A Full Economic Evaluation of Disc Prosthesis vs. Lumbar Fusion in Patients with Chronic Low Back Pain - A Randomized Controlled Trial with Two-year Follow up

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Background: Patients with chronic low back pain may in selected cases be treated with surgery. The gold standard today is lumbar fusion (FUS), using a variety of procedures. Total disc replacement (TDR) aimed at motion preservation is increasing in popularity.

Purpose: Different treatment techniques should be compared with respect to costs, clinical effects and cost-effectiveness.

Study design: We conducted a full health economic RCT comparing cost effectiveness of the surgical concepts of TDR and instrumented FUS in patients with chronic low back pain. The economic perspectives were those of the Society and the Health care sector.

Patient and methods: After approval from the ethics committee, between 2003 and 2005 in all 152 patients with what was understood as discogenic pain in one or two motion segments between L3 and S1 since at least one year, and where conservative treatment had been tried and failed, were randomized using the closed envelope technique. Diagnosis was mainly based on medical history, clinical examination, radiographs, and MRI. Patients in the TDR group (n=80) received Charité/Prodisc/Maverick. Patients in the FUS group (n=72) were operated according to instrumented PLF or PLIF. Directly after surgery patients were told to active. FU in this single center study was two years.

Outcome measures: All relevant direct costs (investigation, treatment, rehab, medication, relatives) and indirect costs (work absenteeism) were identified, measured and valued. Cost information was collected using a comprehensive patient based cost diary after 1-3-6-12-18-24 months, plus information from the participating clinic and from the social insurance system. Clinical effects was assessed using quality of life data (EQ-5D) from the Swedish Spine Register (“SweSpine”:www.4s.nu), which is gathered by questionnaires mailed to all surgically-treated spine patients in Sweden. Incremental cost-effectiveness ratio (ICER) was illustrated in the cost-effectiveness plane. Net benefit was assessed using probabilistic analysis.

Results: FU was 99%. Societal cost for TDR was SEK 599,560 (400,272), and for FUS SEK 685,919 (422,903) (ns). TDR was significantly less costly from a healthcare perspective, SEK 22,996 (43,055- -1,202). Number of days on sick leave among those who returned to work was 185 (146) in the TDR group, and 252 (189) in the FUS group (ns). The total gain in quality adjusted life years over two years was 0.41 units for TDR and 0.40 units for FUS (ns). The net benefit (with CI) was SEK 91,359 (-73,643 - 249,114) (ns).

Conclusion: It was not possible to state whether TDR or FUS is cost-effective after two years. Since disc replacement and lumbar fusion are based on different conceptual approaches, results should be followed over time.