Balloon kyphoplasty versus conservative treatment for acute osteoporotic vertebral fractures with poor prognostic factors - An Propensity-Score-Matched Analysis Using Data from the Two Prospective Multicenter studies –

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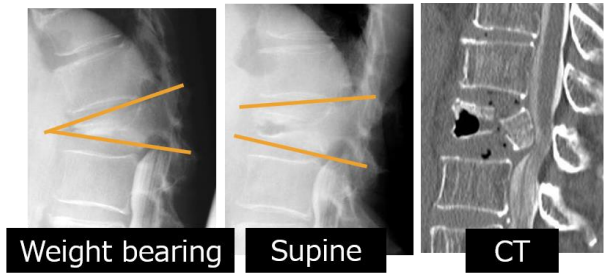
Introduction

Recent studies have revealed that some patients develop delayed union or nonunion, leading to unfavorable outcomes, with residual pain, decreased ADL, and decreased QOL. We previously conducted 2 prospective cohort studies on acute OVFs and identified the characteristic MRI findings that predicts delayed union.

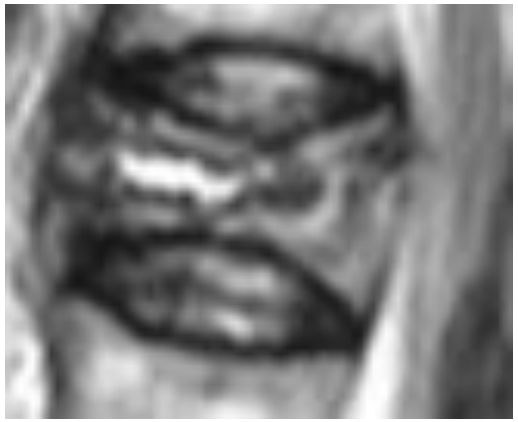
BKP is minimally invasive and safe, even for frail patients with OVFs. However, when surgical costs and complications are taken into consideration, BKP may not be appropriate in all patients with acute OVFs.

Delayed union

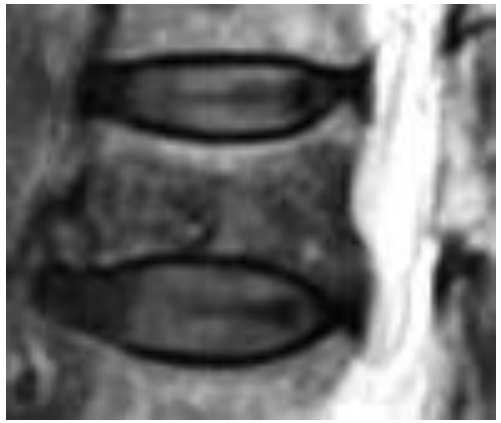


Pain↑
ADL↓ QOL↓

Predictive MRI findings for delayed union



・**High**



・ **Diffuse low**

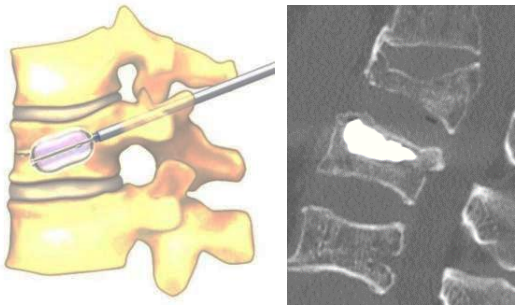
Tujio, Spine, 2011
Takahashi, Osteoporos Int, 2016

on T2-weighted MRI taken in the **acute phase** of OVF

Purpose

To investigate efficacy of balloon kyphoplasty for acute osteoporotic vertebral fractures in patients with poor prognostic factors.

BKP



V.S.

Conservative treatment

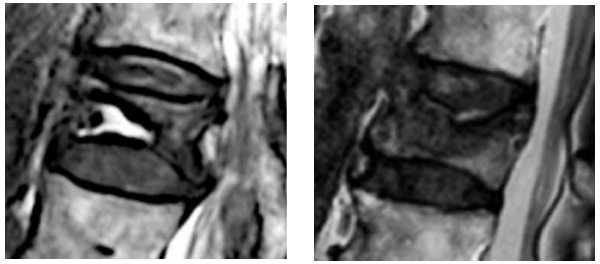
Methods

Study Design : multicenter prospective, single arm, intervention study,

Subjects : ・> 65 years old

・acute OVFs within 2 months after the onset

・with “T2 high” or “T2 diffuse low”



Follow-period : 6 months

BKP 116 cases

V.S.

Control : **Conservative treatment** 116 cases

- the same poor prognostic factors
- from the previous study database.

Methods

Statistical Analysis : Propensity-score matched analysis

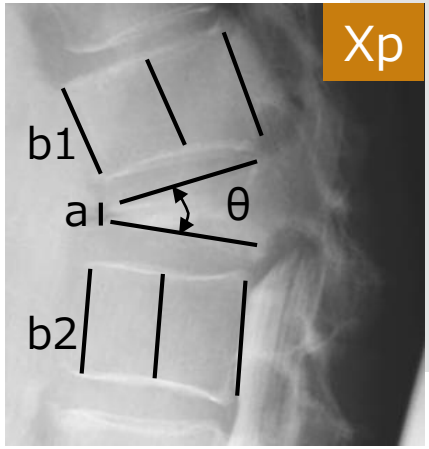
(matched age, sex, number of baseline old fractures, and level of fracture)

Primary Outcome ・Reduction in ADL by at least a single grade at 6 months after fracture

	Rank
Criteria for evaluating the degree of independence (severity of bed-ridden state) during daily living for disabled elderly people	**J** (independent)
	A (requires assistance to leave home)
	B (nearly-bed-ridden)
	C (completely bed-ridden)

Secondary Outcome

- QOL (SF-36 subscales)
- Back pain VAS
- % vertebral body height (%) *(2×a / (b1+b2) ×100)*
- Vertebral body wedging angle (degrees) *θ*
- Adjacent VF rates
- Duration of hospitalization / analgesics
- Complication (investigated in all 116 BKP patients)



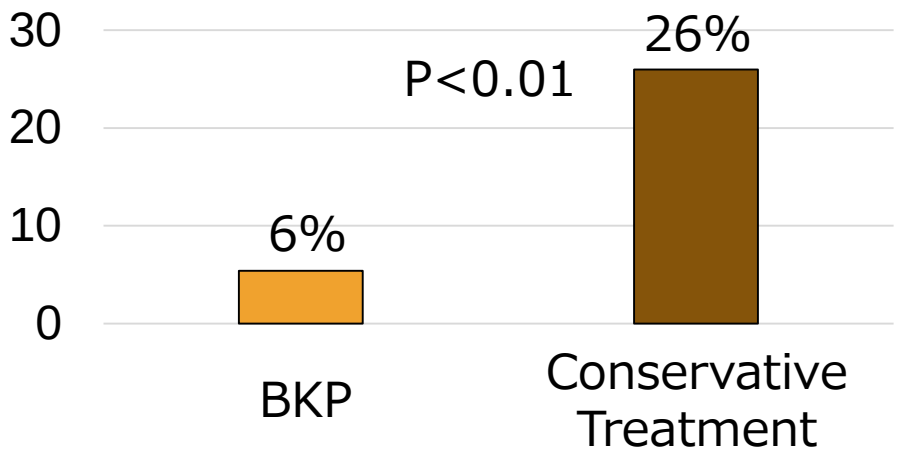
Methods

Patient characteristics :	BKP (N=90)	Conservative Treatment (N=90)	P-value
Age (years)	78.5 (5.1)	77.4 (5.8)	0.18
Female	77 (86%)	77 (86%)	1
Level of fracture			0.29
Thoracic (T5–T10)	2 (2%)	6 (7%)	
Thoracolumbar junction (T11–L2)	79 (88%)	72 (80%)	
Lumbar (L3–L5)	9 (10%)	12 (13%)	
Baseline prevalent fractures			0.73
0	46 (51%)	49 (54%)	
1	23 (26%)	24 (27%)	
2≤	21 (23%)	17 (19%)	
Duration of back pain (days)	39.2 (58.5)	32.4 (26.0)	0.32
Bone density T score	-2.00 (1.32)	-1.89 (0.66)	0.66
Osteoporosis Medication Before Injury	36 (40%)	36(40%)	1
Bisphosphonates	19 (21%)	13 (16%)	0.37
Vitamin D	13 (14%)	21 (20%)	0.11
Estrogen-receptor modulators	2 (2%)	2 (2%)	1
Glucocorticoid use	11 (12%)	13 (14%)	0.64

Results

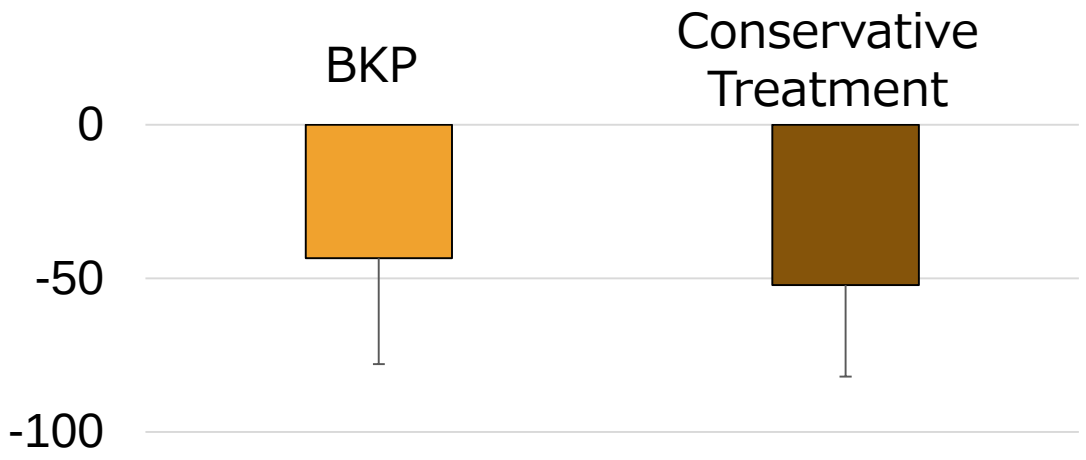
Reduced ADL(%)

※Fisher's PLSD

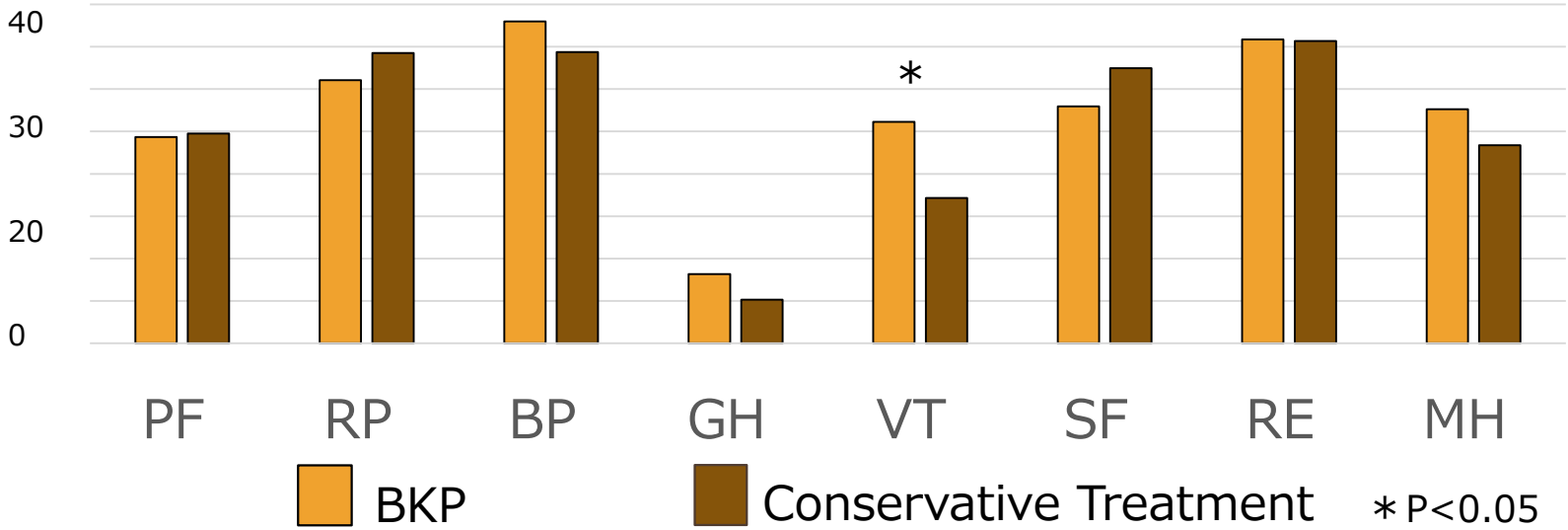


Back pain VAS

** Mixed model*



SF-36 subscales

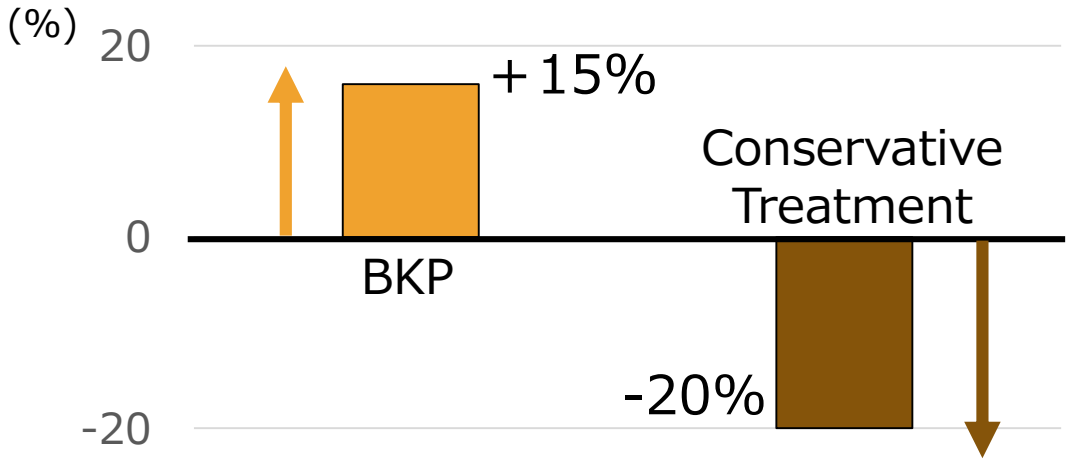


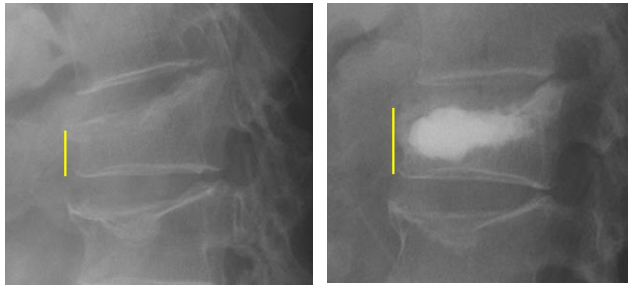
Results

% vertebral body height

** Mixed model*

P<0.001

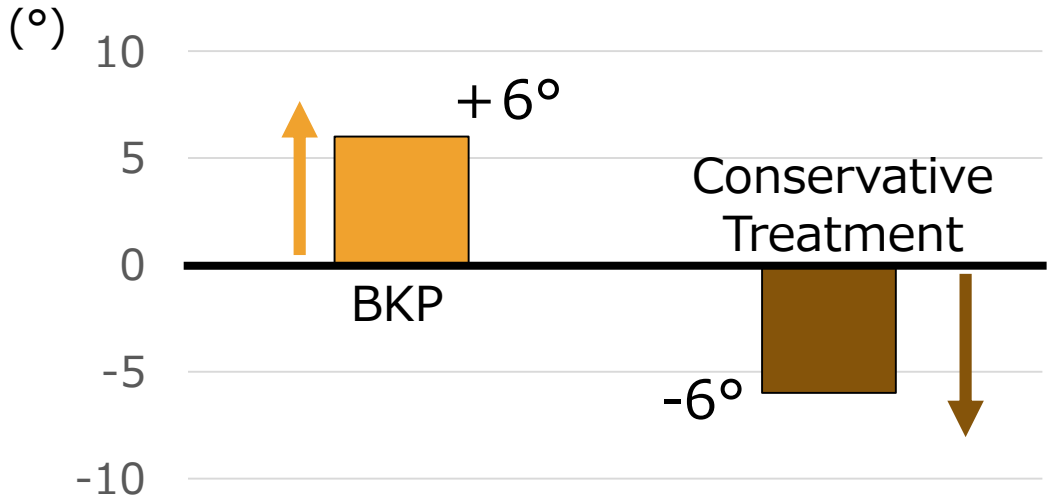


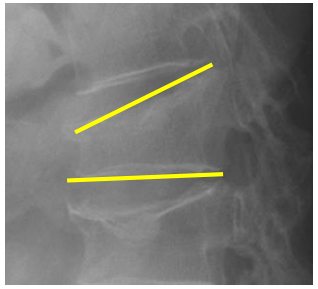


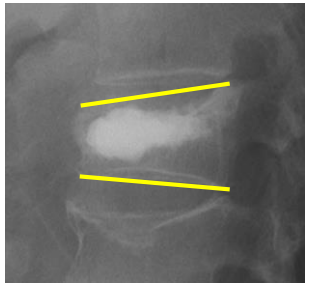
Vertebral body wedging angle

** Mixed model*

P<0.001

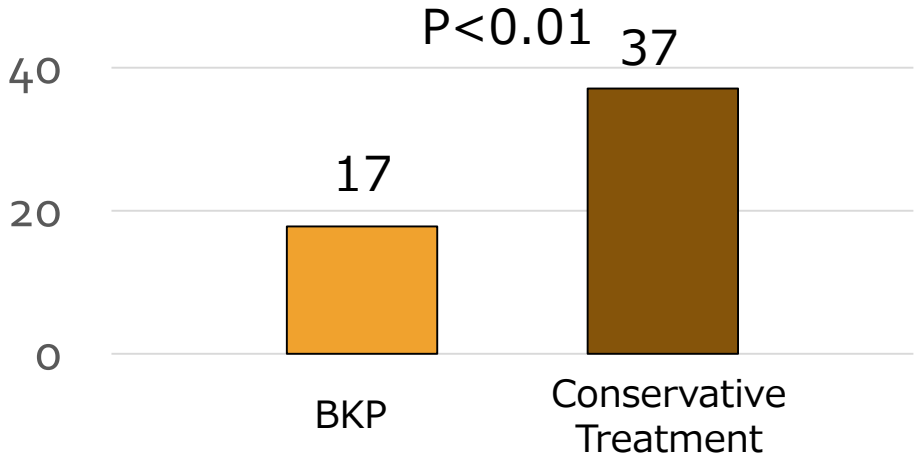




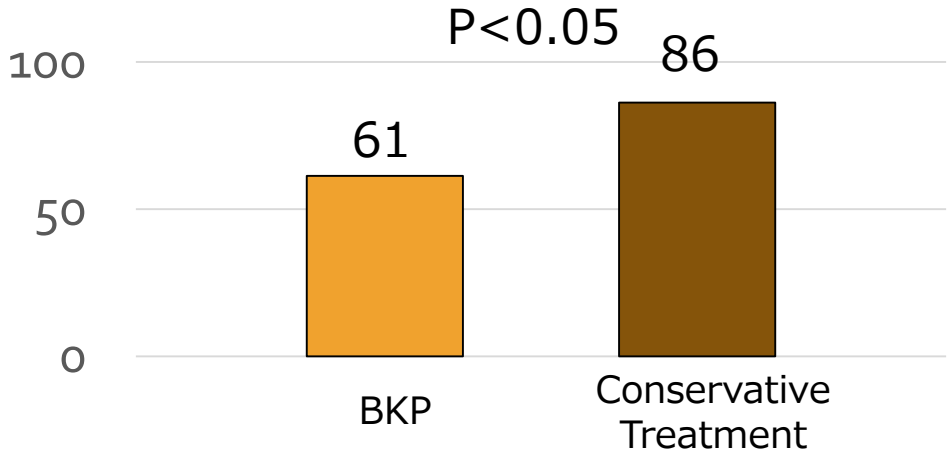


Results

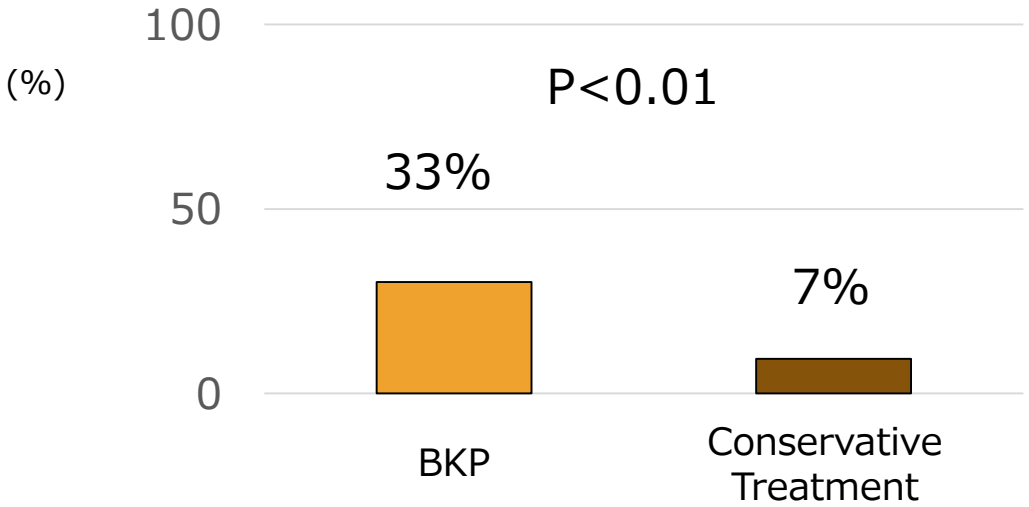
Hospitalization (days)



Analgesics (days)



Adjacent Vertebral Fr.



Complication (investigated in all 116 BKP patients)

- Systemic complication(PE, Infection etc.)

  0 /116cases

- The leakage of cement into the spinal canal

  3 /116cases (2.6%)

- Additional posterior fusion surgery

  4 /116cases (3.4%)

Summary

Outcomes			
ADL	**BKP**	>	Conservative
QOL	**BKP**	>	Conservative
Back Pain VAS	BKP	≒	Conservative
Collapse	**BKP**	>	Conservative
Wedging	**BKP**	>	Conservative
Adjacent Vertebral Fracture	BKP	<	Conservative
Hospitalization	**BKP**	<	Conservative
Analgesics	**BKP**	<	Conservative

Early BKP intervention was more effective than conservative treatment for improving ADL and QOL, preventing vertebral body deformities and shorter hospitalization and analgesic use.

Our conception

Acute OVF

Poor prognostic Factor	(-)	Conservative Treatment
	(+)	BKP

All patients cure !

The treatment concept of selecting either BKP intervention or conservative treatment based on the presence or absence of poor prognostic factors may contribute to improved treatment outcomes for OVFs in an aging population.

Conclusion

Early BKP intervention improved ADLs and QOL and prevented vertebral body deformities at 6 months after injury more effectively than with use of conservative treatment in patients with acute OVFs who had poor prognostic factors.

Disclosure declaration

- The Japan Agency for Medical Researchand Developmentgrant funds were received in support of this work.
- Balloon Kyphoplasty Versus Conservative Treatment for Acute Osteoporotic Vertebral Fractures with Poor Prognostic Factors: Propensity-Score-Matched Analysis Using Data From Two Prospective Multicenter Studies.Hoshino M, Takahashi S, Yasuda H, Terai H, Watanabe K, Hayashi K, Tsujio T, Kono H, Suzuki A, Tamai K, Ohyama S, Toyoda H, Dohzono S, Kanematsu F, Hori Y, Nakamura H. Spine (Phila Pa 1976). 2018 Jun 28. doi: 10.1097/BRS.0000000000002769. [Epub ahead of print]