

A NEW CLASSIFICATION OF SPONDYLODISCITIS: POSSIBILITY OF VALIDATION AND MULTIDISCIPLINARY EXPERT CONSENSUS

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Objective. To perform validation study of the E. Pola classification (2017) and to assess expert consensus on the diagnosis and treatment of infectious lesions of the spine in the national professional community.

Material and Methods. A clinical and radiological database on 15 cases of infectious spondylitis, as well as the information about original article by Pola and a Russian translation of the classification and tactical tables from this article, were distributed to 408 orthopedic traumatologists, neurosurgeons and radiologists who have experience in treating patients with spinal pathology and whose data are available in the registers of the relevant professional associations of the Russian Federation. The coincidence/difference in the responses concerning the definition of lesion types and the choice of treatment tactics, as well as proposals for the use of classification were assessed.

Results. Answers were obtained from 37 respondents from 11 regions of the Russian Federation. The general interobserver agreement index (Fleiss kappa) for all types of spondylodiscitis was 0.388 (95 % CI 0.374–0.402), including for lesion types: type A - 0.480 (95 % CI 0.460–0.499, type B - 0.300 (95 % CI 0.281–0.320), and type C - 0.399 (95 % CI 0.380–0.419). Agreement levels were higher among radiologists (type A - 0.486, type B - 0.484, and type C - 0.477), orthopedic traumatologists (type A - 0.474, type B - 0.380, and type C - 0.479), and specialists with clinical experience less than 10 years (type A - 0.550, type B - 0.318, and type C - 0.437). The pooled data for all 12 lesion subtypes showed general poor agreement (C - 0.477), cI 0.240–0.253), satisfactory level was found for C - 0.4370. The pooled data for all 12 lesion subtypes showed general poor agreement (C - 0.4770, C - 0.2400–0.253), satisfactory level was found for C - 0.4370. The pooled data for C - 0.4370, good agreement (C - 0.4370) was achieved between orthopedic traumatologists for type C - 0.4371. The pooled data for C - 0.4372 and C - 0.5423. And C - 0.5813, good agreement (C - 0.4371) was achieved between orthopedic traumatologists for type C - 0.4373. And C - 0.5424 and C - 0.5425 and type C - 0.4375 and type C - 0.4375 and type C - 0.4375 and type C - 0.4375. And C - 0.4375 and type C -

Conclusion. The Pola classification of spondylodiscitis is currently considered the most successful for tactical algorithms and implementation in broad clinical practice for spondylodiscitis. However, at the stages of its clinical application, there is an unsatisfactory interobserver expert consensus on the types of lesions, and there are limitations related to the etiology, localization and severity of the disease. A modified classification taking into account the identified limitations and including anterior procedures in the tactical options is advisable. **Key Words:** spondylodiscitis, vertebral osteomyelitis, classification, validity, interobserver agreement, consensus, treatment tactics.

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In recent years, one of the most important areas of vertebrology is the development of tactical tools for the diagnosis and surgical treatment of spine pathology. On the one hand, diagnostic and treatment algorithms optimization aims to reduce the number of unsatisfactory treatment

outcomes. On the other hand, the adoption of uniform protocols widens the scope of communication between medical professionals with various backgrounds and levels of clinical experience. It also helps to raise the quantity and quality of multicenter research.

Over the last few decades, tactical classifications of deformities, injuries, degenerative diseases and spinal tumors have proven to be effective. Simultaneously, the first attempts to apply algorithms in the diagnosis and treatment of infectious pathology, primarily acute nonspecific spondylodiscitis, appeared

only in 2016 [1-9]. The first proposed tactical classification of SSC (Spondylodiscitis Severity Code) identified three degrees of spondylodiscitis severity, which were assessed using the differentiation of following criteria: bone destruction, vertebral instability, acute neurologic impairment and involvement of paravertebral soft tissues [2]. A year later, Pola et al. [10] modified the classification of acute spondylodiscitis and added to the above criteria the presence of an epidural abscess and the magnitude of kyphotic deformity. This classification is currently most commonly used in foreign literature but has not been validated in Russia. Furthermore, the classification does not imply the use in destruction beyond the concept of "spondylodiscitis". Meanwhile, no universal tactical classifications of chronic nonspecific (pyogenic) and specific (granulomatous) spondylodiscitis are available.

In light of this, the classification of Pola et al. [10] prompted the following inquiries during the design stage of this study:

- is it currently possible to validate its tactical application of algorithms in acute and chronic nonspecific and specific spondylodiscitis in Russian version of the classification?
- does the clinician's specialization and clinical experience influence his or her assessment of the type of lesion according to the Russian version of the classification?
- is it possible to reach a multidisciplinary expert consensus on the diagnosis and application of algorithms in spondylodiscitis treatment?

The objective is to perform a validation study of the E. Pola classification (2017) and assess expert consensus on the diagnosis and treatment of infectious lesions of the spine in the national professional community.

Research design: open multicenter.

Material and Methods

Research Techniques

At the first stage, the working group participants formed a clinical database with 15 cases of spondylodiscitis and the presentation of the main clinical (patient's age, duration of the disease, severity of clinical manifestations) and radiological (sagittal, frontal, and axial planes of CT and MRI) data. Adult patients (18+) with lesions of all spine departments, both acute and chronic processes, and nonspecific and specific (tuberculosis) causations of disease were included in the study. Clinical information from the Traumatological and Orthopedic Unit No. 3 of the Regional Clinical Hospital No. 2 (Tyumen) and the Spine Surgery Unit No. 6 of the St. Petersburg Research Institute of Phthisiopulmonology was used to create the case database.

The study's clinical database was distributed to 286 members of the Russian Association of Spine Surgeons (RASS), 64 members of the Russian branch of AOSpine, and 58 clinicians who were not members of above organizations. The mailing was done threefold. Additionally, the information about original Pola article and a Russian-language translation of the tables describing the classification of spondylodiscitis and tactical solutions under it were emailed to all potential respondents.

Respondents were presented with the following options in the second stage of the study.

- to identify an infectious lesion's type and subtype in accordance with the classification under consideration;
- to select the treatment options proposed in the original paper, with the additional item "basic treatment option is not required";
- to select/suggest additional treatment options presented by variants of surgeries from anterior approaches; the item "additional treatment option is not required" has been added.

A questionnaire is also presented in order to clarify the respondents' opinion on the Pola classification. It contains 19 questions with answer options in the "yes" or "no" format (presented in the "Results" section).

The study's protocol was approved after an open discussion at the Association of Spine Surgeons' Board meeting (Protocol No. 2 as of May 12, 2022). The

official RASS Board sources and representatives of AO Spine RF provided the mailing addresses for the approved list of clinical cases and questionnaires. The data was collected within eight month period.

Statistical analysis

Version 21.0 of the Statistical Package for the Social Sciences (SPSS) was used to conduct the analysis (SPSS Inc., Chicago, IL, USA). The Fleiss' kappa measure (k) with a 95% confidence interval was used to evaluate the degree of agreement between respondents' conclusions (interobserver reliability) (Table 1). The Landis & Koch system was used to interpret the values of this measure.

Results

Fig. and Table 2 demonstrate the respondents' geographic distribution, areas of expertise and clinical experience in the field of spine surgery.

I. Determination of the spondylodiscitis type

The overall indicator for all the cases reported when evaluating the classification types of lesions was 0.388 (95 % CI 0.374–0.402), which equates to a fair agreement level according to the Landis & Koch interpretation.

The Fleiss' kappa by individual types of lesions:

- type A 0.480 (95 % CI 0.460–0.499);
- type B 0.300 (95 % CI 0.281–0.320);
- type C 0.399 (95 % CI 0.380–0.419).

The following variances were observed depending on the respondents' areas of expertise and their prior experience treating the pathology under discussion (Table 3).

The following results were obtained from the investigation of the respondents' interobserver agreement on the different kinds of spondylodiscitis (Table 4):

- the level of agreement was higher among radiologists (type A-0.486, type B-0.484, type C-0.477) and orthopedic traumatologists (type A-0.474, type B-0.380, type C-0.479);
- regardless of the respondents' specialization and clinical experience, type

A lesions were found to have the highest level of agreement (0.480);

• the level of agreement was higher for each type of lesion among specialists with less than 10 years of clinical experience (type A - 0.550, type B - 0.318, and type C - 0.437), compared to specialists with more work experience

The results of a multi-assessment summary analysis using Fleiss' kappa statistics revealed the following trends:

- with the exception of type B3.2 lesions (k = 0.561, CI 0.542-0.581), which have a moderate agreement level, the general agreement was unsatisfactory (k = 0.247, CI 0.240-0.253);
- orthopedic traumatologists attained a substantial agreement level on type B3.2 (k = 0.726, CI 0.658–0.795);
- a substantial consensus for types B3.1 and B3.2 (k > 0.61) was noted among professionals in radiodiagnosis;
- the level of agreement among neurosurgeons for each type of spondylodiscitis was below moderate one.

II. Determination of treatment tactics (surgical approach option, extent of reconstruction)

The greatest agreement between respondents on the use of the anterior approach was observed for the most severe types of lesions (B3.2, C3 and C4). Meanwhile, the main tactical solution was to perform a 360° fusion in single- or two-stage procedures. The main alternative surgical interventions for these types were anterior debridement only and/or anterior debridement with transpedicular fixation.

The respondents refused to use standard treatment options for type A lesions in 15.1 % of cases, type B lesions – 7.5 % and type C lesions – 3.2 %. However, they indicated a necessity for anterior approach interventions in 24.7 %, 43.0 %, and 46.2 % of the cases, respectively.

III. Limitations on the use of classification

Table 5 lists the respondents' statements regarding the applicability of the classification in the "yes" or "no" format, including absolute and relative indicators.

Notably, nearly all respondents (more than 90 %) mentioned the potential application of the classification for

monosegmental acute lesions of thoracic and lumbosacral localization (apparently including the lumbar spine in this term) and the requirement for combined use of CT and MRI for the diagnosis of spondylodiscitis.

The vast majority of respondents (from 75 % to 90 %) noted the need to detail the criteria for spinal instability and the possibility of applying the classification to chronic processes.

The simple majority (from 50 % to 75 %), in turn, believes that the classification should be supplemented with a more thorough description of the characteristics of the inflammatory response and the possibility of its use in subaxial (C3–C7) cervical lesions. They also believe that the classification is applicable for the subcervical spine only.

Discussion

It is inevitable that well-established classifications, diagnostic and treatment algorithms, and clinical recommendations will be revised as evidence-based healthcare develops with the use of advanced visualization tools and the data bulk accumulation. The findings of multicenter studies, which involves clinicians with a range of specializations and experience, including an assessment of the potential for validating different classifications for musculoskeletal system injuries and disorders, are of particular significance [11, 12].

A recent article [13] is devoted to the reliability of the New Classification of Spondylodiscitis by Pola et al. that uses techniques that are very different from our study. Eight spinal surgeons with

| Fleiss' kappa; agreement levels ranking | | | | |
|---|--------------------------|--|--|--|
| Fleiss' | Agreement level | | | |
| kappa | | | | |
| | | | | |
| 0.00 - 0.20 | Slight agreement | | | |
| 0.21 - 0.40 | Fair agreement | | | |
| 0.41 - 0.60 | Moderate agreement | | | |
| 0.61 - 0.80 | Substantial agreement | | | |
| >0.81 | Almost perfect agreement | | | |

brief work experience (less than three years) determined the different types of lesions. Meanwhile, 35 patients provided a series of clinical cases (a total of 280 cases were analyzed). Only the intra- and interobserver agreement on the definition of lesion types after two readings had been studied.

We consider it possible to assess the classification's validity with a multidisciplinary team of experts with various levels of clinical experience. Meanwhile, surgeons were asked to select or decline the main and additional treatment options in each case, 56.7 % of surgeons and radiologists reported about experience of inflammatory spine lesions treatment/diagnosis for 10 years or more. Furthermore, more than 40.0 % of respondents agreed that anterior approaches should be used for lesions of types B and C. It should be noted that the classification's author, in one of his later publications, discusses the utility of anterior approaches when extensive debridement and reconstruction of the anterior column of the spine are required [14]. Nevertheless, these surgical options are not given in the paper under discussion. In turn, our respondents marked their rejection of the tactics proposed by the authors of the original classification with varying frequency for different types of injury (A - in 15.1 % of responses, B – in 7.5 % of responses, and C - in 3.2 % of responses).

The answers to the questions on the limitations of the use of classification were organized into several blocks. A degree of agreement of more than 61% was reached for each of the following conclusions:

- applicability: the proposed classification cannot be applied to all spine departments; it is not applicable for suboccipital lesions; there are limitations in the assessment of subaxial localizations; the most justified application is for monosegmental lesions in the thoracic and lumbosacral spine. However, limitations with multisegmental and multilevel lesions are also noted;
- etiology: it should not be used for specific granulomatous processes;

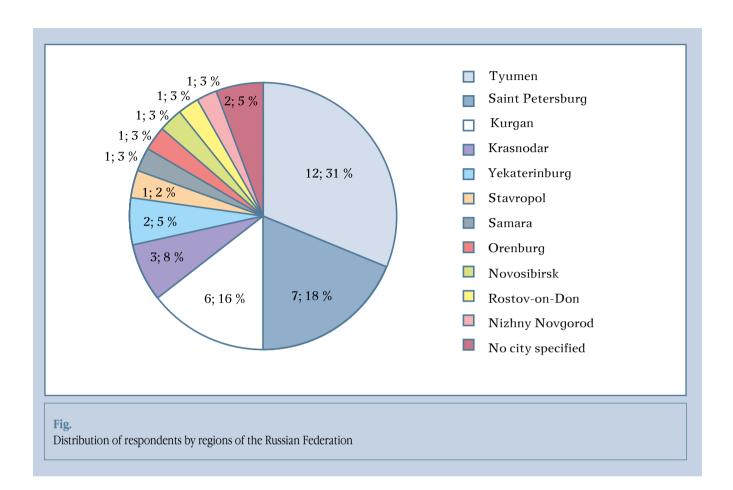


Table 2
Distribution of respondents by specialization and clinical experience, n

| Specialization Treatment/diagnosis | | diagnosis | Treatment/diagnosis | | Treatment/diagnosis experience | | Total |
|------------------------------------|---------------------------------|-------------|--------------------------|-------------|--------------------------------|-------------|-------|
| | experience of less than 5 years | | experience of 5-10 years | | of more than 10 years | | |
| | Non-infection* | Infection** | Non-infection* | Infection** | Non-infection* | Infection** | |
| | | | | | | | |
| Orthopedic traumatologist | 1 | 3 | 2 | 2 | 8 | 6 | 11 |
| Neurosurgeon | _ | _ | 5 | 6 | 7 | 6 | 12 |
| Neurosurgeon + orthopedist*** | _ | 2 | 2 | _ | 6 | 6 | 8 |
| Radiologist | 1 | 1 | 2 | 2 | 3 | 3 | 6 |
| Total | 2 | 6 | 11 | 10 | 24 | 21 | 37 |

- * Non-infectious spine pathology;
- ** Infectious spine pathology;
- *** Clinicians with two valid certificates (Orthopedic traumatologist and Neurosurgeon).
- diagnostics: two imaging methods, CT and MRI, should be used to correctly classify the lesion;
- *instability:* it is essential to clarify the criteria of instability;
- severity of the disease: it is required to consider the severity of the inflammatory process, the evaluation of the sys-

temic inflammatory response syndrome, and sepsis;

- the form of the inflammatory process: the classification is applicable in acute processes. Limitations are noted in chronic cases; the classification does not apply to postoperative spondylodiscitis infections of the surgical site;
- surgical options: the authors have provided an insufficient number of surgical solutions; anterior surgery can be used according to indications for significant bone destruction or paravertebral and intramuscular abscesses that are inaccessible to drainage from the posterior approaches.

Table 3

The level of general inter-expert agreement for all types of lesions, depending on the specialization and experience of the respondents

| General agreement on specialties | Fleiss' kappa | Confidence Interval 95 % | | | |
|--|---------------|--------------------------|-------------|--|--|
| and experience in treatment/diagnosis | | | Upper limit | | |
| | | | | | |
| Orthopedic traumatologist | 0.442 | 0.394 | 0.491 | | |
| Neurosurgeon | 0.321 | 0.277 | 0.365 | | |
| Neurosurgeon + orthopedist | 0.331 | 0.263 | 0.399 | | |
| Radiologist | 0.482 | 0.388 | 0.577 | | |
| Clinical experience of less than 10 years* | 0.424 | 0.390 | 0.457 | | |
| Clinical experience of more than 10 years* | 0.374 | 0.349 | 0.398 | | |
| * Experience in the treatment/diagnosis of infectious spine lesions. | | | | | |

Table 4

The level of inter-expert agreement on the types of lesions depending on the specialization and experience of treatment

| Category | Inter-expert agreement on the types of lesions, k (95 $\%$ CI) | | | |
|---|--|------------------------|------------------------|--|
| | A | В | С | |
| | | | | |
| General agreement | 0.480 (CI 0.460-0.499) | 0.300 (CI 0.281-0.320) | 0.399 (CI 0.380-0.419) | |
| Orthopedic traumatologist | 0.474 (CI 0.406-0.543) | 0.380 (CI 0.312-0.448) | 0.479 (CI 0.411-0.547) | |
| Neurosurgeon | 0.481 (CI 0.419-0.544) | 0.185 (CI 0.123-0.248) | 0.315 (CI 0.253-0.377) | |
| Neurosurgeon + orthopedist | 0.416 (CI 0.320-0.511) | 0.185 (CI 0.123-0.248) | 0.363 (CI 0.268-0.459) | |
| Radiologist | 0.486 (CI 0.355-0.616) | 0.484 (CI 0.354-0.615) | 0.477 (CI 0.347-0.608) | |
| Clinical experience of less than 10 years | 0.550 (CI 0.503-0.596) | 0.318 (CI 0.272-0.364) | 0.437 (CI 0.390-0.483) | |
| Clinical experience of more than 10 years | 0.453 (CI 0.418-0.488) | 0.287 (CI 0.252-0.321) | 0.392 (CI 0.357-0.427) | |

It is essential to detail the classification limitations for multisegmental and multilevel lesions. The first ones include inflammatory processes involving more than one spinal motion segment. The second one includes lesions involving two or more spinal motion segments separated by at least one intact spinal motion segment [15]. Meanwhile, multisegmental lesions are a single pathological process with simultaneous hematogenous carrying of pathogen or that has spread to adjacent segments. The use of the New Classification of Spondylodiscitis should not impose any significant limitation on them. Multilevel types of spondylodiscitis are often characterized by a time interval between the formation of lesion focuses. As a result, classification, use of a diagnostic algorithm and tactical decisions should be carried out independently for each of them.

The main (open debridement, decompression, and stabilization) and additional (debridement and spinal fusion 360° in

one or more stages) options for cervical spine take on the similar meaning. This is because the majority of the intervention is performed anteriorly, and posterior instrumentation is only useful as an additional stabilizing stage for extensive resections of the anterior column of the spine. As a result, with the potential use of the classification under consideration for the cervical spine, a separate consideration of surgical solutions is required, since the primary options are frequently inapplicable.

In the original paper, instability is indicated by angulometric criteria for lesion types at B3.1 <25° and B3.2 >25° without determining the initial deformity criteria. Herren et al. [4] establish the following criteria for spinal instability in infectious lesions: kyphosis of more than 15°, translation of more than 5 mm and destruction of more than 50% of the vertebral height. They effectively supplement the classification under study. The presence of a systemic inflammatory

response syndrome or sepsis in a patient has a significant impact on the treatment strategy. Severe general condition dictates a reduction in surgical invasiveness with delayed instrumentation and reconstruction. Patients who are hemodynamically unstable are treated in the intensive care unit until their vital functions are restored.

The low level of agreement can be explained by the fact that most respondents did not use the classification discussed in everyday practice prior to the survey. We strongly recommend physicians involved in the treatment of spinal diseases to study this classification since it is currently most commonly used in the world literature when discussing non-specific infectious and inflammatory lesions of the spine. Nonetheless, introduction of the Pola classification in regulatory documents governing the provision of care to patients with infectious spinal lesions, including national clinical guidelines, would be premature

Table 5 Respondents' answers to additional questions on the applicability of the Pola classification, n (%)

| Issues for discussion | Answer "Yes" | Answer "No" |
|---|--------------|-------------|
| | 11 (00 5) | 00 (50 5) |
| The classification is applicable to all spine regions | 11 (29.7) | 26 (70.3) |
| The classification is applicable to lesions of the thoracic and lumbosacral spine only | 27 (73.0) | 10 (27.0) |
| The classification allows to classify a monosegmental lesion | 36 (97.3) | 1 (2.7) |
| The classification allows to classify a multisegmental or multileveled lesion | 13 (35.1) | 24 (64.9) |
| The classification allows to classify a lesion of the upper cervical (suboccipital) spine | 8 (21.6) | 29 (78.4) |
| The classification allows to classify a lesion of the cervical (subaxial) spine | 22 (59.5) | 15 (40.5) |
| The classification allows to classify a lesion of the thoracic and lumbosacral spine | 37 (100.0) | 0 (0.0) |
| The classification allows to specific lesions (tuberculosis, brucellosis, etc.) | 9 (24.3) | 28 (75.7) |
| The authors of the classification proposed a sufficient number of treatment options | 11 (29.7) | 26 (70.3) |
| The MRI is sufficient to classify the lesion correctly | 2 (5.4) | 35 (94.6) |
| The CT is sufficient to classify the lesion correctly | 0 (0.0) | 37 (100.0) |
| The MRI and CT are necessary to classify the lesion correctly | 36 (97.3) | 1 (2.7) |
| It is mandatory to supplement the classification with an assessment of the severity of the inflammatory process | 26 (70.3) | 11 (29.7) |
| It is necessary to specify the criteria for instability of the affected spine segment (department) | 33 (89.2) | 4 (10.8) |
| The classification is applicable for any spondylitis | 15 (40.5) | 22 (59.5) |
| The classification is applicable for any acute processes | 36 (97.3) | 1 (2.7) |
| The classification is applicable for chronic spondylitis | 22 (59.5) | 15 (40.5) |
| The classification is applicable when the duration of the disease is more than 2 months | 29 (78.4) | 8 (21.6) |
| The classification is applicable for postoperative (post-procedure) spondylitis | 14 (37.8) | 23 (62.2) |

due to the low interobserver agreement. At this point, its application can only be universally optional, not mandatory. We consider that the New Classification of Spondylodiscitis by E. Pola should be included in the educational program for training subject matter professionals as the most advanced and convenient tool.

Conclusion

The Pola classification of spondylodiscitis is currently considered the most successful for tactical algorithms. However, there is an unsatisfactory expert consen-

sus on the types of lesions at the stage of its clinical application, and there are limitations related to the etiology, localization, and severity of the disease. It is recommended to supplement this classification, including the use of anterior surgery techniques before applying it to a broad clinical practice and with consideration of the identified limitations.

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All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

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