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J Korean Soc Spine Surg 2020 June;27(2):39-47.

Originally published online June 30, 2020;

<https://doi.org/10.4184/jkss.2020.27.2.39>

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pISSN 2093-4378 eISSN 2093-4386

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<http://www.krspine.org/DOIx.php?id=10.4184/jkss.2020.27.2.39>

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Study Design: A prospective observational cohort study.

Objectives: This study was conducted to analyze associations between the volume of the fusion mass and clinical outcomes 1 year after posterior lumbar interbody fusion (PLIF).

Summary of Literature Review: No study has investigated associations between the size of the fusion mass and clinical outcomes after PLIF.

Materials and Methods: The volume of the fusion mass and its clinical correlations after PLIF were analyzed in all patients and in subgroups. When a sufficient amount of local bone was available for grafting, only local bone without a graft extender was used (LbG group, n=20). If an inadequate amount of local bone was present for grafting, a local bone graft with porous hydroxyapatite bone chips was used (LbHa group, n=20). The same amount of demineralized bone matrix was used in both groups. The primary outcome was the relationship between the size of the fusion mass and clinical outcomes in all patients 1 year after surgery. The secondary outcome was a comparison of the size of the fusion mass and clinical outcomes by group.

Results: The volume of the fusion mass was not correlated with any clinical outcomes 1 year after surgery, either in the overall group of patients or in the subgroup analysis.

Conclusions: The volume of the interbody fusion mass was not related to any clinical outcomes 1 year after surgery. Furthermore, in cases with an insufficient amount of local bone for grafting, porous hydroxyapatite could be a relatively good alternative as a graft extender.

Key words: Lumbar spinal stenosis, Fusion mass, Hydroxyapatite, Posterior lumbar interbody fusion

Introduction

The formation of complete solid fusion mass is prerequisite for successful fusion surgery and good prognosis.^{1,2,3,4)} For the formation of complete solid fusion mass, autologous iliac bone grafting is the “gold standard” for bone graft procedures due to its osteoinductive and osteoconductive capabilities.⁵⁾ However, for its limitation of donor site morbidity,^{6,7,8)} recent studies have demonstrated that local bone graft which includes removed spinous process, lamina, and facet joint during decompression procedure is as beneficial as autologous iliac bone graft for posterior interbody fusion (PLIF).^{1,3,9)} Furthermore, in case

Received: February 1, 2019

Revised: March 13, 2019

Accepted: April 3, 2020

Published Online: June 30, 2020

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that the amount of local bone available may not be sufficient for interbody fusion, a bone graft extender such as porous hydroxyapatite and allograft can be used for successful fusion.^{5,10,11–14} These studies focused on how can be improved the formation of fusion mass but overlooked the significance of the volume of the formed fusion mass. For this reason, another important rationale for using an additional bone graft extender is the increase of fusion mass size, because insufficient size of fusion mass may limit effective load transmission.^{2,15} However, there has been no study regarding the association between the size of the fusion mass and surgical outcomes.

Therefore, we aimed to volumetric assessment of fusion mass and its clinical correlation in the posterior lumbar interbody fusion. We hypothesized that the size of fusion mass would be positively associated with surgical outcomes including pain and disability. We also wanted to evaluate whether there was a difference in the size of the formed fusion mass and clinical outcomes depending on the type of bone graft. In the current study, we analyzed the association between the size of fusion mass and clinical outcomes after PLIF using local bone graft alone (LbG group) and local bone graft with porous hydroxyapatite bone chip (LbHa group) for the treatment of lumbar spinal stenosis (LSS).

Materials and Methods

1. Patients and methods

The Institutional Review Board approved this study (E-1208-167-001); informed consent was obtained from all the eligible patients before they were enrolled in the study.

We performed a prospective observational cohort study from December 2012 to October 2014. The inclusion criteria were as follows: (1) an age of 40 to 80 years, (2) an LSS diagnosis, and (3) scheduled PLIF surgery at the single level. LSS was diagnosed when one or more of the following symptoms were present: leg pain, numbness, or motor deficits in the lower extremities and buttocks,^{16,17} along with a confirmed stenotic lesion in the lumbar spine by magnetic resonance imaging (MRI). Patients were excluded if they had a history of peripheral vascular disease, any concurrent serious medical condition causing disability, or general health status that included sepsis or cancer.

Patients were counseled about the surgical procedure,

available fusion materials, and written consent was obtained. In order to volumetric assessment of fusion mass and its clinical correlation in the PLIF, the entire patient was analyzed. Furthermore, to evaluate the difference in the size of the formed fusion mass and clinical outcomes depending on the type of bone graft, patients were categorized into two groups according to a type of bone graft used during the operation. Using the 1 cm³-syringe for volume measurement, local bone of <3 cm³ in the morselized state was considered to be inadequate to fill the prepared disc space for a single-level interbody fusion. If the available local bone was >3 cm³, additional fusion material was not used and patients were categorized to the LbG group. Unless the available local bone was >3 cm³, 0.25 g of porous hydroxyapatite (HA) was added to the local bone as a graft extender, and these patients were categorized to the LbHa group. For osteoinductive agent, 2.5 g of demineralized bone matrix (DBM) (Bone-Fuse®, Bioalpha Inc., Seongnam, Korea) was mixed with the prepared local bone in both groups.

2. Operative procedure

A single midline incision of approximately 8 cm in length was made, followed by exposure of the spine to the facet joints and the lateral tips of the transverse processes to allow for clear identification of the bony landmarks. First, a pedicle screw was inserted using the Weinstein method. Following decompression procedures, including laminectomy and facetectomy, discectomy and endplate preparation were performed. Local lamina and facet bone byproducts were morselized with the removal of soft tissue, sclerotic bone, and cartilage. After the mixture with prepared local bone and DBM was packed in the disc space, 1 or 2 cages filled with local bone graft were inserted. In LbHa group, 0.25 g of porous HA (Bongros-HA®, Bioalpha Inc., Seongnam, Korea) were mixed to local bone with DMB and packed in the disc space. Finally, the rods were assembled with pedicle screws and fastened.

3. Clinical evaluation

Baseline data, which were collected by a blinded clinical research assistant, included sex, age, height, weight, symptom duration, preoperative visual analog scale (VAS) scores for back and leg pain, preoperative Oswestry Disability Index (ODI) score, and general health status using the Short Form (SF)-36.^{18,19} The ODI and VAS scores for back pain and leg

pain were assessed 3 month, 6 month, and 1 year after surgery. The SF-36 score was assessed preoperatively and 1 year after surgery.

4. Radiological outcome assessment

The radiological assessments were performed by 3 independent observers who were blinded to the purpose of the study, the patients' clinical information, and the outcomes recorded by the other observers. The fusion status was assessed using computed tomography (CT) 1 year after surgery according to the Brantigan, Steffee, Fraser (BSF) classification,⁴⁾ which was performed separately by 2 independent observers who were blinded to the purpose of the study, the patient's clinical information, and the other observer's assessment. If there was a difference in categorical fusion grading between the 2 observers, a consensus grade was assigned to arrive at a single assessment. For consensus grading, a third independent observer participated as an adjudicator of the contested fusion grading at the consensus meeting. Agreement between the 2 observers on the grading was regarded as a consensus grade.

For evaluating the size of fusion mass, the volume of the interbody fusion mass was assessed with CT images 1 year after surgery using the Rapidia 3D 2.8 software (Infinitt, Inc., Seoul, Korea). From the lower endplate, a slice was chosen from the region of interest (ROI) where the interbody fusion mass was first observed in the disc space, and each consecutive axial slice was viewed until no fusion mass was visible. Using the Rapidia 3D 2.8 manual segmentation tool, an outline of the fusion mass was traced on the selected axial slices. Tracing the outline of the fusion mass seen in these axial slices ensured that structures from the upper endplate to the lower endplate were included (Fig. 1). With the aid of the Rapidia 3D 2.8 volume tool, the size of the fusion mass was calculated for each axial slice. The summation of the size of the fusion masses in all axial slices was considered as the volume of the interbody fusion mass. To reduce the possibility of including soft tissue rather than bone volume, a thresholding technique was used. The software was directed to include only those pixels that had values between 300 and 1,000 Hounsfield units for the LbG group and 300 and 1,200 Hounsfield units for the LbHa group. Based on previous studies, 3 independent observers considered that a threshold between 300 and 1,000 was optimal for measuring the volume of the fused mass, including

Fig. 1. Volumetric assessment of fusion mass. **(A)** Axial computed tomography images of the interbody fusion mass in the local bone graft (LbG) alone group. **(B)** The observer manually drew an ellipse that included the fusion mass depicted in Figure 1A. Inside the ellipse, the software highlighted the fusion mass area with 300-1,000 Hounsfield units. The highlighted cross-sectional area of the fusion mass was automatically calculated and the summation of the cross-sectional areas was considered to be the volume of the fusion mass.

the cancellous portion, in the LbG group.^{20,21)} For the LbHa group, further adjustment was necessary because of the porous hydroxyapatite bone chip area; hence, the upper range of Hounsfield units was increased to 1,200 (Fig. 1).

For interobserver and intraobserver reliability tests, an interclass correlation (ICC) coefficient (kappa) (3.1) was calculated with a target ICC value of 0.8 and a 95% confidence interval of 0.2, with the setting of a single measurement and absolute agreement.²²⁾ A minimum of 36 cases was required to form the sample size. Following interobserver reliability testing, one of the independent observers repeated the radiographic measurements to assess intraobserver reliability, with an interval of 4 weeks between the 2 measurement sessions.

The primary outcome was the association between the size

of fusion mass and clinical outcomes that included ODI and VAS scores for back and leg pain collected during follow-up assessments and general health status 1 year after surgery, in an entire patient 1 year after surgery. The secondary outcome was a comparison of the size of fusion mass and the clinical outcome by the group.

5. Statistical analysis

Continuous and categorical variables were analyzed in an entire patient and each group using an independent t-test and chi-square test, respectively. The association between the size of the fusion mass and surgical outcomes including VAS for back and leg pain, ODI, and SF-36 1 year after surgery was also evaluated using Pearson correlation test for the fusion cases in an entire patient and each group. The clinical outcome measures, including baseline-adjusted ODI score, VAS score for back pain, and VAS score for leg pain, were assessed for superiority between the 2 groups during all follow-up assessments, along with the 95% CIs. Analysis of variance for repeated measures was performed to examine the surgical outcome measures between the 2 groups over the follow-up assessment period. In addition, general health status (PCS and MCS scores) 1 year after surgery was examined using an independent t-test. Furthermore, in each group, any changes in general health status (PCS and MCS scores) from study enrollment to 1 year after surgery were compared with a Wilcoxon signed-rank test. All statistical analyses were performed with SPSS 20.0.0 statistics package (IBM Corporation, Armonk, NY), with an alpha level of significance set at 0.05.

Results

1. Demographic and baseline data in participants

Between December 2012 and October 2013, 47 patients were assessed for study eligibility. Forty participants met the inclusion criteria. According to the type of bone graft used during the operation, 40 patients were categorized into either the LbG group (n=20) or the LbHa group (n=20). At 1-year assessment after surgery, complete data were available for 36 patients (17 and 19 patients in the LbG and LbHa groups, respectively). The baseline characteristics and preoperative symptom severities of the patients were similar between the 2

Table 1. Demographic Characteristics of each group

	*LbG (20)	[†] LbHa (20)	p-value
Age (years)	70.00±5.62	62.9±6.6	0.409
Female, n (%)	14 (70.0)	15 (75.0)	0.723
BMI (kg/cm ²)	24.45±1.38	23.53±2.59	0.169
VAS (back pain)	6.9±2.5	7.1±2.2	0.835
VAS (leg pain)	6.8±2.9	7.5±2.3	0.431
ODI	40.7±14.9	49.1±19.5	0.134
Symptom duration (months)	13.5±8.3	12.3±5.6	0.322
Walking distance at a single trial (min)	12.8±13.9	10.4±10.8	0.673
SF-36 (PCS)	37.4±8.6	39.7±10.1	0.597
SF-36 (MCS)	32.1±7.8	30.8±6.8	0.822
Operated level (n)	L3–L4: 1	L3–L4: 2	
	L4–L5: 16	L4–L5: 13	
	L5–S1: 3	L5–S1: 5	

*LbG group: fusion using local bone graft alone. [†]LbHa group: fusion using local bone graft plus porous hydroxyapatite bone chip.

BMI: body mass index, SD: standard deviation, VAS: Visual Analog Pain Scale, ODI: Oswestry Disability Index, SF-36: Short Form-36, PCS: Physical Component Summary, MCS: Mental Component Summary.

*Values are mean±SD

groups (Table 1). All patients had a single-level lumbar spinal stenosis.

2. Volumetric assessment of interbody fusion mass and clinical correlation

There was no definite pseudarthrosis (BSF-1) in an entire patient. Analyzing in an entire patient (n=40), the volume of fusion mass was not correlated with any clinical outcome, including ODI score, VAS score for back and leg pain, and PCS/MCS scores of the SF-36 1 year after surgery (ODI, $R = -0.102$, $p = 0.600$; VAS score for back pain, $R = 0.034$, $p = 0.862$; VAS score for leg pain, $R = -0.225$, $p = 0.241$; PCS, $R = 0.014$, $p = 0.485$; MCS, $R = 0.223$, $p = 0.744$) (Table 2).

In subgroup analysis, among patients who were available for CT at 1 year after surgery, there was no significant difference in fusion status between the groups ($p = 0.727$). In the LbG groups, 2 (13.3%) and 15 (86.7%) segments were classified as BSF-2 and BSF-3, respectively. In the LbHa group, 16 (84.2%) and 3 (15.8%) segments were classified as BSF-2 and BSF-3, respectively. The mean volume of the interbody fusion

Table 2. The correlations between size of fusion mass and clinical outcomes 1 year after surgery

Size of fusion mass	ODI	VAS (back pain)	VAS (leg pain)	SF-36 (PCS)	SF-36 (MCS)
Entire patient (n=40)	-0.102 (p=0.600)	0.034 (p=0.862)	-0.225 (p=0.241)	0.014 (p=0.485)	0.223 (p=0.744)
The LbG (n=17)	-0.118 (p=0.639)	0.043 (p=0.618)	-0.254 (p=0.389)	0.056 (p=0.275)	0.245 (p=0.219)
The LbHa (n=19)	-0.099 (p=0.473)	0.024 (p=0.533)	-0.200 (p=0.432)	-0.023 (p=0.742)	0.194 (p=0.535)

ODI: Oswestry disability index, VAS: visual analog pain scale, SF-36: Short Form-36, PCS: Physical Component Summary, MCS: Mental Component Summary.

*Values indicate R (p value). R: correlation coefficient.

Table 3. Comparison of fusion rates (%) and volume of fusion mass (mm³) of each group

		*LbG (17)	†LbHa (19)	p-value
Brantigan, Steffee, Fraser (BSF)'s classification	[‡] BSF-1 (n [%])	0	0	0.727
	[§] BSF-2 (n [%])	2 (13.3)	3 (15.8)	
	BSF-3 (n [%])	15 (86.7)	16 (84.2)	
Volume of fusion mass (mm ³)		4626.9±1841.5	5220.7±1438.4	0.333

*LbG group: fusion using local bone graft alone. †LbHa group: fusion using local bone graft plus porous hydroxyapatite bone chip. [‡]BSF-1: Radiographical pseudarthrosis is indicated by collapse of the construct, loss of the disk height, vertebral slip, broken screws, displacement of the carbon cage, or significant resorption of the bone graft, or lucency visible around the periphery of the graft or cage; [§]BSF-2: Radiographical locked pseudarthrosis is indicated by lucency visible in the middle of the cages with solid bone growing into the cage from each vertebral end plate; ^{||}BSF-3: Radiographical fusion: bone bridges at least half of the fusion area with at least the density originally achieved at surgery.

Radiographical fusion through one cage (half of the fusion area) is considered to be mechanically solid fusion even if there is lucency on the opposite side.

mass was $4626.9 \pm 1841.5 \text{ mm}^3$ and $5220.7 \pm 1438.4 \text{ mm}^3$ in the LbG and LbHa groups, respectively, and no difference in the fusion mass was observed between the 2 groups ($p=0.333$) (Table 3). Furthermore, there were no correlations between clinical outcomes and fusion mass size in each LbG and LbHa group (Table 2).

The measure of fusion mass volume using CT showed satisfactory interobserver and intraobserver reliabilities in that ICC (95% CI) was 0.873 (0.650–0.947) and 0.915 (0.842–0.952), respectively.

Discussion

We aimed to analyze the association between the volume of fusion mass and clinical outcomes 1 year after surgery. Hence, an observational cohort study design was adopted, which can better represent real clinical situations and has no associated ethical issues.

To our knowledge, the method to quantify the amount of fusion mass in the present study was firstly implemented

for volumetric assessment of fusion mass, even though the reference value of Hounsfield units in the fusion mass was reported.²¹⁾ A previous study demonstrated the successful measurement of the jaw bone volume using the method implemented in this study.²³⁾ Another study has shown that the computer-based methods used to estimate the volume of irregularly shaped masses are reliable and recommend their use for film readers with limited radiologic experience.²⁴⁾ However, the fusion mass volume does not always represent a large area of contact surface between the vertebral body and fusion mass in terms of stress distribution and load sharing, as the height of the fusion mass also contributes to the overall volume. Nevertheless, because of the irregular shape of the fusion mass, we considered that the volume of fusion mass would be a better measurement than the cross-sectional area of fusion mass at the endplate.

The results indicate that the volume of the fusion mass was not correlated with the clinical outcomes, including ODI and VAS scores for back pain and leg pain in both the entire patient analysis and subgroup analysis. These results are in

disagreement with the opinion of previous studies.^{2,15)} We supposed that the main reason for disagreement with our result to the previous study was the entire patient formed some degree of solid fusion without any definite pseudarthrosis. If there were varied fusion rates and several cases below the threshold of stabilized fusion rate, it is thought that the size of the fusion mass would have affected the clinical outcomes. The reason why they did not reveal any difference between groups seems to be the same reason. Overall fusion rate of the current study was relatively high, thus the size of the fusion mass and clinical outcomes seem to have no significant difference, although the type of bone graft was different. In addition, this would be possible that a result of sufficient total amounts of bone graft used in each group, apart from HA use.

Subgroup analysis according to types of bone graft has additional importance. LbG and LbHb group represent the case of sufficient and insufficient local bone graft during surgery, respectively. The LbHa group provided similar results regarding bone union rate 1 year after surgery, compared with the LbG group, even though the LbHa group included patients with inadequate local bone graft. Furthermore, there were no differences in the clinical outcomes such as improvement in disability, back and leg pain, and general health status (PCS and MCS scores of the SF-36). Therefore, the current results suggest that the addition of porous HA could be the relatively good alternative as graft extender in cases where local bone is not sufficient to fill the prepared disc space. However, the value of insufficient local bone was less than 3 cm³ in the morselized state, which was not validated.

This study has several limitations. First, most important limitation of this study was that relatively small number (n=40) of patients was analyzed in this study. The relatively high fusion rate in this study was thought to be due to the somewhat small number of patients. If large cohort is targeted, it is possible that there will be a variety of fusion rates, and differences in study results could also occur. Second, it is not sure that the volume of fusion mass has directly positive relation to the quality of the fusion. Even though the volume of fusion mass is small, good clinical outcomes could be seen when the solid fusion would be achieved. While the stability of fusion could be poor despite the volume of fusion mass is large. Third, the definition of insufficient local bone which is less than 3 cm³ in the morselized state was set arbitrarily depending on authors'

experiences. Fourth, the volume of the used graft by the group was not clear. Because the volumetric assessment of fusion mass was the main purpose of this study, in order to achieve solid fusion, DBM was used for entire patients. We only set the insufficient local bone criteria and HA was used as a graft extender if the amount of local bone was insufficient to achieve fusion. A description of the total volume of the used graft and the volume of the local bone would be expected to make the results of the study clearer.

However, the current study also has several strengths. Given that spinal fusion depends on various factors,²⁵⁾ the homogenous diagnosis and treatment (single-level fusion surgery) used for both groups is a strength. In addition, the CT-based summation method using a cross-sectional slice can be applied usefully to other areas of orthopedics.

Conclusions

The present study showed that the volume of interbody fusion mass was not related with clinical outcomes, including ODI scores and VAS scores for back and leg pain 1 year after surgery. Furthermore, porous hydroxyapatite could be the relatively good alternative as a graft extender in cases where local bone is not sufficient to fill the prepared disc space.

Acknowledgement

This study is supported by research grant from Daewoong bio. Co. in Seoul, the Republic of Korea and by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (2016R1A2B3012850).

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후방 요추체간 유합술 후 골이식재에 따른 유합체의 체적 평가와 그 임상적 상관관계

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연구 계획: 전향적 관찰 코호트 연구

목적: 후방 요추체간 유합술 후 1년 추시에서 유합체의 체적량과 임상적 결과의 연관성을 분석하고자 하였다.

선행 연구문헌의 요약: 이전의 연구에서 후방 요추체간 유합술 후 유합체의 체적량과 임상적 결과의 연관성에 대한 연구는 없었다.

대상 및 방법: 유합체의 체적량과 임상적 결과의 연관성을 확인하기 위하여 전체 환자와 하위 군에 대하여 분석하였다. 충분한 양의 국소 조각골이 있는 경우에는 국소 조각골만 사용하였으며(LbG group, n=20), 국소 조각골이 부족한 경우에는 국소 조각골과 다공성 hydroxyapatite 동종골을 혼합하여 사용하였다(LbHa group, n=20). 같은 양의 demineralized bone matrix가 2군에 동일하게 사용되었다. 본 연구의 1차 결과는 수술 후 1년 추시에서 유합체의 체적량과 임상적 수술 결과의 연관성이며 2차 결과는 2군간의 유합체 체적량과 임상결과의 비교였다.

결과: 분석 결과 전체 환자 및 2군간 비교에서 유합체의 체적량은 임상적 결과와 연관성을 보이지 않았다.

결론: 요추체간 유합술에서 유합체의 체적량은 수술 후 1년 추시에서 임상적 결과와 연관성을 보이지 않았다. 또한 국소 조각골이 부족한 경우 다공성 hydroxyapatite 동종골은 이식 보강재로서 좋은 대안이 될 수 있을 것으로 생각된다.

색인 단어: 요추 척추관 협착증, 유합체, hydroxyapatite, 후방 요추체간 유합술

약칭 제목: 유합체의 체적 평가와 그 임상적 상관관계

접수일: 2019년 2월 1일

수정일: 2019년 3월 13일

게재확정일: 2020년 4월 3일

교신저자: 김호중

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