Medtronic News

Kyphon(R) Balloon Kyphoplasty Found Beneficial for Treating Spinal Fractures in Cancer Patients

Study Showed Minimally Invasive Procedure Provided Better Back Function, More Rapid Back Pain Relief and Improved Quality of Life Compared with Non-surgical Care

MINNEAPOLIS, Feb 16, 2011 (BUSINESS WIRE) --

Medtronic Inc., (NYSE: MDT) today announced the results of the first randomized, controlled trial comparing Kyphon Balloon Kyphoplasty with non-surgical care in treating spinal fractures in cancer patients.i The study found that Kyphon Balloon Kyphoplasty provided cancer patients better back-specific function, more rapid back pain relief and improved quality of life compared with non-surgical care one month after treatment.

The study was published today in the online edition of *The Lancet Oncology.* It involved 134 patients with vertebral compression fractures who also had various types of cancer such as breast, lung, and prostate or had multiple myeloma and took place at 22 sites in the U.S., Europe, Australia and Canada.

The study, Cancer Patient Fracture Evaluation or CAFE, was sponsored by the Kyphon Products Division of Medtronic. It provided clinical evidence for the benefits of Kyphon Balloon Kyphoplasty compared with standard non-surgical care. Devices to perform Kyphon Balloon Kyphoplasty for both patients with cancer and those with osteoporosis are sold by Medtronic.

"The results of this landmark study should be welcomed news to cancer patients across the world suffering from the debilitating effects of painful vertebral compression fractures," said Dr. James Berenson, the study's first author and Medical and Scientific Director of the Institute for Myeloma and Bone Cancer Research in West Hollywood, CA. "It is documented that nearly one-fourth (24 percent) of patients with multiple myeloma, 14 percent with breast cancer, 8 percent with lung cancer and 6 percent with prostate cancer suffer painful vertebral compression fractures. With the results of this new randomized study, there is now clinical evidence of a treatment option for spinal fractures in cancer patients that can provide excellent relief of pain and improved quality of life."

Patients in the CAFE study were randomized to either a Kyphon Balloon Kyphoplasty group (n=70) or a non-surgical control group (n=64). Members of both groups were able to receive non-surgical care, such as pain medications, best rest, bracing, walking aids and radiation therapy, as medically appropriate.

Multiple outcomes relating to quality of life, physical function and back pain were evaluated in 129 patients (68 kyphoplasty and 61 non-surgical patients). The primary outcome was the change in back-specific function from baseline to one month between the groups as measured by the validated Roland-Morris Disability Questionnaire (RDQ) score, with 0 equal to no disability and 24 equal to maximum disability.

The key findings of the study were as follows:

- Better Back-specific Function - The Kyphon Balloon Kyphoplasty group's functional status as measured by the RDQ at one month showed clinically and statistically significant improvement, with a mean improvement from baseline of -8.3 points ($p<0.0001$). The control group showed no statistically significant change in RDQ score (0.1 points; $p=0.83$). At one month, more balloon kyphoplasty patients (51/63, 81%) had clinical improvement in RDQ compared with control patients (14/50, 28%) based on the smallest change needed for clinical meaning (the two-point minimal clinically important difference or MCID; $p<0.0001$)
- Rapid Back Pain Relief - Seven days after treatment, Kyphon Balloon Kyphoplasty patients experienced clinically and statistically significant improvement in back pain from baseline of -3.8 points compared with the minimal change of -0.3 points by the control group. The treatment effect for improvement from baseline was --3.5 points ($p<0.0001$) within seven

days and --3.3 points (p<0.0001) at one month, in favor of balloon kyphoplasty.
- Improved Quality of Life (QOL) - Kyphon Balloon Kyphoplasty patients experienced better improvements in QOL compared with the control group as measured by both the SF-36 physical and mental component summaries, which are based on a 36-item Short Form Health Survey. The balloon kyphoplasty group showed a clinically and statistically significant 8.4 point improvement (p<0.0001) compared with the control group in the SF-36 Physical Component Summary (measuring quality of life weighted on physical abilities) at one month. Improvement of 3.5 points is considered clinically meaningful. Additionally, the balloon kyphoplasty group showed a mean 11.1-point improvement (p<0.0001) compared with the control in the SF-36 Mental Component Summary score (measuring quality of life weighted on mental abilities) at one month.
- Safety Findings -Medical adverse events were similar at one month between the two groups (26/70 experienced adverse events within the balloon kyphoplasty group; 19/64 experienced adverse events within the control group). The most common adverse events within one month were back pain (4/70 for kyphoplasty and 5/64 for control) and symptomatic vertebral fracture (2/70 for kyphoplasty and 3/64 for control). One balloon kyphoplasty patient had serious adverse events at one month (intraoperative non-Q-wave myocardial infarction with intermittent atrial fibrillation) related to anesthesia that resolved. There was no difference in radiographic or clinical subsequent vertebral fractures between the two groups at one month. A subsequent vertebral fracture within a month of the index procedure observed in one balloon kyphoplasty patient (with cement leakage to the adjacent disc) was a serious adverse event reported as related to the device.

There are risks associated with the procedure (e.g., cement leakage), including serious complications, though rare, some of which may be fatal. This procedure is not for everyone. A prescription is required. Patients should consult their physicians for a complete list of indications, contraindications, benefits, and risks. Only patients and their physicians can determine whether this procedure is right for a particular patient.

"In the CAFE study, most balloon kyphoplasty patients experienced early pain reduction and improved activity, mobility and ability to take part in daily activities," said Professor Leonard Bastian, director of the Department for Orthopedics, Trauma, Hand, and Reconstructive Surgery at the Klinikum Leverkusen (Germany) and one of the study's authors. "For patients treated conservatively, pain relief was delayed. This rapid effect on pain from balloon kyphoplasty is important for cancer patients today as many need to complete their scheduled cancer treatment."

Limitations

As with all clinical studies, there are limitations. A limitation of this study is that randomization of treatment lasted for only the first month; however, this is considered to be a standard timeframe to assess safety and improvements in pain and function in this population. Due to ethical considerations of limited life expectancy, after one month, patients were allowed to crossover from the control group to receive balloon kyphoplasty and 38 of 64 (59%) chose to do so.' The study was not blinded, so knowledge of treatment may have influenced outcomes; however both treatment groups represent common medical practice. Nonsurgical care was not standardized, but each study center was asked to provide care consistent with local practices. A biopsy was not obtained in every case and, therefore, it is unknown whether a given fracture was due to an osteolytic metastasis, radionecrosis, osteoporosis, or a combination of these.

For more detailed information on the findings of the study, go towww.compressionfracturestudy.com. This study is registered on www.clinicaltrials.gov, number NCT00211237. For more information on Kyphon Balloon Kyphoplasty, go to www.balloonkyphoplasty.com.

About Kyphon Balloon Kyphoplasty

During the minimally invasive Kyphon Balloon Kyphoplasty procedure, working tubes are used to create small pathways into the fractured bone, generally on both sides of the vertebral body. Orthopedic balloons are inserted and then inflated inside the fractured bone in an attempt to return it to its correct position. Inflation and removal of the balloons create cavities in the vertebral body that are filled with bone cement, forming an "internal cast".

Balloon kyphoplasty differs from other surgical therapies for vertebral compression fractures such as vertebroplasty, which is

designed to stabilize the fracture without correcting vertebral body deformity or providing a controlled fill and distribution of bone cement. With balloon kyphoplasty, inflation of the balloons compacts the cancellous bone, which may fill fracture lines. The presence of the space also allows a more viscous bone cement to be injected under low manual pressure.

About the Spinal and Biologics Business at Medtronic

The Spinal and Biologics business is based in Memphis, Tenn. It is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. The Spinal and Biologics business works with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopedic, dental and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle-friendly surgical therapies. More information about the company and its treatment therapies can be found at www.medtronic.com and its patient-education Web sites, www.back.com, www.iscoliosis.com, www.maturespine.com and www.necksurgery.com.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Kyphon Balloon Kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

i Berenson J, Pflugmacher R, Jarzem P, Zonder J, Schechtmann K, Tillman JT, Bastian L, Ashraf T, Vrionis F, for the Cancer Patient Fracture Evaluation Investigators. Balloon Kyphoplasty versus Non-surgical Fracture Management for Treatment of Painful Vertebral Body Compression Fractures in Patients with Cancer: A Multicentre, Randomised Controlled Trial. *Lancet Oncol*. Published Online February 17, 2011.

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