=0,229)
Backward	**-0,243 (p=0,003)**		
BMI			
Full	-0,022 (p=0,83)	-0,001 (p=0,968)	-0,010 (p=0,871)
Backward			
Smoke			
Full	-0,027 (p=0,754)	-0,015 (p=0,622)	0,002 (p=0,966)
Backward			
HCW			
Full	-0,115 (p=0,507)	**-0,902 (p<0,001)**	**0,946 (p<0,001)**
Backward		**-0,948 (p<0,001)**	**0,896 (p<0,001)**
Residents			
Full	**0,305 (p=0,008)**	0,004 (p=0,914)	**0,163 (p=0,024)**
Backward	**0,372 (p<0,0001)**		**0,118 (p=0,051)**
Thyroid Diagnosis			
Full	0,049 (p=0,617)	0,053 (p=0,134)	-0,032 (p=0,598)
Backward			
R^2			
Full	0,264	0,904	0,708
Backward	0,258	0,900	0,702

gression in the multivariate analysis and was not displayed in the backward data. The reason may be a too short follow-up period, involving a longer observation with a specific length, assuming that if it had been longer it could have been significant.

Differently from many others, the assessment of multiple variables in the evaluation of the relationship between IR and HCW was one more highlight of this study. In fact, the appraisal of the population characteristics, age and gender, smoke habits, BMI, roles and a thyroid diagnosis, turned out to be important in a general view, demonstrated in several values obtained.

Some restrictions instead were represented in the exposure of the population, in which have been considered professional categories and not typical IR exposure levels, and thus a variety in the sample without a dose-response relationship, not providing data on radiation exposure dose either.

Even with two measurements it was not possible to get an equal length in every HCW using a retrospective evaluation, but a wide selection based on data available from clinical records.

Although some interesting findings could be emphasized from our study, we did not establish any cut-off value for thyroid diseases, we just defined a variation instead; the study results do not allow us to define the presence or not of pathologies, but to understand that professional category and consequently IR exposure involve an effect on the thyroid gland. The most important and sig-

nificant values considered in this study were free thyroid hormones, commonly not assessed in hospital workers routine checks, while TSH, which was not statistically relevant, is the most common thyroid data for survey and it is not able to describe much about the real thyroid health condition alone.

Moreover, it is not possible to obtain a diagnosis of hypo- or hyperthyroidism or an underlying disease throughout a population analysis without the assessment of the various combinations of the 3 hormones, which allows to understand if the IR exposed has a variation of the thyroid hormones and to find out the individual effective condition.

Conclusion

In conclusion, this study proposes a higher thyroid function alteration risk in health care workers and in general in a hospital population exposed to low-dose IR, stronger in free hormones rather than TSH, and subsequently the need of a regular and more careful thyroid surveillance. Further studies are necessary to confirm this association, the importance of an evaluation of the whole gland parameters and also the importance of defining how much measurements are needed to get an overall and more specific view. Two measurements or more are critical in order to comprehend how deep is the low-dose IR influence in a specific period and in health care population, to see the possible role of different hospital tasks also in association with time and to detect any disease before their manifestation.

Certainly, further studies with larger number of HCW are required to confirm hormones trend, to demonstrate in a wider spectrum the dose-response relationship and to provide a guideline for more suitable precautions for IR exposure.

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Appendix

Table VII. ***Spearman's Correlation coefficient between the Follow-Up variable and variation of thyroid hormones***

	DeltaTSH	DeltafT3	DeltafT4
Follow-Up	-0,006 (p=0,948)	-0,340 (p<0,001)	0,401 (p<0,001)

The univariate analysis shown in Table III demonstrates a correlation between the health care workers follow-up and the thyroid hormones difference, in which there were a statistically significant correlation with DeltafT3 and DeltafT4; in fact, with an increase of follow-up time there is a reduction of fT3 and an increase of fT4.

Table VIII. ***TSH regression models with standardized coefficients in Delta between recent measure (T1) and former measure (T2), considering all variables previously considered, adding Follow-Up variable, in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2***

TSH ß (p)		
	DeltaT Full	**DeltaT Backward**
Age	-0,104 (p=0,545)	
Female Gender	0,075 (p=0,505)	
BMI	0,032 (p=0,776)	
Smoke	-0,010 (p=0,918)	
HCW	0,077 (p=0,689)	
Residents	-0,036 (p=0,778)	
Thyroid Diagnosis	0,305 (p=0,006)	0,292 (p<0,001)
Follow-Up	-0,005 (p=0,958)	
R^2	0,100	0,085

Table IX. ***fT4 regression models with standardized coefficients in Delta between recent measure (T1) and former measure (T2), considering all variables previously considered, adding Follow-Up variable, in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2***

fT4 ß (p)		
	DeltaT Full	**DeltaT Backward**
Age	0,167 (p=0,038)	0,203 (p=0,008)
Female Gender	0,114 (p=0,031)	0,131 (p=0,002)
BMI	-0,001 (p=0,983)	
Smoke	-0,044 (p=0,321)	
HCW	-1,028 (p<0,001)	-1,095 (p<0,001)
Residents	0,065 (p=0,276)	
Thyroid Diagnosis	-0,156 (p=0,002)	-0,135 (p=0,004)
Follow-Up	0,043 (p=0,356)	
R^2	0,808	0,801

Table X. ***fT3 regression models with standardized coefficients in Delta between recent measure (T1) and former measure (T2), considering all variables previously considered, adding Follow-Up variable, in Full row and only statistically significant variables in Backward row, and the coefficient of determination R^2***

fT3 ß (p)		
	DeltaT Full	**DeltaT Backward**
Age	-0,041 (p=0,674)	
Female Gender	-0,078 (p=0,226)	
BMI	-0,012 (p=0,854)	
Smoke	0,002 (p=0,976)	
HCW	0,948 (p<0,001)	0,896 (p<0,001)
Residents	0,160 (p=0,031)	0,118 (p=0,051)
Thyroid Diagnosis	-0,031 (p=0,613)	
Follow-Up	0,011 (p=0,842)	
R^2	0,708	0,702

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MEDICINA DEL LAVORO

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Nitrous oxide occupational exposure in conscious sedation procedures in endoscopic ambulatories: a pilot retrospective observational study in an Italian hospital

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ABSTRACT. **Introduction.** ***Nitrous oxide (N2O) is widely used to induce sedation also outside of operating rooms; there is a chance of workplace exposures for the operators engaged in the outpatient use of nitrous oxide. The aim of this research is to assess nitrous oxide exposure in gastroenterology outpatient settings.***
Methods. ***We performed an observational study marked by N2O environmental testing in a gastroenterology outpatient care; environmental research was supported by biological monitoring with urinary N2O analysis in exposed operators. The research was conducted both without and using a collective security device (NIKI mask).***
Results. ***The study was rolled out in 10 sessions of day shift procedures, totaling 4105 samples. The average N2O concentration in the environment was 27.58 (SD 1.76) and 449.59 (SD 35.29), respectively with and without NIKI Mask; the distribution of gases in the environment under investigation was not homogeneous (Anova-test P=0.001). Biological testing revealed a substantial rise in urinary concentration of 8.97 (p=0.001) between the start and the end of the shift, and the use of the NIKI-mask was effective (p=.003).***
Discussion. ***The exposure levels reported exceed the limits of 50 ppm (Italy operating rooms threshold value) as well as the value of 25 ppm (NIOSH threshold-value), indicating a significant issue in the outpatient use of N2O. Technical measures are needed to contain the occupational risk from N2O exposure outside of operating rooms; for the exposure results detected in this research, it is also evident that workers exposed to N2O must be subject to adequate health surveillance accounting for this occupational risk.***

Key words: *Nitrous Oxide, Occupational Exposure, Conscious Sedation.*

RIASSUNTO. Esposizione occupazionale al protossido di azoto nelle procedure di sedazione negli ambulatori di endoscopia: uno studio pilota osservazionale retrospettivo in un ospedale italiano.
Introduzione. **Il protossido di azoto (N2O) è usato per indurre la sedazione anche al di fuori delle sale operatorie; c'è la possibilità che gli operatori che usano il protossido di azoto in contesti esterni alle sale operatori abbiano un'esposizione professionale. Lo scopo di questo studio è quello di valutare l'esposizione al protossido di azoto nel contesto negli ambulatori di gastroenterologia.**
Metodi. **Uno studio osservazionale è stato condotto testando i livelli ambientali di N2O in ambulatori di gastroenterologia; la ricerca ambientale è stata supportata da monitoraggio biologico con analisi dell'N2O urinario negli operatori esposti. La ricerca è stata condotta sia con che senza l'utilizzo di un dispositivo di sicurezza collettivo (maschera NIKI).**

Introduction

Sedation is an essential part in any gastrointestinal endoscopic procedure since it helps gastroenterologists to relieve patient anxiety and distress while optimizing the endoscopic exam's result (1). Nitrous oxide gas, as well as benzodiazepines and opioids, can be used to induce conscious sedation (2).

Multiple research articles and reviews have thoroughly defined esophagogastroduodenoscopy (EGD) or upper endoscopy sedation monitoring. A basic diagnostic EGD is a reasonably short procedure that only requires 30 minutes of sedation. Sedation may be performed for diagnostic upper EGD with either mild sedation or controlled anesthesia, as part of monitored anesthesia care (MAC) (3,4). Nitrous oxide-sedation is also a safe and reliable alternative for patients undergoing digestive endoscopy (5,6,7).

The use of moderate to deep sedation is becoming more common, which can be difficult for both anesthesiologists and gastroenterologists (8). While deeper sedation helps gastroenterologists to conduct more complex procedures, there is a risk of multiple cardiopulmonary complications, particularly in high-risk patients (8,9,10).

Nitrous oxide has proved clinical efficacy, but at such ambient levels, it may pose a health threat to medical professionals who are chronically exposed.

This study aims to detect the critical issues with the use of this anesthetic gas in ambulatory settings (outside of surgical rooms), by sampling N2O in this setting with and without the usage of the "NIKI 2002" Airnova mask, a double mask used to reduce gas dispersion in the room while administering anesthetic gases to patients, when compared to the use of a traditional mask (11). This study also aims to analyze the exposure conditions of health professionals engaged in these diagnostic procedures. One of the major issues in nitrous oxide conscious sedation is the definition of reference values in ambulatory rooms that are not comparable to those established for operating rooms; to this end, it should be noted that current legislation in Italy establishes environmental criteria for the use of N2O in operating rooms but no specific references for outpatient settings.

Risultati. **Lo studio è stato condotto in 10 sessioni di procedure diurne, per un totale di 4105 campioni. La concentrazione media di N2O nell'ambiente era 27.58 (DS 1.76) e 449.59 (DS 35.29), rispettivamente con e senza la maschera NIKI; la distribuzione dei gas investigata nell'ambiente non era omogenea (test ANOVA p=0.001). Il campionamento biologico ha rivelato un sostanziale aumento di N2O nella concentrazione urinaria di 8.97 (P=0.001) tra l'inizio e la fine del turno, e l'uso della maschera NIKI si è dimostrato efficace (p=.003).** ***Discussione.*** **I livelli di esposizione rilevati eccedevano i limiti di 50 ppm (il valore limite stabilito in Italia per le sale operatorie) e di 25 ppm (valore limite stabilito dal NIOSH), indicando un problema rilevante nell'uso ambulatoriale di N2O. Sono necessarie misure tecniche per contenere il rischio occupazionale di esposizione all'N2O al di fuori delle sale operatorie; visti i risultati dell'esposizione rilevanti in questo studio, è evidente che i lavoratori esposti all'N2O dovrebbero essere soggetti ad adeguata sorveglianza sanitaria, tenendo conto di questo rischio occupazionale.**

Parole chiave: Protossido di azoto, Esposizione occupazionale, Sedazione cosciente.

In surgical rooms, the ventilation system allows anesthetic gas retrieval either locally (through patient's intubation, with a vacuum retrieval system) or through the ventilation system (with an appropriate number of air changes that allows deep gas sedation to be carried out safely). Many ambulatory environments are not equipped with gas retrieval systems and may not have a sufficient number of air changes. This implies that for superficial sedation of the patient, although estimating a low anesthetic gas emission based on the concentrations used, due to a continuous succession of procedures throughout the day, an accumulation of anesthetic gas may occur. For this reason, in order to be able to use outpatient environments that lack the same ventilation systems as surgical rooms, a possible strategy is to perform an aspiration of residual gas, even if the dispersion is not localized because the patient is not intubated, by using devices that allow to retrieve the excess gas (i.e.: the NIKI mask).

In terms of occupational toxicology, the most important factor is obviously persistent exposure to N2O; literature cites numerous findings that correlate chronic exposure to nitrous oxide with the onset of adverse effects on workers exposed to dental procedures. The most often reported side effects are: an increase in the rate of spontaneous abortion, infertility and reproductive difficulties, congenital anomalies and fetal growth delay; an increase in the incidence of cancer in the uterine cervix and kidney, liver diseases; adverse effects on bone marrow function and immune system, generalized neurological disorders and psychomotor dysfunction (12,13,14,15,16, 17).

Occupational exposure, when exceeding TLVs, may trigger nausea, irritability, and headache (18,19), as well as liver, renal, and hematopoietic system defects (20,21), and neurobehavioral shifts (22). Furthermore, exposure to waste anesthetic gases is linked to an increased occurrence of abortion/miscarriage (23,24), decreased fertility (25), and birth defects, which are particularly linked to N2O (26). Chronic exposure can also affect DNA (27).

The study's goal, in addition to evaluating occupational exposure of workers to N2O, is to assist the scientific community in determining the reference environmental values specific for endocrinology ambulatories that use nitrous oxide, with a focus on the pediatric background.

The study's key endpoint measures were associated with the determination of nitrous oxide environmental and biological concentrations during gastrointestinal endoscopic sessions. These tests are taken to monitor the degree of anesthetic gas exposure among operators and to investigate the effectiveness of the preventive system (structure/implant features, anesthesia devices, work procedures, and human factors).

Methods

The study relies on a two-step assessment: the first focus is on the interpretation of data obtained from N2O environmental monitoring, while the second is centered on biological monitoring data from exposed operators at the beginning and at the end of their shifts.

The environmental concentrations of nitrous oxide were detected during a four months' timeframe, for a total of 10 measurements, using the photoacoustic spectrometers Innova-B&K (Brüel & Kjær, Denmark) "Multi-gas monitor model 1312" and Innova-B&K (Brüel & Kjær, Denmark) "Multi-sampler model 1309". Measurements were performed using one of these two instruments for the whole outpatient session. The measuring probes were placed in five different points in the ambulatory (Figure 1).

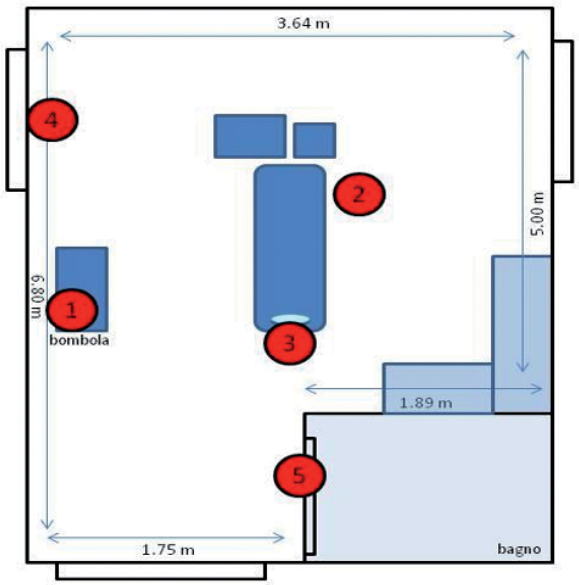

Figure 1. ***The measuring probes were placed in different point (1=Niki; 2=head-window; 3 head-door; 4= stabilized door; 5=access)***

The environmental monitoring assessments were divided into two sessions: the first, in which patients were sedated with an O2/N2O mixture delivered without the use of an evacuation system, and the second, in which patients were sedated with the same O2/N2O mixture, but with the assistance of a mobile double mask evacuation system of type "NIKI 2002 Airnova" capable of intercepting the emitted anesthetic gases.

A descriptive study design was used to assess gas concentrations in a hospital's gastroenterology ambulatories.

For environmental sampling results, the Shapiro-Francia analysis was used to measure data dissemination. The data was then stratified using the categorical variable relating to the use of the NIKI mask. The t-Student parametric test was then used to analyze the averages in relation to the variable of NIKI mask use; the ANOVA variance test was performed in order to investigate the averages of the environmental levels of N2O at the respective sample points, with the averages above two being corrected with the Bonferroni's test.

The study's participants were a team of health professionals who serve in the gastroenterology ambulatory for each colonoscopy session; the team included one gastroenterologist and one nurse. An operator with the qualification of prevention technician was involved in the environmental analysis and the preparation of urinary samples; biological sampling was performed on the urine for the biological analysis. The environmental data and urinary samples were analyzed in validated laboratories.

Sample collection was performed in environments free of pollution due to anesthetic gases. After collection, a urine aliquot was immediately transferred into an hermetically sealed tube; this passage was performed very quickly (t < l minute) so that the vapors loss was negligible (< 5%). The urines were then acidified with sulfuric acid (200 µl of H2S04 9N as antimicrobial agent) and stored for more than 24 h. The vials, appropriately labeled, were transported to the laboratories, through a thermostatic thermal bag and stored at 4°C up to the analysis. The samples were then analyzed in laboratory, through a Thermo Trace GC Ultra with Polaris Q Mass Spectrometer GC/MS System (IET-International Equipment Trading Ltd., Mundelein, Illinois, USA), and Thermo Direct Probe Controller (IET-International Equipment Trading Ltd., Mundelein, Illinois, USA).

A descriptive analysis of the N2O concentrations of urine was performed. Due to the limited sample size, data distribution analysis was performed using the Shapiro-Wilk test. The t-test was thus used to compare the urinary concentration averages of N2O for doctors and nurses at time 0 (T0, start of shift), and the same was repeated at time 1 (T1, end of shift). The t-test was also used to analyze N2O averages between time T0 and T1 in participants who wore NIKI masks and those who did not. Statistical significance was determined by p<.05 values.

Results

The endoscopists and nurses engaged in the outpatient diagnostic procedure were hired for the study; the observation period lasted 10 days, and 48 patients were treated; diagnostic services were conducted during day shifts between 06:57 and 18:23.

3.1 Environmental analysis (Study 1)

The N2O levels in the environment were first stratified in order to compare the conditions under which N2O is used without any emission control mechanism and then with the use of the control mechanism (NIKI mask).

For a total of 10 daily observations performed in a four months' timeframe, 4105 sequential samples were collected for each of the five detection probes; having discovered values well above the exposure limits (50 parts per million, ppm) in the absence of the use of containment mechanisms (NIKI mask), it was decided to discontinue the experimentation in this way and continue the sampling with the use of NIKI masks to safeguard all operators involved. Therefore, only 374 environmental determinations were obtained without using the NIKI mask, while 3731 were obtained using this mask.

The average environmental concentration of N2O in the air was 27.58 (SD 1.76) using the NIKI mask and 449.59 (DS 35.29) without using it. The difference in averages (with and without NIKI) detected was largely significant (P<0.001).

As aforementioned, the environmental probes in the room were placed in five different spots; the average concentration in each individual point (Table I) was significantly different (P<0.001) from the other points, even though a low strength (F16.42) and R2 were found supporting the model only of P=0.017.

Table I. ***Average concentrations in different points***

Sampling point	Number of observations	Mean value (ppm)	S.D.
1- Niki	749	40.00	85.47
	75	436.52	329.59
2- head-window	748	23.59	43.23
	75	518.77	416.95
3- head door	747	26.57	46.19
	75	424.73	308.18
4- stabilized door	746	18.33	32.06
	75	446.06	319.51
5- access	741	29.40	49.59
	73	421.11	348.20
Total	3731	27.58	54.87
	373	449.59	346.62

According to the Threshold Limit Value in the measurements in which the NIKI mask was used, the levels set by National Institute for Occupational Safety and Health (NIOSH) (25ppm) were exceeded in 982 samples, the levels set by Italian law for 'new' operating rooms (50ppm) were exceeded in 645 samples and those for 'old' operating rooms (100ppm) in 288 samples.

There were major variations in environmental concentrations of N2O at the different sample points (Table II), implying that the lack of specific mechanisms for handling air flows and modifications causes areas of greater concentration and, as a result, greater professional exposures to anesthetic gases.

Table II. ***Test Comparison of N2O concentration (in ppm) and sampling points***

	1- Niki	2- head-window	3- head door	4- stabilized door
2- head-window	-16.41* P<0.001			
3- head door	-13.43* P<0.001	2.98 P=1.00		
4- stabilized door	-21.67* P<0.001	-5.26 P=0.62	-8.24 P=0.03*	
5- access	-10.60* P<0.001	5.82 P=0.39*	2.84* P<0.001	11.08* P<0.001

* significant values, P<0.05

Table III. *Comparison of N2O urine concentration averages*

	Observations	Mean value	S.E.	S.D.	95% C.I.	p-value
Comparison of N2O urine concentration averages with the use of Niki mask						
Operators T1	16	10.14	0.94	3.78	8.13 / 12.15	
Operators T0	16	1.17	0.58	2.32	-.06 / 2.41	
Difference	16	8.97	0.88	3.53	7.09 / 10.85	P<0.001
Comparison of N2O urine concentration averages without the use of Niki mask						
Operators T1	4	77.49	33.09	66.17	-27.80 a 182.79	
Operator T0	4	0.62	0.26	0.52	-0.21 a 1.45	
Difference	4	76.87	33.00	66.00	-28.13 a 181.88	P=0.10

3.2 Biological monitoring (Study 2)

There was no discrepancy in urinary concentrations between doctors and nurses when the two classes of operators were examined. The exposure group (nurses and doctors) was then viewed as a single sample with a total of 16 determinations at T0 and 16 determinations at T1.

The urine concentration averages of N2O were analyzed, and the substantial reduction of urinary concentrations in those exposed to N2O in the two groups were compared: while using the NIKI mask the average concentration at T0 was 1.17 (SD 2.32) and at T1 it was 10.14 (SD 3.78), the variation at the start and end of the shift was significant (P=0.001) (Table III); without the mask the average at T0 was 1.01 (SD 0.39) and at T1 was 77.49 (SD 66.17); the protective effect of the NIKI mask was statistically significant (P=0.003).

Discussion

The first interesting finding from this research is that using anesthetic gases in conditions other than operating rooms exposes operators to a risk that exceeds the maximum values set by international agencies such as NIOSH (25 ppm, which is equal to 30 mg/m3 (28,29)).

Furthermore, in an Italian context, there are limits on the environmental concentration of nitrous oxide that are controlled by specific provisions; Memorandum No 5 of 14 March 1989 of the Ministry of Health sets as the reference limit value for operating rooms the threshold of 50 ppm (91 mg/m3) – which rises to 100 ppm for operating rooms that were already in existence at the time of Memorandum.

This research, in addition to discussing a topic not addressed by Italian regulations or national standards on N2O, highlights a professional field – ambulatory where medical gases are used – where operators are exposed to workplace hazards, revealing a deficiency in the health professionals' prevention and safety framework. Despite the limited sample size, the end-of-shift urinary concentration was observed to be 77.49 and 10.14 mg/l without and with a NIKI mask, respectively, against an exposure limit of 27 mg/l.

To be able to use a facility as a safe room for the use of anesthetic gases, mechanisms for reducing emissions and/or air exchange systems that can guarantee compliance with anesthetic gas exposure values must be provided. The use of the NIKI Mask tested in this study seems to be a useful intervention to aid in the reduction of environmental concentrations of N2O below the expected values in the operating rooms; however, it should be noted that, even with the aid of the mask, the average concentration is still higher than the values set for occupational exposures (NIOSH) of 25 ppm, and hence additional containment systems should be studied.

There was no noticeable variation in N2O exposure between doctors and nurses, which was most likely due to their location in the room being near the same area examined by the sampler. In this regard, it is also worth noting that in the absence of complex air collection and control systems, there are areas of higher N2O aggregation and areas with lower concentrations.

A final comment should be made on the health surveillance of the operators involved, including the fact that it is noted that these operators, as well as their counterparts working in the operating rooms, would join the health surveillance program for exposure to anesthetic gases.

The samplers were put in five different points as stated in the room; the average concentrations at the individual points were calculated (Table III) and then a comparison between the averages and the Variance test (ANOVA) was performed, revealing a significant difference (P=0.001) between the points despite a low intensity (F16.42) and an R2 supporting the model of just .017.

The study has been performed following a rigorous methodology, with the number of measurements and sample size appearing large enough to show that what has been assessed in the context of environmental monitoring in the outpatient setting needs structural actions to minimize the workplace exposures of the operators involved. The section on biological monitoring is interesting in terms of providing scientifically valid support for the assumption that outpatient exposures of healthcare professionals are at risk of N2O exposure, but the small size of the observed sample should be noted, as well as the need to expand the study to larger populations in order to provide greater consistency to the data collected in relation to the environmental monitoring.

The present study's findings highlight the need to deepen and enforce technical guidelines, requirements, and systems for the use of N2O in ambulatory settings; in the Italian setting, the need to properly identify the technical standards and exposure limit of N2O outside the operating room through norms and policies is evident.

This study emphasizes the importance of implementing additional precautions for operators who are exposed to endoscopic procedures in ambulatory facilities.

Finally, the authors would consider using nitrous oxide in conjunction with a gas scavenging device to reduce the operators' exposure.

This study also reveals that measuring the gas scavenging system is insufficient to secure operators, who would need to undergo health surveillance measures to track the medium to long-term effects.

The authors intended to add to the debate over the concept of reference standards for nitrous oxide environmental concentrations by highlighting the lack of specific regulatory limits for medical procedures involving nitrous oxide in facilities other than operating rooms.

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MEDICINA DEL LAVORO

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High altitude underground mining. Acclimatization and possible toxicological risks

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ABSTRACT. **Background.** ***Aim of our study was to measure the first responses to hypobaric hypoxia: changes in ventilation minute, heart rate, and hemoglobin saturation which are important parameters involved in the health of mine-workers at high-altitude.***
Material and Methods. ***We develop a study of parameters mentioned on Chilean miners working in an underground mine at high altitude, between 3.070 and 3.656 masl, in an unusual shift system consisting of 12-hour daily work during 4 days, and consecutive 4 resting days. The results obtained at high altitude are contrasted with the corresponding for clerks working at 800 masl.***
Results. ***Either miners who has work less than 6 months at HA as those who are exposed at their workplace to contaminants, as diesel and others, show Hemoglobin Saturation below 90%. Heart Rate increases in response to exposure to acute and/or chronic hypoxia at high altitude. Miners during their resting period at 800 masl or less show an average heart rate lower than clerks no exposed to high altitude. Average Minute Volume of miners at high altitude, on each and every day of the shift, is higher than the mean volume of clerks at 800 masl.***
Conclusions. ***The most of studied miners present acclimatization responses at high altitude in all the studied parameters. The increase in Minute Volume implies a risky condition due to the increase of inhaled toxic inherent to the production process. It appears as an urgency to study the combined effects of hypobaric at high altitude and toxics present at the underground mine.***

Key words: *miners in High altitude, hypobaric hypoxia, unusual work shifts, acclimatization.*

RIASSUNTO. Miniere sotterranee ad alta quota. Acclimatazione e possibili rischi tossicologici.
Contesto. **Lo scopo del nostro studio é stato quello di misurare le prime risposte all'ipossia ipobarica: cambiamenti della ventilazione minuto, della frequenza cardiaca e dell'saturazione della emoglobina, che sono tra i piú importanti parametri di rischio per la salute dei minatori ad alta quota.**
Materiali e Metodi. **Abbiamo condotto uno studio sui parametri menzionati in minatori cileni che lavorano in una miniera in galleria ad alta quota, tra i 3.070**

Introduction

In Chile, the most of the mining extraction is carried out at geographical High Altitude (HA). The 80% of the mining takes place at more than 3.000 masl; besides there are several deposits located at more than 4.000 masl (1). Due to the location of the mines and the requirements of the production processes, unusual shift work is a necessity, since labor is required without interruption. Unusual shifts and high altitude, are clearly risky conditions for these miners. Shift work modality causes various physical, mental, emotional and social distress in workers, the most evident being the alteration of the circadian rhythm. The circadian rhythm is the responsible of synchronizing functions such as sleep and many performances so they might be optimal during the day. If this rhythm is perturbed as a consequence of shift work, several health problems might occur (2). These include sleep disorders, whose morbidity in shift work is significantly greater than that experienced by day workers (3,4). Another risk is cardiovascular disease (5]. Cardiovascular disease morbidity and mortality in shift workers is higher than in non-shift workers, with an incremental risk of 7.1% for every five years of exposure to shift work after the first five years (6). The incidence of obesity and diabetes are also associated with shift work (7,8) and other studies also relate it to the development of prostate cancer (9,10). Some studies suggest that the risk of prostate cancer is 23% higher among shift workers (9). However, the IARC (International Agency for Research on Cancer) classified shift work involving circadian disruptions as probably carcinogenic to humans (Group 2A). It was considered that there is insufficient evidence to classify this working modality as carcinogenic in humans but so it is in experimental animals (11). In addition, shift work is associated with early aging of workers due to the increased need to recover from work and the increased risk of disability (12).

On the other hand, the Chilean miners carry out their work at intermittent HA, that is, they work at HA, and afterwards, when their shift ends, they rest at their homes, generally located in cities that are at most at 800 masl. It is well known that exposure to HA can cause various diseases, such as: acute mountain sickness, pulmonary hypertension, pulmonary edema, cerebral edema (13,14). At

e i 3.656 mslm, sottoposti a turni di lavoro non convenzionali, consistenti in 12 ore di lavoro al giorno per 4 giorni consecutivi, seguiti da 4 giorni di riposo. I risultati ottenuti ad alta quota si mettono in confronto con quelli ottenuti per i dipendenti che lavorano a 800 mslm.
Risultati. **Tanto i minatori che hanno lavorato ad alta quota per meno di 6 mesi quanto coloro esposti in posti di lavoro a contaminanti, quali diesel e altro, evidenziano livelli di saturazione dell'emoglobina inferiori al 90%. La frequenza cardiaca aumenta in risposta all'esposizione all'ipossia acuta e/o cronica ad alta quota. I minatori durante il riposo a 800 mslm, registrano una media della loro frequenza cardiaca inferiore a quella dei dipendenti non esposti alla altitudine. La media del Volume Minuto dei minatori, in ogni singolo giorno del turno, tanto ad alta quota quanto stanti a 800 mslm é sempre superiore alla media del Volume Minuto dei dipendenti che sviluppano le loro funzioni a 800 m.**
Conclusioni. **La maggior parte dei minatori presenta risposte di acclimatazione ad alta quota in tutti i parametri studiati. L'aumento del volume minuto implica una condizione rischiosa dovuta alla maggiore inalazione di tossici propri dei processi di produzione. Appare urgente lo studio degli effetti combinati dell'ipobaria ad alta quota e le sostanze tossiche presenti nella miniera sotterranea.**

Parole chiave: minatori ad alta quota, ipossia ipobarica, turni di lavoro non convenzionali, acclimatazione.

HA, the barometric pressure is reduced and consequently also the partial pressure of oxygen and the inspired pressure of oxygen. The response mechanisms of the human organism to the fall in inspired pressure of oxygen and therefore to hypoxia are: hyperventilation, polycythemia, hypoxic pulmonary vasoconstriction (15), among others. Is called acclimatization to high altitude the set of beneficial changes that occur in the organism in response to hypoxia caused by HA. The most important physiological response in acclimatization is hyperventilation (15). One of the first mechanisms of acclimatization to HA is the increase in minute ventilation in response to hypoxia. It has also been studied that there are changes in heart rate and that the plasma volume decreases to improve the oxygen transport capacity of the blood, which leads to an increase in hematocrit; this occurs during the first 24-48 hours (see Ref. 16 and Refs. Therein). The degree of lung acclimatization is one of the factors that determine the appearance of symptoms of diseases caused by HA. There are different studies about the necessary time acclimatization takes. In the particular case of intermittent exposure to altitude (chronic intermittent hypoxia) of Chilean miners, there are studies that show that for miners who work in shifts of 7 continuous days at high altitude and 7 days of rest at sea level, there is an improvement in their state of acclimatization after 2.5 years of work at HA (17,18).

In this article, we have studied a group of miners who work in the National Copper Corporation of Chile (Codelco[1]) underground mine, Andina Division, between 3.070 and 3.656 masl in an unusual shift system. This shift consists of 12-hour daily work for 4 consecutive days, after which they rest for another 4 days. The 4 days of work are subdivided into 2 day and 2 night shifts. The miners come and go every day of the shift from their houses at sea level, or almost, to the mine at high altitude. The total working-hours for the whole shift is 48 hours.

This article is organized as follows: in section II we present the methodology, in section III we show the results, and in section IV we present the discussion of the results and conclusions.

Material and Methods

The study was made taking 300 miners of an underground mine and 50 clerks (non-miners) of Codelco Andina Chile. The miners do their labors at the underground mine, located between 3070 and 3656 masl, while the Andes clerks perform their duties at 800 masl.

The medical history of all of them was analyzed in order to have only healthy and non-smoking workers in the final samples. As main selection criteria where taken in account males aged between 22 and 60 with low metabolic load, without any chronic or acute respiratory neither hematological or cardiovascular diseases, as well as no consequences of chronic respiratory diseases; no hypertension or obesity diagnosis, no polycythemia, and finally with no obstructive sleep apnea syndrome diagnosis.

The definitive group of healthy and non-smokers miners is composed by 87 workers which carried out their duties between 3070 and 3656 masl and having a work shift called "4x4"; in other words, two 12-hours day shifts and two 12-hours night shifts, followed by 4 resting days. The healthy and non-smokers clerks, located in the city of Los Andes (800 masl), with a usual shift from Monday to Friday during 9 hours at daylight, is composed of 20 employees.

The sampling workers were completely informed of every step and procedure before they gave their formal consent to participate. Codelco Andina Occupational Health Department gave his approval to the experimental protocol to be carry on.

In order to investigate possible compensation and response mechanisms to hypobaric hypoxia at high altitude, the following physiological indicators were measured: hemoglobin oxygen saturation levels (SO_2, expressed in terms of percentage), heart rate (beats per minute) and minute volume (liters), at different altitudes. Minute volume was measured with a Wright / Haloscale Respirometer, and hemoglobin saturation and heart rate were measured with a pulse oximeter, finger oximeter, model RMS-50D. For each physiological indicator were made 3 measurements and the averages were considered as the final data.

[1] Codelco is the biggest producer of copper in the world and it owns the world's largest known copper reserves and sufficient resources for more than 50 years of operation at current production rates.

Each miner working in the underground mine was examined after a 10-15 minute of resting break. Medical checking took place in two different conditions: at high altitude at the mine-health-emergency-center during day work shifts or night work shifts, and at the Codelco Hospital in Los Andes city (800 masl). The examination at the Codelco Hospital was done on two groups of miners: those who were at their days off and others who were on shift at the mine but they went to the Hospital just for these examinations. Following this procedure, the same miner could have been part of more than just one sampling group (see Table I). On the other hand, the Los Andes clerks were examined at 800 masl only once after a resting break of 10-15 minutes. All the exams were performed by a single Codelco nurse previously trained at the "Instituto Nacional del Tórax[2]" in Santiago, Chile. The complete test lasted approximately 30 minutes per worker. The environmental conditions in which the measurements were made were: temperature between 18º and 20ºC, atmospheric pressure in the mine between 546 and 549 mmHg, and in the Hospital in Los Andes approximately 690 mmHg.

In the statistical analyzes, different tests were applied to determine the normality of the data, the arithmetic mean and the standard deviation were calculated for all the indicators. The control group (clerks at Los Andes) was compared with the samples shown in Table I. A confidence level of 95% (C.L. 95%) was used. The tests applied were: Mann-Whitney, Brunner-Munzel, T Independent, Welch's. The python SciPy-library, NumPy-library were used for data analysis.

Results

The effects of altitude on hemoglobin saturation

Hemoglobin saturation was categorized by altitude at workplace. The miner's groups were also divided according work shifts (see Figure 1). Average hemoglobin saturation higher than 95% was observed only at 800 masl, regardless of whether clerks permanently at Los Andes (800 masl) or miners occasionally down at Los Andes (Rest and Work).

The statistical applied tests have shown that there are not significant differences only among those who were measured at 800 masl: between Los Andes vs Work and between Los Andes vs Rest groups as reported in Fig. 1 and Table II.

Furthermore, the hemoglobin saturation (see Fig. 1 and Table II) presents the highest values in miners of Rest group, while the lowest values are founded at the Day 1 shift, which is the first day at high altitude after 4 days of rest. In addition, Los Andes group presents the most homogenous data (smaller CV). On the contrary, the Day 2 group present the most heterogeneous data (highest CV).

The effects of altitude on heart rate

Concerning Heart Rate, the statistical applied tests have shown that only exist significant differences for Los Andes vs Day 1, as reported in Fig. 2 and Table III.

In addition, the heart rate (see Fig. 2 and Table III) presents the highest average at the Day 1 shift, which is the first day at high altitude after 4 days of rest at 800 masl or less. The lowest value corresponds to the Rest group. Furthermore, the Los Andes and Night 1 groups presents the most homogeneous data (lower CV). On the contrary, the Rest group present the most heterogeneous data (highest CV).

When the miners go down to 800 masl, their average heart rate drops more than that of those who do not work exposed to high altitude.

The effects of altitude on minute volume

For the minute volume variable, the statistical applied tests have shown that exist significant differences for all groups of miners compared to Los Andes clerks, as reported in Fig. 3 and Table IV. It is worth to mention, that the mean of minute volume is always higher for miners than clerks at Los Andes (800 masl).

In comparison with clerks, miners present a much higher minute volume while working at the mine at high altitude and when they come down to town at 800 masl.

Table I. ***Samples conformation for statistical analysis***

Sample name	Number of elements in the sample (n)	Medical check condition
Los Andes	20 Employees	800 masl / Workdays
Day 1	61 Miners	Hight Altitud / Day 1 / Shift
Day 2	24 Miners	Hight Altitud / Day 2 / Shift
Night 1	38 Miners	Hight Altitud / Night 1 / Shift
Night 2	25 Miners	Hight Altitud / Night 2 / Shift
Work	36 Miners	800 masl / Workdays
Rest	41 Miners	800 masl / Rest Day

[2] The National Thorax Institute is operated by the Government of Chile, through the Ministry of Health. Since 2007, it has been considered a "highly complex self-managed network establishment", which means that it has a technical complexity higher than that of common healthcare centers. It has a multidisciplinary team specialized in the thorax of patients, where transplants are commonly performed and treatments for main heart and respiratory diseases are practiced.

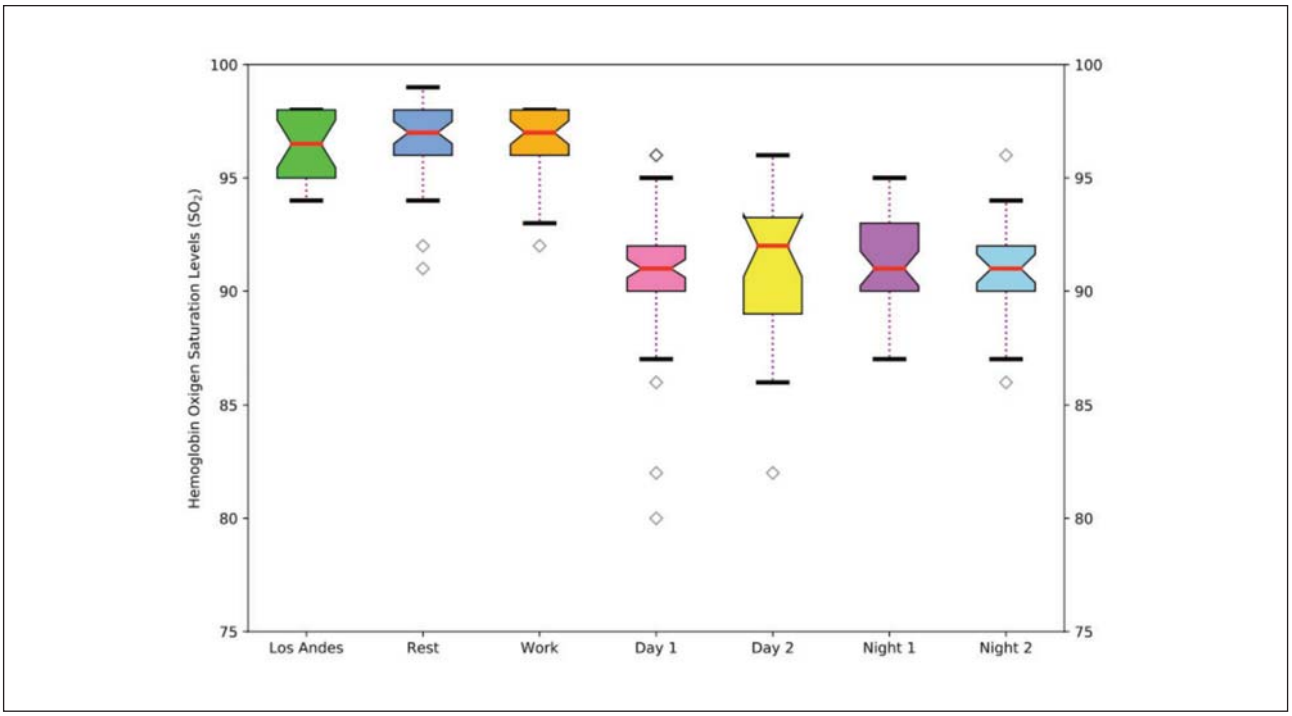

Figure 1. ***Boxplot for the Hemoglobin Saturation (%) for all sampled groups***

Table II. ***Hemoglobin Saturation for all sampled groups. Std dev stand for the standard deviation and CV for the coefficient of variation***

Hemoglobin Saturation (%)			
	Mean	**Std Dev**	**CV**
Los Andes	96,400	1,356	0,014
Rest	96,804	1,863	0,019
Work	96,722	1,464	0,015
Day 1	90,704	2,748	0,030
Day 2	91,041	3,155	0,035
Night 1	91,578	2,208	0,024
Night 2	90,800	2,135	0,024

This means that miners maintain higher minute volume in spite of the altitude where they find themselves.

Furthermore, the minute volume (see Fig. 3 and Table IV) presents the highest average at the Night 2 of the shift, which is the fourth day at high altitude, while the lowest is at Los Andes group (clerks at 800 masl). In addition, Los Andes group presents the most homogenous data (smaller CV).

Discussion

Hemoglobin Saturation

In healthy adults, as in the case of the samples studied, a hemoglobin saturation less than 90% could imply an inadequate supply of oxygen to vital tissues and organs (19), so facilitating the conditions for different diseases to occur. In the sample studied, 32% of the miners when at work at HA either by night shift or in daylight shift saturates less than 90%. On the contrary, in clerks at Los Andes and miners when they go down to Los Andes (800 masl), no values lower than 90% are registered.

Miners with hemoglobin saturation lower than 90% present two interesting characteristics: some have been working at HA for less than 6 months and the others are workers in the same area (level C) and in positions with similar exposure. Is to be concluded that miners working for less than 6 months at HA they still not get acclimated to HA. At least respect to this parameter they don't behave as the ones that are working at HA for 2 years or more. At the area (level C) diesel engines are at work and process are carried on generating different contaminants, among them diesel emissions and crystalline silica. We do not have specific measurements of the chemical contaminants present in this work area. In future studies, it would be important to monitor these workers in order to evaluate the concentration of chemical pollutants in their work area, especially those emitted by internal combustion machinery. An exposure to chemicals that could alter oxygen

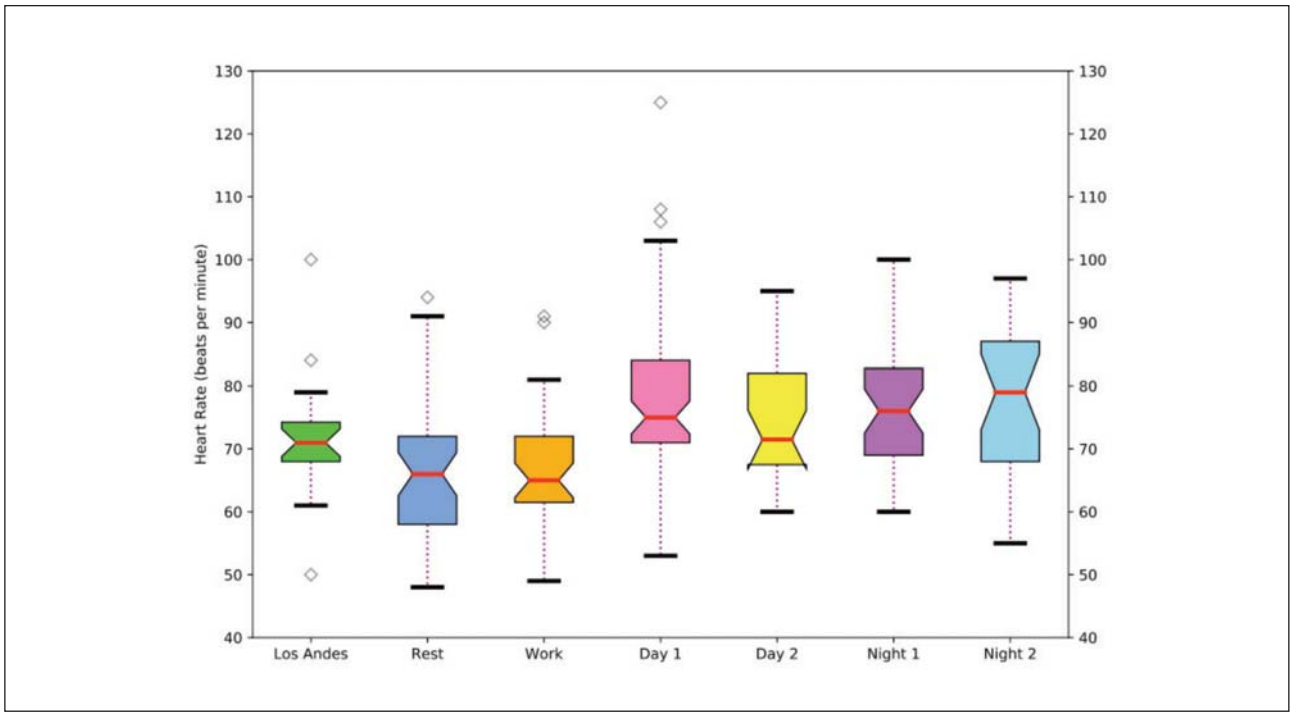

Figure 2. ***Boxplot for the Heart Rate (beats per minute) for all sampled groups***

Table III. ***Heart rate for all sampled groups. Std dev stand for the standard deviation and CV for the coefficient of variation***

Heart Rate (beats per minute)			
	Mean	**Std Dev**	**CV**
Los Andes	71,7	9,6	0,134
Rest	66,7	11,0	0,165
Work	66,8	9,3	0,139
Day 1	78,1	12,7	0,163
Day 2	74,9	10,9	0,146
Night 1	76,2	10,2	0,134
Night 2	76,9	12,3	0,160

saturation is likely to be found in this area. It is urgent to know exactly whether changes in saturation are due only to altitude or also to the presence of some chemical pollutants with asphyxiating characteristics or others.

Some authors maintain that at HA there is an increase in endogenous carboxyhemoglobin even in the absence of inhaled carbon monoxide (20). Due to the characteristics of the mine, ventilation is not the same in all work areas; observations in the field shows that it is necessary to improve ventilation in those areas where the operators with less saturation are found.

When comparing the study groups, it can be seen that there are significant differences in the hemoglobin saturation of the group working at Los Andes (800 masl) compared to group working at high altitude (3070-3600 masl); both in the shift of day and night, and whatever the day of the shift. However, when miners go down to 800 masl, either because they finished the 4 continuous days of the shift and their rest days correspond to them, or because they go to the clinic to take their exams, the hemoglobin saturation behaves again as it does in Los Andes clerks and none of them have a saturation lower than 90%. Therefore, we can conclude that miner's oxygen saturation recovers relatively easily with decreasing altitude. In Fig. 1 it can be observed that the mean saturation of the hemoglobin is significantly higher at 800 masl than at 3000 masl.

In studies of people living in altitude, hemoglobin saturation values are found between 92% and 95% at 3250 masl, and between 90% and 93% at 3600 masl (21). The study clarifies that this data do not apply to non-acclimatized people. In our samples, the vast majority of miners at HA present values in these ranges, so is likely that they present acclimatization characteristics in this parameter.

Heart Rate

Heart rate increases in response to exposure to acute and / or chronic hypoxia at high altitude (22, 23). Our

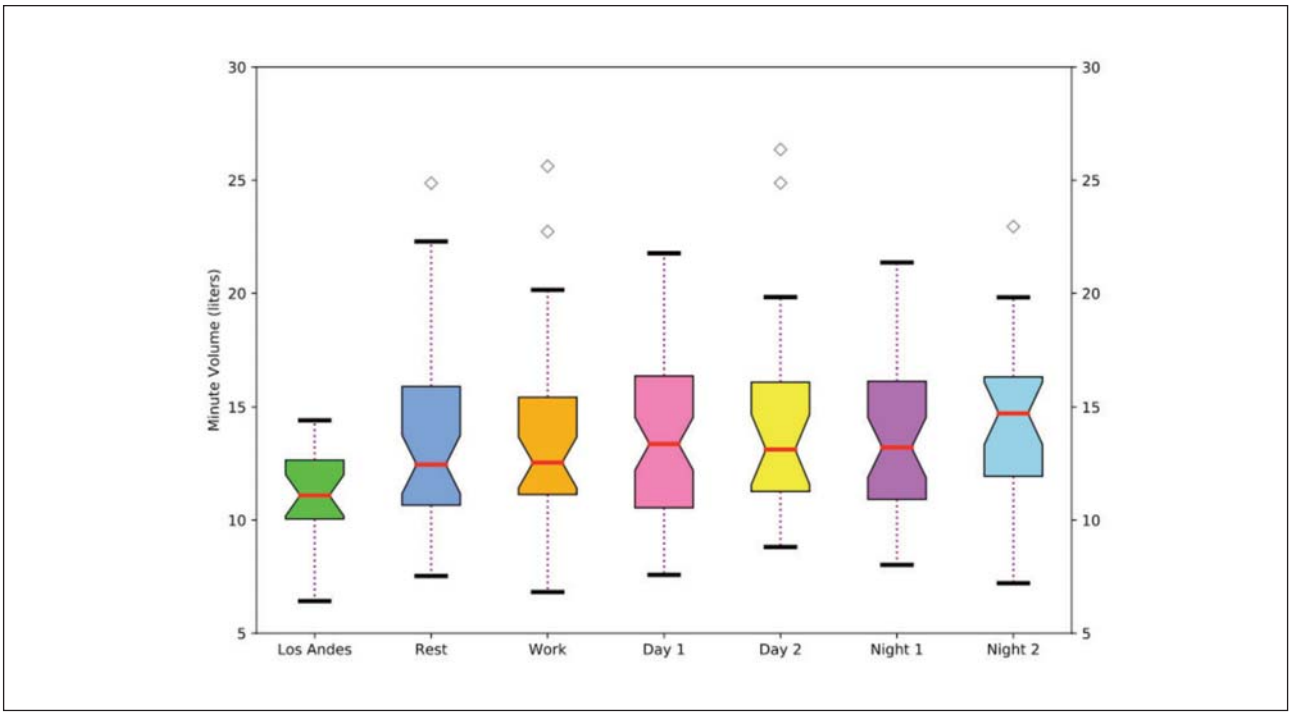

Figure 3. ***Boxplot for the Minute Volume (liters) for all sampled groups***

Table IV. ***Minute Volume for all sampled groups. Std dev stand for the standard deviation and CV for the coefficient of variation***

Minute Volume (liters)			
	Mean	**Std Dev**	**CV**
Los Andes	11,199	2,032	0,181
Rest	13,493	4,094	0,303
Work	13,583	3,961	0,292
Day 1	13,711	3,698	0,270
Day 2	14,257	4,460	0,313
Night 1	13,699	3,400	0,248
Night 2	14,613	3,514	0,240

study confirms that the highest mean heart rate is found in workers who are at HA during all days of their work shift. It is specially significant that when these workers go down to 800 masl, their average heart rate drops more than that of those who do not work exposed to HA, always staying within normal ranges.

An interesting finding emerges when comparing the heart rate of Los Andes clerks with all others groups. Significant differences were found between Los Andes and Day 1 group. It is on the first day of the shift (Day 1) when the highest average heart rate is obtained, while descent in the following shifts. Heart rate increases in the first minutes of exposure to HA and then decreases (24). It is interesting to observe the behavior of the heart rate as a function of working hours during the first day of the shift. In our measurements, the highest frequencies recorded (mean = 95) occurs during the first 4 hours of the morning. In the measurements of the following 8 hours, the average drops to 73. We report that in clinical surveys, miners report that they feel various discomforts on the first day of the shift. We hypothesize that one of the possible causes of these discomforts is that the higher heart rate increases the sensation of fatigue. We consider that it is important to study in depth which and how many other physiological changes are manifested during the first day of ascent at higher altitudes, after 4 days of rest at 800 masl or less.

Minute Volume

Increased pulmonary ventilation is one of the organism's first responses to hypobaric hypoxia caused by high altitude (16). In our study, it can be observed that miners mean minute volume, when they are at high altitude, on each and every day of the shift, is higher than clerk's at Los Andes. Significant differences are found between Los Andes and all other groups. The mean of the minute volume in Los Andes is 11.2, unlike miners, who either on working days at HA or when they go down to

Los Andes have a higher mean of minute volume, between 13.5 and 14.6. We observe that miners, in none of the situations studied, present ventilation values similar to those of clerks at Los Andes (800 masl). We confirm that these miners respond positively to hypoxia with an increase in minute volume. Regarding this last parameter, we emphasize that despite the fact that their work at HA is intermittent, they maintain some acclimatization responses such as hyperventilation even on their rest days.

Increased pulmonary ventilation is one of the most important changes in the acclimatization process (24), which partially compensates hypoxia, which should be considered positive. However, from the point of view of toxic inhalation it is rather alarming. We consider essential to have a special regulation for the permissible limits of chemical contaminants in HA that considers inhaled doses. Most urgent seems the necessity of having an official regulation for diesel emissions and for crystalline silica. There are studies that confirm that at high altitude a higher crystalline silica dose is inhaled (25) and consequently miners who work at HA suffer a prompt development of various pneumoconiosis, among which is silicosis (see Ref. 16 and Refs therein).

On the other hand, it should be taken into consideration that some authors argue that Carbon Monoxide and HA can have additive effects because they are both hypoxia inducers (26). In addition, diesel emissions also contain irritating gases, and therefore is urgent to carry out medical and environmental surveillance in the underground mines located at HA, taking into account the physical (partial pressure of gases) and physiological problems associated with the decrease in the barometric pressure.

About the data variability, we must remark that for all the parameters measured, the most homogeneous data is the one of the Los Andes clerks; miners, instead, are more heterogeneous probably because they present acclimatization responses to HA in different degree according to individual susceptibility. In other words, not all of them go through the acclimatization process in the same way.

Codelco Andina workers have annual controls where a complete medical check-up is carried out, and it is clear that the company shows great concern for the occupational health of its workers. We consider that as part of the medical surveillance, in addition to the annual controls carried out in Los Andes (800 masl), it would be important to implement a program where the physiological parameters analyzed in this study, among other non-invasive parameters, should be measured at high altitude where the mine is located. We emphasize that infrastructure is available since there are permanent medical facilities in the mine. Having hemoglobin saturation measurements by pulse oximetry is not only useful for monitoring oxygen levels, but can also be helpful in the early detection of silicosis in HA miners (27). In addition, having minute volume measurements would allow estimating inhaled doses for different toxic, which would be more appropriate to evaluate the actual exposure to chemical pollutants at high altitude.

Conclusions

The most of studied miners present acclimatization responses at HA in all parameters. These responses are different according to individual susceptibilities and specific workplace conditions. In HA hemoglobin saturation depends on area, job position, and job seniority. The heart rate is higher on day 1 of work in HA after rest. The minute volume is always higher in HA. The increase in Minute Volume implies a risky condition due to the increase of inhaled toxic inherent to the production process.

Acclimatization to altitude in miners implies physiological responses of adaptation that can accelerate the early development of different occupational pathologies exacerbated by the greater inhalation of toxics that occurs at altitude. It appears as an urgency to study the combined effects of hypobaric at high altitude and toxics present at the underground mine.

Acknowledgement

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Conflict of interest

All authors have no conflicts of interest to declare.

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MEDICINA DEL LAVORO

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Studio di mortalità su una coorte di addetti al settore dello spettacolo

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RIASSUNTO. ***Introduzione.*** **Negli ultimi decenni sono stati registrati casi di mesotelioma maligno in lavoratori dello spettacolo, per lo più attribuiti alla presenza negli ambienti di lavoro di materiali contenenti amianto con finalità ignifuga e di fonoassorbenza.**
Obiettivi. **Esaminare la mortalità degli addetti presso uno dei teatri fiorentini nei quali fu rinvenuta negli anni '80 un'ingente quantità di amianto posta in opera venti anni prima.**
Metodi. **Si tratta di uno studio di coorte di mortalità su operatori dello spettacolo, con periodo di follow-up dal 1-1-1970 al 31-12-2018. È stato calcolato il Rapporto Standardizzato di Mortalità (SMR) ed i relativi intervalli di confidenza al 95% (IC95%) per genere e mansione ("operai" e "altre mansioni") utilizzando i tassi età e sesso specifici della popolazione toscana.**
Risultati. **La coorte è composta da 826 soggetti (389 con mansione "operaio" e 437 con "altra mansione") che hanno lavorato nel teatro in esame dal 1-1-1937 al 31-12-1990. Eccessi di rischio sono osservati per tutte le cause negli addetti alle mansioni di operaio sia nei maschi (301 osservati; SMR 304,0; IC 95% 271,5-340,3) che nelle femmine (86 osservati; SMR 429,8; IC 95% 348,0-531,0), mentre in coloro che hanno svolto le altre mansioni si osservano solo deficit di mortalità in entrambi i generi per tutte le cause, tumori e malattie cardiovascolari. Un decesso per tumore pleurico è stato osservato in un uomo che ha svolto la mansione di operaio.**
Discussione. **I risultati ottenuti sono in linea con quelli osservati in altre analoghe situazioni lavorative. Nel teatro fiorentino le esposizioni ad amianto sono state rilevanti solo per il personale addetto alla manutenzione, in quanto frequentava i locali tecnici dove era presente amianto friabile spruzzato diffusamente ed in cattivo stato di conservazione.**

Parole chiave: amianto, mortalità, industria dello spettacolo, studio di coorte.

ABSTRACT. Mortality study in a cohort of entertainment workers. **Introduction.** ***Malignant mesotheliomas have been observed in entertainment workers in the last decades. They have been evaluated as occupationally exposed to asbestos contained in tools used for fireproof and sound-absorbing purposes.***
Aim of the study. ***To evaluate the mortality of workers engaged in a Florentine theatre where a large quantity of asbestos was found in the '80s, put in place 20 years earlier.***
Methods. ***It is a cohort study on entertainment workers with follow-up period ranged from 1-1-1970 till 31-12-2018. Standardized Mortality Ratios (SMRs) and their 95% Confidence Intervals (95% IC) were calculated by gender and job ("manual workers" and "all other jobs"), using age and sex specific mortality rates of Tuscan population.***

Introduzione

L'amianto è un minerale con struttura fibrosa il cui effetto cancerogeno è stato documentato dalla ricerca scientifica. Secondo l'Agenzia Internazionale per la Ricerca sul Cancro (IARC), l'associazione causale è ritenuta certa con il mesotelioma, i tumori del polmone, della laringe e dell'ovaio, e probabile per tumori della faringe, stomaco e colon-retto (1). Ad oggi permangono comunque alcune questioni da chiarire meritevoli di approfondimento, come quella relativa alla variazione dell'effetto cancerogeno successivamente alla cessazione dell'esposizione (2).

Oltre il 90% dell'amianto in fibra prodotta o importata in Italia è stata impiegata nella produzione di Cemento-Amianto (CA), comunemente noto come "Eternit" dal nome della più importante ditta produttrice al mondo. Il settore edile ne è stato il principale utilizzatore a partire dal secondo dopoguerra. Sono comunque molteplici gli usi che ne sono stati fatti per le sue eccellenti proprietà, tra cui essere un ottimo isolante, fonoassorbente, resistente alla corrosione degli acidi e alla trazione, caratteristiche molte delle quali documentate già a partire dagli anni '50 (3), ma sicuramente note anche precedentemente.

Se nella comunità scientifica internazionale il consenso sulle sue proprietà tossicologiche e oncogene si è raggiunto ben presto a metà anni '60 (4, 5), azioni politiche di contrasto si sono osservate nei Paesi occidentali solo a partire dalla seconda metà degli anni '70. In Europa si citano in particolare le direttive UE emanate dal 1980 al 1988 in materia di protezione dei lavoratori esposti (5-10): le direttive n. 80/1107/CEE, n. 82/605/CEE, n. 83/477/CEE, n. 86/188/CEE e n. 88/642/CEE. Successivamente si sono viste azioni più forti di bando sull'utilizzo, l'importazione e l'esportazione di tale minerale da parte di varie nazioni.

In Italia occorre aspettare la metà degli anni '80 con la Circolare Ministeriale n. 45/ 1986 riguardante la mappatura dei materiali contenenti amianto (MCA) all'interno delle scuole e degli ospedali (11), nello stesso anno la Circolare Ministeriale concernente le restrizioni all'immissione sul mercato ad all'uso della crocidolite e i prodotti che la contengono (12) ed il DPR 215/1988 sull'immissione sul mercato e di uso di talune sostanze e preparati

Results. ***The cohort includes 826 workers (389 manual workers and 437 engaged in other jobs) engaged by the Florentine theatre between 01/01/1937 and 31/12/1990. Excesses of mortality for all causes are observed in manual workers, either males (301 cases; SMR 304,0; 95% IC 271,5-340,3) or females (86 cases; SMR 429,8; 95% IC 348,0-531,0). The group of the other workers presents deficits of mortality by all causes, cancers and cardiovascular diseases in both genders. One death for pleural cancer is observed in a manual worker.***
Discussion. ***The results are in line with previous observations in similar occupations. In the examined Florentine theatre the asbestos exposures were important only for the manual workers who worked in the technical rooms characterized by the presence of friable asbestos sprinkled and in a bad state of maintenance.***

Key words: *asbestos, mortality, entertainment industry, cohort study.*

pericolosi (13). Si dovranno attendere i primi anni ’90 per vedere imposto il controllo dell’esposizione professionale con il D.Lgs 277/1991 (14) e poi il bando totale per l’uso diretto di amianto come materia prima sul territorio nazionale con la Legge 257/1992 (15). Vennero concessi due anni di deroga per permettere alle aziende produttrici di CA e materiali da attrito di riconvertire il ciclo produttivo, e fu concesso inoltre di esaurire le scorte di magazzino (16), il che permise l’installazione di MCA fino al 2004.

I settori che sino ad oggi sono stati meglio studiati per le passate esposizioni ad amianto, dato il suo grande utilizzo, sono il settore ferro-tranviario, quello delle costruzioni navali e del trasporto marittimo, della produzione di energia elettrica e della produzione del cemento amianto (17). Ancora oggi è l’edilizia il settore lavorativo a maggior rischio di esposizione (18).

Negli ultimi decenni sono stati registrati casi di mesotelioma maligno (MM) in lavoratori dello spettacolo, per lo più attribuiti alla presenza negli ambienti di lavoro di MCA con finalità ignifuga e di fonoassorbenza (19-22). Questo studio ha preso in considerazione i lavoratori di uno dei due teatri più importanti della città di Firenze nei quali alla fine degli anni Ottanta fu rinvenuta un’ingente quantità di amianto posta in opera negli anni Sessanta.

Nel primo teatro l’amianto fu utilizzato per il rivestimento interno delle condotte dell’aria condizionata in funzione fonoassorbente, sia quelle di mandata che quelle di ripresa, per evitare che nell’auditorium si percepisse il rumore dell’aspiratore dell’impianto che trattava circa 100.000 m^3/h di aria. L’amianto era presente in particolare nelle sale prova, in alcuni locali tecnici (la stazione termica) e soprattutto nel “*soffittone*”, spazio tecnico posto sopra il soffitto del palcoscenico e della platea, frequentato da personale tecnico per motivi di manutenzione o per la gestione scenica. La superficie del soffitto, nota come “Cielo Stellato” per la particolare disposizione dei faretti per l’illuminazione della sala, era coibentata con un intonaco composto da un impasto di amosite e deboli leganti, a sua volta intonacato con gesso per tutta la superficie a vista. Gli addetti alla manutenzione effettuavano periodicamente la pulizia o la sostituzione dei filtri dell’aria condizionata, nonché la pulizia dei sensori dell’impianto recandosi periodicamente all’interno della condotta principale facilmente danneggiabile, in quanto rivestita con questo intonaco in amosite che si sfaldava con un semplice urto o calpestio. È evidente che il personale addetto alla manutenzione fosse esposto a fibre aerodisperse se non protetto da idonei dispositivi di protezione individuale (DPI). Queste opere di manutenzione delle condotte dell’aria, durante le quali le fibre si liberavano, contaminavano indirettamente l’auditorium nel momento in cui l’aria condizionata veniva rimessa in funzione e di conseguenza anche gli spettatori potevano esserne esposti. Nel soffitto furono inoltre eseguiti dei lavori per la correzione acustica dell’auditorium durante i quali furono disposti microfoni ed altoparlanti. I microfoni (circa 100) furono installati sul soffitto e per il loro inserimento furono praticati altrettanti fori con una “punta a tazza” del diametro di circa 10 cm che provocarono un’elevata polverosità nell’auditorium. Gli sfridi della lavorazione cadevano sulle poltrone della platea che erano state preventivamente coperte con teli di plastica. Tutta l’operazione fu effettuata senza alcun presidio tecnico utile a contenere la polverosità e la protezione degli addetti. Negli anni Novanta vennero svolti dei lavori tendenti a prevenire l’immissione di fibre nell’auditorium che consisterono nel dotare le bocchette di uscita dell’aria di “filtri assoluti”. Nel 1990 furono effettuati campionamenti d’aria per il dosaggio delle fibre aerodisperse, sia all’interno dell’auditorium che nei cortili esterni dove veniva espulsa l’aria dell’impianto di condizionamento. Furono rilevate da 1 a 4 fibre/litro di amosite. Negli anni successivi, e fino alla dismissione del teatro, vennero effettuati interventi parziali di scoibentazione (23) ed anche un monitoraggio periodico delle fibre di amianto negli ambienti più spesso frequentati dai lavoratori (ad eccezione del “*soffittone*”) e dagli spettatori. Si stima che l’esposizione a fibre di amianto, sicuramente maggiore per alcuni lavoratori, si sia ridotta notevolmente dopo i lavori effettuati nei primi anni ’90.

Nel secondo teatro, l’amianto fu spruzzato nella seconda metà degli anni Sessanta sulle capriate della sala e del palcoscenico. La rimozione della coibentazione effettuata alla fine degli Ottanta produsse un notevole inquinamento registrato all’interno del teatro, e rilevato ancora dopo oltre un anno dall’intervento sotto forma di residui di amianto caduti sulle condotte di ventilazione, sulle superfici piane soprastanti il palcoscenico, sui sipari e sulle poltroncine. L’indagine ambientale eseguita ad oltre un anno dalla scoibentazione accertò la presenza di fibre di amianto dell’ordine di alcune decine di fibre/litro. Venne quindi predisposto un piano di bonifica dai residui di amianto ancora presenti sulle travature, accompagnato da una pulizia mediante aspirazione degli arredi di palcoscenico (sipari, tendaggi) e di sala (poltroncine) e da un lavaggio dell’aria mediante l’uso di estrattori dotati di filtri assoluti. Tale bonifica, avvenuta nei primi anni ’90 sotto il controllo della USL, fu considerata risolutiva.

Solo per il primo dei due teatri è stato disponibile l’elenco degli addetti allora presenti e pertanto questo studio ha valutato la loro mortalità causa-specifica al 31/12/2018 a distanza di quasi 40 anni dalle opere di bonifica effettuate nei primi anni ’90.

Materiali e Metodi

Dati e fonte dei dati

Sono stati considerati gli elenchi dei lavoratori che pervennero nel novembre del 1990 all'U.O. di Epidemiologia dell'allora CSPO (oggi ISPRO) per utilizzarli a fini di sorveglianza epidemiologica. Gli elenchi disponibili sono 8 e riguardano: dipendenti fissi, ex-dipendenti, a tempo determinato, personale di sala saltuario, personale tecnico serale saltuario, figuranti saltuari a tempo determinato. Si sono costruiti due sottogruppi: quello degli operai (personale tecnico e personale di sala) e quello degli addetti con altre mansioni (orchestrali, cantanti, tersicorei, figuranti).

Ogni elenco contiene le seguenti informazioni che sono state informatizzate: cognome e nome, data e comune di nascita, residenza (comune, via e numero civico), data di assunzione e cessazione dell'impiego.

Alcuni soggetti erano ancora in servizio quando sono stati predisposti gli elenchi nel 1990 ed è stato loro attribuito il 04 luglio 1990 come data di fine lavoro essendo la più recente riportata negli elenchi stessi.

Per il follow-up di mortalità è stato considerato un periodo compreso tra il 01/01/1970, essendo l'amianto presente dal 1960 e pensando ad una latenza di almeno 10 anni per alcune patologie, e il 31/12/2018. L'aggiornamento dello stato in vita è stato effettuato eseguendo un *linkage* fra i soggetti della coorte in studio ed il Registro di Mortalità Regionale (RMR) toscano e, successivamente, con il database relativo all'anagrafe delle persone fisiche residenti in Toscana che contiene sia soggetti viventi che deceduti. Per i soggetti residenti fuori Toscana è stato ricostruito lo stato in vita presso i comuni di loro ultima residenza nota. Per quelli risultati persi al follow-up, si è utilizzata come data di fine follow-up la data di cessazione lavoro più recente disponibile.

Analisi statistica

Utilizzando il programma di analisi STATA 16.1 è stata eseguita l'analisi di mortalità della coorte: è stato calcolato il *Rapporto Standardizzato di Mortalità* (SMR) ed i relativi intervalli di confidenza al 95% (IC95%) distinguendo per genere, mansione ("operai" e "altre mansioni") e utilizzando come standard i tassi età e sesso specifici della popolazione toscana.

Risultati

La coorte è composta da 826 soggetti (389 con mansione "operaio" e 437 con altra mansione) che hanno lavorato nel teatro fiorentino in esame dal 01/01/1937 al 31/12/1990. Per 339 soggetti non era riportata sul libro matricola la data di fine lavoro ed è stata loro attribuita la data più recente disponibile in tali elenchi, ovvero il 4/7/1990. Al 31/12/2018, 572 erano ancora viventi mentre 179 (21,7%) sono risultati deceduti. La prima morte è stata registrata nel 1964. I persi al follow-up sono risultati 75, pari al 9,1%. L'elevata percentuale di soggetti persi al follow-up è presumibilmente dovuta ad errate registrazioni su cartaceo dei soggetti che non sono stati poi ritrovati nei database esaminati. La Tabella I riporta le caratteristiche anagrafiche e legate al lavoro della coorte esaminata.

Le Tabelle II e III mostrano le stime di rischio di mortalità per entrambi i generi e mansione. Sono riportate solo quelle per le quali sono stati osservati almeno 3 decessi nel periodo in esame. Si evidenziano eccessi di rischio per tutte le cause negli addetti alle mansioni di operaio in entrambi i generi, sia nei maschi (301 osservati; SMR 304,0; IC 95% 271,5-340,3) che nelle femmine (86 osservati; SMR 429,8; IC 95% 348,0-531,0). In coloro che hanno svolto le altre mansioni si osservano al contrario deficit di mortalità per tutte le cause sia negli uomini (37 osservati; SMR 52,8; IC 95% 38,2-72,8) che nelle donne (13 osservati; SMR 36,8; IC 95% 21,4-63,3), ed anche per i tumori (negli uomini: 5 osservati; SMR 19,3; IC 95% 8,0-46,3; nelle donne: 3 osservati; SMR 22,9; IC 95% 7,4-70,9) e per le malattie cardiovascolari (negli uomini: 8 osservati; SMR 36,5; IC 95% 18,3-73,1; nelle donne: meno di 3 osservati).

Negli uomini con la mansione di operaio si è osservato anche un decesso per tumore pleurico.

Tabella I. ***Caratteristiche descrittive della coorte***

Caratteristiche		Uomini		Donne		Totale	
		n.	%	n.	%	n.	%
Soggetti nella coorte		540	65,4	286	34,6	826	100,0
Anni-persona		17.786,4		9.440,7		27.227,1	
Durata media follow-up (anni)		10,1		7,0		9,0	
Durata mediana follow-up (anni)		7,3		3,5		5,6	
Età media di entrata nella coorte (anni)		31,4		32,1		31,6	
Stato in vita	Vivo	353	65,4	219	76,6	572	69,2
	Deceduto	140	25,9	39	13,6	179	21,7
	Perso al follow-up	47	8,7	28	9,8	75	9,1
Mansione	Operai	303	56,1	86	30,1	389	47,1
	Altre mansioni	237	43,9	200	69,9	437	52,9

Tabella II. ***Mortalità osservata e attesa, rapporto standardizzato di mortalità (SMR) e relativo intervallo di confidenza al 95% (IC95%) negli anni 1970-2018, utilizzando come standard i tassi età e sesso specifici della popolazione toscana, per le principali cause di morte negli uomini della coorte per gruppo di addetti (in tabella sono inserite solo le cause con almeno 3 decessi osservati)***

Cause di morte	ICD X	Operai					Altre mansioni				
		Osservati	Attesi	SMR	IC 95%		Osservati	Attesi	SMR	IC 95%	
Tutte le cause	A00-Y98	301	0.99	304.0	271.5	340.3	37	0.70	52.8	38.2	72.8
Tumori maligni	C00-C97	33	0.35	94.5	67.2	132.9	5	0.26	19.3	8.0	46.3
Tum. apparato digerente	C15-C26, C48	12	0.09	128.8	73.2	226.8	<3	-	-	-	-
Tum. intestino	C17-C21	5	0.03	146.7	61.1	352.4	<3	-	-	-	-
Tum. fegato	C22	4	0.02	205.8	77.2	548.3	<3	-	-	-	-
Tum. fegato primitivo	C22.0, C22.2-C22.7	3	0.01	268.6	86.6	833.0	<3	-	-	-	-
Tum. apparato respiratorio	C30-C39	12	0.11	109.6	62.2	193.0	<3	-	-	-	-
Tum. polmone	C33-C34	11	0.10	112.0	62.0	202.2	<3	-	-	-	-
Tum.app genito-urinario	C51-C68	4	0.05	82.2	30.8	219.0	<3	-	-	-	-
Mal. cardiovascolari	I00-I99	36	0.34	106.7	77.0	147.9	8	0.22	36.5	18.3	73.1
Cardiopatie ischemiche	I20-I25	14	0.13	109.6	64.9	185.0	<3	-	-	-	-
Mal. apparato respiratorio	J00-J99	5	0.07	71.2	29.6	171.0	3	0.05	63.8	20.6	197.9
Mal. apparato digerente	K00-K93.9	5	0.05	104.9	43.7	252.1	4	0.03	123.0	46.2	327.8
Cirrosi	K70, K73-K74	3	0.02	124.5	40.1	385.9	<3	-	-	-	-

Tabella III. ***Mortalità osservata e attesa, rapporto standardizzato di mortalità (SMR) e relativo intervallo di confidenza al 95% (IC95%) negli anni 1970-2018, utilizzando come standard i tassi età e sesso specifici della popolazione toscana, per le principali cause di morte osservate nelle donne della coorte per gruppo di addetti (inserite solo le cause con almeno 3 decessi osservati)***

Cause di morte	ICD X	Operai					Altre mansioni				
		Osservati	Attesi	SMR	IC 95%		Osservati	Attesi	SMR	IC 95%	
Tutte le cause	A00-Y98	86	0.2	429.8	348.0	531.0	13	0.35	36.8	21.4	63.3
Tumori maligni	C00-C97	11	0.1	171.6	95.0	309.9	3	0.13	22.9	7.4	70.9
Tum. apparato digerente	C15-C26, C48	6	0.0	364.9	163.9	812.1	<3	-	-	-	-
Tum. pancreas	C25	3	0.004	784.0	252.9	2431.0	<3	-	-	-	-
Mal. cardiovascolari	I00-I99	6	0.1	79.6	35.8	177.2	<3	-	-	-	-
Cardiopatie ischemiche	I20-I25	3	0.0	166.5	53.7	516.1	<3	-	-	-	-

Discussione

Dai risultati dello studio di mortalità presentati, si evidenzia per gli operai un eccesso di mortalità per tutte le cause, in entrambi i sessi, mentre nei lavoratori con altre mansioni si osserva un deficit di mortalità per tutte le cause, significativo in entrambi i sessi, probabilmente riconducibile ad un più elevato livello di istruzione che ci si può attendere in lavoratori come direttori di orchestra, artisti del coro, e altre figure professionali dello spettacolo (24).

Per quanto riguarda i decessi per patologia correlabile all'esposizione ad amianto, dal follow-up di mortalità si è osservato un caso di MM pleurico in un operaio di sesso maschile, lo stesso registrato anche dall'archivio del Centro Operativo Regionale (COR) mesoteliomi toscano (comunicazione personale da parte del responsabile del COR toscano). Sono stati evidenziati anche due casi di tumore del peritoneo e retroperitoneo in donne (uno in quelle del gruppo delle operaie ed un altro fra le lavoratrici con altre mansioni) ma, in entrambi i casi, dall'ulteriore documentazione sanitaria raccolta, è stato verificato che si trattava di forme tumorali secondarie e non di provenienza ovarica. Quest'ultima se confermata, sarebbe potuta essere riconducibile ad una pregressa esposizione ad amianto. Nell'archivio del COR mesoteliomi toscano sono stati registrati anche due casi attribuiti a verosimile esposizione ambientale in assidue frequentatrici di questo stesso teatro (comunicazione personale da parte del responsabile del COR toscano).

I due teatri non sono stati risparmiati dall'utilizzo diffuso di MCA che si è registrato in molti settori economici nel nostro Paese principalmente dopo il secondo conflitto

mondiale, soprattutto per adeguarsi a specifiche prescrizioni sull'antincendio e per necessita acustiche. La pubblicazione di Rosato (3) del 1959 riporta l'utilizzo di amianto nei teatri come frangi-fiamma, per ammortizzare le vibrazioni, per fare scatole per il fuoco, per simulare ragnatele in scenografie di ambienti vecchi e disabitati, per simulare la neve in scene invernali, come isolante in cabine insonorizzate, e per proteggere gli ambienti più in generale dagli incendi.

Casi di patologia amianto correlabile in addetti del settore dello spettacolo in Itala si sono registrati negli anni 2000. Nel 2012 sui quotidiani fu riportato il decesso per mesotelioma di un operatore di un teatro di Milano (25) e, pochi anni dopo, anche che ad alcuni lavoratori di un teatro di Roma erano state diagnosticate patologie asbesto correlate (26). Tre casi di MM e un caso di placche pleuriche, osservati presso la Clinica del Lavoro L. Devoto di Milano in lavoratori di teatro e cinema in Lombardia, erano già stati riportati su un articolo nel 2010 (19); per questi era stata ipotizzata un'esposizione ad amianto in matrice friabile presente nei materiali di isolamento, come pure nei tessuti ignifughi utilizzati come tendaggi dei sipari e tappezzerie. Nel 2007 sono stati evidenziati casi di mesotelioma pleurico in un addetto alla proiezione in un cinema di Trieste (20) e in un giocoliere residente nelle Marche (21). Un ulteriore caso di mesotelioma in un addetto del circo è stato poi oggetto di una recente pubblicazione del COR Lombardia (22).

Nel teatro considerato in questo studio è stata impiegata un'ingente quantità di amianto con funzione fonoassorbente come rivestimento delle condotte dell'aria condizionata, la cui presenza è stata oggetto di una prima bonifica mediante filtrazione dell'aria nel 1991, alla quale ne sono seguite altre in altri locali. Da notare che usualmente venivano rivestite le pareti per ridurre notevolmente il tempo di riverbero del suono, sia degli strumenti che dei cantanti e del coro, mentre nel teatro in esame era stato coibentato il soffitto con 5 cm di amosite legata in una matrice molto debole e pertanto friabile. I lavori di bonifica successivi sono sempre stati sotto la vigilanza del Servizio di Prevenzione, Igiene e Sicurezza della locale Azienda Sanitaria e dell'allora Servizio Multizonale di Prevenzione (oggi ARPAT). Le condotte dell'aria non sono comunque mai state bonificate mediante rimozione del coibente.

Nel 2010 vennero alle cronache i casi di due ex lavoratori, un uomo e una donna che avevano lavorato in tale teatro con diverse mansioni, affetti da patologie sospette amianto correlate o correlabili (27, 28). All'uomo, che aveva lavorato come elettricista dal 1972 al 2000, fu diagnosticata un'asbestosi con presenza di placche pleuriche dovuta all'esposizione a fibre di amianto, malattia che gli venne riconosciuta da INAIL come professionale con invalidità. Il secondo caso era quello di una donna che aveva lavorato come macchinista nel 1989 e 1990: le furono diagnosticati un tumore alle ovaie ed uno ai polmoni. Due anni dopo, nel 2012, fu avviata un'inchiesta giudiziaria a seguito di un esposto di un ex lavoratore a cui fu diagnosticata un'asbestosi all'età di 70 anni; aveva lavorato per 28 anni alla manutenzione della caldaia termica, dei bagni e dell'aria condizionata della struttura teatrale in esame, dove era anche addetto alla pulizia degli strumenti contaminati da amianto. Nessuno lo aveva avvisato della pericolosità di quel materiale fino al 1998, suo ultimo anno di lavoro, quando gli furono forniti mascherina e camice. Dopo di lui seguirono le denunce di altri 3 dipendenti, tutti affetti da asbestosi. L'accusa era inizialmente di lesioni colpose gravissime. Alla morte del primo ex dipendente l'accusa di omicidio colposo cadde in prescrizione, ma nel 2014**,** con la morte di un altro ex lavoratore, il Pubblico Ministero chiese al Giudice di modificare il capo di imputazione con quello di omicidio colposo. Nel 2015, l'unico imputato, il sovrintendente del teatro dal 1986 al 1990, venne rinviato a giudizio e nel 2016 morì all'età di 90 anni. Il giudice dichiarò quindi estinti i reati ed emise la sentenza di non luogo a procedere (29).

Dalle storie di asbestosi e placche pleuriche sopra riportate è evidente che uno studio di mortalità come quello presentato abbia dei limiti legati al fatto che è in grado di mostrare solo gli effetti più gravi (i decessi) e le patologie che sono loro causa, non consentendo di evidenziare altri effetti per la salute che non necessariamente possono essere causa del decesso. Solo programmi di sorveglianza sanitaria mirati a queste categorie di lavoratori, se considerati ex-esposti, potrebbero evidenziare queste patologie. Infatti, proprio in seguito ad un intervento di sorveglianza sanitaria vennero avviate inchieste per malattia professionale, oltre che per il caso di mesotelioma pleurico sopra citato (poi riconosciuto da INAIL), anche per un caso di sospetta asbestosi e per sei casi di placche pleuriche. Dal 2017 in Toscana è attivo un programma regionale di sorveglianza sanitaria rivolto agli ex-esposti ad amianto che potrà presumibilmente fornire ulteriori elementi conoscitivi a riguardo (30-31).

Concludendo, lo studio presentato offre dati e spunti di riflessione sulla mortalità di questa classe di lavoratori, che sono risultati in linea con quelli di altre osservazioni sporadiche di esposizione e di casi di patologia asbesto-correlata in addetti del settore dello spettacolo. Nel teatro fiorentino, i cui lavoratori sono stati oggetto di questo studio, vi sono state indubbiamente esposizioni ad amianto (in particolare ad amosite), ma rilevanti solo per il personale addetto alla manutenzione, elettricisti, impiantisti, e tecnici della scenografia, ovvero per gli operai, così genericamente identificati nello studio, in quanto frequentatori dei locali tecnici, dove era presente amianto friabile spruzzato.

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Valutazione funzionale a distanza dopo ricostruzione del LCA in sportivi amatoriali con lavoro sedentario

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RIASSUNTO. Il Legamento Crociato Anteriore (LCA) è il legamento del ginocchio più comunemente danneggiato. Attualmente sono due le condotte chirurgiche più utilizzate: trapianto di terzo medio del tendine rotuleo (bone-patellar tendon-bone: BTB), trapianto dei tendini dei muscoli semitendinoso da solo od insieme al gracile (ST/G).
Scopo. **Obiettivo di questo lavoro è il confronto del recupero funzionale a distanza dal trattamento riabilitativo di sportivi amatoriali con lavoro sedentario sottoposti a trattamento chirurgico di ricostruzione del Legamento Crociato Anteriore (LCA) del ginocchio per mezzo delle due più utilizzate metodiche chirurgiche: trapianto di terzo medio del tendine rotuleo (bone-patellar tendon-bone: BTB) e trapianto dei tendini dei muscoli semitendinoso e gracile (ST/G).**
Metodi. **Sono stati presi in considerazione 30 soggetti suddivisi in due gruppi, (gruppo A 15 BTB e gruppo B 15 ST/G), valutati durante il trattamento riabilitativo e sottoposti a tre follow-up (16, 24 sett, 2 aa). La valutazione comprendeva: esame clinico, test isocinetico e scale di valutazione funzionale: Lisholm e IKDC**
Risultati. **Il valore medio, evidenziato durante i follow up, del punteggio di Lysholm era 78 in entrambi i gruppi a 16 settimane, 91 nel gruppo A e 94 nel gruppo B a 24 settimane, 98 nel gruppo A e 99 nel gruppo B a 2 anni; il valore del punteggio IKDC era 14 nel gruppo A e 15 nel gruppo B a 16 settimane, 12 nel gruppo A e 14 nel gruppo B a 24 settimane, 14 nel gruppo A e 15 nel gruppo B a 2 anni. Non si sono verificate complicazioni maggiori durante la riabilitazione**
Conclusioni. **In ambedue i gruppi si è evidenziata una buona tenuta del neo legamento fino a 24 settimane; al controllo a 2 anni si è evidenziata maggiore instabilità nel gruppo B che impediva lo stesso livello di attività sportiva pre intervento; i soggetti con attività sportive ad alta intensità, a 2 aa, necessitano di incrementare i carichi di lavoro per il potenziamento muscolare, non ancora soddisfacente ed adeguato all'impegno agonistico. I dati di cui disponiamo non evidenziano differenze significative dal punto di vista statistico tra i due gruppi.**

Parole chiave: valutazione funzionale, riabilitazione, legamento crociato anteriore, ginocchio, lavoro sedentario.

ABSTRACT. The anterior cruciate ligament (ACL) is the most commonly injured knee ligament. Currently there are two commonly used surgical procedures: middle third patellar tendon grafts (bone-patellar tendon-bone: BTB) and semitendinosus autografts or semitendinosus combined with gracilis tendon autografts (ST/G).
Purpose. ***The aim of this study is to compare the rehabilitation results over time of amateur sportsmen who have undergone anterior cruciate ligament (ACL) reconstruction surgery by***

Introduzione

Il Legamento Crociato Anteriore (LCA) è il legamento del ginocchio più comunemente danneggiato tra tutti i legamenti del ginocchio (1), soprattutto in traumi di atleti negli sport in cui esistono contatto-contrasto con l'avversario come football, rugby e sci, od in seguito ad incidenti stradali o sul lavoro. Il sesso più colpito è quello maschile e la fascia di età maggiormente interessata va dai 18 ai 30 anni.

La lesione del LCA comporta nell'immediato l'insorgenza di dolore, instabilità e difficoltà nelle attività ricreazionali e sportive, nel lungo periodo predispone ad una evoluzione degenerativa dell'articolazione tibio-femorale (2). Tale evoluzione risulta inevitabile in quanto viene ad essere persa la funzione primaria del LCA, cioè quella di stabilizzatore primario della traslazione anteriore della tibia sul femore e di oppositore all'intrarotazione ed agli stress in valgismo (3); infatti in seguito alla lesione del LCA possono succedersi ripetuti episodi di instabilità associati a lesioni meniscali, erosione della cartilagine articolare ed abnorme attività del metabolismo osseo (4).

La ricostruzione del LCA è riconosciuta ampiamente come la terapia di scelta in soggetti attivi (5), soprattutto se praticanti attività sportive agonistiche, in quanto risulta l'unica scelta terapeutica in grado di restituire stabilità all'articolazione, permettere il ritorno allo sport e ritardare la comparsa dei segni e dei sintomi dell'osteoartrite (6,7).

Attualmente sono due le condotte chirurgiche più utilizzate:

– trapianto di terzo medio del tendine rotuleo (bone-patellar tendon-bone: BTB),
– trapianto dei tendini dei muscoli semitendinoso da solo od insieme al gracile (ST/G).

La scelta terapeutica è dettata in genere dall'esperienza e dalle preferenze del chirurgo.

Dalla revisione della letteratura non si sono evidenziate sostanziali differenze nei risultati tra le due tecniche chirurgiche. Tuttavia alcuni Autori hanno rilevato un maggior numero d'insuccessi ed un incremento nel tempo della lassità del neolegamento (8,9) nei casi in cui è stato utilizzando il solo tendine del semitendinoso; un persistente deficit muscolare in flessione (8,10) e rotazione interna (11,12) nei casi in cui sono stati utilizzati i tendini del semitendinoso e del gracile. Altri Autori hanno messo

means of one of the two most commonly used procedures: middle third patellar tendon grafts (bone-patellar tendon-bone: BTB) and semitendinosus and gracilis tendon autografts (ST/G).
Method. ***30 subjects divided into two groups, (15 BTB and 15 ST / G), were evaluated during rehabilitation and at three follow-up periods (16 weeks, 24 weeks, 2 years). Evaluation involved clinical examination, isokinetic tests, and functional rating scales: Lysholm and IKDC.***
Results. ***The clinical evaluation resulted in the following mean values: the value of the Lysholm score was 78 in both group at 16 weeks, 91 in group A and 94 in group B at 24 weeks, 98 in group A and 99 in group B at 2 years; the value of the IKDC score was 14 in group A and 15 in group B at 16 weeks, 12 in group A and 14 in group B at 24 weeks, 14 in group A and 15 in group B at 2 years. No major complications occurred during rehabilatation***
Conclusions. ***Subjects in both groups showed good neoligament stability up to the 24-week follow up. At the 2-year follow-up the subjects of group B showed poor neoligament stability that prevented the return to the previous level of sporting activity; all the subjects with high intensity sports activity needed a greater muscle strengthening. No statistically significant differences between the two groups are seen.***

Key words: *functional assessment, rehabilitation, anterior cruciate ligament, sedentary work.*

in evidenza il perdurare nel tempo di un deficit di estensione o la presenza di sintomi e segni all'articolazione femoro-rotulea (dolore, scrosci articolari, segni di condropatia) nei casi in cui è stato utilizzato il tendine rotuleo (13,14,15,16), sebbene in letteratura vi siano evidenze che l'utilizzo di protocolli riabilitativi 'accelerati' dia come risultato una più bassa incidenza di dolore anteriore di ginocchio (17).

Lo scopo di questo studio è quello di confrontare il recupero motorio e la funzionalità a distanza in un gruppo di pazienti sportivi amatoriali con lavoro sedentario che avevano riportato una lesione traumatica del LCA ed erano stati sottoposti alle due metodiche chirurgiche suddette: ST/G e BTB.

Materiali e Metodi

- Sono stati presi in considerazione 30 soggetti arruolati consecutivamente (Gruppo A, 15 soggetti, sottoposti a ricostruzione del LCA con tecnica chirurgica con tendine rotuleo (BTB); Gruppo B, 15 soggetti, sottoposti a ricostruzione del LCA con tecnica chirurgica con tendini del muscolo semitendinoso e gracile (ST/G)) tra gennaio 2018 e dicembre 2019 dopo l'intervento chirurgico effettuato presso la Clinica Ortopedica e Traumatologica dello stesso istituto da due diverse equipe: una che ha effettuato l'intervento di ricostruzione solo con BTB ed un'altra solo con ST/G.
- I soggetti di entrambi i gruppi avevano svolto un programma riabilitativo similare, di uguale intensità e durata.

I criteri di inclusione nello studio sono stati:

- lesione unilaterale, con o senza lesione meniscale associata,
- lesione durante attività sportiva,
- non in età adolescenziale con cartilagini di accrescimento aperte,
- non in età maggiore di 49 aa,
- assenza di re interventi di ricostruzione sullo stesso legamento,
- assenza di altre lesioni legamentose nel ginocchio operato,
- assenza di lesioni condrali,
- occupati in un lavoro sedentario.

Tecnica Chirurgica

Trapianto di terzo medio del tendine rotuleo (Bone-patellar Tendon-Bone: BTB)

Nei pazienti seguiti nel nostro lavoro l'equipe chirurgica aveva utilizzato la tecnica artroscopica secondo Kenneth-Jones, utilizzando altresì la tecnica dell'unitunnel (tunnel tibiale completo ed half tunnel femorale), in cui si ottiene un migliore allineamento del tunnel tibiale e di quello femorale e si evita la seconda incisione (18,19).

Trapianto dei tendini dei muscoli semitendinoso da solo od insieme al gracile (Semitendinosus-Gracilis: ST/G)

Nei pazienti seguiti nel nostro lavoro l'equipe chirurgica aveva utilizzato una tecnica ormai ben consolidata con artroscopia diagnostica a tre vie di accesso con fissazione femorale Trans-Fix e tibiale con cambra e vite (20,21).

Tempi di valutazione post-chirurgica

È stata effettuata una prima valutazione (T0) durante la prima visita effettuata presso la Struttura Complessa di Riabilitazione Specialistica della Fondazione Policlinico San Matteo IRCCS di Pavia; le successive valutazioni prese in considerazione sono state eseguite a 16 settimane (T1), a 24 settimane (T2) ed a 2 anni (T3).

Ciascuna valutazione comprendeva: un esame clinico, una valutazione isocinetica e la somministrazione di scale di valutazione funzionale (Lisholm e International Knee Documentation Committee). È stato altresì valutato il tempo trascorso per il ritorno all'allenamento sport specifico ed il ritorno all'attività sportiva.

Valutazione clinica

La valutazione clinica comprendeva:

- massima estensione goniometrica,
- massima flessione goniometrica,
- presenza di versamento,
- termotatto,
- presenza di gonalgia (scala VAS)22,
- mobilità articolazione femoro rotulea,
- ipotrofia muscolare misurata con centimetro a 10 cm dall'emirima articolare femoro-tibiale,
- lassità legamentosa misurata con test di Lachman e pivot-shift.

Valutazione isocinetica

È stata eseguito un test a T1, T2 e T3, con dinamometro isocinetico (Kin-Comâ - Chattex Corp., Chattanoga,

TN, USA) alla velocità di 60° al secondo, considerata la più indicata per valutare la forza muscolare ed il rapporto di forza tra muscoli estensori e flessori.

È stato valutato prima l'arto sano, poi l'arto operato utilizzando il seguente protocollo:
- riscaldamento: 5 minuti di pedalata su cyclette,
- esercizi di stretching per i muscoli ischiocrurali, tricipite della sura, glutei,
- posizionamento corretto sull'apparecchio,
- riscaldamento specifico: 5 ripetizioni con contrazioni submassimali a 100°/sec e 5 a 60°/sec,
- riposo: 20 secondi,
- selezione della velocità e della modalità (60°/sec, concentrica),
- test a 60° sec: 5 ripetizioni massimali,
- riposo: 3 minuti,
- defaticamento: 5 minuti di pedalata su cyclette,
- crioterapia per il ginocchio operato.

Scale di valutazione funzionale

A tutti i soggetti sono state somministrate a T1, T2 e T3, due scale di valutazione funzionale: la scala di Lisholm (23,24) e l'International Knee Documentation Committee (IKDC) (25,26).

Trattamento riabilitativo

I pazienti avevano eseguito una prima visita fisiatrica nell'immediato post-operatorio, da 3 a 10 gg dopo l'intervento, con lo scopo di definire un programma riabilitativo suddiviso in 3 fasi; la progressione da una fase all'altra non era vincolata da limiti temporali, ma in rapporto alle capacità funzionali del soggetto (27,28,29).

Le tre fasi del programma corrispondono a tre funzioni precise da recuperare:
- prima fase: controllo del dolore e della flogosi, recupero dell'articolarità e, parzialmente, delle caratteristiche muscolari (forza, tono e trofismo), autonomia nella deambulazione ed allenamento propriocettivo;
- seconda fase: il recupero della forza, della velocità e della resistenza muscolare; ripresa della corsa (prima in piano e poi con modalità differenti)
- terza fase: riallenamento allo specifico gesto atletico e ripresa agonistica.

Prima fase:
- elettrostimolazioni, per il muscolo quadricipite femorale con ginocchio in flessione di 5 gradi,
- massaggio manuale di scollamento di eventuali fibrosi cicatriziali,
- mobilizzazioni manuali della rotula,
- esercizi passivi e attivi assistiti per il recupero articolare,
- esercizi per il recupero muscolare degli estensori, prima in isometria e poi in Catena Cinetica Chiusa (CCC), e dei flessori in accorciamento.

Seconda fase:
- prosecuzione della cinesiterapia incrementando i carichi,
- esercizi per la propriocezione,
- training del passo.

Terza fase:
- in palestra: esercizi di potenziamento muscolare, propriocettivi, per la coordinazione neuromotoria,
- esercizi in acqua,
- esercizi in isocinetica con carico incrementale di tipo piramidale per un periodo di quattro settimane (30).

Analisi Statistica

Le variabili qualitative sono presentate come conteggi e percentuali, i confronti tra i due tipi di intervento sono stati effettuati con il test $\chi 2$ o il test esatto di Fisher, come più appropriato. Le variabili quantitative sono presentate come media e deviazione standard, i confronti tra i due tipi di intervento sono stati effettuati con i test parametrici (t di Student per dati indipendenti) o non parametrici (test U di Mann-Whitney), a secondo che la distribuzione dei dati fosse o meno normale. I test sono tutti a 2 code ed il livello di significatività prescelto è stato del 5%.

Sono state prodotte statistiche descrittive per tutte le variabili. La media e la deviazione standard (DS) sono presentate per le variabili normalmente distribuite, la mediana e l'intervallo interquartile (IQR) per le variabili non normalmente distribuite, il numero e le percentuali per le variabili categoriali. I gruppi sono stati confrontati con test parametrici o non parametrici, in base alla distribuzione dei dati (test di Shapiro) per le variabili continue, con il test $\chi 2$ di Pearson (test esatto di Fisher, ove appropriato) per le variabili categoriali. Il tempo di ritorno alle attività sportive (allenamento sportivo specifico e competizione) è stato valutato mediante analisi di sopravvivenza (Kaplan Meier e log-rank test). I test a due code sono stati utilizzati ovunque.

I gruppi sono stati confrontati in termini di tutti gli esiti della riabilitazione in ogni momento mediante modelli lineari per misure ripetute.

Risultati

La descrizione dei soggetti dello studio al momento dell'arruolamento è riportata nella Tabella I. L'età media era di 26 anni, la maggior parte erano maschi (86,7%).

Nel corso del periodo di studio, un soggetto del Gruppo A ha lasciato lo studio a causa di un danno al neolegamento a circa un anno dall'intervento.

Gli esiti della riabilitazione a t1-t3 sono riportati nelle Tabella II, III, IV, V, VI, VII, VIII. In breve, sebbene non raggiungano significatività statistica, a T3 il gruppo A mostra una maggiore compromissione del ginocchio e una minore stabilità articolare del gruppo B.

Tutti i soggetti dei due gruppi non hanno mostrato lassità legamentosa al test pivot-shift fino a T2; 3 pazienti del gruppo A (21,43%) avevano lassità del neolegamento di grado 1 a T3, 7 pazienti del gruppo B (46,7%) avevano

Tabella I

		Group A	Group B	p-value
Age	Mediana (IQR)	**22 (18-25)**	**36 (27-40)**	**0.002**
Sesso	Maschi	**14 (93.33%)**	**12 (80%)**	**0.60**
	Femmine	**1 (6.67%)**	**3 (20%)**	
Lesione LCA	Destro	**7 (46.67%)**	**8 (53.33%)**	**0.99**
	Sinistro	**8 (53.33%)**	**7 (46.67%)**	
Lesione Meniscale	No	**8 (53.33%)**	**10 (66.67%)**	**0.71**
	Si	**7 (46.67%)**	**5 (33.33%)**	
Attività Sportiva	Calcio	**8 (53.33%)**	**9 (60%)**	
	Pallacanestro	**3 (20%)**	**1 (6.67%)**	
	Sci	**3 (20%)**	**3 (20%)**	**0.50**
	Trekking	**0**	**2 (13.33%)**	
	Arti Marziali	**1 (6.67%)**	**0**	
Attività Lavorativa	Amministrativi	**8**	**6**	
	Informatici	**3**	**3**	**0.50**
	Insegnanti	**3**	**4**	
	Autisti	**1**	**2**	

lassità, 4 (26,67%) di grado 1, 2 (13,33%) di grado 2, e 1 (6,67%) di grado 3; queste differenze non sono statisticamente significative.

La scala di Lysholm aumenta gradualmente nel tempo in entrambi i gruppi. IKDC non era significativamente diverso tra i gruppi a T1 e T2; solo 1 paziente del gruppo A (6,67%) ha ottenuto punteggi più alti rispetto a tutti gli altri pazienti in entrambe le valutazioni. Al T3 sono state osservate differenze maggiori, peraltro non significative: nel gruppo A solo 3 (21,43%) avevano un grado B, tutti gli altri avevano un grado A, mentre nel gruppo B 1 paziente (6,67%) aveva un grado C, 8 (53,3%) avevano il grado B e 5 (40%) il grado A.

Gli eventi avversi e le complicanze sono stati rari in entrambi i gruppi: al T2 dolore alla rotula era presente in 2 pazienti (13,33%) nel gruppo A, e crepitii articolari in 1 paziente nel gruppo B (6,67%); a T3 2 pazienti del gruppo A (13,33%) hanno avuto dolore nel sito di prelievo, 1 paziente del gruppo A (6,67%) e 2 pazienti del gruppo B (13,33%) hanno avuto crepitii articolari, 1 paziente del gruppo B (6,67%) presentava una rilevante instabilità articolare.

Tabella II. ***Valutazione funzionale***

	Limitazione articolare in Estensione		**Versamento articolare**		**Termotatto**		**Ipomobilità femoro-rotulea**	
	Gruppo A (BTB)	Gruppo B (ST/G)	Gruppo A (BTB)	Gruppo B (ST/G)	Gruppo A (BTB)	Gruppo B (ST/G)	Gruppo A (BTB)	Gruppo B (ST/G)
T_1	0	1	3	4	4	4	3	1
T_2	0	1	1	1	0	0	0	1
T_3	0	0	0	0	2*	0	1*	1

* soggetti che non si erano presentati a T2.

Tabella III. ***Ipotrofia muscolare***
(Δ cm di circonferenza arto sano, arto leso: valori medi a 10 cm dall'emirima articolare femoro-tibiale)

	Gruppo A (BTB)	Gruppo B (ST/G)	p (test U di Mann-Whitney)
T_1	1,46 (SD±1,043118)	1,44 (SD±0,923245)	0,96
T_2	1,44 (SD±0,650444)	1,25 (SD±0,672252)	0,62
T_3	0,82 (SD±0,859125)	0,87 (SD±0,58146)	0,7

Tabella IV. ***Lassita del neolegamento***

		T_3	
Lachman test	Gruppo A (BTB)	Gruppo B (ST/G)	p (test $\chi 2$)
0	11 (78,57%)	8 (53,3%)	
1+	3 (21,43%)	4 (26,7%)	
2+	0	2 (13,4%)	0,16
3+	0	1 (6,7%)	
Totale	14 (100%)	15 (100%)	

	T_1		T_2		T_3		p (test $\chi 2$)
Pivot-shift test	Gruppo A (BTB)	Gruppo B (ST/G)	Gruppo A (BTB)	Gruppo B (ST/G)	Gruppo A (BTB)	Gruppo B (ST/G)	
0	14 (100%)	15 (100%)	12 (85,7%)	14 (93,4%)	11 (78,57%)	8 (53,3%)	
1+	0	0	0	0	3 (21,43%)	4 (26,7%)	
2+	0	0	0	0	0	2 (13,4%)	0,16
3+	0	0	0	0	0	1 (6,7%)	
Totale	14 (100%)	15 (100%)	12 (85,7%)	14 (93,4%)	14 (100%)	15 (100%)	

Tabella V. ***Valutazione isocinetica***

Valori medi del picco di forza (peak torque)	Gruppo A (BTB)	Gruppo B (ST/G)	p
MM estensori			
T_1	97,84 (SD±21,78137)	113,13 (SD±43,00383)	0,24
T_2	114,22 (SD±30,50502)	139,31 (SD±44,35579)	0,12
T_3	131,46 (SD±37,97282)	150,1 (SD±50,03664)	0,28
MM flessori			
T_1	63,97 (SD±18,85839)	65,96 (SD±17,27339)	0,77
T_2	79,92 (SD±20,89386)	85,21(SD±14,24653)	0,46
T_3	80,95 (SD±17,05915)	81,88 (SD±16,93681)	0,88
Rapporto MM estensori/flessori			
T_1	1,6 (SD±0,364985)	1,69 (SD±0,391497)	0,49
T_2	1,44 (SD±0,207188)	1,62 (SD±0,387029)	0,16
T_3	1,62 (SD±0,273744)	1,81 (SD±0,350947)	0,13

Tabella VI. ***Lysholm (95-100 = funzione normale, 84-94 = sintomi durante attività pesanti, <84 = sintomi durante adl)***

Valori medi	Gruppo A (BTB)	Gruppo B (ST/G)	p (T di student)
T_1	77,93333	78,46667	0,97
T_2	91,15385	93,78571	0,04
T_3	98,21429	98,6	0,62
p	0,01	0,01	

Tabella VII. ***IKDC A attività intensa (sport in cui si calcia, si salta, ci si torce), B moderata (sport meno impegnativi come il tennis o pesanti lavori manuali), C leggera, D sedentaria***

	Gruppo A (BTB)	Gruppo B (ST/G)	p (test $\chi 2$)
T1			
A	0	0	
B	1 (7,14%)	0	
C	13 (92,86%)	15 (100%)	
D	0	0	
totale	14 (100%)	15 (100%)	
T2			
A	0	0	
B	12 (100%)	14 (100%)	
C	0	0	
D	0	0	
totale	12 (100%)	14 (100%)	
T3			
A	11 (78,57%)	6 (40%)	
B	3 (21,43%)	8 (53,3%)	
C	0	1(6,7%)	0,07
D	0	0	
totale	14 (100%)	15 (100%)	

Tabella VIII. ***Complicanze***

	Gruppo A (BTB)			Gruppo B (ST/G)			p		
	T_1	T_2	T_3	T_1	T_2	T_3	T_1	T_2	T_3
nessun problema	1 7,14%	7 58,33%	6 42,86%	1 6,67%	2 14,29%	4 26,67%			
necessità di potenziamento muscolare	13 92,86%	4 33,33%	5 35,7%	13 86,67%	11 78,54%	9 60.01%			
dolore in sede prelievo	0 0,00%	1 8,33%	0 0.00%	0 0,00%	0 0,00%	2 13,33%			
instabilità	0 0,00%	0 0,00%	0 0,00%	0 0,00%	0 0,00%	0 0,00%	0,5	0,3	0,2
scrosci articolari	0 0.00%	0 0,00%	1 7,14%	1 6,67%	1 7,14%	2 13,33%			
revisione chirurgica	0	0	0	0	0	0			
	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%			

Attività sportiva

Prima del trauma tutti i soggetti praticavano attività sportiva.

A T2 1 paziente (7,14%) del Gruppo A e 3 (20%) del Gruppo B non avevano ancora ripreso l'allenamento sport specifico.

A T3 i pazienti che non avevano più ripreso l'attività sportiva erano 2 (14,3%) del Gruppo A e 5 (33,3%) del Gruppo B.

La ripresa dell'allenamento sport specifico (Figura 1) del Gruppo A era compreso tra 120 e 198 gg. (media 146 gg.); del Gruppo B era compreso tra 110 e 365 gg. (media 154,2 gg.).

La ripresa dell'attività sportiva (Figura 2) del Gruppo A era compresa tra 160 e 220 gg. (media 185 gg.); nel del Gruppo B era compresa tra 150 e 730 gg. (media 221,5 gg.) (p= 0,89).

Discussione

I dati di cui disponiamo indicano differenze significative soltanto nella valutazione funzionale con scala di

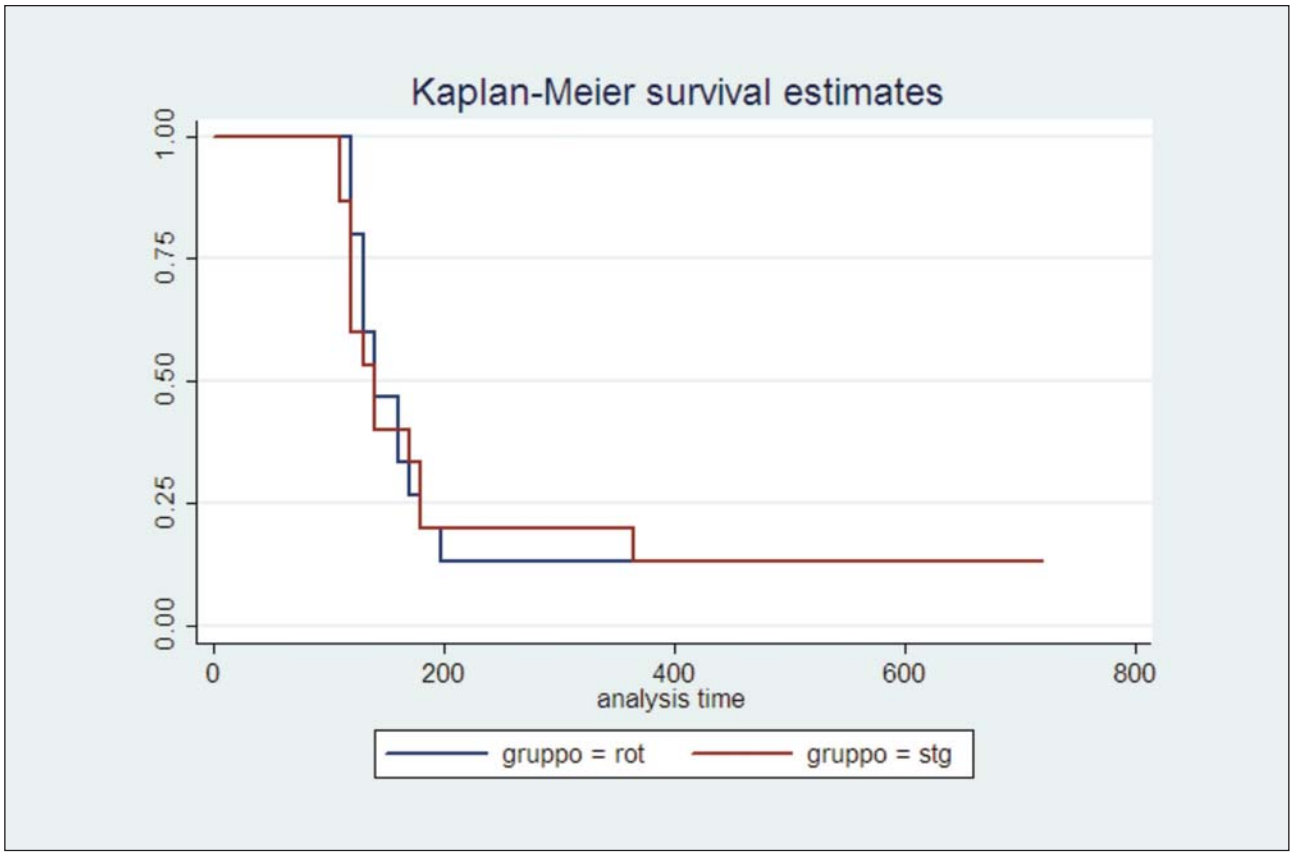

Figura 1. *Stima Kaplan-Meier del tempo per tornare all'allenamento sportivo specifico*

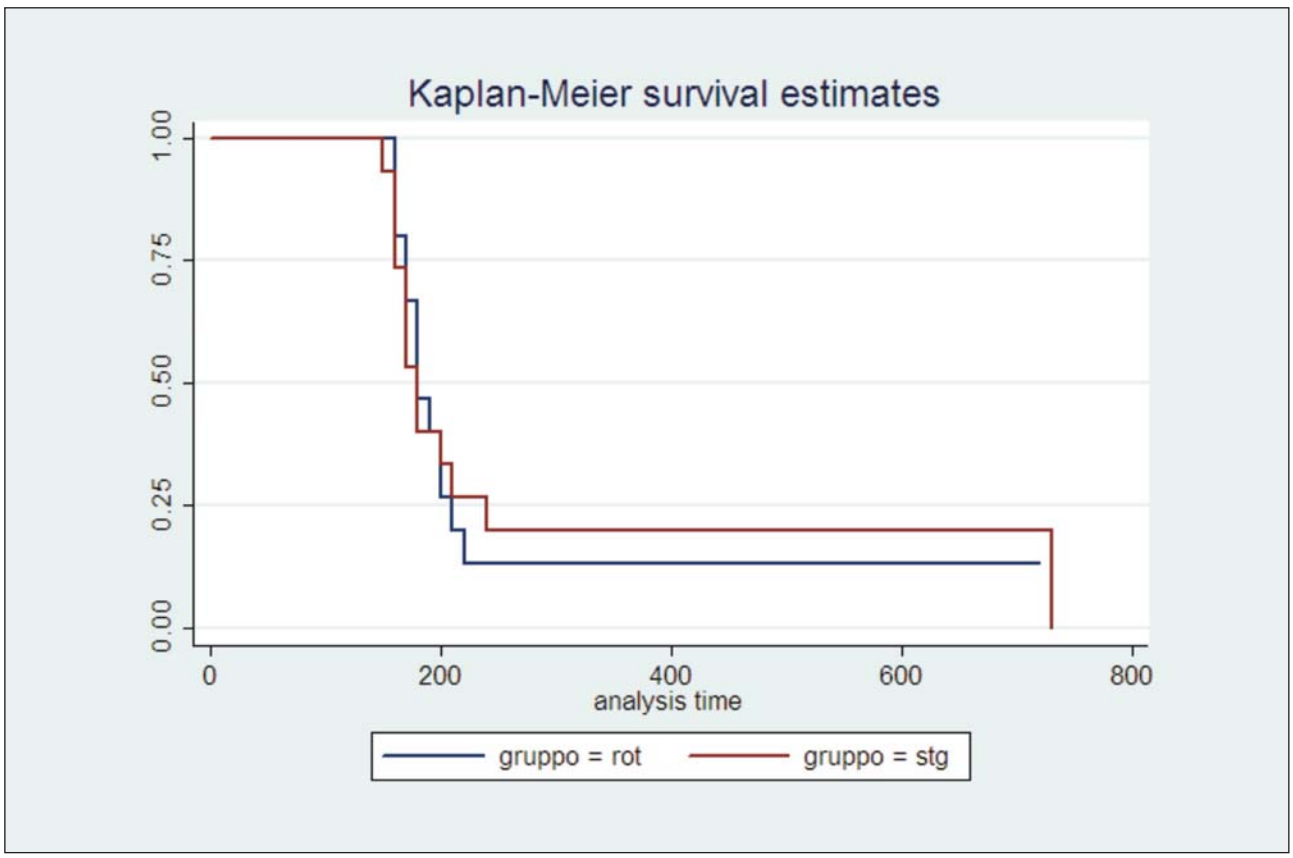

Figura 2. *Stima Kaplan-Meier del tempo per tornare a specifiche attività sportive*

Lysholm dei due gruppi di pazienti trattati rispettivamente con ricostruzione con tendine rotuleo (BTB) o semitendinoso e gracile (ST/G) e soltanto a 24 settimane (tempo T2; T di student p=0,04).

La maggior parte dei nostri soggetti non presentava deficit di articolarità, presenza di flogosi articolare (versamento, termotatto), ipomobilità femoro-rotulea ed ipotrofia muscolare. Tuttavia in 2 casi operati con BTB sono stati riscontrate complicanze nel sito donatore come ipomobilità rotulea e dolore rotuleo, come già riferito in letteratura da Aune AK et alt. (31) e Feller JA et alt. (32).

Per quanto riguarda la stabilità articolare in letteratura non sono state evidenziate sostanziali differenze tra le due tecniche chirurgiche qui considerate, per la presenza di molteplici variabili legate alle differenti metodiche, ai vari metodi di fissazione ed alle differenti mani chirurgiche (8,31,32,33,34,35,50,52)

Nel nostro studio si è evidenziata una buona tenuta del neolegamento fino a 24 settimane (T2) in ambedue i gruppi; al controllo a 2 anni (T3) si è evidenziata nel Gruppo B la comparsa di maggiore instabilità al pivot shift test di II grado in 2 soggetti (13,4%) e di III grado in 1 soggetto (6,7%). Viceversa la migliore tenuta a distanza del BTB era stata messa in evidenza in alcune meta-analisi condotte da Biau et al. nel 2006 (35), da Poolman et alt. nel 2007 (36), da Samuelsen et al nel 2017 (51).

In letteratura tale complicanza è legata ad una fissazione primaria insufficiente del trapianto o a una cattiva legamentizzazione del neolegamento (29).

La valutazione isocinetica ci permette di notare che la dinamica del recupero della forza è condizionata dalla scelta del sito donatore: i soggetti in cui si è usato il BTB mostrano singoli valori assoluti maggiori nella muscolatura flessoria, mentre i soggetti in cui si è usato il ST/G mostrano singoli valori assoluti maggiori nella muscolatura estensoria.

La presenza di deficit stenico nella muscolatura flessoria nei pazienti operati con ST/G era già stato evidenziato anche da Beynnon et al. (37) e nel 2008 (38) da un gruppo di lavoro francese che evidenziava un deficit stenico alla valutazione isocinetica a 2 anni proporzionale al numero di tendini prelevati. Tale deficit muscolare dopo ricostruzione con innesto di ST/G può avere un effetto negativo sulla stabilizzazione dinamica del ginocchio, come già evidenziato da Ageberg E et alt. nel 2009 (39).

Tuttavia il recupero della forza tende ad equivalersi nei due gruppi al controllo a due anni, evidenza notata anche da Aglietti et al. (40).

Concordiamo con Solomonow M et alt. (41) che sia discutibile e non sicuro il ritorno allo sport prima dei 2 anni dopo ricostruzione del LCA in quanto la muscolatura posteriore di ginocchio, principale stabilizzatrice dinamica in termini di forze di taglio sul ginocchio, non ha ancora recuperato completamente le sue caratteristiche.

Anche i nostri dati sulla tempistica della ripresa dell'attività sportiva riflettono la qualità della stabilità articolare, infatti, a T3 i pazienti che presentavano instabilità di grado II e III non avevano ripreso lo stesso livello di attività sportiva pre-intervento. In letteratura tuttavia non si evidenziano differenze significative tra i due gruppi dal punto di vista del ritorno al medesimo livello di attività sportiva (32,33,34,50,52).

I punteggi delle scale di valutazione funzionale (Lisholm, IKDC) sono in linea con la recente letteratura, non mostrando differenze statisticamente significative tra i due gruppi (31,32,40,42,43,50).

La letteratura rimane comunque controversa sull'outcome a distanza delle 2 tecniche chirurgiche, anche in 2 recenti lavori simili al nostro: Sadoghi et al. (44) riportano i risultati di uno studio su 92 pazienti sottoposti a ricostruzione di LCA con ST/G e BTB in cui non mostrano differenze significative tra i due gruppi a 2 anni di distanza sia come punteggio alle scale Tegner, IKDC e WOMAC che alla misura con KT-1000, ma soltanto al pivot shift test che mostra una miglior tenuta nei pazienti operati con ST/G. A. Heijne e S. Werner (45) riportano i risultati di uno studio prospettico randomizzato in cui sono confrontati gli outcome clinici di 68 pazienti dopo intervento di ricostruzione di LCA con ST/G (34 pz) e BTB (34 pz) a 3, 5, 7, 9 mesi, 1 e 2 anni, in cui evidenziano stabilità, pivot shift test, forza dei muscoli posteriori di coscia, livello di attività alla Tegner (con precoce ritorno ad alti livelli sportivi) migliore nei soggetti operati con BTB e soltanto minor dolore anteriore di ginocchio per quelli operati con ST/G.

In un follow-up di 7 anni dall'intervento di ricostruzione condotto da J. Roe et alt.46 non vengono osservate differenze statisticamente significative dal punto di vista dell'articolarità, della stabilità, del recupero muscolare, delle complicanze e del ritorno allo sport tra le due tecniche chirurgiche, tranne che per una maggiore prevalenza di sviluppo di artrosi nei pazienti con BTB (45%) che con ST/G (14%). Viene inoltre osservato un incremento significativo della percentuale di soggetti con deficit di estensione nel gruppo con BTB dall'8% ad 1 anno al 25% a 7 anni.

In una voluminosa review del 2009 Andersson et al (47) prendendo in considerazione le varie tecniche chirurgiche ed i programmi riabilitativi, non hanno evidenziato differenze significative nelle varie metodiche di fissaggio, nel tensionamento del neolegamento, nel successivo sviluppo di osteoartrite di ginocchio, nel recupero della forza muscolare, nell'utilizzo di una ginocchiera nel periodi post-operatorio, tra precoce o tardiva riabilitazione, tra protocolli riabilitativi accelerati e non, tra protocolli domiciliari e non domiciliari, tra programmi con resistenza eccentrica e non. L'unica evidenza dimostrabile riguarda l'utilizzo di programmi di rinforzo con esercizi a CCC che danno meno dolore, lassità e migliori risultati soggettivi nei pazienti operati con BTB.

Un'altra review del 2015 di Xie et (52) al prendendo in considerazione misurazioni della lassità strumentale, test di Lachman, test pivot shift, punteggi obiettivi dell'IKDC, ritorno al livello di attività pre-lesione e morbilità del fallimento dell'innesto, dolore al ginocchio, deficit di estensione e deficit di flessione, non sono riusciti ad identificare quale dei due tipi di innesti fosse significativamente migliore per la ricostruzione del LCA.

Punti di forza e limiti dello studio

Un punto di forza di questo studio è la popolazione omogenea di pazienti, trattati da un'unica equipe chirurgica per tipologia d'intervento, e osservata da un unico valutatore per lungo tempo.

I limiti evidenti sono la piccola dimensione del campione e l'assegnazione non randomizzata all'intervento.

Conclusioni

I nostri dati indicano che il trapianto di tendine rotuleo comporta una maggiore stabilità con minore lassità anteriore e pivot shift, mentre i pazienti con tendine ST/G hanno bisogno di rafforzare maggiormente i muscoli posteriori di coscia; i pazienti con tendine rotuleo tornano allo sport prima e ad un livello superiore di quelli operati con innesti di ST/G. Possiamo ipotizzare che i pazienti operati con tendine ST/G potrebbero aver bisogno di un protocollo di riabilitazione più lento e maggiormente centrato sul potenziamento dei muscoli posteriori di coscia.

Il ritorno al livello di attività pre-lesione è l'obiettivo principale dopo la ricostruzione del LCA e in ambito sportivo occorre che il lavoro riabilitativo venga seguito da un intenso programma di riallenamento. Tale programma deve essere effettuato in maniera graduale, con intensità crescente, con una progressione bilanciata dell'impegno articolare e dei carichi di lavoro per non compromettere il processo di legamentizzazione dell'innesto.

In letteratura non vi sono indicazioni specifiche per soggetti con lavoro sedentario che praticano attività sportiva ma solo controindicazioni all'intervento verso chi ha in generale una vita sedentaria (48) ed a cui viene in genere consigliato un trattamento conservativo (49). Il nostro gruppo di pazienti, sebbene abbia un lavoro sedentario, è stato trattato come qualunque gruppo con attività fisica regolare, quindi sia operato che sottoposto ad un programma riabilitativo accelerato.

Il recupero funzionale non deve considerarsi completo e concluso con il ritorno dell'atleta alla pratica agonistica, ma deve continuare con un costante monitoraggio per consentire la migliore funzionalità articolare al fine di evitare la possibile comparsa di recidive.

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Communicating bad news: attitudes and modes of communication of the health professions

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ABSTRACT. **Background**. ***Information regarding ominous prognoses, which may cause concern and distress, should be provided carefully and cautiously, using non-traumatizing terminology, accommodating the patient's fears, and not excluding elements of hope.***
Goal. ***To analyze the difficulties of health care providers in the process of communicating bad news.***
Materials and Methods. ***An observational, cross-sectional, multicenter study was conducted from March to August 2021 among Italian Physicians and Nurses.***
Results. ***The results of the study indicate a greater participation of Nurse practitioners than Physicians, a fact that may indicate how necessary it is, to overcome the belief that the communication of bad news is of exclusive medical relevance. Among the participants in the study, about half, equal to 46.7% stated that they had no specific training, while the remainder claimed to have attended master's or higher education courses in 8.5% of cases, 23% attended conferences, while 21.8% acquired their skills through work experience.***
Conclusions. ***The communication of bad news, needs to be recognized in the same way as those procedures that characterize care itself, and for which the highest possible quality is sought.***

Key words: *communication, bad news, relationship, care, knowledge.*

RIASSUNTO. **Comunicare le cattive notizie: atteggiamenti e modalità di comunicazione dei professionisti sanitari.** ***Background.*** **Le informazioni riguardanti prognosi infauste, tale (tali) da poter procurare preoccupazione e sofferenza, devono essere fornite con attenzione e prudenza, usando terminologie non traumatizzanti, accogliendo i timori del paziente e non escludere (escludendo)elementi di speranza.**
Obiettivo. **Analizzare le difficoltà degli operatori sanitari nel processo di comunicazione delle cattive notizie.**
Materiali e Metodi. **Da Marzo ad Agosto 2021 è stato condotto uno studio osservazionale, cross sectional, multicentrico, in una popolazione di Medici ed Infermieri**
Risultati. **I risultati dello studio indicano una maggiore partecipazione dei professionisti Infermieri rispetto ai Medici, un dato che può indicare quanto sia necessario, superare la convinzione che la comunicazione di una cattiva notizia sia di pertinenza esclusivamente medica. Tra i partecipanti allo**

Introduction

The communication of bad news is one of the most stressful events to deal with during the course of treatment. During this communication, a deep crisis opens up that involves, not only the patient, but also every member of the family. The person is exposed to a reality that threatens his balance, his sources of certainty and his future plans and this causes a feeling of loss, so much so that it is often experienced as a judgment, with no possibility of a way out (1). Bad news is information that determines, in the person who receives it, such suffering as to drastically and negatively alter the vision of the future. Fallow field and Jenkins (2) define it as "any information that produces a negative consequence in a person's expectations regarding his or her present and future (2). Although it is clear that only the recipient can define how "bad" a piece of news is, in general, bad news can be conceptualized as news that has as its subject matter that of death, injury, or other threats to mental and physical integrity for oneself or a significant other (3). The communication of bad news, is an aspect that brings together two fundamental and interdependent elements: communication and patient interaction. According to the recent increasingly widespread concept of teamwork, nurses have the task of supporting the patient in receiving and reacting to bad news, as well as discussing with the patient where there are doubts, considering the same, not only as a single event, but an entire process in which nursing care alongside the patient allows healthcare professionals to become a point of reference for the patients themselves, spending the most time with the patient. Therefore, nurses could not be excluded from the responsibility of communicating bad news, also favoring the continuity and overall care of the patient. Exemplar is the case concerning palliative care and the path that patients take, where the progress of the disease, the adaptation of therapies, as well as the information and preparation of what will be faced in the final stages of life, lead

studio circa la metà, pari al 46.7% ha dichiarato di non avere alcuna formazione specifica, mentre la restante parte sostiene di aver frequentato master o corsi di alta formazione nell'8.5% dei casi, il 23% ha partecipato a dei convegni, mentre il 21.8 % ha acquisito le proprie abilità attraverso l'esperienza lavorativa.
Conclusioni. **La comunicazione delle cattive notizie, necessita di essere riconosciuta alla stregua di quelle procedure che caratterizzano l'assistenza stessa, e per le quali si cerca di garantire la massima qualità possibile.**

Parole chiave: comunicazione, bad news, relazione, cura, conoscenze.

nurses to have to deal constantly with the patient and sometimes even more frequently with their family members. On the other hand, physicians are involved in the entire process of communication in treatment and prognosis of the patient and also communication involves patient's family, too. Specifically, among healthcare workers, both for physicians and nurses, communication is an important tool for maintaining a therapeutic relationship over time and requires ongoing training of health care professionals. In the last thirty years there has been a revolution in the relationship between health worker and patient, which has led to the transition from a paternalistic conception, of psychological subjection of the patient, to a recognition of the status of citizen as a person, holder of rights and duties, which he intends to exercise even when he is in the condition of disease and suffering. Adequate communication allows the patient to contribute to the choice of proposed therapies, increases compliance and adherence to therapeutic prescriptions, facilitates the sharing of opinions and the possibility for the patient to ask for clarification on any doubts. Undoubtedly, today the scales, due to the increased value placed on patient autonomy and patient requests, have shifted towards the suggestion/obligation to tell the truth and inform the patient about his or her state of health, even if this means giving bad news. The essential elements of good communication are welcoming, understanding the patient's pain, allowing the patient and family members to express themselves, empathy and listening. In the oncology setting, several studies in the literature highlight the importance of communication technique when delivering bad news to patients and their families (4,5). Several studies show how, in the absence of specific training or the support of a psychologist, protocols specifically created to facilitate the health care provider in the role of delivering bad news can be used. Among the contributions related to 'how' to deliver bad news, the indications formulated by Buckman and Baile in the communication of bad news in oncology are the most internationally accepted. According to their protocol, termed SPIKES (6), six steps should be considered when giving bad news: initiate the interview, explore what the patient knows, understand how much the patient wants to know, share the information with the patient, take into account the patient's emotions, and plan and accompany the patient (6). The goal of this model is to enable the physician to adequately prepare for communication, convey the news appropriately, provide support to the patient, and gain the patient's cooperation. In the oncology setting, communication has the following goals: to create a relationship based on trust; to bring out the patient's concerns, needs, and emotions; to lead the patient and family as close to clinical reality as possible; to give complex information, "bad news," and discuss difficult topics, such as transition to palliative care and death (7). A review of studies shows that nurses working in oncology settings can communicate bad news and maintain communication with their patients and families effectively. However, nurses may not be aware that they lack adequate knowledge and skills when communicating bad news (8). Instead, feeling prepared, educated, and well rehearsed can increase confidence and self-efficacy when delivering bad news. Many nurses and physicians perceive a lack of adequate training in communicating bad news in their practice settings (9-13). One of the main functions of communication is to convey some information as "something neutral, quantitatively measurable, relative to a subject who perceives it and ascribes meaning to it" (14,15). Information must always be anchored to highly scientific parameters, eschewing the dissemination of messages promising therapeutic results not endorsed by the scientific community. In health care, the complexity of communication increases in relation to the fears and anxieties of the patient who lives the experience of the disease and often to the lack of training/preparation of health workers towards communication, as a therapeutic tool, which integrates skills of verbal, nonverbal and para-verbal communication, where para-verbal means the tone, volume and rhythm of the voice. Nonverbal and para-verbal communication allow one to strengthen bonds, experience sensory and depth, and understand the character of the person with whom one is relating (16). While for a long time, more importance was given to verbal communication, considering it "noble" than nonverbal communication, several researches have shown how the former alone is not sufficient to express the complex domain of interaction, which instead is complemented and integrated by nonverbal language (17,18). The voice, through tone, rhythm, frequency, pauses, allow to convey emotions (19), while posture, facial expressions, gestures and eye contact, through a kinesic system, assume a predominant role in giving greater importance to what is enunciated. Communicating bad news is also a stressful moment for the healthcare professional, especially when they are inexperienced in how to communicate or the prognosis is particularly grave. The stress of breaking the bad news is reduced when it is certain that the patient wants full disclosure of his or her health condition (20). One study found that involving patients in the care process contributed to greater job satisfaction and engagement of health care providers, especially nurses, as well as greater patient satisfaction, with positive outcomes on clinical outcomes, psychological impact, and patient safety (21). The most successful interventions, therefore, are those that recognize patients not as passive recipients of care but as active decision makers who can use their own social support resources (21,22). Since few studies have been conducted on this topic, we wanted to analyze any differences in bad news communication attitudes associated to the compe-

tence level acquired by each health professional recruited, such as physicians and nurses. Additionally, we also investigated any differences in attitudes in bad news communications existed between nurses and physicians interviewed, too.

Materials and Methods

Study approach

An observational, cross sectional, multicenter study was conducted from March to August 2021. An *ad-hoc* questionnaire was created and then, on-line administered, to all Italian physicians and nurses, through social-professionals' pages in Facebook and Instagram, in order to reach the different realities on the national territory.

The questionnaire was addressed to all physicians and nurses employed in Italy, both in public or private health sector.

The questionnaire

The survey instrument was created ad hoc and was structured into two main sections. In the first part of the questionnaire, socio-demographic data were collected in order to better understand if sampling characteristics could influence attitudes in bad news communication, specifically:

- gender, as female or male;
- marital status, as: single or unmarried, married, separate, widower;
- age, divided into groups of age, as: 20-30 years, 31-40 years, 41-50 years, 51-60 years and 61-70 years;
- years of work experience, as until 5 years and over 6 years;
- job role, as interviewer was a physician or a registered nurse;
- religious beliefs, as: Christian, Islamic, Hindu, Buddhist, Atheist, and other not mentioned before;
- work setting, as: critical area, medical area, surgical area, maternal and child area, prevention and safety territorial area or Covid-19 area;
- training achieved in patient communication; as: conferences or courses, master's degree or higher education course, field experience or non-specific training course.

The second part of the questionnaire contained a total of 22 ad hoc items created to investigate both the attitude and perceptions of the professionals during the communication of bad news, gathering information about the modes of communication and places. The guiding principle in the ideation of this second part in the questionnaire is inspired by the importance given to effective communication for greater patient satisfaction as well as a positive influence on the patient's condition of health does not always go hand in hand with an adequate capacity and preparation of the healthcare personnel who often complain of the lack of adequate training, as well as the absence of adequate places to address issues that can be particularly upsetting for the patient (23). Additionally, for each item, a 4-point Likert scale was associated with each item, where 1 indicates, "Never," 2: "Sometimes," 3: "Often," and 4: "Always." Table I included all the 22 items proposed.

Data Analysis

Data were collected in an Excel spreadsheet and analyzed using the SPSS version 20 program, IBM.

All data, being categorical variables, were presented in numbers and percentages according to job role declared, such as: physician or nurse and then, any differences were

Table I. ***Items proposed to explore attitudes and perceptions in bad news communication among physicians and nurses***

Item no.1:	Do you choose a quiet, private place in advance to communicate bad news?
Item no.2:	Do you make sure there is no interruption?
Item no.3:	Do you schedule time to spend on communication?
Item no.4:	First, do you present to the patient?
Item no.5:	Do you call patients by name?
Item no.6:	Are you looking at the patient's face or eyes while you talk or listen?
Item no.7:	Before starting the conversation, look for a relative or loved one of the patient who already knows the news you are about to communicate?
Item no.8:	Before starting the conversation, try to figure out if the patient knows or has already guessed something?
Item no.9:	Before communicating the bad news to the patient, try to understand in which personal, social, and work life areas it may affect?
Item no.10:	At the point when the patient says they do not want to be informed, do you give them time to think about it?
Item no.11:	Do you tend to facilitate dialogue with the patient or let them vent?
Item no.12:	Does it take into account the patient's opinion?
Item no.13:	Do you use appropriate language to allow the patient to process the news they just received?
Item no.14:	Communicate information in a sequential and organized manner, not giving more information until you are sure that the information given, has been well assimilated?
Item no.15:	Do you ask the patient what their feelings are?
Item no.16:	When the patient's response is anxiety, fear, sadness, aggression, do you maintain an active listening attitude?
Item no.17:	Do you show nonverbal support and understanding?
Item no.18:	When communicating bad news, do you stand assertively, expressing your thoughts with confidence?
Item no.19:	If the patient disagrees, does he/she wait for your proposal to find the solution to the problem?
Item no.20:	Do you observe the emotions that emerge in the patient following the bad news?
Item no.21:	Do you ensure that at the end of the conversation the patient has no doubts or questions?
Item no.22:	Do you establish a plan of care with the patient, if necessary, in order to address the new situation?

assessed thanks to the *Chi square* test. By taking into account the level of personal preparation with respect to the issue of communication with the patient and the job role, linear regressions were performed to each item of the questionnaire proposed in order. All p<.05 values were considered significant. Finally, for any significant association frequencies and percentages were assessed in order to better understand the trend of the significant associations evaluated.

Ethical Considerations

Before answering the questionnaire, each participant had to give his or her free consent to the processing of personal data according to the Declaration of Helsinki and in full compliance with privacy regulations. Complete anonymity of the data collected with the mere purpose of investigating the objective of the study was ensured.

All participants who did not provide consent were not included among the subjects participating in the study. In addition, to ensure that the questionnaires were anonymous and to allow for participant identification, a sequential identification (ID) number was assigned to each registered participant. Each questionnaire, therefore, had an ID number that corresponded to the database ID.

Results

Demographic characteristics of the sample

A total of 317 health care providers, including 265 nurses and 52 physicians participated in the survey (Table I). Most of physicians were male (12.90%), while most of nurses were female (63.40%). Both among physicians and nurses, most of them were married (p=.061), work in several areas without any particular trend (p=.229) and also improved their competences in bad news communication in several training contexts, without any particular relevant frequency (p=.356). Additionally, most of the participants were Christians (p<.001), were employed over 6 years in their roles (p=.002) and also aged between 41-50 years and 51-60 years (p=.006).

Table I. *Sampling characteristics between physicians and nurses (n=317)*

Characteristics	Physicians n=52 (16.40%)	Nurses n=265 (83.60%)	p-value
Gender			
Female	11(3.50%)	201(63.40%)	>.001*
Male	41(12.90%)	64(20.20%)	
Marital status			
Single	12(3.80)	107(33.80)	.061
Married	36(11.40)	131(41.30)	
Separate	4(1.30)	24(7.60)	
Widower	0(0)	3(0.90)	
Age			
20-30 years	1(0.30)	56(17.70)	.006*
31-40 years	13(4.10)	59(18.60)	
41-50 years	14(4.40)	75(23.70)	
51-60 years	22(6.90)	64(20.20)	
61-70 years	2(0.60)	11(3.50)	
Work experience			
Until 5 years	3(0.90)	64(20.20)	.002*
Over 6 years	49(15.50)	201(63.40)	
Religion beliefs			
Christian	37(11.70)	234(73.80)	>.001*
Islamic	3(0.90)	1(0.30)	
Hindu	3(0.90)	0(0)	
Buddhist	2(0.60)	1(0.30)	
Atheist	7(2.20)	20(6.30)	
Others not mentioned	0(0)	9(2.80)	
Work area			
Critical area	14(4.40)	62(19.60)	.229
Medical area	20(6.30)	82(25.90)	
Surgical area	16(5.00)	73(23.00)	
Maternal and child area	2(0.60)	13(4.10)	
Prevention and safety	0(0)	7(2.20)	
Territorial area	0(0)	20(6.30)	
Covid-19 area	0(0)	8(2.50)	
Training in patient communication			
Conferences/courses	9(2.80)	64(20.20)	.356
Master's degree	6(1.90)	21(6.60)	
Experience	15(4.70)	54(17.00)	
Non-specific training course	22(6.90)	126(39.70)	

*p<.05 is statistical significant

Attitudes and modes of communicating bad news

By considering attitudes and perceptions in bad news communication associated to the competence levels acquired and their job roles, as physician or nurse (Table II), the job role seemed to be implicated in the matters dealt with the item no.5 (p=.004), item no.6 (p<.001), item no.12 (p<.001), item no.16 (p<.001), item no.17 (p=.007), item no.20 (p=.038). By considering the competence acquired in the bad news communication, significant associations were assessed for the item no.1 (p=.012), item no.3 (p=.002), item no.9 (p=.038), item no.10 (p=.012), item no.11 (p=.042), item no.14 (p=.016), item no.15 (p=.001), item no.19 (.001), item no.20 (p=.003), item no.21 (p=.018) and item no.22 (p=.001).

By considering significant associations between job role and attitudes and perceptions in bad news communication, Table III showed all frequencies and percentages obtained: both physicians and nurses interviewed always called their patients with their names (item no.5), declared to look at the patient's face or eyes when they talk or listen to them (item no.6), took into account their patients' opinions (item no.12), always or often they maintained an active listening attitude (item no.16), they also payed attention to their non-verbal support (item no.17) and also observed their patients after the communication in bad news (item no.20). Therefore, the job role did not seem to be a discriminant role in the attitude abovementioned, as both physicians and nurses answered with the same trend.

By considering significant associations between attitudes and perceptions in bad news communication according to training courses performed, frequencies and percentages assessed for each significant associations (Table IV), showed that most of the interviewers without any training courses on this topic always:

- chose quiet and private place to communicate bad news (item no.1);
- scheduled also their time to spend on this typology of communication (item no.3);
- before communicating a bad news, they tried to understand in which life areas it could be affected (item no.9);
- when the patient said they did not want to be informed, they give them time to think about it (item no.10);
- tended to facilitate dialogue with the patient (item no.11);
- communicated information in a sequential and organized manner (item no.14);

Table II. ***Attitudes and perceptions in bad news communication associated to job role competence acquired variables***

Items	Job role Physician/Nurse			Competence acquired		
	β	t	p-value	β	t	p-value
Item no.1	-.025	-.443	.658	-.141	-2.521	.012*
Item no.2	.028	.503	.615	-.106	-1.894	.059
Item no.3	.010	.174	1862	-.171	-3.706	.002*
Item no.4	.099	1.765	.078	-.072	-1.277	.203
Item no.5	.163	2.931	.004*	.037	.659	.510
Item no.6	.202	3.660	>.001*	-.066	-1.188	.236
Item no.7	-.004	-.066	.947	-.074	-1.309	-.191
Item no.8	.064	1.137	.257	-.080	-1.433	.153
Item no.9	.098	1.755	.080	-.116	-2.086	.038*
Item no.10	.106	1.913	.057	-.140	-2.522	.012*
Item no.11	.081	1.452	.147	-.114	-2.038	.042*
Item no.12	.195	3.549	>.001*	-.093	-1.696	.091
Item no.13	.025	.449	.654	-.044	-.774	.439
Item no.14	.036	.643	.521	-.135	-2.418	.016*
Item no.15	.082	1.479	.140	-.182	-3.290	.001*
Item no.16	.191	3.451	.001*	-.071	-1.293	.197
Item no.17	.151	2.719	.007*	-.077	-1.381	.168
Item no.18	.050	.883	.378	-.070	-1.237	.217
Item no.19	.049	.883	.378	-.184	-3.317	.001*
Item no.20	.115	2.086	.038*	-.166	-3.011	.003*
Item no.21	-.085	-1.524	.129	-.132	-2.375	.018*
Item no.22	-.096	-1.750	.081	-.193	-3.508	.001*

*p<.05 is statistical significant

Table III. *Attitudes and perceptions in bad news communication between physicians and nurses*

Items /Job role	Never n(%)	Sometimes n(%)	Often n(%)	Always n(%)
Item no.5				
Physician	8(2.50)	14(4.40)	17(5.40)	13(4.40)
Nurse	18(5.70)	50(15.80)	86(27.10)	11(35.00)
Item no.6				
Physician	2(0.60)	8(2.50)	10(3.20)	68(21.50)
Nurse	1(0.30)	3(0.90)	32(10.10)	193(60.90)
Item no.12				
Physician	1(0.30)	6(1.90)	20(6.30)	25(7.90)
Nurse	3(0.90)	5(1.60)	72(22.70)	185(58.40)
Item no.16				
Physician	3(0.90)	8(2.50)	19(6.009)	22(6.90)
Nurse	1(0.30)	11(3.50)	108(34.10)	145(45.70)
Item no.17				
Physician	1(0.30)	11(3.50)	19(6.00)	21(6.60)
Nurse	2(0.60)	14(4.40)	117(36.90)	132(41.60)
Item no.20				
Physician	0(0)	7(2.20)	23(7.30)	22(6.90)
Nurse	5(1.60)	10(3.20)	97(30.60)	153(48.30)

*p<.05 is statistical significant

- asked the patient what their feelings were (item no.15);
- observed the emotions that emerge in the patient following the bad news (item no.20);
- ensured that at the end of the conversation the patient had no doubts or questions (item no.21).

On the other hand, interviewers answered that most often they:

- waited to find the solution to the problem, if the patients disagreed the first solution (item no.19);
- established a plan of care with the patient in order to address the new situation (item no.22).

Discussion

The purpose of our study is to analyze any differences in bad news communication attitudes associated to the competence level acquired by each health professional recruited, such as physicians and nurses. Additionally, we also investigated any differences in attitudes in bad news communications existed between nurses and physicians interviewed, too.

The results of the study indicate a greater participation of nurse practitioners compared to physicians, a fact that may indicate how necessary it is to overcome the belief that the communication of bad news is of exclusive medical relevance (24). Among study participants, approximately half, or 46.7% (n=148), stated that they had no specific training, while the remainder claimed to have attended master's or advanced training courses in 8.5% (n=27) of cases. 23% (n=73) attended conferences, while 21.8% (n=69) acquired their skills through work experience. Our data were in agreement to the current literature, which highlighted the constant need for physicians and nurses to communicate bad news to patients, despite very few emphases on formal training in effective communication was given in the training curriculum. There is also evidence-based literature on how to have difficult conversations in the work place or how to give bad news to a patient. In this regard, several literature addressed to an effective approach in communication, with proposes helpful, practical strategies to effective communication in the workplace during patient care, by requiring adequate preparation, true self-knowledge and responsibility, consideration and good listening skills from both patient and healthcare professional, in order to maintain a positive, hopeful message during the communication, by individualizing information to the specific situation and person, appropriate control of emotions, and efficient plans for support and follow-up after the conversation, too (25). However, from our data emerged a considering significant associations between job role and attitudes and perceptions in bad news communication, as: both physicians and nurses interviewed always called their patients with their names (item no.5), declared to look at the patient's face or eyes when they talk or listen to them (item no.6), took into account their patients' opinions (item no.12), always or often they maintained an active listening attitude (item no.16), they also payed attention to their non-verbal support (item no.17) and also observed their patients after the communication in bad news (item no.20). Therefore, the job role did not seem to be a discriminant role in the attitude abovementioned, as both physicians and nurses answered with the same trend, as literature convey to a unique statement: poor communication may lead to life-threatening difficulties, as better communication practice depend on proper communication training to health care professionals (26-28). In this regard, literature also highlights the need for healthcare professionals to look beyond the traditional focus on communication skills in education and include topics such as working with families, managing ethical dilemmas, conflict resolution, team working

Table IV. *Attitudes and perceptions in bad news communication according to training performed*

Items / Training in patient communication	Never n(%)	Sometimes n(%)	Often n(%)	Always n(%)
Item no.1				
Conferences/courses	2(0.60)	11(3.50)	24(7.60)	36(11.40)
Master's degree	1(0.30)	4(1.30)	14(4.40)	8(2.50)
Experience	5(1.60)	10(3.20)	22(6.90)	32(10.10)
Non-specific training course	13(4.10)	29(9.10)	58(18.30)	48(15.10)
Item no.3				
Conferences/courses	9(2.80)	13(4.10)	34(10.70)	17(5.40)
Master's degree	3(0.90)	10(3.20)	11(3.50)	3(0.90)
Experience	9(2.80)	17(5.40)	32(10.10)	11(3.50)
Non-specific training course	36(11.40)	41(12.90)	51(16.10)	51(16.10)
Item no.9				
Conferences/courses	1(0.30)	12(3.80)	33(10.40)	27(8.50)
Master's degree	3(0.90)	6(1.90)	14(4.40)	4(1.30)
Experience	5(1.60)	11(3.50)	24(7.60)	29(9.10)
Non-specific training course	14(4.40)	35(11.00)	58(18.30)	41(12.90)
Item no.10				
Conferences/courses	1(0.30)	6(1.90)	14(4.40)	52(16.40)
Master's degree	0(0)	5(1.60)	10(3.20)	12(3.80)
Experience	1(0.30)	8(2.50)	18(5.70)	42(13.20)
Non-specific training course	9(2.80)	15(4.70)	50(15.80)	74(23.30)
Item no.11				
Conferences/courses	1(0.30)	4(1.30)	32(10.10)	36(11.40)
Master's degree	0(0)	1(0.30)	18(5.70)	8(2.50)
Experience	0(0)	8(2.50)	31(9.80)	30(9.50)
Non-specific training course	4(1.30)	13(4.10)	80(25.20)	51(16.10)
Item no.14				
Conferences/courses	1(0.30)	3(0.90)	30(9.50)	39(12.30)
Master's degree	0(0)	3(0.90)	13(4.10)	11(3.50)
Experience	2(0.60)	2(0.60)	26(8.20)	39(12.30)
Non-specific training course	7(2.20)	10(3.20)	77(24.30)	54(17.00)
Item no.15				
Conferences/courses	2(0.60)	7(2.20)	24(7.60)	40(12.60)
Master's degree	0(0)	7(2.20)	13(4.10)	7(2.20)
Experience	2(0.60)	8(2.50)	26(8.20)	33(10.40)
Non-specific training course	10(3.20)	30(9.50)	63(19.90)	45(14.20)
Item no.19				
Conferences/courses	1(0.30)	12(3.80)	34(10.70)	26(8.209
Master's degree	0(0)	2(0.60)	15(4.70)	10(3.20)
Experience	3(0.90)	8(2.50)	34(10.70)	24(7.60)
Non-specific training course	4(1.30)	36(11.40)	85(26.80)	23(7.30)
Item no.20				
Conferences/courses	0(0)	2(0.60)	21(6.60)	50(15.80)
Master's degree	0(0)	3(0.90)	10(3.20)	14(4.40)
Experience	0(0)	3(0.90)	26(8.20)	40(12.60)
Non-specific training course	5(1.60)	9(12.80)	63(19.90)	71(22.60)
Item no.21				
Conferences/courses	0(0)	0(0)	24(7.60)	49(15.50)
Master's degree	0(0)	2(0.60)	10(3.20)	15(4.70)
Experience	1(0.30)	3(0.90)	18(5.70)	47(14.80)
Non-specific training course	2(0.60)	9(2.80)	58(18.30)	79(24.90)
Item no.22				
Conferences/courses	1(0.30)	8(2.50)	23(7.30)	41(12.90)
Master's degree	1(0.30)	5(1.60)	15(4.70)	6(1.90)
Experience	1(0.30)	9(2.80)	26(8.20)	33(10.40)
Non-specific training course	9(2.80)	31(9.80)	63(19.90)	45(14.20)

*p<.05 is statistical significant

and supporting coping and adaptation to support bad news such as interpreters and private spaces and the provision of opportunities for structured learning and reflection (29).

From this study, it was found that with regard to the attitudes that are assumed in the communication of bad news, professionals often choose a quiet and confidential

place, try not to be interrupted while interacting with the patient, planning the communication time. Professionals, before starting the conversation, try to understand if the patient has already guessed something, this in addition to facilitating the introduction of the topic is necessary for the professional to disprove erroneous information that the patient has been able to acquire from unreliable sources (30,31), 56.8% of respondents stated that they allow time for the patient to reflect. In the following points it emerges how professionals in most cases, take into account the opinion of the patient, observe his emotions, involve him in decisions and in the care plan, and more than half of the respondents (59.9%) said they always make sure that the patient has understood the information he received, thus recognizing his uniqueness, as already expressed in the study of (32), which emphasizes the importance of patient-centered care. A further aspect is related to the need to use an appropriate language and the respect of the processing time of the news, to allow the acquisition of information that due to the strong emotional impact are often forgotten (33), such as the reduced attention span manifested by patients sometimes in 50.2% (n=159) of cases, and often in 25.6% (n=81). In this regard literature is in agreement to our findings, as providing information is the most important communication goal, and greater experience with communicating bad news is connected with higher ratings of this goal, by also reducing the health professional's discomfort (34).

LIMITATIONS

The results should be interpreted taking into account some limitations. The use of online platforms to collect responses could have led to possible bias selection; the sample is not representative of all the Italian physicians and nurses employed both in the public and private healthcare sector. Additionally, the questionnaire administered was created *ad hoc,* without any validation study before.

Conclusions and implications for clinical practice

Although today care is based on scientific evidence and guidelines, on teamwork between the various professionals who take care of the patient in his uniqueness, the communication of bad news in particular, needs to be recognized in the same way as those procedures that characterize the care itself, and for which we try to ensure the highest possible quality. Aspect still too often underestimated and entrusted to character peculiarities or experience gained during his professional career, recognizes in the protocol S.P.I.K.E.S. a tool that can guide the professional in the conduct of the conversation with the patient, can promote a relationship of cooperation and trust between the parties, but whose knowledge is still not widespread. It emerges from the study the need to train health professionals, especially nurses. The presence of a professional psychologist in all work settings could be useful to allow professionals to better address this moment that for the patient represents a multidimensional process of deep and intimate personal change. In addition, future studies could analyze both the knowledge, attitudes and perceptions of other health professionals with respect to communication.

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Self-compassion e traumatizzazione secondaria: risultati di uno studio osservazionale condotto in reparti ordinari COVID

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RIASSUNTO. ***Introduzione.*** **La relazione tra la *Self-compassion* e il Disturbo da Stress Post-Traumatico non appare indagata tra gli operatori sanitari, nel periodo di pandemia da COVID-19 in atto. Questo studio intende esaminarla in un presidio ospedaliero, dove reparti ordinari sono stati riconvertiti in reparti per i contagiati dal virus.**
Materiali e Metodi. **Lo studio osservazionale trasversale è stato condotto presso un ospedale del Centro Italia, proponendo agli infermieri l'autosomministrazione delle scale IES-R *Impact Event Stress-Revised* e SCS *Self-Compassion Scale*.**
I dati sono stati raccolti, dal 10 gennaio al 10 febbraio 2021, su supporto cartaceo; i moduli sono stati consegnati ai coordinatori infermieristici, che li hanno distribuiti agli operatori.
Risultati. **Il campione, di convenienza, comprende 60 infermieri, prevalentemente di sesso femminile (76,7%), con età media di 43 anni (ds = 11,9) e con presenza in servizio di 14,6 anni (ds = 11,7).**
Il livello medio nella scala della *Self-compassion* totale è di 85,08 (ds = 15,30); il livello medio del Disturbo da Stress Post-Traumatico è di 36,25 (ds = 9,59); è riscontrata correlazione diretta tra la dimensione Umanità comune e i sintomi intrusivi e il livello medio totale del Disturbo da Stress Post-Traumatico e tra la dimensione Autocritica e i sintomi di evitamento.
Discussione e Conclusione. **Il campione manifesta un buon livello nelle dimensioni positive della *Self-compassion* e scarso Disturbo da Stress Post-Traumatico secondario. Necessitano ulteriori studi, trasversali, su specifici campioni più rappresentativi degli infermieri, e longitudinali, per valutare la relazione tra le due variabili, anche in periodo di COVID-19. È raccomandata l'acquisizione di un atteggiamento personale, che accresca la dimensione positiva della *Self-compassion*, per il proprio benessere personale nella professione di aiuto.**

Parole chiave: autocompassione, disturbo da stress post-traumatico secondario, infermieri di reparti ordinari COVID-19.

ABSTRACT. Self-compassion and secondary traumatization: results of an observational study carried out in COVID hospital ordinary units. **Introduction.** ***The relationship between Self-compassion and Post-Traumatic Stress Disorder does not appear to be investigated among health professionals, in the period of the ongoing COVID-19 pandemic. This study intends to examine it in a hospital unit, where ordinary units have been converted into units for those infected with the virus.***
Materials and Methods. ***The cross-sectional observational study was carried out at a hospital in Central Italy, proposing the self-administration of the IES-R Impact Event Stress-Revised and SCS Self-Compassion Scale to nurses.***
The data were collected, from 10 January to 10 February 2021, on paper; the forms were handed over to the nursing coordinators, who distributed them to the operators.

Introduzione

L'autocompassione (*Self-compassion*) è definita da Cristin Neff (2003a) con analogia alla compassione: "*La compassione implica essere aperti e commossi dalla sofferenza altrui, così che si desidera alleviare la loro sofferenza. Implica anche offrire agli altri pazienza, gentilezza e comprensione non giudicante, riconoscendo che tutti gli esseri umani sono imperfetti e fanno errori. Allo stesso modo, l'autocompassione implica l'essere aperti e commossi dalla propria sofferenza, provare sentimenti di cura e di gentilezza verso sé stessi, darsi comprensione, avere un atteggiamento non giudicante verso le proprie inadeguatezze e fallimenti, riconoscere che la propria esperienza fa parte della comune esperienza umana*".

L'autocompassione può manifestarsi, tuttavia, da una parte, come risposta di comprensione per sé e per gli altri, dall'altra, come, severità verso sé e iper-coinvolgimento con l'altro; pertanto, essa si esprime in tre diadi di componenti: 1) dimostrare con sé stessi la gentilezza e la comprensione piuttosto che l'autocritica e il giudizio severi (gentilezza vs giudizio); 2) vedere le proprie esperienze come parte della più ampia esperienza umana piuttosto che come porzioni di vita separate e isolanti (partecipazione vs isolamento); 3) trattenere i propri pensieri e sentimenti dolorosi in una consapevolezza equilibrata piuttosto che identificarvisi eccessivamente (consapevolezza vs iper-identificazione) (Neff, 2003a; Neff, Whittaker & Karl, 2017; Neff, Tóth-Király et al., 2018).

Neff (2003b), che ne ha approfondito lo studio, la colloca entro la cornice di teorie quali la Psicologia Umanistica (Maslow, 1968), il modello del Sé in relazione (Jordan, 1997), la regolazione delle emozioni (Bennett-Goleman, 2001), e ne evidenzia la funzione protettiva sul funzionamento psicologico, poiché si tratta di un atteggiamento emotivamente positivo, che può proteggere dalle conseguenze negative dell'autocritica, dell'isolamento e della ruminazione.

Per la sua natura non valutativa e interconnessa, l'autocompassione può contrastare le tendenze al narcisismo, all'egocentrismo e al confronto sociale discendente con i meno fortunati, associate a tentativi disfunzionali per mantenere l'autostima (Swann, 1992; Damon, 1995).

Results. ***The convenience sample includes 60 nurses, mainly female (76.7%), with an average age of 43 years (sd = 11.9) and with a presence in service of 14.6 years (sd = 11.7). The average level on the total scale Self-compassion 3.02 (ds = 1.26); the average level of Post-Traumatic Stress Disorder is 2.4 (sd = 0.64); there is a direct correlation between the common Humanity dimension and the intrusive symptoms and the mean total level of PTSD and between the Self-Criticism dimension and the avoidance symptoms.***
Discussion and Conclusion. ***The sample shows a good level in the positive dimensions of Self-compassion and low secondary Post-Traumatic Stress Disorder. Further studies, transversal, on specific more representative samples of nurses, and longitudinal, are required to evaluate the relationship between the two variables, even in the period of COVID-19. The acquisition of a personal attitude is recommended, which increases the positive dimension of Self-compassion, for one's personal well-being in the helping profession.***

Key words: *self-compassion, secondary post-traumatic stress disorder, COVID-19 ordinary unit nurses.*

Essa rappresenta un equilibrio tra le polarità, positive e negative, nei periodi e nelle situazioni critiche: porta a "trattarsi con la stessa cura con cui si tratterebbe un buon amico in difficoltà", aiutando a tollerare le emozioni penose quali dolore, disperazione, ansia, rabbia e vergogna; mentre, se difetta, mantiene e aggrava i disagi psichici.

Le ricerche dimostrano, infatti, che livelli più alti di autocompassione sono ripetutamente associati al benessere psicologico (Zessin, Dickhäuser, & Garbade, 2015), mentre livelli più bassi sono associati a maggiori sintomi di depressione (Ehret, Joormann e Berking, 2015), disturbo d'ansia generalizzato (Hoge et al., 2013), psicosi (Eicher, Davis e Lysaker, 2013), disturbi alimentari (Kelly & Tasca, 2016), disturbo bipolare (Døssing et al., 2015) e DSPT – Disturbo da Stress Post-Traumatico (Hiraoka et al., 2015); quest'ultimo inteso propriamente come "traumatizzazione vicaria o secondaria" o "disturbo da stress traumatico secondario" (McCann & Pearlman, 1990; Figley e Kleber, 1995; Bride, Radey e Figley, 2007), poiché il *cluster* sintomatico è identico a quello delle vittime primarie, tranne che per assenza del criterio A.1 del DSM ("avere fatto una esperienza traumatica diretta") (Tatti, 2007).

Le ricerche, che hanno riguardato il personale infermieristico, si sono interessate più frequentemente alla associazione tra la traumatizzazione secondaria e la *Compassion Fatigue,* che è la condizione caratterizzata da esaurimento emotivo e fisico, tale da ridurre capacità di empatia o compassione per gli altri: in pronto soccorso, oncologia, pediatria, hospice (Beck, 2011), in psichiatria ospedaliera (Jacobowitz et al., 2015), in ostetricia (Çankaya e Dikmen, 2020), in psichiatria forense (Lauvrud et al. (2009).

Poco indagata, invece, è l'associazione tra la traumatizzazione secondaria e la *Self-compassion,* secondo Braehler & Neff, (2020), presente, tuttavia, in studi su campioni diversi arruolati da Thompson e Waltz (2018), secondo cui l'autocompassione è inversamente associata al *cluster* di evitamento del DSPT, ma non a quelli di ipereccitazione e della rievocazione rivissuta, in un campione di studenti; da Maheux e Price (2015), secondo cui l'autocompassione è inversamente associata ai sintomi del DSPT in due campioni non clinici; da Scoglio et al. (2018), secondo cui l'autocompassione è correlata inversamente ai sintomi del DSPT, tra le donne in cerca di un trattamento, dopo aver subito violenza interpersonale; da Karatzias e colleghi (2017), secondo cui c'è legame tra autocompassione e il DSPT complesso, che è costituito dalla sommatoria dei criteri DSPT più un insieme di "disturbi nell'auto-organizzazione", cioè degli effetti pervasivi della vittimizzazione cronica sull'affetto, sul senso di sé e sul funzionamento relazionale (Maercker et al., 2013).

La relazione tra la *Self-compassion* e il DSPT secondario, conducendo, in particolare, una ricerca con *PubMed* per campioni di infermieri, con e senza il filtro COVID-19, non trova risultati di studi specifici.

Questo contributo si propone, pertanto, di indagarla con infermieri di reparti ordinari, riconvertiti nell'assistenza a pazienti contagiati dalla SARS-COV 2, nell'ipotesi che si riscontri un livello più basso di DSPT secondario al crescere della misura di autocompassione positiva.

Materiali e Metodi

Uno studio osservazionale trasversale è stato condotto presso reparti ordinari di un ospedale del Centro Italia, riconvertiti per il trattamento di pazienti con COVID-19.

Per il campionamento, di convenienza, non è stato adottato nessun particolare criterio di inclusione/esclusione, se non l'appartenenza lavorativa ai predetti reparti.

La raccolta dei dati è avvenuta dal 10 gennaio al febbraio 2021, mediante supporto cartaceo, che è stato consegnato ai coordinatori infermieristici e da questi distribuito agli operatori.

Sono stati somministrati due questionari:

– La SCS *Self-Compassion Scale* (Neff, 2003b), strumento *self-report*, composto di 26 *item* su scala Likert a 5 punti (da 1 = quasi mai a 5 = quasi sempre), per indagare l'atteggiamento di premura e comprensione verso la propria persona. L'elaborazione restituisce 6 dimensioni, accoppiate due a due, l'una in positivo, l'altra in negativo: *Self-kindness* ("Sono tollerante verso i miei difetti e carenze") e *Self-judgement* ("Sono intollerante e insofferente verso quegli aspetti della mia personalità che non mi piacciono"); *Common Umanity* ("Quando sono giù e sto male, ricordo a me stesso che ci sono molte altre persone nel mondo che si sentono come me") e *Isolation* ("Quando penso alle mie carenze, questo tende a farmi sentire più separato e tagliato fuori dal resto del mondo"); *Mindfulness* ("Quando mi sento giù cerco di avvicinarmi ai miei sentimenti con curiosità e apertura") e *Over-identification* ("Quando non riesco in qualcosa di importante sono logorato dal senso di inadeguatezza"). Le prime due dimensioni comprendono 5 *item*, le altre 4 *item* ciascuna. Per ottenere il punteggio totale di *Self-compassion*, bisogna prima invertire i punteggi degli item delle sottoscale negative, Autocritica, Isolamento, Sovra-identificazione (i.e., 1=5, 2=4, 3=3, 4=2, 5=1): il punteggio complessivo va da 26 a 130, con *cut off* a valore di 65. I punteggi delle singole sei sottoscale si ottengono, calcolando la media

delle risposte nei rispettivi item; il relativo *cut-off* si colloca a 3, rispetto al *range* da 1 - 5. La versione italiana è stata curata e validata da Veneziani et al. (2017).

– L'IES-R *Impact Event Stress-Revised* (Horowitz et al., 1979), per indagare la presenza di sintomatologia di intrusione e di evitamento, riconducibile al DSPT. È un questionario *self-report,* composto da 15 *item*, su scala Likert, con 1 = mai, 2 = raramente, 3 = qualche volta, 4 = spesso. Il punteggio totale di scala, pari a 60, ha il punto di *cut-off* sul valore 30; il punteggio per singolo item e per tipologia di sintomi ha il punto di *cut-off* sul valore 2,5, rispetto al *range* da 1 - 4. I sintomi intrusivi comprendono i ricordi spiacevoli dell'evento traumatico, i sogni spiacevoli collegati all'evento, le reazioni dissociative come se l'evento si stesse ripresentando, la sofferenza psicologica e le reazioni fisiologiche rispetto a situazioni che simboleggiano o assomigliano all'evento vissuto; tra i sintomi di evitamento si ascrivono la deviazione dei ricordi e delle emozioni associati all'evento traumatico, l'elusione di fattori esterni, come persone e luoghi, che suscitano ricordi e vissuti emotivi collegati all'evento. La scala si è dimostrata attendibile, sensibile al cambiamento dei soggetti nel tempo, applicabile a campioni con diversi tipi di trauma, utilizzabile per vari livelli di istruzione e di contesto socioeconomico, ripetibile nel tempo con la stessa persona in riferimento allo stesso evento (Weiss & Marmar, 1996). La versione italiana a 22 *item* è stata tradotta e adattata da Giannantonio (2003).

Considerazione statistiche

I dati raccolti sono stati sintetizzati con indici di centralità e di dispersione, quali media e deviazione standard, calcolate per le variabili *Self-compassion*e DSPT e per le loro componenti.

Nella SCS, il punteggio medio complessivo è stato rapportato al *cut off* di 65; quello delle sei sottodimensioni è stato rapportato al *cut off* di 3. Nella IES-R il punteggio medio complessivo è stato rapportato al *cut off* di 30.

La relazione lineare tra le sottodimensioni della SCS e il livello complessivo di DSPT è stata analizzata mediante il coefficiente *r* di Pearson: l'ipotesi nulla che non ci sia relazione lineare tra le variabili confrontate viene rifiutata, se il test di significatività del coefficiente ne indichi una probabilità inferiore allo 0,05 ($p < .05$).

Considerazioni etiche

Lo studio è stato condotto, previa autorizzazione della Direzione sanitaria e della Dirigenza infermieristica della struttura sanitaria.

I questionari sono stati compilati in forma anonima, recando la sola indicazione delle variabili demografiche, età, sesso e anni di servizio.

Risultati

Il campione è composto da 60 infermieri, è per il 76,7% di sesso femminile, ha un'età media di 43 anni (ds = 11,9) e un'anzianità di servizio di 14,6 anni (ds = 11,7), da un minimo di 1 a un massimo di 40.

La misurazione della *Self-compassion* restituisce, dopo aver invertito le dimensioni negative, la media generale di 85,08 (ds = 15,30), superiore al *cut off* di 65. Il calcolo delle singole componenti restituisce valori medi lievemente superiori al *cut-off* di 3 nelle dimensioni positive (Tab. Ia) e lievemente inferiori in quelle negative, tranne che nell'Autocritica (Tab. Ib): nelle dimensioni negative, i 2/3 degli operatori si addossa giudizi critici, la metà si pone in isolamento e vive sovra-identificazione:

Tabella Ia. ***Punteggio medio delle dimensioni positive della SCS***

N = 60	Media	DS
Auto-gentilezza	3,01	0,95
Umanità comune	3,27	0,90
Mindfulness	3,67	0,76

Tabella Ib. ***Punteggio medio delle dimensioni negative della SCS***

N = 60	Media	DS	N > 2,5
Autocritica	3,01	0,92	42
Isolamento	2,55	0,88	31
Sovra-identificazione	2,61	0,72	29

L'elaborazione dell'IES-R restituisce una media generale di scala pari a 36,25 (ds = 9,59). I sintomi di evitamento registrano una media di 18,95 (ds = 5,40), quelli intrusivi una media di 17,30 (ds = 4,80).

La relazione lineare tra le dimensioni *Self-compassion* e il punteggio totale alla IES-R, analizzata con la statistica *r* di Pearson, è riportata in Tab. II.

Tabella II. ***Correlazioni r di Pearson tra le dimensioni della SCS e il totale dell'IES-R***

	Sintomi intrusivi	Sintomi evitamento	TOT. IES-R
Auto gentilezza	,195	,013	,111
Umanità comune	,255*	,238	,263*
Mindfulness	,234	,035	,144
Autocritica	,138	,302*	,234
Isolamento	-,009	,231	,117
Sovra identificazione	,136	,200	,178

I coefficienti di correlazione sono di segno positivo e significativi per $p < .05$ nell'associazione tra l'Umanità comune e i Sintomi intrusivi e il totale dell'IES-R, tra l'Autocritica e i Sintomi di evitamento.

Discussione e Conclusioni

Il livello medio totale sulle componenti della scala della SCS, rilevato nel campione esaminato, è pari a 3,02

(ds = 1,26), cioè di poco superiore sia al *cut off* di 3 sia al valore medio del campione italiano di validazione pari a 2,92 (ds = 0,60) (Veneziani et al., 2017). Esso deve la sua quota al contributo delle tre dimensioni positive e della componente Autocritica, tutte superiori al *cut-off* di 3; il contributo delle prime è in linea con la valenza protettiva della *Self-compassion,* quello dell'Autocritica, invece, a valenza negativa, ne è in difformità. La misura complessiva dell'autocompassione, nel campione, risulta, dunque, positiva.

La traumatizzazione secondaria è rilevata incipiente, nel contingente degli infermieri, poiché la media generale di 36,25 supera il *cut off* di 30. L'elevazione della quota è dovuta alla lieve maggiore incidenza del *cluster* dei sintomi di evitamento (media = 18,95) rispetto a quelli di evitamento (media = 17,30); risultato analogo è riscontrato negli studi di Thompson e Waltz (2018) e di Capodilupo et al. (2022).

Il calcolo dei coefficienti *r* di Pearson, per esaminare la relazione tra le dimensioni della *Self-compassion* e il DSPT, restituisce valori di correlazione statisticamente poco significativi, diversamente da quanto emerge in altre ricerche, nelle quali è riferita una correlazione significativa diretta tra bassa *Self-compassion* e DSPT secondario, e una correlazione inversa tra alta *Self-compassion* e DSPT secondario (Maheux e Price, 2015; Thompson e Waltz, 2018; Winders et al., 2020).

Gli esperti spiegano che la bassa autocompassione veicola un concetto di sé negativo, si connette a difficoltà relazionali, comporta disregolazione affettiva, determina ipoattivazione dell'angoscia che viene rivolta verso l'interno, causando vergogna, sconfitta e stati di depressione (van der Kolk et al., 2005). Al contrario, l'alta autocompassione aiuta gli individui a migliorare la regolazione affettiva, il concetto di sé e il funzionamento relazionale, riducendo i sentimenti di vergogna, colpa, fallimento e sconfitta (Lee, Scragg & Turner, 2001).

Winders et al. (2020) lamentano, tuttavia, eterogeneità nei disegni degli studi e affermano che il meccanismo dell'effetto protettivo della *Self-compassion* è ancora sconosciuto, auspicando studi prospettici e longitudinali per chiarirlo.

Nel campione in studio, risultano statisticamente significative le correlazioni dirette della componente Umanità comune sia con la media generale che con i sintomi intrusivi del DSPT e della componente Autocritica con i sintomi di evitamento. La prima appare incongruente con il costrutto della *Self-Compassion* e può spiegarsi, verosimilmente, con la ragione che l'Umanità comune, a valenza positiva, possa essere interpretata, da una parte, come comunanza con le sorti di disagio altrui, dall'altra, come riduzione del proprio personale stato di sofferenza; in effetti, in uno studio di Mills et al. (2018), è stata osservata una correlazione negativa tra compassione e autocompassione ($r = -.122$, $p<.05$). La seconda, invece, ne è del tutto coerente, avendo l'Autocritica una valenza negativa. Gilbert (2018), nell'alveo della Teoria dell'attaccamento, afferma che la compassione è un sistema motivazionale prosociale, che è progettato per regolare l'affetto negativo, mettendosi in sintonia con la sofferenza in sé e negli altri, e per orientare l'impegno ad alleviare la sofferenza, attraverso sentimenti di calore e sicurezza; considera, pertanto, l'autocritica come effetto di uno stile di "attaccamento insicuro", tale per cui le persone percepiscono l'autocompassione come un compito troppo impegnativo e ne hanno paura.

Un limite dello studio è dovuto alla composizione del campione: non rappresentativo demograficamente e non omogeneo con l'universo degli infermieri ospedalieri. Pertanto, i risultati non sono generalizzabili.

Un secondo limite è costituito dalla mancanza di confronto con altre realtà ospedaliere, aventi reparti ordinari riconvertiti in assistenza COVID, onde poter raffrontare il contributo dell'autocompassione, nelle sue componenti positive e negative, alla protezione o all'insorgenza del DSPT secondario.

Si rendono opportuni altri studi di settore per approfondire la relazione tra *Self-Compassion* e DSPT secondario tra gli infermieri, specificamente in periodo COVID.

Un approfondimento è, altresì, utile per spiegare la natura della dimensione Umanità comune, da cui comprendere meglio la sua associazione con il DSPT, risultata divergente negli studi.

Nello studio di Chi et al. (2021) si sostiene che l'autocompassione, insieme alla resilienza, in linea generale, possa predire negativamente il DSPT, trasversalmente e longitudinalmente.

I risultati di indagini indicano che, anche tra gli infermieri, l'autocompassione può promuovere la cura compassionevole, il benessere personale, la resilienza e l'intelligenza emotiva (Hagerman et al., 2020), mentre una bassa autocompassione può indurre DSPT, perché diminuisce la motivazione a resistere durante le prove della vita, aumenta i sentimenti di impotenza e disperazione, porta a forti sentimenti di vergogna e colpa che rendono le emozioni ancora più difficili da gestire (Tull, 2021).

Per questo, sono organizzati programmi di formazione pilota all'autocompassione, per fornire prove empiriche a sostegno dei benefici attesi sul benessere personale degli infermieri, per una durata variabile da quattro incontri a otto settimane (Delaney, 2018; Pérula-de Torres, 2019).

Seppure ammettendo difficoltà nell'accrescere l'autocompassione, Tull (2021) sostiene l'utilità di promuoverla, per salvaguardare il benessere personale, propone delle massime guida:

"*riconosci di essere umano: se poni aspettative molto alte che non puoi soddisfare, è difficile provare compassione per te stesso;*

sii consapevole dei pensieri negativi auto-concentrati: solo perché hai un pensiero egocentrico negativo, non significa che sia vero;

pratica la cura di te stesso: quando le persone si accudiscono poco, hanno un rischio maggiore di incorrere in comportamenti autodistruttivi o di isolarsi dal supporto sociale;

convalida le tue emozioni;

pratica atti di gentilezza;

riconosci i tuoi successi".

L'invito è a provare queste strategie e a scoprire quale combinazione funziona meglio per ciascuno. I progressi possono essere lenti, ma anche una piccola quantità di autocompassione può avere un enorme impatto sulla salute mentale ed emotiva.

Una tecnica utile, alla portata di tutti, per esercitare più autocompassione, è suggerita da Hastings (2020), presidente dell'*Emergency Nurses Association* in Schaumburg – Illinois, e consiste nel prendersi il tempo per fermarsi e riflettere durante l'intensa giornata: essere semplicemente fermi nel momento e respirare.

A conclusione, quale ricaduta per la pratica, può desumersi dallo studio l'importanza di:

prestare attenzione alla *Self-Compassion*, come possibile fattore di insorgenza della traumatizzazione secondaria;

verificare la relazione tra *Self-Compassion* e traumatizzazione secondaria in periodi critici, come nel periodo di COVID-19;

praticare uno stile personale, che accresca la dimensione positiva della *Self-Compassion,* per attenuare il rischio del Disturbo da Stress Post-Traumatico secondario.

Contributo degli Autori

Tutti gli autori hanno condiviso i contenuti dello studio, la stesura dell'articolo e approvano la versione finale dello stesso.

Conflitto di interessi

Gli autori dichiarano l'assenza di conflitto di interessi.

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Needle stick injuries among nurses in Italy: a review

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ABSTRACT. **Background.** ***Needle stick injuries (NSI) are a frequent problem among the medical and nurse population: NIS can cause blood exposure pathologies like HCV or HIV. Aim of this study is to determinate an incidence rate and causes of NSI.***
Methods. ***A search was conducted on the main international databases, only studies conducted in Italian nurse are considered.***
Results. ***The incidence rate of NSI varies from 2.2 to 10.77 per 100 nurses per year. The major causes can be traced back to a large night shift, working in the operating block and in the medical departments, and the failure to use adequate devices.***
Conclusions. ***It is important to work on training, on the use of safety devices and on a better night shift.***

Key words: *Nurse, Needle Stick Injury, Prevention.*

RIASSUNTO. Infortuni da puntura da ago tra gli infermieri in Italia: una revisione della letteratura.
Introduzione. **Le lesioni da punture di aghi (NSI) sono un problema frequente tra la popolazione medica e infermieristica: le NIS possono causare patologie da esposizione al sangue come l'HCV o l'HIV. Scopo di questo studio è determinare un tasso di incidenza e le cause di NSI.**
Metodi. **È stata condotta una ricerca sui principali database internazionali considerando gli studi condotti in Italia.**
Risultati. **L'incidenza di NSI varia da 2.2 a 10.77 infermieri per anno. Le cause maggiori possono essere ricondotte in un'ampia turnazione notturna, il lavorare nel blocco operatorio e nei reparti di medicina, e nel mancato uso di device adeguati.**
Conclusioni. **È importante lavorare sulla formazione, sull'uso dei dispositivi di sicurezza e su una migliore turnazione notturna.**

Parole chiave: Infermieri, Infortuni da ago, Prevenzione.

Introduction

Needle stick injuries (NSI) are a frequent problem among the medical and nurse population, and it is difficult to estimate the risk in the world. In Italy every day, about 300 healthcare workers (HCW) sustain an injury caused a contaminated needle or sharp medical device (needlestick and sharps injuries, NSIs), totaling over 100,000 accidents per year, but only an estimated 45% are officially reported (1). These accidents place a high economic burden on healthcare facilities. Indeed, a study conducted in eleven States estimated costs of $ 425 (range $ 48-1,516) for direct costs and $ 322 (range $ 152-413) for indirect costs (2). In Italy each event is estimated to cost around € 375 (3). A study conducted in many hospitals of Liguria indicates an incidence rate of 23.4 per 10000 person per year for all healthcare workers (4). The Directive 2032/32/EC and the Law Decree 81/08, Implementation of Article 1 of Law no. 123, concerning the protection of health and safety in the workplace, with the consequent "Unique Text on Health and Security at Work" (in Italian "TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO") are documents that try to increase the protection about work injuries (5). NIS can cause blood exposure pathologies like HCV or HIV: the prevalence of anti-HCV positivity in healthcare workers ranges from 0% to 9.7% in different studies worldwide, and about 75% of the total occupational exposure is percutaneous (6); Prospective studies of HCWs have estimated that the average risk for transmission after a percutaneous exposure is approximately 0.3% for HIV and range 6-30% for HBV (7). More than 90% of these infections occur in low-income countries and most could be avoided (8). There are many consequences after NIS, and it is important to estimate the risk in Italy. In fact, it is unclear the value of the risk, that change by department and hospital. These data explain the situation of the risk to incur in NIS among nurses: in Italy there many studies that process the problem, but an idea of incidence can give the real scope of the problem. Therefore, there is not an approximate datum of NIS, and the causes are many and varied. Aim of this study is to establish the features of NSI in Italy, understand risk factors, try to give an incidence rate per year and improve the situation.

Method

A search was conducted on the main international databases (PubMed, SCOPUS, CINAHL, Web of Science) for doing a systematic review, considering the studies conducted only in Italy in the last ten years (since January 01 2012). The decision to carry out the research only in the Italian panorama was opted to give a precise idea of the problem in a nursing context as homogeneous as possible. Reviews, studies about students or other HCWs and studies with only surveys are not considered.

Results

At 06/30/2022, the search "needle stick injury Italy" with only studies published from 01/01/2012 has produced 40 results on PubMed, 243 results on Scopus, 10 on Web of Science and 4 on CINAHL. 32 results are duplicate records. After reading title, 56 results are considered. 7 studies concern students, 2 studies other HCWs, 5 results are reviews, 26 studies do not concern the aim of the study. Finally, 15 studies on PubMed, 11 on SCOPUS (10 studies shared in both databases), 2 on Web of Science and 2 on CINAHL (these studies are in all databases) were considered, for a total of 16 studies.

Bianco (9) et al do a retrospective study from 1995 to 2016 referred to the Infectious Diseases Unit of University Hospital "Federico II", showing 1477 injuries (67.1 injuries per year, about 22-23 injuries per year among nurses): 33% of cases are nurses, with a decline from 1995 (3.8% of the total among nurses) to 2016 (1.2%). Most injuries occurred in General Surgery (14.21%), Gynecology and Obstetrics (9%) and Pediatrics (6.49%). In about 34% the HCWs had been exposed to HCV infected fluids. Cofini (10) et al study from January 2010 to December 2016 the injuries of "SS. Filippo e Nicola" Hospital in Southern Italy: 335 injuries occurred, 144 were nurses. Incidence rates of injuries among nurses was 11.8 per 100 people per year in 2010, 3.3 per 100 in 2015, 4.2 per 100 in 2016. Morning is the period in which most injuries occur. D'Ettorre (11) conduces a retrospective observational study among 765 nurses: the period 2009-11 have an incidence rate of 13.5 injuries per 100 full time equivalent (FTE, 46 hours per week, 46 weeks per year) nurse

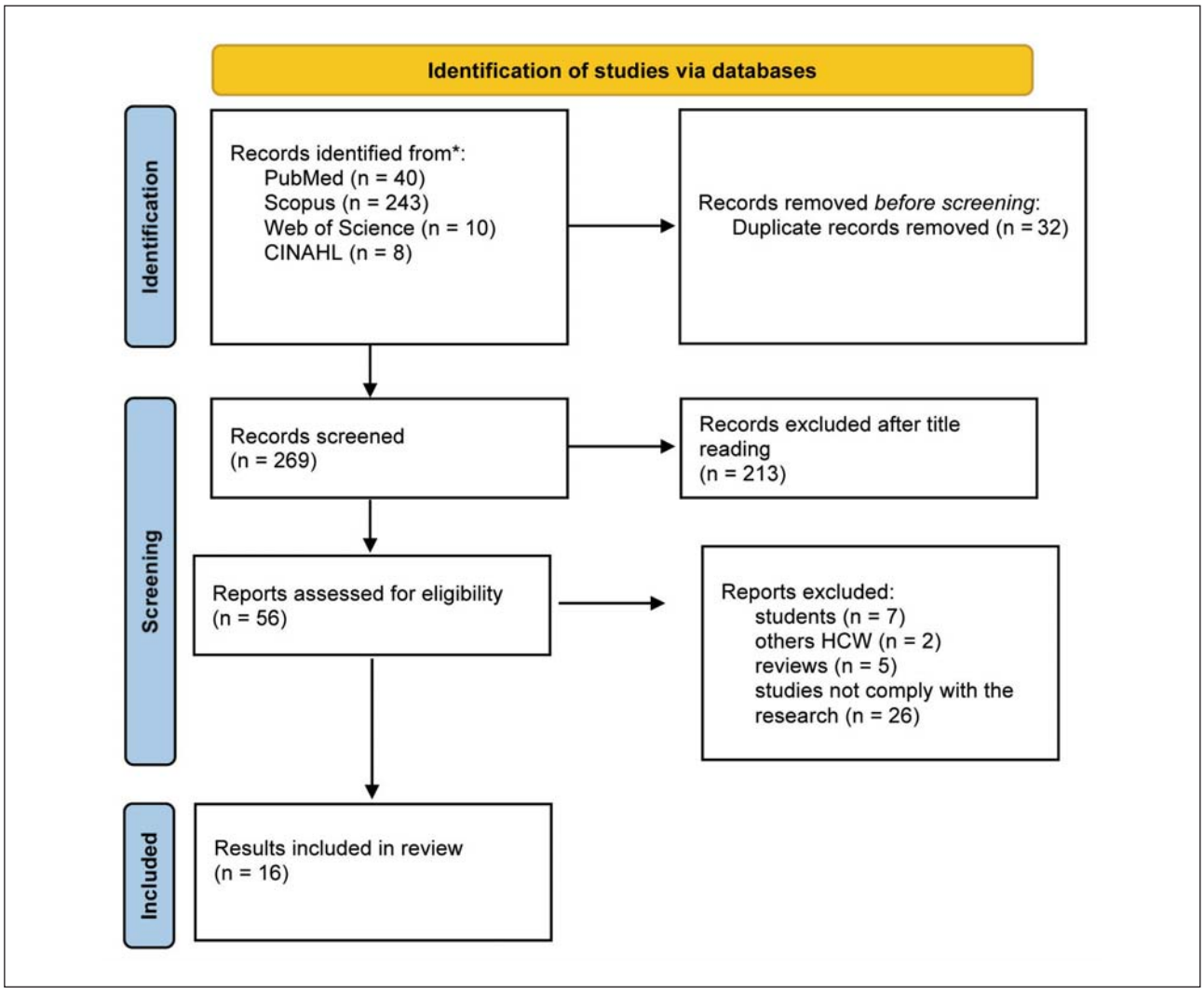

Figure 1. *Flow chart showing the stages of review and item selection*

positions versus 8.5 injuries per 100 FTE positions for the period 2012-14; the period 2012-14 is studied after the adoption of the organizational interventions (for reducing work related stress). Always D'Ettorre (12) in 2017 conduces another study analyzing the period January 2012 - December 2015 (four years), and finding 103 nurse injuries, with an incidence rate of 13.20 injuries per 100 FTE; NSI are frequent in night shifts > 9 compared to night shifts <= 3. D'Ettorre (13) et al show the results of a comparative study, examining 130 nurses of the Emergency Department in the periods January 2013 - December 2015 and January 2016 - December 2018: in the first period there is a rate of 26.15 per 100 FTE; in the second period the rate is 10.77 per 100 FTE, with costs saving estimated at € 13.073,00 per 100 FTE per 3-year. In particular, proactive interventions focused on the area of "Function and organizational culture" consisted in the organization of occupational safety trainings for Head Physicians and Head Nurses (the implementation of an organizational model based on the achievement of occupational safety objectives; the style of management focused on the support towards workers and on the listening skills; the implementation of a safety system managed by Head Physicians and Head Nurses). Ferrante et al (14) investigate with a retrospective observational study from 2013 to 2015 about 5729 HCWs in Public hospital of Catania: 240 NSI occurred, with an incidence rate of 1.4 per year (2013 = 1.8%, 105 NSI; 2014 = 1.2%, 70 NSI; 2015 = 1.1%, 65 NSI). Weekend (Saturday and Sunday) is the period with the minor percentage of injuries, nurses had the 65.8% of total NSI; needle accidents' frequency was higher than accidents by scalpels blades (91.3% vs. 8.8%). Ferrario et al (15) conduct a study in "Fondazione Macchi" Varese Hospital between 2004 to 2011: the nurse population exposed is made up to 11870 nurses (in a total of 3398 exposed person per year), the biological injuries (BI) of nurses are 758 in all the period of study; the total of injuries is 1287 (61% NSI, 31% cut injuries). HCW > 35 years have BI incidence rate 3.88 per 100 person/year, HCW < 35 6.64 per 100 person/year. Operation Room and Emergency Department are the department with higher incidence of BI. Always Ferrario et al (16) conduct a study on 1615 nurses and 1679 nurse assistants between 1 January 2007 and 31 December 2016, showing 759 injuries (70.5% were percutaneous injuries, PI, the rest mucocutaneous, and 83.3% occurred to nurses), with an overall PI rate 3.9 injuries per 100 FTE, 4.4 per 100 FTE for nurses, 2.8 per 100 FTE for nurse assistants. The incidence is higher in night shift nurses respect daily nurses. Maida et al (17) study the risk of exposure to blood and body fluids (BBF) in 2,364 HCW (570 of them being physicians, 739 nurses and 190 auxiliary personnel; moreover, 883 residents, 3,309 medical students and 548 nursing students were present) at the University Hospital in Palermo: in the period of study (from January 1, 2004 to January 1, 2018, 14 years) BBF are 899, 317 occurred at nurses; BBF exposure was needle-stick injury (685, 76.2%, nurses 263, 38.4% of total), 585 out of 685 percutaneous exposures were caused by needles (syringe, peripheral venous catheter, butterfly needles, etc.) and occurred mainly to nurses (224, 38.3%). In all healthcare facilities, 40.5% of the BBF exposures occurred in the patient's room at the patient's bedside, 22.0% in operating rooms and 11.0% in outpatients' clinics. Higher cases of accidents were recorded during blood sampling (14.5%), managing a medical device (12.9%), injection therapy (12.0%), surgery (11.2%) and detection of blood glucose (8.8%). Ottino et al (18) conduct a study between January 2015 and December 2016 in our hospitals (1640 events) for valuing an incidence rate of accident for 100000 needles used: from 2014, in which there were 1044 NSIs (with 209 safety device, SED, related accidents, 20% of the total NSIs, with a use of 77.8% of total SED butterfly, 57.3% peripheral venous catheters, 4% standard needles, 99.1% vacutainer standard needles, 94.4% vacutainer butterfly needles) with an accident rate of 2.8 per 100 HCWs; between 2015 and 2016, the total number of accidents involving SEDs was 298 (167 in 2015, 131 in 2016) out of 1640 total accidents and decreased by 21% from 2015 to 2016. Nurses were involved in 50% (812/1640) and were most exposed to SED-related incidents (231, 78% of the total SED); regarding SED-related injuries, the most frequent security devices involved were butterfly needles (77, 26%), peripheral venous catheters (42/298) and insulin and tuberculin syringes (29/298). Conventional devices NSI are in the operating room, SED NSI in patient room (more 50% of total). Parco et al (19) analyze the biological accidents in Burlo Garofolo Children's Hospital in Trieste between January 2012 and December 2013: 230 nosocomial risk events occurred in the departments of oncology and pediatric-obstetric surgery and in the intensive care unit, 158 reported by health care workers in 2012, comprised 55 needle stick injuries (34.81%), 59 blood splashes (37.34%) and 44 cuts with infected instruments (27.84%); 61 in 2013, comprised two needle stick injuries (3.27%), 35 blood splashes (57.37%) and 25 cuts with contaminated instruments (40.98%). Rapisarda et al (20) conduce a retrospective study about NSI and biological injuries in a university hospital of Southern Italy considering the years 2013 and 2014 and 3250 HCWs. The frequency of accidents during the 2-year period was always lower than 5% of total HCWs. In 2013, 103 cases occurred; in 2014, the number of injuries had significantly decreased (n = 60). 83.4% of injuries are NSI (83 in 2013, 53 in 2014). Nurses and obstetricians have 45% of total NSI in 2013 and 62% in 2014. The most common cause of occupational exposure among HCWs is needle-stick injuries (two-handed recapping, and unsafe collection and disposal of sharp-object waste), while no differences were noticeable as far as work shifts (i.e., night shift) and operational unit. Respect 2013, in 2014 injuries decrease, caused by prevention measures adopted for all HCWs (specific information about biohazards and specific monitoring of personal protective equipment usage and vaccination). Sossai et al (21) investigate about NSI in five public healthcare institutions located in Liguria (San Martino Hospital, Galliera Hospital, Local Health Agency 1, Local Health Agency 4 and Local Health Agency 5) for a total number of person-years at risk 122,464 over a five-year period (2006-2010): 286 NSI occurred, with an overall average NSIR of 23.4 per

10^4 person-years; the risk of NSI due to conventional and safety catheters was respectively 44.9 and 1.8. Stefanati et al (22) conduct a study about NSI occurred to nurses and nursing students in eight departments of the University Hospital of Ferrara from January 01 2002 to December 31 2012 (11 years): 909 biological injuries occurred, 738 on nurses. 84.16% of injuries are NSI. 20.14% of injuries occurred in all Surgical Room Department, 12.43% in Medicine Department, 9.57% in Emergency Department, 8.68% in Surgical Department. Vaccari et al (23) study the numbers of injuries in two Italian hospitals of Lombardia (1,036 activated beds for Hospital 1 and 145 activated beds for Hospital 2 at the time of the study): Hospital 1, the number of injuries fluctuated significantly between 1994 and 2014 (without 2011) with on average of 30 incidents each year; at Hospital 2 (during 2010-2015), the average is 20 injuries per annum. Around 66 per cent of the injuries were percutaneous, while 30 per cent were mucocutaneous; nurses (including students and apprentices), made up 73% of the cases, with the higher frequency leading up to April-June, primarily during the first four working hours and the key areas where the accidents took place was general medicine (21 per cent), followed by first aid (15 per cent), and surgery and psychiatry (11 per cent). Vitale et al (24) show results about injuries in "F. Miulli" Hospital in Puglia between 2014 to 2018 (five years) for a total of 1259 workers: 249 injuries occurred at nurses (165) and nursing students in five years, 75.9% of all injuries are NSI, 82.3% in the upper limb, 55.4% in Medicine Department.

Discussion

The studies selected give different data: the incidence rate varies from 2.2 to 10.77 per 100 nurses per year,

Table I. ***Summary of the reviewed studies about response of students***

First author	Year of publication	Methods	Results
Bianco et al[9]	2019	Retrospective study from 1995 to 2016	490 nurse NSI, 22-23 cases per year
Cofini et al[10]	2018	Retrospective study from 2010 to 2016	144 nurse NSI, incidence rate 4.2 per 100 person in 2016
D'Ettorre[11]	2016	Retrospective comparative study on 765 nurses from 2009 to 2011 and 2012 to 2014	2009-11: 13.5 injuries per 100 FTE 2012-14 8.5 injuries per 100 FTE
D'Ettorre[12]	2017	Retrospective observational study from 2012 to 2015	103 nurse NSI, 13.20 injuries per 100 FTE
D'Ettorre et al[13]	2020	Retrospective comparative study on 130 nurses of ED from 2013 to 2015 and 2016 to 2018	2013-15: 26.15 per 100 FTE 2016-18: 10.77 PER 100 FTE
Ferrante et al[14]	2018	Retrospective observational study from 2013 to 2015 about 5729 HCWs	240 NSI (158 nurses) incidence rate 1.4 per year
Ferrario et al[15]	2012	Retrospective observational study from 2004 to 2011 to an exposed population of 3398 person for year (a total of 11870 nurses)	758 BI BI rate 6.39 per 100 61% of all BI are NSI
Ferrario et al[16]	2021	Retrospective observational study on 1615 nurses and 1679 nurse assistants from 2007 to 2016	759 PI (83.3% nurses) Nurses PI rate 4.4 per 100 FTE
Maida et al[17]	2020	Retrospective observational study on 899 workers (317 nurses) from 2007 to 2016	685 NSI, 263 at nurses
Ottino et al[18]	2019	Retrospective study from 2015 to 2016 after increasing SED	812 nurse NSI, 2.2 per 100 nurses
Parco et al[19]	2015	Retrospective observational study of biological exposure (317 nurses) from 2012 to 2013	55 NSI in 2012, 2 NSI in 2013
Rapisarda et al[20]	2019	Retrospective observational study of biological exposure (3250 HCW) from 2013 to 2014	163 injuries, 83 NSI in 2013, 53 NSI in 2014
Sossai et al[21]	2016	Retrospective observational study of NSI (total number of person-years at risk 122,464) over a five-year period (2006-2010)	286 NSI 23.4 per 10^4 person-years
Stefanati et al[22]	2015	Retrospective observational study of biological exposure on nurses (738) and nursing students in eleven years and a survey	NSI 84.16% of all biological exposures
Vaccari et al[23]	2018	Retrospective observational study of two hospitals: Hospital 1, period 1994-2014 (no 2011), and Hospital 2, period 2010-2015	Average 30 incidents per year at Hospital 1; 20 injuries per years at Hospital 2
Vitale et al[24]	2021	Retrospective observational study of biological exposure on nurses (738) and nursing students in five years	165 nurse NSI

NSI Needle stick injuries; FTE full time equivalent nurse positions; ED Emergency Department; PI percutaneous injuries; SED safety device; BI biological injuries; HCW healthcare workers

taking into consideration only the last chronological value in comparative studies. The incidence drops if we consider all HCWs.

The principal factor that reduces NSI is the use of SED: comparative studies agree about a significant decrease between the period preceding the use of the SED and the period next, and the application of the Directive 2032/32/EC and the Law Decree 81/08 have contributed to the decrease. In Italian literature there are many studies that indicate reduced NIS with the use of SED (25), and the application of the last law indications (26). In fact, it is demonstrated that the use of instrumental needle sticks Prevention Devices occupational exposure to biological risk (from 63% to 100% reduction), costs and number of accidents (21); thank to legislations training and organization are factors that are slowly improving. Furthermore, studies generally agree that the major part of NSI happens in bed patients, and that the Surgical Department and the Medicine Department are the departments with a major incidence of NSI. On other causes, the studies investigate more individually: Cofini indicates the morning, thinking that this is the moment of the day with the most things to do; D'Ettorre in his three studies reports that NSI decrease with work related stress interventions, a lower number of night shift monthly and the implementation of the organization; Ferrario shows the difference of NSI in daily nurses and night shift nurses (higher incidence); Ferrante finds the weekend (the period with fewer activities) the period with the lower incidence of NSI; Vaccari indicates an increase of NSI in the period April-June. It is interesting the causes listed by D'Ettorre: work related stress and night shift are common causes for various problems of nurses, like low back pain (27), burnout, accidents and injuries, absenteeism and, consequently, reduced work efficiency (28). While night shift is a problem difficult to resolve, the stress work related can partially improve through training, lifestyle and periodical rotation in department with high incidence of burnout. Ottino estimates the higher risk of NSI during the use of butterfly needles: it is important supply to a training (or retraining) of the correct use of devices. Finally, Stefanati shows that NSI are the more numerous biological exposures.

Conclusions

It is important to do not underestimate the problem of NSI in HCW and, mainly, in nurses. Significant progress has been made over the past decade, and it is important continue in this direction. SED and training are the immediate and economic solutions to reduce NSI. Night shift nurses have a higher incidence of NSI. At the end, it can be useful to think a better night shift rotation.

Limits

The limitations of the study are represented by the selection of considerably diverse samples: the researches often discuss only some problems about NSI, and results give different types of range; the no use of grey literature can give reduced final results.

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Declaration of Interest

The author declares that he has no conflicts of interest associated with this study.

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Ricordo del Prof. Marcello Imbriani

Queste parole per ricordare il Prof. Marcello Imbriani che ha da sempre sostenuto e supportato la musicoterapia a tutti i livelli. È a lui che si deve l'esistenza del Laboratorio di Ricerca in Musicoterapia presso gli ICS Maugeri di Pavia, il Master in Musicoterapia promosso dall'Università di Pavia e anche questo spazio editoriale. Tante esperienze condivise, un costante supporto e tanti utili consigli…

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ALFREDO RAGLIO

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Background Music in elderly nursing home: a feasibility explorative study

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ABSTRACT. **Introduction.** ***This study explores how a background music-listening program within residential facilities for the elderly can influence the general environment and be effective on psychological and behavioral aspects. The feasibility of this type of intervention was explored.***
Methods and Materials. ***Twenty-nine residents involved in the experiment were observed for 4 weeks in absence of a music intervention and for the same period during the experimental condition. The intervention consisted in music listening programs, designed by trained music therapists for specific objectives according to the different times of the day. Experimental and control condition effects were compared through the administration of clinical scales and observational grids.***
Results. ***The results of clinical scales showed that music listening programs reduced behavioral symptoms in 7 out of 8 people with the most severe neuropsychiatric symptoms. The observational scheme completion showed a clear improvement in all outcomes considered, with the exceptions of agitation (in the morning) and irritability (in the afternoon).***
Discussion. ***The study brings several points to attention, including the need to establish a set of criteria in music listening programs selection and administration (e.g. identification of music characteristics related to objectives and outcomes, assessment strategies, involvement of a team of professionals). Implementing evidence-based clinical practice is crucial and the highlighted results encourage the introduction of music-listening approaches as part of therapeutic interventions in elderly nursing homes.***

Key words: *music listening, music therapy, background music, evidence-based intervention, well-being, cognitive disorders, behavioral and psychological symptoms.*

RIASSUNTO. ***Introduzione.*** **Questo studio di fattibilità ha valutato come un programma di ascolto di musica ambientale all'interno di strutture residenziali per anziani possa influenzare l'atmosfera generale ed agire sugli aspetti psicologici e comportamentali.**
Metodi e materiali. **I ventinove residenti coinvolti nell'esperimento sono stati osservati per 4 settimane in assenza di un intervento musicale e per lo stesso periodo durante la condizione sperimentale. L'intervento consisteva nell'ascolto di playlist musicali, ideate da musicoterapeuti formati per raggiungere obiettivi specifici a seconda dei diversi momenti della giornata. Gli effetti delle condizioni sperimentali e di controllo sono stati confrontati attraverso la somministrazione di scale cliniche e griglie osservazionali.**
Risultati. **Dai risultati delle scale cliniche è stato mostrato come i programmi di ascolto musicale abbiano ridotto i sintomi comportamentali in 7 persone delle 8 che**

Introduction

Music activities can be considered as powerful interventions used in the geriatric field to promote communicative, relational processes and emotional expression (1). The effectiveness of music-based interventions on behavioral and psychological symptoms of dementia have been highlighted by several previous studies (2-5). Therefore, especially in pathological aging, the use of music is very widespread in psycho-social interventions. A first broad distinction occurs between actual music therapy interventions (active or receptive techniques that require the presence of a trained music therapist, a setting, a theoretical background and a specific assessment) and other music-based activities such as general music activities (singing, music listening, etc.) guided by other professionals (staff, formal and informal caregivers, etc.) and supervised by a music therapist (6-8). Among general music activities, listening to preferred music is one of the most employed interventions with elderly to improve well-being and to reduce eventual maladaptive behaviors. The results of a review of the most recent RCTs testing (9) about music listening intervention showed potential benefits on behavioral disturbances. Clear guidelines are required to fully exploit the potential of individualized music listening (10-15), including the definition of specific criteria to select and administer listening programs; moreover, the involvement of trained music therapists could be to identify specific music contents and therapeutic objectives. In addition to individualized music listening, background music intervention can be used to improve the environment in a more global way. Pre-recorded musical programs are created according to specific objectives, offered to different types of people in specific contexts (such as lunchtime, personal care procedures, moments of rest etc.) (16). This type of intervention is often designed for the hospital or nursing home contexts, to promote general well-being and to improve persons' adaptation to the environment. Several studies highlight beneficial effects of background music in reducing agitation and negative social behaviors (17-18), in enhancing cognitive tasks related to verbal fluency and memory (19), in increasing cooperation and improving the relationship during nursing activities and stimulating positive emo-

presentavano i sintomi neuropsichiatrici più severi. La compilazione delle schede osservazionali ha mostrato un netto miglioramento di tutti gli aspetti considerati, ad eccezione di agitazione (al mattino) e irritabilità (al pomeriggio).
***Discussione*. Lo studio porta all'attenzione diversi punti, tra cui la necessità di stabilire una serie di criteri nella selezione e proposta dei programmi di ascolto musicale, tramite l'identificazione delle caratteristiche musicali in base a obiettivi e risultati, la scelta di strategie di valutazione, il coinvolgimento dei caregivers. L'implementazione della pratica clinica basata sull'evidenza è fondamentale e i risultati emersi incoraggiano l'introduzione di approcci basati sull'ascolto musicale come parte degli interventi terapeutici nelle strutture residenziali per anziani.**

Parole chiave: ascolto musicale, musicoterapia, musica ambientale, approcci evidence-based, benessere, disturbi cognitivi, sintomi comportamentali e psicologici.

tions and moods (20-23). An attempt to apply systematically a music listening program during lunchtime was made in a residential center for elderly people (24), with a quasi-experimental design lasting two months: a week with a musical program was alternated to a week without intervention. The results indicate that music programs can improve negative behaviors. Keeping this evidence in mind, the present study proposes a structured listening program within the residential center for the elderly "Villa Flavia" (Pavia, Italy). The main hypothesis is that structured moments of daily music listening can affect general well-being, by improving general quality of life and reducing maladaptive behaviors among the residents.

Materials and Methods

This research adopted a longitudinal (short-term) design, in which single group changes were recorded along a two-month period. The study was conducted in an institution housing autonomous old residents, most of which presented a clinical frame of cognitive decline. Twenty-nine residents involved in the experience were observed for a period of 4 weeks without music stimuli and for the same amount of time during the experimental condition. The experimental condition consisted in specific music listening programs, designed by trained music therapists to accompany different times of the day. Four moments of daily life were identified for the music listening programs; these were chosen in accordance with daily activities of the residential structures and were characterized by absence of other stimuli. The music therapists created 4 different playlists (1 hour each), each one for a different purpose (relaxation or activation). The playlists were broadcast in the common areas of the structure, where residents generally gather. Health staff was instructed to set the beginning of music listening autonomously, using Mp3 players, connected to Bluetooth speakers.

The main hypothesis was to improve the general well-being of the guests, through different musical listening programs designed for specific objectives and according to the time of day. In particular, the main objectives were a) sensory activation and stimulation (at the beginning of the morning and after the postprandial rest); b) socialization (after morning physiotherapy); c) deactivation and facilitation of night rest (after dinner and during preparation for the night). For activating playlists created for stimulation, music was mainly classical and with a positive valence, and had a growing trend, starting from slow tempos such as the *adagios* and then moving on to progressively faster tempos (from *andante*, to *allegro* and *presto* or *vivace* tempos) (a). For the listening program designed to promote socialization, songs familiar to the target population have been introduced to facilitate reminiscence and memory and, consequently, to encourage a common experience that could be shared with others (b). Finally, for the last relaxing playlist, a succession of tracks was created with a regular and calm rhythmic trend, a slow tempo, regular pulsations, a continuous sound without abrupt interruptions, slow melodies, simple harmonies, and constant volumes, favouring the timbre of strings such as the lute and the guitar (c).

All subjects had the possibility, according to their will, to undergo the listening program, which took place at specific times during the day in the living rooms of the two main housing units. The sample characteristics and the setting didn't allow a rigorous research method, for logistic reasons. However, methodological choices were adopted to observe differences between the control and the experimental condition. Twenty-nine residents initially underwent the evaluations and their overall cognitive profile was assessed using the Mini Mental State Examination tool (Folstein et al., 1975.), leading to a sample division into three groups according to the level of impairment, from mild to severe. Furthermore, the NeuroPsychiatric Inventory (Cummings et al., 1994) was administered to evaluate the severity of Behavioral and Psychological Symptoms of Dementia (BPSD).

The evaluation tools adopted during the assessment periods included psychological scales to investigate anxiety and depression symptoms (HADS, Hospital Anxiety Depression Scale, Bjelland et al., 2002), quality of life (The Cornell-Brown Scale for Quality of Life in dementia, CBS-QOL, Ready e Ott, 2008) and neuropsychiatric symptoms evolution (NPI, Cummings et al., 1994). The study design scheduled four different moments of assessment: a first baseline evaluation (T0); another evaluation at the end of the 4-weeks control condition (T1); a third assessment at the end of the experimental condition (T2) and finally a follow-up assessment (T3).

Alongside these evaluations an observational scheme, created ad hoc by the researchers, was filled out by formal caregivers of the residence; this scheme aimed at assessing behavioral disturbances such as anxiety, aggressivity, apathy, agitation, mood deflection, irritability, and physical or verbal aggressivity. Different members of the health staff made the observations twice a day (after the morning and after the afternoon), depending on the presences on each day. Each item was assigned a score from 0 to 1 (0 = absent; 0,5 = partially present; 1 = present). Qualitative analysis of data of the study is presented in the following section.

Results

Demographic and clinical characteristics of the residents involved in the study are summarized in Table I.

Unfortunately, for pandemic-related and clinical reasons, it was not possible to complete the assessments, especially for evaluations at T1 and T3. The more relevant result of the study assessed by clinical scales was that music listening programs reduced behavioral symptoms in 7 of 8 people with higher NPI global scores. Details of these improvements are reported in Figure 1.

The evaluations made using the observational scheme showed a clear improvement in all outcomes considered both in the morning and in the afternoon, with the exceptions of agitation (in the morning) and irritability (in the afternoon). Results concerning the observational scheme are reported in Figures 2 and 3.

Table I. *Demographic and clinical variables of the participants at baseline (n=29)*

Variables	*n*	*%*	*Mean*	*SD*	*Range*
Age			88	5,7	76-96
Gender					
Male	4	13,8			
Female	25	86,2			
Education			5	2,4	
Medical Diagnosis					
Cognitive impairments	6	20,68			
Behavioral disorders	8	27,58			
Psychiatric diagnosis/symptoms	3	10,34			
Other neurological conditions	4	13,8			
MMSE					
Severe dementia (0-9/30)	3	10,34			
Moderate dementia (10-20/30)	9	31,03			
Mild dementia (21-24/30)	9	31,03			
NPI (>=12/144)	8	27,58			

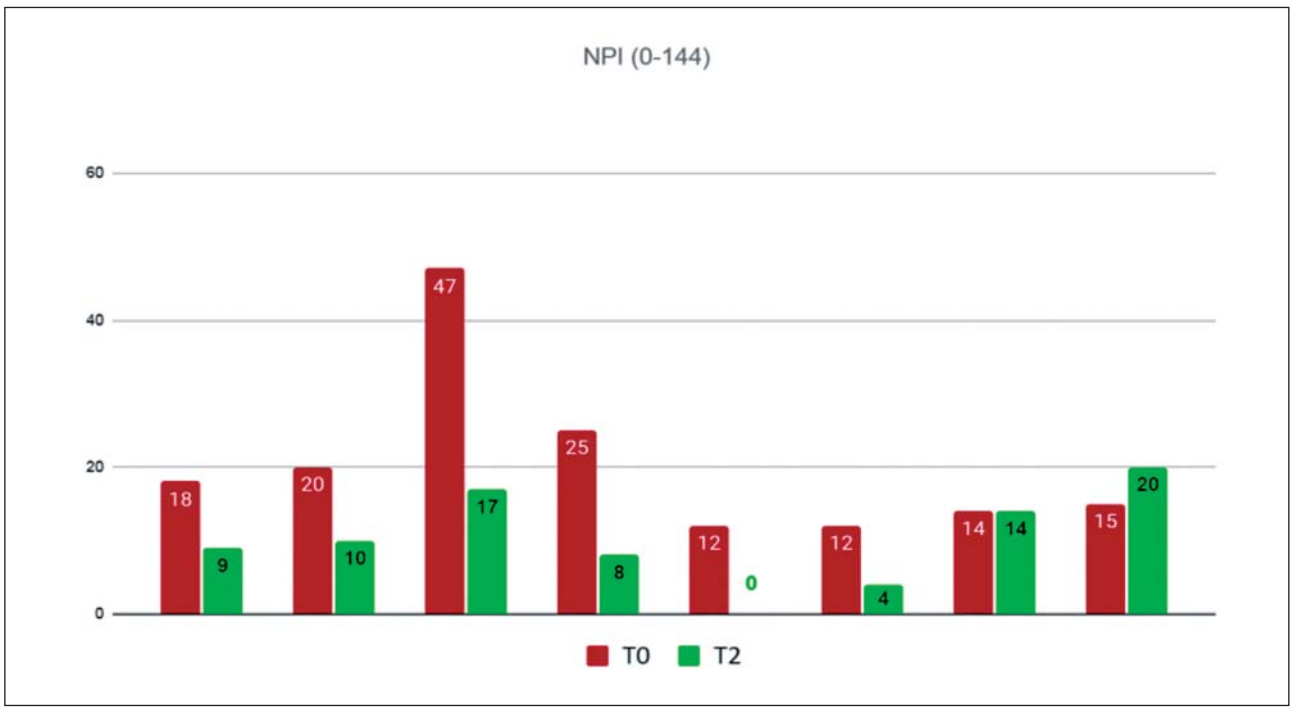

Figure 1. *T0 vs T2 NPI global scores regarding residents with more relevant neuropsychiatric conditions (n=8)*

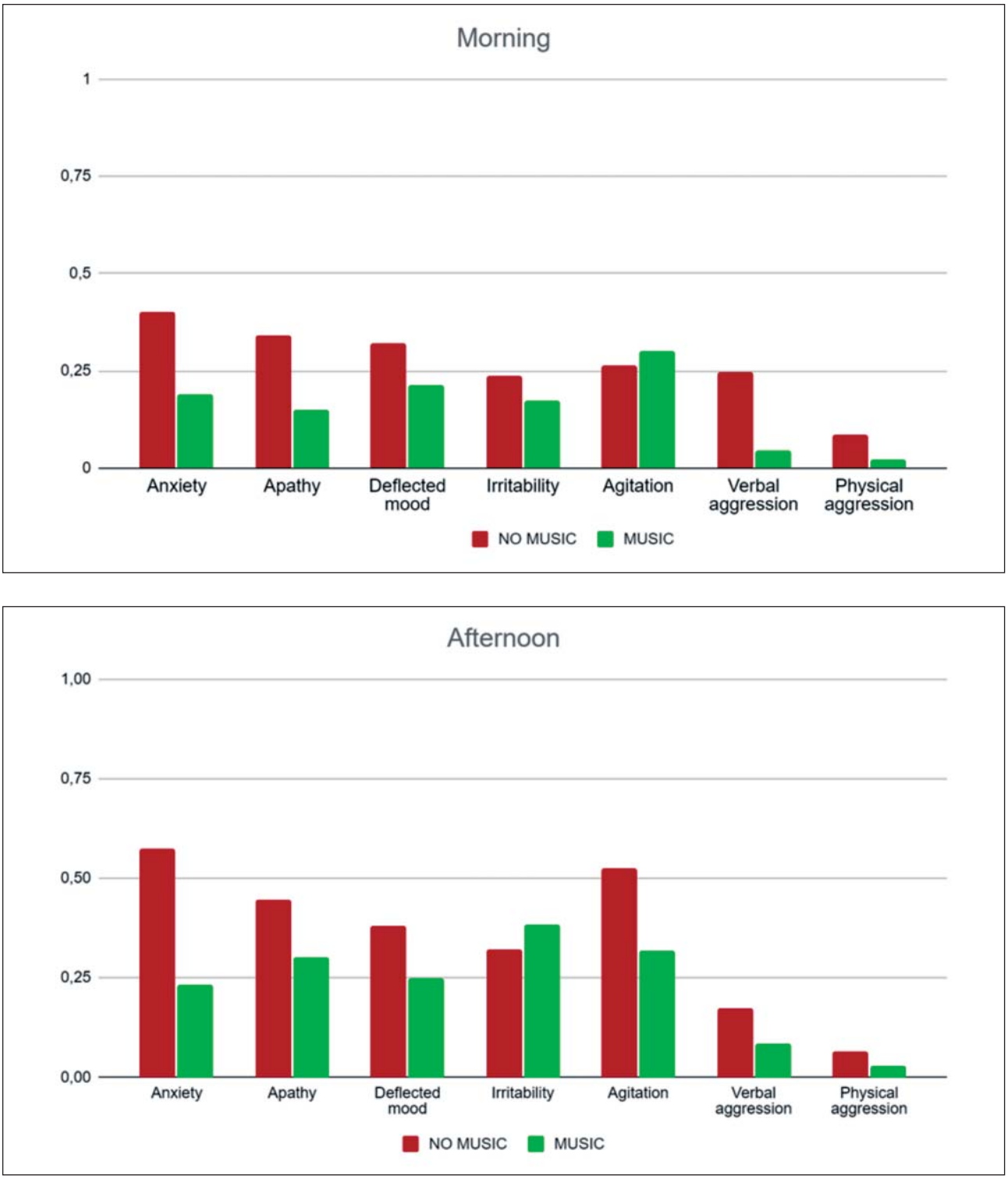

Figure 2. ***Behavioral disturbances observed in the morning and afternoon using the observational scheme. Comparison between the two conditions (with music and without music). Mean scores for all subjects (0 = absent; 0,5 = partially present; 1 = present)***

Discussion

The present research suggests that also background music listening can help to improve behavioral disturbances in elderly population. This encourages the use of techniques using music that can be integrated with conventional care. As suggested by literature (1) these techniques, such as background music, can constitute a model of intervention that includes the music therapy approach as well as a more general use of music. However, such use that may involve (as in the case of this study) formal caregivers, requires the supervision of a music therapist.

The strength of this study is the specificity of the intervention, especially in the study design and in the rationale (music and times of listening choices). The musical

habits of the residents were taken into consideration. All pieces were accurately chosen, examining their specific parameters, and more specific analysis of the pieces characteristics that would directly act specifically on the activation and deactivation states was made. The order of tracks in each playlist was decided according to those specific purposes. Also, to stimulate socialization the most well-known and appreciated songs were proposed.

The main limitation of the study was the impossibility to complete the assessment that was initially designed, leading to a qualitative analysis of the data. The difficulties encountered with this specific population suggest it would be advisable to complete the assessment with more direct observations, such as video recordings. Another call is the need to train adequately the staff involved, in order to obtain a more coherent and uniform application and evaluation of the protocol.

More studies overcoming previous mentioned limitations are needed to strengthen these preliminary results that confirm the positive valence of adequately selected background music. The encouraging results presented here can serve as a reference to introduce this approach as part of therapeutic interventions in elderly nursing homes.

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