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Development of a New Therapy-Oriented Classification of Intervertebral Vacuum Phenomenon With Evaluation of Intra- and Interobserver Reliabilities

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Abstract

Study Design: Diagnostic study, level of evidence III.

Objectives: Low back pain is a common cause of disability among elderly patients. Percutaneous discoplasty has been developed as a tool to treat degenerative disease when conservative management is not successful. Indications for this procedure include low back pain and the presence of vacuum phenomenon. The objective of this study was to describe a new classification of vacuum phenomenon based on computed tomography scan in order to improve the indications for percutaneous discoplasty.

Methods: We developed a classification of vacuum phenomenon based on computed tomography scan images. We describe 3 types of vacuum based on the relationship between vacuum and the superior/inferior endplates and 2 subtypes based on the presence of significant subchondral sclerosis. A validation study was conducted selecting 10 orthopedic residents with spine surgery training to analyze 25 vacuum scenarios. Inter- and intraobserver reliabilities were assessed through the Fleiss's and Cohen's kappa statistics, respectively.

Results: The overall Fleiss's κ value for interobserver reliability was 0.85 (95% CI 0.82-0.86) in the first reading and 0.93 (95% CI 0.92-0.95) in the second reading. Cohen's κ for intraobserver reliability was 0.88 (95% CI 0.77-0.99).

Conclusion: The new classification has shown almost perfect inter- and intraobserver reliabilities for grading the vacuum phenomenon and could be an important tool to improve the indications for percutaneous cement discoplasty.

Keywords

intervertebral vacuum phenomenon, degenerative disc disease, percutaneous cement discoplasty, vacuum classification

Introduction

Degenerative disc disease is an age-related condition that has been extensively analyzed in the literature.[1-5] Vacuum phenomenon (VP), defined as the presence of gas within the joints, has been associated with multiple clinical situations such as advanced degenerative changes, fractures, and abscesses.[6] This anatomical finding can be demonstrated on X rays, computed tomography (CT), and/or magnetic resonance imaging and its clinical significance is still not well understood. Intervertebral VP is a common finding in advanced degenerative disc disease, especially in the lumbar spine and has been associated with low back pain.[7] However, the role of this phenomenon as a pain source has not been clearly established.

The importance of intervertebral VP as a cause of pain in degenerative spine disease has gained new interest since the introduction of percutaneous discoplasty (PD). This minimally

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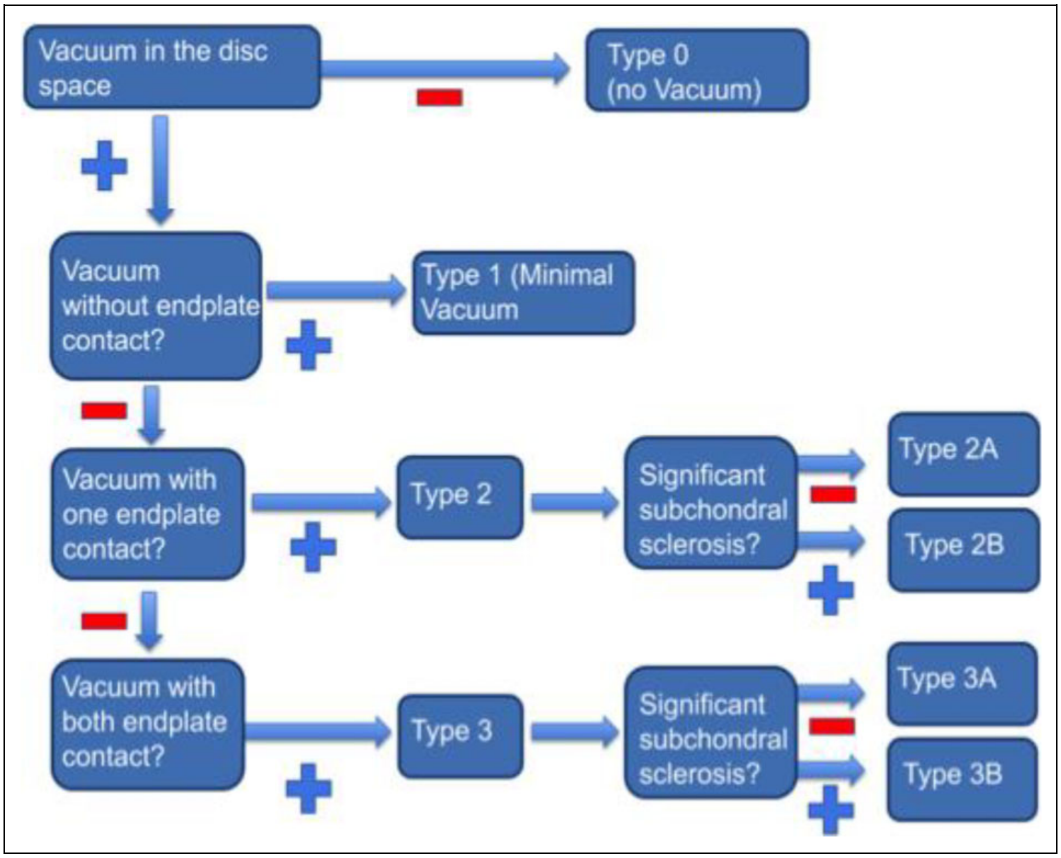

Figure 1. Algorithm for the classification of intervertebral vacuum phenomenon based on computed tomography (CT) scan.

invasive technique, developed by Varga et al[8] is based on the concept of filling the empty disc space with cement, thus stabilizing the level by acting as an intervertebral spacer. This technique has been shown to improve pain and disability and looks like a good treatment option, especially among elderly patients in whom traditional fusion procedures are associated with a higher risk of complications.[9-11] Indications for PD are low back pain or radicular pain along with the presence of VP; however, this imaging finding varies widely and not all cases of VP are considered suitable for discoplasty.

The objective of this study was to develop a new classification of intervertebral vacuum phenomenon based on thoracic/lumbar CT scan and therefore, establish patterns of air distribution that can be considered for percutaneous discoplasty with some recommendations and finally, to evaluate the inter- and intraobserver reliabilities for this new classification.

Materials and Methods

This study was approved by the institutional ethic review board from our institution (protocol number IRB 0003925).

Classification Criteria

The algorithm and the subsequent classification were developed primarily based on 2 tomographic findings:

The first finding consists in the relationship between intervertebral air with the superior and inferior vertebral endplates and the air/disc rate, which determines the type of vacuum (air/disc rate of l: 2 in type 1 meaning that there is less air than disc tissue, 1:1 in type 2 with equal distribution of air and disc and 2:1 in type 3 vacuum, with more air than disc). The second tomographic finding is the presence of subchondral sclerosis extended at least to one-third of the superior or inferior vertebral body and determines the subtype of vacuum, subtype A when there is minimal (not extended to at least one-third of the vertebral body) or even no sclerosis in one or both endplates, and subtype B when the is subchondral sclerosis (see Figure 1 and Table 1).

This classification can be applied to both the nonscoliotic and scoliotic spine. In the nonscoliotic spine, the classification is mainly based on sagittal CT images (see Figure 2). In the sagittal plane, the vertebral body should be divided into 3 parts: right parasagittal, middle sagittal, and left parasagittal.

On the other hand, in the scoliotic spine, the classification is mainly based on coronal CT slices (see Figure 3).

In the coronal plane, 3 CT scan images are analyzed from the anterior, middle, and posterior third of the vertebral disc unit.

Finally, for both the scoliotic and nonscoliotic spine, the vacuum type that prevails in 2 of the 3 CT images (coronal for the scoliotic and sagittal for the nonscoliotic spine) is the most representative and therefore, the final vacuum type.

Terminology: Definition of Different Vacuum Phenomenon Types According to CT Scan Images

Minimal Vacuum Phenomenon

Type 1. This is the less severe type of vacuum phenomenon, usually difficult to observe in conventional X-ray but being usually appreciated on CT scan (Figure 4). Minimal amount of air is observed in the intervertebral disc without significant subchondral sclerosis. Based on our experience this scenario should not be an indication for discoplasty because of clinical and technical reasons. First, the air to be filled with cement is low; therefore, the spacer mechanism is questionable in this type. In addition, the presence of minimal VP is a relatively common finding in asymptomatic elderly patients. Another reason to avoid percutaneous discoplasty in those cases is the potential risk of creating a disk herniation during the procedure due to the remnant disc material.

Table 1. Types[a] of Vacuum Phenomenon in the Thoracic/Lumbar Spine Based on Computed T omography Scan.

Type 0	No vacuum phenomenon, regardless of disc degeneration
Type 1	Small amount of intervertebral air with disk tissue between air and both endplates without subchondral sclerosis. Usually the air/disk tissue rate is 1:2 or lower[b] (minimal vacuum)
Type 2	Air in the disk space, with air in contact with one endplate and disk tissue between air and the other endplate (superior or inferior). Usually the air/disk tissue is 1:1 or slightly lower (partial vacuum)
2A	Without subchondral sclerosis
2B	With subchondral sclerosis
Type 3	Air in the disk space in contact with both endplates, without disk tissue between air and both endplates. The rate air/ disk tissue is usually 2:1 or higher (total vacuum)
3A	Without subchondral sclerosis
3B	With subchondral sclerosis

[a] All types can be applied to scoliotic spine (asymmetrical vacuum) and non-scoliotic spine (symmetrical vacuum).
[b] The air/disk tissue ratio is variable due to Boyle's law for gases (volume and pressure inversely related).

Partial Vacuum Phenomenon

Type 2A. In this stage, air is usually distributed partially in contact with one endplate superiorly or inferiorly and disc tissue is present in contact with the remaining endplate, in the scoliotic curve the air is located on the concavity (Figure 3), comparing with stage 2B, subchondral sclerosis has not developed in this stage or is minimal without extension to the vertebral body. The accordion phenomenon; defined as a variation of Cobb curve between standing and supine position, can be observed in some cases. Percutaneous discoplasty could be performed in this type; however, because of the absence of subchondral sclerosis, there could be an increased risk for adjacent vertebral fracture as well as a risk of disc protrusion during the cement injection due to the presence of disc tissue.

Type 2B. In this case, the typical situation is degenerative scoliosis with VP and subchondral sclerosis at the concave side of the curve, but can also be observed in nonscoliotic spine (Figure 5). In those cases, PD can be performed at the concavity of the curve in the scoliotic spine, with close monitoring of the amount of bone cement in order to control possible disc protrusion.

Total Vacuum Phenomenon

Type 3A. In this situation, the air is in contact with both endplates in CT scan, without subchondral sclerosis (Figure 6A). Accordion phenomenon is significant in such cases. PD can be performed; however, there is a theoretically higher risk of adjacent vertebral fracture due to the lack of subchondral sclerosis.

Type 3B. The most severe degree of vacuum phenomenon is observed in these cases, with air in contact with both endplates and subchondral sclerosis (Figure 6B). The accordion

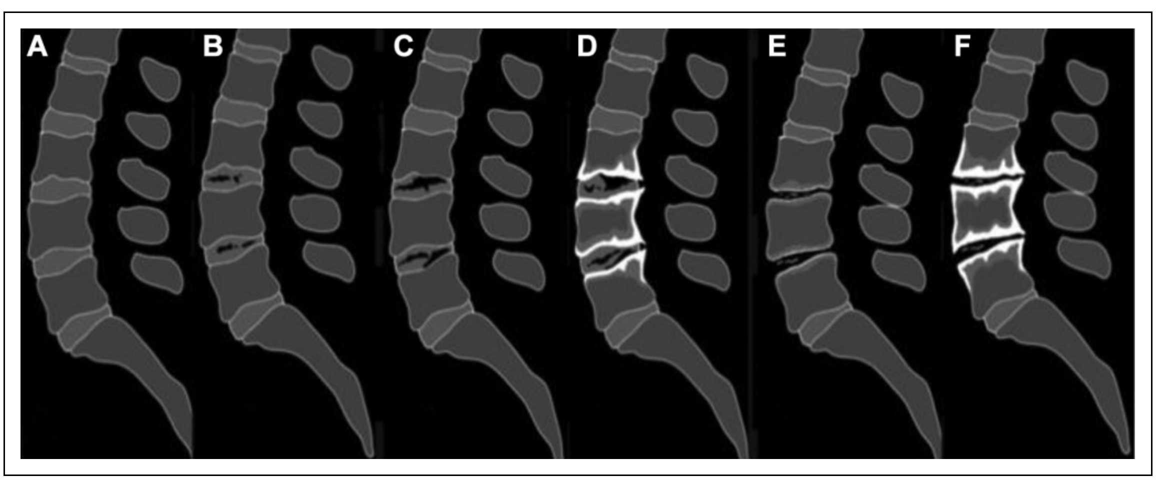

Figure 2. Illustration of the intervertebral vacuum phenomenon classification in a nonscoliotic spine. (A) Type 0 or nonvacuum. (B) Type 1 or minimal vacuum. (C) Type 2A or partial vacuum without subchondral sclerosis. (D) Type 2B partial vacuum with subchondral sclerosis. (E) Type 3A or total vacuum without subchondral sclerosis. (F) Type 3B total vacuum with subchondral sclerosis.

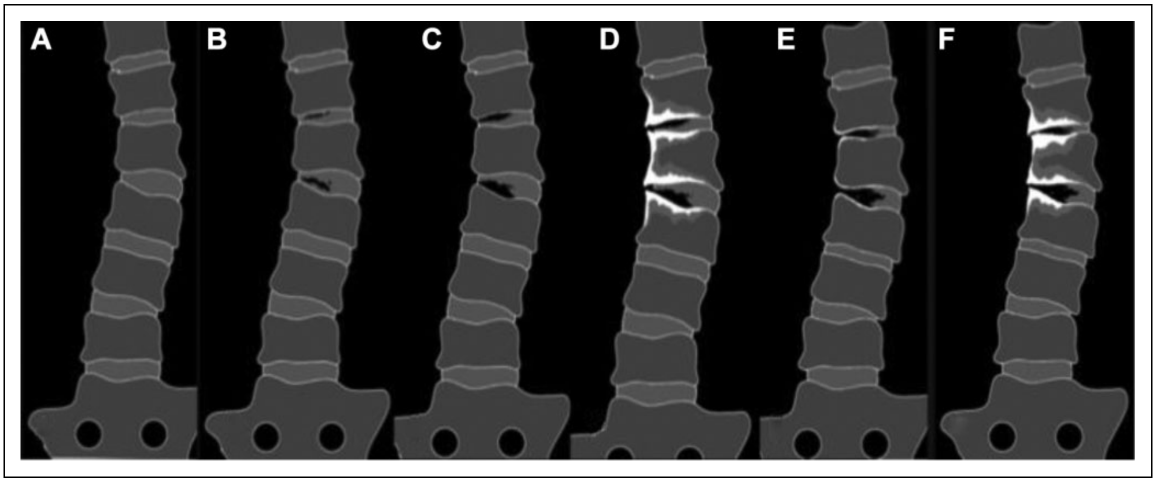

Figure 3. Intervertebral vacuum phenomenon in the scoliotic spine. (A) Type 0 vacuum phenomenon. (B) Type 1 vacuum phenomenon (VP), with minimal air and disc tissue between air and endplates. (C) Type 2 A or partial VP. (D) Type 2B or partial VP with subchondral sclerosis. (E) Type 3A or total VP. (F) Type 3B or total VP with subchondral sclerosis; note that all changes occur at the concave side of the scoliotic spine.

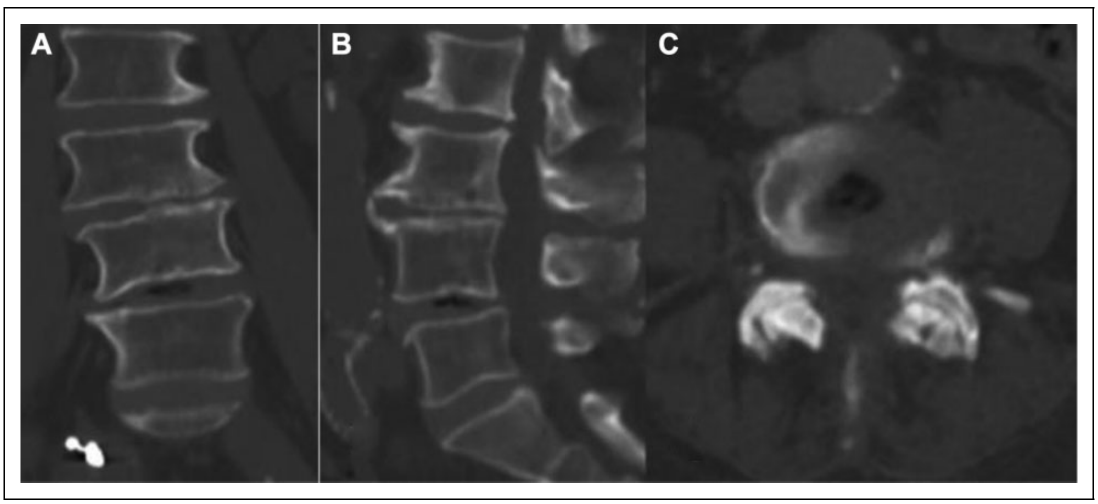

Figure 4. Minimal vacuum phenomenon at L4-L5 lumbar spine, note the central air distribution in coronal (A), sagittal (B), and axial (C) computed tomography scan.

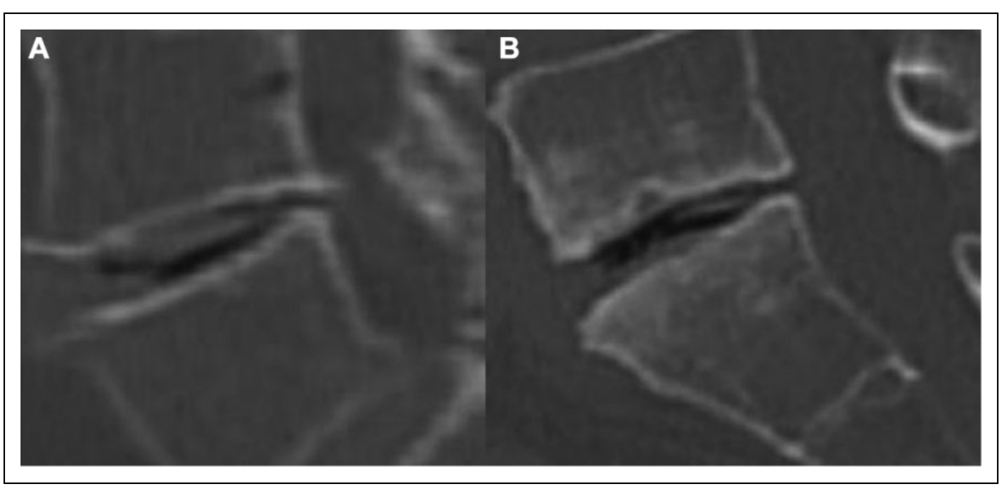

Figure 5. Partial vacuum phenomenon. (A) Sagittal CT at L4-L5 with vacuum and minimal sclerosis (type 2A). (B) Sagittal CT at L5-sacrum with vacuum and subchondral sclerosis (type 2B).

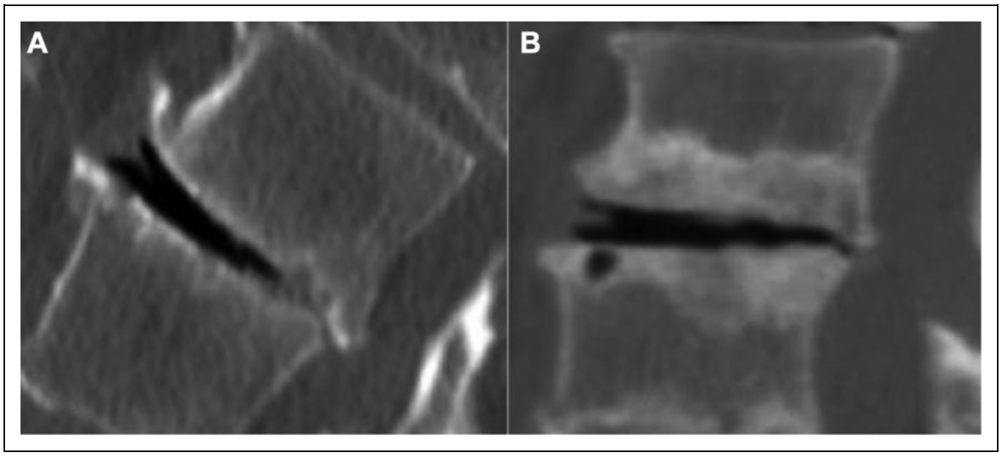

Figure 6. Total vacuum phenomenon. (A) Sagittal 3A stage vacuum phenomenon with minimal sclerosis. (B) Sagittal 3B stage vacuum phenomenon with sclerosis extending to the vertebral body.

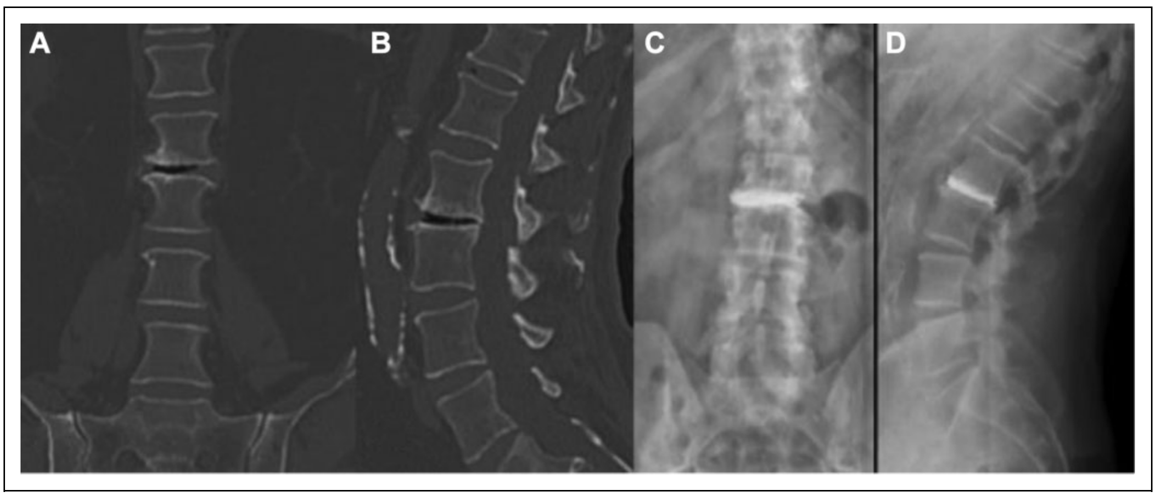

Figure 7. (A, B) Vacuum phenomenon (VP) at L2-L3, subchondral sclerosis, and both endplates in contact with air (type 3B). Minimal VP (type 1) is also observed at T11-T12 and T12-L1. (C, D) Percutaneous discoplasty was performed at L2-L3 disc space.

phenomenon is higher in this grade. To our knowledge, this is the best scenario for PD, because the higher amount of air allows homogeneous cement injection and the subchondral sclerosis theoretically decrease the risk of adjacent vertebral fracture (Figure 7).

Evaluation of the Interrater Agreement

In order to evaluate inter- and intraobserver reliabilities for this new classification, a designer team (authors of this study) selected CT scan images of 25 cases (5 cases of stage I, IIA, IIB, IIIA, and IIIB), each case scenario included 3 CT images each (3 coronal tomographic images from the anterior middle and posterior third of the vertebral disc unit for the scoliotic spine and 3 sagittal tomographic images from the right parasagittal middle and left parasagittal third of the vertebral disc unit for the nonscoliotic spine). All cases derived from our database of approximately 500 surgical procedures from 2013 to 2018 of degenerative lumbar disease in our institution, including our 54 cases treated with PD [11], all cases were selected by the authors of the classification.

We identified 10 readers to evaluate these CT scan images; they were all orthopedic physicians from our institution and consisted in advanced PGY (postgraduate year) orthopedic residents (2 PGY-4, 5 PGY-5, 2 chief residents PGY-6, and 1 spine fellowship PGY-7). The readers, who applied the classification, did not belong to the designer team.

The CT images were sent through a questionnaire to the observers by email, all readers received a 10-minute explanation of the classification and all had access to the classification scheme while grading. The readers sent their conclusion about the type selected to the coordinating center for evaluation by the authors. The same questionnaire was sent to the readers in an aleatory order 2 weeks after the first reading to analyze the intraobserver agreement.

The graded data was collected and analyzed for reliability; intra- and interobserver agreements were assessed for each type of the classification.

Statistical Analysis

Evaluation of the Interrater Agreement. In the first step, we evaluated the interobserver agreement through the calculation of the weighted kappa coefficient for each pair of judges (readers).

The classification categories of VP were prepared as an ordinal variable represented with numerical values from 1 to 5 (1, type 1; 2, type 2A; 3, type 2B; 4, type 3A; and 5, type 3B).

The authors assigned a point to the perfect agreement between each pair of readers, defined as the situation in which both readers assigned exactly the same type classification to the clinical imaging scenario in question. When both readers had a disagreement of more than 1 category, it was represented by a value of zero. When the disagreement was of only 1 category of difference (the same case was evaluated as corresponding to type 2 of the classification by a judge and to type 1 by the other reader), the authors agreed on an intermediate penalty represented by 0.5.

Evaluation of the Degree of Intraevaluator Agreement. To evaluate the degree of intraevaluator agreement (test-retest), we calculated the weighted kappa coefficient according to the same weighting matrix as for the degree of agreement between the different evaluators.

A sample size was determined to provide acceptable variability to assess discrimination among the main types of the classification of vacuum phenomenon and precise reliability estimates. Based on a simulation process, when the sample consisted of 35 cases, each being assessed by ten raters on a 5-category classification system, there would be a greater than 95% chance to reject the null hypothesis that Fleiss's κ is less than 0.7, if the true Fleiss's κ is 0.9. Chance-adjusted Fleiss's and Cohen's κ statistics with 95% CIs were used to determine inter- and intraobserver reliabilities, respectively.[12,13]

The level of agreement (kappa) was established according to Landis and Koch[14] with κ values of 0.00 to 0.20 considered slight agreement, 0.21 to 0.40 considered fair agreement, 0.41 to 0.60 considered moderate agreement, 0.61 to 0.80 considered substantial agreement, and 0.81 to 1.00 considered almost perfect agreement.

Results

The interobserver reliability according to different types of VP based on CT scan images is presented in Table 2; almost perfect agreement was observed in both the first evaluation with 0.85 (95% CI 0.82-0.86) and the second with 0.93 (95% CI 0.92-0.95). The intraobserver analysis is presented in Table 3 and showed an almost perfect agreement among readers with $\kappa = 0.88$ (95% CI 0.77-0.93).

Discussion

A new classification of intervertebral VP has been developed with almost perfect inter- and intraobserver agreement.

Table 2. Interobserver Reliability According to Complication Grades.

Vacuum Phenomenon	First Reading Fleiss's κ (95% CI)	Second reading Fleiss's κ (95% CI)
Type 1	0.97	1.00
Type 2A	0.82	0.95
Type 2B	0.85	0.95
Type 3A	0.78	0.88
Type 3B	0.82	0.88
Overall	0.85 (0.82-0.86)	0.93 (0.92-0.95)

Table 3. Cohen's κ for Intraobserver Reliability.

		95% CI	
Observer	Cohen's κ	Lower Bound	Upper Bound
1	0.90	0.69	1.00
2	0.79	0.70	0.84
3	1.00	0.80	1.00
4	0.90	0.84	0.94
5	0.80	0.62	0.84
6	0.95	0.94	1.00
7	0.70	0.54	0.75
8	0.90	0.78	0.94
9	0.95	0.94	1.00
10	0.95	0.89	1.00
Overall	0.88	0.77	0.93

Degenerative disc disease is a common, age-related phenomenon that represents a normal evolution of disc degeneration. Pfirmann et al[15] developed a magnetic resonance imaging classification system for disc disease that shows the degenerative changes in normal population; however, degenerative changes in the vertebral disc unit continues and the presence of VP could be considered an advanced stage of disc degeneration. This change in elderly patients has been associated with the presence of back pain. However, the role of VP as a source of pain remains unclear. The objective of this study was to develop a new classification based on CT scan characteristics, useful to select better candidates for percutaneous discoplasty.

Treatment strategies in elderly patients with low back pain that do not respond to conservative treatment are challenging due to some risk factors such as increased medical comorbidities and therefore, a higher surgical risk.[16-18] In addition, the higher prevalence of osteoporosis in this population increases the risk of fracture and implant loosening with standard fusion treatments.[19-22]

The introduction of percutaneous discoplasty by Varga et al[8] in 2013 for the treatment of low back pain secondary to advanced degenerative disc disease has opened a new concept of minimal invasive treatment to decrease pain and disability in patients with high surgical risk. This treatment is based on the concept of polymethyl methacrylate (PMMA) injection in the disc space in advances stages of degeneration with vacuum phenomenon, acting as a stabilizer intervertebral spacer, this treatment has demonstrated low back and leg pain improvement and partial correction of spinal balance in unbalanced cases with low complication rates and short hospital stay.[9-11] Yamada et al[23] reported improvement in low back pain in 109 patients with degenerative lumbar scoliosis treated with percutaneous intervertebral-vacuum polymethylmethacrylate injection (PIPI), although the name of the procedure differs, the concept is the same.

A proper patient selection is necessary, with correct identification of the pain source and some image characteristics may contribute to decrease the risk of some complications such as adjacent vertebral fracture, cement leakage, or disc material protrusion associated with PMMA injection. In order to avoid these possible complications, we have identified some CT scan characteristics in the disc-vertebra unit in patients with vacuum phenomenon that require special consideration such as the air distribution within the disc space, the relationship between air and endplates, the presence of subchondral sclerosis extended to the vertebral body and the accordion phenomenon, previously described by the authors.[9] This phenomenon observed in advanced degeneration with VP consist in disc space variation between standing (X-ray) and horizontal position (CT scan), showing disk space collapse in standing and disk opening when the patient is in supine, this phenomenon is observed in advanced degeneration with vacuum phenomenon and could be considered as a source of pain as the change in segmental spine angulation is also associated with mechanical low back pain; however, this phenomenon as a source of pain is theoretical and therefore, needs to be supported by long-term follow-up studies. These parameters had led us to develop a new, therapy oriented, classification of intervertebral VP that may be useful in cases in which a percutaneous discoplasty is considered, or even for new disc-filling therapies in the future. To our knowledge, the presence of VP alone should not be a synonym for indicating a percutaneous discoplasty. Other factors should be considered, such as the amount of vacuum and the presence of clinical symptoms, with mechanical low back pain being the most important. Based on our experience, minimal VP should not be a proper indication for this procedure as it could be associated with increased risk of disk protrusion during the PMMA injection; in addition, smaller amount of PMMA can be injected in this type making the spacer mechanism less effective.

On the other hand, partial VP could be an indication for percutaneous discoplasty, with some concerns regarding the increased risk of adjacent fractures in the absence of subchondral sclerosis (type 2A), the same concept should be applied to type 3A, as we believe that subchondral sclerosis plays a role in preventing vertebral fracture. However, in our case series of 54 patients treated with PD,[11] only 1 case suffered vertebral fracture after PD in a type 2A vacuum and required vertebroplasty, having just a few evidence in the literature, this concept is just theoretical and needs to be supported by biomechanical and clinical studies.

Based on our experience, the best candidates for discoplasty are cases with VP and subchondral sclerosis, 2B, and especially 3B types. We believe that a proper understanding of these concepts is mandatory to achieve a better outcome for this procedure.

Strengths and Weaknesses

Our study has some limitations. First, the authors developed a classification with some recommendations based on personal experience regarding a procedure (percutaneous discoplasty) that has not been universally extended and therefore, without long-term outcomes studies. More studies are required to support this classification and recommendations.

Another limitation of this study relates to the selection of the tomographic cases, which was based on personal experience and therefore, not randomly assessed. This could represent a selection bias by the authors.

In addition, the readers who participated in the inter- and intraobserver analysis belong to our institution, despite the fact that they did not contribute to the development of the classification; this could influence and overestimate the results. Ideally, this classification needs to be analyzed by other authors and institutions to assess its external validity.

More outcome studies are required to understand the role of vacuum phenomenon as a pain source and the real effectiveness of percutaneous cement discoplasty; however, the concept of a spacer acting as a stabilizer opens a variety of minimal invasive techniques in elderly patients in which standard procedures such as a conventional fusion can be associated with increased risk of clinical and surgical complications. This new, therapy-oriented, classification of the intravertebral vacuum phenomenon has shown high inter- and intraobserver reliabilities and can contribute to select better candidates for percutaneous discoplasty.

Conclusion

We developed a simplified tomographic classification of the air distribution in advanced degenerative vertebral discs in both the scoliotic and nonscoliotic spine. Our study showed substantial inter- and intraobserver reliabilities. To our knowledge, this is the first classification of intervertebral VP, and it could be a useful tool when considering percutaneous cement discoplasty as a treatment option. More studies are required to assess the utility of this classification and the usefulness of percutaneous discoplasty as a minimally invasive therapy in elderly patients.

Declaration of Conflicting Interests

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