TLIF versus PLIF in spondylolisthesis

Valorisation

The historical study described in **chapter 2** showed that spinal diseases and injuries have been known since the common era, but treatment was limited due the lack of surgical possibilities. Due to new discoveries, great steps forward have been made over the past 100 years in the development of lumbar interbody fusion surgery, culminating in exceptional growth and possibilities in instrumented spinal fusion procedures today. Low back pain, with or without leg pain, is a common complaint in the general population. It causes disability and other health care problems in the work force, and consequently poses a large economic burden on society. In The Netherlands, spine complaints are responsible for 25% of all health care costs for musculoskeletal diseases [1]. Lifetime prevalence of low back pain is 70%. The prevalence of accompanying leg pain varies greatly with a range of 1-43% [2]. In a number of cases these complaints are caused by lumbar spondylolisthesis (incidence 6%) [3]. Most often, this leg pain is caused by compression and/or stretch of neurogenic structures. If conservative treatment fails, an instrumented spinal fusion procedure can be considered. In case of lumbar spondylolisthesis, the aim of surgery is decompressing neurogenic structures and preventing progression of the spondylolisthesis by additional lumbar pedicle screw fixation and spinal fusion using interbody cage(s). Several spinal fusion techniques are available. Of these, transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF) are most frequently performed in The Netherlands and extensively described in this thesis. The TLIF procedure consists of placement of one cage in the intervertebral space using a unilateral approach. The PLIF procedure consists of placement two identical cages bilaterally in the intervertebral space using a bilateral approach. As described in **chapter 3** the clinical effectiveness of both techniques is similar. We found TLIF to be superior over PLIF considering complication rate, duration of surgery and estimated overall blood loss. A shorter duration of surgery was also confirmed in our retrospective study (**chapter 4**). Current guidelines do not recommend neurosurgeons and/or orthopedic surgeons which surgical technique is preferred [4]. As a result, the choice of technique is largely based on surgeon's experience and preference. As described in **chapter 5** evidence on the most cost-effective surgical treatment is lacking. With a steep increase in the number of instrumented spinal fusion procedures there is a need to develop evidence based treatment recommendations. For that, both clinical and cost-effectiveness data are needed. Each year approximately 100 single level TLIF and PLIF procedures for patients with spondylolisthesis are executed in the province of Limburg alone. By extrapolating this number based on population density, approximately 1.500 such procedures are carried out each year in The Netherlands [5,6]. This number will increase in the near future; in the US, between 1990 and 2011 the number of instrumented spinal procedures has increased 5 fold, the national bill for instrumented spinal fusion has increased 7.9-fold (between 1998 and 2008) and industry sales rised from $225 million in 1994 to $6.6 billion in 2011 (a 30-fold increase) [7–9]. With an aging population this number will only increase further. For these reasons, the Dutch

Neurosurgical and Orthopedic Associations (NVvN and NOV), as well as the Dutch Spine Society (DSS), declared 'instrumented spinal fusion' a point of particular interest.

This, with the findings described in **chapter 2-5**, led to the development of the LIFT study, as described in **chapter 6**. This study proposes to analyse in a high quality design (multicentre prospective randomized controlled trial) effectiveness and cost-effectiveness of the TLIF technique compared to PLIF technique for patients with leg pain caused by single level lumbar spondylolisthesis. This study will be the first to fill the current knowledge gap between daily practice and (societal) need for evidence based medicine for all surgeons specialized in complex spine surgery.

For patients with spondylolisthesis who are eligible for single level lumbar interbody fusion (LIF) surgery through a posterior approach, participating in this study does not pose any extra risks since both techniques are standard practice. The burden for patients participating in this trial is low. They are asked to fill out web based questionnaires concerning Patient Related Outcome Measurements (PROMS) (HADS, ODI, EQ-5D-5L, SF-36, VAS) at five fixed time-points (pre-operatively, 3, 6, 12 and 24 months postoperatively). To determine cost effectiveness productivity related costs (iPCQ) and medical costs (iMCQ)) are recorded additionally at the five time-points.

The proposed RCT will lead to objective (cost) effectiveness results and conclusions, which can be implemented in current health care. With the results of this study, current guidelines will be adapted, thereby contributing to future provision of optimal, efficient, evidence-based treatments for patients with lumbar spondylolisthesis. Since surgeons specialized in complex spine surgery already perform both techniques, which are of similar technical difficulty, there will be limited education required to implement the most effective technique. Both techniques are covered by basic health insurance (same treatment code), therefore we do not expect that restructuring of financing is required before further implementation can proceed. The principal investigator and co-investigators have a broad network in the Netherlands and are (board)members of DSS, NOV and/or NVvN and are in the lead to influence the adaptation of current national guidelines, and implementation of the preferred technique. An assessment-oriented process evaluation will be used to gauge how well the intervention is implemented. By performing both an economic evaluation and a model-based simulation study to project the results nation-wide and over a longer time horizon, the relevance of this study will be high. In case our hypothesis is confirmed, this could lead to a substantial saving to Dutch society of at least 3,2 million Euros annually. Due to shorter surgical time, shorter hospital duration and less expected complications, hospital costs for TLIF are expected to be lower. We additionally expect TLIF patients to recover quicker, leading to lower societal

costs compared to PLIF. Reduction of hospital stay and societal costs will probably lead to an average saving of €3.179 per patient.

Also, the LIFT study should set an example of collection patient data in a standardized method, to enable physicians insight in the effectivity of their treatments. So hopefully in near future it is easier to obtain data and perform reliable retrospective research.

The execution of the LIFT study is in the capable hands of my fellow PhD student, I Caelers, MD. The inclusion started on September 1st 2017. Results of the LIFT study are expected in 2020.

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