



An Initial Evaluation of Cytokine and Growth Factor Enriched Plasma (CRP) on Spinal Patients

Study Prepared and Performed by:
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2012 August

Protocol

All patients had undergone conservative treatment with either Physical Therapy or Chiropractic care of 3 month minimum duration and concluded persistent pain. Patients were contacted by phone at 6 months post injections for assessment of post treatment pain.

Patients with disc herniation were not excluded as long as there was tenderness over the facet joints and no radiculopathy present.

Injections consisted of cytokine and growth factor enriched plasma derived from proprietary methods based on Orogen's extraction methods (ACE Technology).

A total of 33 procedures were performed in the Pilot study with 25 procedures in the lumbar spine and 8 procedures of the cervical spine. Needles were placed under fluoroscopic guidance within the facet capsules.

Positive responders were considered to have at least a 50% improvement with a single set of injections.

Positive responders were divided into:

- 1- Those with 50% to 75% improvement
- 2- Those with greater than 75% improvement.

Treatment consisted of a single set of injections at the involved facet joints bilaterally with follow up at 6 months:

- 1- 1cc of CRP per joint in the cervical patients
- 2- 1 1/2 cc of CRP per joint in the lumbar treated patients

Results

Lumbar Positive Results

1- 15 out of 25 or 66% had positive results

A) Patients with 50 to 75% improvement - $5/15 = 33\%$

B) Greater than 75% improvement - $10/15 = 67\%$

Cervical Positive Results

1- 5 out of 8 = 63% Positive Results

A- 50 to 75% improvement $2/5 = 40\%$

B- Greater than 75% improvement $3/5 = 60\%$

Note:

When eliminating those patients with Disc Herniation's

In the Lumbar Group 5 of the negative patients had significant disc herniation's without radiculopathy. When eliminating these 5, the positive responders increase to 75%.

In the Cervical Group 1 of the non-responders had significant disc herniation's but no radiculopathy. When eliminating this 1 the positive responders increase to 71%.

It is thus likely that a proportion of those patients with disc herniation's and tenderness of the facet joint line had discogenic pain (pain from a herniated disc) as the primary etiology of pain and thus did not respond to facet-based treatment.

Summary

Approximately two out of three patients with facet based pain treated with a single set of injections into the involved facet joints experienced significant improvement in pain that persisted for 6 months utilizing cytokine enriched plasma. Elimination of patients with known herniated discs without radiculopathy appears to increase the response rate as it eliminates most of those patients whose etiology of pain is discogenic and thus is non- facet based. Anecdotally, those patients with only a partial response who have had a second set of injections have shown further improvement in pain levels. Additionally, we have seen a small number of patients return for treatment of other areas of the spine at over one year with ongoing relief of pain in the originally injected area. Clearly, cytokine and growth factor enriched plasma provides effective pain relief in a majority of patients with facet-based pain for up to six months. Further studies will be required to both expand on the number of patients and extend the time frame of response to determine long-term results.