

Development of a documentation instrument for the conservative treatment of spinal disorders in the International Spine Registry, Spine Tango

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Received: 28 August 2009/Revised: 15 April 2010/Accepted: 25 May 2010/Published online: 9 June 2010
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Abstract Spine Tango is the first and only International Spine Registry in operation to date. So far, only surgical spinal interventions have been recorded and no comparable structured and comprehensive documentation instrument for conservative treatments of spinal disorders is available. This study reports on the development of a documentation instrument for the conservative treatment of spinal disorders by using the Delphi consensus method. It was conducted with a group of international experts in the field. We also assessed the usability of this new assessment tool with a prospective feasibility study on 97 outpatients and inpatients with low back or neck pain undergoing conservative treatment. The new ‘Spine Tango conservative’ questionnaire proved useful and suitable for the documentation of pathologies, conservative treatments and outcomes of patients with low back or neck problems. A follow-up questionnaire seemed less important in the predominantly outpatient setting. In the feasibility study, between 43 and

63% of patients reached the minimal clinically important difference in pain relief and Core Outcome Measures Index at 3 months after therapy; 87% of patients with back pain and 85% with neck pain were satisfied with the received treatment. With ‘Spine Tango conservative’ a first step has been taken to develop and implement a complementary system for documentation and evaluation of non-surgical spinal interventions and outcomes within the framework of the International Spine Registry. It proved useful and feasible in a first pilot study, but it will take the experience of many more cases and therapists to develop a version similarly mature as the surgical instruments of Spine Tango.

Keywords Spine Tango · Registry · Low back pain · Neck pain · Treatment · Outcome measures

Introduction

Back pain is the major symptom of spinal disorders with a lifetime prevalence of up to 74% in modern economically advanced societies [20]. On the basis of the underlying database and definition, estimates of low back pain (LBP) prevalence in particular reveal a considerable variation. In specific populations, lifetime prevalence of LBP ranges between 49 and 84% [11]. Hence, LBP is one of the most common complaints of patients consulting a health practitioner today [49]. Four out of five individuals experience an episode of acute LBP at least once in their lifetime, and about 5% develop chronic LBP, which is defined as LBP lasting longer than 12 weeks [50]. The economic cost of treating patients with chronic LBP exceeds that of treating those with acute LBP by a significant amount leading to a high economic burden when treating spinal disorders [17, 39].

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Guidelines already exist supporting the evidence of conservative treatment, claiming different therapies for the treatment of acute, subacute and chronic LBP [5, 9, 19, 51].

The broad spectrum of surgical interventions including underlying indications is adequately presented in the literature. Similar guidelines as for conservative treatment have been developed and further improved [4, 8, 13, 23].

Since 2002, all surgical spinal interventions can be documented in the International Spine Registry, Spine Tango, developed by a working group at the Institute for Evaluative Research in Orthopaedic Surgery (IEFO), University of Berne, Switzerland, under the auspices of and in collaboration with EuroSpine, the Spine Society of Europe [1, 41, 43]. Spine Tango is the first and only International Spine Registry in operation to date. Hitherto, close to 30,000 surgical interventions have been documented by 29 participating spine centres, university hospitals, general hospitals and individual surgeons in and even outside Europe and submitted to the central database at the University of Berne. Details on the genesis and workflow of Spine Tango have already been published [1, 41, 43, 52]. So far, no comparable structured and comprehensive documentation of conservative treatment procedures is described in the literature. The Swedish Lumbar Spine Registry, probably representing the gold standard in this area, is also focussing on the surgical treatment of spinal disorders [16]. However, to our knowledge, no steps have yet been taken regarding the development of a conservative documentation module in either of the two registries.

The high economic burden of treating spinal disorders legitimises the call for a standardised documentation [7, 28, 35]. In addition, there is a lack of evidence and consensus with respect to the significance of conservative treatment options [4] and the natural course of LBP, which is probably the most difficult process to encompass systematically. The integration and standardisation of conservative treatment modalities into the Spine Tango Registry provides a potential opportunity to compare surgical and non-surgical outcomes at a later stage. Hence, new vistas open up for the improvement in spinal treatments. The patients, the community of health care providers and the public might benefit from a scientific evaluation of the data.

Although the majority of published studies—on patient-based surveys—presents the therapeutic success, yet a standardised documentation is lacking [9, 10, 14, 47]. Consequently, interpretation and comparison of studies becomes complicated.

Methods

This prospective feasibility study, which dealt with inpatients and outpatients with cervical or lumbar spinal

disorders or discomfort, reports on the development of a documentation instrument for the conservative treatment of spinal disorders and/or discomfort as well as the usability of this new assessment tool.

For acceptance by an interdisciplinary group of health practitioners the new questionnaire was developed using the Delphi consensus method [24] in three iterative stages.

During a round table the original questionnaire (version 1.0 of ‘Spine Tango conservative’) was presented to national experts in the field of low back and neck pain (orthopaedic and spine surgeons, rheumatologists, a physiatrist, a psychiatrist and pain specialist, physiotherapists, osteopaths and chiropractors). These experts discussed necessary amendments of the questionnaire based on current evidence (with an emphasis on published systematic reviews), theory and practicability. All suggestions for modifications were included by the authors in ‘Spine Tango conservative’ version 1.1.

In stage two, international experts were contacted and the modified questionnaire was sent to them as well as to the national experts of stage one, asking both groups for recommendations regarding further alterations. These were integrated into version 1.2 of ‘Spine Tango conservative’.

In stage three the same experts as in stage two were asked for their final comments on version 1.2 and the questionnaire was revised to version 1.3.

The macrostructure of the questionnaire (e.g., recording of main pathology and its specifications, goals of therapy, initiation and termination of treatment, complications) was transferred from the original Spine Tango questionnaire. In contrast, the microstructure was newly designed.

The content development of the questionnaire was followed by a prospective case series for testing its applicability in a day-to-day treatment setting. Due to methodological reasons, the maximum treatment duration was limited to 6 weeks. The inclusion criteria were acute (<6 weeks), subacute (6–12 weeks) and chronic (>12 weeks) neck and back pain with or without radiation to the extremities. The exclusion criteria were patients <18 years old, presence of red flags, i.e., warning signs for a specific spinal disorder, which might be concealed behind symptoms like fever or weight loss with unknown reason, and thoracic pain. Back pain was defined as lumbar, sacral and coccygeal pain, including radiating pain to the lower limb. Neck pain was defined as occipital and cervical (C0–C7) pain, including radiating pain to the upper extremity.

The treatment assessment with ‘Spine Tango conservative’ was performed at the beginning (T1 = admission) and at the end of the treatment or—at the latest—6 weeks after the beginning of the treatment (T2 = first follow-up or end of therapy). Following the recommendations of the Spine Tango workgroup of EuroSpine, patient-based assessment using the Core Outcome Measures Index

(COMI) the questionnaire was additionally conducted at time points T1 and T2 and 3 months after termination of treatment (T3 = last follow-up) [15, 29]. At T1 and T2 patients completed the questionnaires by themselves on site, allowing for questions to be answered directly by the practitioners. At T3 the questionnaires were completed by a research nurse by means of a telephone survey. If the patients could not be reached on the phone, questionnaires were mailed to them. If the patients failed to return these questionnaires within 2 weeks, a second and last try for a telephone interview was undertaken by the research nurse.

Descriptive statistics were calculated for patient demographics and main pathology. Wilcoxon's rank-sum test was used for comparisons of baseline and follow-up data in continuous variables like Numerical Rating Scale (NRS 0–10); χ^2 test was used when comparing proportions. The studied outcome variables from COMI were COMI score, NRS score, patient satisfaction, quality-of-life statements and usefulness of treatment, as well as work absenteeism, a therapeutic success, which was equal to 2.2 COMI points and a minimal clinically important difference (MCID) in NRS score which was equal to 2 points [48].

All statistical analyses were performed using SAS 9.2 (SAS Institute Inc, Cary, NC). The significance level was set at $p < 0.05$ and 80% power.

Because 'Spine Tango conservative' is a preliminary checklist-like documentation of pathologies, symptoms, interventions and complications in a registry, comprehending cases and treatment details as found in practice, analysis of criterion, concurrent or predictive validity as is common in the framework of evaluation of subjective patient questionnaires was not performed.

Participating practitioners comprised five physiotherapists, three osteopaths, one chiropractor, one rheumatologist and one specialist in physical medicine and rehabilitation. All practitioners were given the opportunity to provide a written feedback on suggestions for improvement to be submitted to the study administration at the end of the study. The feedback forms were evaluated by the study administration including personal interviews with one representative of each group of practitioners regarding the subject-specific content of the questionnaire. Subsequently, the final version 1.3 of 'Spine Tango conservative' was generated, which is accessible for further suggestions to all interested users on the website of EuroSpine http://www.eurospine.org/spine_tango.

Results

Content and structure of 'Spine Tango conservative'

As in the Spine Tango surgery form, the front and back sides of an A4 paper sheet were considered as the

maximum acceptable questionnaire size. The macrostructure follows that of the surgery form; the microstructure is, however, a completely new development, which allows documentation of the most common spinal pathologies or disorders and their conservative treatment to a satisfactory extent. There are four subforms: admission/pathology, therapy, therapeutic measures and end of therapy.

Admission/pathology

After defining the level and initiation date of therapy, the therapist can record if he/she treats a functional, a structural or a mixture of both diseases, which is regarded as main pathology. Functional diseases are defined as lacking a structural or pathomorphological finding. The diagnosis is based on a manual-therapeutic physical examination. Structural diseases can be subdivided into degenerative disease, deformity, spondylolisthesis, inflammation (determined by elevated ESR and/or CRP) and any other pathology. Furthermore, the first page deals with the duration of disease, the number of previous spine surgeries for the same pathology and spinal level, the number of previous therapy sessions during the past 12 months, medication at beginning of therapy and the presence of flaps (red, yellow, orange, blue and black) [21, 27].

Therapy

In this subform the therapist indicates his goals of therapy and his personal professional credentials.

Therapeutic measures

The first subform on page two of the questionnaire specifies the therapeutic details. There are eight main groups with further subspecifications allowing for multiple answers when multiple treatments are used: invasive pain therapy, pain medication, physiotherapy, manual therapy, physical modalities, group programme, psychological intervention and occupational medicine measures. If the applied therapy cannot be assigned to one of these main groups, there is a last group 'other' for free text specifications.

End of therapy

In the last subform, the end date of therapy and complications, if any, are recorded as well as the measures for treating them and their status at the end of the therapy. In addition, the accomplishment of the goals of therapy from the therapist's point of view, an eventual referral to a medical consultant and other scheduled therapeutic measures are captured.

In summary, a ‘Spine Tango conservative’ form consists of a minimum of 20 and a maximum of 36 questions, depending on the case in question.

Follow-up questionnaire

A follow-up questionnaire was also developed within the framework of the project. The single-page form covers issues like follow-up interval, work status, achievement of goals of therapy, medication, rehabilitation, outcomes and decision for future measures. There is also a subform about complications following the end of therapy (time of occurrence, type and therapeutic measures). In the feasibility study it became clear, however, that it can hardly be used in the outpatient setting, which is the predominant setting for the conservative therapy. A mail- or telephone-administered patient-based follow-up can be conducted, but rarely do patients meet their therapist for a follow-up visit, if not for a second therapy series, which is documented with a second ‘Spine Tango conservative’ questionnaire.

Workflow and time investment for ‘Spine Tango conservative’

The implementation of ‘Spine Tango conservative’ in daily practice is easy. In this study, all forms were completed on paper and the data entered online by a research nurse. At the last follow-up the COMI was administered by phone or sent out to the patients with a stamped and addressed envelope. Once the ‘Spine Tango conservative’ is integrated in daily routine the questionnaires can be completed by the therapist while the patient is filling in the COMI.

Completing a paper-based ‘Spine Tango conservative’ form takes 2 min on average for a trained user. Online entry needs an additional minute for each form provided that all forms are completed error-free. The time spent may vary due to external factors such as internet speed.

Subjects

In this prospective feasibility study, 97 patients (69 females and 28 males) with a mean age of 46.9 years (SD 13.0 years) were documented, consecutively, by employing ‘Spine Tango conservative’ and COMI; 60 patients experienced back pain (including possible leg pain) and 37 patients, neck pain (including possible arm/shoulder pain). For three patients no data were available at T3 as these patients could neither be reached by phone nor by mail.

Descriptive data on main pathology, type and duration of disease, number of previous spine surgeries, overall pain medication and medication at admission, level of intervention, kind of therapy and number of previous therapy

sessions during the past 12 months are shown in Tables 1 and 2.

COMI and NRS score improvement between admission and follow-up

Between T1 and T3, a score decrease greater or equal to the MCID was achieved by 63% of patients in the COMI back, by 53% in the NRS back and by 45% in the NRS leg.

Table 1 Main pathology, type and duration of disease and number of previous spine surgeries

	%
Main pathology	
Functional disease	52
Structural disease	1
Functional and structural disease	47
Type of structural disease ^a	
Spondylarthrosis	60
Disc herniation	38
Discopathy	27
Spinal canal stenosis	15
Segmental instability	8
Other	6
Type of functional disease ^a	
Myosclerosis	75
Articular blockade	64
Segmental dysfunction	52
Osteopathic visceral dysfunction	46
Muscular shortening	35
Malposition	31
Muscular insufficiency	20
Osteopathic cranial dysfunction	20
Segmental instability	18
Muscular hypotony	8
Whiplash	7
Hypermobility	4
Pseudoradicular syndrome	1
Paralysis	1
Other	6
Duration of disease	
<6 weeks	13
6–12 weeks	20
4–6 months	10
7–12 months	10
>12 months	46
Number of previous spine surgeries	
None	94
1	6

^a Multiple choice answers—adds up to >100%

Table 2 Overall pain medication and medication at admission, level of intervention, kind of therapy and number of previous therapy sessions during the last 12 months

	%
Pain medication	
No	57
Yes	43
Medication at admission^a	
NSAID	62
Non-opioid analgesics	45
Weak opioids	10
Tricyclic antidepressants	2
Level of intervention	
Cervico-thoracal	26
Thoraco-lumbo-sacral	25
Lumbosacral	20
Cervico-thoraco-lumbar	12
Lumbar	7
Mid and lower cervical spine	4
Coccygeal	3
Upper cervical spine	2
Thoracolumbar	1
Kind of therapy^a	
Soft tissue techniques	88
Mobilisation	74
Visceral techniques	55
Manipulation	50
Stretching	34
Craniosacral techniques	27
Neuromeningeal mobilisation	10
Trigger-point techniques	8
Massage	3
Other	1
Number of previous therapy sessions during the last 12 months	
Unknown	21
None	5
1–9	38
10–18	23
19–27	9
>27	4

^a Multiple choice answers—adds up to >100%

Similarly, the MCID was reached by 57% of patients in the COMI neck, 46% in the NRS neck and 43% in the NRS arm. The drop in NRS back and neck was greater than that in NRS leg and arm.

Mean reduction between T1 and T3 was 2.9 points in the COMI back and 3.0 in the COMI neck score (both $p < 0.001$). NRS back improved by a mean of 2.5 points, NRS leg by 1.8 points (both $p < 0.001$). NRS neck

improved by a mean of 2.4 points ($p < 0.001$) and NRS arm by 1.4 points ($p = 0.02$).

Table 3 displays the differences between assessment points for COMI back and neck as well as for all NRS scores stratified by age group, gender, previous treatment, presence of flags at admission and use of medication.

General linear modelling of all scores (COMI back and neck; NRS back and leg; NRS neck and arm) for the time points T1 (admission), T2 (first follow-up or end of therapy) and T3 (last follow-up) showed significant differences for COMI neck, NRS neck and arm at T3 when stratified by acute, subacute and chronic LBP group. There were no differences for COMI back, NRS back and leg or other time points (T1 and T2). The pair-wise comparison (acute vs. subacute group; acute vs. chronic; subacute vs. chronic) demonstrated only significant differences between subacute and chronic groups. COMI neck (0.5 vs. 2.4; $p < 0.01$), NRS neck (0.4 vs. 3.1; $p < 0.05$) and NRS arm (0.3 vs. 2.7; $p < 0.05$) were significantly lower in the subacute versus chronic group. Only four patients with neck pain were included in the acute, 10 in the subacute and 21 in the chronic groups.

Quality of life, patient satisfaction, work absenteeism, usefulness of treatment

Quality of life of patients with lumbar and cervical spinal disorders at admission and last follow-up is shown in Fig. 1. At the last follow-up no patient with neck problems reported a poor or very poor quality of life.

The patients with back pain (87%) and those with neck pain (85%) were very satisfied with the received treatment; 2% (back) and 6% (neck), respectively, were somewhat satisfied; 11% (back) and 9% (neck), respectively, were neither satisfied nor dissatisfied.

Work absenteeism at admission in the back pain group was 1–7 days in 18% of patients and 8–14 days in 17%, decreasing to 7 and 4%, respectively, at last follow-up. Work absenteeism at admission of 15–21 days in 3% of patients slightly increased to 4% at last follow-up. Work absenteeism greater than 22 days was only reported at admission, given for mere 3% of all patients.

In patients with neck pain, work absenteeism of 1–7 days occurred in 24% of all cases and absenteeism of 8–14 days in 3%, declining to 0% at last follow-up in both groups. No patient with neck pain reported work absenteeism of 15–21 days in this study; the percentage of patients with work absenteeism of greater than 22 days stayed identical at admission and at last follow-up being 3%.

Thus 89% of back pain patients and 91% of neck pain patients declared their treatment had ‘helped’ or ‘helped a

Table 3 COMI and NRS back and neck, NRS leg and arm, by age group, by gender, by previous treatment, by flags and by medication

Variable	N	Mean and standard deviation					
		COMI back	COMI neck	NRS back	NRS leg	NSR neck	NSR arm
Overall							
Admission	60	5.0 ± 2.2	5.0 ± 2.1	4.6 ± 2.7	3.0 ± 2.9	4.5 ± 2.7	3.2 ± 2.8
First follow-up	60	3.5 ± 2.2	3.0 ± 2.0	3.0 ± 2.4	1.9 ± 2.6	2.4 ± 2.2	1.5 ± 2.0
Last follow-up	57	2.1 ± 2.4	2.0 ± 2.1	2.1 ± 2.5	1.2 ± 1.9	2.1 ± 2.5	1.8 ± 2.2
Age group							
<40							
Admission	21	3.9 ± 2.1	4.5 ± 2.1	3.8 ± 2.8	2.3 ± 2.9	4.1 ± 2.6	3.1 ± 2.5
First follow-up	21	2.6 ± 1.8	3.0 ± 1.9	2.1 ± 1.8	1.3 ± 2.3	2.5 ± 2.5	2.2 ± 2.3
Last follow-up	20	1.1 ± 1.6	1.5 ± 1.8	1.6 ± 2.0	0.3 ± 1.0	1.8 ± 2.2	1.5 ± 2.1
40–59							
Admission	27	5.4 ± 2.0	5.7 ± 2.2	5.0 ± 2.5	3.1 ± 2.8	5.3 ± 2.8	3.3 ± 3.0
First follow-up	27	3.5 ± 2.1	2.8 ± 1.9	2.0 ± 2.0	1.7 ± 2.0	2.0 ± 1.7	0.9 ± 1.5
Last follow-up	26	2.8 ± 2.7	2.7 ± 1.9	2.8 ± 2.8	1.8 ± 2.0	2.7 ± 2.9	2.3 ± 2.5
≥60							
Admission	12	6.1 ± 2.1	4.8 ± 2.1	5.3 ± 3.0	4.2 ± 3.0	3.4 ± 2.7	3.0 ± 3.5
First follow-up	12	4.9 ± 2.6	3.3 ± 2.9	4.3 ± 3.3	3.6 ± 3.5	2.7 ± 2.4	1.2 ± 1.0
Last follow-up	11	2.4 ± 2.3	2.3 ± 2.9	1.5 ± 2.3	1.5 ± 2.3	2.0 ± 2.8	1.5 ± 2.3
Gender							
M							
Admission	20	5.2 ± 2.7	5.2 ± 2.6	4.9 ± 2.8	2.8 ± 2.8	4.5 ± 2.9	1.1 ± 1.9
First follow-up	20	3.6 ± 2.3	2.1 ± 1.6	3.1 ± 2.5	1.3 ± 2.2	1.4 ± 1.2	0.8 ± 1.2
Last follow-up	19	2.8 ± 2.7	0.4 ± 0.7	2.6 ± 2.9	1.4 ± 1.9	0.6 ± 0.8	0.3 ± 0.5
F							
Admission	40	4.9 ± 1.9	4.9 ± 2.1	4.5 ± 2.8	3.2 ± 3.0	4.5 ± 2.7	3.7 ± 2.7
First follow-up	40	3.4 ± 2.2	3.2 ± 2.1	2.9 ± 2.3	2.3 ± 2.7	2.6 ± 2.3	1.8 ± 2.1
Last follow-up	38	1.8 ± 2.1	2.6 ± 2.2	1.9 ± 2.3	1.1 ± 1.9	2.5 ± 2.7	2.2 ± 2.3
Previous treatment							
No							
Admission	17	6.0 ± 2.2	4.0 ± 2.4	5.5 ± 3.1	3.1 ± 2.9	4.0 ± 3.3	1.5 ± 2.1
First follow-up	17	2.8 ± 2.3	1.6 ± 1.2	2.4 ± 2.8	1.6 ± 2.4	1.1 ± 1.4	0.9 ± 1.2
Last follow-up	15	1.7 ± 1.8	0.8 ± 1.1	1.2 ± 2.0	0.4 ± 0.9	0.9 ± 1.5	1.1 ± 1.8
Yes							
Admission	43	4.6 ± 2.1	5.3 ± 2.0	4.3 ± 2.5	3.0 ± 2.9	4.6 ± 2.6	3.6 ± 2.8
First follow-up	43	3.7 ± 2.2	3.3 ± 2.1	3.2 ± 2.1	2.0 ± 2.6	2.7 ± 2.3	1.7 ± 2.1
Last follow-up	42	2.3 ± 2.5	2.4 ± 2.2	2.5 ± 2.6	1.5 ± 2.1	2.5 ± 2.7	2.0 ± 2.3
Flag(s)^a							
No							
Admission	49	4.8 ± 2.2	4.8 ± 2.2	4.4 ± 2.7	2.9 ± 2.9	4.3 ± 2.8	3.1 ± 2.9
First follow-up	49	3.2 ± 2.1	2.9 ± 2.1	2.7 ± 2.3	1.8 ± 2.5	2.4 ± 2.3	1.4 ± 2.0
Last follow-up	48	2.1 ± 2.4	1.8 ± 2.0	2.2 ± 2.6	1.2 ± 1.9	1.7 ± 2.3	1.5 ± 2.1
Yes							
Admission	11	6.1 ± 1.9	6.5 ± 1.2	5.6 ± 2.9	3.7 ± 2.9	6.3 ± 1.5	3.8 ± 2.1
First follow-up	11	4.8 ± 2.4	3.5 ± 1.3	4.4 ± 2.2	2.5 ± 2.8	2.3 ± 1.3	2.8 ± 1.7
Last follow-up	9	2.5 ± 2.2	3.9 ± 1.9	2.0 ± 1.8	1.3 ± 1.9	5.3 ± 2.1	3.8 ± 2.4
Medication							
No							
Admission	31	4.5 ± 1.9	4.7 ± 2.2	4.0 ± 2.8	2.6 ± 2.8	4.0 ± 2.7	3.5 ± 2.8

Table 3 continued

Variable	N	Mean and standard deviation					
		COMI back	COMI neck	NRS back	NRS leg	NSR neck	NSR arm
First follow-up	31	2.7 ± 1.5	2.9 ± 2.1	2.3 ± 1.8	1.8 ± 2.3	2.2 ± 2.1	1.8 ± 2.2
Last follow-up	29	1.2 ± 1.2	2.3 ± 2.3	1.4 ± 1.9	1.0 ± 1.8	2.5 ± 2.6	2.3 ± 2.5
Yes							
Admission	29	5.6 ± 2.3	5.6 ± 2.0	5.3 ± 2.6	3.5 ± 2.9	5.4 ± 2.5	2.5 ± 2.6
First follow-up	29	4.2 ± 2.6	3.1 ± 2.1	3.7 ± 2.7	2.1 ± 2.8	2.7 ± 2.4	1.0 ± 1.4
Last follow-up	28	3.1 ± 2.9	1.6 ± 1.8	2.9 ± 2.9	1.4 ± 2.0	1.4 ± 2.3	0.8 ± 1.3

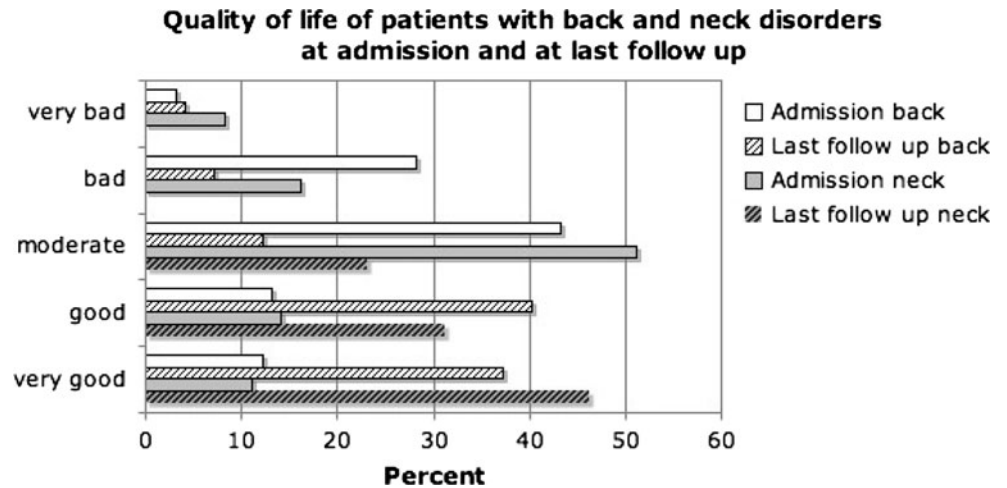
Table 3: first follow-up took place at end of therapy or at 6 weeks after admission at the latest

Last follow-up took place exactly 12 weeks after first follow-up

COMI Core Outcome Measures Index, NRS Numerical Rating Scale, *Flags* Biomedical, psychosocial, socioeconomic, psychiatric and occupational risk factors

^a Can be one or several flags at time point T1/T2/T3

Fig. 1 The last follow-up took place within a range of 13–18 weeks after admission, but always exactly 12 weeks after the first follow-up. No patient with neck disorder reported poor or very poor quality of life at the last follow-up



lot’. Only 4 and 3% of patients, respectively, indicated the received treatment ‘didn’t help’.

Discussion

The current study presents the development of a first version of a questionnaire for documentation of conservative spinal treatments in the framework of the International Spine Registry Spine Tango and a feasibility study on 97 consecutive patients in a predominantly outpatient setting. In its version 1.3, the questionnaire proved useful and suitable for documentation of pathologies, conservative treatments and outcomes of patients with low back or neck problems; this is in conjunction with the patient-administered COMI neck and back questionnaires that are already in use in the surgical arm of the Spine Tango Registry. About 40–60% of patients reached the MCID in pain relief

and COMI for their back/leg or neck/arm disorders at 3 months following end of therapy.

Limitations

The repeated Delphi method is only one of various possibilities for consensus finding on a broad expert basis. In the current study this method was applied for receiving an initial input from many different conservative treatment philosophies. However, because ‘Spine Tango conservative’ primarily applies to therapists employing body-related therapies in this first development stage we did not involve a psychologist or neurologist. This will be addressed in the next development stages. Our results on differences in score changes (COMI and NRS) when stratified by acute, subacute and chronic LBP do not allow to draw any detailed conclusions regarding implications for clinical practice due to the small size of different groups. This issue

should be taken into consideration in the sample size calculation when designing a follow-up study to generate meaningful data for clinical practice. The feasibility study we undertook is not a validation study in the actual sense, the reason therefore being the still preliminary character of the ‘Spine Tango conservative’ questionnaire. A systematic evaluation of reliability, with inter-observer and intra-observer variability is only meaningful when all structural and content deficiencies of the questionnaire have been resolved. As experience with the surgical questionnaires showed, it can possibly take years of further developments and refinements and several thousands of documented conservative interventions until a final solution is at hand. We are already conceptually planning such a validation study based on the methodology of Peabody’s clinical vignettes [25, 36, 37], where fully formulated patient and treatment histories will be studied by various therapists and then individually recorded on the documentation questionnaires. The procedure will be repeated with the same vignettes and therapists within 48 h. Variations between the therapists and between the first and second administration will be analysed and a final questionnaire version designed. The vignettes are validated and have a methodological value similar to standard patients (actors), but they are ethically, organisationally and financially advantageous. The chiropractor, the rheumatologist and the physiatrist only documented one patient each. All other users were from the field of physiotherapy and osteopathy. This may have led to an overrepresentation of the latter therapists’ views. A broader and more balanced use of ‘Spine Tango conservative’ in the different fields should eliminate this potential problem in future versions.

The COMI questionnaires were originally developed and validated for preoperative and postoperative assessment of surgical patients [29]. Using them in the conservative predominantly outpatient setting showed some comprehension and application problems that will probably make necessary the development and validation of a slightly adapted COMI version for the non-surgical patient population. Especially the follow-up question No. 9 about additional treatments for the lower back or neck caused difficulties because many patients could not differentiate for which part of their back the conservative treatment had actually been. This is easier to understand for patients after a surgical intervention. Misunderstandings were also caused by question Nos. 6 and 7 about restrictions in the last 4 weeks at the assessment time point T2, i.e., at the end of therapy. A short two-session treatment for an articular blockage spanning over not more than a week’s time makes the patient give a mixed judgement about the 3 weeks before therapy and the 1 week during therapy, where an acute improvement of pain status may have taken place. This gives a blurred picture about the treatment success.

Strengths

The comparability of conservative treatments and outcomes will become easier with a standardised and validated instrument like ‘Spine Tango conservative’. The development of its first version is based on almost 10 years experience in the domain of documentation of surgical spinal interventions, and the instrument can be integrated into an existing multifunctional online documentation system. Thanks to our methodological consensus approach with the Delphi method and a feasibility study it can be postulated that we have worked up an interdisciplinary instrument that allows the depiction of the many different spinal pathologies and conservative treatments. With ‘Spine Tango conservative’ an evidence level of at least 3 can be achieved; in hypothesis-driven nested cohort studies with a control group an evidence level of 2 is even possible. The feasibility of such studies has already been shown in the surgical arm of the registry [2, 38]. It is slowly recognised that randomised controlled trials have their own limitations, especially regarding external validity of findings [45]. They are finally always ‘experiments’ in an artificial clinical setting and they do hence rather deliver evidence about efficacy rather than effectiveness [3]. Especially in the surgical disciplines an almost insurmountable series of ethical, financial and organisational obstacles have to be dealt with. Therefore, observational studies with lower evidence levels but higher external validity and feasibility represent acceptable alternatives in the routine clinical setting [6, 31, 42].

The online statistical tools make the mining of own data, pool data and of comparing own outcomes with the rest of the user community [44] a fascinating possibility. Finally, the awareness and support of Spine Tango have made significant advancements over the past years. In this manner, the initial and the future feedback from the hopefully rapidly growing user community will help to finalise the development of ‘Spine Tango conservative’ in a faster way than for the surgery forms.

General aspects of ‘Spine Tango conservative’

On the basis of ‘Spine Tango conservative’ many spinal problems can be documented on the level of dysfunctions and/or structural alterations. With this instrument it is possible to describe a patient, his spinal morbidity, the conservative treatments he/she received and the outcomes that resulted in a comprehensive and more detailed way than with routine clinical notes. Moreover, the categorised and not text based storage of information makes it readily available and usable for statistical analyses. A further and even more interesting possibility seems the potential for comparing patients that received surgical or conservative

treatments for similar pathologies in the overall framework of one and the same registry. The feedback of all involved in the development process can be summarised as follows:

- A syllabus accompanying the questionnaire would be helpful. This document will be available on the same web page as the ‘Spine Tango conservative’ questionnaire.
- The learning curve for completion of the form in an acceptable amount of time (~3 min) takes about 10 patients. Thereafter, the instrument can be considered as suitable for routine day-to-day use.
- A therapist-based follow-up assessment was performed so rarely that implementation of a ‘Spine Tango conservative’ follow-up questionnaire seems to be of secondary importance at this point in time. Due to cost-benefit reasons, for most cases in this feasibility study no follow-up was planned or indicated.
- A mail- or telephone-based assessment of mid- to long-term outcomes with the COMI questionnaires appears as the more feasible option. To further strengthen this data collection mode, a slight adaptation of the COMIs for conservative treatments seems recommendable.

Main clinical findings

There was a mean reduction of 2.9 points between T1 and T3 in COMI back and of 3.0 in COMI neck score, respectively. NRS back improved by a mean of 2.5 points, NRS leg by 1.8 points, NRS neck dropped by a mean of 2.4 points and NRS arm by 1.4 points, respectively. Accordingly, between 43 and 63% of patients reached the MCID in pain relief and COMI. It became obvious that low back and neck pain had improved to a greater extent than leg and arm pain. In the surgical domain the opposite effect is often reported. Although the mechanisms causing pain in the broad variety of spinal disorders are far from being understood, a clear line can be drawn between leg/arm and back/neck pain and the relief following an intervention. In the majority of cases the underlying pathomorphological cause for clearly defined radicular pain can be identified as a compression of nerve roots or the dural sac [22]. On the other hand the treatment approaches to spinal disorders with predominant back pain are numerous and each of them is discussed controversially. Reporting on them would go far beyond the aims of the presented study. It can be assumed that in contrast to surgical treatments, conservative therapy targets on specific pathophysiological mechanisms of the involved structures, not ideally addressed by surgery. This has led to a good perception of the treatment results in our study, as 87% of patients with back pain and 85% of patients with neck pain at last follow-up were very satisfied with the received treatment.

Improvement of low back and neck pain in this feasibility study showed to be comparable to findings in other studies [12, 30, 33, 34].

Implications for practice and research

‘Spine Tango conservative’ is a documentation instrument for many conservative treatment scenarios in patients with spinal complaints or morbidities. From the socioeconomic point of view, the amount of costs caused by these patients is disproportionately larger compared with other diseases [7, 18, 26]. Following the basic principles of a community based on mutual solidarity, a closer monitoring of what is done for whom and with what outcome must be permitted. Therefore, possibly all spinal treatments, the surgical and non-surgical ones should be documentable and documented by the involved disciplines.

EuroSpine, the Spine Society of Europe and its Spine Tango working group have made the development and implementation of a set of tools for reaching the above goals one of their fundamental missions. The voluntary participation of the community, however, is still reluctant. Governmentally mandated spinal registries like SWISS-spine do have a dramatically different adherence [40, 46]. Nevertheless, if these registries make use of the scientific spadework of professional societies and involve them, academic expert institutions and other important stakeholders in a joint venture with equal voice, the way is paved for successful, meaningful and useful outcome research and quality assurance in the spinal field.

Conclusion

‘Spine Tango conservative’ is based on the concept of Spine Tango, the originally surgical spinal registry of EuroSpine, the Spine Society of Europe. It makes use of the generic MEMdoc documentation platform of the Institute for Evaluative Research in Orthopaedic Surgery at the University of Berne. The documentation of surgical spinal interventions with Spine Tango is far advanced and despite over 25,000 stored cases in the database, the overall representation of the participating countries is still low [32]. In the conservative sector, however, no comparable project currently exists. It does hence make sense to develop and implement a complementary system for documentation and evaluation of non-surgical spinal interventions and outcomes. With ‘Spine Tango conservative’ a first step has been taken in this direction. It remains in the hands of the community of practising conservative therapists to spread the use of the new instrument and develop it into its final version.

Acknowledgments We gratefully acknowledge the experts of the first round table: Norbert Boos, MD, MBA, Bogdan Radanov, MD, Florian Brunner, MD, PhD, Beat Wälchli, MD, DC. Furthermore, we would like to thank our international experts from stage two, John O'Dowd, MD and Margareta Nordin, PT, Dr. Sci. Last but not least we would like to thank all practitioners (Florian Brunner, MD, PhD, Daniel Meier, MD and Fredrik Granelli, DC), the team of physiotherapists at Balgrist University Hospital, Zurich (Evelyn Bärtschi, PT, Sibylle Früh, PT, Carolin Heitz, PT, MSc, Manuel Bischofberger, PT and Silvia Rauber, PT) and the osteopaths at the Center for Osteopathy Zurich (Marc Piske, CO and Hanspeter Stucki, CO) for providing us with patient treatment and patient data.

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