A comparative study of cement-augmented pedicle screw fixation combined with vertebroplasty and PKP alone in the treatment of osteoporotic vertebral burst fracture

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Article

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Abstract

To compare the clinical efficacy of cement-augmented pedicle screw fixation combined with vertebroplasty (PS-VP) and PKP alone in the treatment of osteoporotic vertebral burst fracture (OVBF), The clinical data of 41 OVBF patients admitted to our department from January 2017 to December 2022 were retrospectively analyzed, including 18 patients who underwent PS-VP and 23 patients who underwent PKP alone. The age, BMI, LSS, NRS, ODI, KA and AHR were compared between the two groups to assess the efficacy of the two procedures. The differences between the postoperative clinical indicators of the two procedures were statistically significant compared with the preoperative ones (P 0.05). The NRS, ODI, KA and AHR showed great difference between the two groups at 6 months postoperatively(P 0.05). The KA and AHR in the PS-VP group at 6 months postoperatively were close to those at 3 days (P 0.05), whereas the KA in the PKP alone group at 6 months postoperatively was larger and AHR was lower than that at 3 days postoperatively with statistical significance (P 0.05). To conclude, there is no significant difference in the near-term efficacy between PS-VP and PKP alone for OVBF, but the former has advantages in improving clinical symptoms and dysfunction, restoring height of the injured vertebra and maintaining spinal loading capacity in the medium and long term.

1. Introduction

With the development of the aging society, the incidence of osteoporosis is increasing in the middle-aged and elderly population. This population is susceptible to osteoporotic vertebral burst fracture (OVBF) by axial violence. Vertebral burst fracture was first proposed by Holdsworth[1] in 1970 followed by Dennis[2]. The ‘Three column theory’ proposed by Dennis defined it as a compression fracture involving both the anterior and middle columns with loss of vertebral height, spinal loading instability and possible spinal canal invasion. OVBF is easily diagnosed in patients with significant low back pain, combined with typical signs of fracture invasion of the anterior and middle columns as shown by CT and MRI.

There are currently no guidelines or expert consensus on the treatment of OVBF. However, as a specific type of spinal fracture, the classical surgical methods for the treatment of spinal fracture, such as PKP and pedicle screw system, have been applied to OVBF, and have achieved certain therapeutic effects[3–8]. Vertebroplasty was first used to repaired bone destruction caused by vertebral hemangioma[9, 10], and later widely used in the treatment of osteoporotic vertebral compression fracture. This procedure can effectively restore the height of the vertebral body and relieve clinical symptoms such as low back pain in a short period time by strengthening the injured vertebrae with bone cement[6, 11]. It has advantages of being minimally invasive and economical. However, PKP is also linked to the risk of cement leakage, collapse of vertebral body, worsening of kyphosis and recurrent symptoms[7, 12]. Pedicle screw fixation (PSF) is commonly applied to treating vertebral burst fractures, lumbar spondylolisthesis and other spinal instability diseases, and this procedure has advantages in restoring vertebral height and maintaining spinal loading and stability, but it is prone to screw cutting, loosening, displacement and even prolapse when applied to osteoporotic patients. In recent years, cement-augmented screws have been used in clinical practice to reduce the rate of screw loosening[13]. The combination of vertebroplasty is expected to further optimize the clinical outcomes. In this study, we retrospectively analyzed the clinical data of 41 patients with OVBF admitted to our department from January 2017 to December 2022 to compare the clinical efficacy of PS-VP and PKP alone in the treatment of OVBF with a view to providing a reference basis for clinical decision-making in such situation.

2. Materials and methods

2.1 Clinical Data

Cases of OVBF admitted to our department from January 2017 to December 2022 were selected, and a total of 41 cases were obtained after screening by inclusion and exclusion criteria, including 18 cases (3 males and 15 females, age 69.39 ± 5.29 years old) who underwent PS-VP and 23 cases (5 males and 18 females, age 70.17 ± 4.22 years old) who underwent PKP alone.

2.2 Inclusion and Exclusion Criteria

Inclusion criteria: Burst fracture of a single vertebra from T_{12} to L_3; Dual-energy X-ray diagnosis of osteoporosis with a BMD T≤-2.50SD; A load-sharing score ≥ 7; No manifestation of spinal cord or nerve root injury; Follow-up for more than 6 months and clinical information obtained.

Exclusion criteria: Cardiopulmonary insufficiency unable to tolerate anesthesia; Combined with injuries such as fractures of extremities or damage to vital organs; Combined with other serious underlying diseases; Multi-segment fractures of thoracolumbar spine; Refusal to surgical treatment; Incomplete follow-up information.

2.3 Surgical Methods

As mentioned earlier, there are no guidelines or expert consensus for the treatment of OVBF. However, PKP and pedicle screw system have been shown to be safe and effective, and both are consistent with therapeutic principles[3–8].

PS-VP group: The patient was placed in the prone position after general anesthesia and routinely disinfected and toweled. A posterior mid-lumbar incision of about 10 ~ 15 cm in length was made, and the skin was cut and hemostatically coagulated subcutaneously. The lumbar dorsal fascia was incised along the spinous process about 1 ~ 2 cm, and the articular eminence was exposed along the multifidus interval. The upper and lower segments of the injured vertebra were positioned under the guidance of the C-arm machine, and the positioning guide pins were placed. Hollow lateral pedicle screws of appropriate length were placed with reference to the positioning pins. A cement connecting rod was placed and an appropriate amount of drawn PMMA bone cement was pushed into each of the hollow lateral pedicle screws under the guidance of the C-arm machine. A pre-curved spinal rod was placed on one side of the pedicle screw, properly propped and tightened with the caudal nail securely in place. On the other side of the injured vertebral arch, a C-arm machine guided cement connecting rod was placced into the injured vertebral body and an appropriate amount of drawn PMMA cement was pushed in. The spinal rods were placed, properly supported and then tightened with the caudal nail to secure them. The wound was irrigated and the fascial, subcutaneous and skin tissues were sutured layer by layer by electrocoagulation. Disinfection and wound dressing. End of surgery.

PKP alone group: The patient was placed in prone position and routinely disinfected and toweled. The C-arm machine was used to guide the localization of the injured vertebral arch. Lidocaine was used for local infiltration anesthesia, and the anesthetic effect was satisfactory. The puncture needle was placed and guided by the C-arm machine up to the vertebral body. A working channel was established. A balloon dilator ws placed and slowly propped open to 180 ~ 220 psi under pressure monitor, with no further pressure drop and contact with the end plate. The balloon was removed and the appropriate amount of drawn PMMA bone cement was slowly pushed in under the guidance of the C-arm machine, and the push-tube was rotated out after solidification. The wound was covered with a sterile dressing after pressure hemostasis and disinfection. End of surgery.

All procedures were performed by the same treating surgeon. The arch nail rod system used in the operation was from Tianjing Zhengtian Company; the bone cement and push rod used were from Shanghai Kelitai Company.

Patients in both groups received routine postoperative care and clean wound dressing changs. Active anti-osteoporosis treatment was performed after discharge from the hospital.

2.4 Evaluation Indicators

1. Numerical rating scale (NRS): Pain intensity is assessed by numbers, ranging from ‘0’ to ‘10’, with ‘0’ indicating ‘no pain’ and ‘10’ indicating ‘unbearable pain’. The patient selects a number according to the subjective pain sensation. The bigger the number selected, the greater the pain intensity.
2. Oswestry disability index (ODI): The degree of functional impairment in life was assessed by a questionnaire. The questionnaire includes 10 questions on the degree of back and leg pain, personal care, lifting heavy objects, walking, sitting, standing, sleeping, sexual life, social life and travelling ability. Each question is scored 0 ~ 5, total 50 points. Final score = score of questions answered / (5×number of questions answered) ×100%. The higher the score, the greater the degree of functional impairment in life.
3. Kyphotic Cobb angle (KA): The angle of intersection of the superior and inferior drapes of the injured spine measured by DR lateral radiographs in the local kyphotic Cobb angle. The larger the angle, the greater the degree of the compression and the deformation.
4. Anterior height ratio (AHR): AHR is calculated by DR frontal and lateral radiographs. AHR=(height of the anterior edge of the injured vertebra×2/the sum of the heights of the anterior edges of the adjacent upper and lower vertebral)×100%. The smaller the AHR, the greater the degree of compression and the more severe the injury.

2.5 Statistical Analysis

IBM SPSS Statistics 25.0 software was applied for statistical analysis. The measurement data confirmed to normal distribution and chi-square and were expressed as $\bar{x}$±s. Data between PS-VP and PKP alone groups were compared by independent samples t-test or Fisher's exact probability method, and within-group preoperative, 3-day and 6-month postoperative data were compared by ANOVA, with two-way comparisons between them using the LSD-t test. The test level α = 0.05 and P 0.05 were considered statistically significant differences, and the results obtained were recorded with two decimal places.

2.6 Statement

The study was reported in accordance with Declaration of Helsinki.

3 Results

Clinical baseline indices of the two groups are shown in Table 1; NRS, ODI, KA and AHR levels at preoperative, 3-day and 6-month postoperative follow-up are shown in Table 2; Complications such as cement displacement and recurrence of low back pain are shown in Table 3; Typical figure legends are shown in Figs. 1, 2 and 3.

Table 1
Clinical baseline

	PS-VP group	PKP alone group	Statistical values	P value
Number of cases	18	23		
Sex				
Male	3	5	0.17	0.68
Female	15	18		
Age (year)	69.39 ± 5.29	70.17 ± 4.22	-0.53	0.60
BMD (SD)	− (3.22 ± 0.42)	− (3.37 ± 0.45)	1.04	0.30
LSS	7.78 ± 0.65	7.52 ± 0.67	1.24	0.22
Injury time(day)	3.00 ± 0.84	2.96 ± 0.77	0.17	0.86
Distribution				
T_{12}	2	3	0.40	0.94
L_1	6	9		
L_2	8	8		
L_3	2	3		
Preoperative NRS (score)	7.28 ± 0.96	6.83 ± 1.03	1.44	0.16
Preoperative ODI (score)	40.67 ± 1.85	39.87 ± 1.79	1.40	0.17
Preoperative KA (°)	19.69 ± 2.51	20.20 ± 1.87	-0.74	0.46
Preoperative AHR (%)	70.55 ± 2.23	71.88 ± 2.89	-1.61	0.12
Comorbidities				
Hypertension	8	12	0.24	0.62
Diabetes Mellitus	11	15	0.07	0.79

Table 2
NRS, ODI, KA and AHR levels at each stage

	PS-VP group	PKP alone group	t value	P value
NRS (score)				
Preoperative	7.28 ± 0.96	6.83 ± 1.03	1.44	0.16
3 days postoperative	2.22 ± 0.73[a]	2.39 ± 0.78[a]	-0.71	0.48
6 months postoperative	1.44 ± 0.62[a, b]	2.17 ± 0.78[a, c]	-3.26	0.05
F value	295.49	208.91		
P value	0.05	0.05		
ODI (score)				
Preoperative	40.67 ± 1.85	39.87 ± 1.79	1.40	0.17
3 days postoperative	23.00 ± 1.14[a]	22.70 ± 1.22[a]	0.82	0.42
6 months postoperative	15.28 ± 1.97[a, b]	18.57 ± 1.65[a, b]	-5.83	0.05
F value	1067.91	1187.81		
P value	0.05	0.05		
KA (°)				
Preoperative	19.69 ± 2.51	20.20 ± 1.87	-0.74	0.46
3 days postoperative	10.07 ± 1.46[a]	12.24 ± 1.49[a]	-4.68	0.05
6 months postoperative	10.33 ± 1.56[a, c]	14.35 ± 1.56[a, b]	-8.19	0.05
F value	149.47	143.41		
P value	0.05	0.05		
AHR (%)				
Preoperative	70.55 ± 2.23	71.88 ± 2.89	-1.61	0.12
3 days postoperative	90.43 ± 1.39[a]	87.35 ± 1.47[a]	6.82	0.05
6 months postoperative	89.78 ± 1.32[a, c]	84.36 ± 1.31[a, b]	13.10	0.05
F value	795.78	379.78		
P value	0.05	0.05		

[a]: Compared with preoperative data, P 0.05; [b]: Compared with 3-day postoperative data, P 0.05; [c]: Compared with 3-day postoperative data, P 0.05.

Table 3
Complications

	PS-VP group		PKP alone group		P value
	Number of incidents	Incidence	Number of incidents	Incidence	
Bone cement displacement	0/18	0	2/23	8.70%	0.50
Implant failure	0/18	0	0/23	0	0.99
Back and leg pain	1/18	5.56%	3/23	13.04%	0.62

The differences in clinical baseline indicators between the two groups were not statistically significant and the data were comparable. The differences in each clinical index at 3 days postoperative and 6 months postoperative follow-up were statistically significant in both groups compared with preoperative. The differences between NRS and ODI in the PS-VP group at 3 days postoperatively compared with the PKP alone group were not statistically significant; KA in the PS-VP group was smaller than that in the PKP alone group, and AHR was larger than that in the PKP alone group with statistical significance. At 6 months postoperatively, NRS, ODI and KA were smaller in the PS-VP group than in the PKP alone group, and AHR was greater than in the PKP alone group, and all differences were statistically significant. The differences in KA and AHR at 6-month postoperative follow-up in the PS-VP group compared with 3 days postoperative were not statistically significant; KA at 6-month postoperative follow-up in the PKP alone group was greater than that at 3 days postoperative, and 6 months postoperative AHR at follow-up was less than at 3 days postoperatively, and all differences were statistically significant. Intraoperative bleeding, bone cement use, operative time, length of stay and related medical expenses were greater in the PS-VP group than in the PKP alone group. The incidence of complications such as bone cement displacement and low back pain at 6 months after surgery were not statistically different between the two groups.

4 Discussion

The vertebrae of osteoporotic patients are prone to burst fractures under minor external forces, especially in the thoracolumbar segment and other human physiological stress junction areas, mainly manifesting as loss of height of injured vertebrae, localized kyphotic deformity, reduced spinal stability and loading capacity, and in severe cases, spinal instability, canal invasion, impaired spinal cauda equina function and even paraplegia. Osteoporotic vertebral compression fractures are the initial stage of OVBF, and with the slow loss of bone mass and accumulation of microfractures, that progressive spillover to the anterior and middle columns or even the three columns eventually progresses to OVBF. Combined with radiographic, CT and MRI findings and clinical symptoms, OVBF is easily diagnosed. With an increasing number of people suffering from osteoporosis, the incidence of OVBF in growing, which not only reduces the quality of patients' lives, but also imposes a heavy health and economic burden on society.

The choice of treatment modality for OVBF is controversial at this stage[14]. For OVBF without neurological symptoms, it has been suggested that conservative treatment modalities such as brace immobilization, bed rest, NSAIDs and anti-osteoporotic drugs can be used with better health economic benefits than surgical treatment[15, 16]. The clinical efficacy of teriparatide in stable OVBF can be achieved[17]. Although conservative treatment can avoid the trauma of surgery, it increases the time of bed rest and the risk of secondary spinal cord injury, which is less effective than surgical treatment[18]. Therefore, conservative treatment should be carefully selected after a rigorous evaluation of the patients' condition. Surgical treatment is recommended by the majority of clinicians. At this stage, common surgical procedures include PKP, vertebral fusion intervertebral fusion, PS-VP, etc. In terms of surgical indications and fixed segments, according to the TLICS (thoracolumbar injury classification and severity score, TLICS) system proposed by Vaccaro et al[19] in 2005 to assess the degree of the thoracolumbar injury, a score of less than or equal to 3 is recommended for non-operative treatment, a score of more than or equal to 5 is recommended for operative treatment and a score of 4 is both. Parker et al[20] proposed a loading-sharing scoring system (LSSS) based on the degree of vertebral body comminution, fracture fragment displacement and posterior convex deformity and concluded that a score of 6 or less for short-segment posterior internal fixation could achieve satisfactory clinical results and a score of 7 or more for anterior support fixation, posterior short-segment fixation combined with anterior support implants or long-segment posterior fixation. Clinicians can choose the appropriate surgical strategy according to the specific situation of the injured spine.

For OVBF without symptoms of spinal cord and nerve root compression, PKP is a better option. This procedure takes the form of the local anesthesia which is tolerated by most elderly patients. PKP injects bone cement into the injured vertebrae through a working channel, effectively restoring vertebral height in a short period time, relieving symptoms such as low back pain, greatly shortening the patients' bed rest and reducing the occurrence of long-term bed rest complications like deep vein thrombosis, hypostatic pneumonia, decubitus and disuse muscular atrophy[8, 21, 22]. PKP works through the pedicle, and most studies have shown that the unilateral approach has similar efficacy compared to the bilateral approach, but the former in quicker, less invasive, less expensive and has a lower risk of cement leakage and displacement[23, 24]. In this study, a unilateral approach via the pedicle was adopted. The statistical results showed that the NRS and ODI after PKP were significantly smaller than those before surgery, and there were significant differences in KA and AHR compared with those before surgery, suggesting that the recent efficacy of PKP is positive. However, the AHR at the 6-month postoperative review was generally less than 3 days postoperative, the KA at 6 months postoperative was greater than 3 days postoperative, and both differences were statistically significant, indicating that there was a certain degree of height loss and worsening of the posterior convex deformity in the operated spine at 6 months postoperative, and the medium- and long-term efficacy was not satisfactory to some degree. Among the 23 PKP patients enrolled in this study, 2 cases were found to have cement displacement and obvious height loss of the injured vertebrae at the 6-month postoperative review with recurrent symptoms. The integrity of the posterior wall of injured spine is disrupted in OVBF patients, and there is a greater risk of intraoperative and postoperative cement leakage into the spinal canal and intervertebral foramen[25, 26]. However, as a classical procedure in spinal surgery, PKP has advantages of being minimally invasive, economical and with good short-term outcomes for the treatment of OVBF.

Internal fixation with the 'nail and rod system' is an important method for treating burst fractures and provides reliable stability for the spine. However, in patients with osteoporosis, the implanted screws do not have sufficient grip on the surrounding osteoporotic bone tissue and are prone to loosening, displacement or even dislodgement. Therefore, for patients suffering from osteoporosis (BMD≤-2.5SD), we believe that bone cement-augmented screws can receive better results. By injecting bone cement around the screws to strengthen the holding power and resistance to extraction of cancellous bone, the complications of screw loosening and prolapse will be reduced[27, 28]. The cement-augmented pedicle screws commonly used in clinical practice are usually divided into 2 types, one with bone cement and solid pedicle screws injected into the pre-set nail channel and the other with hollow lateral hole design[13]. In this study, the latter one was adopted. Combining vertebroplasty can further restore the vertebral height and enhance the stability of the spine. Biomechanical studies have indicated that the cement pedicle screw system can effectively improve the stability and loading capacity of the spine, and the reinforcement effect is related to the cement material, volume, injecting time, degree of osteoporosis and design of pedicle screws[29]. Compared with PKP alone, the results of this study showed that PS-VP had better overall postoperative NRS, ODI, AHR and KA outcomes, and was superior in terms of clinical symptom relief, functional impairment improvement, vertebral body height restoration and spinal deformity correction. The PS-VP treatment of OVBF can achieve satisfactory clinical results.

In summary, with regard to treating OVBF, both PS-VP and PKP alone have produced effective recent outcomes. PKP is less invasive, quicker and more economical, but there may be delayed vertebral body collapse. PS-VP has better results in relieving clinical symptoms, improving functional impairment, restoring injured vertebral height and correcting posterior convex deformity with satisfactory medium- and long-term results.

This study has the following shortcomings: The absence of substantial sample data and the relatively small number of instances that were chosen.   The relatively short follow-up period.   This study is a single-center retrospective analysis and the clinical data was obtained from the electronic medical record information system with possible errors and a fairly low level of clinical medical evidence.

Declarations

Author contributions

J. Z.: Designing the research, analyzing the data, generating the figures and tables and editing the manuscript. Y. W., C. G., Q. Z., Y. X.: Collecting the data. T. D.: oversighting the entire study. All authors contributed to the paper and approved the submitted version.

Competing interests

The authors declare no competing interests.

Data availability

The datasets generated and analysed in this article are available from the corresponding author or the first author on reasonable request.

Ethics declarations

The study was approved and agreed by the Ethics Committee of Wuxi People's Hospital, and all patients enrolled had signed the informed consent form when admitted to hospital, declaring that their clinical data would be applied in scientific research.

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Figures

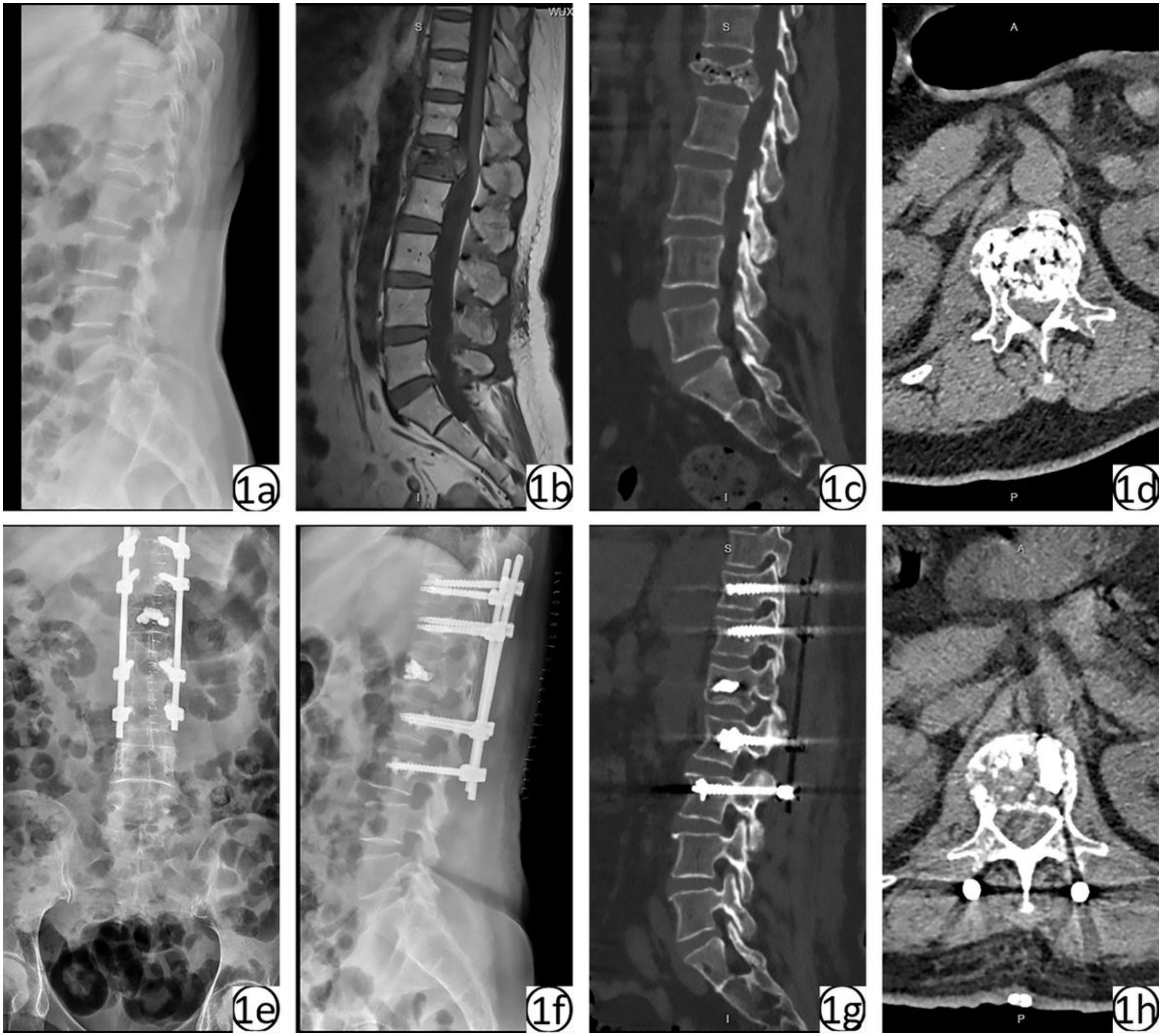

Figure 1

Imaging of a typical patient performing PS-VP. Preoperative (1a) radiograph, (1b) sagittal MRI, (1c) sagittal and (1d) axial CT, 3-day postoperative (1e) frontal and (1f) lateral radiograph and 6-month postoperative (1g) sagittal and (1h) axial CT (60-year-old woman).

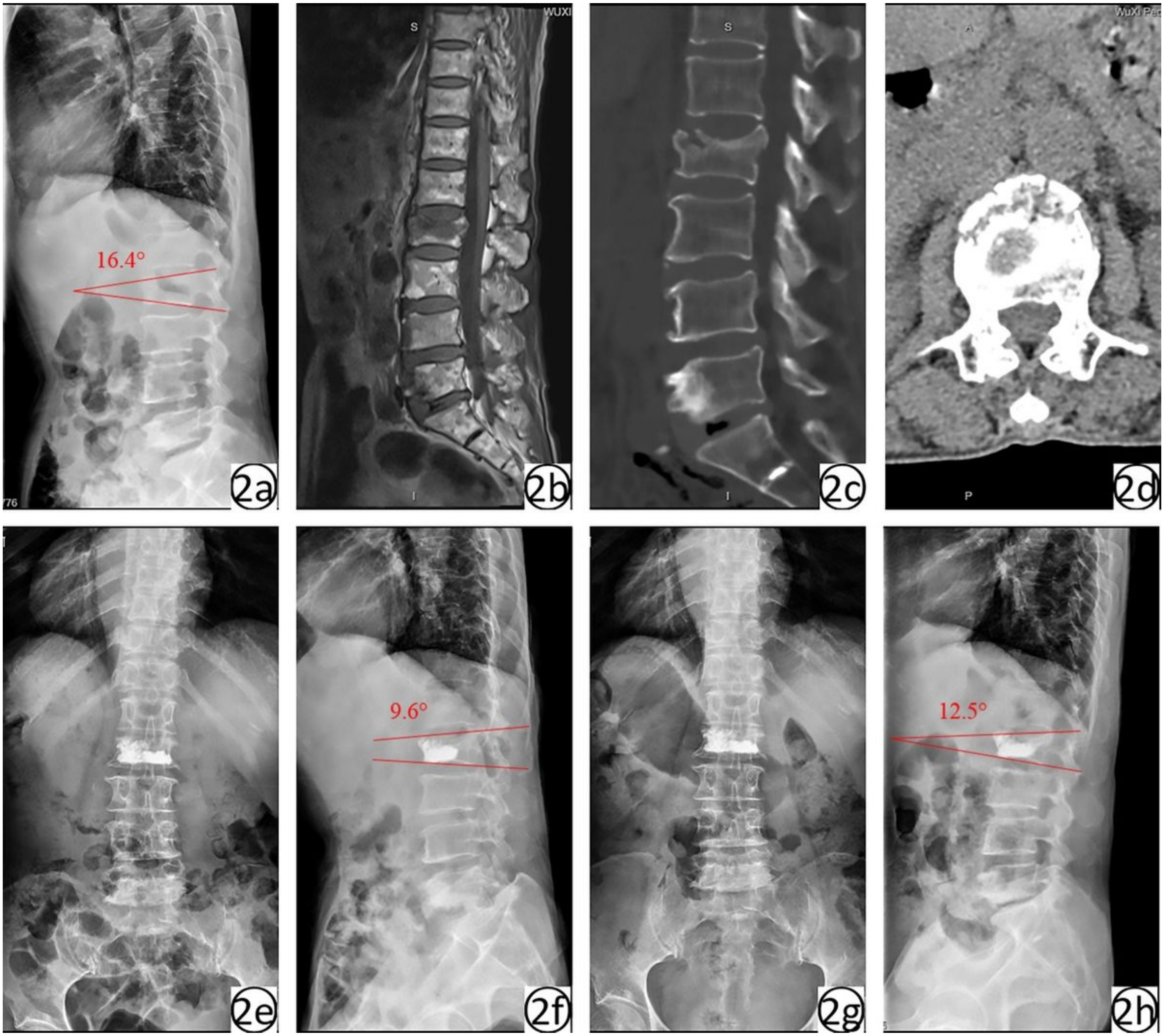

Figure 2

Imaging of a typical patient performing PKP alone. Preoperative (2a) radiograph, (2b) sagittal MRI, (2c) sagittal and (2d) axial CT, 3-day postoperative (2e) frontal and (2f) lateral radiograph and 6-month postoperative (2g) frontal and (2h) lateral CT (64-year-old woman).

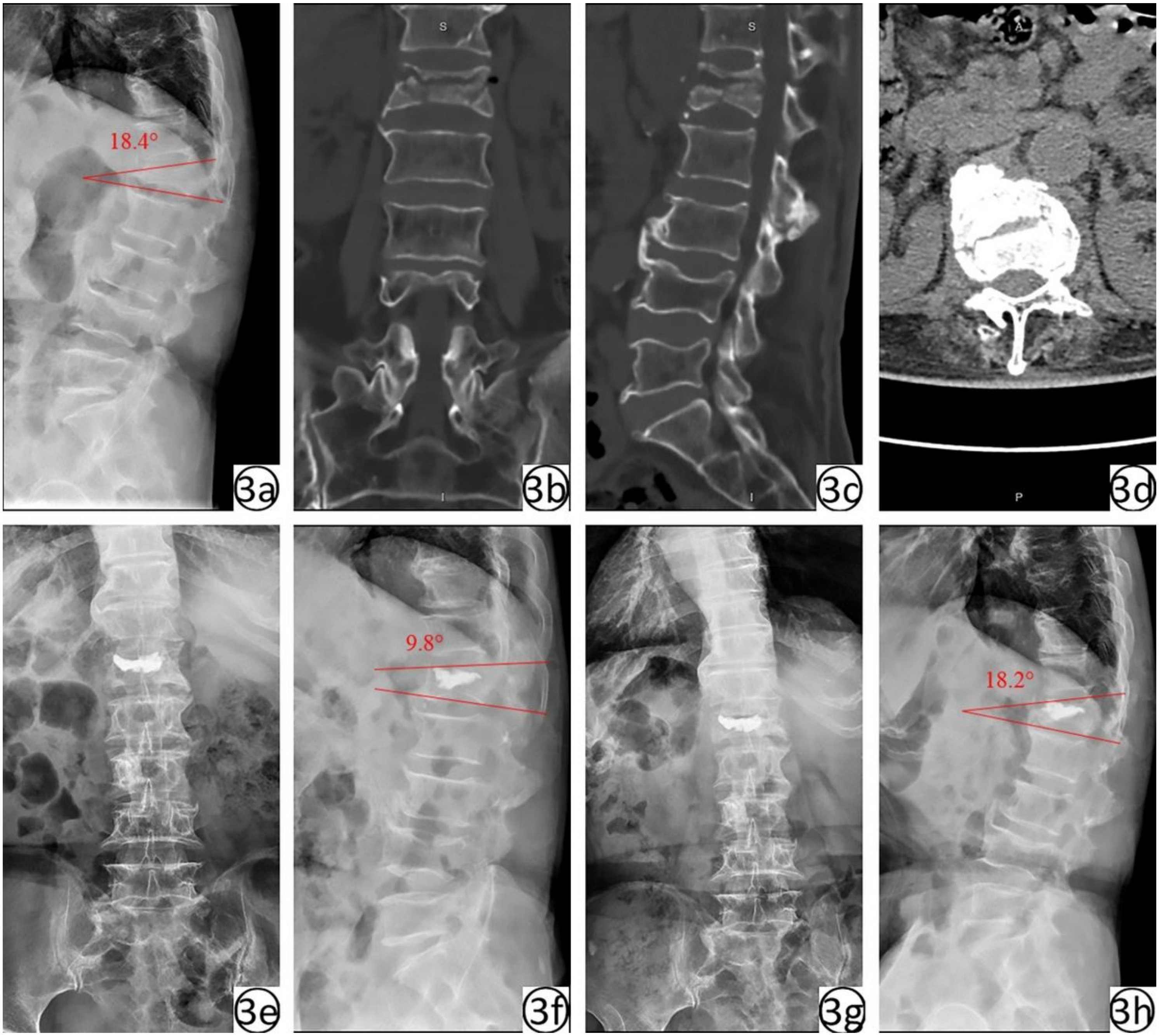

Figure 3

Imaging of a typical patient with unsatisfactory outcome after PKP alone. Preoperative (3a) radiograph, (3b) sagittal MRI, (3c) sagittal and (3d) axial CT, 3-day postoperative (3e) frontal and (3f) lateral radiograph and 6-month postoperative (3g) frontal and (3h) lateral CT (67-year-old woman).