ROUNDUP360

Spine

Single posterior approach for severe kyphosis

Flying against the conventional wisdom of a combined anterior and posterior approach for severe congenital kyphosis, surgeons in **Hamburg (Germany)** have been performing a single-incision posterior approach. Reasoning that the anterior approach places the vascular supply and visceral organs at risk, and if correction can be achieved through a posterior-only approach then it would avoid these risks, this has become the authors practice at their centre. The authors present the results of a single-incision posterior instrumented correction performed on ten patients. The patients had a mean age of 11.1 years (5.4 to 14.1) and underwent a variety of surgical techniques with both pedicle subtraction osteotomy and vertebral column resection with instrumented fusion performed through a single posterior approach. Patients presented with a mean kyphotic deformity of 59.9° (45° to 110°) and improved to 17.5° (3° to 40°) at a minimum follow-up of two years (29 to 85 months). While this is a rare condition the sequelae of complications are significant, and life-long. The surgical team used spinal cord monitoring in all cases and they did not report any complications in any of their cases.[1] While just a small case series, the surgical team was able to achieve a significant correction and the results look promising. We would encourage the authors to present a larger series and re-report these patients at skeletal maturity. Late progression is not unheard of in spinal deformity, and the type of posterior instrumentation used here is not working in a biomechanically favourable environment. The early results look good, and if bourne out in a longer-term study would more than justify the use of this single incision approach.

Risk factors for recurrent disc herniation

The natural history of lumbar disc herniation can include a relapsing and remitting course, not just of the symptoms, but also with recurrent prolapses. It is not entirely clear which patients are most likely to suffer recurrent symptoms. Researchers in **Kanazawa (Japan)** undertook a comparative review of patients, all of whom had lumbar disc prolapses requiring surgical decompression. The cohort of 298 patients was operated on over a three-year period. The authors collated baseline demographic characteristics including age, gender, BMI, smoking status and alcohol use, sports activity and occupational lifting and driving. The authors investigated these risk factors for recurrent lumbar disc herniation (LDH). There was a recurrence rate of 10.7% (n = 32). Univariate analysis revealed only current smoking and occupational lifting, while a multivariate model revealed that smoking was still related to recurrent disc prolapse (OR 3.47, 95% CI 1.55-7.80).[2] Patients undergoing lumbar disc decompression should be encouraged to give up smoking given the significant cause and effect found here which would, according to this study, cut recurrence rates over three-fold in this group of patients.

Dysphagia and cervical disc replacement or fusion

Dysphagia is a distressing complication following anterior spinal surgery and previous research has demonstrated that it's a complication associated with surgical technique. It has been suggested that the number of levels treated and implant selection might have an effect on the reported incidence of dysphagia as an adverse event. Researchers in **Stockholm (Sweden)** used data from a prospective randomised controlled trial to determine differences in self-reported dysphagia between patients randomly treated with either a disc replacement or anterior cervical decompression and fusion (ACDF). Data were collated from 136 patients randomised to cervical disc replacement or ACDF (either one or two surgical levels) and the dysphagia short questionnaire was administered pre-operatively, at four weeks, three months, and one and two years post-operatively. There were no baseline differences between the groups in the dysphagia short questionnaire or demographics pre-operatively. As would be expected at the first post-operative evaluation (four weeks), incidence of dysphagia symptoms and the short dysphagia scores had risen significantly in both groups. There were no significant differences seen between the groups in any measure until follow-up at two years. While the differences were statistically significant, the small differences in scores are unlikely to be clinically relevant. The authors undertook a logistic regression analysis to establish if there was a stronger association between type of implant or number of levels treated. There was little association between numbers of levels and so the differences are likely due to implant factors (either bulk or the stiffening effect of the c-spine).[3] As the authors of this paper rightly note, it is dangerous sometimes to over-interpret marginal differences in subset analysis or secondary outcome measure analysis of specific randomised controlled trials. We would agree with their conclusion that 'it is doubtful if differences between the groups in this study can be interpreted as a clinically important difference'.

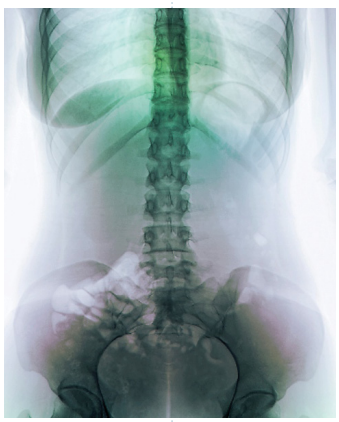
Hang on to your topical antibiotics – they don't do any good!

The use of prophylactic antibiotics is a worldwide standard of care when metallic implants are to be used. The initial evidence from John Charnley in hip replacement surgery is interpreted across the board as applicable to all varieties of orthopaedic implants and all varieties of antibiotics. Paranoid about infections, surgeons are ever looking to reduce their infection rates, and consequently the use of topical antibiotics has taken off. Evidence in bone cement is positive in registries (although there is not a large effect), but what about spinal surgery? Surgeons at

the Ganga Hospital in **Coimbatore (India)** set out to establish the efficacy of topical antibiotics in spinal surgery. Noting there were a number of retrospective and prospective case series previously reported, they designed a prospective randomised controlled trial of 907 patients undergoing spinal surgery within an 18-month study period to efficacy, or otherwise, of topical gentamycin when combined with prophylactic systemic antibiotics. Patients were randomised to either control (systemic antibiotics alone) or study (systemic antibiotics and topical vancomycin). Patients were drawn from a range of spinal surgical procedures, and details including demographic, comorbidities, pathology, blood loss, nutritional status, and haemoglobin were recorded. The study team saw just eight infections (1.68%) in the control group and seven infections (1.61%) in the study group. There were no differences in the incidence of instrumentation, rate or type of infections between the two groups. While there were no observed adverse effects of the vancomycin powder, the authors conclude that there is no benefit to topical antibiotic application in this study.[4] This is clearly the case from the results reported here, although there is a temptation to wonder if with such a low event rate more patients would really be required to see any difference?

Cost-effective lumbar disc replacement

Lumbar disc replacement has been dogged by controversy during the past few years. The staple of early adopters, this surgical technique has never really gained traction and universal acceptance. However, it remains one of the only surgical options in widespread use for chronic low back pain. Researchers in **Trondheim (Norway)** bravely set out to establish the cost effectiveness of a total disc replacement (TDR) *versus* multidisciplinary rehabilitation (MDR) in a group of patients presenting with chronic low back pain. Over a three-year period, 173 patients who fit the inclusion criteria for the study (chronic lower back pain for > 1 year) were included in the randomised study. Patients were randomised to either a TDR (n = 86) or the MDR pathway (n = 87). The treatment effects were estimated with the Euro QoI 5D (EQ-5D) and Short Form 6D (SF-6D). Health economic analysis was undertaken using relevant direct and indirect costs at regular time intervals up to 24 months of follow-up. The primary outcome measure for the study was the gain in quality-adjusted life years (QALYs) after two years, and cost effectiveness was estimated as an incremental cost-effectiveness ratio. Unusually for intervention studies in low back pain, these patients significantly improved over the duration of the study in both groups but the TDR group outperformed the MDR group (1.29 *versus* 0.95) which equated to a significant difference of 0.34 QALYs. The mean total cost of treatment was high in both groups and not significantly different (€87,622 *versus* €74,116). With similar costs and a higher QALY improvement, not surprisingly the TDR fared slightly better. However, interpretation of the results is tricky. Using the EQ-5D to estimate improvement the TDR is cost effective (€39,748) while the SF-6D suggested it was not cost effective (€128,328), a massive variation between estimates. The picture becomes even trickier when looking at the analysis methods used. There was a high dropout rate in the study with one in five patients declining surgery and one in four failing their rehabilitation. Consequently, analysis using per-protocol rather than intention-to-treat principles suggests that TDR cost is ineffective, using both outcome scores.[5] With confusing results such as these it is possible to present the study in any light the reader or investigator chooses. Here at *360* we would suggest that this study hasn't yet reached its conclusion. A further cost-effectiveness analysis at five years will surely answer the question.



Anxiolytics no role to play in acute lumbar back pain

Common practice in management of acute lumbar back pain is the administration of strong analgesia (often opioid) in combination with anxiolytic medication to relieve anxiety. Use of anxiolytics such as promethazine has been demonstrated in the emergency room setting to improve acute pain management, however, its effects on the long-term management of pain and eventual outcome are unknown. Researchers in **Nottingham (UK)** designed a prospective blinded randomised controlled trial to establish the effects of opioid analgesia alone (control group) or in combination with promethazine as an anxiolytic (intervention group). Fifty nine patients were recruited into the study and randomised to either IV morphine + saline (29 patients) or IV morphine + promethazine (30 patients). Outcomes were assessed using pain and anxiety visual analogue scores. There were no significant differences in the reduction in pain between the two groups (43 mm control *versus* 39 mm study group) or anxiety ratings (19 mm control *versus* 13 mm study). However, there were some differences in the secondary outcome measures. The average ED stay was 78 minutes longer in the study group due to the sedative effect of promethazine. Measures of satisfaction and adverse events were similar in both groups.[6] It does appear that based on these results there is no advantage to the simultaneous administration of anxiolytics and morphine for acute onset lumbar back pain. The extra resource required (over an hour per patient) would suggest that there is no place for the use of promethazine in these patients.

Surgery best for lumbar disc herniation

The SPORT study (Spine Patient Outcomes Research Trial) has yielded some of the most valuable additions to knowledge surrounding spinal surgery, symptoms, pathology and outcomes over the past few years. The study is a complex combination of randomised and observational cohort studies carried out in parallel. Surgeons in **Lebanon (USA)** have recently undertaken one of the most important analyses of this dataset to date, evaluating the operative *versus* non-operative outcomes of patients following lumbar disc prolapse in the randomised cohort. Patients fulfilling the trial entry criteria were randomised to operative or non-operative treatment in 13 spinal centres, yielding a study cohort of 501 participants. Patients were randomised to open discectomy or non-operative care and the primary outcome measures were change in general health status (SF-36) and spinal specific outcome measures (Oswestry Disability Index). These were assessed at six weeks, three and six months, then annually. The surgical cohort had better outcomes in the intent-to-treat analyses for all outcome measures tested (other than work status, interestingly). However, there was significant crossover between the groups, with 49% of non-operative patients receiving surgery and just 60% of those assigned to surgery, resulting in these observed effects being insignificantly in favour of surgery. Subsequent comparison of secondary outcomes was significantly in favour of the operative group, including sciatica tolerance, satisfaction and self-rated improvement. Analysis on

an 'as-treated basis' revealed treatment effects for all primary outcome measures in favour of surgery: SF-36 bodily pain (45.3 *versus* 34.4), physical function (42.2 *versus* 31.5), and Oswestry Disability Index (-36.2 *versus* -24.8).[7] Operative intervention appears to show a significant benefit in this randomised controlled trial. Group crossover is a difficult problem to overcome, and highlights the difficulties of treating patients with this diagnosis. Our boffins here at *360* think an 'as treated analysis' is indicated in this setting; the difficulty, of course, being that this changes a randomised controlled trial to a partly randomised trial.

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