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FACT SHEET

LANDMARK STUDY COMPARING KYPHON® BALLOON KYPHOPLASTY TO NON-SURGICAL CARE

Study Overview

One-year results from the largest multicenter randomized controlled study comparing Medtronic's KYPHON® Balloon Kyphoplasty to non-surgical care for the treatment of acute vertebral compression fractures (VCFs) were published in February 2009 by *The Lancet*.ⁱ

The study involved 300 patients at 21 sites in eight European countries. Some 149 patients were randomized to balloon kyphoplasty. Another 151 patients were randomized to solely receiving non-surgical care such as analgesics, bed rest, bracing, physiotherapy, rehabilitation programs and walking aids. Intent-to-treat analysis of the one-year follow-up results were reported in 2009 on 234 patients -- 124 who were treated with balloon kyphoplasty and 110 who received non-surgical care.

In order to qualify for enrollment in the study, patients had to have one to three VCFs with edema. At least one of the fractures had to show at least a 15% decreased height. In keeping with the indications for use in the United States, the fractures had to be caused by osteoporosis or certain types of cancer.

The study only focused on balloon kyphoplasty and did not address other surgical options for VCFs. It was sponsored by Medtronic, Inc.



Key Results

The balloon kyphoplasty patients showed *faster and significantly better outcomes* compared to the patients solely receiving non-surgical care one month after surgery. The benefits of balloon kyphoplasty were sustained on average throughout 12 months.

Compared to the control group, balloon kyphoplasty patients showed:

- **Improved Quality of Life:** Balloon kyphoplasty patients demonstrated greater improvement in their quality of life as measured by two quality-of-life scores. They showed greater improvement in *SF-36 physical component summary score* at one month and was maintained on average over the 12-month period. They also showed significantly greater improvement in *EQ-5D quality of life measures* at one month and 12 months.
- **Quicker Return of Physical Function:** Balloon kyphoplasty patients showed more improvement in back function as measured by the *Roland-Morris Back Function Scale* at one month and at 12 months. They also showed significantly greater improvement in several *SF-36 physical function subscale scores* at one month and were maintained on average through 12 months. Additionally, they reported *fewer days of limited activity due to back pain* and *less walking aid usage* over the 12-month period.
- **Faster Pain Relief:** Balloon kyphoplasty patients reported *less back pain* and *reduced usage of analgesics* over the 12-month period.

Additionally, the study showed:

- **Safety:** There was no significant difference in the overall frequency or severity of adverse events with balloon kyphoplasty compared to non-surgical care. While there was a haematoma and urinary tract infection in the BKP group, there were no procedure- or device-related myocardial infarctions, pulmonary embolisms, neurological injuries, or deaths.
- **Clinical Relevancy:** The study is the largest multicenter randomized controlled trial (level 1 clinical evidence) comparing balloon kyphoplasty to non-surgical care.

Study Significance

- The study addresses a major health issue by comparing treatment options for the 1.4 million VCFs suffered annually worldwideⁱⁱ that cause pain, disability and diminished quality of life.
- Although other studies have reported improved pain and function after balloon kyphoplasty,^{iii iv v} the study provides data from a large, randomized, multicenter trial to assess the clinical outcomes of balloon kyphoplasty compared to non-surgical care of VCFs.
- Study findings will help patients and physicians make informed decisions about the use of balloon kyphoplasty as an early treatment option.
- Study results show statistically significant improvements in quality of life, physical function and back pain in patients receiving balloon kyphoplasty compared to those solely receiving non-surgical care one month after surgery. The benefits of balloon kyphoplasty were sustained on average throughout 12 months.
- Study results demonstrated no significant difference in the overall frequency of adverse events or serious adverse events between the balloon kyphoplasty and nonsurgical groups.

About Balloon Kyphoplasty

Balloon kyphoplasty is a minimally invasive procedure marketed by Medtronic's Spinal and Biologics Business that is intended to reduce pain and disability and correct the angular deformity caused by VCFs. Balloon kyphoplasty is the only procedure that utilizes a catheter and balloon to restore vertebral body height and correct the angular deformity caused by VCFs.

Although the complication rate with KYPHON Balloon Kyphoplasty has been demonstrated to be low, as with most surgical procedures, there are risks associated with the procedure, including serious complications. This procedure is not for everyone. A prescription is required. Please consult your physician for a full discussion of risks and whether this procedure is right for you.

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ⁱ Wardlaw W, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. 2009; Vol 373. Published on www.thelancet.com on February 24, 2009.

ⁱⁱ Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporos Int* 2006;**17**(12):1726-33.

ⁱⁱⁱ Garfin SR, Buckley RA, Ledlie J. Balloon kyphoplasty for symptomatic vertebral body compression fractures results in rapid, significant, and sustained improvements in back pain, function, and quality of life for elderly patients. *Spine* 2006;**31**(19):2213-20.

^{iv} Grafe IA, Da Fonseca K, Hillmeier J, et al. Reduction of pain and fracture incidence after kyphoplasty: 1-year outcomes of a prospective controlled trial of patients with primary osteoporosis. *Osteoporos Int* 2005;**16**(12):2005-2012.

^v Komp M, Reutten S, Godolias G. Minimally invasive therapy for functionally unstable osteoporotic vertebral fracture by means of kyphoplasty: prospective comparative study of 19 surgically and 17 conservatively treated patients. *J Miner Stoffwechs* 2004;**11** (Suppl 1):13-15;original article in German, English translation available.