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ORIGINAL ARTICLE

Internet based multicenter study for thoracolumbar injuries: a new concept and preliminary results

Christian Knop · Maximilian Reinhold · Christoph Roeder · Lukas Staub · Rene Schmid · Rudolf Beisse · Volker Bühren · Michael Blauth

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Abstract This article reports about the internet based, second multicenter study (MCS II) of the spine study group (AG WS) of the German trauma association (DGU). It represents a continuation of the first study conducted between the years 1994 and 1996 (MCS I). For the purpose of one common, centralised data capture methodology, a newly developed internet-based data collection system (http://www.memdoc.org) of the Institute for Evaluative Research in Orthopaedic Surgery of the University of Bern was used. The aim of this first publication on the MCS II was to describe in detail the new method of data collection and the structure of the developed data base system, via internet. The goal of the study was the assessment of the current state of treatment for fresh traumatic injuries of the thoracolumbar spine in the German speaking part of Europe. For that reason, we intended to collect large number of cases and representative, valid information about the radiographic, clinical and subjective treatment outcomes. Thanks to the new study design of MCS II, not only the common surgical treatment concepts, but also the new and constantly broadening spectrum of spine surgery, i.e. vertebro-/kyphoplasty, computer assisted surgery and navigation, minimal-invasive, and endoscopic techniques, documented and evaluated. We present a first statistical overview and preliminary analysis of 18 centers from Germany and Austria that participated in MCS II. A real time data capture at source was made possible by the constant availability of the data collection system via internet access. Following the principle of an application service provider, software, questionnaires and validation routines are located on a central server, which is accessed from the periphery (hospitals) by means of standard Internet browsers. By that, costly and time consuming software installation and maintenance of local data repositories are avoided and, more importantly, cumbersome migration of data into one integrated database becomes obsolete. Finally, this set-up also replaces traditional systems wherein paper questionnaires were mailed to the central study office and entered by hand whereby incomplete or incorrect forms always represent a resource consuming problem and source of error. With the new study concept and the expanded inclusion criteria of MCS II 1, 251 case histories with admission and surgical data were collected. This remarkable number of interventions documented during 24 months represents an increase of 183% compared to the previously conducted MCS I. The concept and technical feasibility of the MEMdoc data collection system was proven, as the participants of the MCS II succeeded in collecting data ever published on the largest series of patients with spinal injuries treated within a 2 year period.

Keywords Thoracic spine · Lumbar spine · Multicenter study · Prospective · Fracture treatment · Web-based · Spinal cord injuries · Spinal injuries · Spinal fractures

C. Knop (✉) · M. Reinhold · R. Schmid · M. Blauth
Trauma Surgery and Sports Medicine,
Innsbruck Medical University, Innsbruck, Austria
e-mail: christian.knop@uibk.ac.at

C. Roeder · L. Staub
Institute for Evaluative Research in Orthopaedic Surgery,
University of Bern, Bern, Switzerland

R. Beisse · V. Bühren
Trauma Surgery, Trauma Center Murnau,
Murnau, Germany

The surgical treatment of injuries of the spine underwent major changes in the past decade due to rapid developments in surgical techniques and technologies. Examples are endoscopy, navigation, and percutaneous instrumentation and augmentation procedures just to mention a few. The spectrum of the different procedures remained wide and has possibly even enlarged further. At the same time, there is still a significant disagreement about what kind of treatment is the most appropriate one in order to reach the treatment goal. Looking at the most frequently occurring injury, the burst fracture (AO/ASIF type A 3), with its different subtypes and appearances, there are still concurring treatment solutions ranging from non-surgical to various surgical interventions with single posterior, anterior or combined posterior-anterior procedures.

Since spinal injuries are rather rare consequences of accidents, valid study results are scarce. Information regarding the specific complications and outcomes of the established surgical procedures is restricted by small sample sizes and can only vaguely be evaluated by means of meta-analyses. The golden standard remains the standardised, prospective, and multicentric collection of data about treatment modalities and outcomes.

With the first multicenter study (MCS I) of the German trauma association's spine study group, valuable information about the surgical treatment of injuries of the thoracolumbar junction was gained. In the years between 1994 and 1996, 682 patients with acute and surgically treated injuries of the thoracolumbar junction (Th10–L2) were documented and a respectable number of 372 (80%) out of a total of 472 included cases were followed-up [11–13]. Therefore MCS I represents a thorough inventory analysis for the above mentioned injuries.

In the following years, the therapeutic concepts also have changed significantly, because of the findings of MCS I: the limitations of the routinely and most frequently used purely posterior surgery were confirmed, the importance of a sustainable reconstruction of the anterior column was increasingly recognised [9, 10, 14, 15, 19]. The morbidity of the more complex combined procedures and the weaknesses of the anterior approach and reconstruction techniques became clear. More advanced technologies like implants for vertebral body replacement, navigation and endoscopic instruments were not yet available at the time of MCS I and have only been established in recent years [4, 10, 16, 17].

Because of the above mentioned changes, a new MCS became necessary and was initiated as MCS II by the spine study group of the German trauma association at the beginning of the new millennium. As an extension of the previous study, all surgically treated injuries of the whole thoracic and lumbar spine were to be recorded as well as relevant non-surgically treated lesions. Further, new procedures more typically used in the traumatology of the aged population, like kypho- and vertebroplasty were included.

The method of data collection of MCS I had certain disadvantages: All study forms had to be posted to the study administrator. One center had to put up with the whole data input into the local data bank system. In case of missing data or obviously corrupt data, these forms had to be sent back for revision and re-submission via post [11]. The offer to function as a pilot user of the new web based documentation sytemand to transfer the duty of data input to each participating center was gladly accepted.

The first aim of this publication was the presentation of the ongoing MCS II with its goals and preliminary results with regard to the included patient population and the chosen treatment. The described study also served as the first large-scale pilot study for the newly developed web based documentation system of the University of Bern. This documentation system is presented and discussed in detail. The follow-up results of MCS II should be presented in a separate publication after closing of the follow-up period in the near future.

Materials and methods

Study goals

- Collection of epidemiological data regarding incidence of spinal injuries and co-lesions and their causes;
- Frequency of the various surgical and conservative treatment concepts;
- Advantages and disadvantages of the different methods and techniques;
- Complications of procedures;
- Duration of treatment, rehabilitation and absence from work;
- Analysis of the radiographic and clinical courses with subjective outcomes.

Inclusion criteria

- All acute, traumatic injuries from Th1 to L5, that were

a) surgically treated or
b) conservatively treated if fractures were of pincer type (A 2.3) or of a more severe type (A 3, B, C);

- Initiation of treatment within three weeks after the accident;
- All patients treated with kypho-or vertebroplasty.

Data collection: content

- *Date* of accident, admission, surgery and possible revision procedures, discharge;
- Type of accident;
- *Localisation* and *classification* of spinal injury according to the AO/ASIF classification by Magerl et al. [20];
- *Neurological status:* classification according to the Frankel-/ASIA-Score [1, 7] at the time of admission and at discharge;
- *Overall severity of injuries:* abbreviated injury scale for calculation of the Injury severity score [2, 3], in order to comprehensively assess the severity of spinal injuries and co-lesions in a comparable way;
- *VAS spine score for assessment of the overall spinal status before the injury*: this is a subjective score based on a visual analogue scale with a maximum of 100, that serves as outcome assessment and preop-postop comparison [18];
- *Details about the surgical or conservative treatment:* type and duration of external immobilisation, approaches, implants, bone substitutes and fusion techniques, number of posterior or anterior instrumented and/or fused segments, decompression of the spinal canal, endoscopy, navigation, kypho-/vertebroplasty, duration of surgery and radiographic exposure, blood loss;
- *Complications:* all general and surgical complications were recorded, whereby a difference was made between revised and non-revised cases. Within the surgical complications, the neurological ones were treated separately;
- *Analysis of pre- and postoperative radiographic and computertomographic images:* height of the anterior and posterior vertebral wall for the assessment of general postural angles and sagittal index, angles of cervical and caudal endplate, scoliosis angle, relative sagittal and lateral displacement, and relative narrowing of the spinal canal based on CT imaging;
- *Follow-up examination:* outcome assessment was conducted at least one year after surgery or initiation of conservative treatment start or at least half a year after implant removal. Follow-up assessment was based on a separate protocol which we will report about in a different article.

Data collection: technology

In the year 2000, the Institute for Evaluative research in orthopaedic surgery at the University of Bern (former Department of education and documentation of the Maurice E. Müller foundation) initiated the development of a medical IT innovation for centralised collection of data. The MEMdoc system (www.memdoc.org) is based on the principle of an application service provider (ASP) which means a centrally controlled application that is made available to all users in the periphery via the World Wide Web. The obvious advantage of this technology is the preclusion of unnecessary purchase, installation and maintenance of local software for reasons of data capture. Since the only prerequisite on the user side is a standard internet browser like Microsoft Internet Explorer™ or Netscape Navigator™, multicenter studies can be conducted in an easy and cost- effective way. Value is also added by the generic and flexible IT architecture which allows the implementation and alteration of new study content in a quick and efficient way.

MCS II served as the first large-scale pilot for testing the technical feasibility and user friendliness of the MEMdoc application. The case report forms were-treated as online questionnaires which are broken-up into so-called sub forms, reflecting the time and place where relevant information occurs during the treatment pathway. That way, prospective data collection at source is enabled and information can be entered at different times and places (emergency room, ward, OR, outpatient clinic) by the involved staff in a team effort. Several levels of validation and a direct communication with the central data base upon data entry and when the content is finally saved, guarantee the desired completeness and correctness standards. Data sets not meeting the pre-programmed criteria are rejected.

The study co-ordinator can take on the profile of a MCS administrator which is connected to certain monitoring and management features enabling user access to MCS forms, overview of participants' activities, number of pending and submitted forms, date of last log-in, download of MCS data pool, etc.. MCS are generally managed as closed user groups on the MEMdoc system. This means that MCS participants have to register with MEMdoc in order to be granted

access to all public content. Only thereafter can the MCS administrator give further access rights to restricted sections with passwords he himself generates and distributes with his tools. As soon as a user enters the MCS password, the access rights to the respective MCS forms are linked to his regular username/password. With a ''study end date''–function the MCS administrator can centrally close the study and withdraw access rights from all users.

Data security is granted by means of selective access control, regular data base back-ups, mirrored server technology and physical protection of machines, i.e. locked server room with climatisation and sprinkler system. In order to comply with the legal precepts for protecting patient information MEMdoc employs 128-Bit encryption. Also, adhering to recommendations of ethics committees, all patients gave informed consent about participating in the study and the mode of data collection though their records were anonymised.

Data management: legal aspects

The MCS II is an observational data collection for medical research. Nevertheless, the data transfer to outside the hospital for analysis necessitates the formal approval of an ethics committee. The study administrator applied for consent to the ethics committee of the Innsbruck Medical University. Additionally, the other participating centers applied for formal approval by their local ethics commitees with the above mentioned consent as the test case. All patients were asked for consent to participate.

During completion of data personal information as patients names had to be kept to minimize the risk of mistaken identity of cases. After submission of all personal data (i.e. patients' names) were anonymised for data evaluation. Every participating institution used its own codes to conceal the surgeons'names.

The spine study group of the German trauma association is the owner of the data. According to the publication management principles of the study group, each participating center is the owner of its own data set with the right to publish their results separately. The statistical analysis of the total data set is performed by the study, administration and the publication, to be legalised by the study group(Tables 1, 2).

Results

Only the preliminary results are presented here since collection of follow-up data was still ongoing at the time of this intermittent analysis. 18 trauma departments from Germany and Austria have participated in MCS II (Table 1). From January 2002 till December 2003, 1,251 patients (61% male) with a mean age of 47 (9–95) years were recorded.

The study sample consisted of 826 operated (group ''OP''), 228 non-operatively treated (group ''NON-OP'') and 114 patients who were treated with a kypho- or vertebroplasty (group ''PLASTY''). Interventional data of 83 patients are still missing. 18% of injuries were located in the thoracic spine (Th1–Th10,

Table 1 Participating centers (n = 18) and members of the spine study group, German Trauma Association

Center	Collaborators
Augsburg, Germany	M. Essler, E. Mayr, C. Schultz
Berlin, Germany	N.P. Haas, F. Kandziora, C. Klostermann, R. Pflugmacher, M. Scholz
Duisburg-Buchholz, Germany	I. Emmanouilidis, P.-M. Hax, W. Jung
Feldkirch, Austria	B. Meusburger, M. Osti, H. Philipp
Frankfurt/Main, Germany	P. Leucht, B. Maier, I. Marzi, S. Rose
Freiburg, Germany	W. Köstler, M. Markmiller
Gera, Germany	H.J. Friedrich
Homburg/Saar, Germany	A. Pizanis, T. Pohlemann, B. Reischmann
Innsbruck, Austria	M. Blauth, A. Kathrein, C. Knop, M. Reinhold, R. Schmid
Kiel, Germany	H.J. Egbers, M. Müller, A. Seitz
Klagenfurt, Austria	W. Doskar, R. Pranzl, N. Schwarz
Leipzig, Germany	T. Blattert, O. Gonschorek, C. Josten, S. Katscher
Ludwigshafen, Germany	F. Holz, H. Kohler, S. Matschke, G. Zimmermann
Mainz, Germany	E. Gercek, P.M. Rommens
Murnau, Germany	R. Beisse, V. Bühren, S. Hauck, M. Maier, F. Zentz, P. Ziegler
Ulm, Germany	M Arand, E. Hartwig, L. Kinzl, M. Schultheiss
Wien-Meidling, Austria	V. Hagmüller, A. Sailler
Würzburg, Germany	U. Ebentreich, N. Kremer, A. Weckbach

Table 2 Percentage of patients with neurologic deficit: comparison between multicenter studies MCS I (1994–96) and MCS II (2002–03)

	MCS I (n = 682) (%)	Difference (%)	MCS II (n = 1,251) (%)
ASIA/Frankel E (No neurologic deficit)	79	+3	82
ASIA/Frankel B-D (Incomplete paraplegia)	16	–5	11
ASIA/Frankel A (Complete paraplegia)	5	+2	7

n = 231), 69% at the thoracolumbar junction (Th11–L2, n = 862), and 13% in the lumbar spine (L3–L5, n = 158) (Fig. 1)

Group OP

The mean age was 42 (10–89) years. 474 (57%) patients suffered from a compression (type A), 205 (25%) from a distraction (type B), and 147 (18%) from a rotational injury. 619 patients (75%) did not show any neurological deficits after the accident, 130 (16%) patients had an incomplete paraplegia (Frankel/ASIA D-B), and 77 patients (9%) were completely plegic (Table 2). About half the cases were treated with an isolated posterior procedure (n = 427, 52%), 43% (n = 43) with an isolated anterior one. Combined posterior-anterior surgery was chosen in 310 (38%) patients; in 46 (6%) patients the combined procedure was performed in a staged procedure (Fig. 2).

Group NON-OP

The non-operatively treated patients had a mean age of 54 (9–95) years. 147 (65%) patients received a functional treatment, in 47 (32%) a 3-point fixation brace and in 7 (3%) a conventional body cast was used. In the conservatively treated group 222 (97%) A-, 5 (2%) B-, and 1 C-type fractures were treated.

Group PLASTY

The patient group receiving kypho- or vertebroplasty had the highest overall mean age of 71 (45–92) years. 105 (92%) patients were treated with kyphoplasty, 9 (8%) with vertebroplasty.

Discussion

The number of centers that participated in the prospective multicenter studies of the spine study group of the German trauma association remains unaltered and high, with 18 from 1994 to 1996 (MCS I) and 18 from 2002 to 2003 (MCS II). All hospitals were located in Germany and Austria. This reflects the unchanged willingness of the members of the spine study group to carry out and support its own research endeavours. MCS II was regarded as necessary because of major

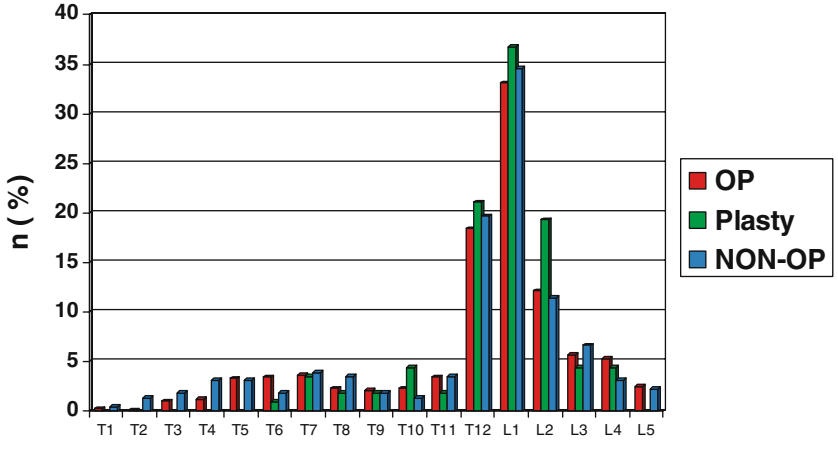

Fig. 1 Frequencies for localisation of the injured/treated vertebrae and frequencies of treatment groups (operative "OP", vertebroplasty/kyphoplasty "Plasty", non-operative "NON-OP")

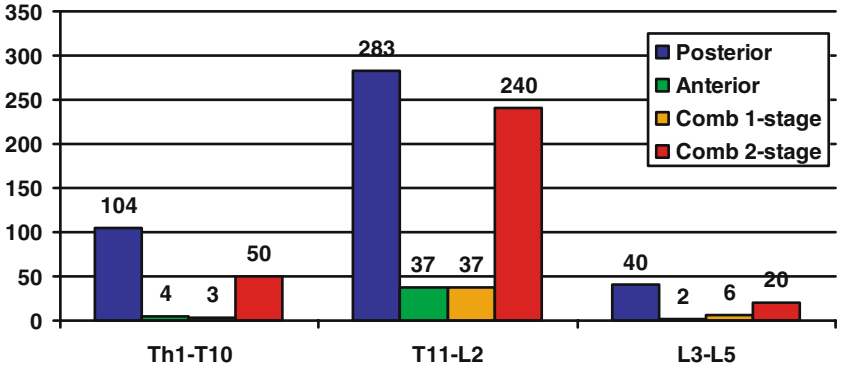

Fig. 2 Frequencies of chosen method of surgical treatment, percentage for "posterior", "anterior", and "combined posterior-anterior" (sum of one-stage and two-stage procedures), divided into the three different regions (n 826): "Thoracic (Th1–Th10)", "Thoracolumbar (Th11–L2)" "Lumbar (L3–L5)"

innovations in surgical techniques. In MCS I all anterior approaches were conventional open ones. Surgical development becomes obvious in that two thirds of all anterior approaches in MCS II were carried out minimally invasively, i.e. thoracoscopically. In addition, the frequently used distractible implants for vertebral body replacement were not yet available during 1994–1996. Comparing the group of operatively treated patients of MCS II, a difference was noted in the frequencies of injury types: In MCS I, the frequencies were comparable to those published by Magerl et al. in 1994 [20]. In the OP group of MCS II, the frequency of compression injuries (type A) decreased from 65 to 57%. Type B injuries increased from 20 (MCS I) to 25% (MCS II) while type C lesions increased from 15 to 18%. A first explanation is the higher rate of severe injuries in a group of only operatively treated patients. As we included all injuries from T1 to L5 in MCS II, an additional reason might be the different injury pattern at the thoracic spine: A rate of only 25% type A, 38% type B, and 37% type C lesions were observed at the level of T1–T10.

For MCS I, the case report forms were completed on paper and mailed to the study co-ordinator for entry into the central database. In case of incorrect or incomplete forms, the questionnaires were sent back to the respective centers for revision and/or correction [11–13]. This cumbersome mode of data collection was replaced by a web based direct data entry from the periphery into the central database. The striking advantage is the relocation of the place of data entry and validation checks from the center to the periphery. That way, the clinics themselves become responsible for entering their data, whereby system inherent validation and completeness check routines ensure that only data sets of the desired quality can be saved in the data base. To make possible real time data collection at source in a team approach, the questionnaires can be completed in several sessions from different locations and by different users, corresponding with the aforementioned subform architecture of each case report form. Consequently, data consistency and quality is increased and the documentation burden can be shared amongst staff members.

Although the new documentation system was still in a prototype stage at the beginning of MCS II, the implementation and practical application did not cause major problems. Slow line speed and restricted web access due to firewalls were the main initial obstacles for some centers. Thanks to a close cooperation between hospital IT departments and the software developers at the University of Bern, solutions were found in due time.

Questions and concerns regarding transfer of patient data across the web, access rights and data retrieval were discussed and cleared out before the study launch, mainly based on written study protocols and agreements. Emphasis was placed on the publication management principles of the German trauma association and the approval by the ethics commission of the Innsbruck Medical University as a precedence case. Nevertheless, all participants also acquired ethics approval from their local center's ethics committees.

The MEMdoc system undergoes constant improvements. Meanwhile, users can carry out statistical online queries of their own data and also of the data pool. Hence, benchmarking mechanisms are in place to compare the own performance with an ''average'' established by all users. Version 1 of the download function for the multicenter administrator was limited to a certain questionnaire size. The new version 2 is capable of handling any form size. The few studies that exceeded the capacities of the first download tool could directly be handled by the University of Bern and the complete data set was afterwards sent to the respective MCS administrators. The learning curve for users and administrators proved to be flat so that most of the initial problems and ''friction'' disappeared soon after entry of some cases.

A first, statistical overview comparing MCS I and MCS II quickly revealed large differences. As opposed to the solely surgically treated cases collected by 18 clinics in MCS I, the 18 participants of MCS II collected a significantly higher case number of cases in a shorter period of time, mostly because of the expansion oof the complete thoracolumbar spine, the inclusion of conservatively treated patients and those receiving vertebro- and kyphopasty. The latter group more or less represents its own entity of osteoporotic spinal lesions.

The content concept was based on the positive experiences of MCS I. Dispensable questions were discarded, adaptations of technical innovations were made and a validated scoring system was integrated. Hence, MCS II is based on an established concept, yet adequately responding to innovations in spine surgery techniques and technologies. In both studies patient samples with more than 600 cases were prospectively documented. Similarly, large studies can only be found in one published multicenter study by Gertzbein et al. [8] or in retrospective meta-analyses [5, 6, 21]. In addition to retrospective meta-analyses, prospective multicenter studies such as MCS I and II are the only feasible methods for collecting data from large, homogenous patient samples when targeting those rather rare types of spinal injuries.

The concise data collection period and the sophisticated method of documenting treatments and outcomes allow representative and meaningful conclusions. Nevertheless, we still see potential for methodological improvements in future studies. Randomization of treatments within a small cohort is desirable, but has,until to date, not been possible despite a close collaboration amongst the members of the spine study group.

The constant on-site availability of a web based application enables data collection directly from the OR or the emergency room. This, not only improves, but also accelerates the process of data collection. Not only can important details be better remembered and recorded immediately but also can the information be gathered by several staff members. A cumbersome retrospective documentation by external research personnel can thus be avoided.

Consequently, the study design of MCS II in connection with the MEMdoc data collection instrument accounts for current trends of electronic communication and transfer of information (telemedicine, electronic patients chart and accounting systems, electronic health networks) that increasingly gain influence in the day-to-day workflow of medical staff.

Financial aspects cannot be ignored any more in a modern research environment. In this respect, the centralised electronic data collection significantly contributes to reducing direct and indirect costs. Participating centers do not have to install or maintain local software and data bases, and data migration and consolidation at the end of the study become obsolete. The freed financial and human resources can thus be used for other projects.

Patients and insurances have increasing demands regarding evidence based treatments and quality assurance. This makes it necessary the consequent surveillance of own activities and outcomes. During follow-up, investigator meetings of the spine study group participants reflect on their own data and the data pool. That way, methods with questionable impact or high complication rates can be identified and improved. This can be regarded as an effective way of quality assurance in spine surgery and will help bringing forward evidence based research and treatments in the spine study group of the German trauma association.

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