



HANYANG UNIVERSITY SEOUL HOSPITAL

**Efficacy and Safety of Escherichia coli-derived
recombinant human bone morphogenetic
protein-2 in additional posterolateral lumbar
fusion
: minimum 1 year follow-up**

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Introduction

The purpose of this study

- ❖ To confirm the **efficacy** and **safety** of 1mg of E.BMP-2 used with autogenous local bone for posterolateral fusion unilaterally
- ❖ To determine the **minimal dose of E. BMP-2** to achieve successful 1 or 2 segmental lumbar interbody fusion

Materials and Methods

- Jan. 2009 ~ Dec. 2019 (10 years)
- **121 patients** with DSS or foraminal stenosis with spondylolisthesis
- Op : **open TLIF with cages + additional PLF unilaterally**
- Follow-up more than 1 year
- Exclusion criteria: trauma, spinal tumors, infectious diseases,
or past histories of lumbar fusion

Materials and Methods

- Divided into two groups(AIBG vs. E. BMP-2)
- C group (**AIBG group**)
 - ✓ TLIF : 2 PEEK cage + local bone
 - ✓ Additional PLF unilaterally : **AIBG + local bone**
- E group (**E.BMP-2 group**)
 - ✓ TLIF : 2 PEEK cage + local bone
 - ✓ Additional PLF unilaterally : **local bone + 1mg of E.BMP-2 + HA carrier**

Results

- **121 patients**
- **Group C (69 patients)**
 - ✓ 34 one-level fusion / 35 two-level fusion
- **Group E (52 patients)**
 - ✓ 23 one-level fusion / 29 two-level fusion
- **One-level fusion: 57 cases**(L2-3: 4 cases, L3-4: 3 cases, L4-5: 39 cases, L5-S1: 11 cases) /
Two-level fusion: 64 cases(L1-3: 2 cases, L2-4: 1 case, L3-5: 33 cases, L4-S1: 28 cases)

Results

Table 2. Comparison of **clinical outcomes**

	Group C (n=69)	Group E (n=52)	<i>P</i>
Preoperative VAS-BP	5.2 ± 1.5	5.8 ± 1.9	0.075
Preoperative VAS-LP	6.4 ± 1.4	6.6 ± 2.1	0.491
Preoperative K-ODI	28.7 ± 4.6	29.2 ± 6.1	0.584
Final VAS-BP	2.9 ± 1.1	3.0 ± 1.3	0.701
Final VAS-LP	3.1 ± 1.4	2.8 ± 1.4	0.280
Final K-ODI	17.9 ± 4.4	18.4 ± 6.2	0.656

Values are given as mean ± standard deviation.

VAS-BP, visual analogue scale-back pain; VAS-LP, visual analogue scale-leg pain; K-ODI, Korean Oswestry disability index.

Results

Table 3. Comparison of **perioperative complications**

	Group C (n=69)	Group E (n=52)	P
Respiratory Cx.	4 (5.8%)	4 (7.7%)	0.724
Neurologic Cx.	3 (4.3%)	1 (1.9%)	0.634
Cardiac Cx.	3 (4.3%)	4 (7.7%)	0.461
Infectious Cx.	6 (8.7%)	2 (3.8%)	0.464
Urologic Cx.	10 (14.5%)	5 (9.6%)	0.420
DVT	0 (0%)	1 (1.9%)	0.430
Wound dehiscence	0 (0%)	2 (3.8%)	0.183
Malignancy	0 (0%)	0 (0%)	-
Radiculopathy	0 (0%)	0 (0%)	-

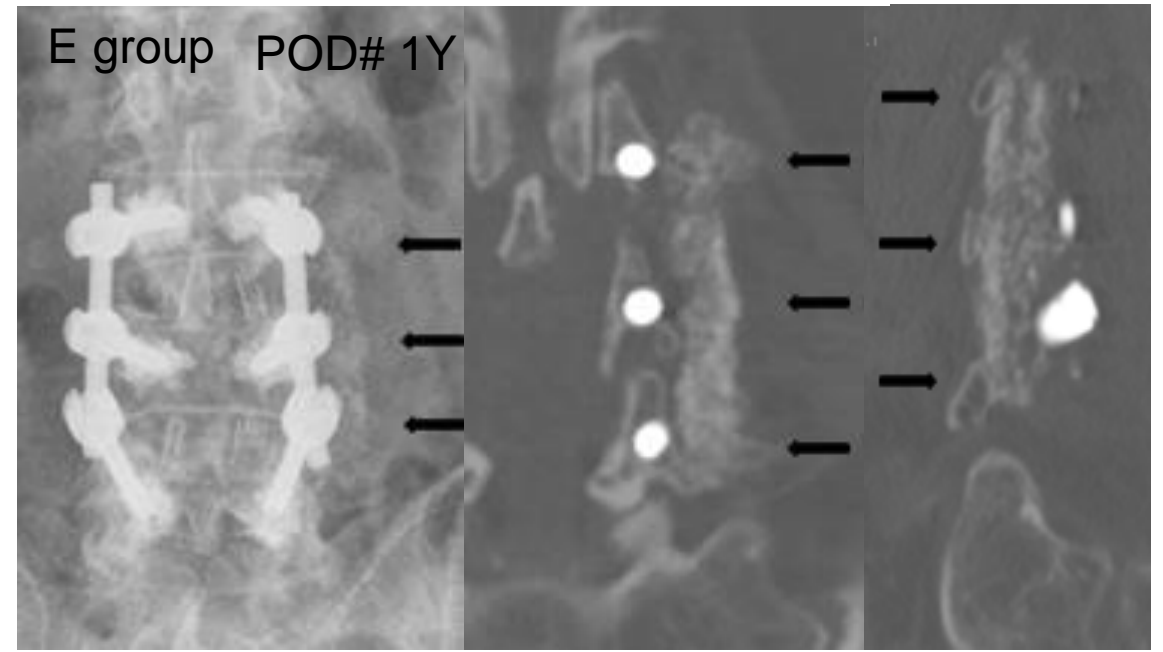
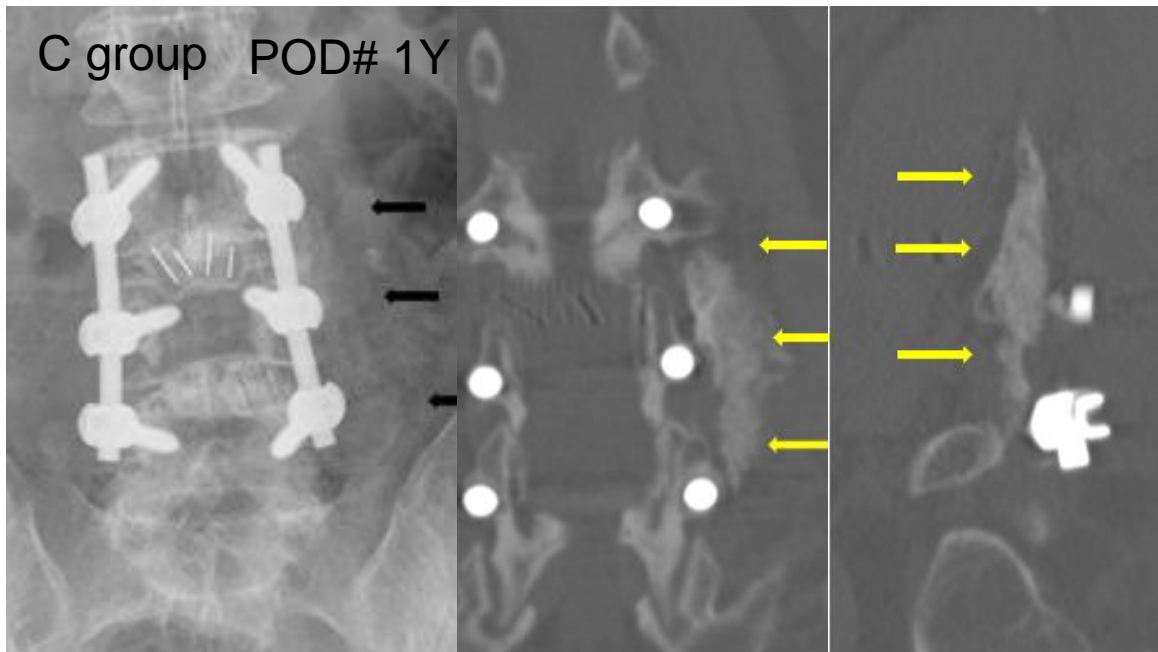
Cx., complication; DVT, deep vein thrombosis.

Results

Table 4. Comparison of **radiological fusion rates**

	Group C (n=69)	Group E (n=52)	<i>P</i>
Fusion rate			
PLF_6 months	55 (79.7%)	43 (82.7%)	0.679
PLF_1 year	65 (94.2%)	52 (100%)	0.134
LIF_6 months	49 (71.0%)	37 (71.2%)	0.987
LIF_1 year	67 (97.1%)	52 (100%)	0.506

PLF, posterolateral fusion; LIF, lumbar interbody fusion.



Results

Table 5. Comparison of **implant complications on radiographs**

	Group C (n=69)	Group E (n=52)	<i>P</i>
Screw pull-out	4 (5.8%)	3 (5.8%)	1.000
Screw breakage	1 (1.4%)	4 (7.7%)	0.164
Halo sign	12 (17.4%)	10 (19.2%)	0.795
Cage subsidence	3 (4.3%)	5 (9.6%)	0.287
Cage migration	3 (4.3%)	4 (7.7%)	0.461
Rod breakage	0 (0%)	0 (0%)	-

PLF, posterolateral fusion; LIF, lumbar interbody fusion.

Results

Table 5. Comparison of fusion rate between 1- and 2-level fusions in group E

	1-level (n=23)	2-level (n=29)	<i>P</i>
PLF_6 months	18 (78.3%)	25 (86.2%)	0.486
PLF_1 year	23 (100%)	29 (100%)	-
LIF_6 months	16 (69.6%)	16 (72.4%)	0.822
LIF_1 year	23 (100%)	29 (100%)	-

PLF, posterolateral fusion; LIF, lumbar interbody fusion.

Discussion

- **CHO.BMP-2**
 - ✓ Various doses of CHO.BMP-2; similar fusion rates
 - ✓ Low yield rate, high production cost
 - ✓ **Complications**
 - Osteolysis; excessive amounts of CHO.BMP-2
 - Spinal tumors (with 40mg, 3.8% patients had tumors at two-year follow-up after PLF)
 - Radiculopathy
 - Seroma

Discussion

- **No significant differences** between two groups(group C vs. group E)
 - ✓ VAS-BP, VAS-LP, and K-ODI
 - ✓ PLF rates and LIF rates at six months and one year
 - ✓ Mechanical complications
 - ✓ Perioperative complications

Discussion

- **Subgroup analysis of group E**
 - ✓ **1 mg of E.BMP-2** used for PLF (not TLIF)
 - ✓ **1 or 2 level fusion** (23 cases / 29 cases)
 - ✓ **100% fusion rates** at one year follow-up
- ❖ **0.5mg to 1mg of E.BMP-2 per level** might be sufficient to obtain **osteoiduction** in LIF and additional PLF unilaterally with **localized laminar bone** and/or **allogenuous bone substitutes**

Conclusion

- **1mg of E. BMP-2** with **localized autogenous laminar graft** in unilateral PLF in addition to LIF showed **similar outcomes** as using **autogenous iliac bone graft**
- Use of **1 mg of E. BMP-2** in PLF is a **safe** and **effective osteoinductive** material in short-level lumbar PLF surgery

Thank you

Disclosure declaration

none of the authors has any potential conflict of interest

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