Injections of Concentrated Bone Marrow Aspirate as Treatment for Discogenic Pain

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Abstract

Low back pain (LBP) affects up to 84% of the U.S. adult population with the highest rate of incidence between the ages of 45 and 64 years. While the causes are numerous and complex, one of the primary causes of LBP is discogenic, mechanical pain. This can be secondary to internal disc disruption (IDD) and/or degeneration of the intervertebral disc (IVD), also known as degenerative disc disease (DDD).

Physical and medical therapies are successful in relieving pain in approximately 90% of LBP cases. The remaining 10% develop chronic low-back pain (CLBP), a serious public health problem.

Effective treatment for discogenic LBP would provide physical and financial relief for a large population of individuals as well as for the health care system and society at large. Treatment with Mesenchymal Stem Cells (MSCs) via injections of concentrated bone marrow aspirate (cBMA) capitalizes on the regenerative potential of MSCs while reducing the risk of infection or rejection.

- 29/33 patients who received the injection reported overall improvement in their LBP.
- More than 30% of the patients reported >50% improvement in their level of pain.
- Mean responses to the each of the pain and functioning questionnaires showed statistically significant improvement

cBMA injections as treatment for LBP are a promising treatment modality worthy of further study.

Introduction

Current treatment options for discogenic CLBP range from conservative therapies to invasive surgical procedures. While each treatment modality has shown varying degrees of success, none has demonstrated consistent high degrees of efficacy.

The most common surgeries involve destructive procedures such as insertion of metal prosthetics (artificial discs) or spinal fusions. The disturbance of natural motion and function can actually accelerate the degenerative cascade at the operative vertebral level and adjacent segments. There is a clear need for effective, early treatment for discogenic LBP that may prevent, slow, or reverse degeneration in the intervertebral disc.

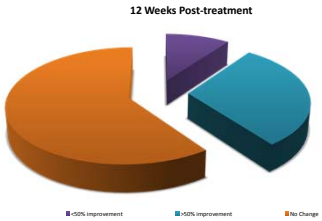

Figure 1: At 12 weeks post-treatment, 40% of patients reported noticeable treatment. Thirty percent said that they had experienced greater than 50% improvement over their original pain level.

CBMA and MSCs possess a combination of growth factors and potential for differentiation which play crucial roles in the the healing and regeneration of injured tissue. CBMA is a good source of a source of MSCs and growth factors. As an autologous source of these elements, CBMA has the potential to facilitate the regeneration of vertebral discs while lowering the risks of infection or rejection inherent in the use of MSCs from a heterologous source.

The purpose of this study is to retrospectively evaluate the clinical outcomes in a population of patients with discogenic CLBP, treated with intradiscal injection of autologous CBMA. While the sample population will be small, the analysis could provide meaningful insight into the efficacy of the treatment overall and into the efficacy of the treatment based on different pre-treatment scenarios. These insights will contribute to the continued development of the treatment as an option for patients with CLBP and other types of degenerative joint pain.

	2 Week	6 Week	12 Week	6 Month	12 Month
Outcomes					
% Improvement Reported by Patient					
<50%	1 (3.0)	5 (16.1)	3 (9.4)	1 (3.5)	3 (13.0)
>50%	3 (9.1)	5 (16.1)	9 (28.1)	5 (17.2)	7 (30.4)
No Change	23 (69.7)	18 (58.1)	18 (56.2)	22 (75.9)	10 (43.5)
Worse <50%	6 (18.2)	2 (6.5)	1 (3.1)	1 (3.5)	2 (8.7)
Worse >50%	0 (0)	1 (3.2)	1 (3.1)	0 (0)	1 (4.5)

Table 1: Frequencies and proportions of percentage improvement/worsening as reported by patients.

Methods

For this procedure, an autologous bone marrow sample was drawn from each patient's hip. The aspirate was then filtered and processed to produce concentrated bone marrow aspirate (CBMA). In a separate procedure the CBMA was injected into the affected lumbar disc under fluoroscopic guidance.

Follow-up with the patients occurred at 5 specified, post-procedure intervals through office visits, written questionnaires, and telephone communication. Patients were asked to report improvement or worsening of their pain in percentage form.

Patients were also asked to complete the following assessments:

- Oswestry LBP Disability Questionnaire
- Short Form (SF) 36 Health Survey
- Visual Analog Scale

The patients' responses to the assessments were scored according to appropriate guidelines and the gathered data was examined in light of the aforementioned areas of interest.

Results

Thirty three patients were initially included in this retrospective case series. When asked whether they had experienced overall improvement in their CLBP, 29 of the 33 patients reported at least some improvement. The patients were asked at follow-up intervals of 2 weeks, 6 weeks, 12 weeks, 6 months and 12 months post-intervention to assign a percentage by which their pain had improved or worsened. The responses to that question are in Table 1. 30.4% of patients responding at the 12 month interval reported at least a 50% improvement in their level of pain, with an additional 13% of patients reported noticeable improvement in their pain levels.

	Baseline	2 Week	6 Week	12 Week	6 Month	12 Month
Instrument	Mean Score					
VAS	5.3	5	3.8	3.1**	3.8**	3.8*
SF-36	53.5	49.5*	60.3	72.1*	72.1**	64.1
OSWESTRY	36.8	38.5	26.6	22.1**	20.7**	24*

** Denotes P-Values < 0.05 using Wilcoxon Sign Rank after adjusting for multiple comparisons from baseline.
* Denotes P-Values < 0.10 using Wilcoxon Sign Rank.

Table 2: Mean values of patients' responses to VAS, SF-36 and Oswestry demonstrating overall patient improvement according to each instrument.

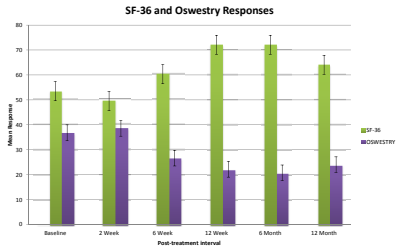

Figure 2: Mean values of patients' responses to SF-36 and Oswestry, demonstrating trend of improvement with statistically significant improvement at 1 year post-intervention.

The patients were also asked to complete three evaluative instruments: the Oswestry Low Back Pain Disability Questionnaire, the Short Form 36 Health Survey (SF-36), and a Visual Analog Scale (VAS). Table 2 shows the mean responses to each questionnaire. Responses to each of the three questionnaires demonstrated statistically significant improvement in patients' perceived pain and functioning. Responses to the SF-36 showed an average improvement of 34.7%. Responses to the Oswestry questionnaire showed improvement of 43.8%. Zero patients reported complications with the procedure.

Discussion and Conclusions

A more effective curative treatment for CLBP would mark a major landmark in the provision of health care in the U.S. The expense is shared between patients, providers, insurance companies, and the companies or employers affected by the patients' ability to work. Symptomatic management has continued to make only minor strides in the relief of patients' pain, and invasive procedures carry relatively high risks of short and long term complications. Care providers have remained unable to provide curative, low-risk treatment to long-suffering patients. Therefore, the possibilities surrounding innovative, regenerative treatments demand investigation. The employment of concentrated bone marrow aspirate, with its inherent supply of growth factors and mesenchymal stem cells represents one such treatment.

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