Spinal Cord (2007) 45, 404–410

www.nature.com/sc

Original Article

A multicentre follow-up of clinical aspects of traumatic spinal cord injury

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Study design: Prospective, multicentred follow-up (FU) observational study.
Objectives: Prospectively evaluate survival, complications, re-admissions and maintenance of clinical outcome in people experiencing traumatic spinal cord injury (SCI).
Setting: Seven spinal units and 17 rehabilitation centres participating in the previous GISEM (ie Italian Group for the Epidemiological Study of Spinal Cord Injuries) study.
Method: A total of 511 persons with SCI, discharged between 1997 and 1999 after their first hospitalisation, were enrolled. A standardised questionnaire was administered via telephone.
Results: Of the 608 persons originally enrolled, 36 died between discharge and follow-up (mean 3.8 ± 0.64 years). Of the remainder, 403 completed telephone interviews, 72 refused to participate and 97 could not be contacted. More than half of the patients interviewed (53.6%) experienced at least one SCI-related clinical problem in the 6 months preceding interview; the most frequent being urological complications (53.7%). At least one re-admission was recorded in 56.8% of patients between discharge and FU interview. Of the patients interviewed, 70.5% reported bowel autonomy and 86% bladder management autonomy. On multivariate analysis, lack of bowel/bladder autonomy was the most common variable with a strong predicting value for mortality, occurrence of complications and re-admissions.
Conclusion: Re-admission and major complications seem common after SCI and should be considered when planning facilities. Failure to obtain bowel/bladder autonomy upon discharge from rehabilitation proved to be the most common predictive factor of poor outcome during the period between discharge and FU interview.
Spinal Cord (2007) **45,** 404–410; doi:10.1038/sj.sc.3101991; published online 14 November 2006

Keywords: follow-up; traumatic spinal cord injury; survival; complications; re-admission; clinical outcome

Introduction

Spinal cord injury (SCI) causes serious disability in young people at the height of their social and working life. Besides the strong social impact, those with SCI can experience a range of conditions that require lifelong medical care,[1] and often affect the quality of life of these people, considering how complications and frequent re-admissions may hamper their work and personal relationships. Early identification of patients at risk of complications has the potential to allow for suitable prevention thus minimising the call for re-admission.[2] As the life expectancy of people with SCI has sharply increased in recent decades,[3] now more than ever it is important to provide facilities for the prevention and care of SCI-related complications in persons aging with SCI. Health outcomes and quality of life may be dependent on the health-care system and the community facilities available for SCI persons, which vary from country to country[4] and sometimes even within the same country. In Italy, the GISEM (Italian Group for the Epidemiological Study of Spinal Cord Injuries) survey was performed to determine the standing of health care and rehabilitation made available to acute SCI patients.[5] The data obtained pointed to a number of critical points, such as lack of standardised treatment owing to an uneven distribution of SCI centres in the country, and lack of an early comprehensive approach to rehabilitation. As a result, patients can have a long wait before being admitted to SCI centres and frequently present with complications, such as pressure sores, that call for a prolonged length of stay (LoS) and represent a poor prognostic factor for being discharged home. These problems have the potential not only to influence rehabilitation outcome, but also subsequent health-

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related outcome and opportunities of interpersonal relationships and social participation, which in turn can jeopardise the quality of life of those with SCI.[6,7]

The aim of this study was to prospectively evaluate survival, complications, re-admissions and the maintenance of the clinical outcome in individuals with SCI who had been enrolled in the GISEM study during their acute and rehabilitative hospitalisation, and to identify possibly related variables.

Methods

Participants

Twenty-four SCI centres, seven spinal units (SU) and 17 rehabilitation centres (RC), participated in the present GISEM follow-up study. SU, being located in large hospitals, have facilities for treating patients immediately after the SCI and supplying comprehensive rehabilitation, whereas RC have only rehabilitation facilities.[5]

Five hundred and eleven out of 608 first-admission traumatic SCI patients discharged to home from 24 centres participating in the previous epidemiological prospective survey,[5] were located. Four hundred and three subjects (79%) completed the interview, 72 (14%) abstained from giving their consent, whereas the remaining 36 (7%) had died. We assume that most of the 97 patients lost to FU had re-located sometime during the observation period, as they were not contactable at their recorded address, although some may have died. The 36 deceased patients were recorded but the date and cause of death were not, owing to difficulties in obtaining reliable data.

At the time of follow-up, participants' mean time since discharge was 3.8 years (median 3.8 years, range 2.7–5.2 years). The 403 subjects who completed the interview were all living at home. The male/female ratio was 4:1, the mean age was 41.9 years, the majority of persons were single (57.5%) and 63.9% were employed when SCI occurred. The injury was predominantly at a thoraco-lumbar level (63.2%) and complete (Asia Impairment Scale A) in 50.1%. Forty-six per cent of subjects had been discharged from the seven SU. To determine the extent to which the patients included in the present study were representative of the initial population, the follow-up group was compared to those lost to follow-up by means of the following variables: age, gender, marital status, employment at the moment of SCI, neurological category – paraplegia/tetraplegia, completeness of injury, bladder and bowel autonomy. A high level of homogeneity between the groups was obtained, with no significant difference for each variable considered.

Procedure

A prospective, multicentred follow-up observational study was performed with centralised data collection and analysis. A 24-item standardised telephone questionnaire was used to collect data, and reliability validated on a sample of SCI people in a pilot study.[8] The questionnaire explored the following fields: health status and management of clinical conditions, social integration, occupation, autonomy, mobility, sentimental relationship and quality of life. The questionnaire was administered during a single phone call by the same psychologist, and all patients were interviewed during the first 6 months of 2002.

The patients' data were centrally collected and compared with those previously recorded in the GISEM study for statistical analysis. The data were verified for internal consistency and reply to at least 95% of items in the questionnaire was assured.

Health status and management of clinical conditions were appraised through questions in the first part of the questionnaire which determined whether a planned clinical check-up (CU) was conducted, and if so, where and by whom; whether clinical problems (defined as 'complications' afterwards) occurred in the 6 months before the interview, whether re-admission occurred in the period between discharge and follow-up interview, and if so, how often (once, twice, more than twice) and why. The total number of re-admissions of all patients in the whole period between discharge and follow-up interview was summed up. Given the underestimation owing to 'more than twice' re-admissions calculated as $=3$, the crude average annual rate of re-hospitalisation was estimated dividing the total number of re-admissions by the mean observation period multiplied by the number of subjects interviewed.

The questionnaire also evaluated whether the outcome stated on discharge, namely bladder management, bladder and bowel autonomy (patient's ability to perform bladder/bowel management without assistance), bowel continence (absence of 'unplanned bowel evacuations'), residing at home and feeling of dependence (FoD) evaluated on an eleven-point scale (0 corresponding to complete independence, 10 to complete dependence) was maintained. Whereas the complications and the causes of re-admission were recorded by the interviewer, classification into the predetermined categories was made by physicians involved in the study. The cause of re-admission was recorded as an 'assessment' when the main intervention was not immediately defined on admission, thus requiring a clinical evaluation, and as 'rehabilitation' when the main intervention concerned maintenance or improvement of functional goals. The other causes included were urological problems (urethral stenosis, bladder calculi, bladder diverticulum, uretero-idronephrosis, urinary tract infections, renal failure); osteoarticular problems (fractures, contractures, heterotopic ossification, arthritis); pressure sores; pain; spasticity; removal of spinal instrumentation; and other, such as respiratory disorders, bowel disorders, autonomic dysreflexia, etc. Bowel and bladder autonomy upon discharge was evaluated by the physician, whereas it was self-evaluated in the follow-up.

Mortality, complications and re-admissions were considered dependent variables and were correlated with the following independent variables: age, gender,

marital status, occupation, discharging centre (SU/RC), LoS, time between event and admission (TEA), neurological category (para/tetraplegia), completeness of lesion, bladder and bowel autonomy, and pressure sores. When re-admission was analysed as a dependent variable, complications were considered as independent. The mean FoD value was calculated. FoD was analysed as a dichotomic dependent variable (higher *versus* lower/same value between discharge and follow-up interview) and was correlated with the same dependent variables as above, as well as other variables in the questionnaire concerning occupation, autonomy in leaving the house, driving, ability to stay home alone for at least 3 days, and usual practice of sports and hobbies.

Statistical analysis

A descriptive analysis was conducted to define the characteristics of the FU population. Whenever multiple answers were possible, the sum of the percentages of each answers was higher than 100.

Descriptive analysis was performed with standard procedures for the calculation of frequencies, position indicators and dispersion indicators (variances, standard deviations, confidence intervals (CI)).

Bivariate tests have been applied as a first screening procedure using χ^2 with the calculation of the odds ratio (OR) for dichotomic variables to test the significance of categorical covariates and parametric (Student's *t*-test, Fisher's F analysis of variance, ANOVA and correlation indexes) and non-parametric tests (Kruskal–Wallis, median test and *U*-test of Mann–Whitney) to test the significance of continuous covariates. A multivariate analysis, aimed to allow inter-correlation of variables excluding confounding effects, was performed using logistic regression models. Inclusion of explicative variables in the models followed stepwise (forward and backward) procedures. All variables significant at the alpha level of 0.1 were entered into the analysis. Individual variables included were reported with the OR where appropriate. Significance of each coefficient in the model was examined and non significant variables ($P<0.05$) were eliminated from the model one at a time, beginning with the variables having the highest probability levels**.** The integrity of the model was checked each time a variable is eliminated, via the Hosmer–Lemeshow Statistic. Evaluation of the goodness of fit was performed with the receiver operating characteristic (ROC) method. The ROC characteristic is a measure for the goodness of fit of a logistic regression model similar to the R^2 statistic in OLS regression. Statistical analysis was carried out using 'SPSS 13.0 for Windows' statistical software.

Results

Descriptive analysis

More than half of the FU subjects (216, 53.6%) had SCI-related clinical complications in the preceding 6 months, the most common being urological (53.7%), pain, spasticity and pressure sores (Figure 1).

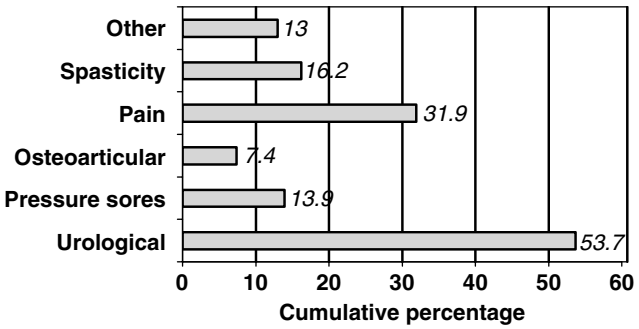

Figure 1 Complications in the 6 months before interview (as multiple answers were possible, the sum of percentages of each complication recorded is >100)

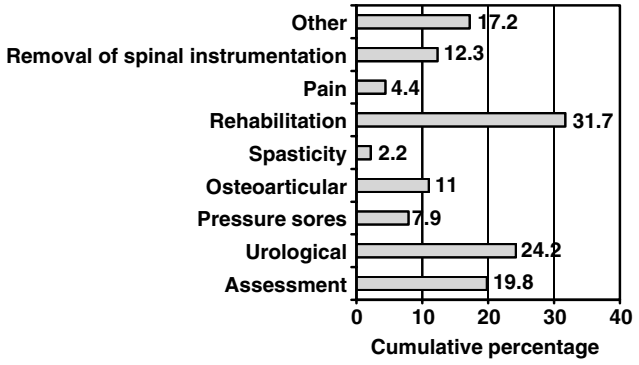

Figure 2 Causes of re-admission (as multiple answers were possible, the sum of percentages of each cause recorded is >100)

When a clinical complication occurred, patients reportedly consulted their GP (75, 34.7%), an SCI specialist from the centre they had been discharged from (67, 31.0%) or from a different centre (26, 12.0%), a specialist in the specific field (68, 31.5%), or no medical aid was requested (15, 6.5%).

One or more re-admissions were recorded in 229 patients (56.8%) during the period between discharge and FU interview: 51.6% of patients were re-admitted once, 19.6% twice and 28.8% more than twice. Thus, an average of at least 108 re-admissions/year for the whole population can be estimated, indicating a crude rate of 0.26 re-admission/patient/year. The main reasons reported for re-admission were: rehabilitation 31.7%, urological complications 24.2%, assessment 19.8%, removal of spinal instrumentation 12.3%, pressure sore 7.9%, osteoarticular complications 11% (Figure 2).

A total of 70.5% of respondents had bowel autonomy. Full 'continence' was recorded in 311 (77.2%), partial in 81 (20.1%) and no continence in 11 (2.7%) cases. Eighty-five per cent of subjects required no assistance in bladder management. In 30.8% of cases micturition was spontaneous, and in 40.4% self-catheterisation was performed (Figure 3).

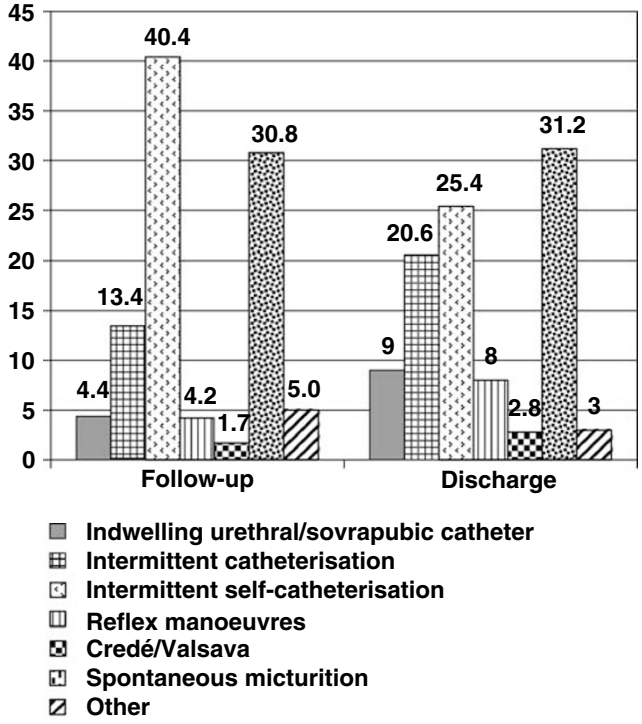

Figure 3 Bladder management recorded at follow-up (left) and at discharge (right). Percentage values

On comparing the outcome recorded on discharge and on FU interview, there was an increase in the number of subjects with bowel function autonomy (63.7 *versus* 70.5%; $P<0.001$). Non-autonomous subjects became autonomous in 44.0% of cases, whereas loss of bowel autonomy occurred in 15.4%. Bladder autonomy was recorded in 70.5% of subjects on discharge *versus* 85.4% on FU interview ($P<0.001$), with an increased intermittent self-catheterisation at FU interview. Non-autonomous people became autonomous in 61.0% of cases, whereas loss of autonomy occurred in only 4.3%.

The 327 subjects who answered, both on discharge and FU interview, the question regarding the FoD showed a statistically significant increase, considering the mean value (4.13 *versus* 5.23, $P<0.0005$). On FU interview, FoD had the same or a lower value in 149 subjects (58 and 91, respectively) and higher in 178 subjects.

Bivariate analysis

Bivariate analysis revealed significant correlation between complications and older age (mean 44.8 ± 16.2 *versus* 38.6 ± 15.5 years, $P<0.001$), longer LoS in rehabilitation (155.5 ± 91 *versus* 128.2 ± 87.8 days, $P<0.005$), longer TEA (36.3 ± 39.3 *versus* 28.9 ± 31 days, $P<0.05$), lack of bladder/bowel autonomy on discharge ($P<0.001$) and completeness of lesion ($P<0.001$). No statistical significant difference was found for gender, marital status, neurological category and type of centre they were discharged from (SU or RC).

The occurrence of re-admission was greater for male subjects ($P<0.05$), patients with longer LoS in rehabilitation (155.9 ± 97.2 *versus* 125.5 ± 77.7 days, $P<0.001$), without bladder/bowel autonomy ($P<0.001$) and with a complete lesion ($P<0.01$). People experiencing complications in the previous 6 months had a higher probability of being re-admitted between discharge and FU interview ($P<0.0001$), although no correlation was found between re-admission and age, TEA, marital status, neurological category para/tetraplegia and type of centre they were discharged from (SU or RC).

Mortality showed significant correlation with older age (59 ± 21 *versus* 42 ± 16 years, $P<0.001$), female gender ($P<0.05$), being retired at the time of the event ($P<0.001$), tetraplegia ($P<0.001$), lack of bladder/bowel autonomy ($P<0.001$), shorter LoS in rehabilitation ($P<0.05$) and pressure sores ($P<0.001$) on discharge. No significant association was found with marital status, completeness of injury and type of centre they were discharged from.

A higher FoD value on FU interview occurred to a larger extent among those subjects who were no longer autonomous in leaving their house (OR 1.95, CI 1.13–3.37), driving the car (OR 1.81, CI 1.06–3.1), staying home alone for at least 3 days (OR 1.9, CI 1.17–3.1) and in those who did not practice sport (OR 1.77, CI 0.99–3.2) or hobbies (OR 1.63, CI 1.02–2.59). No significant correlation was found with the other variables analysed, namely age, gender, marital status, occupation, discharging centre, neurological category, completeness of the lesion, bladder/bowel autonomy, occurrence of complications and re-admissions during the FU period.

Multivariate analysis

In the multivariate analysis (Table 1), the variables which independently correlated with occurrence of complications were: lack of bladder/bowel autonomy, completeness of the lesion and to a lesser extent older age and longer LoS in rehabilitation. Re-admissions were independently associated with lack of bladder/bowel autonomy, male gender and longer LoS. Strong prognostic variables for death were lack of bladder/bowel autonomy, pressure sores on discharge and female gender, whereas older age and shorter LoS in rehabilitation were more weakly associated to mortality in the same model.

Discussion

SCI has a strong social impact and entails lifelong care to prevent or treat specific SCI complications, which often call for hospitalisation. These health-related problems can hinder a regular working-life, personal relationships and leisure time activities and worsen quality of life. Indeed these problems may even be life-threatening.[6,7]

As has been previously demonstrated by Ivie and De Vivo,[2] who recorded 21% of lost to FU after the first

Table 1 Multivariate analysis

	Beta	*OR (95% CI)*	P-*value*
Complications			
Age	0.033	1.034 (1.019–1.049)	<0.0001
LoS	0.003	1.003 (1.000–1.005)	0.029
No B/b autonomy	0.790	2.202 (1.357–3.574)	0.001
Asia A	0.812	2.251 (1.431–3.542)	<0.0001
Intercept	−2.272	0.103	<0.0001
Area under ROC curve = 0.714, 95% CI = 0.663–0.764			
Hosmer–Lemeshow goodness-of-fit test χ^2 (*df* 8) = 4.638, $P = 0.795$			
Re-admissions			
No B/b autonomy	0.740	2.097 (1.306–3.366)	0.002
LoS	0.003	1.003 (1.001–1.006)	0.007
Male gender	0.635	1.886 (1.090–3.263)	0.023
Intercept	−0.926	0.396	0.004
Area under ROC curve = 0.645, 95% CI = 0.591–0.700			
Hosmer–Lemeshow goodness-of-fit test χ^2 (*df* 8) = 2.681, $P = 0.953$			
Death			
Age	0.042	1.043 (1.021–1.065)	<0.0001
LoS	−0.006	0.994 (0.989–0.999)	0.026
Female gender	0.993	2.699 (1.134–6.426)	0.025
No B/b autonomy	1.697	5.457 (2.350–12.670)	<0.0001
Pressure sores	1.233	3.431 (1.215–9.684)	0.020
Intercept	−5.169	0.006	
Area under ROC curve = 0.820, 95% CI = 0.740–0.900			
Hosmer–Lemeshow goodness-of-fit test χ^2 (*df* 8) = 10.320, $P = 0.243$			

Abbreviations: OR, odds ratio; CI, confidence interval; LoS, length of stay; B/b, bowel/bladder; ROC, receiver operating characteristic
Variables independently related to occurrence of complications, re-admissions and death in the period between discharge and follow-up interview

year up to as much as roughly 48% by the fifth year, it is somewhat difficult to obtain comprehensive and reliable follow-up data on people with SCI. In the current study, we retrieved data so as to quantify survival for 511 out of 608 subjects (84.0%) and managed to obtain complete information on 439 interviewed or deceased persons (72.2% of the entire population), and found homogeneity between the follow-up group and those lost to FU. As such, the current findings indicate that the population interviewed is a representative cross-section of the initial population and their health-related problems.

Thirty-six subjects (7%) died during the period between discharge and FU interview; however, this may be an underestimation, as the persons who were not retrieved are excluded. Unfortunately, the phone interviews failed to provide us with reliable information as to the date and cause of death, thus a comparison between our cumulative mortality data and those in literature could not be made.[9–11] Nevertheless, a statistical analysis was performed to define the variables which independently predicted death during the time between discharge and FU interview. As described in literature,[12,13] age, neurological category and completeness of the lesion are prognostic factors for death. In our observational study, apart from the mild effect of older age and a shorter LoS, the only variables with consistent prognostic significance for death during the 4-year period proved to be lack of bladder/bowel autonomy, presence of pressure sores on discharge and female gender.

More than 50% of the people interviewed were re-admitted at least once in the mean period of 3.8 years between discharge and FU interview, for the treatment of complications or further rehabilitation. The choice of interviewing prevented us from registering the exact date of admissions; therefore, the annual rate of re-admission could not be estimated nor compared with that reported in literature.[14–16] The major cause of re-admission was the need for further rehabilitation, unlike reports elsewhere which indicate specific complications as being the most common cause.[14,17,18] Re-admission of patients for further rehabilitation may suggest an effort to improve function at the highest achievable level. Nevertheless, the high costs of hospitalisation in SCI centres[11,12,16,19,20] and the shortage of hospital beds for comprehensive management of acute SCI, and its subsequent complications, point not only to the need to plan hospital services for re-admission after SCI, but also to set up specific outpatient rehabilitation facilities throughout the territorial network, thereby possibly preventing unnecessary stay in the hospital.

Besides unchangeable factors such as age, gender and completeness of lesion, the lack of bladder/bowel

autonomy on discharge was found to be the most common predictive factor of poor outcome as judged by mortality, occurrence of complications and re-admissions during the period between discharge and FU interview. It is a more significant predicting factor than both the initial management of SCI (centre type – RC/SU and TEA) and personal factors (occupation, marital status, etc.), and even more predictive than the neurological descriptors of the lesion, that is, category (para/tetraplegia) and completeness, whose role in predicting re-hospitalisation has indeed been debated.[2,16] As such, bladder/bowel autonomy is to be considered a good target for rehabilitative intervention.

The maintenance of bladder/bowel autonomy in the period between discharge and the FU interview gave encouraging results, showing an improvement, and an increasing trend in the use of self-catheterisation, which occurred to an even larger extent than that reported elsewhere.[21] The use of indwelling urethral catheters was also recorded in a considerably low percentage of patients in comparison to the data reported in literature.[22,23] The results of the present study show that bladder/bowel autonomy was so strongly associated with outcome that it would appear crucial to address every possible effort towards the provision of outpatient facilities to attain or maintain bladder/bowel autonomy, especially in older or incomplete-lesion patients whose discharge from hospital cannot always to be considered the final step in the course of rehabilitation. Although it could be speculated that improvement in bladder/bowel autonomy may be merely dependent on neurological improvement when there is an incomplete lesion, we should not overlook the need for a continued intervention after discharge to ensure autonomy.

The only other modifiable factor showing any correlation with the occurrence of complications and re-admission was a longer LoS in rehabilitation. How LoS in previous rehabilitation affects the occurrence of complications and re-admissions after discharge is an interesting point to be pondered, as although undertaking practices that result in an earlier discharge might help prevent complications and re-admissions, simply discharging patients earlier has the potential to have the opposite effect,[24] as indicated by the weak association between shorter LoS and mortality found in the multivariate analysis. These interesting yet controversial findings are to be further studied, as it may be postulated that factors, which were not considered in the present study, such as a complicated course during the first admission, multiple trauma or other factors that are not dependent on the severity of the lesion, may play a role in explaining this association.

FoD worsened during FU compared to discharge. A correlation with variables concerning social life, mobility and autonomy was found, whereas no significant correlation with the characteristics of the lesion, the management of bladder/bowel dysfunction or the occurrence of complications and re-admission in hospital was observed, suggesting that the patients weigh up their gain in ability during hospitalisation with their dependence when re-experiencing life at home, most likely comparing their current skills with their pre-trauma skills and those of others around them.

The persons contacted (whether interviewed or not) were all living at home. Although we do not have information on those subjects who re-located, we speculated that they may account for all those who did not maintain the outcome of living at home. Even so, almost 80% of subjects were living at home about 4 years after discharge, which is consistent with the results in our earlier study.[25]

The current findings support the importance of providing for the clinical needs after discharge of SCI persons, especially re-admissions and management of complications, in qualified centres. Failure to obtain bowel and bladder autonomy on discharge proved to be the most common predictive factor of poor clinical outcome. Therefore, thorough training during the stay in hospital and after discharge represents a principal goal in the rehabilitation of SCI.

Acknowledgements

We thank the 'Istituto Superiore di Sanità' and the 'Fondazione M Taramelli per la Ricerca sulla Mielolesione' for supporting the study and the grants for the psychologist's interviews. We also thank Michele Kildea for the English revision.

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