# Medtronics Infuse rhBmp-2

Posted by islandtommy - 14 Sep 2011 19:50

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I was diagnosed with adhesive Arachnoiditis in Dec of 2009, three months after an L 3L4 fusion using rhBmp-2. Within one week after the surgery I started to experiance severe pain in both of my legs, feet and occassionly my arms and hands. It wasn't until a few months ago that sweveral articles were published in The Spine Journal regarding the dangers of rhBmp-2 and the cover up of side effects by the doctors doing the trial in 2000 for FDA approval. One article I will referance is titled "BMP-2 and spinal arthodesis: the basic science perspective on protien interaction with the nervous system" by Anton E. Dmitriev PhD and R.A Lehman M.D.  There seems to be much recent research into the effects bmp-2 has on neuroinflammation and other side effects. The doctors who did the intial trial research were paid millions of dollars(US) for "consulting" and "royalties" "unrelated to the Infuse Trial". Many in the medical community have spoke out about this "pay for results" research. As we have learned that Depo-Medrol was a leading cause of Arachnoiditis I believe, and only research will tell, that rhBmp-2 also causes Arachnoiditis. I ask that anyone who has had surgery and experianced pain or was diagnosed with Arachnoiditis after their surgery to post your experiance. I want to bring this issue to the forfront of the medical and legal community.

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# Re: Medtronics Infuse rhBmp-2

Posted by Kim - 14 Sep 2011 22:02

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Hi again Tommy

Just Googled Medtrontics BMP fusion. Disaster!! My fusion was with bone from my own hip and was successful. Shame the nerve damage came from myelogram and successive epidurals.

I am sorry Tommy I can only repeat my Mantra - the whole of the skeleton body and it's organs are designed to protect the brain and spinal cord and why any human being let alone a physician think they can penetrate that area with impunity is beyond me and any responsible person.

Kepp us up to date and I will try to get an opinion from DocSarah

Take care

Kim

PS I am not medically qualified just sadly experienced

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# Re: Medtronics Infuse rhBmp-2

Posted by Kim - 21 Sep 2011 15:01

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POSTED by Kim - SOURCED by DocSarah

A comprehensive review of the safety profile of bone morphogenetic protein in spine surgery.

Benglis D, Wang MY, Levi AD.

Source

Department of Neurological Surgery, University of Miami Miller School of Medicine, Miami, Florida, USA.

Abstract

WE REVIEW OUR current understanding of the development and potential clinical applications of bone morphogenetic protein (BMP) in spine surgery. We also review the evidence for adverse events associated with the use of BMP and suggest potential reasons for these events and means of complication avoidance. Bone morphogenetic protein 2 (rhBMP-2) is approved by the Food and Drug Administration for anterior lumbar interbody fusion; rhBMP-7, on the other hand, is approved for long bone defects and has received a humanitarian device exemption for revision posterolateral lumbar operations and recalcitrant long bone unions. Nevertheless, "off-label" use in various spinal procedures has been reported and is increasing in frequency. Specific guidelines for rhBMP-2 and rhBMP-7 use are lacking because of the limited availability of randomized controlled clinical trials and its diverse use in many spinal applications. Mechanisms of delivery, carrier type, graft position, surgical location, and variations in BMP concentration may differ from one surgery to the next. Adverse events linked to either rhBMP-2 or rhBMP-7 use include ectopic bone formation, bone resorption or remodeling at the graft site, hematoma, neck swelling, and painful seroma. Other potential theoretical concerns include carcinogenicity and teratogenic effects. In this review, we provide the reader with a historical perspective on BMP, current and past research to support its use in spinal procedures, and a critical analysis of the complications reported thus far.

Spine (Phila Pa 1976). 2010 Apr 20;35(9 Suppl):S86-104.

Complications related to osteobiologics use in spine surgery: a systematic review.

Mroz TE, Wang JC, Hashimoto R, Norvell DC.

Source

Neurological Institute, Center for Spine Health, Departments of Orthopaedic and Neurological Surgery, The Cleveland Clinic, Cleveland, OH 44195, USA.



Abstract

STUDY DESIGN:

Systematic review.

OBJECTIVE:

The objectives of this systematic review were to identify the character and rates of complications in patients after the use of BMP in spine fusion surgery and to determine whether there is a dose-response relationship of BMP with complications.

SUMMARY OF BACKGROUND DATA:

BMP is used on-label for ALIF with LT-CAGE and off-label for various spine fusion applications in the cervical, thoracic, and lumbar spines because of its effectiveness in promoting arthrodesis. Multiple studies published over the past several years have highlighted complications associated with BMP in a variety of clinical fusion scenarios. There are no systematic reviews on this topic, and thus, the complication profile of off-label use or physician directed use of BMP in spinal fusion surgery is not well characterized. Some of the reported complications are unique to BMP, which underscores the need for this thorough literature review.

METHODS:

A systematic review of the English language literature was performed for articles published between 1990 and June 2009. Electronic databases and reference lists of key articles were searched to identify articles examining the use of BMP in spine surgery. Two independent reviewers assessed the level of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria and disagreements were resolved by consensus.

RESULTS:

Two hundred forty-' articles that assessed outcomes after BMP use in spinal surgery were identified from the literature; of these, 31 articles were selected for inclusion. We determined that multiple complications are associated after the use of rhBMP-2 in both cervical and lumbar spine fusion surgery. There is a mean incidence of 44%, 25%, and 27% of resorption, subsidence, and interbody cage migration reported for lumbar spine interbody fusion surgery although reoperation or long-term detrimental effect was rare. Cervical studies report a mean 5.8% of postoperative soft tissue problems, including dysphagia, when rhBMP-2 is used for ventral cervical fusion. It was determined that the strength of evidence of the peer-reviewed literature that report on types of complications is high for the lumbar and low for the cervical spine, respectively, and that the current strength of evidence on rates of complications with BMP is moderate and low, respectively.

CONCLUSION:

The complication profile of BMP-2 for ALIF with LT-CAGE is well characterized. Because of the lack of substantive data, the same is not true for other types of lumbar fusions, or for cervical or thoracic fusion applications. BMP has been associated with a variety of unique complications in the ventral cervical and lumbar spines. The published data on BMP fail to precisely profile this product's use in fusion surgery; hence, it should be used only after a careful consideration of the relevant data. Well-designed and executed studies are necessary to completely define the incidence of various complications relative to type of BMP, type and region of fusion, surgical technique, dose, and carrier, and importantly, to define the natural history and management of associated complications.

There are also more recent articles (2011) on adverse effects but they don'#t have abstracts and I can't access the full article. (see Medline www.pubmed.com under bmp-2)

Hope this helps.

DocSarah

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## Re: Medtronics Infuse rhBmp-2

Posted by Eldridge - 26 Oct 2011 04:30

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My husband is scheduled for spinal fusion at L-4,5 and L-5,S1 using INFUSE rhBMP-2 on 10/31/2011. The surgery admission order states "anterior/lateral/posterior fusion" They also told him that he has a fractured vertebre although he doesn't remember which one. I am in fear of the outcome after reading the informed consent he had to initial and sign. He feels he has no options because of the chronic pain he is in. I also noted this shouldn't be performed if you are undergoing treatment for cancer. Although he received neither chemo or radiation he had had a wedge resection of one lung for BAC June 7 2011 and has a spot on the other lung. He is due for a followup CT scan in January to gauge the growth of the second. There will be another surgery if indicated. He also has CKD III and sleep apnea. He has had breathing tests done by 3 separate doctors all showing mild chest restriction with numbers like 68% before and 72% after using an inhalant. Can you explain if any of his other ailments might affect this soon to happen surgery? It is hard enough to have him go through with this choice. Thank you very much

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## Re: Medtronics Infuse rhBmp-2

Posted by Kim - 26 Oct 2011 18:44

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Written by DocSarah Posted by Kim

I'm sorry, this case looks extremely complex and as I am not one of his attending doctors, I think it would be inappropriate (unethical) for me to comment or advise. The only suggestion I can make is for you and your husband to fully discuss all of your concerns prior to his surgery.

Best wishes

DocSarah

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# Re: Medtronics Infuse rhBmp-2

Posted by Eldridge - 27 Oct 2011 01:24

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Thank you. I do understand your position. We will continue in prayer and I will let you know of the results.

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