

People with Spinal Cord Injury in Italy

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EPIDEMIOLOGY OF SPINAL CORD INJURY IN ITALY

According to data from the Gruppo Italiano Studio Epidemiologico Mielolesioni study,¹ the incidence of spinal cord injury (SCI) is estimated to be 2500 cases per year with a prevalence of 60,000 to 70,000 cases for a population of 60 million in Italy. Main causes of traumatic SCI include traffic accidents (54.8%), falls (22%), sports (8%), and work-related (10%) accidents, whereas for nontraumatic SCI, neoplastic tumors (25%), vascular (25%), inflammatory (19%), degenerative (19%), and other diseases (12%) were the main etiologies. Of all SCI cases, 67% were of traumatic origin and 33% were of nontraumatic origin. Sixty percent of patients are paraplegic and 40% tetraplegic. Men are 3 times as often affected as women (4 times as much for traumatic SCI). The median age for SCI is 43 years with a median age of 34 years for traumatic SCI and 58 years for nontraumatic SCI. Fifty-two percent of the traumatic SCI and 24% of the patients with nontraumatic SCI present with a complete lesion.¹ There are no systematic data on mortality in the first year, but it seems that mortality is higher in patients with cervical injury and in ventilated patients.

As there is no national register for SCI in Italy contemporary and reliable information about incidence is lacking, it is difficult to assess epidemiological trends. However, preliminary data from the National Agency for Regional Health Systems study² (2013–2014) indicates that there is a higher mean age of traumatic SCI (48 years), a decrease of SCI from traffic accidents (41%), and an increase in incidence from falls (42%), with a total incidence of 12 to 22 SCI cases per million per annum. A study from the Istituto Studi Direzionali Foundation (2010) showed a relative increase in nontraumatic SCI (45% vs 55% of traumatic SCI).³

THE PATIENTS' JOURNEY THROUGH THE CHAIN OF CARE

In the event of traumatic SCI, rescue is provided by an integrated emergency service, which allows the transportation of

the injured to a trauma center, and in particular, unipolar spinal units (USU) are designated for the complex treatment of patients with SCI. The main characteristic of a USU is its multidisciplinary and integrated intervention model. These units take in account clinical, social, and rehabilitative needs, and the acute care and stabilization phases are tightly linked to the rehabilitation phase, which is carried out immediately afterward in the same unit. Unfortunately, only a few USUs exist in Italy, and most of them are located in the Northern areas. In other cases, upon stabilization of the patient, non-unipolar spinal units or general rehabilitation departments provide inpatient rehabilitation. This phase, both in unipolar and non-unipolar spinal units, include medical assistance, nursing, physiotherapy, occupational therapy, psychological rehabilitation, and in some cases, vocational therapy.

On the other hand, in the event of nontraumatic SCI, a dedicated chain of care is still lacking. In particular, a clinical pathway for neoplastic patients with SCI is not available.

After discharge, outpatient rehabilitation is managed in both the spinal units and community-based services, and a follow-up program for long-term care is generally provided by the spinal units. Unfortunately, the links between spinal units and community services are often lacking, and this is an important problem that needs to be addressed.

LIVING WITH SCI

Spinal cord injury has a significant impact on the social life of patients. According to Franceschini et al.⁴ (2012), more than half of the people with SCI reported to be unemployed (57.9%), 34.7% reported to have a job, 7.2% were students, and 0.2% were working students at the time of the interview. Nevertheless, 43.7% had lost their previous employment, whereas 2.0% had gained a position of employment for the first time in their life. Furthermore, among the employed persons, many workers had changed their job type, job timetable, or other job characteristics. Among them, 62.0% reported a worsening in their income after injury. The main causes of unemployment included the difficulty to find a suitable job (31.9%), the public welfare subsidy (31.0%), or industrial accident insurance (34.1%). The source of the economic livelihood comprised of welfare subsidy and salary in 61.3% and 34.7% of the participants, respectively. Approximately 15% of the participants reported to have an underpaid job.⁴

THE HEALTH AND REHABILITATION SYSTEM

The Italian National Health System (NHS) is organized as a public insurance system that provides universal health care coverage. The NHS was created in response to Article 32 of

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the Italian Constitution that asserts that the State is responsible for safeguarding the health of its citizens as an individual asset and a community interest. In addition, Article 32 requires that the State guarantees free care to the citizens in need. Reformation Act no. 833 (December 23, 1978) defined the aim of the functions, facilities, services, and activities of the NHS, namely, to promote, preserve, and recover the physical and mental health of population. The intent was to place the individual at the center of the NHS, who has the right to health.

National legislation from 1992 to 1993 and later amendments (1997 and 2000) radically transformed the NHS. Now the political, administrative, and financial responsibility for the health care was delegated to the 20 Italian regions. The result is a variety of health care systems, with predominantly private systems in Northern Italy and mainly public systems in the central and southern areas. This situation makes it difficult to describe the Italian NHS as a unique national system. The Italian State retains a limited general supervisory function, and its sole responsibility remains to ensure uniform and essential levels of health services and assistance across the whole country.

The first organization of physical and rehabilitative medicine (PRM) services took place in 1998, with the publication of the *Italian Guidelines for Physical and Rehabilitation Medicine Services*.⁵ This document established a PRM strategy and a general plan for the treatment of disease, functional and diagnostic assessment, and the development of an individualized PRM project performance evaluation for intervention programs. In this plan, treatments are organized in the following settings: acute inpatient PRM, postacute inpatient PRM (including day hospitals), long-term care and nursing homes, outpatient care, and home care. Reimbursement is based on the setting and the intensity of care, and the daily fee is independent of the severity of the disability. In the context of this very fragmented picture, in 2010, the health minister developed the Italian National Physical and Rehabilitative Medicine Plan to promote homogeneous development of physical and rehabilitative medicine in Italy.

In this plan, the definition of PRM needs is based on clinical complexity, disability, and multimorbidity. Disabled inpatients in the acute phase must be provided with an integrated plan for their individual rehabilitative project (IRP), which contains the various therapeutic settings of the PRM network. The decision-making process is led by a physiatrist who drafts the IRP, taking into account the functional prognosis, the potential modification of the disability, the patient's degree of clinical stability, and his or her participation in the program. Areas of specific intervention; objectives; professionals involved; settings, methodologies, and methods of PRM; timing for realization; and verification of the intervention are also included in the IRP. The IRP also defines the role of the spinal units.

WHAT IS THE STATE OF SPECIALIZED CARE?

The previously published guidelines (1998) reported the definition of the USU, a multidisciplinary professional organization specialized for the therapeutic, rehabilitative, and psychosocial needs of people with SCI. The clinical pathway starts from the earliest stages of the SCI through prevention of immediate complications, toward the full

recovery of residual functions and the highest possible level of autonomy in the later stages.⁶ The activities that take place within the USU affect all aspects of disability resulting from the SCI: respiratory, neuromotor, bladder-sphincter, psychological, and sexual functions. In addition, in collaboration with the USU, rehabilitation of patients with SCI is also performed in emergency departments to assist clinically stabilized patients with bone marrow lesions of the traumatic and nontraumatic type (infective, vascular, and neoplastic) and without serious respiratory problems.^{6,7}

A critical point is the lack of ad hoc formation in postgraduate medical training. In fact, as recently pointed out in a document developed by the International Spinal Cord Society,⁸ there are several skills and competencies that a trainee would need to develop to work as a medical practitioner in a spinal cord unit, and Italian physical medicine and rehabilitation residency program should be upgraded by focusing on these specific items.

THE SOCIAL RESPONSE TO SCI

Social services provide the possible pathways for return to work for persons with SCI. Specific legislation (Legislative Decree No. 68/99) sets out a specific percentage of the overall work force of a company that must be dedicated to the employment of disabled people. Unfortunately, vocational rehabilitation and specific job training are not part of the Italian rehabilitation facilities except within the network of work injury insurance (National Institute of Insurance Against Work Accidents).

In everyday life, people with disabilities in Italy face several problems. Public buildings and areas are generally not easily accessible to people in wheelchairs, and there is only a limited accessibility to public transportation available. There is also a low awareness of the needs of people with SCI, despite public health campaigns directed specifically to SCI prevention. At the same time, however, several patient organizations for people with SCI exist in Italy, and they play an important role in helping to achieve integration and full participation for all persons with disabilities.

THE INTERNATIONAL SPINAL CORD INJURY (InSCI) COMMUNITY SURVEY

What Do We Hope to Gain from Participating in the InSCI Study?

We are using the opportunity of the InSCI study to improve not only the epidemiological information about SCI in Italy but also, and more importantly, to get a sense of the needs and requirements of this group. In fact, even if several scientific societies such as SIMS (Italian Society for Spinal Cord), CNOPUS (Italian Organization of Spinal Unit Professionals) and SIPLeS (Italian Society of SCI Psychology) are actively involved in improving the standards of care and research in Italy, there has been very little amount of literature produced on the health and functioning of persons with SCI in Italy, and this study will help to fill gaps in this research.

We will focus on patients with SCI living in the community; both traumatic and nontraumatic (caused by vascular conditions, infections, benign tumors) cases, among Italian-speaking resident

adults (older than 18 years) who have completed their first rehabilitation. We will exclude nontraumatic, progressive SCI (caused congenitally or from inflammatory and autoimmune disease, malignant tumors, toxic agents, radiations, other neurological progressive conditions) and people with cognitive impairments. Our sampling frame will be drawn from patients' associations, sport associations, the Workers' Injuries Insurance Institute database, and clinical databases from Spinal Unit network. Partners will be contacted to obtain the patient's contact information. Disabled peoples' organizations are often linked to outpatient clinics, including spinal units, so their database will be used (although there may be some bias, since these patients tend to be more active and motivated). There is also a risk of missing data about nontraumatic patients who are often referred to departments other than rehabilitation. First contact will be made by letter or e-mail. Before this, to sensitize the SCI population, posters and flyers will be posted in participating hospitals and announcements made on patients' organization Web sites and newsletters. Before the start of the survey, information on sex, age, level of lesion, and educational level will probably be available for most of the patients.

First contact will be made by an invitation letter or by e-mail invitation letter (with written informed consent). A telephone reminder will be planned 1 month and 2 months after the letter or e-mail in case of nonresponse. We chose a mixed-mode data collection using paper-pencil and online questionnaire. An electronic informed consent form will be provided in the online version of the questionnaire. The paper-pencil questionnaire will be sent after receiving the signed informed consent form. In case of nonresponse after 1 month from the date of sending the paper pencil questionnaire, a telephone reminder will be made. Ethical approval will be carried following standard procedures.

The local database will include patients' personal data (name, age, sex, contacts, and local and international IDs) and basic clinical data (time of lesion and SCI level). The questionnaire data will be stored in a central database at Swiss Paraplegic Research, Nottwil, Switzerland. Data backup will be provided automatically for both databases. Paper-pencil questionnaire will be locally stored in locked rooms. Confidentiality of data will be guaranteed by the use of local and international IDs. Standard procedures will be required for ID assignments, data

entry, and data check and data protection, using local and international passwords.

Once an Italian version of the questionnaire is available, the survey will be conducted in a preparatory and operational phase. The preparatory phase will include fund raising, reaching agreement with envisioned partners, preparing documentation for ethics application, hiring study coordinator and investigators, preparing databases, and checking and preparing availability of information technology infrastructure and other resources. The operational phase includes ID management, mail order and reminder management, daily response management and documentation, systematical filing of paper questionnaires and consent forms, data entry in database, and data quality control.

CONCLUSION

The societal response to the health and social needs of people with SCI is still inadequate in Italy. The most relevant challenges to face include improving health services, in particular, the uneven distribution of spinal units in Italy, and responding to the social impact of the disability associated with SCI. Italy needs better implementation of accessibility to public services and a better integration with job placement services to improve employment after SCI. Nonetheless, some encouraging signals are present, in particular, the key role played by patients' associations that can highlight patient needs and raise awareness across the country.

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