



Evidence Matters

The Value of Innovation in Osteoporosis Research

July 31, 2008

Rachael Fleurence, MBA, PhD,
Director Health Economics, United BioSource
Corporation



Overview

- The value of innovation in osteoporosis research
- Research into risk factors, treatments, diagnostic devices and genetics
- Research that changed treatment patterns: the WHI
- Economic value of medical innovation
- Take home messages

The Value of Innovation in Osteoporosis Research

- Significant human and economic burden of osteoporosis for patients and society.
- Advances in medical research can help prevent and treat osteoporosis and significantly alleviate the human and economic burden to society.
- Medical innovation in osteoporosis can provide a large return on investment.

Examples of Research in Osteoporosis: Risk Factors

- The Study of Osteoporosis Fractures – a 20-year study, found that bone mineral density (BMD) of the hip is one of the best predictors of fracture for women.
- Weight loss in the elderly and a family history of hip fractures are two of the most important risk factors for this condition.

Examples of Research in Osteoporosis: Nutrition and Physical Activities

- Clinical studies in nutrition and physical activity interventions have shown that fractures can be prevented, even in older individuals.
- A meta-analysis showed that calcium supplements have been shown to reduce the risk of vertebral fractures by around 23%.
- Another meta-analysis showed that vitamin D supplements reduced the risk of fractures by around 37%.
- A study that looked at the combination of vitamin D and calcium found that hip fractures were reduced by 43%.

Examples of Research in Osteoporosis: Pharmacological Treatments (1)

- Randomized controlled trials have shown that some pharmacologic interventions can reduce the risk of fracture by 40 to 50%.
- Bisphosphonates are a class of drugs used to prevent and treat osteoporosis in high risk patients.
- Alendronate has been shown to reduce vertebral fracture risk by 45% and hip fracture risk by 53%.
- Risedronate has been shown to reduce vertebral fracture risk by around 41% and hip fractures by around 30%.

Examples of Research in Osteoporosis: Pharmacological Treatments (2)

- Ibandronate has been shown to reduce the risk of new vertebral fractures by 62%.
- Zoledronic acid reduces the risk of vertebral fractures by around 70% and the risk of hip fracture by 41%.
- Teriparatide, a recombinant form of parathyroid hormone, has been shown to increase vertebral bone mineral density (BMD) by 9 to 13%.
- Teriparatide has been shown to decrease vertebral fractures by around 65%.
- Raloxifene, a selective estrogen receptor modulator, has been shown to decrease vertebral fractures by up to 50%.

Examples of Research in Osteoporosis: Surgical Interventions

- Patients with vertebral fractures who underwent kyphoplasty, a procedure that stabilizes fractures of the spine, were found in one study to have reduced pain, fewer new fractures, and less health care utilization for at least 12 months.

Examples of Research in Osteoporosis: Genetic Research

- Researchers have identified a gene that strongly influences peak bone mass in mice.
- The gene was not known to be involved in bone biology previously.
- This discovery can help researchers develop drugs that could prevent or reverse bone loss leading to osteoporosis.

Examples of Research in Osteoporosis: Diagnostic Tests

- Researchers are looking at the use of micro-computed tomography (3D-scans) and magnetic resonance imaging to better understand the relationship between bone structure and fracture risk.
- Ultra-sounds and dental X-rays are also being investigated.
- A study showed that universal bone densitometry combined with alendronate was highly cost-effective in elderly women diagnosed with osteoporosis.

Examples of Research in Osteoporosis: The Women's Health Initiative

- The Women's Health Initiative was a large randomized controlled trial sponsored by the NIH.
- 161,000 women were randomized to placebo or to estrogen and progestin replacement therapy.
- For years, ERT was offered to postmenopausal women to reduce bone loss and for its putative cardioprotective effects.
- The WHI showed that while there were some fracture risk reductions, there were no cardioprotective effects of ERT and in fact in some groups the risk of a cardiovascular event was increased.
- This study was a landmark in ERT treatment and changed treatment patterns very significantly.
- WHI Follow-up Study confirms health risks of long-term combination Hormone Therapy outweigh benefits for postmenopausal women

Economic Value of Medical Innovation in Osteoporosis

- Research has estimated that hip fracture prevention in at-risk postmenopausal women saves \$333 million annually.
- Advances in medical research can lead to significant reductions in the human burden associated with osteoporosis as well as decrease the economic burden of the disease.

Take Home Message

- Investments in medical research will provide a significant return on investment.