Implementation of an assessment checklist for patients with spondyloarthritis in daily practice

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Abstract Objective

To analyse the feasibility and changes in the collection of clinical measures after the implementation in daily practice of a checklist designed for an optimal evaluation and monitoring of patients with spondyloarthritis (SpA).

Methods

An observational prospective study was performed. The feasibility of the assessment checklist (paper/on-line format) for patients with SpA was tested (time to complete the checklist, simplicity, amenity clarity, usefulness). Through a medical files review, changes in the number of the checklist variables collected were analysed previous to the implementation of the checklist and 6 months later. A descriptive and bivariate analysis was performed.

Results

A total 6 hospitals and 11 rheumatologists participated. The median time to checklist completion was 15 (12-20) minutes, and the mean scores for the rest of variables of the feasibility test were in general positives. A total of 83 and 68 medical files pre-implementation and post-implementation were reviewed respectively. We observed a significant increase in the collection of many of the checklist variables after the implementation. The record of BASDAI increased from 46.2% to 73.1% (p=0.001), physical activity from 48.2% to 88.2% (p<0.0001), physician global (VAS) from 28.0% to 73.5% (p<0.0001), patient global (VAS) from 48.8% to 85.3% (p<0.0001), morning stiffness from 62.8% to 84.8% (p=0.003), ASDAS from 12.2% to 32.8% (p=0.002), BASFI from 43.7% to 65.7% (p=0.008), or DAS28 from 24.7% to 46.3% (p=0.006). These changes were observed irrespectively of SpA classification.

Conclusion

The implementation of an assessment checklist in daily practice is feasible and improves the assessment of SpA patients.

Key words spondyloarthritis, checklist, implementation, feasibility, assessment, daily practice

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Introduction

The spondyloarthritis (SpA), including psoriatic arthritis (PsA), comprise a heterogeneous group of diseases, which, due to their clinical variability, require a monitoring with a broad variety of assessments. This includes for example the evaluation of different domains such as pain, disease activity or physical function, as well as the identification of extra-articular manifestations or comorbidities. For this purpose, different instruments are recommended like the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI) or the Ankylosing Spondylitis Disease Activity Score (ASDAS) (1, 2).

Nowadays, despite international and national guidelines on the evaluation and management of SpA (3-6), several studies have depicted a sub-optimal assessment of these diseases (7). The emAR study II was developed in 2009-2010 through a review of 1,168 medical files of patients with SpA randomly selected from Spanish hospitals (7, 8). This study showed that in 66% of the medical files there was no BASDAI record during the previous 2 years and a BASFI register was found only in 9.8% of the files. The same way, the RHEV-ER network in France reviewed a total of 456 medical files from 228 patients with axial SpA (axSpA), and found that BASDAI + C-reactive protein (CRP) and BASFI were reported in 16.7% and 5.7% of them (9). On the other hand, it has also been reported that although the prevalence of comorbidity in these population is remarkable, a high percentage of patients are not monitored according to prevailing recommendations and screenings (10-12).

Different factors may explain this situation. The lack of time in busy clinics together with scarce human and material resources do not contribute positively (13). Besides, the increasing number of variables of interest like comorbidity, PROs or the development and implementation of imaging techniques in clinical practice are also making the evaluation of SpA patients a challenge. Recently, we have published the ONLY TOOLS project in which we tried to standardise clinical assessment of patients with axSpA and PsA designing a practical and structured checklist, based on best evidence, and patients and rheumatologist experience (14). The aim of the present work was to implement the checklist in order to determine in daily practice the feasibility of this assessment tool and the changes in the frequency of the collection in the medical files.

Methods

Study design

An observational prospective study supported by the Sociedad de Reumatología de la Comunidad de Madrid (SORCOM) was performed. The study was approved by all the ethical committees of participant hospitals, and it was conducted in accordance with Good Clinical Practice and the current version of the revised Declaration of Helsinki (World Medical Association Declaration of Helsinki). In a first step, once the checklist was implemented in daily practice, its feasibility was tested, and then, the changes in the clinical evaluation of patients were evaluated.

Checklist development and features

The design and characteristics of this checklist for the assessment of patients with SpA including PsA in daily practice (ONLY TOOLS project) have been previously described (14). Briefly, this was a qualitative study that included: 1) a nominal group of 18 SpA experts; 2) literature reviews of the measures (types and psychometric features) as well as national/international recommendations in the assessment of patients with SpA, including the the Assessment of SpondyloArthritis international Society (ASAS) handbook (1); and 3) two focus groups, one with rheumatologists (different of those of the nominal group) and another with patients with SpA. Using the information from the reviews and focus groups, the experts discussed, selected and agreed (using Delphi techniques) the measures to be included in the checklist based on their relevance, feasibility, and the outcome type. The checklist includes variables for the evaluation (and periodicity) of personal history, physical examination, comorbidities, activity and function, laboratory tests, imaging studies and treatments. It also defines risk factors of radiographic progression, predictors of the response to biological therapies, and comprises measures of excellence. It could be used during or right at the end of the clinical consultation, in order to assure that the rheumatologist has completed the patient evaluation following recommended variables. Besides, it could also be used to register data. The checklist is free for use in its paper and electronic formats.

Hospitals and participants selection

For the purposes of the study, we selected a convenience sample of 6 hospitals from Madrid region (almost 6,500,000 population), with different characteristics regarding to their resources, attending population, or rheumatology department features. In each hospital, depending on their characteristics, 1 to 4 rheumatologists were invited for participation.

Sample size calculations

For the estimation of the sample size to assess changes after the implementation of the checklist we took into account data reported in the EmAR II study, performed in Spain, that showed that in the medical files of SpA patients, just 34% of them registered a BASDAI score (7). We hypothesised that the implementation of the checklist in daily practice would lead to an increase a 20% on the reporting of BASDAI and DAS28. Assuming an alpha error of 5% and a power of 80%, with 15% of incomplete medical files, we estimated a final sample of 113 patients pre-implementation (50% axSpA, 50% PsA) and another 113 patients post-implementation and another 113 patient's post-implementation (50% axSpA, 50% PsA), according to physician's diagnosis, but different from the 113 of the pre-implementation group. Each hospital was informed to include a total of 40 patients (20% pre- and 20 post-implementation, 50% axSpA, 50% PsA). Furthermore, we also assumed that the use of the checklist was feasible (we estimated a time to complete the checklist of no more than 15 minutes).

Table I. Main features of the hospitals and participant rheumatologists*.

Hospitals (n=6)	01.007	
≥200 Inpatient beds	81.8%	
n. Rheumatologists [†]	5.7 ± 4.6	
n. Rheumatology consultations/day	13-266	
With Rheumatology training programme	54%	
Rheumatologists (n=11)		
Sex (women)	81%	
Age (years) [†]	39.4 ± 7.8	
Residents	19%	
Years working as a rheumatologist [†]	11.1 ± 6.3	
Public and private activity	28%	
Only public activity	72%	

*Results are expresses as percentage, unless otherwise indicated. †Mean ± standard deviation.

Table II	. Results	of the	feasibility	analysis*.
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Variable	Description	
Time to checklist completion (minutes)	15.5 ± 4.8	
Simplicity (0-10) [†]	6.9 ± 1.1	
Amenity (0-10) [†]	6.9 ± 0.8	
Clarity (0-10) [†]	7.5 ± 1.2	
Usefulness (0-10) [†]	7.5 ± 1.4	
Need a revision (No), percentage	100%	
Additional comments	-"Too many variables"	
	-"I would include more tests for spinal mobility"	
	-"I would include the adherence"	

*Results are expressed as mean ± standard deviation, unless otherwise indicated.

[†]Simplicity, amenity, clarity and usefulness were evaluated from 0 to 10, the highest score, the better consideration.

Implementation of the checklist and data acquisition

First of all, the objectives and development of the project were presented and discussed in a meeting in which participants were also instructed in the use of the checklist, using the paper and electronic formats. In a first step, medical files of consecutive patients with at least one visit in the last year were reviewed to complete the pre-implementation CRF. At the same time, hospitals and participant rheumatologist characteristics were also collected with the baseline CRF. Then, rheumatologist used in daily practice the checklist in their preferred format for 1 week and complete the feasibility CFR. And, 6 months later, the medical files of consecutive patients were used to fulfil the post-implementation CRF.

Variables

The following variables were collected by the participant rheumatologists using the specifics electronic CRFs. Baseline CRF included hospital fea-

tures (number of inpatient beds, number of rheumatologists, number of rheumatology consultations per day, disposition of a rheumatology training programme) and rheumatologist characteristics (age, sex, residents, years working as a rheumatologist, public and private clinical activity). The feasibility CRF recorded: 1) time to complete the checklist (minutes); 2) simplicity (from 0 to 10; 0=very complicated, 10=very simple); 3) amenity of paper and electronic formats (from 0 to 10); 4) clarity of the variables of the checklist (from 0 to 10); 5) subjective evaluation of the checklist usefulness (from 0 to 10); 6) need for a revision (yes/no); 7) additional comments. Finally, in the implementation CRFs we collected if the checklist variables were registered in the medical files (see original publication for further details (14)), but in summary it includes data related to 1) patient like age, sex, physical activity, or smoking status; 2) SpA like disease duration or a positive family history; 3) comorbidities including

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obesity or depression; 4) biomarkers as rheumatoid factor, HLA-B27, and ACPA; 5) physical examination including enthesitis or dactylitis; 5) activity and function variables as joint counts and specific questionnaires (BASDAI, BASFI, etc.); 6) laboratory tests; 7) imaging studies; and 8) treatments.

Statistical analysis

Quantitative variables were described by means \pm standard deviations (SD) and qualitative variables with frequencies and percentages. For comparisons, Pearson chi square test for qualitative variables, and the two-sample *t*-test were used. A *p*-value <0.050 was considered statistically significant. Analyses were performed using Stata 12 statistical software (Stata Corporation, College Station, TX).

Results

The characteristics of the included hospitals (n=6) and participant rheumatologists (n=11) are depicted in Table I. Most of the included hospitals have ≥ 200 inpatient beds (81.8%), and a mean number of rheumatologists of 5.7±4.6. With regard to the rheumatologists, 81% were women, with a mean age of 39.4±7.8 years and a mean time working as a rheumatologist longer than 10 years.

Feasibility of the checklist

Table II shows the results of the feasibility analysis of the checklist. The mean time to checklist completion was 15.5 ± 4.8 minutes, and the mean scores for the rest of variables were in general positives. They varied from 6.9 ± 1.1 (simplicity) and 6.9 ± 0.8 (amenity), to 7.5 ± 1.2 (clarity) and 7.5 ± 1.4 (usefulness). Although the participants did not consider a need for a checklist revision, some of them would have included other variables or considered the checklist a bit long to be implemented in clinical practice.

Changes after the

implementation of the checklist

As presented in Table III, the pre-(n=83) and post-implementation samples (n=68) were very similar. Mean age at diagnosis was 42.3 ± 1.6 and 40.3 ± 1.3 years, respectively. In both study samTable III. Main features of study samples*.

	Pre implementation (n=83)	Post implementation (n=68)	<i>p</i> -value
Age at the beginning of symptoms [†] (yr)	39.6 ± 1.8	37.3 ± 1.5	0.342
Age at the diagnosis [†] (yr)	42.3 ± 1.6	40.3 ± 1.3	0.326
Men (%)	45.8%	57.3%	0.157
SpA classification [‡]			0.383
axSpA	40.2%	44.8%	
PsA	47.6%	47.8%	
IBD	3.7%	1.5%	

yr: years; SpA: spondyloarthritis; axSpA: axial; pSpA: peripheral spondyloarthritis; PsA: psoriatic arthritis; IBD: bowel inflammatory disease.

*Results are expressed as percentage (%), unless otherwise indicated. [†]Mean ± standard deviation. [‡]According to the Assessment of SpondyloArthritis international Society (ASAS) criteria.

Table IV. Changes in the variables registered in the medical records regarding to patient and family history after the implementation of the checklist*.

Variable	Pre implementation (n=83)	Post implementation (n=68)	<i>p</i> -value
Allergies	62.6%	79.4%	0.025
Smoking status	79.5%	94.1%	0.010
Alcohol consumption	50.6%	76.5%	0.001
Physical activity	48.2%	88.2%	<0.0001
Work status	95.2%	97.1%	0.691
Family history			
SpA	56.1%	73.1%	0.031
Psoriasis	64.6%	82.3%	0.015
IBD	40.0%	62.1%	0.008
Biomarkers			
HLA-B27	82.3%	88.1%	0.331
Rheumatoid factor	60.5%	73.1%	0.111
ACPA	48.7%	52.2%	0.671
Extra-articular symptoms and signs			
Diarrhoea/IBD	49.4%	70.6%	0.009
Psoriasis	83.9%	95.6%	0.032
Urethritis/cervicitis	20.0%	44.1%	0.002
Uveitis	51.8%	72.1%	0.012
Comorbidities			
Arterial hypertension	71.9%	91.2%	0.003
Diabetes Mellitus	59.8%	91.2%	<0.0001
Hyperlipidaemia	64.6%	92.6%	<0.0001
Cardiovascular events	46.3%	69.1%	0.005
Peptic ulcer	51.8%	57.3%	0.502
Depression	27.2%	45.6%	0.019
Obesity	43.7%	66.2%	0.006
Gout/Hyperuricaemia	36.6%	67.6%	<0.0001
Renal failure	35.4%	66.2%	<0.0001
Osteoporosis	21.2%	25.0%	0.589

SpA: spondyloarthritis; IBD: bowel inflammatory disease; HLA: human leukocyte antigen; ACPA: autoantibodies against citrullinated antigens.

*Results are expressed as percentage (%), unless otherwise indicated.

ples around a half of patients were men, and axSpA and PsA were equally distributed as well (40.2% and 44.8% preand post-implementation for axSpA and 47.6% and 47.8% for PsA).

In Tables IV, V and VI we show the changes in the number of variables found in the medical files 6 months after the implementation. First, we analysed

changes connected to personal and family history, biomarkers, extra-articular symptoms and signs and comorbidities (Table IV). We found an important and significant increase in the number of variables registered in many of the variables of the checklist. For example, before the implementation of the checklist, alcohol consumption was reported in the 50.6% of medical files whereas after it, it was found in the 76.5% of them (p=0.001). In the same way data regarding to physical activity increased from 48.2% to 88.2% (p<0.0001). The record of extra-articular symptoms and signs and all of the comorbidities but for osteoporosis and peptic ulcer significantly improved. The percentage of change ranged from 20% (extra-articular symptoms and signs or arterial hypertension) to 30% (diabetes mellitus, hyperlipidaemia, gout/hyperuricaemia and renal failure).

On the other hand, other checklist variables increased but not significantly. However, some of them like the HLA-B27 or work status were already recorded (before the implementation of the checklist) in the 82.3% and 95.2% of medical files, respectively.

As shown in Table V, we also observed an increase in the collection of the variables related to physical examination in the medical records after the implementation of the checklist, though not all were statistically significant. A total of 9 variables were related to disease examination, in which the registration of hip examination, chest expansion and cervical rotation changed from 73.2%, 26.8% and 30.5% to 86.8% (p=0.041), 51.5% (*p*=0.002), and 61.2% (*p*<0.001) respectively. The rest of the checklist variables, excluding the abdominal perimeter dramatically improved. They accounted for weight, height, body mass index and arterial pressure.

When analysing the changes pre-and post-implementation of the checklist regarding to the use of other assessment tools including questionnaires (Table VI) the results were as follows: Physician global from 28.0% to 73.5% (p < 0.0001), patient global from 48.8% to 85.3% (p<0.0001), morning stiffness from 62.8% to 84.8% (p=0.003), AS-DAS from 12.2% to 32.8% (p=0.002), BASDAI from 46.2% to 73.1% (p=0.001), BASFI from 43.7% to 65.7% (p=0.008), DAS28 from 24.7% to 46.3% (p=0.006). However, in the case of laboratory tests and imaging, although almost of the variables experimented an increase in their recording, only x-ray lumbar spine remained significant, from 70.7% to 85.1% (p=0.038).

Table V. Changes in the variables registered regarding to physical examination in the medical records after the implementation of the checklist*.

Variable	Pre implementation (n=83)	Post implementation (n=68)	<i>p</i> -value
Number of swollen joints	93.7%	94.0%	1.000
Number of tender joints	93.7%	94.0%	1.000
Enthesitis	76.2%	86.6%	0.113
Dactylitis	68.3%	77.9%	0.187
Skin/nail	65.4%	75.0%	0.205
Hip	73.2%	86.8%	0.041
Modified Schöber test	53.7%	66.2%	0.120
Chest expansion	26.8%	51.5%	0.002
Cervical rotation	30.5%	61.2%	<0.0001
Weight	26.8%	63.2%	<0.0001
Height	16.0%	61.8%	<0.0001
BMI	9.9%	42.6%	<0.0001
Abdominal perimeter	-	3.0%	0.203
Arterial pressure	14.6%	52.9%	<0.0001

BMI: body mass index.

*Results are expressed as percentage (%), unless otherwise indicated.

Table VI. Changes in the variables registered regarding to questionnaires, laboratory tests and imaging in the medical records after the implementation of the checklist*.

Variable	Pre implementation (n=83)	Post implementation (n=68)	<i>p</i> -value
Other disease related assessment	instruments		
Physician global (VAS)	28.0%	73.5%	<0.0001
Patient global (VAS)	48.8%	85.3%	<0.0001
Morning stiffness	62.8%	84.8%	0.003
ASDAS	12.2%	32.8%	0.002
BASDAI	46.2%	73.1%	0.001
BASFI	43.7%	65.7%	0.008
DAS28	24.7%	46.3%	0.006
Laboratory tests and imaging			
Haemogram	100%	100%	-
ESR	92.7%	86.8%	0.229
CRP	100%	100%	-
Clinical biochemistry	100%	100%	-
Lipids	91.5%	94.1%	0.755
Uric acid	95.1%	98.5%	0.247
Vitamin D	60.0%	65.7%	0.479
Urine analysis	92.7%	92.6%	0.993
x-ray of the whole pelvis	65.4%	70.1%	0.542
x-ray lumbar spine	70.7%	85.1%	0.038
x-ray peripheral joints	67.9%	79.4%	0.114
MRI of the sacroiliac joint	48.8%	59.7%	0.184
DXA	11.0%	10.4%	0.918

VAS: visual analogue scale; ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; DAS: Disease Activity Score; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; MRI: magnetic resonance imaging; DXA: dual energy x-ray absorptiometry scanning. *Results are expressed as percentage (%), unless otherwise indicated.

We finally evaluated these changes according to the type of SpA. In axial SpA, apart from a significant better characterisation of comorbidities, we would like to comment the changes of the assessment using disease-related questionnaires like ASDAS from 27.3% to 43.3% (*p*=0.182), BASDAI from 62.5% to 86.7% (*p*=0.042), BAS- FI from 57.6% to 70.0% (p=0.306), and DAS28 from 0% to 20.7% (p=0.008). The tendencies were very similar for patients with PsA.

Discussion

In this study we have examined the implementation in daily practice of an assessment checklist for patients with SpA including PsA. We found that the implementation of this checklist was feasible and clearly improved the evaluation of this group of patients.

In daily practice, it is recommended to evaluate patients with spondyloarthritis (SpA) according to clinical signs, symptoms and acute-phase reactants (3-6). However, there is evidence of a sub-optimal assessment (7-9, 12, 15). Lack of time, resources, motivation or knowledge could be reasons that explain this situation, and the basis to design a practical, structured and standardised checklist for the assessment of SpA in routine care (14). It includes the evaluation of personal history, physical examination, comorbidities, activity and function, laboratory tests, imaging studies and treatments using validated instruments as proposed by national and international organisations (1, 3, 16). Besides, through different signs, the checklist also facilitates the identification of variables associated to the response to biological therapies (17) or radiographic progression (18, 19). In this work we have reported the results of the implementation of the checklist in daily practice.

Regarding to the collection of patient and family history related variables, almost all of them significantly increased. The frequency of recording of biomarkers and work status did not changed but in the pre-implementation sample they were already high. But in this setting we would like to highlight the positive changes in the recording of comorbidities (including cardiovascular risk factors) except for peptic ulcer and osteoporosis. In the emAR II study, developed in 2009-2010 in our country (15), half of the medical files of SpA patients did not have any registered comorbidity and diabetes was recorded in 6% of them. In the pre-implementation sample all of the medical files reported at least one of the checklist comorbidities, and with the implementation the rate of individual comorbidities but the exposed clearly improved. This finding is very important as the prevalence and impact of comorbidities is high, and because it has been published an under-reporting and screening of many of them (10-12, 20).

In the case of physical examination, the changes in the recording of joint counts, enthesitis, dactylitis in medical files were not significant but even in the pre-implementation sample were high, especially if compared with the emAR II results in which it was less than 20%. However, we found that although the frequency of the modified Schöber test, chest expansion and cervical rotation improved, almost half of the files did not have them registered. Even in the sub-group of patients with ax-SpA the rate was low. Other reports have depicted similar results (9).

Finally, when we analysed the assessment of activity and function domains of the SpA, the frequency of the reporting of all of the variables improved. This change was impressive for the physician and patient global and the morning stiffness. BASDAI, BASFI and DAS28 also improved but did not achieve a very high rate of reporting. Only ASDAS remained in a low collection rate. However this finding was in part expected, as this is an instrument that it has been recommended for assessment in SpA more recently and physicians are more familiar with BASDAI. We are confident that it will be progressively implemented in daily practice. Interestingly, the collection of laboratory tests and imaging did not change but in general even in the preimplementation sample the reporting was very high except for dual energy x-ray absorptiometry scanning (DXA). On the other hand, although the results in this study are very positive we have also identified some areas for improvement that will probably need further actions. One is the evaluation of osteoporosis and fracture risk factors (registered only in one fourth of the files). Osteoporosis frequently occurs in axSpA and can lead to vertebral fractures at a young age (21, 22). In fact, it has been reported in a cohort of early axSpA that 15% of patients showed at least one vertebral fracture (23). In PsA the rates of osteoporotic fractures published varied from 12% to 40% of patients (24). Depression collection significantly increased but we consider that it is insufficient (less than a half after the implementation). The risk of anxiety and depression in axSpA and PsA is variable depending on the study but high as their impact on patients (25-27). The reporting of the assessment of spinal mobility, especially for patients with axSpA should be a key target in the future as well.

Although we did not address associated factors to under-reporting, we consider that lack of time could be the main contributor. In busy clinics physicians might find more useful for the decision-making disease activity variables than those related to functionality. Connected to comorbidities, physicians besides might not be aware (lack of knowledge) of the real prevalence and impact of some of them like osteoporosis and depression and/or consider that other health professionals may be those responsible for dealing with them.

Finally, although the mean time to complete the checklist could be a bit long for busy clinics, we are confident that this time will rapidly decrease as clinicians use it in daily practice.

To our knowledge, this is the first study analysing the effect of the implementation in daily practice of a specific and structured checklist for the assessment of SpA patients including PsA. Previously, Che and colleagues showed that a consensual meeting proposed to report at least the BASDAI score in the medical file of every ax-SpA patient at every follow-up visit. Afterwards medical files were reviewed and a significant increase in the collection of BASDAI plus CRP was observed (9). The results of this work reinforce the need to implement and evaluate initiatives to improve SpA patient's assessment.

On the other hand, we have to point out the limitations of the study and checklist. As described in the results section, this checklist is a bit long for some (but not the majority) of the participants. But taking into account the positive results and the potential benefits of an optimal assessment we consider that our checklist is suitable for using it in daily practice. Additionally, we did not reach the estimated sample sizes. Therefore it could be argued that there might be an over-estimation in the collection rates because more motivated participants are those who have entered more pa-

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tients and the same way have collected more variables in the files. However, as we have demopnstrated, the frequency of the collection of many of the variables improved but not for all. In fact, in some assessments there was little or no change, suggesting that other different factors are probably determining some attitudes to the reporting.

In summary, since the emAR II (2009-2010) study that highlighted the poor reporting of the assessment of SpA patients including PsA (15), different national and international recommendation initiatives based on key studies in the field and experts knowledge have been developed to improve the assessment and monitoring of these patients (1, 3, 16). This is probably the reason why ten years later when we analysed the pre-implementation sample the frequency of the collection of many variables had already improved. But most importantly, what we would like to conclude as the main finding of this work is that the implementation in daily practice of the checklist was feasible and led to a clear and significant improvement of the monitoring in patients with SpA. This effect was visible even 6 months later of the implementation.

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