Abstracts

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THE SYMPTOMATIC, FUNCTIONAL AND QUALITY OF LIFE IMPACT OF MULTIPLE SCLEROSIS. REPORT ON A QUALITATIVE INVESTIGATION OF THE PATIENTS' PERSPECTIVE

Doward LC¹, McKenna SP², Meads DM², Kavyasiddhi D², Hampson NE², Mayo KW³

¹Galen Research, Manchester, UK; ²Galen Research, Manchester, Manchester, UK; ³Novartis Pharma AG, Basel, Basel, Switzerland **OBJECTIVES:** To determine patients' views on the impact of multiple sclerosis (MS) in terms of symptoms experienced, impact on day-to-day functioning and overall quality of life (QoL). METHODS: In-depth, unstructured qualitative interviews were conducted with MS patients recruited via the MS Society in the UK. Thematic analysis was conducted on interview transcripts to identify key impact areas. Interpretive phenomenological analysis (IPA) was conducted to explore and interpret participants' perceptions of impact; specifically, the meaning and importance patients ascribed to areas of impact. **RESULTS:** Interviews were conducted with 35 individuals (15 males / 20 females). Patients were aged 31-75 (mean 50; SD 13.2) years with MS duration of 2-58 (mean 17.7; SD 14.2) years. Eleven (31.4%) had relapsing-remitting MS, 10 (28.6%) had secondary-progressive, two (5.7%) primary-progressive, two (5.7%) benign MS and one (2.9%) progressive-relapsing. MS-type was unknown by nine (25.7%) individuals. Key areas of symptomatic impact reported were fatigue, pain, incontinence and mood fluctuation. Impact on memory and broader cognitive problems were less commonly reported. Key areas of functional impact related to physical incapacity (difficulty/inability walking, difficulty using stairs), problems conducting/completing activities of daily living, personal care, impact on social functioning, sexual functioning and work life. IPA analysis revealed that the most profound effects of symptomatic and functional problems were experienced in relation to impact on quality of intimate and social relationships, self-esteem, loss of identity, personal development/fulfillment and fear of the future. CONCLUSION: The interviews provided a rich source of information about the nature of the impact of MS and the concerns of affected individuals. These data will be used to generate content for new MS-specific patient reported outcome scales of symptoms, functioning and quality of life (QoL) suitable for use in clinical trials.

OSTEOPOROSIS

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Schnitzer TJ¹, Stephenson JJ², Chen YT³, Sen SS⁴, Long S², Abbott T² ¹Northwestern University Feinberg School of Medicine, Chicago, IL, USA; ²Thomson Medstat, Philadelphia, PA, USA; ³Merck & Co., Inc, West Point, PA, USA; ⁴Merck & Co., Inc, Whitehouse Station, NJ, USA OBJECTIVE: To conduct a systematic review of the effect of ibandronate on bone mineral density (BMD) and fractures in postmenopausal women (PMW). METHODS: We followed the Cochrane collaboration methodology to identify randomized placebo-controlled trials comparing PMW receiving ibandronate to those not receiving ibandronate. Trials were included in our review if they had study duration of ONE year or longer and reported BMD or fracture incidence as outcomes. A priori hypotheses dealing with mode and frequency of administration, dosage, study duration and severity of osteoporosis were developed to help explain heterogeneity of treatment effects. Heterogeneity testing was conducted using regression models. All

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analyses were performed using Comprehensive Meta-Analysis, version 2.2, software. RESULTS: Nine trials met eligibility criteria. The trials included a total of 8784 women; 6111 received ibandronate and 2673 placebo. Study results were reported at one, two and three years for five, two and two studies, respectively. Ibandronate dose and frequency varied across studies and all trials had > one treatment arm. In all studies, ibandronate was found to increase BMD in the spine and hip compared to placebo; the average increase in spine BMD was about 4% and hip BMD about 2.75%. The BMD increase varied significantly by severity of osteoporosis, mode and frequency of administration, dosage, and study duration. Only two studies reported data on fractures. In one study (Chesnut et al, JBMR 2004), ibandronate reduced the risk of vertebral fractures but not nonvertebral fractures compared to placebo after three years of treatment. In the other study (Recker et al, Bone 2004), risk reduction was observed for neither vertebral nor non-vertebral fractures. CONCLUSIONS: Ibandronate appears to increase BMD and reduces the incidence of vertebral fractures but not non-vertebral fractures. Additional data are required to better assess the impact of ibandronate on BMD and fractures in postmenopausal osteoporosis.

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CLINICAL EFFICACY AND SAFETY OF BALLOON KYPHOPLASTY FOR THE TREATMENT OF VERTEBRAL COMPRESSION FRACTURES: A SYSTEMATIC REVIEW OF THE LITERATURE

<u>Taylor RS</u>¹, Rebecca JT^1 , Frtizell P²

¹University of Birmingham, Birmingham, UK; ²Falun Hospital, Falun, Sweden

OBJECTIVES: Balloon kyphoplasty and vertebroplasty are increasingly used in non-surgical management of patients with vertebral compression fractures (VCF). To date there has been no published systematic review that has compared the two procedures. METHODS: Number of electronic databases (MEDLINE, EMBASE and Cochrane Library) were searched through to March 1, 2004. Citation searching of included studies and no language restrictions were applied. All controlled and non-controlled study designs were included. Two reviewers carried out study selection. RESULTS: Total of 4 comparative observational studies (3 versus conventional medical management [CMM] & 1 versus vertebroplasty) and 13 case series for balloon kyphoplasty and 2 comparative observational studies (1 study versus kyphoplasty and one study versus CMM) and 57 case series for vertebroplasty were identified. Across studies, majority (>80%) of VCF patients were osteoporotic, had experienced pain for an average of five to seven months and were refractory to CMM. Compared to CMM alone, statistically significant gains in pain relief and functional improvement were observed following both balloon kyphoplasty and vertebroplasty. Although the magnitude of pain relief appears to be similar for both procedures, there is consistent evidence of substantive enhancement in quality of life following balloon kyphoplasty, evidence that is more limited for vertebroplasty. A total of 8% and 40% of operated vertebrae experienced cement leakages following balloon kyphoplasty and vertebroplasty, respectively. Unlike balloon kyphoplasty, a number of vertebroplasty cement leakages are symptomatic (5% of patients) and a number of serious adverse events have also been reported (e.g. neurologic injury and pulmonary embolism). CONCLUSION: This review demonstrates there is level III evidence to support the use of balloon kyphoplasty and vertebroplasty in the management of osteoporotic VCFs. Compared to vertebroplasty; balloon kyphoplasty appears to have a superior safety profile. The results from