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Improving response to treatment for patients with DDD by the use of molecular markers

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Background: Protein biomarkers associated with lumbar disc disease have been studied as diagnostic indicators and therapeutic targets. A cartilage degradation product, the Fibronectin-Aggrecan complex (FAC) identified in the epidural space, has been shown to predict response to lumbar epidural steroid injection in patients with radiculopathy from herniated nucleus pulposus (HNP) and identified in patients with DDD. A therapeutic agent that prevents the formation of the G3 domain of aggrecan will reduce the fibronectin-aggrecan G3 complex and accordingly may be an efficacious treatment. Since the production of G3 domain of aggrecan is catalyzed by different known classes of proteases, a common inhibitor of all of these proteases could be an ideal therapeutic agent. Such a protease inhibitor is found in plasma and synovial fluid, alpha-2-macroglobulin (A2M).

Aim: Determine the ability of FAC to predict response to biologic therapy with concentrated autologous A2M for patients with LBP from DDD.

Methods: Study Design/Setting: Prospective cohort, Patient Sample: 24 patients with LBP pain and MRI positive for DDD, Outcome Measures: Oswestry disability index (ODI) and visual analog scores (VAS) were noted at baseline and at 3-month follow-up. Primary outcome of clinical improvement was defined as patients with both a decrease in VAS of at least 3 points and ODI>20 points. All patients underwent lavage for molecular discography and delayed FAC analysis and injection of platelet poor plasma rich in A2M at the time of the procedure.

Results: There were 13 males and 11 females. Age range 24-62 (avg- 44.3) 13 pts had 1 level, 6 pts 2 level, and 5, 3 level procedures. 12 discs were FAC + in 10 pts, out of 40 discs tested. 11 pts improved, versus 13 who did not. Patients with FAC-positive assays were significantly more likely to show improvement in their VAS and ODI at follow-up. Mean VAS improvement in FAC-positive patients was 4.9±0.9, compared to 1.5±1.2 in those with negative FAC ($p<0.0001$; ANOVA). Similarly, ODI improved on average 37±9.3 points in FACT-positive patients compared to 9.4±11.9 in FAC-negative patients ($p<0.0001$; ANOVA). Correlation analysis demonstrated that a FACT-positive test correlates with improvement in VAS (Pearson $r = 0.83$; $p < 0.0001$) and ODI (Pearson $r = 0.71$; $p<0.0001$).

Conclusions: Patients who are "FAC+" are more likely to demonstrate clinical improvement following autologous A2M injection. The results of this investigation suggest that not only FAC is an important biomarker in identifying who will improve, but also that autologous A2M is an important biologic treatment in discogenic diseases, a true theranostic. We utilized a definition of clinical improvement that was in excess of the minimal clinically improved difference (MCID). Additionally, our defined outcome measure was a combination of two universally accepted outcome parameters (ODI and VAS). The current study bridges the gap between the presence of a biomarker and clinical outcomes.

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