

# Early-Onset Anterior Endplate Fractures of Adjacent Vertebrae in Balloon Kyphoplasty and SpineJack®

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## Abstract

**Background:** Vertebral compression fractures (VCFs) occur most commonly on the thoracolumbar junction, which are the most vulnerable biomechanical regiments at the thoracolumbar junction between the thoracic kyphosis and lumbar lordosis. Percutaneous vertebroplasty and kyphoplasty are currently the primary minimally invasive surgical treatments for thoracolumbar VCFs. The principal aim of this study is to compare the clinical efficacies of percutaneous balloon kyphoplasty (BKP) and SpineJack® (SJ) techniques in the treatment of thoracolumbar VCFs by evaluating the risk factors for early-onset adjacent level fractures (ALFs) over a 6 month follow-up.

**Methods:** A total of 106 patients with thoracolumbar (T11-L2) VCFs, treated with kyphoplasty techniques (64 with BKP and 42 with SJ), were enrolled in this retrospective study. Patterns of preoperative, postoperative day 1, and postoperative 6 month thoracolumbar spine images and discrepancies of long-term kyphosis correction functions were compared using two different kyphoplasty procedures.

**Results:** A total of 19 new early-onset ALFs were found within one month postoperatively (9 in BKP and 10 in SJ groups), and all presented as anterior vertebral endplate fractures. The early-onset ALFs in the BKP group were anterior inferior endplate fractures at the superior vertebral levels mainly. The preoperative anterior-type and severe VCFs were the statistically significant risk factors for early-onset ALFs. The timing of kyphoplasty intervention for acute VCFs within 1 month and patients with advance age were also presented risk factors to developed early-onset ALFs in our study ( $p=0.018$ ;  $p<0.001$ ).

**Conclusion:** There was no superiority in the occurrence rate of early-onset ALFs and kyphosis correction effects of BKP or SJ techniques in the treatment of thoracolumbar VCFs. The factors, including pre-OP anterior-type and severe VCFs, patients with advance ages, and kyphoplasty timing within one month since the appearance of symptoms, are the primary risk factors for subsequent early-onset ALFs after kyphoplasty to thoracolumbar VCFs.

**Keywords:** Vertebral compression fracture • Thoracolumbar • Adjacent level fracture • Balloon kyphoplasty • SpineJack

## Abbreviations

(VCF) Vertebral Compression Fracture; (BKP) Balloon Kyphoplasty; (SJ) SpineJack®; (ALF) Adjacent Level Fracture; (pre-OP) Preoperative; (MRI) Magnetic Resonance Imaging; (BMD) Bone Mineral Density; (Xr) X-ray; (post-OP) Postoperative; (PMMA) Poly Methyl Methacrylate

## Introduction

A vertebral compression fracture (VCF) of the spine occurs with a vertebral collapse and is the most common problem associated with osteoporotic fractures worldwide. The prevalence of VCFs increases with elderly age and especially female gender, accounting approximately 9%-24% of Asian women aged  $\geq 65$  years and 11%-26% of women aged  $\geq 50$  years worldwide [1]. VCFs commonly occur at T12 and L1 levels, which are the most vulnerable biomechanical regiments at the thoracolumbar junction between the thoracic kyphosis and lumbar lordosis [2].

Thoracolumbar VCFs can influence the daily activity or impair the mobility of patients due to severe pain, spinal deformity with consequent neurological

deficiency, or abdominal and thoracic cavity restriction. Conservative treatments include the use of osteoporosis medications, analgesics, and back brace. Brace is a noninvasive option to support and correct spinal deformity or instability. However, ineffective restoration of spinal deformity and poor brace tolerance had been demonstrated in elderly patients with thoracolumbar VCFs treated with conservative treatments [3]. Percutaneous vertebroplasty and kyphoplasty are currently the primary minimally invasive surgical treatments for thoracolumbar VCFs [4]. Percutaneous kyphoplasty has been reported to be superior to vertebroplasty with regard to more effective vertebral height restoration and kyphosis correction and less leakage of bone cement [5,6]. However, some complications of kyphoplasty have been reported, such as subsequent adjacent level fractures (ALFs). Nowadays, two major different kyphoplasty techniques, SpineJack® (SJ; Stryker Corp, Kalamazoo, MI) and balloon kyphoplasty (BKP) are available; however, which of these two displays better clinical efficiency in thoracolumbar VCFs remains controversial. Therefore, this study aimed to compare the clinical efficacy of both the techniques for the treatment of thoracolumbar VCFs over the 6 month follow-up period.

## Methods

### Study design

A retrospective analysis was performed and approved by the institutional review board at our institution, a general reference teaching hospital, between July 2013 and June 2019. Patients with thoracolumbar VCFs (T11-L2) who were treated with BKP or SJ was enrolled. After the exclusion of underlying malignancy, previous history of any spinal surgery, and no regular follow-up images ( $\geq 6$  months), 106 patients with VCF who were treated with kyphoplasty techniques (64 with BKP and 42 with SJ) were enrolled in this study. A series of thoracolumbar spinal images were obtained, including preoperative (pre-OP) magnetic resonance imaging

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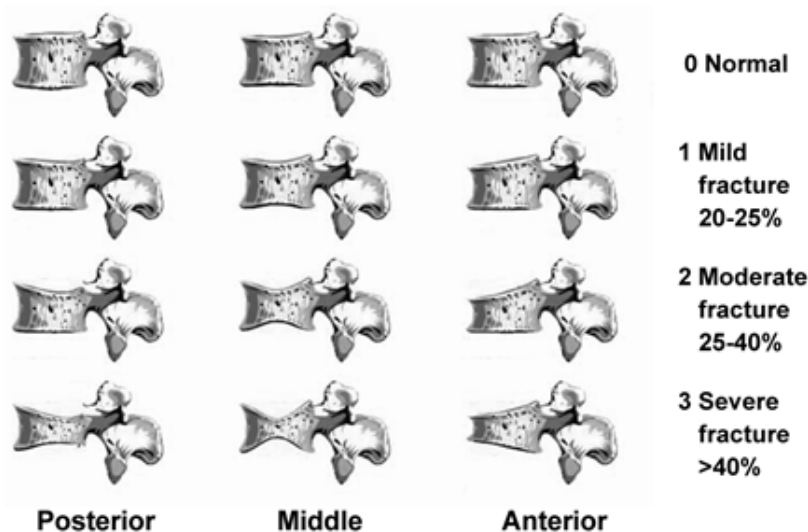
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(MRI), bone mineral density (BMD), and lateral X-rays (Xrs) of the pre-OP, postoperative (post-OP) day 1, and post-OP 6 month periods. Segmental (lordosis/kyphosis) Cobb angles, severity, and fracture type of VCFs were recorded from lateral Xrs or MRIs. Through the imaging data analysis, risk factors of newly developed ALFs were determined, including the therapeutic effects of two different surgical techniques and future surgical corrections for kyphotic thoracolumbar VCFs without neurological deficits.

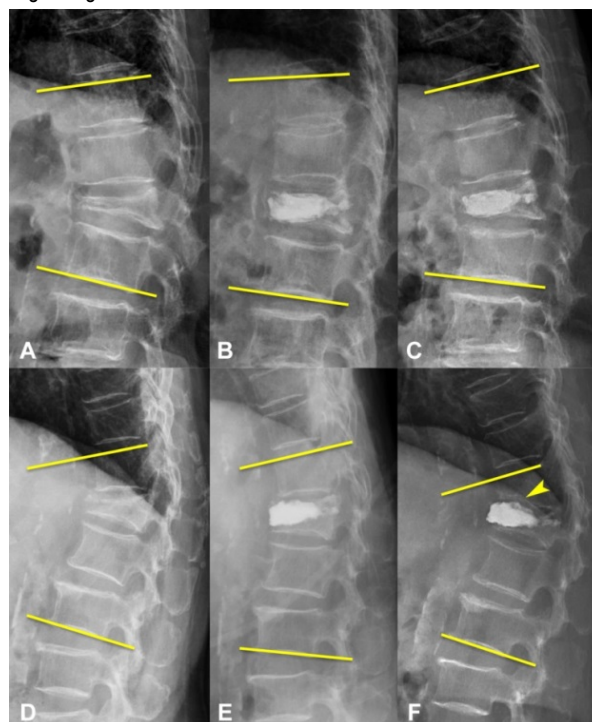
### Imaging assessment

All symptomatic patients with acute benign VCFs were surgically treated with BKP and SJ after complete preoperative images, including MRI, BMD, and Xrs, with compatible characterizations of acute VCFs. All patients were scheduled for spinal MRI to differentiate acute or chronic and benign or malignant VCFs. MRI patterns of these benign acute VCFs showed low signal in sagittal T1 MRI, high signal in short T1 inversion recovery

images, or enhanced contrasted MRI without paravertebral soft tissue mass presentations [7]. The BMD was evaluated using T-scores at lumbar segment (L3-5) or femoral neck from dual-energy X-ray absorptiometry, and osteoporosis was defined as T-scores of -2.5 or lower. The severity and type of fractured vertebrae were evaluated by pre-OP spinal MRI and graded according to Genant's semiquantitative assessment, mild (grade 1, 20%-25% reduction in the anterior, middle, and/or posterior vertebral height), moderate (grade 2, 25%-40% reduction in any vertebral height), severe (grade 3,  $\geq 40\%$  in any vertebral height), and borderline (grade 0.5,  $<20\%$  in any vertebral height) (Figure 1) [8]. The Cobb angle of the thoracolumbar spine was measured from the superior upper endplate of T11 to the inferior endplate of L2 vertebrae on the lateral thoracolumbar spine Xr. Cobb angles were recorded at the three stages: pre-op (angle<sub>pre</sub>), post-op day 1 (angle<sub>post</sub>), and end-point (angle<sub>end</sub>, post-op 6 months or new occurrence of ALFs) (Figure 2).



**Figure 1.** Genant's semiquantitative visual grading scheme for vertebral fracture assessment.



**Figure 2.** The Cobb angle of the thoracolumbar segment (upper T11 to lower L2) at different stages. (A) pre-OP (angle<sub>pre</sub>), (B) post-OP day 1 (angle<sub>post</sub>) and (C) end-point (angle<sub>end</sub>, post-OP at 6 months or new occurrence of adjacent level fractures). A-C: An 84-year-old woman with compression fracture treated with balloon kyphoplasty, L1; three different stage of thoracolumbar spine lateral X-rays. D-F: A 76-year-old woman with vertebral compression fracture treated with balloon kyphoplasty, T12, three different stages of thoracolumbar spine lateral X-rays, pre-OP, post-OP day 1, and new occurrence of anteroinferior endplate fracture at L1 within 1 month (yellow arrowhead).

### Surgical procedures

All surgeries were performed in prone position under general anesthesia. After identifying the fractured vertebrae, a bilateral transpedicular approach was used to insert working cannulas into the posterior part of the vertebral body. The working space from the anterior to posterior vertebral body was created using reaming tools to insert appropriate balloons or SJs, which were implanted at the center between the endplates and anterior two-thirds of the vertebral body. A balloon was inflated slowly until adequate vertebral height or pressure of up to 250 psi was restored. Similarly, SJs were expanded to correct the vertebral height. Then poly (methyl methacrylate) (PMMA) bone cement was injected via the working cannulas until the appearance of impending cement extravasation. All procedures were performed under the assistance of a C-shaped intraoperative fluoroscopic device.

### Data evaluation

After determining the eligibility of this study, medical records of patients treated with kyphoplasty procedures were reviewed. Two neurosurgeons as reviewers enrolled the qualified patients following the exclusion criteria mentioned above. Then, age, gender, BMD (T score), fractured vertebral levels, and timing and type of kyphoplasty of each patient were recorded. Radiographic parameters were recorded, including the severity and type of fractured vertebrae, and the Cobb angles of thoracolumbar spine at pre-OP, post-OP day 1, and post-OP end stages. The occurrence time and patterns of newly developed ALFs were also recorded. Extracted medical records were independently analyzed by two neurosurgeons. Any divergence of recorded data was resolved through discussion.

### Statistical analyses

Statistical analyses were performed using SPSS 21.0 (IBM Corp). The univariate analyses of patients' demographic and radiographic parameters to induce ALFs and the timing of kyphoplasty intervention to symptomatic VCFs were evaluated using chi-squared tests. Statistical significance with correlation was identified as  $p < 0.05$ . Based on these results, significant or potential risk factors for ALFs or the effect of maintaining surgical kyphosis correction in different techniques were identified using the Firth's logistic regression analyses.  $P < 0.05$  was identified as significance in all analyses.

## Results

### Patient demographics

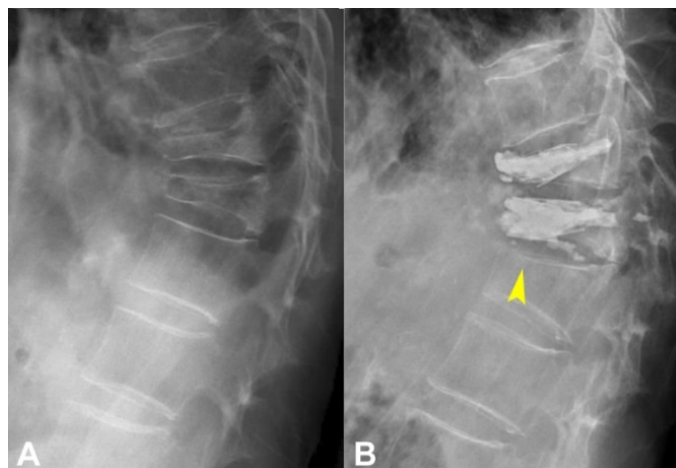
In this study, 106 VCF patients with 115 fractured vertebrae were identified, including 64 who underwent BKP and 42 SJ surgeries. There were 25 males and 81 females. General data and comorbidities are listed in Table 1. Follow-up imaging evaluations were terminated at postoperative 6 months or during the detection of newly developed ALFs. The occurrence rate of new early-onset ALFs within post-OP 1 month was higher in the SJ (10/42; 23.81%) compared with the BKP (9/64; 14.06%) groups seemingly. Notably, all 19 early-onset ALFs (9 in BKP group and 10 in SJ group) were presented as anterior vertebral endplate fractures; 8 early-onset ALFs in the BKP group were anterior inferior endplate fractures at the superior vertebral levels and 1 was anterior superior endplate fracture at the inferior vertebral level; 6 early-onset ALFs in the SJ group were anterior inferior endplate fractures at the superior vertebral levels and 4 were anterior superior endplate fracture at the inferior vertebral level (Figures 2 and 3). Three patients presented delayed-onset ACFs at  $> 1$  month after the performance of BKP (1 on the superior adjacent level, 1 on the inferior adjacent level, and 1 on the inferior nonadjacent level), and all delayed-onset ACFs presented with anterior-type VCFs. No delayed-onset ACF was found in SJ group.

**Table 1.** Demographic characteristic of patients.

Characteristic	BKP	SJ	p value
	(N=64)	(N=42)	
Age	74.81 ± 10.17	74.60 ± 10.27	0.915

Gender			0.327
Male	13	12	
Female	51	30	
Level			0.124
T11	12	5	
T12	20	17	
L1	25	10	
L2	7	10	
Type			0.001
anterior	33	35	
middle	31	7	
Severity			0.062
Mild	16	3	
Moderate	10	9	
Severe	38	30	
Osteoporosis			0.153
Yes	38	19	
No	26	23	

Abbreviation: BKP: balloon kyphoplasty; SJ: SpineJack®



**Figure 3.** A 91-year-old man with vertebral compression fracture treated with SpineJack®. T11, T12, two different stages of thoracolumbar spine lateral X-rays, (A) pre-OP, (B) new occurrence of anterior superior endplate fracture at L1 within 1 month (yellow arrowhead).

### Risk factors to early-onset adjacent level fracture

In the univariate analysis, anterior-type and severe type VCFs were indicated as risk factors for the occurrence of subsequent ALFs following the BKP or SJ managements ( $p < 0.05$ ) (Table 2). Logistic regression analysis was further used to evaluate the risk factors of new early-onset ALFs, the anterior part of VCFs presented was more statistically significant than the severity of VCFs to induce early-onset ALFs (Table 3).

**Table 2.** Risk factors to early-onset adjacent level fracture.

Variable	Adjacent Fracture		$\chi^2 / t$	p value
	Yes (n=19)	No (n=87)		
	n (%) / mean (SD)	n (%) / mean (SD)		
Severity			7.44	0.022

Mild	0 (0%)	19 (100%)		
Moderate	2 (10.53%)	17 (89.47%)		
Severe	17 (25%)	51 (75%)		
<b>Treatment</b>			5.62	0.018
<1 month	14 (26.92%)	38 (73.08%)		
>1 month	5 (9.26%)	49 (90.74%)		
<b>Op</b>			1.64	0.201
SpineJack	10 (23.81%)	32 (76.19%)		
Balloon	9 (14.06%)	55 (85.94%)		
<b>Osteoporosis</b>			3.69	0.055
Yes	14 (24.56%)	43 (75.44%)		
No	5 (10.2%)	44 (89.8%)		
<b>Sex</b>			0.08	0.999
Female	15 (18.52%)	66 (81.48%)		
Male	4 (16%)	21 (84%)		
<b>Type</b>			9.42	0.002
Anterior	18 (26.47%)	50 (73.53%)		
Middle	1 (2.63%)	37 (97.37%)		
Age	81.05 (6.79)	73.34 (10.27)	4.04	<0.001
Angle <sub>pre</sub>	21.87 (11.43)	19.37 (9.24)	1.02	0.309
Angle <sub>post</sub>	14.91 (11.94)	14.80 (8.80)	0.05	0.963
Angle <sub>end</sub>	24.16 (12.59)	20.57 (10.01)	1.35	0.18
Angle <sub>pre</sub> : preoperative Cobb angle; angle <sub>post</sub> : Cobb angle at the postoperative day 1; angle <sub>end</sub> : Cobb angle at postoperative 6 months or new occurrence of adjacent level fractures				

**Table 3.** Comparison of risk factors to early-onset adjacent level fractures.

Variable	β	SE	p value	OR	95% C.I. for OR	
					Lower	Upper
Severity (Moderate vs. Mild)	1.292	1.72	0.419	3.641	0.125	106.08
Severity (Severe vs. Mild)	2.219	1.589	0.094	9.199	0.409	206.995
Timing (<1 month vs. >1 month)	-1.644	0.66	0.008	0.193	0.053	0.704
Type (Anterior vs. Middle)	1.679	0.9	0.036	5.358	0.918	31.265
Age	0.112	0.036	0.001	1.119	1.042	1.201

Advanced age and osteoporosis have been reported as risk factors of ALFs in the previous studies [9,10]. However, we found only advanced age to be a strong risk factor of early-onset ALFs in the logical regression analysis (p=0.001). As the patients were >1 year in age, an increased risk of early-onset ALFs was evident (OR=1.119; 95% CI 1.042–1.201). Osteoporosis seemed to be a potential factor to trigger early-onset ALFs (p=0.055). Among 19 patients with early-onset ALFs in this study, 14 patients had

underlying osteoporosis and 5 had osteopenia.

The timing of kyphoplasty intervention from the appearance of clinical symptoms to the performance of surgery within one month was one of the risk factors for early-onset ALFs (p=0.018). The timing of kyphoplasty intervention within one month presented one significant factor to early-onset ALFs by using logistic regression analysis (p=0.008).

**Kyphosis correction effect evaluation**

The Cobb angle of the thoracolumbar segment from superior upper endplate at T11 to the inferior endplate at L2 vertebra on the lateral thoracolumbar spine Xrs was measured. Effects of kyphosis correction were evaluated using the following calculation formulas: immediate correction effect (anglepre minus anglepost); delayed correction effect (anglepre minus angleend), and postoperative loss of correction at final (anglepost minus angleend); negative values indicated progressive kyphosis and positive values indicated kyphosis correction. Univariate analyses of the BKP and SJ groups to the radiographic parameters demonstrated common postoperative patterns of immediate correction effects with improved kyphosis after operations and kyphosis with progression at post-op 6 month follow-up. No significant differences were observed in immediate or delayed kyphosis correction effects between BKP and SJ groups (Table 4).

**Table 4.** Comparison between two types of surgery.

Variables	BKP	SJ	p value
	(N=64)	(N=42)	
Angle			
preoperative	20.39 ± 10.55	18.95 ± 8.15	0.457
postoperative	15.45 ± 9.57	13.90 ± 9.16	0.411
end	21.93 ± 11.29	20.11 ± 9.31	0.385
Immediate correction effect	4.87 ± 5.83	5.05 ± 4.58	0.867
Delayed correction effect	-1.55 ± 6.54	-1.16 ± 5.85	0.754
Loss of correction at final	-6.40 ± 6.85	-6.21 ± 5.21	0.882
Abbreviation: BKP: balloon kyphoplasty; SJ: SpineJack®			

**Discussion**

Issues on ALFs following VCFs, treated with vertebroplasty, kyphoplasty, or nonsurgical treatment, have been widely discussed. No significant difference on risks for adjacent level fracture between vertebroplasty, kyphoplasty, and nonsurgical treatment to VCFs has been demonstrated in the recent meta-analysis review studies [11,12]. The wide range of ALF incidence in patients with VCFs treated by kyphoplasty has been reported from 0%-23.73%, and the incidence was found to be higher at the thoracolumbar segment as compared with other spinal segments [13,14]. However, to the best of our knowledge, this is a rare study that focused on the type of early-onset ALF within one month after the BKP or SJ was performed for thoracolumbar VCF managements. In this retrospective study, early-onset ALF incidences were 14.06%w (9/64) in the BKP group and 23.81% (10/42) in the SJ group.

The goals of BKP are to restore the vertebral height and correct kyphosis through bone cement deposition within the cavity created by inflation and deflation of the balloon within the vertebral body. The biomechanical studies have demonstrated that subsequent segmental loads by the bone-cement interface, compactness ratio of the trabeculae region, and the tendency of trabecular collapse of the adjacent superior vertebra were higher than at the inferior adjacent level after the vertebral PMMA bone cement augment

treatments [15,16]. In our study, the early-onset ALFs occurred on superior adjacent levels (8/9). In addition, more bone cements were deposited within the cavity created by balloon in BKP than the trabecular space in vertebroplasty. The increased magnitude of vertebral height restoration and amount of PMMA cement applied during the vertebral augmented procedures are highly related to the incidence of subsequent ALFs [17,18]. In contrast to BKP, the advantages of SJ are the lasting restoration of more vertebral body height over time with demand of less cement through the direct up and down expansion of titanic implantations [19], and that can explain the result of similar early-onset ALFs (4 superior and 6 inferior levels) in the SJ group of the current study. The specific phenomenon of different early-onset anterior endplate fractures at adjacent vertebral levels in the BKP and SJ groups could perhaps explain the amount of bone cements in BKP or direct up and down expansion function in SJ that produce different loads to adjacent vertebrae, respectively.

The timing of surgical management of VCFs was a risk factor for occurrence of early-onset ALFs ( $p=0.008$ ) in this study. An optimal surgical timing was suggested at least 1 month after the occurrence of symptomatic VCFs to achieve satisfactory results and less risk of bone cement leakage [20]. In this study, the immediate and delayed kyphosis correction effects demonstrated non-superiority in both BKP and SJ groups, consistent to the findings of the previous studies [21,22]. Although the phenomenon of progressive kyphosis after both surgical managements was found in our study over 6 months, no surgical reintervention at the fractured level was presented in the medical records. Hence, managements of kyphotic VCFs in the thoracolumbar segment are required in large, randomized studies to compare the longtime therapeutic effect of minimal kyphoplasty, surgical posterior fixation operations, or combined.

Several limitations exist in this study. First, the number of enrolled patients with VCFs in the BKP and SJ groups was not large enough to precisely compare with each other. Second, other traditional risk factors, such as patients' body mass, volume and shape of the bone cement deposition, change of anterior vertebral height, and other many factors that perhaps also contribute to subsequent ALFs were not recorded and demonstrated. Third, the strict standing position as patients had lateral Xr examinations was not allowed in the retrospective study and large bias was observed in the measurements of Cobb angles from patients' lateral Xr images.

## Conclusion

There was no superiority of occurrence rate of early-onset ALFs and kyphosis correction effects of BKP or SJ techniques in the treatment of the thoracolumbar VCFs. Different patterns of anterior endplate fractures in adjacent vertebral levels were presented specifically in BKP and SJ groups, respectively. The factors, including pre-OP anterior-type and severe VCFs, patients with advance ages, and kyphoplasty timing within one month since the appearance of symptoms, are the primary risk factors for subsequent early-onset ALFs after kyphoplasty operations.

## Ethics Approval and Consent to Participate

The ethical approval for this study was obtained from the human research ethics committee of the institution (IRB number: B202005032), the consents to enrolled participants are not required for this retrospective study.

## Availability of Data and Materials

The data that support the findings of this retrospective study are available on request from the first author, KN Chou, and are not publicly available with the ethical restrictions.

## Author Contributions

DT Ju designed this study and advised drafting of the manuscript. MH Chung and PW Wang collected and analyzed the data. KN Chou draws the manuscript, including tables and figures. All authors approved the final

manuscript.

## Competing Interests

There are no competing interests to declare.

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