Symposium
Modern concepts in treatment of chronic low back pain in secondary care
Thursday, 20 April 2017
Sint Maartenskliniek

Programme
## Index

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme</td>
<td>4</td>
</tr>
<tr>
<td>Sponsor acknowledgement</td>
<td>6</td>
</tr>
<tr>
<td>Word of welcome</td>
<td>7</td>
</tr>
<tr>
<td>Institutional spine registry in Sint Maartenskliniek</td>
<td>8</td>
</tr>
<tr>
<td><strong>Morning session - part 1</strong></td>
<td></td>
</tr>
<tr>
<td>Traditional paradigm in CLBP treatment</td>
<td>10</td>
</tr>
<tr>
<td><strong>Morning session - part 2</strong></td>
<td></td>
</tr>
<tr>
<td>Paradigm shift 1: from “one size fits all?” to “patient profiling”</td>
<td>11</td>
</tr>
<tr>
<td>Identification of patient profiles based on treatment outcomes</td>
<td></td>
</tr>
<tr>
<td>Defining success &amp; failure &amp; decision tooling</td>
<td></td>
</tr>
<tr>
<td>Identification of patient profiles based on risk stratification</td>
<td>12</td>
</tr>
<tr>
<td>Risk stratification - universal language</td>
<td></td>
</tr>
<tr>
<td>From trials to routine outcomes measurement in daily practice:</td>
<td>14</td>
</tr>
<tr>
<td>Where do we stand?</td>
<td></td>
</tr>
<tr>
<td>The scene in Nordic countries. Spine registries &amp; 4 NIG studies</td>
<td></td>
</tr>
<tr>
<td><strong>Afternoon session</strong></td>
<td></td>
</tr>
<tr>
<td>Paradigm shift 2: from stepped care to personalised modelling</td>
<td>16</td>
</tr>
<tr>
<td>and prediction of outcomes</td>
<td></td>
</tr>
<tr>
<td>Value-based healthcare in spine care</td>
<td></td>
</tr>
<tr>
<td>Methodologies: Next generation outcome measurement:</td>
<td>17</td>
</tr>
<tr>
<td>A future for PROMIS</td>
<td></td>
</tr>
<tr>
<td>Future diagnostic modalities: Imaging and biomarkers to personalise care</td>
<td>18</td>
</tr>
<tr>
<td>Putting it all together: Personalized spine care (consortium)</td>
<td>20</td>
</tr>
</tbody>
</table>

<sup>© DePuy Synthes Companies, 2015  DSEM/SPN/0215/0286</sup>

---

**The Expedium® Spine System**

DePuy Synthes offers world-class education, delivered by leading spinal professionals. Our training programs focus on your needs and advancing patient care.

Join a group of leading professionals who trust our Expedium Spine System.

**EXPECT EXTRAORDINARY.**
Programme

Chairman: Marinus de Kleuver

09.00-09.30 Welcome & registration

09.30-11.00 Morning session - part 1
09.30 Opening  
Marinus de Kleuver, Nijmegen (NL)
09.35 Welcome  
Mark van Houdenhoven (CEO SMK, NL) & Marinus de Kleuver

Setting the scene
Institutional spine registry SMK
09.40 Case presentation 1 'NDT - straightforward'  
Marinus de Kleuver, Nijmegen (NL)
09.50 Case presentation 2 'NDT - controversial'  
Philip Horsting, Nijmegen (NL)

Traditional paradigm in CLBP treatment
10.00 Surgery and combined physical and psychological treatment as competitive treatment options for all patients with longstanding LBP: "one size fits all?"  
Randomised controlled trials in low back pain: 10 year follow up head to head comparison of surgery vs CPP: What have we learnt?  
Jeremy Fairbank, Oxford (GB)

10.30-11.00 Coffee break

11.00-12.30 Morning session - part 2
Paradigm shift 1: from "one size fits all?" to "patient profiling"
11.00 Identification of patient profiles based on treatment outcomes  
Defining success & failure & decision tooling  
Raymond Ostelo, Amsterdam (NL)
11.30 Identification of patient profiles based on risk stratification  
Risk stratification - universal language  
Steven Glassman, Louisville (US)

From trials to routine outcomes measurement in daily practice: Where do we stand?
12.00 The scene in Nordic countries  
Spine registries & 4 NIG studies  
Peter Fritzell, Jönköping (SE)
12.30 Case presentation 3 'live surgery'  
Robert Jan Kroese, Nijmegen (NL)

12.45-14.00 Lunch - live surgery - Eat & Interact  
Maarten Spruit, Nijmegen (NL) & Jan van Loon, Nijmegen (NL)  
Moderators: Robert Jan Kroese & Marinus de Kleuver

14.00-16.00 Afternoon session
14.00 Discussion - What is considered a failure in relation to surgery?  
Outcomes vs complications and re-operations

Paradigm shift 2: from stepped care to personalised modelling and prediction of outcomes
14.20 Value-based healthcare in spine care  
Steven Glassman, Louisville (US)
14.40 Methodologies: Next generation outcome measurement: A future for PROMIS  
Caroline Terwee, Amsterdam (NL)
15.10 Future diagnostic modalities: Imaging and biomarkers to personalise care  
Dino Samartzis, Hong Kong (HK)
15.40 Putting it all together: Personalized spine care (consortium)  
Marinus de Kleuver, Nijmegen (NL)

16.00 Closure & reception
It is a great pleasure to welcome you to the spine symposium ‘Modern concepts in treatment of chronic low back pain in secondary care’, which is organized at the Sint Maartenskliniek Nijmegen, The Netherlands.

The spine specialists of Sint Maartenskliniek and Radboudumc composed an attractive and interactive programme led by an international respected faculty, for all medical professionals and researchers in the field of surgical and non-surgical care for patients with chronic low back pain (CLBP; i.e. chronic degenerative lumbar spinal disorders).

A programme which will offer you, through keynote lectures based on case presentations and a live surgery demonstration, insights in the methodology of outcomes monitoring and decision-tooling – i.e. getting insight in which patients benefit from or fail to respond to spine surgery or non-surgical treatments. These concepts may lead to paradigm shifts in the diagnostics and treatment of CLBP; from ‘one size fits all’ to ‘prognostic patient profiles’ and from ‘stepped care’ to ‘parallel and personalized care’. These paradigm shifts contribute to improvements in the quality of spine care delivered and ultimately to improved value-based spine care.

We feel privileged that medical professionals with different backgrounds, researchers, and policy advisors, from both the Netherlands and abroad will be attending.

The symposium will be in the English language. We expect animated discussions and ideas to further develop.

The spine specialists from the spine unit of Sint Maartenskliniek and Radboudumc.

Scan the QR code to view the thesis ‘Towards a paradigm shift in chronic low back pain?’ by M.L. van Hooff online.

For more information about this symposium, go to: www.maartenskliniek.nl/spinesymposium
Systematic and continuous patient-related outcome monitoring in patients with spine-related disorders is important to assess future value (outcomes relative to cost) of care delivered and future reimbursement. Standardization of patient-related (i.e. clinical and patient-reported) outcomes and continuous outcome monitoring of outcome measures covering relevant domains from a patient’s perspective is needed. Outcome monitoring through a registry is expected to contribute to quality improvement. An outcome registry is an organized system that uses observational study methods and could be used to describe care patterns, including appropriateness of care and disparities in the delivery of care. Treatments for patients with chronic low back pain (CLBP) are still controversial. CLBP is a heterogeneous condition that lacks diagnostic clarity. Registry data could be used to understand variations in treatment and outcomes, and to identify and select subgroups in the heterogeneous CLBP population with a probability of successful or poor outcome. We recently performed a systematic review that showed a lack of evidence that outcome registries actually have an impact on the quality of spine care. To improve the quality of evidence we presented some recommendations. These recommendations concern the organization and methodology of a (spine) outcome registry, the outcomes and related contributing factors to be registered, analysis and reporting of results and practical issues are mentioned. To improve the institutional quality of surgical and non-surgical care the spine unit of Sint Maartenskliniek started a spine registry. Since May 2012 all new patients are web-based registered before first consultation and treated patients are systematically followed over time.

The institutional spine registry of Sint Maartenskliniek is the common thread in the (case) presentations of the spine unit during the symposium. This registry is the fundament for monitoring the quality of care delivered on a patient group basis and for the individual patient, for research purposes, and for the Nijmegen Decision Tool for Chronic Low Back Pain (NDT-CLBP). The NDT-CLBP fulfills the (inter-)national recommendation to develop a classification system (i.e. prognostic model), based on patient profiles consisting of biomedical and psychosocial indicators that are thought to influence the outcomes of these interventions. This system could be used to triage patients with CLBP to surgical and non-surgical secondary care. The NDT-CLBP is developed using a literature review and a modified Delphi study among CLBP experts from various disciplines and has been implemented in the Dutch interface of SweSpine, i.e. spine outcome registry of Sweden. It currently consists of a web-based patient-reported screening questionnaire, in which indicators predicting treatment outcome or a persistence of back pain complaints are assessed, and includes systematic monitoring of outcomes after treatment. The institutional registry is connected to the national spine registry, the Dutch Spine Surgery Registry (DSSR) that follows the design and structure of SweSpine.

The ultimate purpose of the NDT-CLBP is to reliably identify, in two phases, patients benefitting most from certain interventions. The first phase is aimed at identifying prognostic patient profiles, based on patient-reported characteristics predicting either ‘response’ or ‘non-response’ to treatment, to enhance timely patient triage to a spine surgeon or a non-surgical specialist for consultation. In the second phase, based on further diagnostics (e.g. imaging), the profiles will be refined to include both the indicators from the first phase as well as from the diagnostic phase, to reliably predict the right treatment for each patient. The current NDT-CLBP is a ‘proof-of-concept’ of the first phase, which will be implemented in different hospitals to further validate and to study its impact on the quality of delivered spine care. Ultimately, the aim of the NDT-CLBP is to personalize spine care and to lead to an efficient use of scarce healthcare resources as well as improved treatment outcomes that in future might lead to a reduced global burden of low back pain.

Institutional spine registry in Sint Maartenskliniek

Miranda van Hooff, Nijmegen (NL)
Surgery and combined physical and psychological treatment as competitive treatment options for all patients with longstanding LBP: “one size fits all?”

Randomised controlled trials in low back pain: 10 year follow up head to head comparison of surgery vs CPP: What have we learnt?

I shall consider aspects of the RCT’s of subjects with chronic back pain that have compared spinal surgery (spinal fusion and disc replacement) with CPP or usual care physiotherapy.

- Admission criteria and stratification
  » Seems to be similar but not identical for these studies
  » How important is imaging and pathology for stratification?
- Outcome measures
- 10 year follow-up data
- Treatment paradigms
  » Why do we have similar results from surgery based a hypothesis that movement is painful and one which encourages movement?
  » How much responsibility will the patient take for their own therapy?
  » Importance of pain control - I shall discuss a high frequency (10Hz SCS) trial
  » Response to treatment is the main basis for stratification

The use of Patient Reported Outcomes (PROs) in clinical research is gaining ever more attention but various challenges exist. First of all it needs to be established what domains are important and need to be measured and how they should be measured. Core Outcome Sets may be very useful to address this issue. During this presentation various COSs relevant for LBP will be discussed. A second issue concerns what is the best estimate of the outcome (or treatment success) and how to interpret this best estimate. Two different concepts to define treatment success are commonly used: relative change values and absolute values. As always, both methods have their PROs and CONs but, in general, both don’t take the context into account. The Smallest Worthwhile Effect is a method that aims to overcome this shortcoming. Also it is important to realize that all these methods focus on TREATMENT SUCCES and the question is how that relates to estimates for TREATMENT FAILURE. In this presentation these methods will be discussed and examples of how they can be applied in clinical research will be presented.
Identification of patient profiles based on risk stratification
Risk stratification - universal language

Steven Glassman, Louisville (US)

Risk stratification is a term that has permeated the literature over the last several years. A concept, identifying those factors which predict complications or outcomes, is simple and intuitive. The application is much more difficult. This lecture examines the use of risk stratification techniques in the management of lumbar degenerative disease.
The Scene in Nordic countries
Spine registries & 4NIG studies

Peter Fritzell, Jönköping (SE)

Registers in the Nordic countries. National spine registers have been used in Sweden-Denmark and Norway during the last 20 – 9 years. The coverage, completeness and FU is high, in Swespine 95-75-75 percent respectively.

The three registers are following the ICHOM-recommendations, e.g. have agreed on using a similar core data set in order to be able conduct relevant comparisons/bench-marking. However, it should also be important to account for possible differences in patient populations at base-line, e.g. to include case-mix adjustments.

Three ongoing register based projects;
1. Dialogue support: Swespine has developed an instrument that can be used in a clinical situation, where case-mix adjusted predictions can be presented online. This can facilitate communication between the surgeon and the patient, and help reaching a relevant decision whether to operate or not.

2. Sveus project: In order to develop value based follow up systems, a Swedish national cooperative register study was conducted. In all 7 regions were engaged, and five national registries were used to capture data from 12 months before surgery for LDH and LSS, to 24 months after surgery (the whole period = the Index Episode). Case-mix adjusted results indicated that socio-economic factors played a major role in patient reported outcome. The most important predictors of worse outcome were; smoking-educational level-born outside EU.

Patient reported outcome was not associated with process measures as indoor stay, time on sick leave, consumption of primary care. The resource utilization/costs was primarily associated with the organization of the health care system, the processes.

The conclusion was to recommend analyzing/securing the; resource utilization, coverage-completeness-FU in Swespine, case-mix adjustment when comparing outcome, the whole process linked to a certain disease (the Index Episode), and legal conditions to simplify the usage of registries in FU of value based outcome.

3. With the results from the ICHOM cooperation (creation of a core data set) and the experiences from the Dialogue and Sveus projects presented above, the 4NIG (Four Nation ICHOM Group; Sweden-Denmark-Norway-The Netherlands) project was initiated in 2013. The idea is, using the recommended core data set, to pooling data from three Scandinavian countries with similar socio-economic conditions and similar data capturing techniques in a common database, and to compare both observed (un-adjusted) and case-mix analyzed (adjusted) outcome one year after spine surgery for LDH, LSS and CLBP. The Dutch colleagues will compare these results with results presented in RCTs found in the literature in order to evaluate validity.

All three registers are collecting data at Baseline-Surgery-1 year FU. At Baseline for example socio-demographic information is captured together with Pain (NRS), Function (ODI) and quality of life (EQ5D). The surgeons' role in data capturing is limited. ODI is used as the primary outcome measure.

Some preliminary results; It seems as the outcome is rather similar between the three countries, irrespectively of surgical technique and irrespectively of case-mix adjustment. This could indicate that the socio-economic conditions are similar. The surgical incidence differ substantially.

Lessons learned so far: In order to trust outcome comparisons it should be important to use the same core data set, e.g. measure outcome in the same way. Equally important should be to adjust for relevant patient characteristics at baseline. It is possible to develop decision tools based on register data for use in a clinical situation. It is important to analyze different processes linked to a condition/disease, as these could be the main cause for resource utilization and costs. Legal issues are – an issue.
Value-based spine care has become an important goal for all providers. The assessment of value is based on principles of healthcare economics which are unfamiliar to most spine care providers. This talk examines and basics of healthcare economics and the transition from patient recorded outcomes to value-based spine care.

Patient Reported Outcomes Measures (PROMs) are essential in the management of low back pain (LBP) but their routine use is hampered because they are considered too time consuming, often include items that are not relevant for all patients, and scores are not comparable across PROMs.

A promising alternative is PROMIS, a new innovative generic assessment system for measuring patient-reported health. PROMIS consists of item banks, which are large sets of questions that all measure the same construct (e.g. physical functioning). An item bank can be administered through Computerized Adaptive Testing (CAT) to obtain a tailored measurement for each individual patient. In a CAT, items are selected from the item bank, based on the person’s responses to previous items. With CAT, patients get more relevant questions and need to complete only on average 3-7 questions to get a reliable score. CATs combine the advantages of disease-specific instruments and generic instruments. They cover the whole construct and can be used across patient populations with high levels of reliability and responsiveness. PROMIS CATs have the potential to replace disease-specific traditional PROMs. In addition, CATs offer opportunities for answering new research questions through momentary assessments using affordable smart technologies in research and clinical practice.

It would be a major improvement if in the near future clinicians and researchers would all use the same outcome measures. This is a big challenge, which requires head-to-head comparisons of PROMIS CATs with the traditional PROMs and the willingness to let go of traditions and personal preferences.
Low back pain is the world’s most disabling condition. Spine degeneration is believed to be related to such pain but is not always synonymous. Management outcomes for low back pain have not always been satisfactory. The past decade has seen a rise of an increased understanding of spinal phenotypes on imaging, blood markers and omics technology that could shed some light as to why the spine degenerates, who may be more likely to have pain, predict management outcomes, and potentially improve clinical decision making. The following talk will touch upon such issues and describe their role towards a more personalized approach to the management of low back pain.
Background:
Current clinical decision tools - not robust to guide LBP treatment
• Improper diagnoses,
• Generalized management algorithms
• Unsuitable therapeutics
• Unsatisfactory outcomes
• Increased health-care costs to patient and provider. Not value based

A personalized approach to understand clinical and systemic profiles is needed!
• Improve screening and diagnosis
• Enhance clinical decision-making
• Tailor-make... precision... LBP care. From one size fits all, to personalised care
• Value based

Patient First? Personalised optimisation of the pre-operative decision proces:
Currently in many health care systems around the world benchmarking of outcome and process indicators is being performed by hospitals, but often also by stakeholders such as regulators and payers (e.g. insurance companies). The aim is to inform patients to allow shared decision making, to reduce risks and improve outcomes.
That will require personalised prediction of the a) risk and b) benefits.

1. Prediction modelling: Risk vs benefits
   1a. prediction modelling for the risk of complications:
       Models include SpineSage, NSQIP surgical risk calculator, and the Seattle based S3 (Seattle Spine Score) can be used.

   1b. prediction modelling for the benefits, i.e. functional outcome
       Modelling for Chronic Low Back Pain, based on 48 Patient reported indicators (within 5 domains: Pain, Somatic, Psychosocial, Sociodemographic, Functioning & QoL)

Preliminary data, based on decision modelling, suggests that based on these indicators for certain patients (around 10%) with Chronic Low Back Pain we can predict positive outcome (i.e. response) to surgery, as defined by predicting an ODI < 22 at 1 year follow-up.

Whereas for certain patients (also about 10%) with Chronic Low Back Pain this modelling suggests that based on these indicators we can predict a negative outcome (i.e. non-response) to surgery, as defined by predicting an ODI > 40 at 1 year follow-up. These patients may understand that surgery is not a realistic option for them.

It is important to realise that for most patients we cannot yet predict outcome accurately. Furthermore all current models have limited external validity (generisability, applicability in other settings), and explain only a limited part of the variance.

The next step involves improving our diagnostic capabilities, with imaging and biomarkers, ultimately leading to the right intervention for the right patient.
It's not just what we make, it's what we make possible.

The Bendini® spinal rod bending system expedites manual rod manipulation via computer-assisted bend instructions. This is designed to benefit both you and your patients with:

- **Decreased O.R. Time**
  Predictable, reproducible rod bending helps surgeons create rods which often require a single pass.

- **Restored Alignment**
  Surgeon driven menus enable rapid intraoperative alignment assessment and rod customization. Coronal and Sagittal design tools help guide surgeons to achieve alignment goals prior to exiting the O.R.

- **Minimized Forces**
  Implant-specific rods are designed to minimize forces on the screw bone interface and prevent unnecessarily preloading of the construct.

**EFFICIENT SPINAL ROD BENDING DESIGNED TO ACHIEVE ALIGNMENT**

©2017 NuVasive, Inc. All rights reserved. NuVasive, Bendini, and IGA are registered trademarks of NuVasive, Inc.
PLUG AND PLAY
COMPATIBLE
REPRODUCIBLE
PRECISION

Your innovation partner in thermal bone ablation

Meet us at the booth or request more information at
spine.europe@medtronic.com

UC201705459EE ©2016 Medtronic Inc. All Rights Reserved.