Two-year Outcome of Hydroxyapatite Mixed with Autogenous Bone Marrow and Local Bone Graft for Posterolateral Lumbar Fusion

Vera Sathira-Angkura MD*, Sombat Kunakornsawat MD*,
Bunsin Assawachutithamrong MD**, Rachata Tungsiripat MD***

** Institute of Orthopedics, Lerdsin General Hospital, Bangkok, Thailand*
*** Pua Crown Prince Hospital, Nan, Thailand*
**** Ramkhamhaeng Hospital, Bangkok, Thailand*

Objective: *To determine the outcome of hydroxyapatite (HA) mixed with autogenous bone marrow (BM) and local bone graft in posterolateral lumbar fusion.*
Material and Method: *Twenty-three patients who had posterolateral fusion with posterior instrument using HA mixed with BM and local bone graft between December 2003 and August 2005 were prospective analyzed. Degree of pain using visual analog scale (VAS) was evaluated at preoperative and 2, 4, 6, 9, 12, and 24 postoperative months. Radiographs were assessed for spinal fusion at 4, 6, 9, 12, and 24 postoperative months.*
Results: *The improvement of pain was demonstrated in all patients postoperatively. Radiographic outcomes revealed solid and doubtful fusion in one of 23 patients (4.3%) and 13 of 23 patients (56.5%) at six months respectively. After two-year follow-up, one patient had solid fusion while 22 patients (95.6%) had doubtful fusion.*
Conclusion: *Despite the posterolateral lumbar fusion using HA mixed with BM and local bone graft provided good clinical results, the radiographic results of spinal fusion were questionable in most cases.*

Keywords: *Hydroxyapatite, Posterolateral fusion*

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Pseudarthrosis rate in posterolateral lumbar fusion generally ranges from 5% to 44%[1-3]. In an effort to improve the fusion rate, the standard technique of combining the transpedicular instrumentation with intertransverse process autologous bone grafting has been widely used. The iliac crest remains the practical source of autologous bone. However, the harvesting procedure is associated with more or less morbidity. The major complications were reported up to 10%[4] which included iliac wing fracture, pelvic ring instability[5], vascular tears and or hematoma formation requiring surgical revision[6-9], severe pain[10] and lumbar abdominal wall herniation[11-13]. The minor complication rate of up to 39% also has been reported. They included chronic pain at the donor site[10,14], dysesthesia[9], diminished sensitivity in the superior cluneal nerve territory[4,12], increased hospital length of stay, increased blood loss, and superficial infections[15]. Furthermore, in some circumstances, such as multisegmental fusions or revision surgeries, the autogenous bone graft may be insufficient and allograft bone has been used as an alternative to autologous bone to avoid donor site-related complications[16,17]. Unfortunately, the risk of infection[18], an inferior rate of union[19-22] and inferior mechanical strength[23] have limited its use.

Hydroxyapatite (HA) bone substitutes have been used with good clinical success for reconstruction of metaphyseal defect in the long bone fractures[24-26]. However, few prospective studies have reported the outcome of HA mixed with bone marrow (BM) and local bone graft in posterolateral lumbar fusions. Therefore, the objective of the present study was to determine the clinical and radiographic outcomes of bovine bone-derived HA mixed with BM and local bone graft in the posterolateral lumbar region.

Correspondence to:
Sathira-Angkura V, Institute of Orthopaedics, Lerdsin General Hospital, 190 Silom Rd, Bangkok 10500, Thailand.
Phone: 0-2353-9800-1, Fax: 0-2353-9836
Email: vsathira@hotmail.com, geennikul@gmail.com, geennikul@hotmail.com

Material and Method

The spinal stenosis or spondylolisthesis patients who had posterolateral fusion using HA mixed with autogenous bone marrow (BM) and local bone graft at Lerdsin Hospital between December 2003 and August 2005 were prospective analyzed. The patients who were younger than 20 or older than 70 years old, who have metabolic bone diseases, spinal tumors, previous spinal trauma, or more than two level spinal fusions, and psychosocial instability were excluded from the present study. The present study has been approved by the Medical Ethical Committee of Lerdsin Hospital. The patients were divided into two groups depending on the number of fusion levels (group 1: one-level fusions and group 2: two-level fusions). For comparison, data of the patients who had posterior decompression, posterior instrumentation, and posterolateral fusion with iliac crest autograft at Lerdsin Hospital were reviewed. These patients were also divided into two groups (group 3: one-level fusions and group 4: two-level fusions). HA used in the present study was bovine bone derived HA produced by Department of Medical Sciences, Ministry of Public Health.

The present study was approved by the Medical Ethical Committee of Lerdsin Hospital.

Surgical techniques

All patients were treated with laminectomy and posterior instrumentation using pedicular screw system. The operations were performed by two surgeons (Sathira-Angkura V and Kunakornsawat S). In group 1, 15 cc of HA mixed with 20 cc BM and 5 cc local bone graft were packed onto both sides of intertransverse processes of the fusion area. For group 2, 30 cc of HA mixed with 40 cc BM and 10 cc local bone graft were used. Bone marrow aspiration technique was shown in Fig. 1 (A-F). The patients were mobilized with a soft lumbar corset on the third postoperative day. They were instructed to wear the corset for eight to 12 weeks postoperatively and full activities were resumed at three months.

Outcome assessments

Back and iliac crest pain were evaluated by using pain scale (VAS) at preoperative period and 2, 4, 6, 9, 12, and 24 months postoperative. Fusion was evaluated using plain AP, lateral and oblique lumbosacral spine radiographs at 4, 6, 9, 12, and 24 months postoperatively. The radiographic classification system proposed by Christensen et al[27] was used to determine the fusion mass. Fusion was defined as the continuity of intertransverse bony bridge detected at both ends of the fusion mass (Fig. 2A). Non-union meant lack of fusion at one or more of the intended levels (Fig. 2C). Doubtful fusion meant suboptimal bony bridge at one or more levels including fusion mass hidden behind the instrumentation (Fig. 2B). Fusion was radiographically determined by two radiologists who had no knowledge of the clinical status of the patients. The flexion-extension kinetic radiographs were also used to evaluate the fusion.

Statistical analyses

All data were analyzed by the SSPS statistic program (version 11 SPSS, Inc. Chicago, IL). The Wilcoxon Signed Ranked test and McNamer test were used to determine the difference between the two groups. Kruskall-Wallis test and Chi-square test were used to determine the difference among the four study groups. A p-value of less than 0.05 was considered statistical significant difference.

Results

Between December 2003 and August 2005, 23 patients had been treated with posterolateral

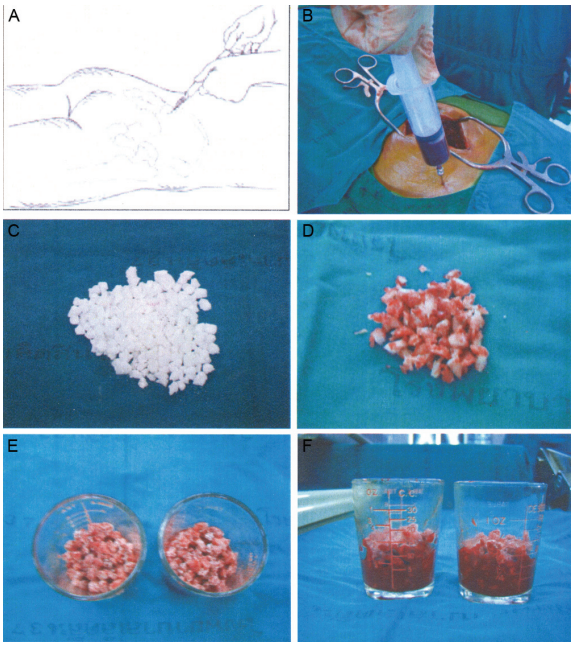

Fig. 1 (A and B) bone marrow aspiration from the posterior iliac crest graft, (C) hydroxyapatite, (D) local bone graft, (E and F) the mixture of hydroxyapatite, bone marrow and local bone graft

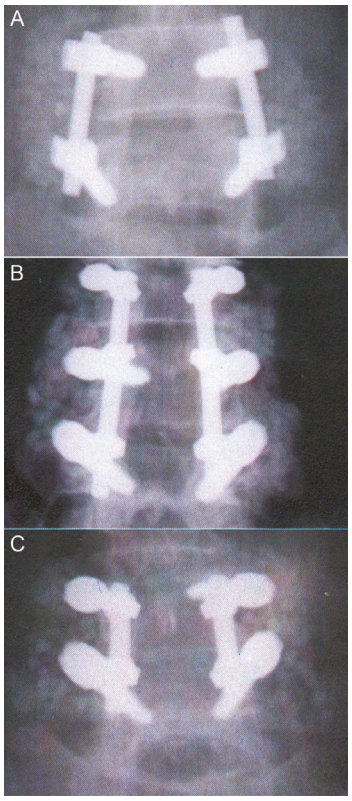

Fig. 2 Radiographic assessment showed (A) fusion, (B) doubtful fusion and (C) nonunion

fusion using HA mixed with BM and local bone graft at Lerdsin hospital. The average age was 53 year old (21-68). The diagnoses were spondylolisthesis in nine patients, spinal stenosis in 10, and spinal stenosis with spondylolisthesis in four patients. The average follow-up period was 24 months. There were 12 patients in group 1 (1-level fusions) and 11 group 2 (2-level fusions) patients. Comparison was done with the control groups (fusion with iliac crest graft), there were 10 patients in group 3 (1-level fusions) and 10 in group 4 (2-level fusions).

The average age and body weight in each group was similar. When comparing among one-level and two-level groups, the operative time was not statistically significant different. The hospitalization time in group 3 was longer than group 1 ($p < 0.05$). The amount of bleeding in the two-level group was higher than the one-level group both intraoperative and postoperative periods. However, no difference was found in the number of fusion level operations using HA and iliac crest (Table 1).

Postoperatively, all groups demonstrated improvement of VAS for back pain at 2, 4, 6, 9, 12, and 24 months after surgery. The mean back pain VAS in the iliac crest group (group 3 and group 4) was slightly higher than that of HA group (group 1 and group 2) but the difference was not statistically significant. In group 4, pain at the donor site of the bone graft was more intense than the back pain during the first six month postoperative period (Table 2).

Regarding the radiographic assessment of fusion (Table 3), at the sixth months postoperative, nine out of 20 patients (45%) in the iliac crest group demonstrated solid fusion (6 in group 4 and 3 in group 3) while only one of 23 patients (4%) in HA group (group 1) demonstrated solid fusion. However at the sixth month, doubtful fusion was found in 13 of 23 patients (56.5%) of the HA group (7 patients in group 1 (58%) and six patients in group 2 (54%).

At the ninth month, 12 of the iliac crest group demonstrated solid fusion (60%) while one patient in

Table 1. Characteristic data of the study groups

	Group 1 HA + BM 1-level (n = 12)	Group 2 HA + BM 2-level (n = 11)	Group 3 Iliac crest 1-level (n = 10)	Group 4 Iliac crest 2-level (n = 10)
Age (years)	51 (45-68)	55 (27-66)	55 (39-69)	53 (21-66)
Body weight(kgs)	58 (45-70)	59 (49-70)	62 (51-74)	61 (46-78)
Operative time(hrs)	2.10 (1.33-2.50)	2.52 (2.00-3.00)	2.29 (2.00-3.25)	2.39 (2.00-3.15)
Hospitalization(days)	7 (4-10)	9 (5-17)	10 (8-21)	9 (6-11)
Pre-op VAS	7 (7-9)	8 (7-10)	8 (7-10)	7 (6-9)
Intra-op blood loss (ml)	320 (100-600)	582 (300-1,000)	463 (200-700)	705 (300-1,200)
Post-op blood loss (ml)	344 (140-615)	368 (100-600)	374 (140-550)	516 (200-800)

Data were presented as mean and range
HA = hydroxyapatite; BM = bone marrow

Table 2. VAS for back pain at pre-op, 2, 4, 6, 9, 12 and 24 months postoperative

	Pre-op VAS	2 months	4 months	6 months	9 months	12 months	24 months
Group 1							
Back	6.7	1.1	0.7	0.4	0.1	0	0
Group 2							
Back	8.2	1.2	0.7	0.4	0.3	0	0.1
Group 3							
Back	7.6	2.6	3.2	2.7	2.3	1.3	1.3
Iliac		2.7	2.5	1.6	1.5	1.0	0.9
Group 4							
Back	7.5	2.4	1.5	1.6	0.9	0.3	0.3
Iliac		3.4	4.1	2.2	0.7	0.5	0.5

Data were presented as mean

Table 3. Postoperative radiographic results of spinal fusion at 6, 9, 12 and 24 months

	Nonunion	Doubtful fusion	Fusion
Group 1: HA (1-level) (n = 12)			
6 months	4	7	1
9 months	1	10	1
12 months	0	11	1
24 months	0	11	1
Group 2: HA (2-level) (n = 11)			
6 months	5	6	0
9 months	1	10	0
12 months	0	11	0
24 months	0	11	0
Group 3: iliac crest (1-level) (n = 10)			
6 months	1	6	3
9 months	1	4	5
12 months	0	4	6
24 months	0	4	6
Group 4: iliac crest (2-level) (n = 10)			
6 months	1	3	6
9 months	0	3	7
12 months	0	3	7
24 months	0	3	7

the HA group (group 1) revealed solid fusion. After two years, only one patient in the HA group (group 1) had solid fusion. Twenty-two patients (95.6%) had doubtful fusion. Thirteen patients (13/20) of the iliac crest group had solid fusion (65%) (6 patients in group 3 and 7 patients in group 4). Four patients in group 3 and three patients in group 4 had doubtful fusion. No non-union was found. Patients in the iliac crest group were 20 times more likely to have solid fusion than patients in the HA group ($p < 0.05$).

Three patients had minor complications. One patient in group 1 and another in group 3 had superficial wound infections and one patient in group 4 had temporary foot drop.

Discussion

Alternatives to iliac crest autograft for lumbar fusion were extensively reviewed by Rihn[28]. Platelet gels, demineralized bone matrix, synthetic bone graft and bone morphogenetic protein (BMP) are potential

options for bone graft supplementation or substitution. BMP (rh-BMP2) has been shown to provide similar or even increased fusion rates over autograft iliac crest bone. There are, however, potential safety concerns associated with the use of BMP that are not fully understood. Hydroxyapatite, a calcium phosphate compound is one of the synthetic bone grafts that has been commonly used. It provides an osteoinductive scaffold for bony ingrowth and can be combined with bone marrow aspiration or used as a carrier for osteogenic factors. The efficacy of hydroxyapatite in posterolateral lumbar fusion has been studied in animal models[29]. Fusion rate in posterior fusion of T10-12 in New Zealand albino rabbits using coralline HA graft was 61%[30]. The use of coralline HA with bone marrow, autograft and bovine-derived osteoinductive bone protein extract in posterolateral lumbar fusion in New Zealand white rabbit provided the 0%, 50%, and 100% fusion rate at five weeks respectively[31]. Boden et al[32], Takahashi et al[33], and Konichi et al[34] reported that HA containing recombinant human bone morphogenetic protein-2 (Rh BMP2) enhanced the rate of spinal fusion in animal models.

Although HA has been used in the cervical interbody fusion[29,35,36], its inferior strength compared to iliac crest graft caused graft fragmentation and settling, but it provided similar fusion rate and clinical outcome[36]. Totoribe et al[37] evaluated 5-year radiographic and histologic outcome in four patients who had posterolateral fusion using HA block. They found that HA block alone had not functioned effectively as a complete graft substitute in posterolateral lumbar fusion. The use of hydroxyapatite-bioactive glass ceramic composite (Chitra-HABg) is not recommended as a standalone graft for posterolateral fusion because of high rate of poor consolidation[38]. Korovessis et al did not support the use of coralline HA in posterolateral fusion because of the low surface area of the bleeding bone. However, it may be appropriate to be used in the posterior fusion[39]. The combination of autograft and coralline HA was appropriate to be used in the posterior fusion in idiopathic adolescent scoliosis[40] and should be used in combination with such osteoinductive material to obtain good bone formation in spinal fusion.

In the present study, HA was not used as standalone graft. It was mixed with BM and local graft in order to increase the fusion rate. The important advantage of the HA group was the prevention of donor site pain which usually disturb the patients more than the residual back pain. Though early clinical improvement depends on various factors such as success of the decompression, the instrumentation methods, the long-term outcomes still depend much on the fusion rate. However, the radiographic outcome of the spinal fusion at the end of the first year in the HA group was inferior to the iliac crest group. At the 2-year follow-up period, the clinical outcome of the HA group was not statistically significantly different from the iliac crest group. In order to determine the usefulness of HA with BM and local graft, longer term follow-up period was needed.

The strength of the present study was its prospective nature. For the fusion measurement method, it is still the matter of controversy. Kant et al[41] reported poor correlation between the interpretation of the plain radiographs and the actual fusion status of the spine regardless of the time interval from instrumentation to exploration. Only 68% accuracy of x-ray interpretation of fusion was found and L4-5 level was the most difficult level to interpret. It demonstrated that using plain radiographs alone to determine the solidity of spinal fusion could be misleading. However, Blumenthal SL and Gill K[42] reported that the plain radiographic and fusion correlation rate was 69%. The problems of using plain radiography to determine the fusion were the radio-opaque density of HA on x-rays and its slow remodeling. In order to enhance the accuracy of fusion assessment, computed tomography (CT scan) is recommended. However, the cost of CT scan may preclude its routine use.

Conclusion

At one year, clinical improvement of the HA group was not different from the iliac crest group, though fusion rate as determined by plain radiographs was lower in the HA group. However, the HA group had no involvement of the donor graft area and could avoid the potential morbidity of the iliac crest. Long-term follow-up is needed to determine the actual fusion rate of the HA mixed with autologous BM and local graft.

Potential conflicts of interest

None.

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ผลการรักษาการเชื่อมกระดูกสันหลังส่วนเอวชนิด posterolateral โดยใช้ส่วนผสมของ ฮัยดรอกซีอะปาไตต์ร่วมกับไขกระดูกของผู้ป่วยและส่วนของกระดูกที่ตัดออกจากผู้ป่วยเองบริเวณใกล้เคียงกับที่ทำผ่าตัด

วีระ สถิรอังกูร, สมบัติ คุณากรสวัสดิ์, บุญสินธพ์ อัศวชุติธำรง, รัชตะ ตั้งศิริพัฒน์

จุดประสงค์: *เพื่อศึกษาผลของการรักษาการเชื่อมกระดูกสันหลังส่วนเอวโดยใช้ส่วนผสมของฮัยดรอกซีอะปาไตต์ร่วมกับไขกระดูกของผู้ป่วยและส่วนของกระดูกผู้ป่วยที่ตัดออกจากผู้ป่วยบริเวณใกล้เคียงกับที่ทำผ่าตัด*

วัสดุและวิธีการ: *ได้ทำการศึกษาแบบไปข้างหน้าในผู้ป่วยจำนวน 23 ราย ที่ได้รับการผ่าตัดการเชื่อมกระดูกสันหลังชนิด posterolateral โดยการใส่วัตถุยึดตรึงทางด้านหลังโดยใช้ฮัยดรอกซีอะปาไตต์ ร่วมกับไขกระดูกของผู้ป่วยและส่วนของกระดูกที่ตัดออกจากผู้ป่วยบริเวณใกล้เคียงในระหว่างเดือน ธันวาคม พ.ศ. 2003 ถึง สิงหาคม พ.ศ. 2005 ศึกษาผู้ป่วยด้านความปวดจากมาตรวัดความเจ็บปวดชนิดภาพภูมิ ทั้งก่อนและหลังการผ่าตัดที่ 2, 4, 6, 9, 12 และ 24 เดือน และศึกษาภาพรังสีถึงผลการเชื่อมต่อของกระดูกหลังผ่าตัดที่ 4, 6, 9, 12 และ 24 เดือน*

ผลการศึกษา: *ผลด้านความปวดจากมาตรวัดความเจ็บปวดชนิดภาพภูมิดีขึ้นในผู้ป่วยทุกราย ผลด้านการเชื่อมต่อของกระดูกไขสันหลังโดยภาพรังสี เมื่อระยะ 6 เดือนหลังผ่าตัดให้ผลเชื่อมต่อดี 1 ใน 23 ราย (ร้อยละ 4.3) และเป็นที่น่าสงสัย 13 ใน 23 ราย (ร้อยละ 36.5) ที่ระยะ 1 ปี หลังผ่าตัด ให้ผลเชื่อมต่อดี 1 ราย ส่วนอีก 22 ราย จาก 23 ราย ให้ผลเป็นที่น่าสงสัย*

สรุป: *แม้ว่าผลการผ่าตัดเชื่อมกระดูกสันหลังชนิด posterolateral โดยใช้ฮัยดรอกซีอะปาไตต์ร่วมกับไขกระดูกของผู้ป่วยและส่วนของกระดูกที่ตัดออกจากบริเวณที่ผ่าตัดให้ผลดีในการรักษา แต่ผลของการเชื่อมต่อของกระดูกสันหลังจากภาพรังสียังเป็นที่น่าสงสัยในผู้ป่วยส่วนใหญ่*