

Preliminary testing of the SAGIT[®] tool: A tool to help endocrinologists in their management of patients with acromegaly in clinical practice

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Context and objectives

- Acromegaly is a rare, chronic, hormonal disorder caused by excessive growth hormone (GH) and insulin-like growth factor 1 (IGF-1) production resulting predominantly from pituitary adenoma.
- Confirmed diagnosis of acromegaly requires both clinical and biochemical examinations (measure of tumour shrinkage and GH and IGF-1 concentration levels).
- No reference tool is currently available for use in clinical practice to describe disease severity and rapidly evaluate the control/progression of acromegaly or of a treatment response in patients with acromegaly before and during treatment. A group of international experts in acromegaly developed a new clinician tool, the SAGIT. It reports 5 elements: Signs and symptoms (S); Associated comorbidities (A); Growth hormone concentration level (G); Insulin growth factor (I); Tumour (T). The objectives of pilot testing were to assess acceptability, understanding and ease of use of the newly developed SAGIT tool with practising endocrinologists and to identify potential areas for improvement.

Methods

Study overview (Figure 1)

- Study conducted in France (FR), Germany (DE), Italy (IT), Spain (SP), the UK and Brazil (BR)
- SAGIT completed for each patient with pre-intervention (surgery or medical treatment) and post-intervention data

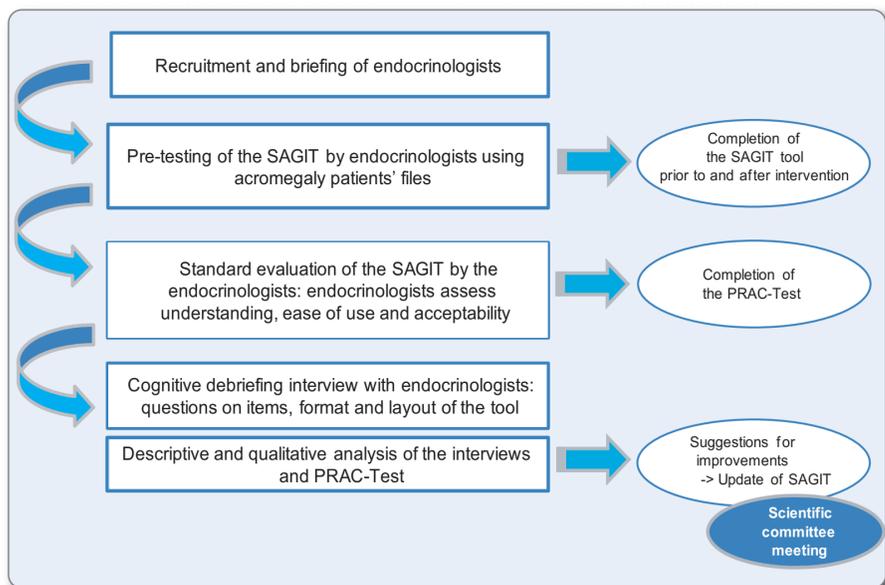
Participants

- 11 practicing endocrinologists
2 per country, except Germany (n = 1)
- Endocrinologist selection criteria
Hospital-based or working in outpatient clinics
Currently treating and managing 3 or more patients with acromegaly
Never used / were not familiar with / had not been briefed on SAGIT prior to study
- 39 patient medical records
3 patient medical records per endocrinologist
Data necessary for completion of SAGIT available in the medical records of the patients who met the inclusion criteria

Assessments

- PRAGmatic Content and face validity Test (PRAC-Test[®]) evaluation form completed to assess the global acceptability of the SAGIT by endocrinologists
– 32 items
– Elements assessed: acceptability, ease of use, ease of comprehension, relevance, usefulness, scientific credibility, objectivity (no conflicting interest), logical progression and layout
- Cognitive debriefing interview conducted with each endocrinologist to assess understanding and identify potential areas for improvement
– One-hour phone interview conducted by MAPI-trained interviewers in English upon completion of the SAGIT and PRAC-Test
– Questions on items and instructions assessed endocrinologists' understanding, interpretation of each item, content, structure and layout of the tool
– Qualitative analysis of recorded interviews

Figure 1: Overview of the pre-testing phase of the study

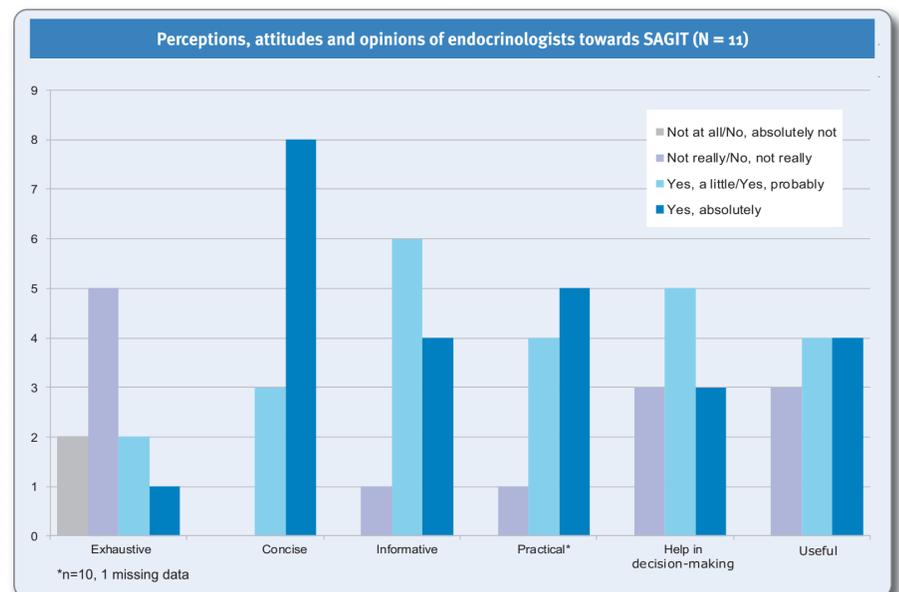


Results

PRAC-Test results

Utility of the information collected with SAGIT (N = 11)							
Questions	BR	FR	DE	IT	SP	UK	Total
To assess response to therapy	1	2	1	2	2	1	9
As a document to be included in the patient's file	1	2	1	1		2	7
To contribute to therapeutic decision-making	2	1	1	1		1	6
To help healthcare professionals to adapt treatment to patients	1	2	1	1		1	6
To contribute to the diagnostic process	2	1	1	1			5
For scientific purposes	2		1			2	5
To screen patients	1					1	2
To monitor compliance or adherence				1		1	2
To assess side effects				1			1
No use							0

BR, Brazil; FR, France; DE, Germany; IT, Italy; SP, Spain; UK, United Kingdom
N = 2 endocrinologists per country, except DE (n=1)
*Figures correspond to the number of endocrinologists who selected the utility listed in PRAC-Test



Qualitative analysis of endocrinologist interviews

Endocrinologists' feedback on the elements of SAGIT	
Elements of SAGIT	General comments / Difficulties reported
Title : SAGIT	<ul style="list-style-type: none"> Informative No need for improvement
<ul style="list-style-type: none"> Signs and symptoms (S) 3 signs and symptoms – Headache – Sweating – Joint symptoms Score ranges from 0 to 3 according to number of symptoms 	<ul style="list-style-type: none"> Lack of instructions on how to interpret the score and to score the SAGIT Need for a severity ranking scale for assessment of symptoms List of symptoms fine; some additional symptoms proposed (e.g. acral changes, fatigue / asthenia, visual symptoms, paraesthesia in feet or legs, skin changes, facial dysmorphism, cardiopathy)
<ul style="list-style-type: none"> Associated comorbidities (A) 5 comorbidities – Diabetes – Hypertension – Sleep apnoea – Heart disease – Hypopituitarism Score ranges from 0 to 5 according to number of comorbidities 	<ul style="list-style-type: none"> Lack of instructions on how to interpret the score and to score the SAGIT Need for a severity ranking scale for the assessment of co-morbidities List of comorbidities fine; additional comorbidities proposed (e.g. visual signs, intestinal polyps, obesity, cancer) Definition needed for each comorbidity listed
<ul style="list-style-type: none"> GH nadir with OGTT* (G) 5 ranges of concentration Score ranges from 0 to 4 • ≤ 0.4 µg/l • > 0.4 to < 1.0 µg/l • ≥ 1.0 to < 2.5 µg/l • ≥ 2.5 to < 5.0 µg/l • ≥ 5.0 µg/l GH random or series 5 ranges of concentration Score ranges from 0 to 4 • ≤ 1.0 µg/l • > 1.0 to < 2.5 µg/l • ≥ 2.5 to < 5.0 µg/l • ≥ 5.0 to < 10.0 µg/l • ≥ 10.0 µg/l 	<ul style="list-style-type: none"> Item well understood Ranges and units well adapted but loss of sensitivity for small improvements because ranges of the concentration categories are too large GH nadir with OGTT and GH random or series not always reported in the patient medical record, or not always performed routinely at each consultation Highest concentration of GH nadir with OGTT proposed is not high enough Meaning of "series" not understood
<ul style="list-style-type: none"> IGF-1 (I) 4 ranges of concentration Score ranges from 0 to 3 • < 1.3 ULN • ≥ 1.3 to < 2 ULN • ≥ 2 ULN 	<ul style="list-style-type: none"> Item well understood Ranges and units well adapted, but loss of sensitivity for small improvements because concentration ranges are too large
<ul style="list-style-type: none"> Tumour (T) 6 categories of tumour size Score ranges from 0 to 5 • Pituitary mass not visible • < 10 mm intrasellar • ≥ 10 mm • Suprasellar • Invasive, ≤ 40 mm • ≥ 40 mm 	<ul style="list-style-type: none"> Some categories are not sensitive enough Importance to differentiate invasive from non-invasive tumours, parasellar/laterosellar vs. intrasellar vs. suprasellar tumours, sinus vs. chiasm vs. cavernous sinus vs. sphenoidal sinus invasion

N = 10: one endocrinologist was not interviewed
* OGTT, oral glucose tolerance test; ULN, upper limit of normal

Overall impression of the endocrinologists towards SAGIT	
Positive attributes	Attributes for improvement
<ul style="list-style-type: none"> Useful in clinical practice Subjectivity removed (score) Rapid evaluation Evaluation of the control/progression of the disease Evaluation of patient's current treatment Evaluation of new treatment or intervention Discussion with patients Standardisation (multicentre; national and international studies) Easy, comprehensible Good and adapted format (simple and easy to carry in clinical practice) Quicker to complete than other existing questionnaires 	<ul style="list-style-type: none"> Missing elements Instructions (how to complete SAGIT; how to calculate a score) Tool not yet psychometrically validated Acceptance by the scientific and clinical community Recommendations on management based on scores Need for evidence in terms of correlations between SAGIT and prognosis, for recommendation for management Other tools in use in clinical practice Acromegaly quality of life questionnaire Not useful in clinical practice Discrepancies between patient and clinician reporting Already done on everyday basis, without the help of the tool Too short, thus SAGIT risks being Not comprehensive Not informative

Conclusions

- The SAGIT tool was well accepted by endocrinologists, who found it well adapted to clinical practice and useful for their therapeutic decision-making
- Proposed areas for improvement:
 - Add instructions to facilitate the understanding and the use of the tool
 - Define scoring rules and recommendations for patient management based on the scores
- Remove the subjectivity in the severity ranking of the symptoms and associated comorbidities + add a ranking severity scale
- The SAGIT was updated based on the results of pilot testing
- The updated version is currently being pilot tested in a cross-sectional study. Validation of scoring rules will confirm the utility of the tool to improve patient management