First Interim North American Results of a Multicentre, blinded, pilot study of a Novel Peptide in promoting Lumbar Spine Fusion.

Peter Jarzem BSc(Eng), MD, FRCSC; Zeeshan Sardar MD.CM., M.Sc; Greg Anderson MD
1.McGill University Health Centre, McGill University, Montreal, Quebec, Canada
2.Thomas Jefferson Hospital, Philadelphia, Pennsylvania, USA

Introduction

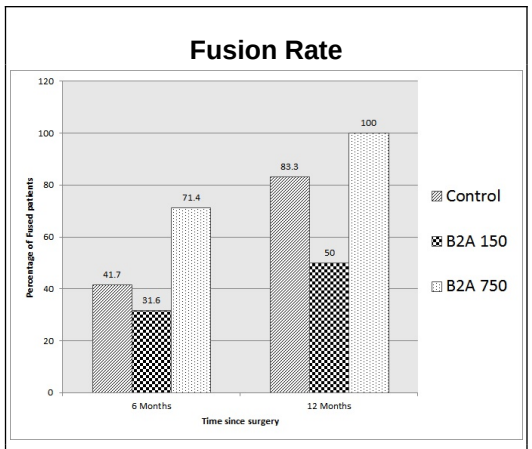
Fusion failure in transforaminal lumbar interbody fusion(TLIF) procedures is a challenging problem that can lead to poor functional outcomes. B2A is a synthetic peptide that amplifies the biologic response to native BMP-2 and has proven efficacy in achieving fusion in animal models. It may be a cheaper but safer alternative to other BMPs while avoiding iliac crest bone graft (ICBG) harvesting morbidity.

Purpose:

The Purpose of this study was to: (1) Evaluate effectiveness of B2A enhanced ceramic granules in achieving fusion in patients undergoing single level TLIF, (2) Evaluate effectiveness of B2A in improving functional status of patients undergoing single level TLIF, and (3) Evaluate the safety profile of B2A enhanced ceramic granules.

Methods

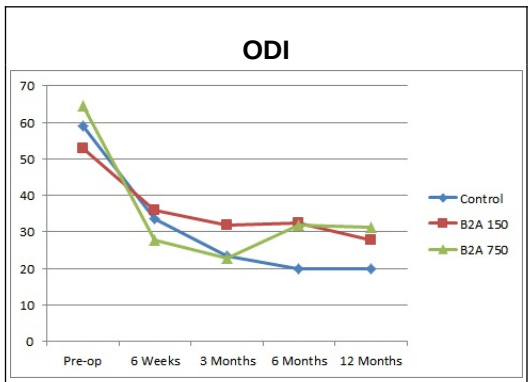
This is a multicenter North American, prospective randomized control trial. Skeletally mature patients with single level degenerative disorders at L2-S1 requiring single level TLIF were randomized to 3 groups: Iliac crest bone graft (ICBG), B2A 150 (150 mcg B2A/cc of ceramic granules) and B2A 750 (750 mcg B2A/cc of ceramic granules). 39 patients (13 Control, 19 B2A 150, 7 B2A 750, 24 Canada, 15 USA, 19 males, 20 females) were enrolled between 2009-2010. Outcome measures included Oswestry Disability Index(ODI), Visual Analog pain Scale(VAS), and fusion as assessed by CT and dynamic flexion/extension x-rays. Patients were evaluated at 6 weeks, 3, 6 and 12 months after surgery.



Fusion rate at 6 - 12 month post-op

Results

Mean blood loss during surgery was higher in ICBG (431cc) than both B2A 150 (251cc) and B2A 750 (314cc).



ODI at different points

The mean ODI was 19.9 for ICBG, 31.1 for Prefix 750 and 27.8 for Prefix 150 at 12 months; differences were not statistically significant (p = 0.037).

Fusion at 6 months was 42%, 32%, and 71% for ICBG, B2A 150 and B2A 750 respectively. However, these differences were not statistically significant (p = 0.19). At 12 months, fusion was 83%, 50%, and 100% for ICBG, B2A 150 and B2A 750 respectively. These differences were statistically significant using one way ANOVA (p = 0.03).

There were no significant differences in serum chemistry between groups. No subjects developed antibodies to B2A.

Complications related to surgery included; 1 adjacent level infection needing reoperation (B2A 750), 1 seroma that was drained without consequence (B2A 150), 2 reoperations due to non-union (B2A 150), and 1 superficial wound infection each in B2A 150 and B2A 750.

Conclusions

B2A is a promising material with possibly a dose related effect. It provides a safe alternative to ICBG and avoids donor site morbidity. B2A 750 showed superior fusion rate to autograft at 12 months. Both B2A groups and autograft were equivalent in improving ODI at all time-points up to 12 months.

References

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