

Observational Study

e Age, Gender, Level and Side Differences in the Anatomical Distinctions of Unilateral Percutaneous Kyphoplasty through the Transverse Process-Pedicle Approach

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Background: Unilateral and bilateral percutaneous kyphoplasty (PKP) have been widely adopted to treat osteoporotic vertebral compression fractures (OVCFs). Unilateral PKP has a shorter operation time and less radiation exposure time compared with bilateral PKP, but the anatomical distinctions of unilateral PKP are not identical in all cases.

Objective: The aim of this study was to examine the significance of age, gender, level, and side in relation to the anatomical distinctions of unilateral PKP for lumbar OVCFs through the transverse process-pedicle approach (TPPA).

Study Design: This was a retrospective study of 200 patients.

Setting: The research took place at General Hospital of Shenyang Military Area Command of Chinese PLA.

Methods: Researchers examined 1000 lumbar spines (L1-L5) of 200 patients and simulated PKP on the 3D-CT scans through unilateral TPPA. The distance between the entry point and the midline of the vertebral body (DEM), the puncture inclination angle (PIA), the safe range of the inner inclination angles (SRA), and the success rate (SR) of puncture were measured and compared.

Results: There were significant differences ($P < 0.05$) in the mean DEM between men and women, and between the left and right sides. The DEM was significantly larger in men than women and in right than left. The DEM from L1 to L5 was significantly increased ($P < 0.05$), from 22.4 ± 2.0 mm to 34.1 ± 4.3 mm. The right maximum PIA was significantly larger than the left. The maximum puncture angle and SRA in men was larger than that in women except for L5. The SRA from L1 to L5 was significantly increased ($P < 0.05$), from 20.1 ± 6.0 mm to 44.2 ± 8.8 mm. The SR from L1 to L5 was significantly increased ($P < 0.05$), from 88.3% to 100%. The SR in men was significantly higher than that in women for L1 and L2.

Limitations: Sample size was relatively small.

Conclusions: The DEM was 22.4 mm to 34.1 mm according to different levels. There were significant gender, side, and age differences in the DEM and PIA. The values of DEM, PIA, SRA and SR were significantly increased from L1 to L5.

Key words: Lumbar, osteoporotic vertebral compression fracture, unilateral, percutaneous kyphoplasty, transverse process.

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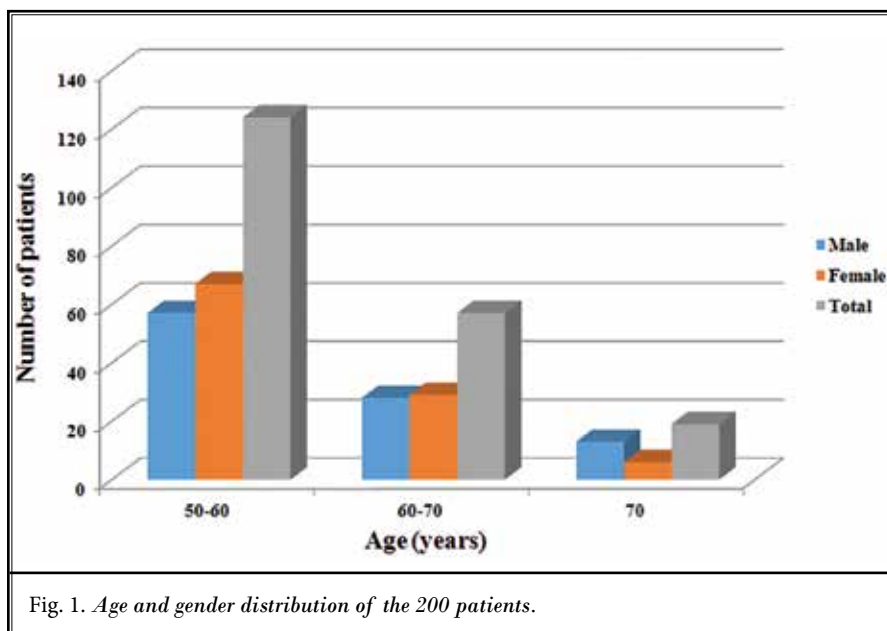
In recent years, osteoporotic vertebral compression fractures (OVCFs), which result in debilitating pain and spinal deformity, have attracted more and more attention around the world; OVCFs are the most common form of fractures among the elderly, especially the female elderly in China (1-3). Percutaneous kyphoplasty (PKP), a technique that has been widely adopted to treat OVCFs, presents with the advantages of lesser trauma and hemorrhage, slight pain, few complications, and rapid recovery (4-12). Unilateral PKP has been shown to have a shorter operation time, less radiation exposure time, and lower dosage of polymethyl methacrylate (PMMA) than bilateral PKP (13,14). Many recent systematic reviews and clinical studies have showed that unilateral and bilateral PKP are both effective for the treatment of OVCFs (13-18).

Although many puncture approaches have been devised, PKP using the bilateral or unilateral transpedicle approach is the most commonly adopted method (13-19). Researchers have introduced the transverse process-pedicle approach (TPPA) to perform the unilateral PKP to treat painful lumbar OVCFs (20,21); unilateral PKP through TPPA has the advantages of lower radiation dose, less operation time, higher degree of deformity correction, and fewer complications than bilateral PKP. Because of the anatomical distinctions of unilateral TPPA is not identical in all cases. The objective of this study is to examine the significance of age, gender, level, and side in relation to the anatomical distinctions of unilateral PKP for lumbar OVCFs through the TPPA, based on 3-dimensional-computed tomography (3D-CT) imaging of 200 patients.

METHODS

Study Population

The 3D-CT scans of L1-L5 from 200 outpatients (98 men, 102 women), aged between 50 and 85 years (average age, 58.9 ± 7.0 yrs), presenting with lower back pain regardless of lower radicular symptoms, were collected from 1 May 2015



to 20 December 2016 (Fig. 1). Inclusion criteria were as follows: patients experienced lower back pain that could be determined with CT scans available. Exclusion criteria were as follows: developmental abnormalities, vertebral abnormalities, and a history of lumbar surgery. A GE Light Speed VCT 64-Slice CT (GE, {AU: city?}, USA) was used for CT scans; raw data in Digital Imaging and Communications in Medicine (DICOM) format with a scan slice of 0.625 mm was collected. Measurement software Aquarius iNtuition (Aquarius iNtuition, Foster City, CA) was used to perform measurements with a length precision of 0.1 mm and an angles precision of 0.1° . Two spinal surgeons measured and collected the data, and the average values were considered as the final measurement values. This study was approved by the ethics committee of our hospital. Informed consent was obtained from all patients.

Puncture Simulation and Measurement Methods

The distance between the entry point and the midline of the vertebral body (DEM), the puncture inclination angle (PIA), the safe range of the puncture inclination angles (SRA), and the success rate (SR) of puncture were measured and compared (Fig. 2). Methods used were those

described in the study by Wang et al (21). The PIA is the angle measured between the midline and the line joining the point of entry to the target point. The SRA is the angle measured between point N and point B (NB) and between point N and point D (ND) line. The puncture course passed through the midpoint C. It turned out that only with a distance of more than 2 mm between point B and C did the puncture accomplish success. The SR is defined as the rate obtained when successful punctures are compared with all punctures involved in the methods.

Statistical Analysis

All data were analyzed using SPSS Version 24.0 (IBM Corporation, Armonk, NY). Differences in mean values were analyzed with paired t tests or independent t tests. The enumerated data was analyzed using the chi-squared test. $P < 0.05$ was considered statistically significant.

RESULTS

DEM

The mean DEMs were significantly different between different levels ($P < 0.05$). The mean DEM between the left and right sides, and between men and women, were significantly different. The DEM from L1 to L5 was significantly increased ($P < 0.05$) from 22.4 ± 2.0 mm to 34.1 ± 4.3 mm. There were significant age differences in the mean DEM except for L5 (Table 1).

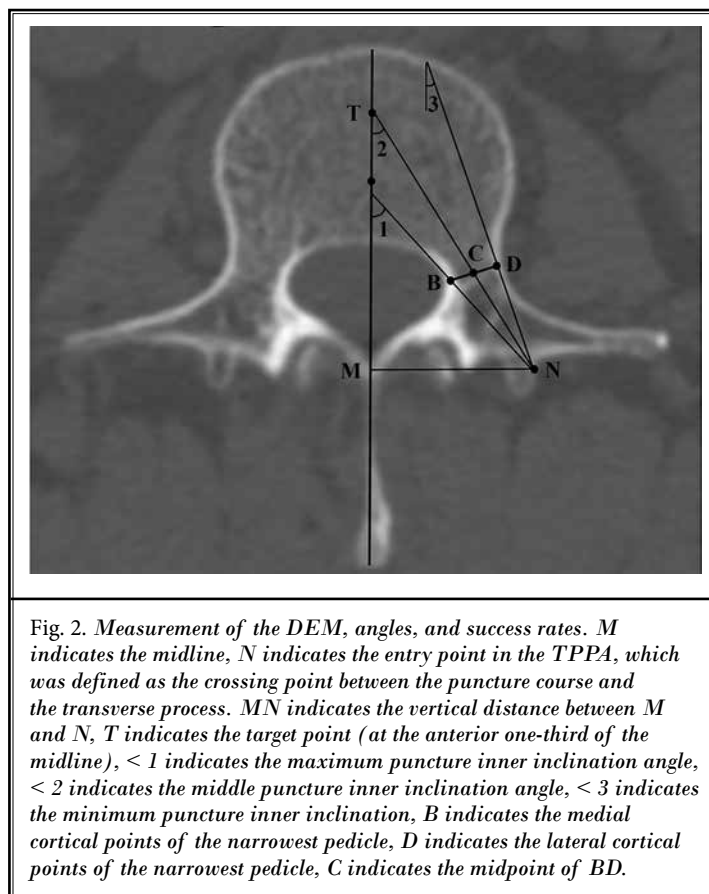


Fig. 2. Measurement of the DEM, angles, and success rates. *M* indicates the midline, *N* indicates the entry point in the TPPA, which was defined as the crossing point between the puncture course and the transverse process. *MN* indicates the vertical distance between *M* and *N*, *T* indicates the target point (at the anterior one-third of the midline), $\angle 1$ indicates the maximum puncture inner inclination angle, $\angle 2$ indicates the middle puncture inner inclination angle, $\angle 3$ indicates the minimum puncture inner inclination, *B* indicates the medial cortical points of the narrowest pedicle, *D* indicates the lateral cortical points of the narrowest pedicle, *C* indicates the midpoint of *BD*.

PIA and SRA

The maximum PIAs were significantly different between different levels ($P < 0.05$). For L1 to L5, the right maximum PIA was significantly larger than the left. The maximum PIA in men was significantly larger than that in women, except for L5. The maximum PIA in the 60-70 age range group was significantly larger than that in the 50-60 age range group for L1, L2, and L3 (Table 2).

Table 1. Distance from the puncture to the midline of the vertebra (mm).

Distance	Gender		Side		Age (yrs)			Mean
	Men	Women	Left	Right	50-60	60-70	≥ 70	
L1	23.3 ± 2.0	$21.6 \pm 1.6^{\&}$	22.0 ± 1.9	$23.0 \pm 2.0^{\&}$	22.2 ± 1.9	$22.9 \pm 2.0^*$	$23.0 \pm 2.5^*$	22.4 ± 2.0
L2	23.9 ± 2.1	$22.2 \pm 1.6^{\&}$	22.5 ± 1.8	$23.5 \pm 2.1^{\&}$	22.7 ± 1.9	$23.5 \pm 2.0^*$	$23.5 \pm 2.5^*$	$23.0 \pm 2.0^{\dagger}$
L3	25.8 ± 2.6	$24.2 \pm 1.8^{\&}$	24.6 ± 2.1	$25.3 \pm 2.5^{\&}$	24.7 ± 2.0	25.2 ± 2.7	$25.9 \pm 2.9^*$	$25.0 \pm 2.3^{\dagger}$
L4	27.5 ± 2.5	$25.9 \pm 2.2^{\&}$	26.4 ± 2.5	$27.1 \pm 2.4^{\&}$	26.5 ± 2.4	$27.1 \pm 2.4^*$	27.0 ± 2.9	$26.7 \pm 2.5^{\dagger}$
L5	35.1 ± 4.1	$33.3 \pm 4.3^{\&}$	33.5 ± 3.9	$34.8 \pm 4.5^{\&}$	33.8 ± 4.4	34.7 ± 3.8	34.5 ± 5.0	$34.1 \pm 4.3^{\dagger}$

[&]significant difference compared to upper level-mean value; [&]significant difference between men and women or left and right; ^{*}significant difference compared to 50-60 age group; [†]significant difference compared to 60-70 age group

The SRA in men was significantly larger than that in women, except for L5. The SRA in the 60-70 age range group was significantly larger than that in the 50-60 age range group for L2, L3, and L4. The SRA from L1 to L5 was significantly increased ($P < 0.05$) from $20.1^\circ \pm 6.0^\circ$ to $44.2^\circ \pm 8.8^\circ$ (Table 3).

SR

The differences in the SR between each level were significant from L1 to L3 ($P < 0.05$). The SR in men was significantly larger than that in women for L1 and L2. There were no significant differences in the SR between right and left. The differences in the SR between the 50-60 age range group and the 60-70 age range or ≥ 70 age range were significant. The SRs for L1 to L5 were 88.3%, 95.0%, 99.5%, 100.0%, and 100.0% in the TPPA group. The SR from L1 to L5 was significantly increased ($P < 0.05$) from 88.3% to 100% (Table 4). The rates of one side SR (OSS) from L1 to L5 were 7.5%, 6.0%, 1.0%, 0, and 0, respectively.

DISCUSSION

Many recent systematic reviews and clinical studies

have shown that unilateral and bilateral PKP are both effective for the treatment of OVCFs (13-18); however, unilateral PKP has a shorter operation time, less radiation exposure time, and lower dosage of PMMA compared with bilateral PKP (13,14). PKP using the bilateral or unilateral CTPA is the most popularly adopted method (13-19). Because of the anatomical distinctions of unilateral TPPA is not identical in all cases. So, we carried out the study to explore the significance of age, gender, level, and side in relation to the anatomical distinctions of unilateral PKP for lumbar OVCFs through the TPPA.

The entry point of the TPPA is localized outside of the pedicle projection and close to the vertebral body, so the inner angle of inclination was larger than the conventional transpedicular approach (21). Significant differences between men and women, and between the left and right sides in the mean DEM, were shown. The DEM was significantly larger in men than women and in right than left. The DEM from L1 to L5 was significantly increased from 22.4 ± 2.0 mm to 34.1 ± 4.3 mm. The previous study showed that the DEM gradually increased from L1 (20.6 ± 2.2 mm) to L5 (28.6 ± 2.9

Table 2. Maximum, middle, and minimum inner inclination angles ($^\circ$).

Levels	Angle	Gender		Side		Age (yrs)			Mean
		Men	Women	Left	Right	50-60	60-70	≥ 70	
L1	Max	38.2 \pm 3.9	36.4 \pm 3.6 [§]	35.9 \pm 3.6	38.7 \pm 3.6 [§]	37.0 \pm 3.8	37.9 \pm 4.0 [*]	37.1 \pm 3.7	37.3 \pm 3.9
	Mid	28.6 \pm 2.4	28.5 \pm 2.4	27.4 \pm 2.1	29.6 \pm 2.1 [§]	28.4 \pm 2.4	28.8 \pm 2.3	28.5 \pm 2.5	28.5 \pm 2.4
	Min	16.0 \pm 4.0	18.3 \pm 3.5 [§]	15.7 \pm 3.6	18.6 \pm 3.7 [§]	17.3 \pm 3.7	16.9 \pm 4.2	17.1 \pm 4.2	17.2 \pm 3.9
L2	Max	39.7 \pm 4.1	38.4 \pm 3.4 [§]	37.7 \pm 3.5	40.4 \pm 3.7 [§]	38.6 \pm 3.8	40.0 \pm 4.0 [*]	39.1 \pm 2.9	39.1 \pm 3.8 [†]
	Mid	29.1 \pm 2.4	29.2 \pm 2.3	28.0 \pm 1.9	30.3 \pm 2.2 [§]	29.0 \pm 2.3	29.6 \pm 2.3 [*]	29.2 \pm 2.3	29.2 \pm 2.3 [†]
	Min	15.3 \pm 4.0	17.6 \pm 3.7 [§]	15.2 \pm 3.9	17.8 \pm 3.7 [§]	16.6 \pm 3.9	16.1 \pm 4.5	16.9 \pm 3.5	16.5 \pm 4.0 [†]
L3	Max	44.3 \pm 5.1	43.1 \pm 4.5 [§]	42.0 \pm 4.5	45.4 \pm 4.5 [§]	43.2 \pm 4.6	45.0 \pm 5.1 [*]	43.2 \pm 4.3	43.7 \pm 4.8 [†]
	Mid	31.7 \pm 2.7	31.6 \pm 2.7	30.5 \pm 2.5	32.8 \pm 2.3 [§]	31.4 \pm 2.6	32.1 \pm 2.9 [*]	31.7 \pm 2.8	31.6 \pm 2.7 [†]
	Min	15.1 \pm 4.7	17.2 \pm 4.2 [§]	15.0 \pm 4.4	17.4 \pm 4.4 [§]	16.3 \pm 4.3	15.5 \pm 5.2	17.3 \pm 3.7	16.2 \pm 4.6
L4	Max	51.9 \pm 4.8	50.3 \pm 4.8 [§]	49.4 \pm 4.5	52.8 \pm 4.5 [§]	50.8 \pm 4.6	51.9 \pm 5.0	50.7 \pm 5.4	51.1 \pm 4.8 [†]
	Mid	36.0 \pm 2.8	35.6 \pm 3.5	34.6 \pm 3.2	37.0 \pm 2.6 [§]	35.7 \pm 3.2	36.0 \pm 3.1	35.6 \pm 3.1	35.8 \pm 3.2 [†]
	Min	13.9 \pm 6.2	15.8 \pm 5.5 [§]	13.4 \pm 6.0	16.3 \pm 5.5 [§]	15.4 \pm 5.7	13.7 \pm 6.3 [*]	14.9 \pm 5.8	14.9 \pm 5.9 [†]
L5	Max	64.3 \pm 4.9	63.8 \pm 5.1	61.8 \pm 4.6	66.4 \pm 4.3 [§]	63.8 \pm 5.1	64.6 \pm 4.8	64.1 \pm 5.0	64.1 \pm 5.0 [†]
	Mid	45.7 \pm 3.8	45.8 \pm 4.3	44.1 \pm 3.7	47.4 \pm 3.7 [§]	45.7 \pm 4.1	45.9 \pm 3.9	45.4 \pm 3.8	45.7 \pm 4.0 [†]
	Min	19.3 \pm 7.9	20.4 \pm 7.0	17.5 \pm 6.9	22.2 \pm 7.3 [§]	20.4 \pm 7.6	19.0 \pm 7.1	19.2 \pm 7.6	19.9 \pm 7.5 [†]

[†]significant difference compared to upper level-mean value; [§]significant difference between men and women or left and right; ^{*}significant difference compared to 50-60 age group; [‡]significant difference compared to 60-70 age group

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Table 3. Safe range of the inner inclination angles ($^{\circ}$).

Distance	Gender		Side		Age (yrs)			Mean
	Men	Women	Left	Right	50-60	60-70	≥ 70	
L1	22.2 \pm 6.2	18.1 \pm 5.1 [*]	20.2 \pm 6.0	20.1 \pm 6.0	19.7 \pm 5.7	21.0 \pm 6.8	20.0 \pm 5.8	20.1 \pm 6.0
L2	24.4 \pm 6.7	20.8 \pm 5.2 [*]	22.6 \pm 6.4	22.5 \pm 6.1	22.1 \pm 5.9	23.9 \pm 7.1 [*]	22.1 \pm 4.8	22.6 \pm 6.2 [#]
L3	29.2 \pm 8.1	25.9 \pm 6.6 [*]	27.0 \pm 7.5	28.0 \pm 7.5 [*]	26.8 \pm 7.2	29.6 \pm 8.5 [*]	25.9 \pm 5.6 [§]	27.5 \pm 7.5 [#]
L4	38.0 \pm 8.9	34.5 \pm 7.5 [*]	35.9 \pm 8.7	36.5 \pm 8.1	35.4 \pm 8.0	38.1 \pm 8.9 [*]	35.8 \pm 8.7	36.2 \pm 8.4 [#]
L5	45.0 \pm 9.8	43.5 \pm 7.6	44.2 \pm 9.0	44.2 \pm 8.5	43.5 \pm 8.7	45.7 \pm 8.5 [*]	44.9 \pm 9.5	44.2 \pm 8.8 [#]

^{*}significant difference compared to upper level-mean value; ^{*}significant difference between men and women or left and right; ^{*}significant difference compared to 50-60 age group; [§]significant difference compared to 60-70 age group

Table 4. SR of each puncture according to gender, side, level, and age group.

Distance	Gender		Side		Age (yrs)			Total
	Men	Women	Left	Right	50-60	60-70	≥ 70	
L1	187 (95.4)	166 (81.4) [*]	177 (88.5)	176 (88.0)	218 (87.9)	103 (90.4)	32 (84.2)	353 (88.3)
L2	193 (98.5)	187 (91.7) [*]	188 (94.0)	192 (96.0)	229 (92.3)	113 (99.1) [*]	38 (100) [*]	380 (95.0) [#]
L3	196 (100)	202 (99.0)	199 (99.5)	199 (99.5)	246 (99.2)	114 (100)	38 (100)	398 (99.5) [#]
L4	196 (100)	204 (100)	200 (100)	200 (100)	248 (100)	114 (100)	38 (100)	400 (100)
L5	196 (100)	204 (100)	200 (100)	200 (100)	248 (100)	114 (100)	38 (100)	400 (100)
Each	196	204	200	200	248	114	38	400

^{*}significant difference compared to upper level-mean value; ^{*}significant difference between men and women or left and right; ^{*}significant difference compared to 50-60 age group; [§]significant difference compared to 60-70 age group

mm) based on data from 30 patients (21). We think the current study may be more persuasive because we collected 1000 lumbar spines (L1-L5) from 200 patients.

The maximum PIA was significantly larger in the right side than in the left. The maximum PIA and SRA in men were larger than those in women except for L5. The SRA from L1 to L5 was significantly increased from 20.1 $^{\circ}$ \pm 6.0 $^{\circ}$ to 44.2 $^{\circ}$ \pm 8.8 $^{\circ}$. The SR from L1 to L5 was significantly increased from 88.3% to 100%. The SR in men was significantly higher than that in women for L1 and L2. The puncture needle could more easily reach or surpass the midline, and bone cement could be distributed symmetrically. Through the study, we can see that it is reasonable and safe to select unilateral TPPA in men for L1 to L4. It is very important and necessary to observe the 3D reconstruction and display of medical image data, carefully measure and compare different puncture approaches, and choose the optimal and safe puncture approach for each individual and level. The results were consistent with the previous study that showed that the safe range of the TPPA was wider, and the SR of the TPPA much higher, than that of the traditional transpedicle approach (21). In the current study, we take a deep

analysis of the age, gender, level, and side differences in the anatomical distinctions of unilateral PKP for the elderly through the TPPA; the data will be beneficial for orthopedists treating elderly patients who present with OVCFs through the TPPA.

Limitations

There are some limitations to this study. Although 200 patients were included, the sample size was still relatively small. Given the symmetry of the human vertebrae, there is a likelihood that the differences between left and right arose due to vertebral rotation during patient positioning for the CT scans or even due to clinical or subclinical scoliosis. We admit that our conclusions would be more persuasive if all of the included patients had lumbar fractures, but it was not possible to find enough patients who presented with different level fractures to investigate the age, gender, level, and side differences. The patients who presented with fractures were all excluded from previous imaging anatomical studies on percutaneous kyphoplasty or vertebroplasty (19,21); the researchers pointed out that patients with lumbar fractures, spondylolisthesis, tumors, and deformities might affect measurements (21). The diameters

of the vertebral body, width of the pedicles, iliac crest block, operator's experience, and ancillary equipment may affect the success of the unilateral puncture.

CONCLUSIONS

The DEM was 22.4 mm to 34.1 mm according to different levels. There were significant gender, side, and age differences in the DEM and PIA. The

values of DEM, PIA, SRA, and SR were significantly increased from L1 to L5. It is very important and necessary to observe the 3D reconstruction and display of medical image data, carefully measure and compare different puncture approaches, and choose the optimal and safe puncture approach for each individual and level.

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