indicate safety and feasibility of the procedure. Two patients elected to proceed with a surgical procedure following the injection. The results suggest that autogenous BMC may provide a clinical benefit as a nonsurgical treatment of DDD in the lumbar spine. These patients will continue to be followed for a minimum of 2 years.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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61. Outcome of Lumbar Nerve Root Block in Patients with Sciatica and Lumbar Disc Prolapse

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BACKGROUND CONTEXT: A recent review (UK Health Technology Assessment programme 2013) reported that selective lumbar nerve root block (SLRB) may be effective and cost-effective in treatment strategies for lumbar radicular pain, although there are conflicting results from studies, possibly related to problems such as heterogeneous patient groups and confusion with back and radicular pain. Review of 842 patients with SLRB in our centre, produced 740 with acceptable data quality (28-day pain diaries with pre-injection VAS 0-10 scores plus post-treatment data). Mean pre-injection VAS was 6.4. Mean VAS was 4.5 at two days following injection. At 28 days, mean VAS was 5.1. Some patients had major reduction in VAS in the first 24 hours, but this did not predict improvement at 28 days. However, within this group, 10% of patients had VAS scores no higher than 2/10 from seven days onwards, suggesting there may be worthwhile outcomes for sub-groups of patients.
PURPOSE: To study outcome (pain response and likelihood of proceeding to surgery) for patients with lumbar disc prolapse treated with SLRB.
STUDY DESIGN/SETTING: A prospective cohort study measured outcomes in 61 patients, referred by family doctors, to a neurosurgery department providing a dedicated spinal surgery service. Entry criteria were single-level radicular pain secondary to disc prolapse occupying 50% or less of the canal cross-sectional area, with clinical and radiological correlation of involved nerve root level, no osteophytic or other cause of root compromise, accepted for discectomy but consenting to SLRB followed by surgical review rather than immediate wait-list for surgery, following discussion about natural history of disc prolapse and treatment options. Patients with more than one nerve root compromised, and those with canal or bony lateral recess stenosis, or spondylolisthesis, were excluded. Any patient with major neurological weakness or previous lumbar surgery was excluded.
PATIENT SAMPLE: All 61 patients were seeking treatment up to and including surgery for sciatica.
METHODS: All patients received SLRB with a standardized technique. Via posterolateral approach with fluoroscopic guidance, a roentgenogram was obtained with contrast medium, followed by injection of 1ml bupivacaine 0.5% + 1ml triamcinolone 40mg/ml. Pain diaries covering 28 days were issued. Patients were advised to score the severity of sciatica (buttock and leg pain), and returned to the clinic after a minimum of 28 days.
RESULTS: Mean duration of sciatica was nine months and mean VAS pain score was 7.0 pre-injection. Over the 28 days, mean VAS score from day 2 to day 28 remained in the range 2.2-3.0, and was 2.5 at day 28. Surgical status was reviewed with a mean follow-up of more than 12 months. Of 61 patients, 21 (34%) had received surgery or were on a waiting list, and 40 (66%) had been managed conservatively.
CONCLUSIONS: Worthwhile treatment outcomes following SLRB may be masked in studies with heterogeneous groups of patients, and perhaps without differentiation between spinal and radicular pain. This study follows a cohort of lumbar disc patients many clinicians would accept as having ''moderate but intrusive symptoms'' and seeking definitive treatment, as commonly seen in clinical practice. While lacking the weight of a randomized trial, the pain outcomes measured and the fact that 66% of patients escaped the need for surgery may be encouraging for patients and clinicians. Importantly, many lumbar disc patients are mid-life productive workers with restricted performance due to sciatica. A robust randomized study, perhaps with economic as well as clinical outcome analysis, may further influence practice and allocation of resources for this patient group.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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62. A Phase II Study Demonstrating Efficacy and Safety of Mesenchymal Precursor Cells in Low Back Pain Due to Disc Degeneration

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STUDY DESIGN/SETTING: Multicenter, randomized, blinded, placebo controlled trial comparing outcomes of a single intradiscal injection of adult allogeneic mesenchymal precursor cells (MPC) mixed with a hyaluronic acid (HA) carrier to saline placebo or HA carrier control injections in patients with chronic discogenic back pain.
METHODS: 100 patients with moderate to severe low back pain persisting for more than 6 months caused by early disc degeneration were enrolled at 13 sites in the United States and Australia. They were randomized to receive intradiscal injection of saline (n= 20), HA (n=20), 6 million allogeneic MPCs (6M, n=30) or 18 million allogeneic MPCs (18M, n=30). Patients were evaluated for safety and efficacy over 12 months.
RESULTS: Allogeneic MPC treatment was well tolerated. The most frequently reported adverse event of back pain occurred across all treatment groups. The two control groups (HA and saline) performed similarly, and as predefined, were pooled for analysis. While baseline Visual Analog Scale (VAS) scores were similar across all groups, mean pain reduction at 12 months after injection was 27 mm for placebo, 37 mm for the 6M group (p=0.11 vs placebo) and 40 mm for the 18M group (p=0.046 vs placebo). A significantly greater proportion of MPC treated patients achieved minimal residual back pain (VAS $\leq$ 20mm) at 12 months than controls (6M group 52%, 18M group 42%, pooled controls 18%, p=0.01 and p=0.05, respectively). A significantly greater proportion of MPC treated patients achieved at least a 50% reduction in low back pain at 12 months than controls (6M MPC 69%, 18M MPC 62%, pooled controls 33%, p=0.009 and p=0.038, respectively). Mean opioid use was about two-fold higher in saline and HA controls than in MPC treated patients achieving at least 50% reduction in back pain. By 12 months, 25% saline controls had undergone additional surgical or injection intervention at the treated disc level, compared with 10% HA controls, 6.9% of 6M MPC and only 3.3% of 18M MPC treated patients (p=0.024 and p=0.010 for saline vs 6M and 18M MPC groups, respectively). At 12 months, mean reduction from baseline in the Oswestry Disability Index (ODI) functional score was 43% for 18M group, 35% for 6M group, 30% for HA and 28% for saline (p=0.09 for 18M vs saline). A greater proportion of MPC treated patients achieved minimal residual functional

disability (≤ 20) at 12 months compared to controls (18M group 39%, 6M group 36%, pooled controls 18%, p=0.14 for both MPC groups). At 12 months, MPC treated patients demonstrated a significant reduction in translational movement of the disc (also as corrected for degree of rotation), suggesting a treatment effect on disc degeneration, anatomy and disc stability. The 18M MPC group had a mean translational movement of 1.3%, the 6M MPC group 2%, the HA group 2.5%, and the saline group 3.5% (p=0.021 between groups).
CONCLUSIONS: Intradiscal injection of allogeneic MPCs to treat chronic discogenic back pain was well tolerated and reduced pain, reduced opioid use and the need for additional interventions and improved function compared to controls. These results suggest that the use of MPCs should be further evaluated as a potential treatment for degenerative disc disease after conservative measures have failed.
FDA DEVICE/DRUG STATUS: adult mesenchymal precursor cells (MPC) (Investigational/Not approved)

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63. Is There Clinical Improvement Associated with Saline Injection for Discogenic Low Back Pain: Comparison of RCTs

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BACKGROUND CONTEXT: Recently, several multicenter clinical trials studying the effect of biologic substances or cell-based injections on lumbar intervertebral disc repair have been completed. These studies all included a placebo injection with saline as a control. These studies were early, randomized, double blinded, and prospective. Their intent was to investigate novel treatment options for intervertebral disc repair. The findings of these studies highlight a possible reduction in pain and disability related to the saline injection.
PURPOSE: The purpose of this analysis was to evaluate saline related outcomes from multiple intervertebral disc injection studies all conducted at one institution.
STUDY DESIGN/SETTING: Post hoc comparison was performed using data derived from four similar studies conducted at a single site that were prospective, randomized controlled, and double-blinded.
PATIENT SAMPLE: Posthoc analysis included all patients in studies (A, B, C, D). Patients had symptomatic disc disease at lumbar levels of L1 to L5-S1, had a positive provocative discography and failed at least 3 months of nonoperative treatment. Patients (males & females) ranged from 18 to 65 years of age and were randomized into placebo (saline) or treatment (investigational substance) intervertebral disc injection groups.
OUTCOME MEASURES: Visual Analog Scale for back/buttock pain (VAS) common among studies.
METHODS: Self-administered questionnaires including the Visual Analog Scale for back/buttock pain (VAS, 100-mm line, with 'No Pain' indicated at the left of the horizontal scale and 'Most Severe Pain' at the right end of the scale) and the Oswestry Disability Index (ODI, a likert type scale calculating functional disability) for low back pain, along with surgeon administered physical exam were completed at pre-treatment visit (pretx) and at least at 3, 6, 12 months postinjection. Only study B utilized the Roland-Morris Disability Questionnaire instead of the Oswestry Questionnaire. For all studies, side effects and adverse events were systematically collected throughout as per clinical trial standard operating procedures at the site. Statistical analysis included % change variable calculated as: postinjection score minus pretreatment score divided by pretreatment score per individual patient. Averages of these per patient change scores were calculated for reporting overall improvement. Multiple variable analysis of variance (ANOVA) was applied to specific outcome score measures with a grouping factor for treatment (saline versus investigational treatment) and a repeated factor for outcome score over time (ie, 12mo vs pretreatment) controlling for age, gender and specific study.
RESULTS: Across the studies, by 12 months, there was 58.5% less VAS pain for saline injected patients compared to 36.6% less pain for investigational treatment injected patients (S: 20.4 mm vs I:37.7mm p<0.01, ANOVA controlling for age and gender). Additionally, across the studies there was a statistically significant main effect of decrease in VAS pain for both the investigational treatment or saline injected patients (p< 0.004 at 3 months; p<0.007 at 6 months; p<0.0001, 12 months compared to pretreatment). Control Variables: Gender and age were controlled in the overall analysis. A higher percentage of males were enrolled across the four studies (61.5% A, 61.5% B, 60% C, 94% D) with 74% males (37/50) in the combined analysis. VAS: Males reported slightly less VAS improvement as well as less VAS pain than females preoperatively. This difference was not significant. (Males: 66.8mm VAS pain at pretreatment, 39.6mm VAS pain at 12 months post-treatment, with a 41.5% difference. Females: 81.3mm VAS pain at pretreatment, 32.4mm VAS pain with a 40.6% difference at 12 months post treatment). Age was only related to VAS at 12 months (p< 0.04, r=0.31, 9.6% of common variability).
CONCLUSIONS: An intervertebral disc injection regimen of saline may offer patients a chance for some pain resolution and decreased disability, or may merely introduce less substance reaction and injection trauma. Noting the 50% or greater improvement observed for saline injected patients in this study provides a potentially higher threshold and means to define the MCID for injection type treatments. Independent from the underlying reason for the observation herein, future injection studies now have a high baseline improvement threshold. A more thorough understanding of the "saline effect" is needed. Future directions include testing for this effect in an independent sample, with more patients, and a longer follow-up period. Sham procedures will be included in future clinical injection studies to fully differentiate between a placebo effect and a true saline effect
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Wednesday, November 12, 2014
2:05 – 3:05 p.m.
Surgical Outcomes

64. Effect of Zoledronic Acid on Bone Fusion after Lumbar Surgery for Osteoporotic Patients

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BACKGROUND CONTEXT: Spinal instrumentation and fusion is a widely used treatment for spinal instability, trauma and deformity. The growth of the elderly population is not only increasing opportunities for spinal fusion in elderly patients, but also increasing the prevalence of osteoporosis. As we known, osteoporosis-related bone fragility is the primary reason for vertebral compression fractures (VCFs) above or below the fusion sites, implant fixation failure, etc. Bisphosphonates have the ability to increase vertebral strength and prevent VCFs through the inhibition of osteoclast-mediated bone resorption. But the successful bone fusion is achieved through the appropriate balance between bone formation and resorption. In our study, we evaluate the effect of zoledronic acid on the healing process in patients who have undergone spinal instrumentation and fusion operation.
PURPOSE: The object of this prospective randomized controlled study was to evaluate the effect of bisphosphonate medication (zoledronic acid, Aclasta) on spinal fusion for osteoporotic patients through radiographic, clinical and biological assessments.