Hospital for Joint Diseases Participates in International Spine Registry Spine Tango after Successful Pilot Study

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Abstract

Spine Tango is currently the only international spine registry in existence. It was developed under the auspices of Eurospine, the Spine Society of Europe, and is hosted at the University of Bern, Switzerland. The HJD Spine Center successfully tested Spine Tango during a 3-month pilot study and has since expanded documentation activities to more surgeons. Workflow integration and dedicated research staff are key factors for such an endeavor. Participation enables benchmarking against national and international peers and outcome research and quality assurance of surgical and non-surgical treatments.

Spine Tango is the international spine registry of Eurospine, the Spine Society of Europe. It is developed, hosted, and administered by the Institute for Evaluative Research in Medicine at the University of Bern, Switzerland. The project was initiated in the year 2000, and first online versions of the Spine Tango questionnaires were available in 2002. The breakthrough of the project happened in 2005 with a drastic consolidation and reduction of the question catalogs on the surgery, staged-surgery, and follow-up forms and an introduction of paper versions of the formerly purely online questionnaires. At that time, a new generation of patient oriented outcome questionnaires for spinal treatments became available, and due to their conceptual approach, psychometric properties, and brevity, the so-called COMI (Core Outcome Measures Index) for back and neck patients was endorsed by Eurospine as the official outcome instrument of Spine Tango. The initial European focus of the project has long been extended since there is no other international spine registry existing until today, and many hospitals from countries outside Europe such as Australia, Brazil, Mexico, or the Middle East have joined the registry. The first US spine center with 11 surgeons became part of the Tango data collection effort in 2007 and has since contributed over 6,000 cases to the data pool, which does meanwhile have the respectable size of over 50,000 cases from over 50 centers worldwide.

In 2009, the first version of a documentation questionnaire for recording the non-surgical spinal treatments was made available within the framework of Spine Tango and the HJD Occupational and Industrial Orthopaedic Center (OIOC), a therapeutic unit for non-surgical spinal treatments with a focus on return to work is the first participant to collect data in this new part of the project since June 2010. In December 2009, the spine center at HJD started a 3-month pilot study with four spine surgeons to assess practicability and feasibility of documentation with Spine Tango in its routine care setting. The current article presents the chosen workflows at the HJD spine center, exemplary data analysis, and future outlooks for Spine Tango.

Materials and Methods

After IRB approval, the pilot group consisting of four spinal surgeons (JB, JS, MM, TP) with a focus on the degenerative spinal diseases set-out to document all their surgical interventions and the short-term follow-ups in the period from December 2009 to February 2010. Goal of the pilot
was not a scientific collection of clinical and outcome data but rather an assessment of the possibility to integrate the Spine Tango documentation with surgeon and patient based data capture into the daily clinical routines. The following questionnaires were used:

- Spine Tango surgery
- Spine Tango follow-up
- COMI back
- COMI neck
- Oswestry disability index (ODI)
- EuroQol 5-D (EQ-5D)

While a research coordinator took care of administering the patient forms (COMI, ODI, EQ-5D) during preadmission testing, the spine fellows were mainly responsible for completing the Spine Tango surgery forms. In the outpatient clinics, the surgeons themselves or their physician assistants completed the Spine Tango follow-up forms while patients documented their outcomes with the same instruments as preoperatively (i.e., COMI, ODI, and EQ-5D). After form completion, the research coordinator took care of data entry using the Spine Tango online interface or an optical mark reader (OMR) for scanning the forms. All involved in the process of data collection were individually instructed before the pilot. Data were entered into the US module of Spine Tango, a satellite server located in Florida which serves for anonymization of patient and user data so that only strictly non-identifiable datasets are forwarded and stored in the central database in Switzerland.²

Results
The main question of the pilot study was the possible rate of captured preoperative patient information in the preadmission testing situation, the compliance of surgeons and fellows in completing the surgery forms, the integration of physician or physician assistant based follow-ups in the outpatient clinics, and the postoperative capture of patient information in the same setting. Therefore, the responsible study nurse recorded all cases and the reasons for not recording those where information could not be gathered.

Figure 1 shows the individual results for the four participating surgeons and the overall results for the pilot group with respect to patient enrollment during preadmission testing from December 2009 to end of May 2010. The enrollment rate of 82%, defined as consented completion of all preoperative patient forms, is an excellent result and shows the well planned
workflows at HJD. Only 14 out of 225 patients were truly missed and other reasons for non-enrollment like language (5 patients) or refusal (15 patients) cannot easily be overcome. Hence, the potential enrollment rate was 90%.

Figure 2 shows the individual results for the four participating surgeons and the overall results for the pilot group with respect to completion of the Spine Tango surgery forms. At any given point in time in, there will be a certain number

Figure 4 Comparison of distribution of main pathologies between NYU HJD pilot study and international Spine Tango data pool (106 HJD cases are compared with 26,726 international cases).

Figure 5 Pre- to postoperative quality of life improvement in certain degenerative disease groups in NYU HJD patient sample. G1: disc herniation (N = 18, p = 0.05 for pre- to postop score), G2: spinal stenosis (N = 25, p < 0.001 for pre- to postop score), G3: disc herniation and spinal stenosis (N = 12, p = 0.11 for pre- to postop score), G4: other degenerative pathologies (N = 28, p < 0.001 for pre- to postop score).
of pending forms from hospitalized patients or forms that still need to be completed despite surgery having already happened. This applies to about 22% of forms in Figure 2, categories “Need to be completed” and “Pending (Need Discharge Info).”

Figure 3 shows the current rates of documented follow-ups and some special challenges that occur in the follow-up situation. For example, about 12% of patients had no appointment, and therefore forms can only be mailed to them or administered by phone. In some hospitals and depending on surgical spectrum, this patient group can make up 30%, which makes it difficult and expensive to achieve good follow-up documentation rates.

Figure 4 shows an example of the online statistical benchmarking possibilities where the surgical profile of a participant or department can be compared with the aggregated international data pool.

Figure 5 is an example of pre- and postoperative quality of life improvement in the HJD patient sample in four different spinal pathologies, as measured with the cost-utility measure EuroQol and plotted as box plots. The score ranges from -0.6 (quality of life worse than death), to 0 (quality of life equals death) to 1 (best possible quality of life).

**Discussion**

The current article reports the successful implementation of the Spine Tango registry at NYU HJD in the framework of a pilot phase and the following extension of participating surgeons as well as conversion of the documentation activities into routine clinical practice. First results of the pilot phase and benchmarking with the international Spine Tango data pool are presented.

Given the sophistication and maturity level of the Spine Tango software and instruments after 10 years of development, the main challenge for all participants is the integration of the new processes into the hospital’s routine workflows. This ideally happens in a pre-pilot planning phase where all involved are explained the general set-up of the Tango, where the desired level of documentation is discussed (e.g., physician based documentation only, with patient based documentation, with one or several outcome instruments per case, with one or several follow-ups per case), and where possible caveats of proposed workflows are identified. In order to properly do this, it takes expertise from both sides, for example, an experienced registry representative and one or several hospital staff members who oversee patient-physician, patient-nurse, or patient-administration interactions, the patients’ way through the treatment path and lines of communication and information exchange possibilities by means of hospital information systems. Given the fellowship based one-year presence of the Spine Tango project leader at HJD, there was extensive time for meetings and instructions sessions with all involved. This unusual situation led to an accordingly good preparation of the registry implementation which becomes visible in the presented results.

Figure 1 demonstrates that the large majority of patients that are asked for informed written consent and completion of quality of life questionnaires during preadmission testing agree to do so. Only a small percentage refuses participation. Further, only a small percentage of participants are missed. The use of validated English and Spanish translations for all patient questionnaires seems sufficient for reaching the large majority of patients. Additional languages add cost and complexity to the project and would most likely not increase the documentation rates to a justifiable extent.

Spine fellows are responsible for completion of the surgery forms in the HJD workflow setup, this for reasons of an unbiased documentation of surgical measures and complications. The literature describes the fact that surgeons are prone to overestimate the outcomes of their own surgeries and underestimate complications and their bothersomeness for the patient. Moreover, the fellows have an oversight about the postoperative course of the patient history until discharge, and hence the completion of the “Discharge” subform of the Spine Tango surgery questionnaire is also executed by the fellows. This solution proves to be extremely advantageous since many hospitals struggle with completion of this last part of the questionnaire. Delegated to, for example, residents on the ward who discharge the patient, forms often get lost or remain incomplete. Consequently, an important piece of information, namely discharge date and complications, measures taken to control them, and their status at discharge is missing. As result of the responsibility being in the hands of only one person, surgery forms can also remain in one place, for example, in the OR where the fellows check their forms regularly, complete those where the patients have meanwhile been discharged, and make them available for the supervising study nurse for data entry in the Tango database. Figure 2 shows that this solution has proven effective although a considerable number of forms still “Need to be completed” (light grey section), which means that surgery has occurred but the forms are still empty. One can hence derive an about 20% of cases being documented retrospectively. An increasing time distance from surgery to form completion may introduce a certain recall bias and should hence be avoided. With discipline and well planned processes, the surgeon based documentation can be achieved to the largest extent. The most successful Spine Tango participants reach a 98% documentation rate of their surgeries, not without investing into dedicated research staff with a full- or at least part-time assignment. The patient side is the true caveat of all documentation efforts. While a relatively small percentage of preoperative patient based assessments are lost for reasons of language, refusal, or being missed, the follow-up situation is more problematic: patient compliance is lower since the surgery is over and the patient may take the needs of the treatment team as less relevant, the interaction time with physician or physician assistant is much shorter, and research staff is less frequently available. Moreover, as previously mentioned, patients who
Tango application still remains a separate system outside the hospitals clinic information systems (CIS). To avoid the resulting change in media for conducting quality assurance and outcome research, an implementation of the Spine Tango set of questionnaires into the CIS is a desirable and elegant solution. It also helps increasing the documentation compliance by making form completion a condition for case closure, and it can reduce documentation burden by pre-filling fields where the information is readily available in the CIS. The new web-service feature of the Spine Tango 2011 software release allows exporting the content and validation scripts of the forms for CIS implementation and later pushing CIS data into the Spine Tango international database for feeding the benchmark and being able to make statistical comparisons of own data against the pool. The largest CIS providers should be contacted by their own customers interested in Spine Tango documentation for exploring possibilities and costs of this option.

Disclosure Statement

None of the authors have a financial or proprietary interest in the subject matter or materials discussed, including, but not limited to, employment, consultancies, stock ownership, honoraria, and paid expert testimony.

References


Outlook

Once the ST documentation has become a clinical routine, the Spine Tango add-on question generator may be used for piggybacking in-house studies with additional hypothesis driven add-on questions that are used for a certain time according to study protocol. That way, prospective studies can be conducted with little additional efforts and nearly no change in the documentation workflows. If desired, other hospitals can program the same add-on questions and the study can be conducted in a multicenter setup. First results of such studies are already available in the literature.6,7

While the number of participants is steadily increasing, the documentation forms are revised to even more sophisticated levels, and the patient and user privacy concerns are met with the highest standards of encryption. The Spine Tango application still remains a separate system outside the strain for human and financial resources. Hence, the 80% follow-up rate that NASS currently demands for generating level I evidence in prognostic observational studies is a challenge and needs a study-like organizational set-up which goes beyond the efforts of outcome documentation in the framework of routine clinical processes without additional dedicated human resources.

A documentation system has to offer easy-to-handle tools for making immediate use of the collected data. The Spine Tango online statistical interface allows frequency queries of own data, the data pool, and direct comparisons as shown in Figure 4. Subgroups can be created with conditions like patient sex, age, time intervals, and all outcomes of all parameters (e.g., all male patients older than age 40 with degenerative spinal disease and disc protrusion that were operated in 2009). For this patient group, all parameters of the Tango questionnaire and the respective follow-up information can be queried and compared to the international pool. Soon, country specific benchmarks will additionally become available for the United States, Germany, and Switzerland where the currently largest patient samples are documented. The Spine Tango export tools allow the users to download their own data at any time for more extensive data analysis in appropriate software packages. Finally, larger anonymized datasets can be acquired from the Spine Tango committee for hypothesis driven outcome studies that make use of the complete US national data pool or even the international one.

References