EULAR/ACR Provisional Classification Criteria for Polymyalgia Rheumatica

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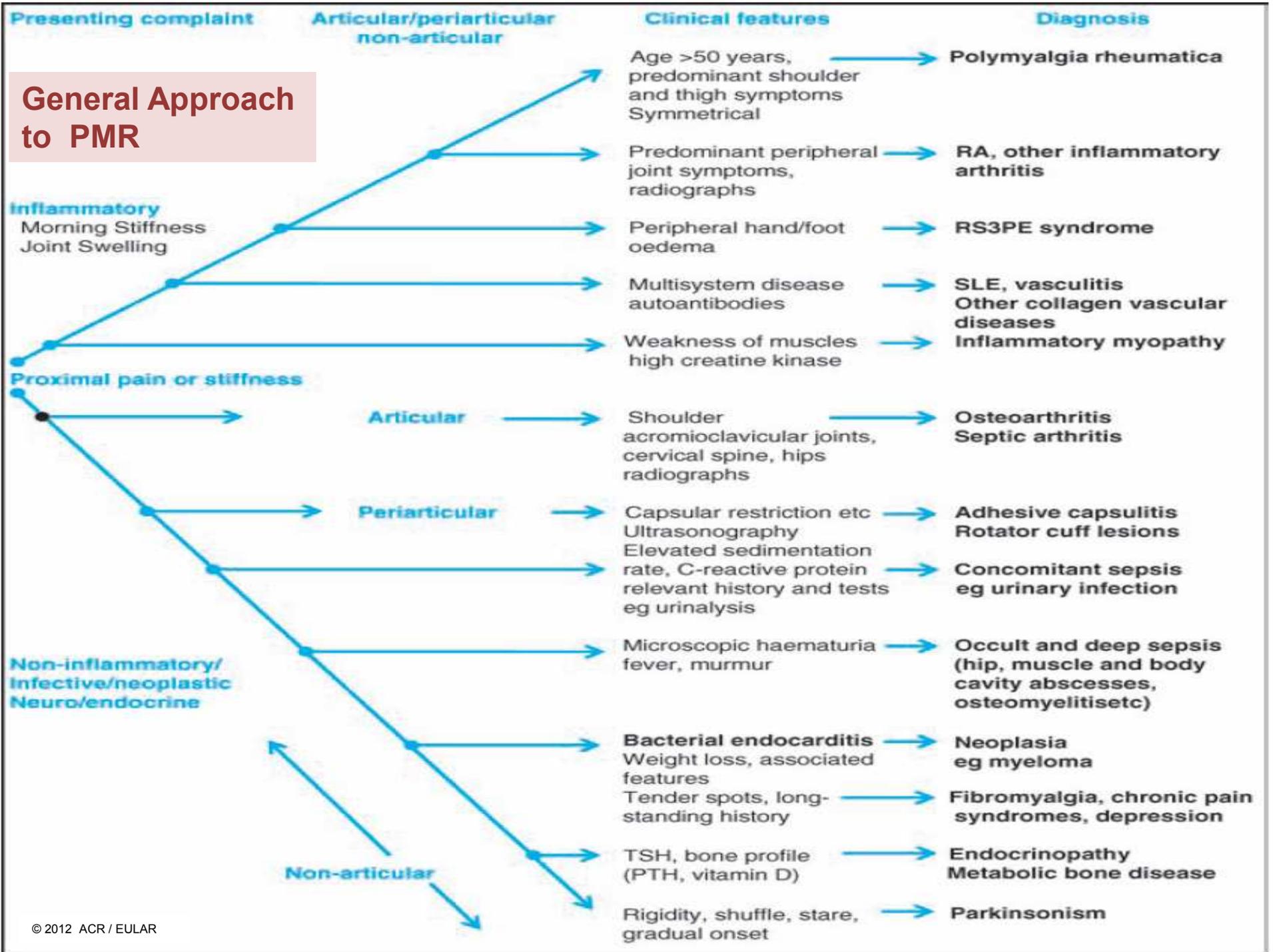EDUCATION · TREATMENT · RESEARCH

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Background

- PMR is the most common inflammatory rheumatic disease of the elderly.

- Accurate diagnosis is difficult in PMR because proximal pain and stiffness syndrome, a commonly accepted phenotype of PMR, can occur in many other rheumatologic and inflammatory illnesses.

- Lack of standardized classification criteria has been a major factor hampering development of rational therapeutic approaches to management of PMR.

Presenting complaint	Articular/periarticular non-articular	Clinical features	Diagnosis

General Approach to PMR

Inflammatory
Morning Stiffness
Joint Swelling

Proximal pain or stiffness

Articular

Periarticular

Non-inflammatory/ Infective/neoplastic Neuro/endocrine

Non-articular

Age >50 years, predominant shoulder and thigh symptoms Symmetrical → **Polymyalgia rheumatica**

Predominant peripheral joint symptoms, radiographs → **RA, other inflammatory arthritis**

Peripheral hand/foot oedema → **RS3PE syndrome**

Multisystem disease autoantibodies → **SLE, vasculitis Other collagen vascular diseases**

Weakness of muscles high creatine kinase → **Inflammatory myopathy**

Shoulder acromioclavicular joints, cervical spine, hips radiographs → **Osteoarthritis Septic arthritis**

Capsular restriction etc Ultrasonography Elevated sedimentation rate, C-reactive protein relevant history and tests eg urinalysis → **Adhesive capsulitis Rotator cuff lesions** → **Concomitant sepsis eg urinary infection**

Microscopic haematuria fever, murmur → **Occult and deep sepsis (hip, muscle and body cavity abscesses, osteomyelitisetc)**

Bacterial endocarditis Weight loss, associated features → **Neoplasia eg myeloma**

Tender spots, long-standing history → **Fibromyalgia, chronic pain syndromes, depression**

TSH, bone profile (PTH, vitamin D) → **Endocrinopathy Metabolic bone disease**

Rigidity, shuffle, stare, gradual onset → **Parkinsonism**

Classification Criteria for PMR are Needed for Major Reasons

- To classify this **clinical syndrome** as a distinct disease entity

- To compare like groups of patients across populations of patients seen in different countries

- To facilitate prediction of disease- and treatment-related outcomes

- To develop management guidelines across different treatment settings

Objective

To develop EULAR/ACR classification criteria for PMR by assessing the performance of candidate criteria in a prospective longitudinal study of patients presenting with **new onset bilateral shoulder pain.**

Methods

- **Candidate inclusion/exclusion criteria** for classification of PMR were defined through a consensus conference and a wider Delphi survey

- **International prospective study** (21 centers in 10 countries) to evaluate the utility of candidate criteria for PMR in patients presenting with the polymyalgic syndrome

- **Study population:** 125 subjects with PMR and 169 comparison subjects with conditions mimicking PMR (49 RA, 29 new-onset seronegative arthritis or connective tissue disease, 52 shoulder conditions, 39 other)

- **Follow-up:** Baseline, weeks 1, 4, 12 and 26

- **Statistical analyses:** chi-square and rank sum tests, logistic regression models, concordance c statistic, factor analyses, classification trees, gradient boosting regression tree models

Study Design

New-onset PMR cases → PMR cases

~15-17%

Potential control subjects → Non-PMR controls

~10%

Baseline — 1 week — 4 weeks — 12 weeks — 26 weeks

Measurements
- Demographics
- Vital signs
- Weight, height
- Family history
- Clinical history
- Labs
- Steroid therapy
- Physician&patient
  -based measures
- Ultrasound

Measurements
- Labs
- Steroid therapy
- Physician&patient
  -based measures

Measurements
- Labs
- Steroid therapy
- Physician&patient
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Univariate Logistic Regression Models to Distinguish PMR Subjects from Comparison Subjects

Variable	PMR vs. All Comparison Subjects		PMR vs. RA		PMR vs. Shoulder Conditions*	
	OR (95% CI)	C	OR (95% CI)	C	OR (95% CI)	C
Duration of symptoms ≥2 weeks	1.1 (0.3, 4.0)	0.50	1.3 (0.2, 7.3)	0.50	0.6 (0.1, 5.4)	0.51
Shoulder pain or limited range of motion	2.1 (0.7, 6.8)	0.52	1.3 (0.2, 7.3)	0.50	1.9 (0.4, 8.6)	0.51
Shoulder tenderness	1.1 (0.7, 1.9)	0.51	0.7 (0.3, 1.7)	0.52	1.8 (0.9, 3.6)	0.56
Hip pain or limited range of motion	2.5 (1.5, 3.9)	0.61	3.0 (1.5, 6.0)	0.63	4.4 (2.1, 9.1)	0.67
Hip tenderness	2.3 (1.4, 3.8)	0.60	2.8 (1.3, 5.8)	0.61	4.3 (1.9, 9.5)	0.65
Neck aching	1.1 (0.7, 1.8)	0.51	0.9 (0.5, 1.8)	0.51	1.2 (0.6, 2.3)	0.52
Morning stiffness >45 minutes	4.5 (2.6, 7.7)	0.67	1.5 (0.7, 3.3)	0.54	13.6 (6.0, 31)	0.79
Weight loss > 2kg	1.8 (1.1, 3.0)	0.56	1.2 (0.6, 2.4)	0.52	6.8 (2.3, 19.9)	0.64
Carpal tunnel syndrome	1.0 (0.5, 1.8)	0.50	0.6 (0.3, 1.5)	0.54	--	--
Peripheral synovitis	0.7 (0.5, 1.2)	0.54	0.1 (0.08, 0.3)	0.72	2.4 (1.1, 5.0)	0.59
Other joint pain	0.5 (0.3, 0.9)	0.57	0.2 (0.1, 0.4)	0.67	0.8 (0.4, 1.5)	0.53
Abnormal ESR or CRP	13.8 (5.3, 36)	0.67	4.0 (1.2, 13)	0.55	33.5 (11, 98)	0.78
Abnormal RF or ACPA	0.4 (0.2, 0.7)	0.57	0.2 (0.07, 0.4)	0.66	0.9 (0.3, 2.6)	0.51
Abnormal serum protein electrophoresis	2.0 (1.1, 3.6)	0.58	1.9 (0.8, 4.8)	0.58	2.0 (0.8, 5.1)	0.59
MHAQ (per 1 unit increase)	2.3 (1.6, 3.4)	0.66	1.3 (0.7, 2.2)	0.55	6.7 (3.2, 14)	0.78

Univariate Logistic Regression Models to Distinguish PMR Subjects from Comparison Subjects

- Criteria items related to hip involvement have significant ability to discriminate PMR from all comparison subjects.

- Early morning stiffness, Modified Health Assessment Questionnaire (MHAQ), weight loss, and raised laboratory markers distinguish PMR from comparison subjects, particularly those with shoulder conditions.

- Presence of ACPA or RF, peripheral synovitis and joint pains have significant ability to distinguish PMR from RA.

- Shoulder pain and abnormal ESR/CRP were defined as required criteria in the scoring algorithm for PMR.

Multivariable Logistic Regression Models

Criterion	Model based on factors		Model based on factors w/o shoulder tenderness plus abnormal RF/ACPA		Model based on factors plus abnormal RF/ACPA and MHAQ	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Pain/ limited hip range of motion	2.7 (1.5, 4.8)	0.001	2.1 (1.1, 4.0)	0.019	1.6 (0.8, 3.2)	0.16
Other joint pain	0.4 (0.2, 0.6)	<0.001	0.4 (0.2, 0.7)	0.002	0.3 (0.1, 0.6)	<0.001
Morning stiffness > 45 min	5.2 (2.9, 9.4)	<0.001	6.2 (3.2, 11.8)	<0.001	4.8 (2.4, 9.6)	<0.001
Shoulder tenderness	0.9 (0.5, 1.8)	0.80				
Abnormal RF/ACPA			0.3 (0.1, 0.8)	0.009	0.3 (0.1, 0.8)	0.013
MHAQ, per 1 unit					2.4 (1.4, 4.2)	0.002
Likelihood ratio test for additional terms			P<0.001		P<0.001	

Three multivariable models were considered. The second model shown in table above (with hip pain, other joint pain, morning stiffness, and abnormal RF/ ACPA) was the best multivariate logistic regression model.

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Scoring Algorithm without Ultrasound – *3 required criteria: age ≥50 years, bilateral shoulder aching, abnormal ESR/CRP*

Optional classification criteria	OR (95% CI)	Points
Morning stiffness >45 minutes	6.2 (3.2, 11.8)	2
Hip pain or limited range of motion	2.1 (1.1, 4.0)	1
Normal RF or ACPA	3.0 (1.3, 6.8)	2
Absence of other joint pain	2.7 (1.4, 5.0)	1

- **Optimal cut-off point = 4**
- A score of 4 had 72% sensitivity and 65% specificity for discriminating all comparison subjects from PMR.
- The specificity was higher (79%) for discriminating shoulder conditions from PMR and lower (61%) for discriminating RA from PMR.
- The c-statistic for the scoring algorithm was 75%.
- A total of 34 (28%) PMR cases and 59 (35%) of comparison subjects were incorrectly classified.

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Scoring Algorithm with Ultrasound – *3 required criteria:*
age ≥50 years, bilateral shoulder aching, abnormal ESR/CRP

Optional classification criteria	OR (95% CI)	Points
Morning stiffness >45 minutes	5.0 (2.8, 9.1)	**2**
Hip pain, limited range of motion	1.4 (0.8, 2.6)	**1**
Normal RF or ACPA	5.2 (2.1, 12.6)	**2**
Absence of other joint pain	2.2 (1.3, 4.0)	**1**
ULTRASOUND CRITERIA		
At least 1 shoulder with subdeltoid bursitis and/or biceps tenosynovitis and/or glenohumeral synovitis AND at least 1 hip with synovitis and/or trochanteric bursitis	2.6 (1.3, 5.3)	**1**
Both shoulders with subdeltoid bursitis, biceps tenosynovitis or glenohumeral synovitis	2.1 (1.2, 3.7)	**1**

Optimal cut-off point = 5

- A score 5 had 71% sensitivity and 70% specificity for discriminating all comparison subjects from PMR.
- The specificity was higher (86%) for discriminating shoulder conditions from PMR and lower (65%) for discriminating RA from PMR.
- The c-statistic for the scoring algorithm was 78%.
- A total of 32 (29%) PMR cases and 47 (30%) of comparison subjects were incorrectly classified.

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Conclusions

- Patients >50 years old presenting with new bilateral shoulder pain (not better explained by an alternative diagnosis) and elevated CRP/ESR can be classified as having PMR in the presence of morning stiffness >45 min, and new hip involvement in the absence of peripheral synovitis or positive RA serology.

- Ultrasound findings of bilateral shoulder abnormalities or abnormalities in one shoulder and hip may significantly improve both sensitivity and specificity of the clinical criteria.

- Determining the utility of the criteria will require clinic-based studies in the primary and specialty care settings.

- Development of better disease biomarkers is needed for diagnosis and activity assessment in PMR.

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Blinded Multi-rater Evaluation of Diagnosis and Candidate Classification Criteria for Polymyalgia Rheumatica

Background

- Polymyalgia rheumatica (PMR) is a common inflammatory rheumatic disease of the elderly, and there is considerable uncertainty in diagnosis of PMR.

- Following a large international study for classification of PMR, the investigators performed a formal diagnostic re-evaluation of candidate classification criteria.

Objective

To assess multi-rater discrimination of polymyalgia rheumatica (PMR) from other conditions mimicking PMR

Methods

- 23 investigators blindly rated 30 patient profiles (10 PMR cases and 20 controls)

- Data provided: clinical features, examination findings (i.e., restricted shoulder/hip movement, synovitis), inflammatory markers, RF, anti-CCP serology and steroid response

- Each criteria was rated on a 5-point scale reflecting the degree of confidence of a PMR diagnosis
  - 1=strongly influences diagnosis of PMR
  - 5=strongly influences the diagnosis was *not* PMR
  - See weighting scale

Methods

- Investigators were asked to provide a diagnosis of PMR or other condition and indicate whether they would enter such a subject in a clinical trial.

- A mean rating across all raters was taken in order to assess the diagnostic accuracy of each candidate criteria.

- A composite score was used to determine the areas under the ROC curve (AUC) and c-statistic.

- Patients were categorized into 3 groups based on raters' misclassification rates.
    - Group 1: greater than 50% misclassified
    - Group 2: 20%- 50% misclassified
    - Group 3: less than 20% misclassified

Results

- Misclassification proportion was high in 10 of the 30 patients.

- **Group 1: >50% misclassified** (n=3, 1 case, 2 control subjects) – Factors that contributed to the misclassification were normal (either ESR and/or CRP), poor or ill-sustained corticosteroid response and RF positivity without peripheral synovitis.

- **Group 2: 20-50% misclassified** (n=7; 4 cases, 3 controls) – Misclassification was related to persistent synovitis, lack of complete/sustained corticosteroid response, RF or CCP positivity and low baseline ESR and/or CRP.

- The AUC c-statistic suggested that gender, duration of symptoms, systemic symptoms such as weight loss, neck pain, limitation of movement and serum electrophoresis were unhelpful to the blinded rater, in discriminating cases from controls (c-statistic < 0.8 in all).

- Bilateral hip pain, morning stiffness, ESR and CRP levels (pre- and especially post-CS), and corticosteroid response were good discriminators of cases from controls (c-statistic > 0.8 in all; see Table in next slide).

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Conclusions

- A significant proportion of cases/controls are difficult to classify.

- A stepped diagnostic process and most candidate criteria items perform well in discriminating PMR cases from controls.

- Questions that require further investigation:
  - Does PMR always adequately respond to steroids?
  - Can polymyalgic RF-positive disease without peripheral synovitis occur?

Patient-reported Outcome Measures in Patients with Polymyalgia Rheumatica:

Results from an international, prospective, multi-center study

Background

- There is considerable uncertainty in classification and continued evaluation of patients with PMR.

- PMR may have a heterogeneous disease course.

- Patient-reported outcome measures are routinely used in clinical practice and research studies of patients with rheumatic diseases.

- The value of patient-reported outcome measures for outcome assessment in PMR is unknown.

- It is also unknown whether patient-reported outcome measures in PMR correlate with steroid response and inflammatory markers.

Objective

To evaluate the disease course and performance of patient-reported outcome measures in patients with PMR

Methods

- **Study population:** 112 patients with new onset PMR

- **Corticosteroid treatment:** Prednisolone/ prednisone dose of 15 mg daily and tapered gradually over 26 weeks

- **Follow-up:** Clinical and questionnaire-based assessments at baseline and weeks 1, 4, 12 and 26 following start of steroid therapy

- **Measurements:** Personal and family history, clinical signs and symptoms, laboratory results, treatment details, ultrasound evaluation of shoulders and hip, disability (MHAQ), quality of life (SF36), and patient-reported outcomes (PRO) of global pain, PMR pain, shoulder pain and fatigue obtained using visual analogue scales (VAS)

- **Statistical analysis:** Spearman methods were used to assess correlations between improvement measures

Results

- **Initial presentation:** 99% patients had shoulder pain and 71% had hip pain. Median duration of morning stiffness was 120 minutes with median global pain VAS 60.5, median MHAQ 1.1, fatigue VAS 60. 98% patients had abnormal CRP or ESR.

- **Δ at 4 weeks:** All PRO parameters improved dramatically (70% improvement) in the majority of the patients. 71% of patients for global VAS, 74% for PMR VAS and 56% for fatigue VAS. 64% of patients had normal CRP/ESR values at 4 weeks.

- **MHAQ:** Median change in MHAQ from baseline to 4 weeks was -0.875. Median change from baseline to 26 weeks was -1.0. The sections of MHAQ that are particularly influenced by early morning stiffness such as rising, dressing, reaching showed very significant change (p< 0.001) with treatment.

Results

- **SF 36 PCS:** The physical QOL as measured by physical component score (PCS) of the SF-36 showed severe impairment at baseline (35). This was lower than values typically seen in other rheumatic diseases such as RA. PCS showed a dramatic improvement with corticosteroid therapy, reaching 41 at 4 weeks and 48 at 12 weeks.

- **SF 36 MCS:** The mental component score (MCS) did not show any impairment at baseline and remained relatively stable throughout follow-up.

Clinical and Patient-Reported Outcomes in Patients with PMR

	Baseline (N=112)	Week 1 (N=108)	Week 4 (N=109)	Week 12 (N=108)	Week 26 (N=108)	p value
Shoulder pain	111 (99)	63 (61)	39 (36)	31 (29)	24 (23)	<0.001
Hip pain	79 (71)	26 (25)	15 (14)	8 (8)	11 (10)	<0.001
Global pain VAS, median (IQR)	60.5 (47, 80)	22.5 (8.5, 45)	7.0 (2.0, 18.0)	4.0 (1.0, 13.0)	5.0 (1.0, 19.0)	<0.001
Morning stiffness duration (min), median (IQR)	120 (60, 240)	7.5 (0, 30)	0 (0, 10)	0 (0, 0)	0 (0, 0)	<0.001
MHAQ, median (IQR)	1.1 (0.8, 1.6)	0.4 (0.1, 0.8)	0.1 (0, 0.4)	0 (0, 0.1)	0 (0, 0.1)	<0.001
Fatigue VAS, median (IQR)	60 (35, 78)	26 (7, 44)	9 (2, 30)	8 (1, 24)	4 (2, 22)	<0.001
PCS SF36, median (IQR)	35 (31, 39)	41 (35, 46)	46 (41, 50)	48 (43, 51)	48 (41, 51)	<0.001
MCS SF36, median (IQR)	47 (42, 53)	46 (41, 51)	48 (43, 53)	48 (44, 52)	46 (45, 53)	0.025
Abnormal ESR	94 (88)	42 (57)	25 (29)	28 (30)	21 (25)	<0.001
Abnormal CRP	98 (95)	26 (41)	17 (25)	21 (26)	14 (19)	<0.001
Prednisone dosage, median (IQR)	15 (15, 15)	15 (15, 15)	12.5 (12.5, 12.5)	8.8 (7.5, 10)	5.0 (5, 7.5)	<0.001
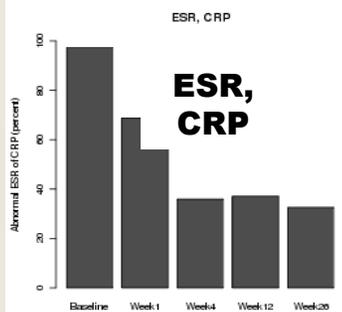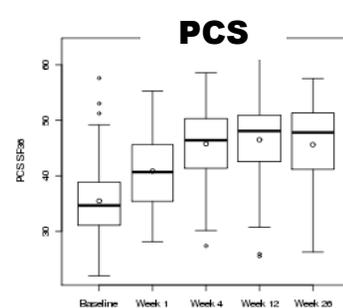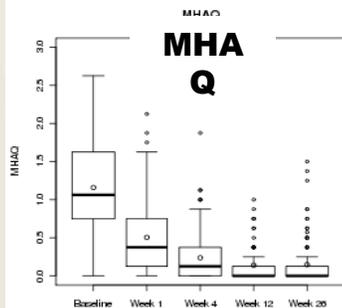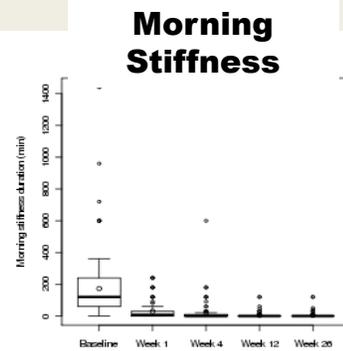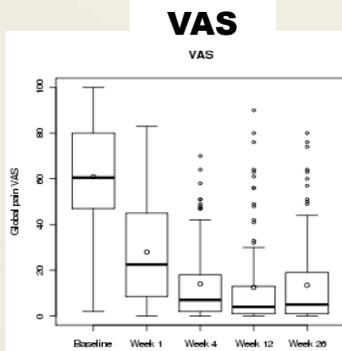
Change in patient-reported outcomes and ESR/CRP over time

Algorithm score versus steroid response in PMR: Lack of association confirms why steroid responsiveness cannot be used as criteria item

Comparison of score (<4 vs. ≥4) by algorithm and response* at 4 weeks		
Score	**Did not respond**	**Responded**
< 4	12 (32%)	25 (68%)
≥ 4	16 (27%)	44 (73%)
Chi-square test p=0.54		

Comparison of score by algorithm and response* at 4 weeks		
1	3 (60%)	2 (40%)
2	3 (38%)	5 (62%)
3	6 (25%)	18 (75%)
4	6 (32%)	13 (68%)
5	7 (35%)	13 (65%)
6	3 (14%)	18 (86%)
Spearman correlation coefficient examining the association between score by algorithm (continuous) and percent improvement (continuous) is 0.12 (p=0.24)		

Comparison of score (<4 vs. ≥4) by algorithm and response* at 26 weeks		
< 4	5 (20%)	20 (80%)
≥ 4	10 (23%)	34 (77%)
Chi-square test p=0.79		

Conclusions

- Patient-reported outcome measures, including MHAQ, global, PMR and fatigue VAS, and inflammatory markers, perform well in assessing disease activity in PMR.

- Percent improvement in patient-reported outcome measures are highly correlated with each other, but ESR and CRP correlate less strongly.

- A minimum set of outcome measures consisting of measures of shoulder pain and function and an inflammatory marker can be used in practice and clinical trials in PMR.

Utility of Ultrasound in the Classification Assessment of Shoulder Pain in
Polymyalgia Rheumatica:
Results From an International, Prospective,
Multi-Center Longitudinal Study

Background

- Polymyalgia rheumatica (PMR) is the most common inflammatory rheumatic disease of the elderly.

- There is considerable uncertainty in classification of PMR.

- Musculoskeletal ultrasound has become an important tool in clinical practice in rheumatology, and has demonstrated value across a range of rheumatic conditions.

- The classification value of ultrasound in distinguishing PMR from other conditions mimicking PMR is unknown.

Objective

To evaluate the performance of musculoskeletal ultrasound in the initial assessment and follow up of patients aged 50 years and over presenting with recent onset bilateral shoulder pain
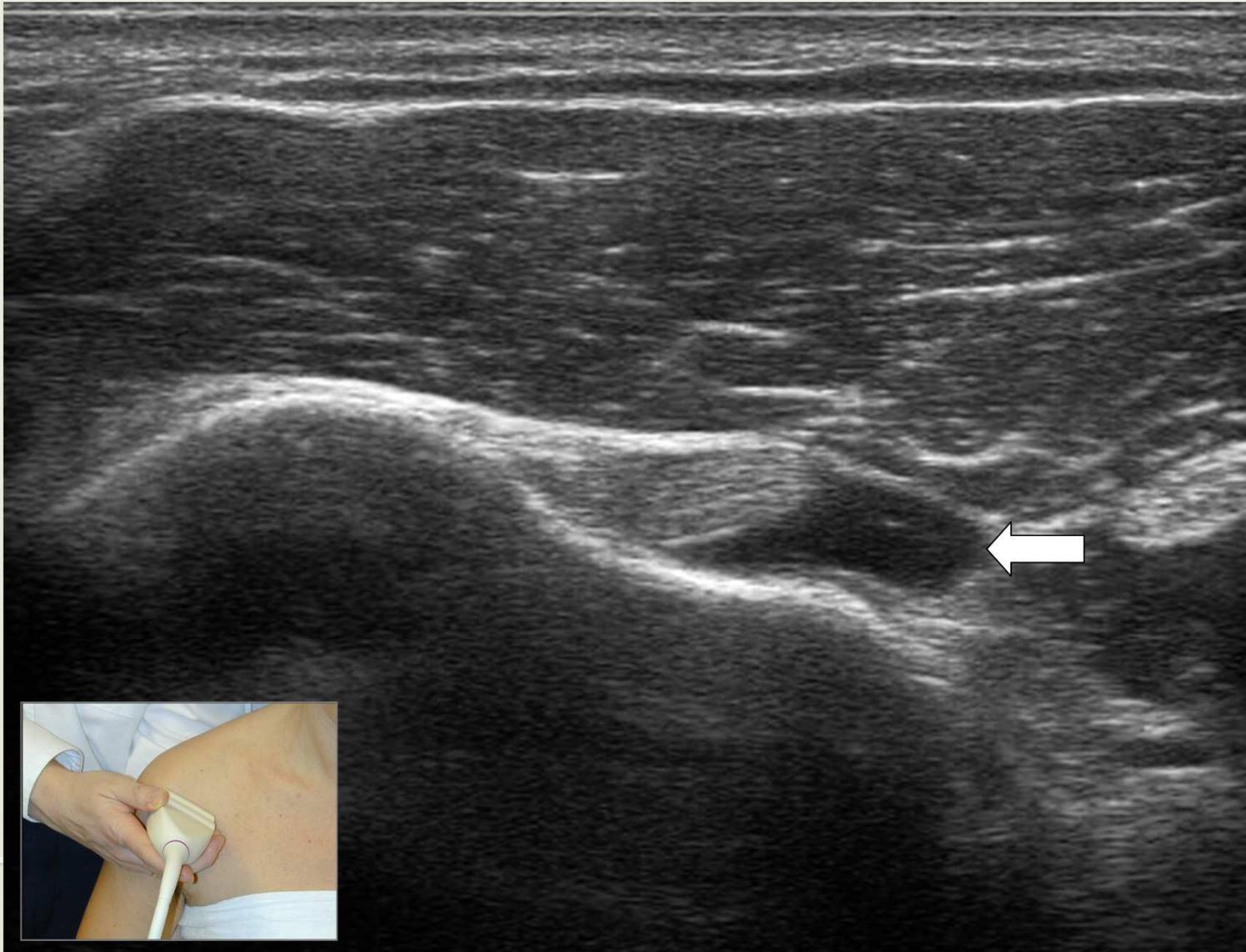
Methods

- **Study population:**
  - 120 patients with PMR
  - 154 control subjects with newly diagnosed conditions mimicking PMR including:
    - 46 RA with shoulder involvement
    - 47 non-RA shoulder conditions
    - 21 controls without shoulder pain or known shoulder condition

- **Standard ultrasound protocol developed** as part of a 6-month prospective study and included assessment of subdeltoid bursitis, biceps tenosynovitis, glenohumeral or hip synovitis, and trochanteric bursitis.

- A preceding **training and standardization exercise of operators at different sites in the study** demonstrated very good inter-center comparability of results.

Ultrasound Findings

	PMR (N=120)	All Controls (N=154)	RA with Shoulder Involvement (N=46)	Non-RA Shoulder Condition (N=47)	Controls without Shoulder Conditions (N=21)
At least ONE shoulder with subdeltoid bursitis, biceps tenosynovitis, or glenohumeral synovitis	83%	70%**	78%	62%**	19%**
BOTH shoulders with subdeltoid bursitis, biceps tenosynovitis, or glenohumeral synovitis	59%	43%**	65%	26%**	0%**
At least ONE shoulder with subdeltoid bursitis or biceps tenosynovitis	82%	63%**	72%	53%**	19%**
BOTH shoulders with subdeltoid bursitis or biceps tenosynovitis	57%	35%**	52%	21%**	0%**
At least ONE hip with synovitis or trochanteric bursitis	38%	23%*	30%	18%*	0%**
BOTH hips with synovitis or trochanteric bursitis	19%	8%**	9%	4%	0%*
At least ONE shoulder and ONE hip with findings as above	33%	16%**	17%	11%**	0%**
BOTH shoulder and BOTH hips with findings as above	12%	7%	6%	2%*	0%

*p<0.05; **p<0.01 compared to PMR

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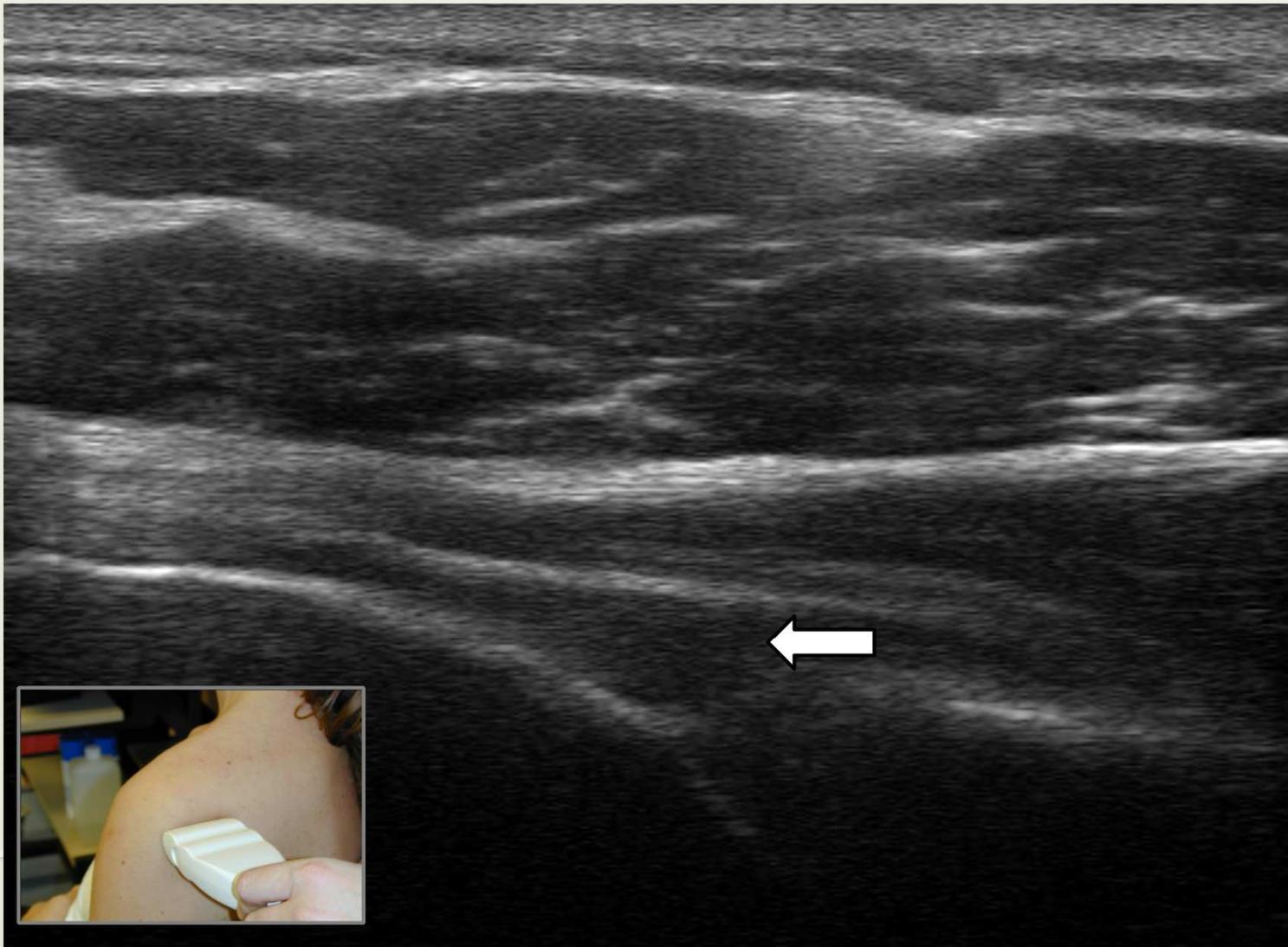EDUCATION · TREATMENT · RESEARCH

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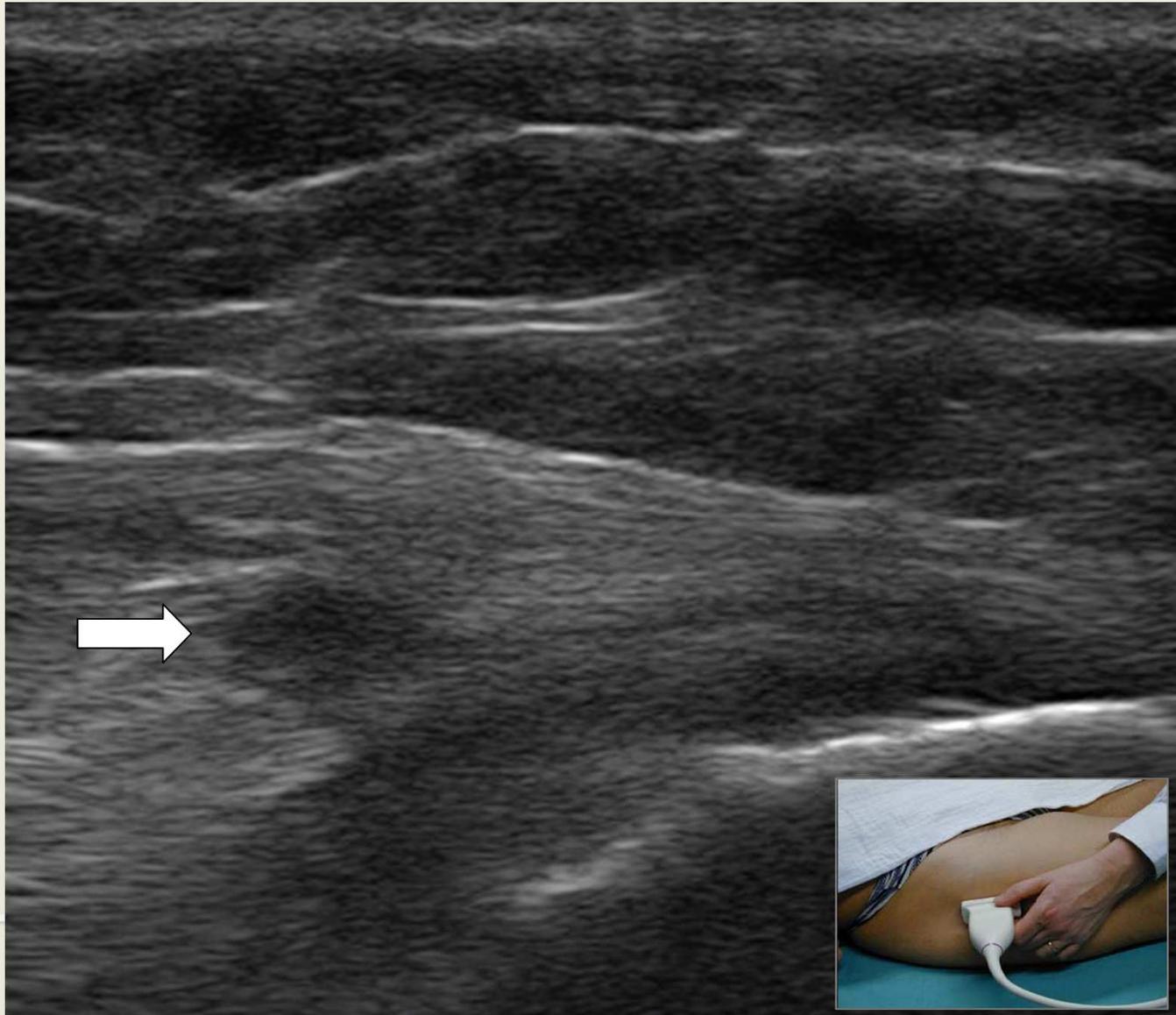# Biceps longus tenosynovitis (transverse)
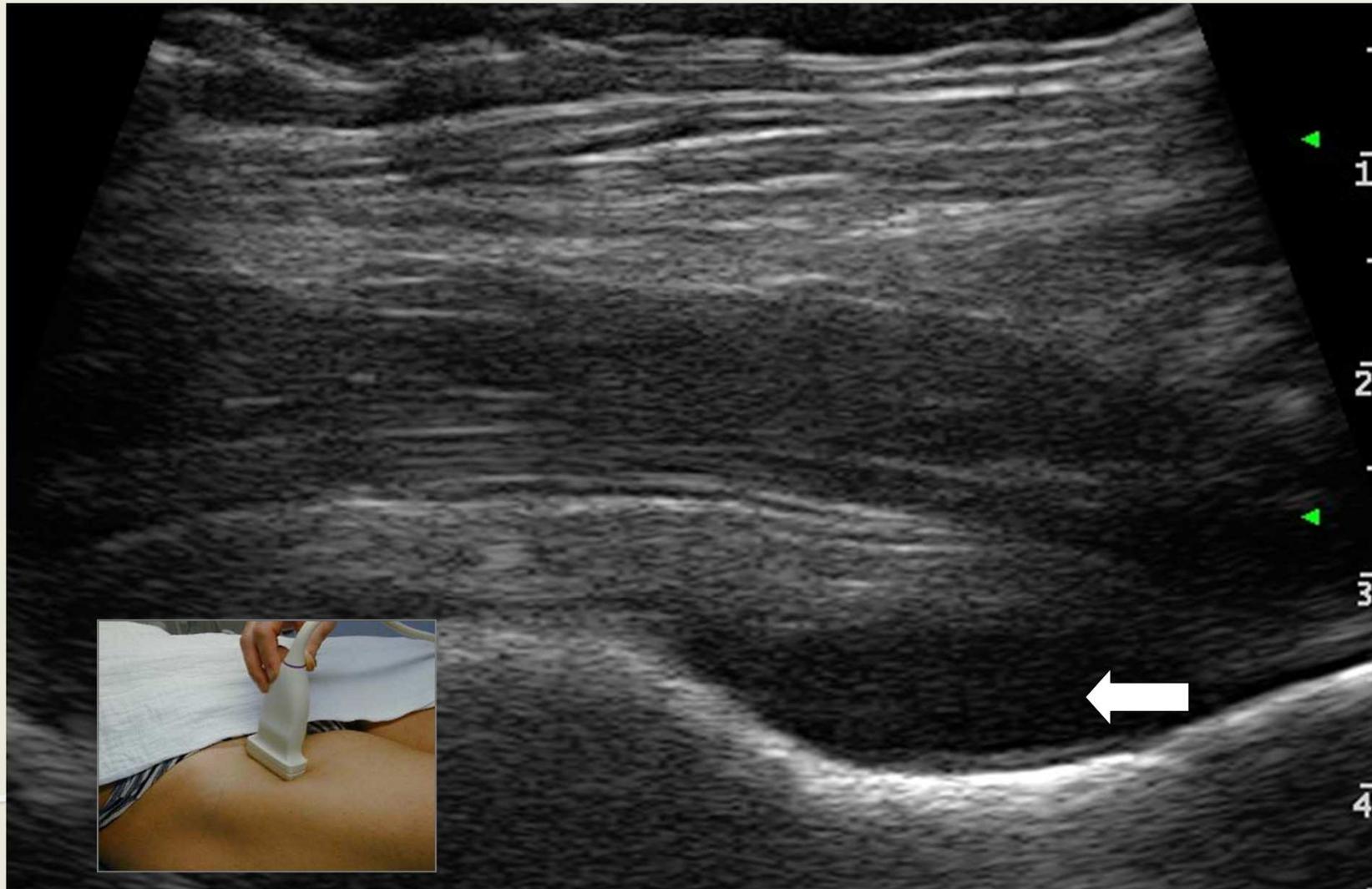
Subdeltoid bursitis

Glenohumeral joint effusion (from dorsal)

Trochanteric bursitis

Hip joint effusion

Results

- Patients with PMR were more likely to have abnormal ultrasound findings in the shoulder (particularly subdeltoid bursitis and biceps tenosynovitis), and somewhat more likely to have abnormal findings in the hips than control subjects, as a group.

- PMR could not be distinguished from RA on the basis of ultrasound, but could be distinguished from non-RA shoulder conditions and subjects without shoulder conditions.

Conclusions

- In this largest and first multicenter study of ultrasound in PMR, most subjects with PMR have abnormal findings on shoulder ultrasound.

- Ultrasound has limited value in distinguishing PMR from RA, but has value in discriminating PMR from other conditions associated with shoulder pain.

- Ultrasound of the shoulders and hips may have added value for classification as PMR.