

An International Consensus based on the Delphi Method to Define Failure of Medical Treatment in Pyogenic Spinal Infections

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INTRODUCTION: Pyogenic spinal infections (PSI) are severe conditions with high morbidity and mortality. If medical treatment fails, patients may require surgery, but there is no consensus in the literature regarding the definition of treatment failure. The aim of our study was to determine criteria for defining the failure of medical treatment in PSI through an international consensus of experts using the Delphi method, a scientifically validated process.

METHODS:

The study was conducted according to the guidelines and recommendations for the Delphi method. We created an online survey with 10 criteria reported in the literature to define the failure of medical treatment in PSI (Table 1). We sent this survey via email to 150 experts from 22 countries, chosen for being authors or co-authors of clinical guidelines or indexed publications on the topic. Each criterion included in the survey was evaluated on a scale of 1 to 9 (1 being no relevance and 9 being highly relevant), and agreement among the participants on relevant criteria (those with a score ≥ 7) was determined. We considered 80% as high agreement, 70-79% as moderate agreement, 50-69% as low agreement, and $< 50\%$ as no agreement. Additionally, participants were given the opportunity to suggest any new criteria they deemed relevant for the definition using a free-text field in the survey.

Two months later, the second round of evaluations was sent. An extra criterion suggested by 10 responders during the first round (The patient develops deformity or instability at the site of infection) was incorporated into the second-round survey. The final version was reached with the criteria considered relevant and with high agreement.

RESULTS:

Forty-one experts responded to the first round, and 33 out of 41 responded to the second round. Two criteria had a score ≥ 7 from more than 80% of the evaluators. In the first round, 85.3% considered the criterion "There is an uncontrolled sepsis despite broad spectrum antibiotic treatment" as relevant, which passed directly into the final definition. In the second round, 85.3% considered the criterion "There is an infection relapse, following a six-week period of antibiotics with clinical and laboratory improvement" as relevant, and it passed into the final definition. The extra criterion suggested by 10 respondents and included in the second-round survey did not reach sufficient agreement to be included in the final definition.

DISCUSSION AND CONCLUSION:

The criteria in this definition for failure after non-surgical treatment of PSI are "There is an uncontrolled sepsis despite broad spectrum antibiotic treatment" and "There is an infection relapse, following a six-week period of antibiotics with clinical and laboratory improvement." Other criteria as the onset of new neurological compromise or progressive neurological compromise during antibiotic treatment did not reach enough consensus. Also, the development of spinal deformity or instability at the site of infection did not reach sufficient agreement. These results can be explained because poor outcomes such as poor functional status, persistent pain, or neurological impairment may better reflect the severity of PSI rather than indicating treatment failure. Criteria based on MRI or CT scan progression also did not achieve enough agreement. This finding can be attributed to the recommendation that MRI should not be routinely used as a follow-up imaging modality, as MRI changes often continue or worsen during treatment, even in cases with successful outcomes. Our study's proposed definition for failure after nonsurgical treatment of PSI, obtained through a consensus among international experts, provides a standardized approach, can help guide clinical decision making and improve scientific reporting in this field.

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First round	Score ≥ 7 by $\geq 80\%$ of experts	Second round	Score ≥ 7 by $\geq 80\%$ of experts	Final definition
1. The patient dies during or immediately after treatment due to causes related to the infection.	No	Included	No	-
2. There is an infection relapse, following a six-week period of antibiotics with clinical and analytical (laboratory) improvement.	No	Included	Yes	Final definition
3. There is an infection persistence, defined as positive culture in samples after six weeks of antibiotic treatment but following a period of clinical and analytical improvement.	No	Included	No	-
4. There is an uncontrolled sepsis despite broad spectrum antibiotic treatment.	Yes	Final definition	-	Final definition
5. New neurological compromise or progressive neurological compromise during antibiotic treatment.	No	Included	No	-
6. Persistence of back pain (VAS 6 or more) after six weeks of medical treatment.	No	Excluded	-	-
7. Increase in previous back pain by 2 points in VAS after six weeks of medical treatment.	No	Excluded	-	-
8. Evidence of MRI or CT scan progression, such as the occurrence of new lesions, after 6 weeks of antibiotic therapy.	No	Included	No	-
9. Evidence of MRI or CT scan progression, such as the increase in size of previous lesions, after 6 weeks of antibiotic therapy.	No	Included	No	-
10. Evidence of MRI or CT scan progression, such as failure to decrease in size of previous lesions, after 6 weeks of antibiotic therapy.	No	Included	No	-
		11. The patient develops deformity or instability at the site of infection.	No	-