primary studies - published RCT

Efficacy of pamidronate for osteoporosis in patients with cystic fibrosis following lung transplantation.

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Study design (if review, criteria of inclusion for studies)

Randomised controlled trial, parallel design, trial duration 2 years.

Participants

Single centre, university hospital, USA; Inclusion criteria:- CF, 1 to 12 months post-lung transplantation, ambulatory; Exclusion criteria:- primary graft failure or other post-operative morbidities that precluded long-term survival, renal insufficiency (serum creatinine > 3.0 mg/dl), or pregnancy; N = 34 (16 in treatment group); 17 female (7 in treatment group). Groups similar in age, gender, baseline T-scores, renal function, hospitalisation rates, immunosuppressant levels, change in lung function and body mass index over study period. 13 in treatment group and 12 controls had baseline T-scores

Interventions

Intravenous pamidronate (30 mg every 3 months) for study duration of 2 years; All participants received oral vitamin D (800IU/day) and oral calcium (1g/day).

Outcome measures

Primary outcome: BMD (spine; 0, 6, 12, 18, 24 months; DXA Hologic QDR 1000/W Waltham MA). Bone biomarkers (serum osteocalcin, urine cross-linked N-telopeptides of type 1 collagen, urine free deoxypyridinoline; 0, 3, 12, 24 months; also 2, 14 days after first pamidronate infusion in intervention group); Serum calcium, vitamin D (25-hydroxyvitamin D, 1,25-dihydroxyvitamin D) and PTH levels (0, 3, 12, 24 months); Survival. Withdrawals; Secondary outcomes: BMD (femur; 0, 6, 12, 18, 24 months; DXA Hologic QDR 1000/W Waltham MA); Kyphosis angles (degrees; 0, 24 months; thoracic spine curvature using lateral chest radiographs using a modification of method of Cobb); Adverse events (number during study; thrombophlebitis, cellulitis, bone pain, fever, hypocalcaemia defined as serum calcium < 7.8 mg/dl, hypervitaminosis defined as serum 25-hydroxyvitamin D > 55 ng/ml); New fractures (number of fractures during study; long bone using clinical data, rib using posteroanterior chest radiographs, vertebral using lateral chest radiographs);

Main results

The patients treated with pamidronate gained 8.8 +/- 2.5% and 8.2 +/- 3.8% in spine and femur BMD after 2 yr in comparison to control subjects, who gained, on average (+/- SD), 2.6 +/- 3.2 and 0.3 +/- 2.2%, respectively (p </= 0.015 for both). Seven and six fractures occurred in the control and pamidronate groups, respectively (p > 0.2). Measures of bone resorption were highest immediately after lung transplant and improved with both pamidronate and time. Measures of bone formation were very poor after lung transplant, but recovered in the first post-lung transplant year irrespective of therapy

Authors' conclusions

pamidronate was more effective than control in improving bone mineral density after lung transplantation in patients with CF and appears to be one of the most promising agents studied to date for posttransplant osteoporosis.

See also

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Keywords

Adolescent; Adult; Bisphosphonates; Bone Density Conservation Agents; Bone Diseases; Drug Administration Schedule; Intravenous; Lung Transplantation; non pharmacological intervention - surg; Osteoporosis; pamidronate; pharmacological_intervention; transplantation; Oral;