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Cross-sectional and prospective data-collection in North Macedonia—methodological considerations

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Abstract

Study design Cross-sectional and prospective cohort-study.

Objectives To describe methodological issues, experienced challenges related to data collection in North Macedonia and to discuss possible improvements of epidemiological data collection in future studies.

Setting Clinic for Traumatology, Orthopedics, Anesthesia, Reanimation, Intensive Care Unit and Emergency Center, Mother Teresa Skopje University Hospital, Skopje and community settings, North Macedonia.

Method A description of methodological challenges experienced in collecting data from 78 persons with acute and chronic traumatic spinal cord injury (SCI) examined and interviewed in 2015–2017 using a semiquantitative questionnaire and standard assessments tools.

Results This study identified three major challenges with data collection in this setting: (1) research logistics and procedures, such as recruitment, infrastructure, and compensation, (2) ethical issues and the initial lack of mutual trust and understanding between researchers and participants, and (3) scientific quality and interpretation, including representativeness.

Conclusions Methodological issues influenced by settings, are important to consider when interpreting study results. Healthcare systems vary between (and sometimes in) countries, language and culture may introduce barriers to understanding, and epidemiological research also rely on infrastructure and surroundings. For this study, making time for and listening to the participants without being intruding was of special importance in building trust and a good relationship with the participants during recruiting participants and collecting data. We here provide suggestions regarding how to facilitate future epidemiological data collections in North Macedonia.

Introduction

Over the past 50–60 years, the situation for persons with traumatic spinal cord injury (SCI) in Western Europe and the United States (US) has changed considerably. Acute and long-term survival has increased significantly and medical care has steadily improved both in the acute and the longer term setting. Modern SCI rehabilitation began in the United Kingdom (UK) and the United States (US) in the 1940s, where specialized centers were established for this purpose.

After World War I, the survival rate was nearly nil within the first years after a SCI, whereas today, the gap in mean life expectancy between the general and SCI population has decreased and the causes of death are becoming more similar [1]. North Macedonia (previously The Former Yugoslav Republic Of Macedonia) is generally poorly adapted for disabled people, i.e., major barriers for people with wheelchairs or mobility disabilities in general. A recent study compared incidence and survival in persons with SCI in Thessaloniki and Stockholm [2]. The annual case mortality rate after acute traumatic SCI was nearly 20% in Thessaloniki and nil in Stockholm. This dramatic difference was postulated to different approaches to care, one systematic and the other not.

There are ~2 million inhabitants in North Macedonia. Mother Teresa, the University Hospital in Skopje is the only public hospital that treats persons with SCI in North Macedonia. Thus, this hospital has the largest data collection and longest experience with this patient group in the

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country. There is no centralized or systematic rehabilitation of patients with SCI in North Macedonia, and as far as we know, no epidemiological studies of persons with acute and long-term SCI have been conducted in this country.

Epidemiological data are of importance [3] but often depend on household, social factors, healthcare system, economic barriers, and personal values. It is important to understand that such factors can influence the data, therefore many studies employ mixed methods research with standardized questionnaires and semistructured interviews, many of which take place in participants' homes and communities, in order to better capture complex epidemiological data. Consequently, we wanted to study persons with SCI in North Macedonia, including survival, causes of death, and the health status among both acute- and long-term survivors, using a mixed models approach with clinical examinations, semistructured questionnaires, as well as standardized questionnaires in both home and hospital settings. In this paper, we will describe and discuss methodological issues, experienced challenges related to data collection in North Macedonia, as well as to discuss possible improvements of epidemiological data collection in future studies.

Materials and method

Inclusion, setting and participants

We included patients with traumatic SCI admitted for initial treatment and rehabilitation at Skopje University Hospital between (a) 1999 and 2004 and (b) 2015 and 2016. The data collection took place between 2015 and 2017. We used medical records from the University Clinic for Traumatology, Orthopedics, Anesthesia, Reanimation, and Intensive Care Unit and Emergency Center (TOARILUC), Mother Teresa Skopje University Hospital, Skopje, North Macedonia, to identify eligible patients with a long term SCI. Eligible patients for study part (a) were invited to the clinic at the hospital or to have a home visit. This visit included an interview on their health status, a clinical examination, and answering of semistructured and standardized questionnaires (Table 1). In study part (b), patients with an acute traumatic SCI were asked to participate as soon as possible after the injury. Participants with acute SCI were interviewed and clinically examined within the first 24 h after injury, on daily basis until discharge, and after 12 months. For the 12 months follow-up, participants were invited to the clinic or to have a home visit for a new interview and clinical examination (Table 2).

The study parts (a) and (b) were similar in their use of mixed methods. Both studies included the possibility of home visits, qualitative and quantitative data from

Table 1 Study (a) Questionnaires and clinical examination

International SCI Activity and Participation Basic Data Set Version 1.0 English [7]
International SCI Skin and Thermoregulation Function Basic Data Set Version 1.0 English [8]
International SCI Bowel Function Basic Data Set Version 1.1 English [9]
International SCI Pain Basic Data Set Version 2.0 English [10]
International SCI Lower Urinary Tract Basic Data Set Version 1.0 English [11]
A self-made questionnaire [6]
International SCI Core Data Set Version 1.1 English [12]
Quality of life basic data set (Version 1.0), English [13]
International Standards for Neurological Classification of Spinal Cord Injury, including AIS [5]

SCI spinal cord injury; *AIS* American Spinal Cord Injury Association (ASIA) Impairment Scale

Table 2 Study (b) Questionnaires and clinical examination

International SCI Activity and Participation Basic Data Set Version 1.0 English
International SCI Skin and Thermoregulation Function Basic Data Set Version 1.0 English
International SCI Bowel Function Basic Data Set Version 1.1 English
International SCI Pain Basic Data Set Version 2.0 English
International SCI Lower Urinary Tract Basic Data Set Version 1.0 English
A self-made questionnaire
International SCI Spinal Column Injury Basic Data Set Version 1.0 English [14]
International SCI Spinal Interventions and Surgical Procedures Basic Data Set Version 1.0 English [15]
International SCI Core Data Set Version 1.1 English
Quality of life basic data set (Version 1.0), English
International Standards for Neurological Classification of Spinal Cord Injury, including AIS

SCI spinal cord injury; *AIS* American Spinal Cord Injury Association (ASIA) Impairment Scale)

participants and their caregivers. All questionnaires (Table 1), were translated from English to Macedonian by two independent translators, according to the International Spinal Cord Society recommendations [4].

Measures

Our protocol was based on data from four different sources: (a) medical records, (b) clinical examinations, (c) interviews including semistructured and standardized questionnaires, and (d) either clinic attendance or visits to the participant's home. Information extracted from each patient's medical record was to include: demographic data (gender, age at

injury, and current employment status), date of admission and discharge from the hospital, past medical history, injury-related information, type of injury, neurological level of injury (NLI), and American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS) classification [5], associate injuries, injury-related complications, and mortality. The clinical examination was to include NLI and AIS. An interview with fixed questions was especially developed based on previous research [6] and clinical experience. The interview included the following topics: complications, sequela, and ailments, mobility and sports aids/equipment, transport, home adjustments, and the use of personal assistance. In addition, the interview included standardized International SCI Data Sets (Table 1) [5, 7–15]. For data collection during in-hospital stay and at home visits, the researcher used paper-printed questionnaires including standardized International SCI Data sets and added notes when appropriate. After the data collection was completed, data were anonymized and plotted into data-files. Based on a study by Holden et al. [16], we divided methodological challenges into (a) research logistics and procedures; (b) ethical issues, trust and understanding; and (c) scientific quality and interpretation. These methodological aspects, as well as ethical issues, were discussed among the authors, and with a group of researchers at Sunnaas rehabilitation hospital.

Results

The main proportion of persons with SCI enrolled were residents in northern, eastern or southern areas of North Macedonia. However, persons with SCI from all areas of the country were represented.

Methodological challenges study part (a)

In this part of the study, we originally intended to include traumatic SCI patients living with their injury for 20 years or more in North Macedonia, similar to a study done by Lidal et al. [4]. Patients with traumatic SCI were from April 2015 to May 2015 identified by review of medical charts in the archives at the University Clinic for TOARILUC in Skopje. The medical histories were archived at the scientific medical documentation center in the hospital Mother Theresa, which TOARILUC is a part of. The oldest files that were available were from 1999 and onwards. We therefore had to include persons living with their SCI for more than 10 years, rather than 20 years. In North Macedonia, TOARILUC was the only department treating traumatic SCI patients between 1999 and 2004. The second author (general surgeon and trained in International Standards for Neurological Classification of SCI (ISNCSCI) [5]

assessment from Sunnaas rehabilitation hospital, Norway) conducted the archive search, and later on the clinical examinations and interviews for study part (a).

We experienced several problems during patient inclusion: information registered in the medical records from the hospital were often incomplete, in terms of neurological examination (NLI and AIS or Frankel [17]) on admission, medical history, addresses, and telephone numbers. We therefore decided our inclusion criteria to allow for “identified with a fracture or dislocation of the spine” as a diagnosis written in the medical charts with a coexisting ICD code. All medical charts reviewed contained an ICD code. A total of 203 persons with traumatic SCI and/or spine injury or dislocation were admitted to Skopje University Hospital between 1999 and 2004. A letter, with study and contact information (address and cell phone number) and participation’s agreement form, was sent to all 203 identified persons. They were to leave a signal on a cell phone and they would then be contacted afterward. Out of 203 letters we received 20 positive replies. Address, cause of death, and emigrations registers were not available at the time of data collection in North Macedonia. Thus, we did not know/could not assess how many of the potential participants were deceased or had moved within the country or abroad after the SCI. All 20 were offered the opportunity to come to Skopje for an outpatient examination, out of which 13 preferred a home visit. To recruit more participants, we selected 60 of the 183 remaining nonrespondents, to whom we attempted home visits. The home visits were conducted in the period from June 2015 to July 2016. Out of the 60 selected home visits, 20 persons agreed to participate in the study, 31 were migrated to foreign countries or were not possible to locate due to false or incomplete address information. Furthermore, seven persons refused to engage in conversation/declined to participate and two were deceased. In the end, 40 subjects were eligible to enter the study. All individuals were at least 10 years postinjury when our study part (a) was performed. The second author (VMJ) carried out all home visits; due to security reasons a male assistant accompanied. In general, the data collection was very time-consuming and often there were address related challenges, including changes of street names and dirt roads without names. On one occasion the home visit had to be postponed due to flooding of roads. Altogether, several days were spent searching for potential participants without result. Some persons with SCI were localized with the help of previous neighbors or the local cafe or grocery store. During data collection, the researcher experienced that participants expressed uncertainty on whether participation would be helpful, whether the researcher could be trusted or they misunderstood the research or researcher. At home visits, participants requested researcher identification. Sometimes the researcher felt that it was unpleasant to be in

someone's home. Sometimes differences in language and personal norms made data collection difficult. Some participants forgot scheduled data collection appointments, and some had problems recalling information about disease or therapy. It was also experienced that the need for conversation with a physician for the participants, was very time consuming for the researcher. As a medical doctor, the researcher was viewed upon as a clinical expert and was asked for medical advice and care plan repeatedly; male gender participants especially were interested in medications for potency. Some participants were afraid that they would lose support as governmental financial support and social benefits they were currently receiving if they talked to the researcher. Participants expressed interest in receiving physiotherapy, more aid, and modern wheelchairs. A center for addressing and solving problems and socializing with persons with similar injuries was also inquired about.

Methodological challenges study part (b)

Every (aged 16–80+ years of age) patient admitted at TOARILUC with a traumatic injury to the spinal cord in the period from March 1st 2015 to February 29th 2016 was asked to participate. Colleagues working at the trauma ward and emergency center were informed about the study and the researcher was called whenever a new patient with a spinal column injury or contusion was incoming. Clinicians insisted on not being disrupted in their clinical work, confining data collection to odd hours. The second author (VMJ) examined all patients at admission or within hours. Due to low numbers of included patients with SCI, we extended the inclusions period to August 31st 2016. During the last 2 months of inclusion, an assistant trained by the second author in interview technique and ISNCSCI examination was helping with inclusions and interviews. Only one participant was recruited during these 2 months. A total of 38 patients were diagnosed with a SCI in the period from March 1st 2015 to August 31st 2016. Out of 38 patients, all participants or their nearest relatives agreed to participate in the study. Rehabilitation was continued after primary care at different rehabilitation institutions, without further routine follow up. Of the 26 patients discharged alive, 18 participants were retrieved and contacted one year after the SCI (2017) and completed the follow-up interview and clinical examination.

During the data collection period, several challenges were encountered. Medical records from the hospital were not complete. Autopsy was not performed on patients deceased in the hospital, making cause of death a clinical judgment. We experienced some language barriers with Albanian patients, and maintaining participant privacy and confidentiality was on some occasions difficult due to the lack of private areas in the clinic where the interviews with the participants were carried out. Examination and

interviews were sometimes challenging due to both light and sound-conditions. Also, family members, friends, bystanders, or visitors were sometimes present during interviews, making the interview situation more complex. For some of the participants it was unsure if they would survive and also whether their trauma would make them disabled. At this difficult time in their life, we were recruiting them by asking: "Will you participate in a study so that we can see how our treatment strategy may influence the outcome for you and many other people with the same condition?" We registered different reactions to this invitation: most of them felt there was someone (the scientist and physician conducting the study) who was there just for them, and this was of great satisfaction for them. The fear of losing someone (the scientist and physician conducting the study) who is there when they are vulnerable, may also be a reason for consent.

Discussion

With conducting the first epidemiological studies of persons with SCI in North Macedonia, we experienced methodological and ethical challenges. This paper brings forward some important aspects from conducting epidemiological studies in North Macedonia and may have transferability to other settings. No similar methodological issues were reported in published articles from neighboring regions [2, 18]. Holden et al. reports similar methodological concerns when describing two studies conducted in the USA [16]. Methodological issues influenced by the setting, are important to consider when interpreting study results. Health-care-systems varies between (and sometimes within) countries, language and culture may introduce barriers to understanding, and epidemiological research also rely on infrastructure and surroundings. We observed various challenges during our data collection, some of which posed threats to the scientific quality of the data and the ethics related to treatment of vulnerable individuals. We divided our methodological challenges into (a) research logistics and procedures; (b) ethical issues, trust and understanding; and (c) scientific quality and interpretation [16]. Challenges related to research logistics and procedures, such as recruitment included missing medical documentation and lack of addresses and access to national address-, death- and emigration registers, travel distances, road conditions, missing road names, and compensation (money, service, etc.). For future epidemiological studies in North Macedonia or similar settings, it would be advisable to make enquiries about medical records, accessibility to and standard of national registers and infrastructure. Challenges related to ethical issues included initial lack of mutual trust and understanding between researcher and participants. For

this study, making time for and listening to the participants without being intruding was of special importance in building trust and a good relationship with the participants during recruitment and data collection. The last major group of challenges was concerned with scientific quality and interpretation, including issues of validity, reliability, and representativeness. External validity could be reduced when reading incomplete, unstructured, and large amounts of medical records. Challenges of identification of potential participants and declining to do recruitment through home visit because of safety reasons could influence the representativeness of data. The disadvantages of direct recruitment by research personnel are also associated with the risk of biased recruitment. Issues of mutual understanding and trust may have directly influenced data accuracy and completeness, while issues of recruitment and compensation may have biased the sample. The asymmetry of power and knowledge between the researcher and the participants could interfere with both recruitment and data sampling. The data collection and examination were relatively time consuming for both researcher and participants and thus exhausting for both parts, lowering concentration and accuracy. In the in-hospital part of our study, there were privacy issues related to securing an interview room in the clinic, perhaps influencing the conversation, and hence the reliability of the information collected. Furthermore, the majority of the participants from west North Macedonia with Albanian ethnicity did not respond to the invitation letter to participate in study (a). According to the North Macedonian Statistical yearbook of 2016 (https://en.wikipedia.org/wiki/Demographics_of_North_Macedonia), the demographics of North Macedonia in 2002 were as following: Macedonians (64%), Albanians (25%), Turks (4%), Romani (3%) and Serbs, Bosnians and Aromanians (4%). Therefore, comments can be made on the representativeness of the study, including the nonresponder limitations and the possibility that individuals with more severe conditions may be less likely to participate in population surveys; on the other hand, some eligible persons with SCI might be too busy to participate. Also, cross-sectional data reflect the respondents' situation at a certain point in time, and our retrospective questions might have introduced a risk of recall bias since the participants were expected to report experiences from the past. Our self-made questionnaire has limitations, as it cannot be compared to other studies.

The strengths of this study are that in North Macedonia, TOARILUC was the only department treating patients with SCI previously. At the time of the study (b) TOARILUC was the only public department treating patients with SCI. In recent years, private hospitals have been established in Skopje that are able to treat patients with SCI, but the cost is very high, thus excluding most citizens. To the best of our knowledge, private hospitals received acute patients with

tSCI from Kosovo during our inclusion period (study (b)). The second author (VMJ—general surgeon and trained in ISNCSCI assessment from Sunnaas Rehabilitation Hospital, Norway) conducted the archive search and later the majority of the clinical examinations and interviews. As one author was directly involved in the data collection of the study the majority of the time, she was able to identify a very large number of data collection challenges. In a systematic review of challenges related to informed consent from developing countries [19], the authors recommend that local language to be used, as we did. Another study [20], investigating management research in China, concludes that in order to increase the validity of data, a multimethod approach is recommended. Some of the challenges described in our study related to the quality of data are also addressed in the latest International Perspectives of SCI report [21]. The report recommend to ensure that all SCI data are reported using the International SCI Core Data Set as a minimum [21], as we did in our study, thus strengthening our methodology and also comparability to other studies.

Conclusion

Collecting both structured and less structured data are potentially very productive but requires the anticipation of various challenges. We provided illustrations and suggestions from our own studies in an effort to facilitate future epidemiological data collections in North Macedonia and similar settings. We recommend making enquiries about medical records, accessibility to national registers, infrastructure, and safety. Based on our knowledge of the North Macedonian health care services, our claim is that the results of study (b) are valid, reliable and important whereas our study (a) is reliable but not generalizable. We argue that both studies (study (a) in preparation and study (b) submitted [22]) contribute to the knowledge base of acute and long-term SCI in North Macedonia.

Data archiving

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author's contributions EK was responsible for designing and writing the protocol, assisting in conducting the study, extracting and analyzing data, interpreting results, and writing the manuscript. VMJ was

responsible for designing and writing the protocol, conducting the study including the data collection, extracting and analyzing data, interpreting results, writing the article and providing feedback on the article. IBL was responsible for designing the protocol, interpreting results and writing the manuscript and providing feedback on the article. FB contributed to designing the protocol, extracting and analyzing data, writing the article and providing feedback on the article.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statements of Ethics We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. This study was approved by the Norwegian Regional Committee for Medical and Health Research Ethics South East (Approval No: 2014/2041) and local authorities at the Skopje University Hospital, Mother Teresa in North Macedonia. The project was carried out in accordance with The Declaration of Helsinki—ethical principles for medical research involving human subjects.

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