Unmet needs in axial spondyloarthritis. Proceedings of the French spondyloarthritis taskforce workshop

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Review

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Highlights

- The progress achieved in the different areas of axial spondyloarthritis represents significant advances.
- Not all questions are resolved, unmet needs persist.
- A French task force individualized points to consider regarding these unmet needs.
- These elements can represent the basis of a research agenda for the years to come.

Abstract

The progress observed over the last 30 years in the field of axial spondyloarthritis (axSpA) has not made it possible to answer all the current questions. This manuscript represents the proceedings of the meeting of the French spondyloArthitiS Task force (FAST) in Besançon on September 28 and 29, 2023. Different points of discussion were thus individualized as unmet needs: biomarkers for early diagnosis and disease activity, a common electronic file dedicated to SpA nationwide, a better comprehension of dysbiosis in the disease, a check-list for addressing to the rheumatologist, adapt patient reported outcomes thresholds for female gender, implementation of comorbidities screening programs, new imaging tools, in research cellular and multi omics approaches, grouping, at a nationwide level, different cohorts and

registries, therapeutic strategy studies, consensual definition of difficult to treat disease and management, preclinical stage of the disease, mastering AI as a tool in the various aspects of research. These elements may represent a framework for the research agenda in axSpA for the years to come.

- Previous article in issue
- Next article in issue

Keywords

Spondyloarthritis
Epidemiology
Diagnosis
Genetics
Comorbidities
Evaluation
Research
Imaging
Therapeutics

Spondyloarthritis (SpA) is a polymorphic disease with a phenotypic presentation that takes into account axial damage, peripheral rheumatological manifestations, extra-musculoskeletal damage and comorbidities [1], [2]. Many advances have been made in recent years on the epidemiological, nosological, biological and imaging levels, in parallel with the provision of new therapeutic options with targeted treatments, and also new concepts of therapeutic strategy. These advances have not yet made it possible to provide an answer to all the questions related to the disease and its management and have sometimes even given rise to new questions. We report here the summary of a workshop dedicated to unmet needs in axial SpA (axSpA).

1. Methods

A group of French rheumatologists (French spondyloArthritiS Taskforce, FAST) particularly involved in the field of SpA and having carried out work in this area met during a 2-day seminar in Besançon on September 28 and 29, 2023. The group is formed by 21 senior academic rheumatologists from all over France to help draw up the program and prepare the meeting.
Preparatory work consisted of the development of different themes of interest to be addressed. The experts were distributed across different themes (selected by a steering committee), with the mission of carrying out a summary of the current situation and highlighting unmet needs. During the face-to-face meeting, these elements were presented to the entire group, a starting point for an open discussion which allowed the individualization of certain points to be considered, consensually without any voting, and possibly prospects for actions to be carried out.

2. Results

2.1. Epidemiology, genetics, environment

On an epidemiological level, databases (big data) represent a new tool likely to advance our knowledge of the disease. However, a certain number of pitfalls appear in routine use, particularly concerning the national health data system (*Système National des Données de Santé* [SNDS]): on the one hand the difficulty of individualizing patients suffering from SpA, on the other hand the absence of data regarding phenotypic classification, and disease activity and severity [3]. Different registers and cohorts at the locoregional or national level exist, with the possibility of access to clinical information and disease activity. However, they are very diverse in the items collected. One option could be, at the level of rheumatological care structures, including medical practices, the use of a common electronic file, with a core of minimal information relevant to SpA. Ideally, it would be appropriate to provide a link with the SNDS.
From a genetic point of view, at best 30% of the heritability of the disease is explained by genetic markers, ¾ of which comes from HLA-B27. Recent results in genetics represent only minimal progress in diagnosis [4], [5], [6]. Techniques are evolving, with the possibility of studying the entire genome. Current needs are mainly for biological collections and funding for genetic analyses to look for elements that impact heritability, including microbiota, rare variants, and epigenetic factors. This requires well-phenotyped cohorts and accurate genotyping.
In terms of the environment, current data show an important role for the microbiota, particularly intestinal microbiota and dysbiosis, characterized by a reduction in certain bacterial classes producing butyrate, and an increase in other classes (Ruminococcus *gnavus*). Analyzes of the microbiota and their interpretation remain difficult, and additional studies are necessary to know if this dysbiosis is the primary causal factor of the disease. Therapeutic modulation of the microbiota in SpA remains in its embryonic state, fecal transplantation trials in psoriatic arthritis are negative, as is the use of certain probiotics in SpA. This should be weighed against the beneficial effect of the Mediterranean diet. Tobacco and infections in childhood are also to be taken into account in the environmental factors associated with the disease, as well as stress (mechanical and neuropsychological) [7]. The important question in this environmental field is to know if there is a dysbiosis specific to SpA which could at that time serve as a diagnostic marker preceding the occurrence of clinical manifestations [8].

2.2. Diagnosis and referral

Diagnosis, and in particular early diagnosis, remains a major problem for the clinician in the management of axSpA. This problem oscillates between 2 elements: on the one hand the observation of a diagnostic delay which remains several years, and which has not been reduced over the last 2 decades [9], on the other hand the risk of excess diagnosis due to an over-interpretation of certain imaging changes (in particular MRI) or linked to the sole positivity of HLA-B27. It is important to recall that the diagnosis is based on a concordant body of anamnestic, clinical and paraclinical evidence. The ASAS group (Assessment in SpondyloArthritis international Society) had proposed recommendations for early referral [10]. These recommendations have to be adapted to the specific characteristics of the healthcare systems within each nation. The early referral could be optimized on the one hand by raising awareness among the general population, with a self-screening questionnaire, and on the other hand by health professionals with a “checklist” for addressing to the rheumatologist. Such an earlier and more systematic approach would, however, have to be compared with the possibilities of access to the rheumatologist within the correct time frame.

2.3. Biomarkers and Patient Reported Outcomes (PRO)

Many biomarkers are available for axSpA, but few of them have been properly studied in terms of sensitivity and specificity depending on the objective (diagnosis, disease activity, prognosis, etc.) [11]. Several needs emerge in this theme. In particular, a biomarker, or a combination of biomarkers for early diagnosis and disease activity, is missing. It would also be necessary to define thresholds for the different patient tools to define a flare-up. The extra-musculoskeletal manifestations have a significant weight in the evaluation of the disease and the therapeutic effect, an activity score of these extra-musculoskeletal manifestations is missing, usable by the rheumatologist in the form of an overall global score of the disease including all components (joint, skin, gut, ophthalmological). The question of adapting PRO thresholds for the female gender also arises, since recent work has shown a difference in pain perception and therapeutic response in women [12].

2.4. Comorbidities

Comorbidities are frequent and diverse during SpA [13], [14], they contribute greatly to the excess mortality observed in the disease, and which has remained stable over recent decades [15]. We currently lack recent data on the effect of targeted treatments, notably anti IL-17 and JAK inhibitors, on mortality and cardiovascular events, particularly in the populations most at risk (which are usually excluded from therapeutic trials) and according to the phenotype (radiographic or non-radiographic, and extra-musculoskeletal manifestations) of the disease. Furthermore the impact of peripheral SpA endotype, i.e. (peripheral and/or axial involvement) dramatically changes health trajectories. Hence, systematic screening for comorbidities for the subsequent progression of the disease and quality of life, by implementing screening programs in practice is recommended in SpA patients. These pluri-professional program could be handled by rheumatology nurses, particularly during periodic review of the disease [16].

2.5. Imaging

Imaging has made great progress in recent decades and occupies an important place in the diagnostic approach in particular [17]. In this approach, it is important to avoid a certain number of pitfalls, particularly in the interpretation of MRI with the risk of over-diagnosis [18], [19]. It is important to consider that the rheumatologist must interpret the images and not rely on a simple report and recall the points to consider in this interpretation (topography of the lesions), taking into account age, BMI, morphology and anatomical variants. The interest in new imaging techniques (low-dose scanner, new ZTE or VIBE MRI sequences, for better analysis of structural lesions, PET-CT with new tracers) is part of current research work. Opportunistic screening for pelvic or spinal lesions during an abdominal-pelvic scan is a possibility to remember and can represent a means of retrospective studies without having to repeat radiation examinations.

2.6. Translational research

This is a particularly broad subject, based on pathophysiological advances [5] with different aspects of which only some were addressed during the meeting. Observations from the Drosophila model expressing HLA-B27 encourage further exploration of the involvement of TGF-β and BMP (bone morphogenetic proteins) [20]. Modeling using organoids would make it possible to study host-pathogen interactions and could contribute to the discovery of biomarkers and test therapeutic options. Cellular approaches allow a more detailed exploration of the IL-23/IL-17 axis and the interdependence of these two cytokines [21].

These investigations can be carried out on circulating cells but would be relevant on tissues of interest (enthesis, spinal structures). It is therefore important to organize access to tissue samples, with the issue of their collection and conservation (building a bank). A multiomics approach could study, in patients naïve to targeted treatment, variations in various parameters after several weeks of treatment with a search for correlation with therapeutic response [22]. This could shed light on pathogenetic hypotheses and reveal prognostic factors.

2.7. Cohorts and registers

Many cohorts and registries exist. They are not uniform, their constitution being guided by different initial questions. These may be cohorts constructed ad hoc [23], with disease or treatment as an inclusion factor. They can be prospective or retrospective. Large big data databases (SNDS, data hubs) also represent a source of information (see 2.1). The grouping of several monothematic registers is possible (EUROSPA, for example) [24]. The census of the different existing cohorts and registers (and their content) concerning SpA at the national level would be a first step to consider the possibilities of grouping and sharing information, being aware of the heterogeneity of all these registers. A project for a registration platform for SpA patients initiating targeted treatment is underway, supported by the SFR (French Society of Rheumatology); it will make it possible, among other things, to study therapeutic sequences.

2.8. Therapeutics

The expansion of the therapeutic arsenal for axSpA in recent years raises a certain number of questions regarding strategy. Although recent recommendations provide the broad guidelines for the use of targeted treatments [25], certain specific situations do not currently have a formal answer. The paucityof head-to-head studies in first line (anti TNF versus anti IL-17)(in ax SpA, compared to psoriasis and psoriatic arthritis) or second line (anti TNF versus anti IL-17, JAKi versus anti-TNF or anti IL-17) is a major concern. How effective are anti IL-17 and anti JAK in cases of normal CRP and negative MRI? What strategy in case of an anti-IL-17 treatment failure in the first line? How to optimize treatment in the event of a partial response to targeted treatment? What place for combinations of targeted treatments? The answers to these different questions (non-exhaustive list) will require large-scale prospective studies which are unlikely to be initiated by the pharmaceutical companies. The concept of SpA difficult to treat (D2T) or rather difficult to manage is a recent concept which is the subject of work within the ASAS group [26]. The concept of treat to target (T2T) is not currently validated in current practice and would again require prospective studies [27].

2.9. Predictive factors

2.9.1. Of disease

This ties in with the problem of diagnosis and its precocity. As already mentioned, it is imperative to reduce the diagnostic delay. For this, alongside rapid referral strategies, it is important to develop biomarkers targeting populations at risk of progressing to SpA and possibly a pre-clinical stage of SpA [28]. This involves, in particular, the prospective study of relatives of patients with SpA [29] and the monitoring of patients developing extra-musculoskeletal manifestations (uveitis, psoriasis, inflammatory bowel disease) [30], [31]. Factors associated with later severity of the disease had been individualized several years ago (young age, diagnostic delay, coxitis, high activity, inflammatory syndrome, functional and

structural impact, etc.) [32]; they deserve to be updated in light of the evaluation means and cohorts currently available.

2.9.2. Of the persistence of targeted treatments

This need is based on the observation of insufficient long-term persistence, associated with the paucity of the data associated with this maintenance, in particular for anti-IL-17, JAK inhibitors and depending on sex. To date, no biomarker has been reliably identified.

2.9.3. Of therapeutic response

If we have some leads for anti TNF agents (male gender, high CRP, positive sacroiliac MRI, absence of smoking, low BASFI, short duration of illness are classically associated with a better response) [33], we lack data for anti-IL-17 and JAK inhibitors. The factors associated with achieving remission are similar, but inconsistent across studies [34]. We lack data on this.

2.10. Artificial intelligence

This is not a theme specific to SpA, but rather a transversal tool, usable in studies aimed at answering the questions asked. We easily understand the contribution of AI in everything relating to image analyzes [35], but also large-scale genetic analyses, microbiota analyses, database analyzes (big data), construction of diagnostic algorithms or therapeutic strategies based on prognostic factors [36], [37]. This approach falls outside the area of expertise of the rheumatologist and requires collaboration with specialized and competent teams.

3. Conclusion

This manuscript reflects the findings of a national working group on current axSpA issues in different areas, summarized in Box 1. Different questions are arising, thus representing a potential research agenda for the community, paving the way for further investigations in order to improve the practical care of patients with SpA.

Box 1
Summary of proposals for unmet needs in axial spondyloarthritis.

The need for biomarkers for early diagnosis and disease activity.
The need for a common electronic file dedicated to SpA nationwide.

The need for a better comprehension of dysbiosis in the disease.
The need for a check-list for addressing to the rheumatologist.

The need to adapt patient reported outcomes thresholds for female gender.

The need for implementation of comorbidities screening programs in practice.

The need to develop and validate new imaging tools (MRI sequences, PET-CT).

The need to develop in research cellular and multi omics approaches.
The need for grouping, at a Nationwide level, different cohorts and registries.

The need to develop Nationwide therapeutic strategy studies.

The need for a clear consensual definition of Difficult To Treat disease and management.

The need for recognition and individualization of a preclinical stage of the disease.
The need for mastering AI as a tool in the various aspects of research.

The authors declare no conflict of interest concerning this manuscript.

Funding

No funding.

Acknowledgements

Unrestricted grant (organisation support): Abbvie, Amgen, Biogen, Janssen, Lilly, Novartis, Pfizer, Sandoz, UCB, Viatris.

Logistic: Véronique Gordin, Medic-Evènement.

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