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Role of Anabolic & Antiresorptive Therapy Before and After Spine and Other Skeletal Surgeries: Rationale & Evidence

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Role of Anabolic & Antiresorptive Therapy Before and After Spine and Other Skeletal Surgeries: Rationale & Evidence

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Disclosures

- Nothing to disclose

The Problem

Managing patients with OP requiring spine surgery is a challenge because

1. Difficulty in instrumentation
2. Concern for nonunion/non-healing
3. Adjacent level fracture

There are animal studies regarding medication treatment, graft incorporation and fusion

However, only limited human clinical evidence

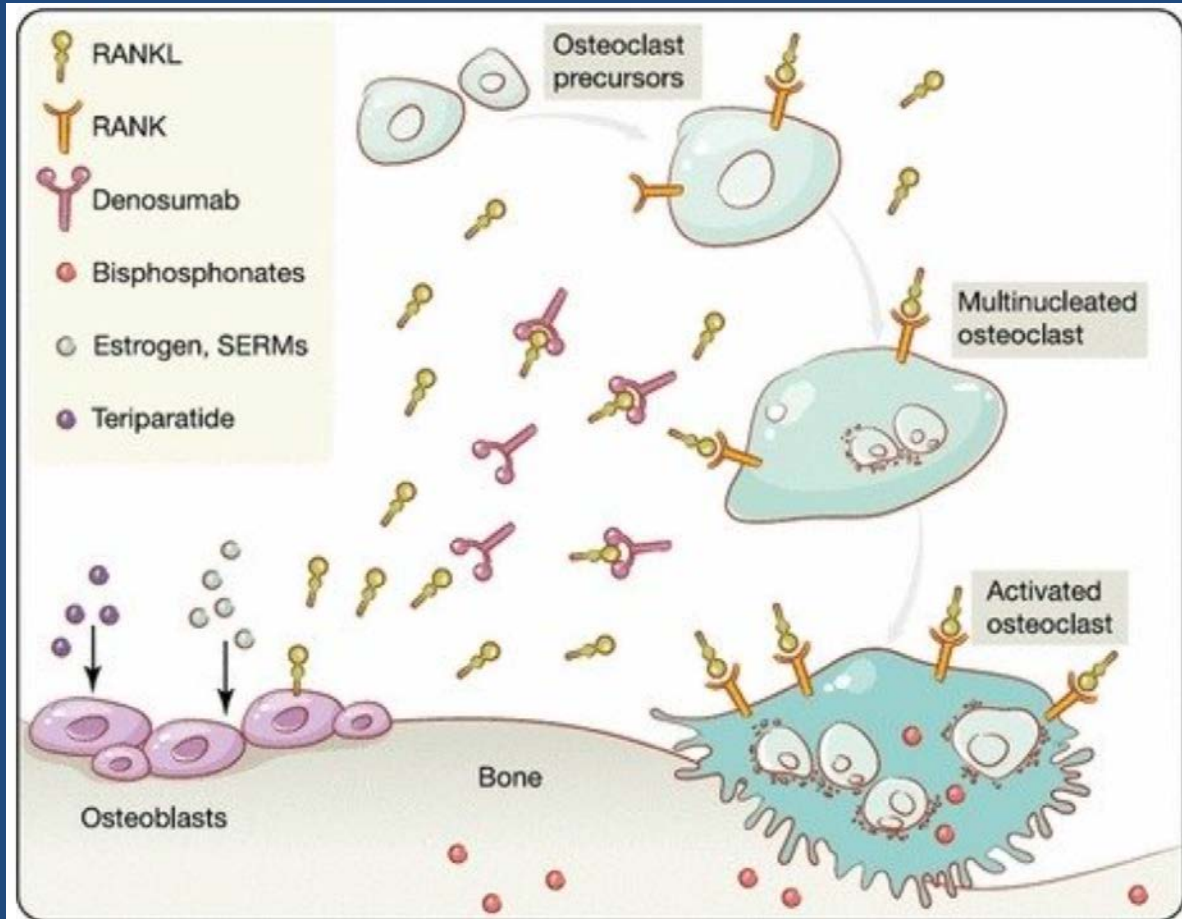
Objectives

- Review current data on bisphosphonate (BP) use in patients with OP undergoing spine surgery
- Review current data on anabolic therapy use in patients with OP undergoing spine surgery
- Deduce what would be reasonable treatment options based on the best available data

Drug Therapies

- Oral & IV Bisphosphonates
- Anabolic therapies
 - Teriparatide
 - Abaloparatide

Bone Physiology



Drug Therapies

- Bisphosphonates
 - 1) **Anti-fracture effect**
 - 2) **Reduction in morbidity**
 - 3) **Reduced health-care costs**
 - 4) **Reduced mortality**

Bisphosphonates

Previous studies using animal models suggested that bisphosphonates show negative effects on spinal fusion

The Effect of Zoledronic Acid on the Volume of the Fusion-Mass in Lumbar Spinal Fusion

Ye-Soo Park, MD, Hong-Sik Kim, MD, Seung-Wook Baek, MD, Dong-Yi Kong, MD, Jeong-Ah Ryu, MD*

*Departments of Orthopaedic Surgery and *Radiology, Guri Hospital, Hanyang University College of Medicine, Guri, Korea*

- Retrospective study
- 44 patients with symptomatic degenerative lumbar spinal stenosis
- 1-2 level fusion
- IV Zoledronic acid 2 weeks after surgery

Divided into 4 groups:

- Group 1: autograft and zoledronic acid
- Group 2: allograft/autograft and zoledronic acid
- Group 3: autograft alone
- Group 4: allograft/autograft

Radiography and 3D CT used to evaluate and quantify the volume of the fusion-mass

Results/Conclusion

- Most patients showed bone union at 6 months after surgery
- There were no significant differences in fusion rates among the 4-groups
 - A single dose of zoledronic acid does not decrease the volume of the fusion-mass in patients with OP undergoing spinal fusion

Effects of Zoledronic Acid on Bone Fusion in Osteoporotic Patients after Lumbar Fusion

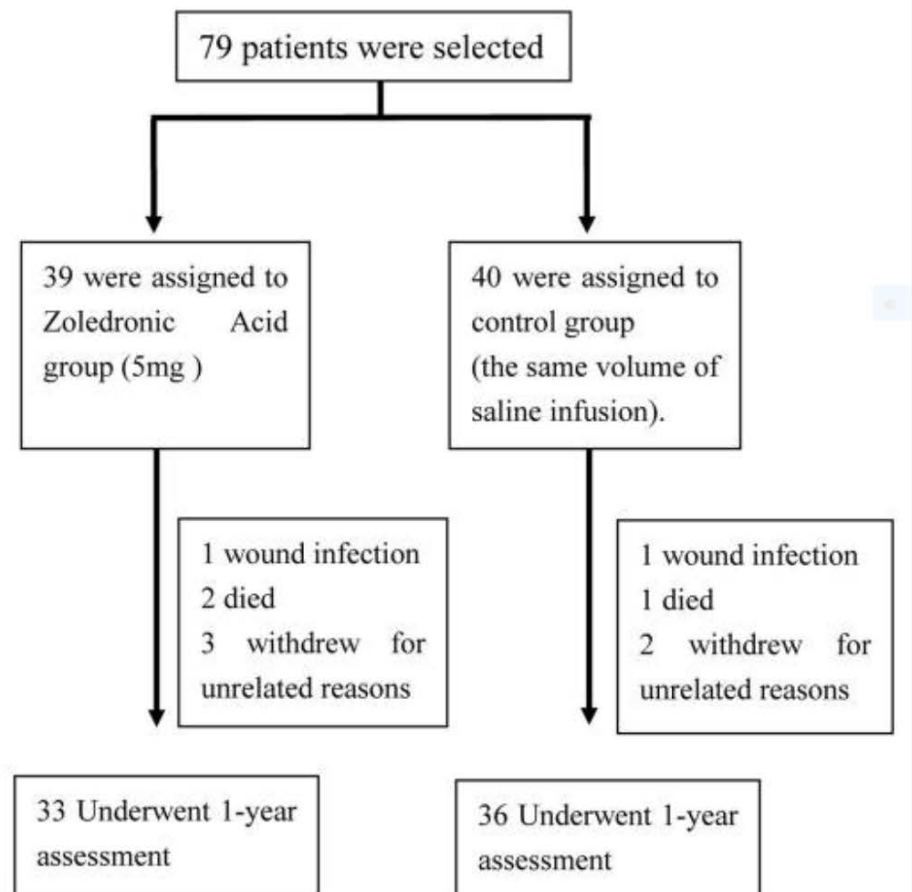
[Fei Chen](#), MD, PhD,¹ [Zhehao Dai](#), MD, PhD,^{1,*} [Yijun Kang](#), MD, PhD,¹ [Guohua Lv](#), MD, PhD,¹ [Evan T. Keller](#), DVM, PhD,^{3,4,5} and [Yebin Jiang](#), MD, PhD^{2,3,5}

Inclusion Criteria:

- Patients were diagnosed with single level lumbar degenerative spondylolisthesis
- Patients had low back and/or leg pain, which can not be relieved by conservative treatment and continued for at least 3 months.
- The T-score, measured with DXA for the lumbar spine BMD and/or femoral neck BMD ≤ -2.5
- Informed consent was obtained

Exclusion Criteria:

- The spinal tumor, infection, vertebral fractures, a history of spinal surgery, a anti-osteoporosis medication history, severe spinal deformities, uncorrected bleeding diatheses
- Creatinine Clearance Rate < 35 ml/min.



All patients underwent decompression and posterior lumbar interbody fusion surgery at the level of spondylolisthesis and received 1000 mg/d elemental calcium and 800 IU/d of vitamin D.



Figure 2

Representative sagittal reconstructed computed tomography (CT) images demonstrate a 3-category grading system to evaluate bone formation. Grade A: bridging bone bonding with adjacent vertebral bodies; Grade B: bridging bone bonding with one vertebral body; and Grade C: incomplete bony bridging.

Results

- Grade A or B bridging bone was more frequently observed in zoledronic acid group at 3, 6, and 9 months post-operation compared to the control group ($p < 0.05$)
- At 12-months there was no significantly difference between groups
- No patients in zoledronic acid group showed adjacent vertebral compression fractures (VCF), whereas 6 patients (17%) in the control group did ($p < 0.05$)
- Zoledronic acid prevented immobilization induced bone loss in the hip (BMD data)

Conclusions

Treatment with zoledronic acid in osteoporotic patients with spinal fusion

1. Shortens the time to fusion
2. Improves the fusion rate
3. Prevents subsequent aVCFs

Drug Therapies

Anabolic therapy: Teriparatide/abaloparatide

- 1) Builds new bone**
- 2) Significantly reduces the risk of subsequent vertebral and nonvertebral fragility fractures in patients with OP**
- 3) Improve both spine and hip BMD quickly & robustly**

SURGERY

Teriparatide Accelerates Lumbar Posterolateral Fusion in Women With Postmenopausal Osteoporosis

Prospective Study

Seiji Ohtori, MD, PhD, Gen Inoue, MD, PhD, Sumihisa Orita, MD, PhD, Kazuyo Yamauchi, MD, PhD, Yawara Eguchi, MD, PhD, Nobuyasu Ochiai, MD, PhD, Shunji Kishida, MD, PhD, Kazuki Kuniyoshi, MD, PhD, Yasuchika Aoki, MD, PhD, Junichi Nakamura, MD, PhD, Tetsuhiro Ishikawa, MD, PhD, Masayuki Miyagi, MD, PhD, Hiroto Kamoda, MD, PhD, Miyako Suzuki, MD, Gou Kubota, MD, Yoshihiro Sakuma, MD, Yasuhiro Oikawa, MD, Kazuhide Inage, MD, Takeshi Sainoh, MD, Masashi Takaso, MD, PhD, Tomoyuki Ozawa, MD, PhD, Kazuhisa Takahashi, MD, PhD, and Tomoaki Toyone, MD, PhD

Teriparatide Accelerates Spine Surgery Fusion in Women with Osteoporosis

- 57 postmenopausal women had spinal decompression at 1 or 2 levels
- 29 received teriparatide 20 mcg/d and 28 received risedronate 17.5 mg weekly
- Medication was started 2 months prior to surgery and continued 8 months post surgery

Teriparatide Accelerates Spine Surgery Fusion in Women with Osteoporosis

- The rate of bone union was 82% in the teriparatide group and 68% in the bisphosphonate group
- Average duration of bone union was 8 months in the teriparatide group and 10 months in the bisphosphonate group

Teriparatide Accelerates Spine Surgery Fusion in Women with Osteoporosis

- Conclusion: The rate of bone union in the teriparatide group patients were significantly better than in the bisphosphonate group
- Bone union: defined as bridging bone formation across the transverse process between adjacent vertebrae (CT done at 6 and 12 mo)

Comparison of Teriparatide and Bisphosphonate Treatment to Reduce Pedicle Screw Loosening After Lumbar Spinal Fusion Surgery in Postmenopausal Women With Osteoporosis From a Bone Quality Perspective

Seiji Ohtori, MD, PhD, Gen Inoue, MD, PhD, Sumihisa Orita, MD, PhD, Kazuyo Yamauchi, MD, PhD, Yawara Eguchi, MD, PhD, Nobuyasu Ochiai, MD, PhD, Shunji Kishida, MD, PhD, Kazuki Kuniyoshi, MD, PhD, Yasuchika Aoki, MD, PhD, Junichi Nakamura, MD, PhD, Tetsuhiro Ishikawa, MD, PhD, Masayuki Miyagi, MD, PhD, Hiroto Kamoda, MD, PhD, Miyako Suzuki, MD, PhD, Gou Kubota, MD, Yoshihiro Sakuma, MD, Yasuhiro Oikawa, MD, Kazuhide Inage, MD, Takeshi Sainoh, MD, Masashi Takaso, MD, PhD, Tomoaki Toyone, MD, PhD, and Kazuhisa Takahashi, MD, PhD

Pedicle Screw (PS) Loosening After Lumbar Spinal Fusion Surgery

- 62 women with osteoporosis had spinal fusion at 1-2 levels
- Drugs were started 2 mo prior to surgery and continued for 10 mo after surgery with 12 mo F/U

PS Loosening

- 13% in the teriparatide group had PS loosening
- 26% in the risedronate group
- 25% in the control group
- PS loosening was significantly lower in teriparatide group compared to risedronate or control group ($P < 0.05$).

TABLE 2. Number of Fusion Level and Evaluation of PS Loosening

	Teriparatide	Risedronate	Control	Statistical Analysis
No. of patients	20	20	22	
No. of fusion level	1 level: 15 patients, 2 level: 5 patients	1 level: 14 patients, 2 level: 6 patients	1 level: 14 patients, 2 level: 8 patients	
No. of patients showing loosening of PS (%)	2 (10%)	5 (25%)	6 (27%)	
No. of loosening of PS (%)				
Evaluation by radiography	6 (7%)*	12 (13%)**	15 (15%)**	*, ** $P = 0.03$
Evaluation by CT	12 (13%)*	24 (26%)**	26 (25%)**	*, ** $P = 0.04$
Total no. of evaluated PS	90	92	102	

$P < 0.05$ was considered statistically significant. * and ** denote data for statistical analysis.

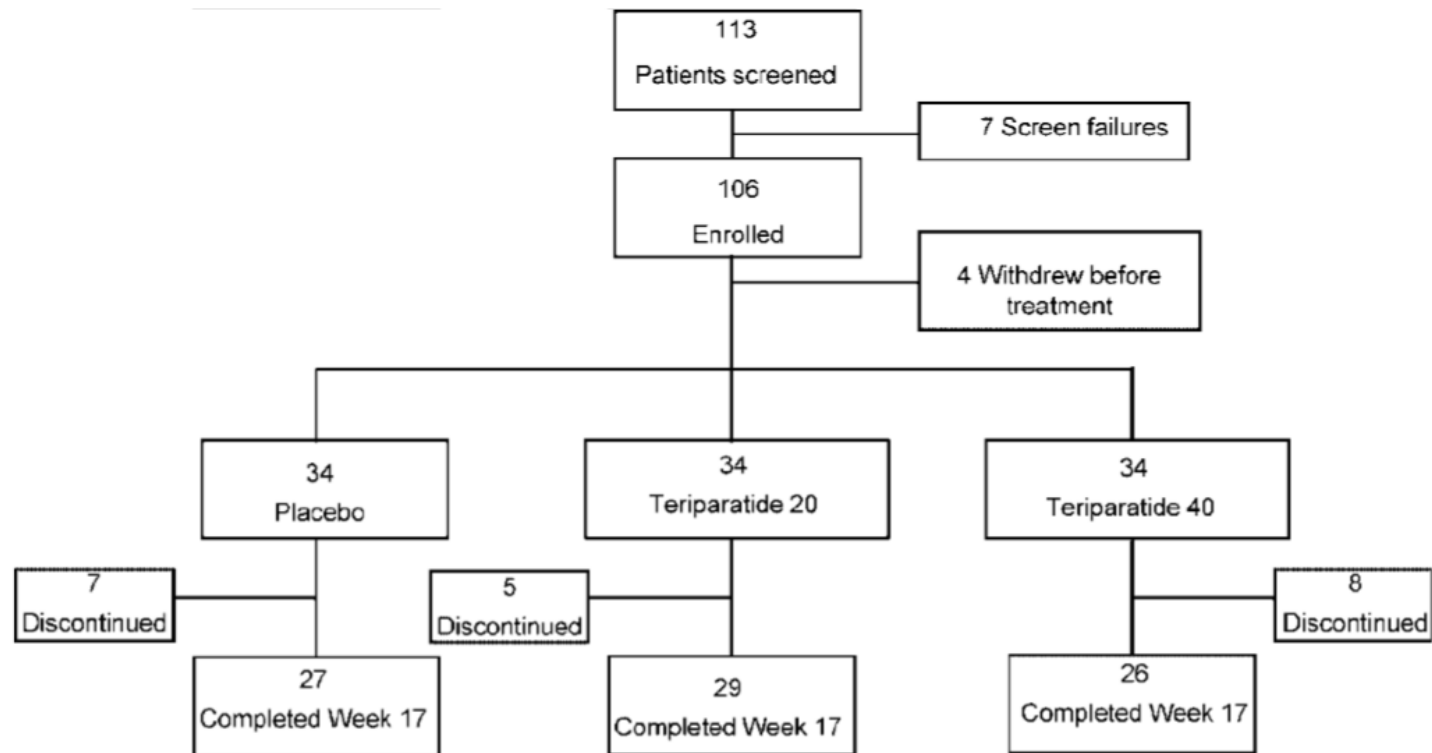
CT indicates computed tomography; PS, pedicle screw.

Conclusion

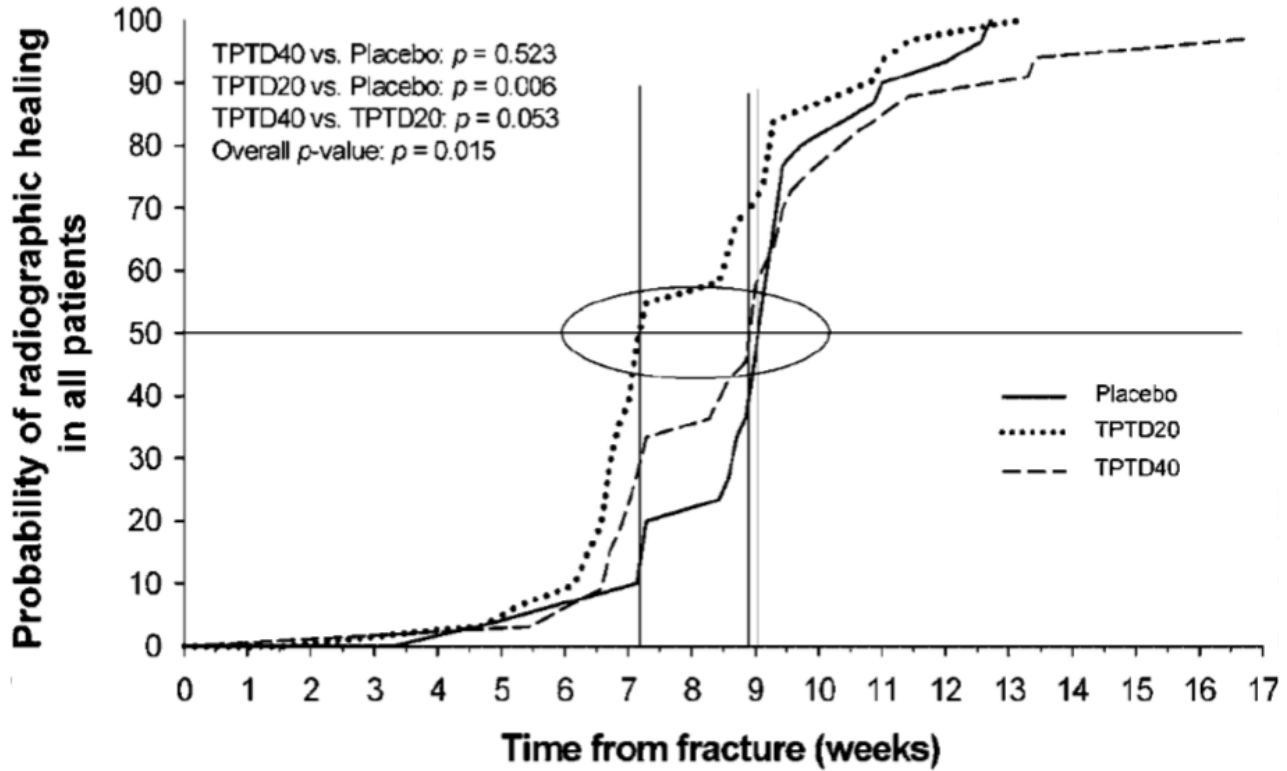
- This study suggests that anabolic therapy with teriparatide increased the quality of the lumbar spine bone and pedicle cortex.

Teriparatide for Acceleration of Fracture Repair in Humans: A Prospective, Randomized, Double-Blind Study of 102 Postmenopausal Women With Distal Radial Fractures*

Per Aspenberg,¹ Harry K Genant,^{2,3} Torsten Johansson,¹ Antonio J Nino,⁴ Kyoungah See,⁴ Kelly Krohn,⁴ Pedro A García-Hernández,⁵ Christopher P Recknor,⁶ Thomas A Einhorn,⁷ Gail P Dalsky,⁴ Bruce H Mitlak,⁴ Anke Fierlinger,³ and Mark C Lakshmanan⁴



A



Study Conclusion

Teriparatide 20 mcg dose significantly shortened the median time to healing compared to placebo.

Conclusion: Effects of Drugs in Spine Fusion

- A single dose of zoledronic acid does not decrease the volume of the fusion-mass in patients with OP undergoing spinal fusion
- Less screw loosening with teriparatide
- Teriparatide speeds up fusion (healing based on distal radial fracture data)

So which patients should we consider?

- Severe osteoporosis
- If spine surgery can be delayed for 2-3 months
- Remodeling based patient selection
 - TPTD or Abaloparatide if low (Serum CTX <200)
 - BPs if high (Serum CTX >500)
- Patient without contra-indications for BPs or anabolic therapy
 - Paget's disease of bone, Hypercalcemia, prior radiation to the skelton etc.
 - GI intolerance, renal dysfunction etc for BPs

Team Work

- Multidisciplinary approach
- Spine surgeon, Endocrinologist, PCP