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ARTICLE

Pain characteristics in Italian people with spinal cord injury: a multicentre study

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STUDY DESIGN: Multicentre cross-sectional study.
OBJECTIVE: The objective of this study is to evaluate prevalence, location and characteristics of pain in hospital inpatients people with spinal cord injury (SCI).
SETTING: Ten Italian rehabilitation centres specialized in spinal injury care, where inpatients are admitted both after the acute lesion and for late complications (time since injury, median [IQR]: 0.8 [0.2–8.2] years).
METHODS: All the persons were submitted to AIS scale assessment [1] and modified Ashworth scale [2]; personal data and anamnesis were recorded; any pain within 1 week was investigated and the International Spinal Cord Injury Pain Basic Data Set (ISCIPBDS) Italian version [3] was administered by physicians expert in type of pain definition.
RESULTS: Of 385 included persons, 275 (72%) suffered pain, with the score value median [IQR]: 6 [4–8]. The worst pain of the person was nociceptive in 52% and neuropathic in 48% of the cases; 46% of nociceptive pain was located in the neck–shoulder region, whereas 67% of neuropathic pain was located in the sublesional part of the body. In 48% of the whole population, spasticity was observed but only 74% of them had pain. Being old and female are associated with high pain development, OR (95% CI): 1.24 (1.01–1.04) and 1.83 (1.05–3.20), respectively.
CONCLUSIONS: A high prevalence of pain is confirmed in persons with SCI, with both nociceptive and neuropathic pain characteristics. Only old age and female sex resulted as variables highly associated with pain.

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INTRODUCTION

Persons with spinal cord injury (SCI) are affected by many symptoms related to the lesion as follows: motor and sensory dysfunction, and bladder and bowel dysfunction. Pain is a symptom perceived by people with SCI as a high problem: many type of pain can be suffered and they could determine a poor quality of life [4, 5]. Spasticity is a motor dysfunction observed with high prevalence in this population; only in some cases it is perceived as painful.

Among persons with neurological conditions, the highest prevalence of chronic pain was observed in persons with SCI (64%) [6]. Studies on pain prevalence in people with SCI demonstrate that up to 81% suffer from pain and in about 30% of them it is a severe pain [7, 8].

A multicentre study on pain in persons with SCI in Germany showed a high prevalence of pain in this population (66%) with a high intensity in about 70% of the cases [9]. High prevalence of pain (68.9%) was observed in individuals with SCI living in Switzerland, with a higher risk of chronic pain in women and in older persons [10]. A study in persons with SCI from Denmark

confirmed a high prevalence of pain of 73% with a mostly moderate–severe intensity [4].

Many different types of pain, both in terms of characteristics (nociceptive or neuropathic pain) and location, are referred by people with SCI [11] and often more than one type or location of pain is present [12].

In the clinical practice, the identification of the neuropathic pain is very important, because the treatment approach is specific, challenging and requires experience from the prescriber to be effective. The clinical diagnosis is based on different characteristics as follows: neuropathic pain is described by the patients as 'burning, stinging, knife-blade, tingling, electric shock, squeezing, pressing cold and shooting pain'; the location correspond to the underlying lesion (SCI); and hypoalgesia, hyperalgesia and allodynia are associated signs. On the other hand, the nociceptive pain is indicated as a pain referred to an organ disease as musculoskeletal or visceral dysfunction. A pain referred to part of the body affected by spastic hypertonia, which increases when the spastic muscle in stretched or during muscle spasms, is considered as spasticity related and is labelled as

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Fig. 1 Location of the Italian Hospital Spinal Cord Centre participating. Each star represents one participant centre; the star sizes are proportional to the sample size of persons examined in the hospital centre.

nociceptive [https://www.iscos.org.uk/international-sci-pain-data-sets]. Only in some cases spasticity results in being painful and the mechanisms of pain perception in spastic muscle is not clarified [13].

The prevalence of neuropathic pain in persons with non-traumatic pain in Swedish was 38%; the presence of this pain causes severe problems in daily life [14]; even in persons with traumatic SCI, a high prevalence of neuropathic pain was observed, in particular in older persons [15].

In the past 10 years, the right evaluation and treatment of pain has been recognized as one of human rights worldwide [16]. In Italy, a specific pain law was issued in 2010, stating that doctors and nurses must deal with the pain of their patients by applying appropriate effective assessments and therapy [17]. Consequently, the scientific community has dedicated a particular attention to develop effective evaluation tools and therapies for pain. For the SCI population, the International Spinal Cord Society (ISCoS) developed the pain data set in 2008, revised in 2014 [https://www.iscos.org.uk/international-sci-pain-data-sets, 18]. An Italian translation was validated in 2019 [3]. The results of a multicentre data recording about pain in persons with SCI in Italy are presented in the study. The aim of the study is to evaluate the prevalence and characteristics of pain in hospital SCI inpatients, and analyse the factors that could predict pain development.

METHODS

Ten SCI Hospital specialized centres, located in different Italian areas, participated in the study: four from the North (Emilia Romagna, Liguria,

Lombardia and Veneto), four from the Centre (Abruzzo, Marche, Toscana and Umbria) and two from the South (Sardegna and Sicilia) (Fig. 1). The study was carried from 1 March 2018 to 31 August 2019. All patients admitted in the participant hospitals as inpatients after the acute lesion or because of complications in the chronic phase were submitted to an anamnesis and a neurological assessment before being included in the study. Inclusion criteria were both traumatic and non-traumatic (i.e., degenerative: vertebral disc herniation, stenosis of the vertebral canal and compressions ab extrinseco; transverse myelitis; and vascular myelopathy) SCI; exclusion criteria were as follows: paediatric age (<14 years old), multiple sclerosis, neoplastic disease, drug addiction and psychiatric disease.

The data collected with the sheet created translating the International SCI Core Data Sets [19] in Italian language (see Supplementary Information) were as follows: (a) personal data: age and sex; (b) characteristics of the lesion: time of onset and aetiology, and (c) drug therapy. The lesion was defined sub-acute if the time of onset was ≤1 year and chronic if >1 year. The patient was examined by a physician of the clinical staff and was assessed using the American Spinal Injury Association Impairment Scale (AIS) [1] and the Modified Ashworth Scale (MAS) to measure segmental spasticity [2]. The spasticity was exanimate in each person in the shoulder, elbow and wrist for upper limbs, and the hip, knee and ankle for the hind limbs. Finally, the higher score value was recorded on database and used in the statistical analysis.

When pain was present, the Italian version of the International Spinal Cord Injury Pain Basic Data Set (ISCIPBDS) [3] was administered by physicians expert in type of pain; the distinction of neuropathic from musculoskeletal pain was based on clinical aspect and no other scale was administered, as indicated by ISCoS. The classification of pain used in this study, is the one applied by ISCoS pain evaluation. 'In addition to musculoskeletal, visceral and neuropathic pain at level and above level, other (nociceptive) pains are recorded by referring to nociceptive pain that

Table 1. Characteristics of the population.

Personal and lesion data			
	Aetiology of the lesion		
	Traumatic 250 (65%)	Non-traumatic 135 (35%)	Total 385
Age: years			
Mean (SD), median [IQR]	50.7 (15.5), 51 [40–62]	59.3 (15.2), 63 [52–69]	53.7 (15.8), 54 [43–66]
Gender {frequency %}; mean (SD)			
Female	48	58	106 {27.5}; 56 (17)
Male	202	77	279 {72.5}; 53 (16)
Time since injury: years {frequency %}			
<1	112	77	189 {49.1}
1–3	27	12	39 {10.1}
3–6	21	12	33 {8.6}
>6	83	23	106 {27.5}
Missing value			18 {4.7}
Mean (SD), median [IQR]	7.4 (10.6), 1.4 [0.2–11.5]	3.7 (7), 0.4 [0.2–4]	6.2 (9.7), 0.8 [0.2–8.2]
Age at injury: years			
Mean (SD), median [IQR]	43.3 (18.7), 42 [28–59]	55.8 (16.7), 60 [45–67]	47.6 (18.9), 49 [31–63]
AIS {frequency %}			
A	105	47	152 {39.4}
B	38	12	50 {13.0}
C	52	42	94 {24.4})
D	55	34	89 {23.1}
Injury severity {frequency %}			
C1–C4	33	15	48 {12.5}
C5–C8	56	13	69 {17.9}
T1–S5	106	73	179 {46.5}
AIS D	55	34	89 {23.1}

may be present but do not fall into the musculoskeletal or visceral categories. Examples include pain associated with ulceration of the skin and headache. These pain may be directly related to SCI (e.g., pressure areas and dysreflexic headache) or unrelated to SCI (e.g., migraine). Pains that are not associated with a lesion or disease affecting the spinal cord or nerve roots, yet are nevertheless neuropathic, can be classified as others (neuropathic); examples include post-herpetic neuralgia, pain associated with diabetic neuropathy, central post-stroke pain and compressive mononeuropathies' [https://www.iscos.org.uk/international-sci-pain-data-sets].

Location and value of the highest pain score of each patient were recorded, as the ISCIPBDS dictates only up to three different pains per person were collected. All recorded data were sent by the participating hospitals to the Coordinator Centre (Pisa University Hospital) to be analysed. The statistical analysis was applied to the worst pain: felt as the pain of highest intensity. The prevalence of pain type was studied and the pain intensity, location and duration were compared between nociceptive and neuropathic pain.

Statistical analysis

Categorical data were described by absolute and relative frequency, continuous data by mean, SD, median and range. Assessment of qualitative variables were performed by χ^2-test and z-test for two proportions, whereas for quantitative variables t-test for independent sample (two-tailed) was applied. The correlation between personal and lesions data with the presence or absence of pain and pain characteristic (nociceptive or neuropathic) of the first worst pain were studied. To evaluate the correlation between quantitative variables, Pearson's correlation analysis was used. To analyse the pain risk factors, univariate analysis was performed, followed by multivariate analysis based on binary logistic regression. Significance was fixed at 0.05. All analyses, descriptive and inferential, were carried-out with SPSS version 26.

Table 2. Number of pain types.

Type of pain	Frequency	Percentage
0	106	27.5
1	172	44.7
2	70	18.2
≥3	37	9.6
Total	385	100.0

RESULTS

The data of 385 persons from the ten Hospitals participating were analysed by the Coordinator Centre: 106 women and 279 men, ratio 1 : 2.6 and the mean (SD) age of participants was 56 (17) and 53 (16) years, respectively. The SCI median [interquartile range, IQR] occurence was 0.8 [0.2–8.2] years before the subject recruitment on this study. About half of them were in the acute phase: 49.1% within the first year after injury (Table 1). The SCI was traumatic in 65% and non-traumatic in 35% of cases; all the AIS categories were represented with a predominance of AIS A. Moreover, the group of the higher injury severity (C1–C4) resulted in a minority with respect to all the other groups (Table 1).

Pain was experienced in 279 persons, with only one type of pain in 172 and more than one pain in 107 persons (Table 2). The intensity of the worst pain was median [IQR]: 6 [4–8]. There was a prevalence of severe pain Numeric Rating Scale (NRS): 7–10 (43%) vs. the mild one NRS: 1–3 (18%) ($p < 0.001$).

The MAS score median [IQR] of all the population is 0 [0–2]. Between the persons affected by spasticity (MAS 1–5, $n = 186$),

Table 3. Comparison between pain presence and other variables.

	Univariate analysis			Multivariate analysis		
	No pain 106 (28%)	Pain 279 (72%)	*p*-Value	RC	OR (95% CI)	*p*-Value
Age	49 (17)	55 (15)	0.0005	0.024	1.24 (1.0–11.04)	0.002
Gender			0.019	0.605	1.83 (1.05–3.20)	0.033
Female	20	86				
Male	86	193				
Religious practicing			0.428			
Yes	67	164				
No	39	115				
Worker–student			0.066	0.164	0.85 (0.53–1.37)	0.503
Yes	52	108				
No	54	171				
Sport activity			0.636			
Yes	33	80				
No	73	199				
Cohabitants	1.8 (1.2)	1.7 (1.2)	0.358			
Schooling	11.0 (4.0)	11.0 (4.0)	0.590			
Etiology			0.175			
T	75	175				
NT	31	104				
Completeness of the lesion			0.187			
Complete (AIS A)	48	104				
Incomplete (AIS B, C, D)	58	175				
Injury severity			0.927			
C1–C4	15	33				
C5–C8	19	50				
T1–S5	49	130				
AIS D	23	66				
Time since injury			0.990			
<1	54	135				
1–3	12	27				
3–6	7	26				
>6	29	77				
Missing data	4	14				

Note: time and age are expressed in years. Statistics: mean (SD).
95% CI 95% confidence interval, *NT* non-traumatic, *OR* odds ratio, *RC* regression coefficient, *T* traumatic.

137 had pain, 68 neuropathic (49.6%) and 69 nociceptive (50.4%). The NRS pain score was median [IQR]: 5 [0–7]. There was no correlation between spasticity score and the worst pain intensity.

The explanatory factors for experiencing pain were studied by applying both a univariate and a multivariate statistic study of correlation between personal data and lesion characteristics: the presence of pain is higher in older persons ($p < 0.002$), but no difference in pain intensity, pain type and pain location was found between elderly persons (aged ≥ 65 years old) and the younger population. Women have a higher risk of pain feeling ($p < 0.03$) (Table 3), but no difference in pain intensity, pain type and pain location was found between women and men.

The characteristic of the worst pain suffered by 279 persons with SCI was nociceptive in 142 cases (52%) and neuropathic in 133 cases (48%). Most of the variables studied (sex, lesion severity and aetiology, pain intensity, spasticity) are not associated with a predominance of nociceptive or neuropathic pain; only a trend of neuropathic pain preference is observed in the older age ($p = 0.08$) (Table 4).

All worst pain started median [IQR]: 3 [0–49] months after spinal SCI; the neuropathic pain started earlier (1 [0–27] months after SCI) than the nociceptive pain (4 [1–93] months after SCI) ($p < 0.003$). Pain duration was median [IQR]: 4 [1–28] months; no significant difference between neuropathic pain (5 [1–29] months) and nociceptive pain duration (3 [1–20] months) was observed.

The neuropathic pain intensity in persons with complete SCI is similar to that in persons with incomplete lesions and in persons with acute lesions (onset ≤ 1 years) vs. chronic one (onset > 1 years). Nevertheless, neuropathic pain in the persons with complete SCI is more frequent in the chronic phase after lesion than in the acute one, and the opposite happens for the person

Table 4. Comparison between variables associated with pain characteristic.

Personal and lesion data	Total 275[a]	Nociceptive 142 (52%)	Neuropathic 133 (48%)	p-Value
Age: years		53.8 (16)	57 (14)	0.082
Gender				0.678
Female	86	46	40	
Male	189	96	93	
Etiology of the lesion				0.152
T	175	95	80	
NT	100	47	53	
Completeness of the lesion				0.345
Complete (AIS A)	104	58	46	
Incomplete (AIS B, C, D)	171	84	87	
Injury severity				0.210
C1–C4	31	17	14	
C5–C8	50	31	19	
–T1–S5	128	66	62	
AIS D	66	28	38	
Pain intensity (1–10)	Median [IQR] 6 [4–8]	Median [IQR] 6 [4–8]	Median [IQR] 6 [4–8]	0.675
				0.376
Mild (1–3)	49	27	22	
Moderate (4–6)	*105	49	56	
Severe (7–10)	119	66	53	
Spasticity score (MAS)		1.09 (1.3)	1.07 (1.3)	0.883
Pain location{frequency%}				
Head	13 {3.5}	12 {92.3}	1 {7.7}	0.003
Neck/shoulders	74 {20.1}	65 {87.8}	9 {12.2}	<0.0001
Arms/hands	43 {11.7}	20 {46.5}	23 {53.5}	0.464
Frontal torso/genitals	41 {11.2}	20 {48.8}	21 {51.2}	0.692
Back	62 {16.8}	30 {48.4}	32 {51.6}	0.561
Buttocks/hips	33 {9.0}	9 {27.3}	24 {72.7}	0.003
Upper legs/thigh	39 {10.6}	6 {15.4}	33 {84.6}	<0.0001
Lower legs/feet	63 {17.1}	13 {20.6}	50 {79.4}	<0.0001

Statistics: frequency (%) or mean (SD).
NT non-traumatic, T traumatic.
*$p < 0.001$.
[a]The pain characteristic and location were missing in 4 out of 279 persons with pain.

with incomplete SCI where the neuropathic pain is more frequent in the acute phase ($p < 0.001$) (see Table V a and b in Supplementary Information).

The frequency order of the worst pain type experienced by persons with SCI are shown in Fig. 2. They are located in almost all parts of the body, some pain occurring in more than one location. The more frequent locations are neck/shoulders (20.1%), lower legs/feet (17.1%) and back (16.8%) (Table 4). The nociceptive skeletal-muscle pain was in 121 patients and they were located in the sublesional part of the body in 64 cases, above level of lesion in 32 cases, in regions at level in 13 and in 12 cases the pain was highly extended in body region above, at and below level.

There is a significant correlation between pain localizations and pain characteristics (nociceptive or neuropathic). The nociceptive pain has a preferential localization in the head and neck/shoulder, whereas pain in the buttocks/hips, upper leg/thighs and lower legs/feet are more frequently neuropathic. The arms, frontal torso and back localization has no preference of pain type (Table 4 and Fig. 3). The preferential location of nociceptive pain in supralesional region means that they are pain only indirectly secondary to SCI.
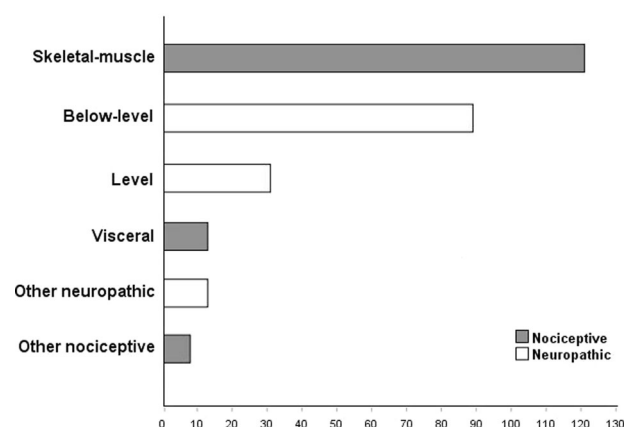

Fig. 2 **Distribution of different type of pain.** The different types of pain are illustrated in a decreasing order of frequency from top to down. The X-axis is the number of persons. Each person with SCI can have one or more pain, but each person is represented by only one pain: the worst one.
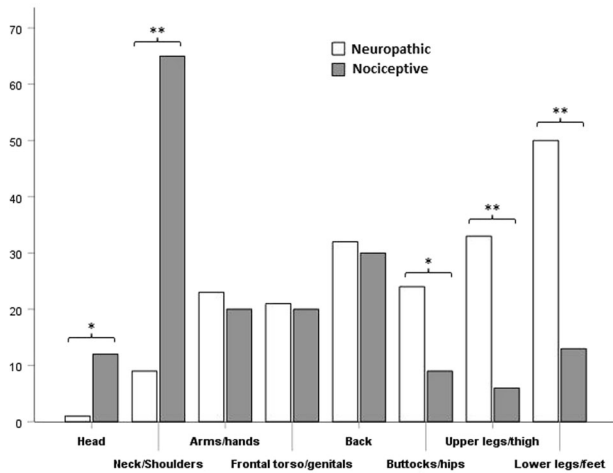
Fig. 3 Localization of pain. The different locations of pain are illustrated from head to feet; the Y-axis is the number of pain: some persons have the worst pain with more than one location. *$p < 0.005$, **$p < 0.001$.

Not all the persons suffering a pain received an analgesic drug therapy: only 164 out of 279 (59%) assumed drugs. The persons affected by a nociceptive pain were 133 and only 79 assumed analgesic drugs (59%). The persons affected by a neuropathic pain were 142 and only 85 of them were on pain medications (60%).

DISCUSSION

The high prevalence of pain (72%) in a subgroup of persons with SCI, those admitted in hospital centres specialized in SCI care, confirms the results of studies published in the last 5 years, in large samples of SCI population by self-administrated questionnaire, with a prevalence of 73%, [4], 69% [10] 84% [6] and 71% [20]. The diffusion of a standard pain evaluation to be applied in persons with SCI, i.e., the ISCIPBDS [18], could be contributing to an easier comparison between studies in different setting. The aforementioned rating scale, translated in Italian language [3] was used as an instrument to record pain in persons with SCI in the present study and 72% of the whole population examined were pain suffering, with 38.3% referring more than one pain, as resulted in previous studies [9, 10, 20]. Statistical analysis was then applied only to the worst pain (felt by the person as the pain of highest intensity).

The high level of pain intensity (NRS median score of 6) and the prevalence of severe pain confirm the results of studies in people with SCI in different parts of the world [4, 5, 10, 21]. The high pain intensity and the presence of many different types and locations of pain make this symptom one of the most important complications of SCI [6].

The present results confirm that nociceptive skeletal-muscle is more often localized in body region above the lesion level: they are mainly the neck, shoulder and head locations. The definition of the pain type (neuropathic or nociceptive) could be difficult when the pain is located below SCI level and a nociceptive pain could be masked by the neuropathic one, but the pain nature results clearer if the observer is an expert physician. In addiction, we have observed many skeletal-muscle pain located in the trunk and some in the buttocks (regions that are often sublesional). The widespread localization throughout the body regardless of the lesion site and the finding that shoulder and neck pain are prevalently nociceptive and lower leg pain neuropathic are in agreement with many studies' results [7, 10, 11, 20]. All these pain

referred by persons with SCI are differently correlated to the spinal cord lesion; in fact, pain located in supralesional regions as the head, neck and shoulder are prevalently nociceptive, because they are secondary consequence of the SCI: in the shoulder, e.g., the pain is due to joint overload repeated over time, each time the person with paraplegia moves from bed to wheelchair and vice versa [22]. On the other hand, pain located in the legs of person with paraplegia is prevalently neuropathic, because it is a direct consequence of the neurologic lesion of the spinal cord.

In the present study, the pain duration results different between subjects; neuropathic pain tends to appear earlier than nociceptive pain. The difference could be explained by the fact that neuropathic pain is a consequence of the neuronal lesion and develops starting from the injury itself, whereas most of the nociceptive pain are due to unnatural use of the musculoskeletal system to compensate for the loss of function. The long time need to develop the shoulder nociceptive pain suggests the possibility to prevent this pain, reducing the amount of burden during the persons movements, utilizing new technological aids and promoting alternative modality of moving such as walking when possible.

In the present study, spasticity was detected in 48% of the population, with a lower incidence with respect to the pain (72%). A higher prevalence of spasticity in persons with SCI (71–83%) resulted in another study [4] but a different study method was applied: their population consisted of outpatients and a questionnaire on the subjects' perceptions of spasticity (NRS 1–10) was administered. In the present study, only inpatients participated and the physician observed and measured objectively the spasticity applying MAS scale [2]. The pain score in the persons affected by spasticity is not different to that of persons without spasticity. In fact, the perceived pain is both neuropathic and nociceptive in a percentage similar to that of persons without spasticity, and no correlation between spasticity score and pain intensity was found. This results confirm that even if 'neuropathic pain and spasticity are multifactorial and complex consequences of maladaptive neuronal plastic' [13] (the first two lines of conclusions session) and some drugs are efficacious on both pain and spasticity, they are different symptoms, not correlated to each other.

The results of this Italian study suggest that older age and female sex are risk factors for developing pain as was found in other European Countries [4, 10, 20]. Sex and age prevalence are independent factors: in fact, the mean age of women results was no different than that of men. The higher prevalence of pain in women compared to men in people with SCI reflects the general population, where a high prevalence of pain is observed in women [23]. A correlation between neuropathic pain and higher age was found both in persons with non-traumatic [14] and traumatic SCI [15]. No other personal or lesion's characteristics result associated with pain development.

Both neuropathic and nociceptive pain can affect persons with SCI, a similar prevalence of the two types of pain results, as in other studies [7, 10, 20, 21]. No difference of pain intensity score was found between neuropathic and nociceptive pain (both median 6). Based on the published studies up to now, it is not clear whether there is an association between lesion completeness and the presence of neuropathic pain: a prevalence in complete vs. incomplete SCI was found by Mahnig et al. [21]; no differences resulted in other studies [14, 15]. In the present study, there is no difference in neuropathic pain score intensity between persons with complete and incomplete SCI but neuropathic pain appears more frequently in the chronic phase in persons with complete than in persons with incomplete SCI (see Table V in Supplementary Information). Moreover, in all these studies, the completeness of the lesion is defined by clinical observations only,

based on AIS evaluation, but we cannot exclude that some complete lesions are actually discomplete [24].

With regard to the time since injury, there are studies demonstrating that neuropathic pain is more severe 1 year after the SCI [5]. In the present study, no significant difference of neuropathic intensity score was found between persons with acute and chronic SCI.

The recorded data on pain treatments demonstrated that the analgesic drugs are poorly used in both nociceptive and neuropathic pain, as only 59% and 60% of persons with SCI referring to specialized hospital service (Spinal Units) suffering pain are treated.

CONCLUSIONS

A high prevalence of pain is confirmed in the population of persons with SCI; both neuropathic and nociceptive pain afflicts these people. Only advanced age and being a woman resulted as risk factors for the onset of pain, as in the general population. The location of pain is widespread on many body regions. The long time it takes for nociceptive pain localized to the shoulder or neck and trunk to develop suggests the possibility of preventing this type of pain by reducing the overload of work in these areas of the body.

DATA AVAILABILITY

The data sets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS
GS was responsible for designing the protocol, writing the protocol and report, researching and interpreting the results. Finally, she wrote the scientific document. AG was responsible for collecting data from Pisa Spinal Cord Unit patients, accepted the single databases posted from each of the Ten Centres participating to the study and elaborated the final database including all the received databases. Moreover, she collaborated in writing the scientific document. RM was responsible for the statistical data analysis and elaborated the tables and the figures. GF, MM, AM, MPO, WC, EA, GC, CM and VC were responsible for collecting data from their inpatients, elaborated their Hospital database and sent it to Pisa Spinal Cord Unit.

ETHICS STATEMENT
The study followed the guidelines of the Declaration of Helsinki. All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. The Local Ethical Committee approved the study (643, 21/07/2015).

COMPETING INTERESTS
The authors declare no competing interests.

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