Minimally invasive surgery for lumbar spinal stenosis

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Recent trends in spine surgery, such as endoscopic and other “micro” techniques, promise less invasive procedures with better outcomes compared to conventional open techniques for decompressing nerves. Minimally invasive surgery (MIS), highly promoted by commercial parties for instrumented cases in particular, is popular with patients and physicians [1]. Widespread adoption of these techniques should always be preceded by careful evaluation to ensure safety and determine added value of such so-called surgical innovation [2, 3]. Actual and controversial topics concerning MIS for lumbar spinal stenosis (LSS) were recently addressed in high-quality studies: open laminectomy versus microdecompression by Nerland et al. and decompression versus interspinous process implant by our group [4, 5]. In some way, the opposite of MIS was addressed in a recent landmark study by Försth et al.; does decompression versus decompression plus instrumented fusion for LSS yield better outcomes [6]? The three studies address very relevant issues of the neurosurgical daily practice and will be discussed hereafter.

Open laminectomy versus microdecompression

Nerland and colleagues’ study compares the “traditional” surgical treatment for spinal stenosis, open laminectomy, with a newer and less invasive alternative technique, the

microdecompression [4]. Patients with a central stenosis of the lumbar spine at one or two lumbar levels underwent either an open laminectomy with resection of the spinous process, laminae and medial aspects of the facet joints, or a microdecompression. In a microdecompression, performed through a smaller skin incision with a bilateral or unilateral approach, the spinous process and the supraspinous and interspinous ligaments are left intact.

The authors analyze data from a large, well-maintained and comprehensive national registry in Norway (the Norwegian Registry for Spine Surgery, NORspine). Thirty six out of 40 centers performing lumbar spine surgery in Norway record data prospectively in NORspine, making it a one of the unique national resource for spine research. Nerland and colleagues identified 885 eligible patients (out of 2745 screened) of whom 81 % completed the 1-year follow-up.

Open laminectomy and microdecompression were associated with similar and statistically equivalent improvements in Oswestry disability scores and quality of life (EuroQol EQ-5D) at 1-year follow-up. Furthermore, the techniques did not differ in older people and obese patients in predefined subgroup analyses. The number of patients with complications was higher in the open laminectomy group (15.0 vs. 9.8 %, $P = 0.018$), but this difference did not hold after propensity matching ($P = 0.23$). Patients in the microdecompression group had shorter hospital stays, both for single-level decompression (difference 1.5 days, 95 % confidence interval 1.7–2.6, $P < 0.001$) and two-level decompression (0.8 days, 1.0–2.2, $P = 0.003$).

The authors concluded that microdecompression is the treatment of choice for patients with stenosis of the lumbar spine for the technique shows good clinical results, equal to open laminectomy at 1-year follow-up. Theoretically,

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microdecompression may also induce less postoperative instability and thus reduce the need for later spinal instrumentation. Furthermore, microdecompression is associated with a beneficial risk profile and a significantly shorter hospital stay. It is even questionable whether patients with large bony decompressions really do need a longer hospital stay than those requiring less invasive surgery. When a provider switches to microdecompression as the preferred option, the mindset also shifts into the “less is better” paradigm: Patients will be admitted on the day of surgery instead of the day before, and discharged the next day instead of 2 days later.

Interspinous process devices versus microdecompression

Spinal implants are widely used for different indications, ranging from indisputable indications such as reconstruction of the destabilized spine by trauma and reconstruction after surgical resection of vertebral tumors, to less clear reasons such as stabilization for degenerative spinal conditions. Most implants are used for degenerative spinal diseases, one of which is LSS. The reported successful clinical outcome after bony decompression, the gold standard treatment, is only 64 % and many patients remain to have associated low back pain [5, 7–9]. In an effort to improve clinical outcome, a French group introduced a new non-rigid fixation [interspinous process devices (IPDs)] for patients with LSS and associated back pain in 1984: the Wallis system [10–12].

The Wallis system implants were tested for durability in cadaveric studies and were first implanted in humans in 1986 [11]. The results of these first procedures were retrospectively studied. Only after this period was patients included in a (non-comparative) prospective study, during which the device was implanted in over 300 patients. The study showed good recovery in 60 % of patients [12]. After this study, commercial development of the system was started. While the research group was planning to perform a randomized controlled trial (RCT), such a prospective comparative study of this implant is not available in Pubmed. After the introduction of this implant by Senegas, the development of other IPDs followed, such as Minns, X-stop and Coflex [13–16]. Cadaveric studies did not show any biomechanical difference between the various IPDs, and they were therefore considered as interchangeable, although differences in clinical effectiveness were not investigated [15].

After introduction of these devices, various studies were conducted to test the effectiveness and safety of IPD treatment for LSS. However, most of these studies did not compare the results with other interventions, and most did

not have prospective study designs [17]. It took 30 years (from 1984 until 2013) until two prospective studies were published that compared IPD treatment with conventional (surgical) care [5, 18, 19]. These studies showed that treatment with IPD was not superior compared to bony decompression without implants and that IPD treatment resulted in a higher reoperation rate. A third study was terminated because of the high number of reoperations (complications) in the experimental (IPD) group [20].

The problem of lacking evidence for IPD use extends beyond LSS. Nowadays there are multiple questionable indications for implantation of IPDs: Some are used as stand-alone for LSS, others as adjuvant to surgical bony decompression for LSS in the hope to decrease back pain, and yet others to prevent disease at adjacent lumbar segments. For these indications, IPDs remain in use without any evidence of treatment benefit. Furthermore, the lack of evidence for treatment of LSS extends beyond IPDs. Before the introduction of IPDs, lumbar spines that were “destabilized” after LSS were frequently rigidly stabilized by pedicle screws, and since the mid-nineties of the last century vertebral interbody cages were added to this process [21–23]. However, pedicle screws and discal interbody cages, whose use is widespread for LSS, were introduced without any evidence of added value compared with conventional surgical decompression without implants, or even any evidence of incidence of spinal instability [24–26].

Thirty years after the first introduction of IPDs for LSS, it is now clear that there is no justification for treating LSS patients with IPDs. Although precise numbers about the number of implanted IPDs are not available, at least three hundred thousand patients have been implanted with these devices since their introduction [27]. How was it possible that patients were not protected from these harmful devices and society from the use of these costly implants by regulations or any other measurements?

Decompression versus decompression with instrumented fusion

While the use of surgical decompression alone to treat lumbar spinal stenosis, as caused by degenerative facet-joint arthrosis, has declined slightly in recent years, the use of a combined procedure of decompression and instrumented fusion has increased dramatically [1]. This practice is not supported through scientific data, while evidence supporting fusion in degenerative spondylolisthesis (slip of two adjacent vertebra), intuitively associated with progressive postsurgical spinal “instability”, is lacking as well [28, 29]. Besides the paucity of data reporting a clear beneficial effect of instrumented fusion, these “advanced”

techniques are associated with an almost threefold risk of life-threatening complications. Furthermore, the societal burden of lumbar stenosis surgery will explode once instrumented fusion becomes standard of care due to prolonged surgery-/hospital admission times and use of titanium implants [1]. Nevertheless, 96 % of surgically treated patients with degenerative spondylolisthesis in the USA undergo instrumented fusion [30]. This trend, albeit perhaps to a lesser extent, is likely to extend to other Western countries.

Försth and colleagues compared in their recent study the “classical” standard surgical bony decompression for lumbar stenosis with elaborate techniques combining bony decompression with instrumented fusion [6]. In the Swedish Spinal Stenosis Study (SSSS) the authors included one- or two-level lumbar stenosis patients with spondylolisthesis and patients without spondylolisthesis. Overt spinal instability, as can be demonstrated by flexion–extension radiography, was not involved. The authors randomly assigned 247 patients to undergo either decompression surgery alone or decompression surgery plus fusion surgery with randomization stratified according to the presence or absence of preoperative degenerative spondylolisthesis.

There was no significant difference in Oswestry disability scores at 2 years ($P = 0.24$) or in the results of a 6-min walk test (405 m in the decompression-alone group, 397 m in the fusion group, $P = 0.72$), irrespective of the presence of a spondylolisthesis. The results of these clinical outcomes remained unchanged for a follow-up of 5 years in available cases. The mean length of hospitalization was 7.4 days in the fusion group and 4.1 days in the decompression-alone group ($P < 0.001$). As expected, surgical costs were higher in the fusion group compared to the decompression-alone group. During a mean follow-up of 6.5 years, additional lumbar spine surgery was performed in 22 % of the patients in the fusion group and in 21 % of those in the decompression-alone group.

This study, in concordance with the earlier large scale observational cohort study of the SweSpine Register, demonstrates that treatment for classical lumbar stenosis without instability should be limited to decompression alone [31]. Decompression with instrumented fusion was associated with higher costs but not with greater clinical benefits on any outcome in this sufficiently powered RCT. Additional fusion should be withheld and restricted to spinal destruction by trauma, tumors, infections or congenital spondylolisthesis, adult scoliotic and postsurgical deformities, or neuroforamen stenosis with compressed exiting nerves caused by postsurgical disk collapse, although essentially even for this indications good scientific evidence is lacking [32]. The absence of firm evidence favoring fusion for lumbar stenosis should augment further

debates in these latter indications and prompt the urgency for further studies. In degenerative lumbar stenosis without instability, spinal fusion after decompression does not add any value and might be seen as an obsolete historical treatment.

Conclusion

The research performed addresses several aspects of MIS for LSS and nicely demonstrates the clear benefits of proper registration of patient outcomes in spinal surgery. We might conclude that surgery for LSS can be performed in a microdecompression fashion without standard instrumented fusion or an interspinous process device for equal or better clinical outcomes against lower costs.

Studies of big data are clearly useful for evaluating surgical treatments and add a different dimension to the results of more selective randomised trials [31]. In concordance with the IDEAL framework phase 3, all new surgical techniques must be evaluated more robustly in the future, starting with high-quality randomised trials with health care and societal cost analysis [33], followed by good long term follow-up using registries to address safety and additional benefits. Medical implant devices are frequently introduced without adequate evidence of safety and efficacy [34]. While percutaneous minimally invasive techniques for lumbar interbody fusion are used widely, to date not a single randomized trial exists that has demonstrated a clear benefit over traditional open surgery. Implementation without thorough evaluation might result in harmful medical practices for patients, and we strongly feel that steps should be taken to strengthen regulation for device development and introduction. Two measures are most feasible in the short term: (1) requiring prospective studies before device approval, and (2) developing registries in order to monitor and evaluate new medical devices and all surgical implants [3].

In conclusion, surgical innovation shapes our practice, but should always be critically evaluated against the current practice. Only in that way we can offer our patients the best treatment. The studies discussed here have the justified potential to influence our practice to a large extent.

Compliance with ethical standards

Conflict of interest None.

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