Radiology Result and Complications of Percutaneous Balloon Kyphoplasty in Patients with Osteoporotic Vertebrae Compression Fracture

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ABSTRACT

Introduction. Percutaneous balloon kyphoplasty is a minimal invasive surgical intervention offering promising results for address both the fracture related pain and kyphotic deformity due to osteoporotic vertebral compression fracture who failed with conservative mean. The objective of the study is to evaluate of low back pain, radiology results and complications after percutaneous balloon kyphoplasty procedure.

Materials and methods. This research used retrospective study design, there are 38 patients with osteoporotic compression vertebrae fracture and had been done percutaneous balloon kyphoplasty Evaluation was done by compare of low back pain using Visual Analog Score (VAS), radiology results (anterior and middle part of vertebrae body height, wedge shape ratio, Cobb Angle/kyphotic angle) between pre-operatively and post operatively, and also evaluate some complications within this procedure.

Results. The result showed that there are significant difference between pre-operatively and post operatively about patient’s Visual Analog Score and radiology results (vertebrae body height, wedge shape ratio, except Cobb angle/kyphotic angle) by Z test with α 0.01. Based on Spearman Rho test showed significant correlation between changing of kyphotic angle with pain improvement but no correlation with wedge shape ratio improvement. Fracture of the adjacent vertebrae is the frequent complication which is found.

Conclusionsk. Percutaneous balloon kyphoplasty procedure is useful in treatment patients with chronic pain due to osteoporotic compression vertebrae fracture who failed with conservative mean.

Keywords: percutaneous balloon kyphoplasty, osteoporosis, low back pain, Cobb Angle, complications
ABSTRAK

Pendahuluan. Penelitian ini bertujuan untuk mengetahui perbandingan keluhan nyeri punggung bawah, perbaikan radiologi serta evaluasi jenis komplikasi setelah dilakukan kifoplasti balon perkutaneus.

Bahan dan cara kerja. Sebanyak 38 pasien dengan fraktur kompresi vertebrae yang sudah dilakukan kifoplasti balon perkutaneus diikutkan dalam penelitian. Penilaian efek terapi dilakukan praoperatif dan post operatif terhadap perbaikan nyeri punggung bawah dengan memakai Visual Analog Score (VAS), perbaikan radiologis dari tinggi korpus vertebrae bagian anterior dan tengah, wedge shape ratio, sudut Cobb atau sudut kifosis, serta komplikasi yang terjadi.

Hasil. Hasil penelitian menunjukan adanya perbaikan yang signifikan terhadap keluhan nyeri punggung bawah pasien, tinggi korpus vertebrae dan wedge shape ratio, kecuali perbaikan terhadap sudut kifosis dan sudut Cobb hasilnya tidak signifikan, dengan Z test α 0,01.

Simpulan. Hasil uji Spearman Rho menunjukkan hubungan bermakna antara perbaikan keluhan nyeri punggung bawah terhadap perbaikan sudut kifosis dan sudut Cobb, tetapi pada perbaikan wedge shape ratio pascaoperasi tidak menunjukkan hubungan yang bermakna. Komplikasi fraktur pada vertebrae lain pascaoperasi merupakan jenis komplikasi yang paling sering ditemukan.

Kata kunci: kifoplasti balon perkutaneus, osteoporosis, nyeri punggung bawah, Cobb Angle, komplikasi

Introduction
Reduction in bone mass due to osteoporotic process in elderly is the main caused of pathologic fracture, which is found mostly at proximal humerus, distal radius, proximal femur and vertebrae.\(^1\)\(^-\)\(^3\) The location can be isolated or combination with risk is proportional with the age escalation.\(^4\)\(^,\)\(^5\)

Nowadays there is new health problem showed increasing incidence of osteoporotic vertebrae fracture in some countries which spend highly cost annually, with sex proportion in woman is higher than man.\(^6\) For example in Holland has 40.000 patients was reported annually.\(^7\) In United State has 700.000 patients annually and has spent of $746.000 for last 10 years since 1990.\(^8\)

Once this fracture happened on one vertebrae in elderly, the risk of fracture and progressive collapse on another vertebrae will increase.\(^9\) It can cause disturbing pain with kyphotic deformity and decrease of body height, ultimately decrease the patient’s quality of live and increasing the complications at once.\(^10\) However, only one third from all of them will come to the medical service due to intractable pain.\(^11\)

Initial treatment for symptomatic stable compression vertebral fracture without neurological deficit are bed rest, analgesic with spinal bracing and followed by physiotherapy program soon after pain subside.\(^11\),\(^12\)

Prolong bed rest due to pain for elderly will stimulate systemic complication such as cardiovascular problem, atrophy of musculoskeletal system, metabolic system disorder, decrease of immune system and decrease of bone mineral density progressively.\(^11\) Ultimately unresolved pain can cause chronic pain, progressive deformity and disability.\(^7\),\(^9\)

Actually 85% of those patients, pain as a chief complain can be resolved conservatively and may return into their daily activities. Only 15% still have persistent pain and need further alternative treatment, such as surgery.\(^5\) Due to decrease of bone quality in elderly make some obstacles on the spine surgery especially for instrumentation, therefore minimal invasive surgery, such as percutaneous balloon kyphoplasty, may be as an alternative of choices to give optimal result without put
the osteoporotic vertebrae fracture patients in high risk of prolong spine surgery.\textsuperscript{13}

Percutaneous balloon kyphoplasty as minimal invasive surgery is useful to handle pain due to osteoporotic vertebrae compression fracture who failed by conservative mean by polymethylmethacrylate augmentation into intravertebral cleft within vertebral body after balloon tamp inflation.\textsuperscript{9,11,14,15}

Theoretically this method has more advantages compare with vertebroplasty, but still less information regarding of effectiveness and complications in clinical practices until now. We tried to answer if percutaneous balloon kyphoplasty is safe and effective to alleviate low back pain and improve kyphotic deformity of patients with osteoporotic compression vertebral fracture. We hypothesized that percutaneous balloon kyphoplasty was effective and save to alleviate low back pain on elderly patients with osteoporotic vertebral compression fracture who failed by conservative mean. The objective of the study was to describe and analyze clinical and radiological efficacy and complications of percutaneous balloon kyphoplasty as an alternative treatment for alleviate pain in osteoporotic vertebral compression fracture who failed by conservative mean.

Materials and methods.
This retrospective study was conducted at Hamawaki Orthopaedic Hospital, Hiroshima, Japan, started in March until August 2012. Sampel consists of all the patients who suffered from osteoporotic vertebrae compression fracture, had already done percutaneous balloon kyphoplasty since April 2011 until June 2012 due to failed with conservative treatment with total number is 39 patients. We included all patients with all osteoporotic compression vertebral fracture patients who failed with conservative treatment whom involved vertebrae level were between the fifth thoracal and lumbar vertebral, with minimal diameter of pedicle of 5 mm on CT Scan. The patient should also had a maximum number of vertebrae involved less than two with intact posterior vertebral body, without neurological deficit or other contraindication for surgery, and has agreed to participate in this study. Those presented with metastatic bone disease or those who require instrumentation were excluded from the study. We measured the visual analog scale (VAS), anterior and middle vertebral body height, wedge shape ratio, as well as the Cobb angle prior to and after kyphoplasty. Statistical analysis was carried out using Microsoft excel 2010 by Z test with $\alpha$ 0.01 and correlation analysis between decreasing score of VAS with improvement of wedge shape ratio dan kyphotic angle by Spearman Rho test.

Results
There are total 39 patients who had percutaneous balloon kyphoplasty procedure, during April 2011 until June 2012 but 1 of them must be excluded in this study due to instrumentation was done following this procedure.

From 38 patients, 31(81.6%) patients were female and 7 (18.4%) patients were male. The mean age was 78.5 years old, ranging from 60 to 92 years old. The procedure were done mostly in age group of 76 to 85 years old. The mean bone mineral density was 0.79 gr/cm\textsuperscript{2} and mean T score was (-2.3).

Based on location, this procedure was done mostly at level vertebrae thoracal XII (9 vertebrae bodies 23.7%) and lumbar I (14 vertebrae bodies 36.8%)

Mean wedge shape ratio, anterior vertebral body height, middle vertebral body height were 34.9, 37.2, and 43.5 preoperatively and 495, 57.1, and 62.5 postoperatively. Mean Cobb angle were 34.7 preoperatively and 29.8 postoperatively.

Based on VAS evaluation from all 38 patients post operatively, although majority of them, 31 patients (81.6%) had good progress, but there were 2 patients (5.2%) still had persistent pain, 5 patients (13.1%) had pain increase progressively. Mean of VAS from those 31 patients showed significant result post operatively with result 5.9±2.2 preoperatively and 1.6±1.8 postoperatively. Based on Spearman Rho test showed significant correlation between improvement of kyphotic angle post operatively with pain relieve of patients.

Mean time for conservative treatment before percutaneous balloon kyphoplasty in this study was 54.7 days. Mean time for follow up postoperatively was 4.1 months, ranging between 1 to 14 months.

During follow up, collapse of adjacent vertebral body was found mostly with total 10 patients (26.3%) and treated conservatively by spinal bracing, analgesic and physiotherapy. There was no other major complications in this study.

Discussions
Percutaneous balloon kyphoplasty is a minimal invasive procedure that useful to alleviate pain and elevate end plate of collapse vertebral body due to osteoporotic vertebral compression fracture by filling a void intravertebra with bone cement after balloon tamp inflation. This procedure is modification of previous procedure which is called vertebroplasty, but there is still lack information about its outcome and complications.\textsuperscript{12,16}

Mostly 81.6% patients have good response with showed by VAS postoperatively, similar with multicenter study on 2194 vertebrae fracture which showed 90% improvement of pain postoperatively.\textsuperscript{9} and study and another study with 85% improvement.\textsuperscript{10}
Although evaluation of pain relieve within 1 month post operatively by VAS in this study, showed significant difference between pre operatively (mean score 5.9) and post operatively (mean score 1.6), this result is almost similar with study of Manson et al,10 but in this study there were 7 patients (22.5%) had pain still unchanged even increase. This was happened due to multiple osteoporotic vertebrae bodies fracture previously and there were new adjacent collapse of vertebrae bodies post operatively as complications.11,17

Actually pathophysiology of pain relieve after balloon kyphoplasty is still controversy until now, but there is significant correlation between improvement of kyphotic angle with pain relieve as showed by decrease of VAS in this study. Because by improvement of this angle will influence kyphotic deformity changing and improvement of sagittal balance at once by center gravity shifting more posteriorly, this mechanism influence contraction of paravertebra muscle more relax and relieve muscle fatigue as well.11,12,17

More over pain relieve may caused indirectly by augmentation of bone cement into the void which is created by inflation of balloon tamp previously intravertebra. This bone cement will give immobilization effect and prevent from friction motion of pseudoarthrosis intravertebra rather than anatomic correction of affected vertebrae body in pain relieve mechanism.

Mean of Kyphotic deformity changing by evaluation of Cobb angle post operatively in this study is not big, but only 5°, different with Manson et al10 that showed cobb angle correction until114°. This is because the patients within this study mostly already had multiple osteoporotic vertebrae compression fracture pre operatively, meanwhile percutaneous balloon kyphoplasty was not done to all osteoporotic vertebrae compression fracture but just focused onto specific vertebrae body which is correlated with chief complain of pain at admission, after confirmed by physical examination and further investigation.18

Besides, this procedure was done mostly on the affected vertebrae which had already collapse more than 50% that make restoration effort for kyphotic deformity is more difficult.

Theoretically complication of Balloon kyphoplasty procedure is less than Vertebroplasty. In this study is showed 26.3% collapse of adjacent vertebrae body was happened post operatively. On the other hand, study of Li et al20 with vertebroplasty showed larger proportion of complication, about 38% within 3 months follow up post operatively.

Higher proportion of this complication by vertebroplasty may caused by some factors. Beside due to decrease of bone quality as osteoporotic process and also due to excessive correction effort for deformity by augmentation of bone cement with high pressure, finally increasing the stress pressure until 13%-18% and biomechanical effect of bone cement onto adjacent vertebrae body after vertebroplasty during activities.5,19,21

Location of adjacent vertebrae body collapse mostly happened directly at upper and lower level of affected vertebrae that had this procedure (peak of deformity). It can be happened due to biomechanical pressure is higher directly at the upper and lower level of the peak deformity (segment vertebrae with Balloon Kyphoplasty).5,19,21

Although bone mineral density value and bone cement volume may take a part as variables that may influence this complication, but further cohort study is needed to prove it in future.3,17

There is no major complication was found within this study due to closed monitoring and examination at preoperative stage especially when determine inclusion criteria for the right patients and all the procedure was done strictly with high standard procedure and skillful spine team.

Conclusions
In short term follow up, percutaneous balloon kyphoplasty is safe and effective to alleviate chronic low back pain due to osteoporotic vertebrae compression fracture who failed by conservative treatment. Due to higher risk of adjacent vertebrae fracture post operatively, closed monitoring of each patient will be needed, informed consent clearly in activity daily living modification and spinal bracing application as well in order to improve patient’s quality of live later on. Due to lack number of patients and short time in this study, further cohort study will be needed in the future with large number of sample, add another variable such as functional outcome to evaluate impact and complication post operatively.

References
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