Long-Term Results (12-Months) of a Prospective, Multi-Center, Open-Label Clinical Trial Comparing Intradiscal Biacuplasty (IDB) to Conventional Medical Management (CMM) for Discogenic Lumbar Back Pain (LBP)

Mehul J. Desai[a,b], Leonardo Kapural[c], Jeffrey D. Petersohn[d], Ricardo Vallejo[e], Robert Menzies[f], Michael Creamer[g], Michael Gofeld[h]

[a]George Washington University Medical Center, Washington, DC, USA; [b]International Spine, Pain, and Performance Center, Washington, DC, USA; [c]Center for Clinical Research, Winston-Salem, NC, USA; [d]PainCare, Linwood, NJ, USA; [e]Millennium Pain Center, Bloomington, IL, USA; [f]JPS Orthopedic and Sports Medicine, Arlington, TX, USA; [g]Compass Research, Orlando FL, USA; [h]Center for Pain Relief, University of Washington Medical Center, Seattle, WA, USA

INTRODUCTION

- **Primary Objective**
  - To evaluate the efficacy of IDB by comparing it to CMM for treating discogenic pain of the lumbar spine 12-months after the initiation of each method
    - *-Effect on Pain (Visual Analog Scale (**VAS**))*
- **Secondary Objective**
  - To determine the effects of each treatment on physical and emotional functioning, disability, and health-related quality of life at 12-months post-treatment
    - *-SF36-Physical Functioning (**SF36-PF**)*
    - *-Oswestry Disability Index (**ODI**)*
    - *-Beck's Depression Index (**BDI**)*
    - *-Patient Global Impression of Change (**PGIC**)*
    - *-Quality of Life Index (**EQ-5D**)*

ELIGIBILITY

Main Inclusion Criteria

- Completion of the 6-month follow up of the original effectiveness study
- Consent to continue follow up for additional 6 month following either IDB after crossing over or remaining in CMM group

Main Exclusion Criteria

- Major deviations from protocol

STUDY DESIGN (Original Protocol)

- **Prospective, randomized, crossover, open-label, multi-center (nine) clinical study**
- **IDB + CMM**
  - One ablation procedure/patient
- **CMM**
  - Physical Therapy
  - Pharmacological Management
  - Interventions
    - -Lumbar-epidural injections
    - -Sacro-iliac joint injections
    - -Facet-joint or nerve interventions
  - Behavioral Therapy
  - Weight Loss
  - Acupuncture
  - CMM subjects could elect to cross-over to IDB + CMM at 6-months, or to continue CMM-alone to 12-months
- **Prior Medications**
  - Continued as usual – both study groups
- **Non-Invasive Interventions**
  - Permitted as needed – both study groups
- **Surgical Interventions**
  - Not permitted
    - -IDET
    - -Spinal fusion
    - -Discectomy

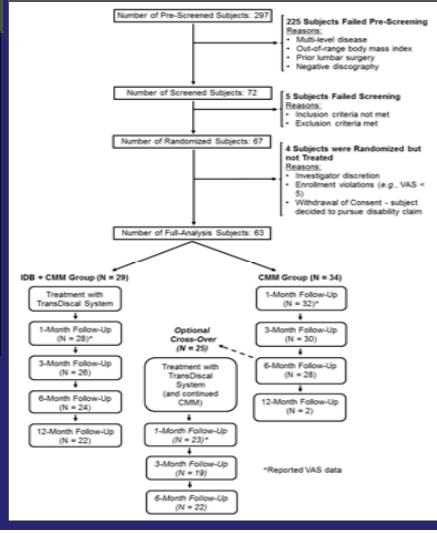
This study was sponsored by Halyard Health, Inc.

Conflict of interest mitigation: the study was monitored by independent monitors according to United States Food and Drug Administration standards.

METHODS

- **Intradiscal Biacuplasty**
  - Sedated, conscious patients
  - Fluoroscopy-guided
  - Generator Settings to Ablate Nerves
    - -Bipolar: temperature = 50°C, ramp rate = 2°C/minute, and ablation time = 15 minutes
    - -Monopolar: temperature = 60°C, ramp rate = 80°C/minute, and ablation time = 2.5 minutes
- **Data Analysis**
  - P-values were determined by Analysis of Variance – Significance: VAS, $p \leq 0.05$
  - A clinically significant score-change for SF36-PF is ≥ a 15-point increase, for ODI is ≥ a 10-point decrease, and for EQ-5D is ≥ 0.081
- **Follow-Up**
  - Primary and secondary outcomes were collected during the first 6-months (Spine 2015 Epub ahead of print)
  - Patients in the CMM group were allowed to cross-over after 6-months
  - Data of both the original IDB + CMM and the crossed- over IDB + CMM groups were collected at the 12-month follow-up visit

STUDY HISTORY



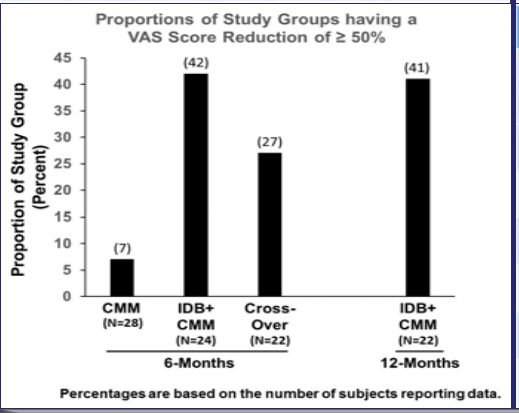
RESULTS

Twelve-Month Outcomes: Original IDB + CMM Group

Outcome	Mean Baseline Score	Mean 12-Month Score	Significant Difference?	Mean 12-Month Score-Change	Clinically Significant Score-Change?
VAS	6.7 (1.3 (SD)) (N = 29)	4.4 (2.9) (22)	Yes ($p = 0.001$)	-2.2 (2.9) (22)	N/A
SF36-PF	48 (27) (29)	62 (28) (22)	Yes ($p = 0.003$)	15 (21) (22)	Yes
ODI	42 (16) (29)	30 (21) (22)	Yes ($p = 0.002$)	-14 (18) (22)	Yes
BDI	8 (7) (28)	8 (9) (22)	No ($p = 0.86$)	-0.24 (6) (21)	N/A
PGIC	4.4 (1) (28)	2.9 (1.5) (22)	Yes ($p < 0.001$)	-1.7 (1.6) (21)	N/A
EQ-5D	0.57 (0.21) (29)	0.71 (0.26) (22)	No ($p = 0.04$)	0.13 (0.23) (22)	Yes

Six-Month Outcomes: Cross-Over Group

Outcome	Mean Baseline Score	Mean 6-Month Score	Significant Difference?	Mean 6-Month Score-Change	Clinically Significant Score-Change?
VAS	7 (2 (SD)) (N = 23)	4.7 (3) (22)	Yes ($p < 0.001$)	-2.4 (3) (22)	N/A
SF36-PF	42 (25) (23)	56 (27) (22)	Yes ($p < 0.001$)	17 (19) (22)	Yes
ODI	42 (15) (23)	29 (16) (22)	Yes ($p < 0.001$)	-13 (14) (22)	Yes
BDI	8 (5) (23)	7 (5) (22)	No ($p = 0.18$)	-1.6 (5) (22)	N/A
PGIC	4.7 (1) (23)	3 (1.5) (22)	Yes ($p < 0.001$)	-1.8 (2) (22)	N/A
EQ-5D	0.54 (0.2) (23)	0.71 (0.2) (22)	Yes ($p = 0.005$)	0.17 (0.2) (22)	Yes



Cross-Over Group vs. CMM-Alone Group or Original IDB+CMM Group - Mean Outcome Scores by Statistical Significance at Six-Months

	Significantly Different Mean Score at 6-Months Compared to Baseline?		
	CMM-Alone	Cross-Over	Original IDB + CMM
VAS	No ($p = 0.081$)	Yes ($p < 0.001$)	Yes ($p < 0.001$)
SF36-PF	No ($p = 0.6$)	Yes ($p < 0.001$)	Yes ($p < 0.001$)
ODI	No ($p = 0.87$)	Yes ($p < 0.001$)	Yes ($p = 0.005$)
BDI	No ($p = 0.8$)	No ($p = 0.18$)	No ($p = 0.81$)
PGIC	No ($p = 0.32$)	Yes ($p < 0.001$)	Yes ($p < 0.001$)
EQ-5D	No ($p = 0.79$)	Yes ($p = 0.005$)	No ($p = 0.021$)

CONCLUSIONS

- **The outcomes of this study suggest that:**
  - IDB + CMM more effectively reduces discogenic LBP than CMM-alone, and can rescue individuals who continue suffering from discogenic pain
  - IDB + CMM enables better physical functioning, less disability, and a greater positive impact on patients' health compared to CMM-alone
  - The positive effects of IDB + CMM are durable, lasting up to 12-months after a single IDB treatment
- **The superior performance of the IDB + CMM treatment with respect to all study outcomes suggests that IDB + CMM is a more effective treatment for discogenic LBP than CMM-alone**