

PP209 Analysis Of The Efficacy And Safety Of Robotic Spinal Surgery

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Introduction. Robotic surgery (RS) can offer benefits compared to freehand surgery (FS) in the treatment of patients with spinal diseases. The aim of this study was to assess efficacy and safety of RS versus FS in spinal fusion. The outcomes considered were accuracy in the placement of pedicle screws, surgical times, hospital stay, exposure to radiation, and complications.

Methods. A systematic review and meta-analysis were performed by researchers at the Instituto de Salud Carlos III (ISCIII). Studies published until June 2019 in the English, Spanish, or French languages were retrieved. The data analyses and risk of bias assessments were undertaken using RevMan 5.3.

Results. Eight randomized controlled trials including 610 patients (RS: 308, FS: 302) were found. The mean age of the patients ranged from 56 to 68 years in the FS group and from 55 to 68 years in the RS group. The percentage of women included ranged from 46 to 73 percent undergoing FS and from 33 to 70 percent undergoing RS. The main diagnosis was degenerative spine disease. The number of screws implanted ranged from 22 to 584 for FS and 23 to 532 for RS. The robots used were the SpineAssist and Renaissance Guidance System (Mazor Robotics, Ltd) and the TiRobot® Orthopaedic Robotic System (Beijing Tinavi Medical Technologies Co., Ltd). Pedicle screw placement within the safety zone (Grades A and B on the Gertzbein and Robbins scale) ranged from 93 to 100 percent in FS and from 85 to 100 percent in RS (relative risk 1.0, 95% confidence interval [CI] 0.99–1.03; $p = 0.36$) ($I^2 = 75\%$; $p = 0.0005$). Regarding intervention time, the meta-analysis showed a mean difference (MD) of 15.2 minutes (95% CI 5.35–25.05; $p = 0.002$) ($I^2 = 0\%$; $p = 0.39$) in favor of FS. The MD in hospital stay was 0.36 days (95% CI -1.03–0.31; $p = 0.30$) ($I^2 = 62\%$; $p = 0.07$), which was not statistically significant. Contradictory results were found for fluoroscopy time, although RS was associated with a lower radiation dose than FS ($p < 0.05$). In relation to safety, studies only reported on rates of surgical revision, which ranged from 0 to 2 after FS and from 0 to 10 after RS. The risk or bias was unclear in most studies.

Conclusions. We found no conclusive results suggesting benefits for spinal fusion using RS compared with FS. Further research with adequate selection of patients, type of robot, and comparator is needed.

PP215 An Evaluation Of The Scottish Medicine Consortium Detailed Advice Document

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Introduction. The Scottish Medicines Consortium (SMC) conducts early health technology assessment (HTA) of new medicines. The advice is implemented at the local level by 14 Health Board Area Drug and Therapeutics Committees (ADTCs). The primary output is a published document, the Detailed Advice Document (DAD), which aims to describe the strengths and weaknesses of the evidence considered and the rationale for the decision. We examined how the DAD is being used to determine areas for improvement.

Methods. We conducted semi-structured interviews with a purposive sample of SMC and ADTC members and formulary pharmacists, who are one of the key audiences. Interviews were recorded and transcribed using Microsoft Teams and coded in NVivo. The results were assessed via thematic analysis, which included major themes such as the structure and content of the DAD and its usefulness in supporting implementation of the advice from an ADTC perspective.

Results. Following initial interviews ($n = 7$), some early themes have emerged. The DAD is a valued tool describing the assessment of a medicine's clinical and cost effectiveness. The current length of the DADs and the technical language used can limit the accessibility of information, and there have been suggestions on how to improve the structure and content. Additional interviews are still being completed and full interview results (available early 2021) will be analyzed to identify key themes.

Conclusions. The DAD is the primary output of SMC's HTA process, which includes decisions on whether a medicine can be routinely prescribed in the National Health Service Scotland. DADs have increased in length over the years, reflecting the increasing complexity of new medicines and a corresponding increase in the size of pharmaceutical company submissions. The interviews conducted to date suggest that the DADs are highly regarded and support implementation of new medicines advice by the ADTC. The findings of this evaluation will lead to an action plan for improvement.

PP216 Indirect Treatment Comparison Assessment: An Improvement Intervention In The Scottish Medicines Consortium

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Introduction. The Scottish Medicines Consortium (SMC) conducts early health technology assessment (HTA) of new medicines on behalf of the National Health Service Scotland based on pharmaceutical company submissions. As the appraisals are conducted close to the point of marketing authorization, there is often a lack of direct head-to-head data. In 2019, assessment of relevant comparative efficacy was informed via indirect treatment comparisons (ITC) in 55 percent (36/66) of submissions. While the ITCs are essential to the decision-making process, they are frequently incomplete.

Methods. A focus group was conducted with the clinical assessment team ($n = 11$) to explore problems in the submission process

and to identify areas for improvement. It was agreed that providing improved guidance to companies prior to submission may prevent future inconsistencies. A working group (n=5) was tasked with identifying and implementing potential solutions. The group reviewed the focus group findings, relevant literature, and guidance from other organizations. Draft guidance was developed that was reviewed by two pharmaceutical industry representatives (SMC subcommittee members).

Results. Findings from the focus group highlighted issues broadly related to the incomplete presentation and reporting of ITCs. The improved guidance document outlined specific requirements in a checklist format for reporting and presenting the results of different ITC data. This guidance was published in February 2020. To evaluate the impact of the updated guidance and to identify any further changes required, a follow-up focus group and survey of industry representatives is planned for March 2021.

Conclusions. The aim of the ITC guidance is to provide pharmaceutical companies with direction to improve the quality and transparency of reporting, which will in turn improve the quality of HTAs and thus strengthen the recommendations provided by the SMC. The follow-up focus groups and survey will assess the impact of the guidance. It is acknowledged that the results of this process may be limited by the small sample size and short duration of the assessment.

PP219 Combining Healthcare Solutions For Cataract Surgery. An Incremental Benefit Analysis From The Perspective Of The Russian Healthcare System

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Introduction. Rising health expenditures lead to increasing budgetary pressures, which often manifest in budget managers seeking more for the same resources or trying to maintain the status quo with less. Consequently, enablers that drive efficiencies throughout the entire care pathway have come under increasing focus. This is particularly true in the operating room (OR) setting where considerations around operational efficiency, clinical excellence, and patient-centered care pose challenging questions. While a comprehensive solution set should be formulated, small parts of the solution can be applied now to prime systems for easy integration into future solutions. The objective of this analysis was to estimate the impact of combining custom healthcare solutions for cataract surgery from the perspective of a Russian hospital.

Methods. A decision-analytic model was developed to assess the aggregated impact of combining the following products or services for cataract surgery: an intraocular lens delivery-system; process-redesign; a phacoemulsification machine; and a phaco tip. The model and underlying assumptions were validated by clinical experts. OR time-savings was chosen as the variable of efficiency underpinning the analysis. Inputs were estimated from the literature, expert opinion, and the local cost databases. Two scenarios were defined that reflected technologies commonly used in surgical practice. The model scenarios assumed that a

hospital performs 2,000 cataract procedures per year, with 100 percent adoption and equal acquisition costs.

Results. Choosing a combination of healthcare solutions for cataract surgery was associated with an incremental benefit of RUB5,935,982 per year (EUR71,364) and generated an OR time saving of approximately 237 cataract procedures.

Conclusions. This analysis highlighted that, compared with treating technologies on an individual level, combining healthcare solutions commonly used for cataract surgery has the potential to drive efficiencies and cost savings for hospitals and to reduce surgical wait lists.

PP222 Efficacy And Safety Of Foot Reflexology

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Introduction. Foot reflexology is a type of complementary manual therapy that consists of applying pressure or massage to the sole of the foot to produce various therapeutic effects in other body areas or organs. This technique has been used in many different clinical indications, but there is uncertainty about its real effect. A health technology assessment (HTA) was conducted to analyze the efficacy and safety of foot reflexology within the framework of the "Health Protection Plan Against Pseudo-Therapies," which was established in 2018 by the Spanish Ministry of Health and the Ministry of Science and Innovation.

Methods. A systematic review and metaanalysis was conducted to synthesize the available scientific literature on the efficacy and safety of foot reflexology in people of any age with any disease or medical condition.

Results. Sixty-eight randomized controlled studies were included. Pooled estimates indicated that foot reflexology had no effect on pain, fatigue, depression, quality of life, quality of sleep, or blood pressure, compared with non-reflexological foot massage. Improvements in pain (standardized mean difference [SMD] -1.11, 95% CI: -1.70 - -0.52), fatigue (SMD -0.93, 95% CI: -1.36 - -0.51), sleep quality (SMD -1.11, 95% CI: -1.68 - -0.34), and systolic (mean difference [MD] -7.36, 95% CI: -8.49 - -6.23) and diastolic (MD -5.07, 95% CI: -0.98 - -0.22) blood pressure were obtained when reflexology was compared with usual care or no intervention. In the case of anxiety levels, the benefit obtained with foot reflexology compared with any comparator (SMD -0.6, 95% CI: -0.98 - -0.22) was attenuated when compared with non-reflexological foot massage (SMD -0.2, 95% CI: -0.36 - -0.03). Very few studies reported on the safety of foot reflexology.

Conclusions. There was no evidence for any specific effect of reflexology for any condition when compared with non-reflexological foot massage, except for a positive effect on anxiety levels.