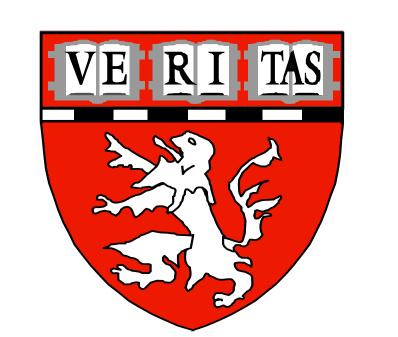
# The Role of Objective Measures vs. Patient Reported Outcomes (PROs) as a Reflection of Flares in Patients with RA: Results from the Brigham RA Sequential Study (BRASS)



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## Introduction

BRASS

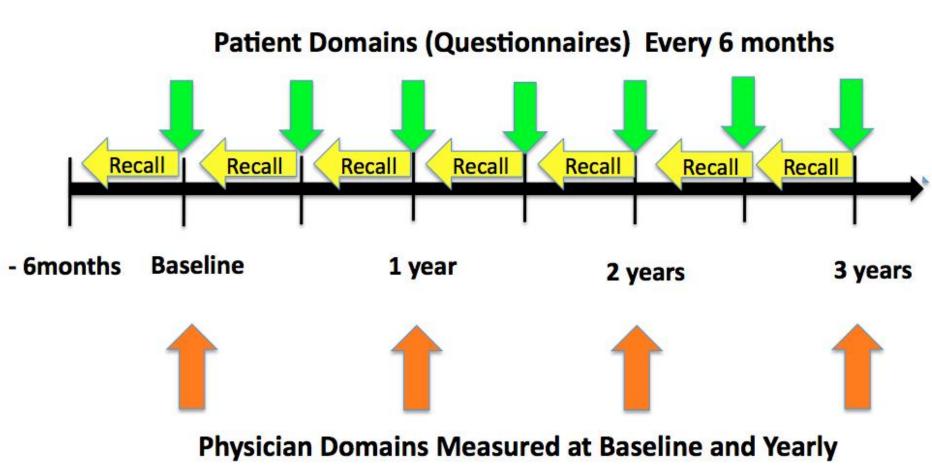
- Worsening of disease activity or RA flare can be severe enough to warrant a change of therapy.
- Little is known about how frequently flares occur in RA or which measures best reflect a flare of RA.

#### Aims

- To describe frequency of self-reported flares in a population of patients with RA
- To determine which variables best relate to patients' recall of flare in the prior 6 months.

### Methods

- Eligible subjects: RA patients enrolled in a prospective single- academic center observational cohort (BRASS)
- RA patients treated according to preference of their rheumatologist
- Patients questioned every 6 months if they'd had a flare of their disease, what the duration was and how the flare was treated



- Variables analyzed included patient reported outcomes (PROs), composite indices of disease activity and laboratory measures
- Statistical Analysis
  - Univariate logistic regression analyses using generalized estimating equations (GEE) were performed to determine possible variables associated with flares over the next 6 months
  - Disease measures with a p<0.10 were included in a multiple logistic regression model using GEE (model 1). Additional multiple logistic regression models were performed with PROs alone (model 2) and with physician measures alone (model 3)

#### Results

- Of 1095 RA patients, 567 with 3 yrs follow-up reporting at least one flare were included for this analysis
- Variables significantly associated with recall of flare in the multivariate analysis overall, were pain, physician global, tender joint count (TJC), and age

## Results

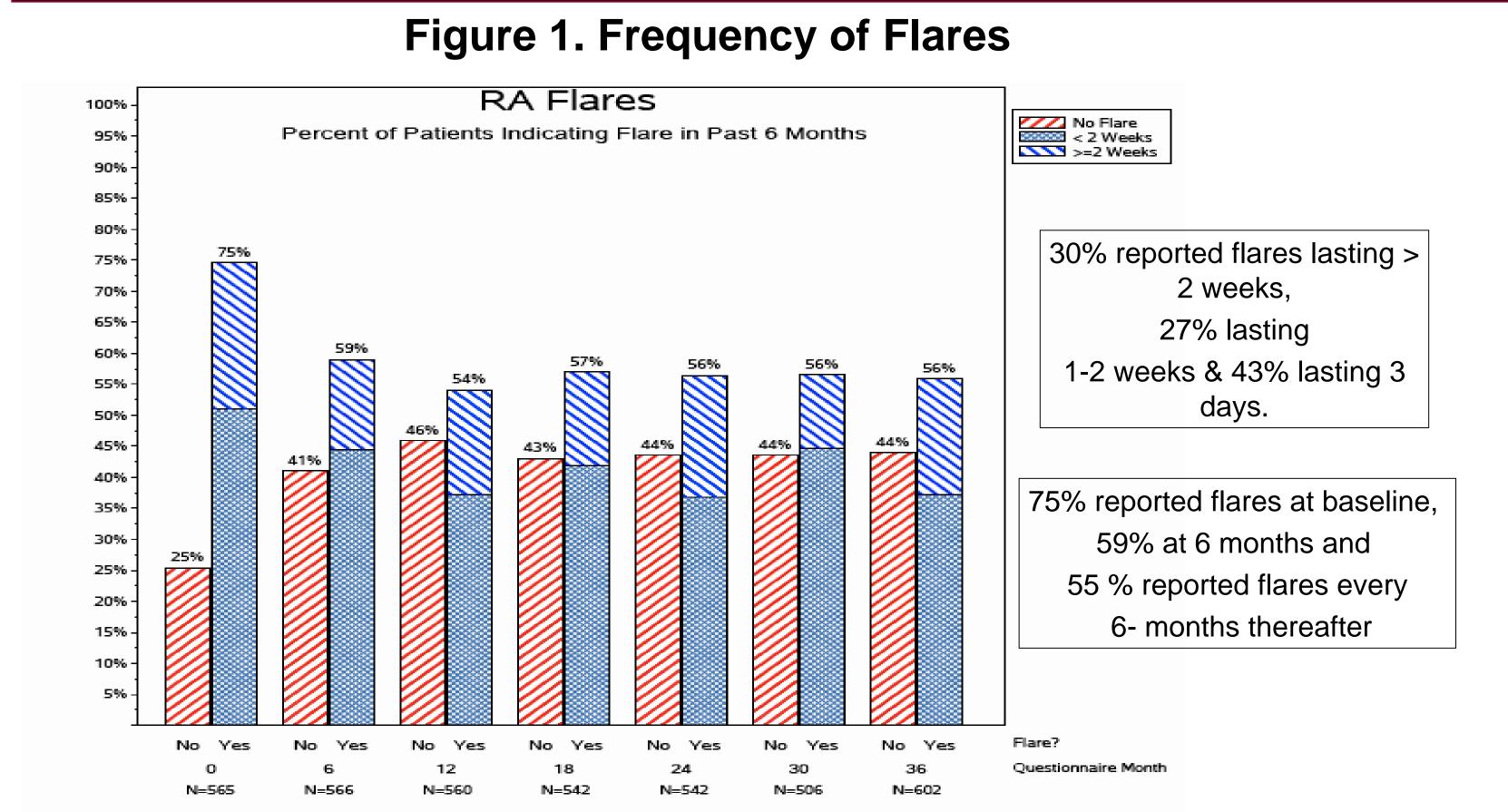


Figure 2. Medication Use in Patients Reporting Flares

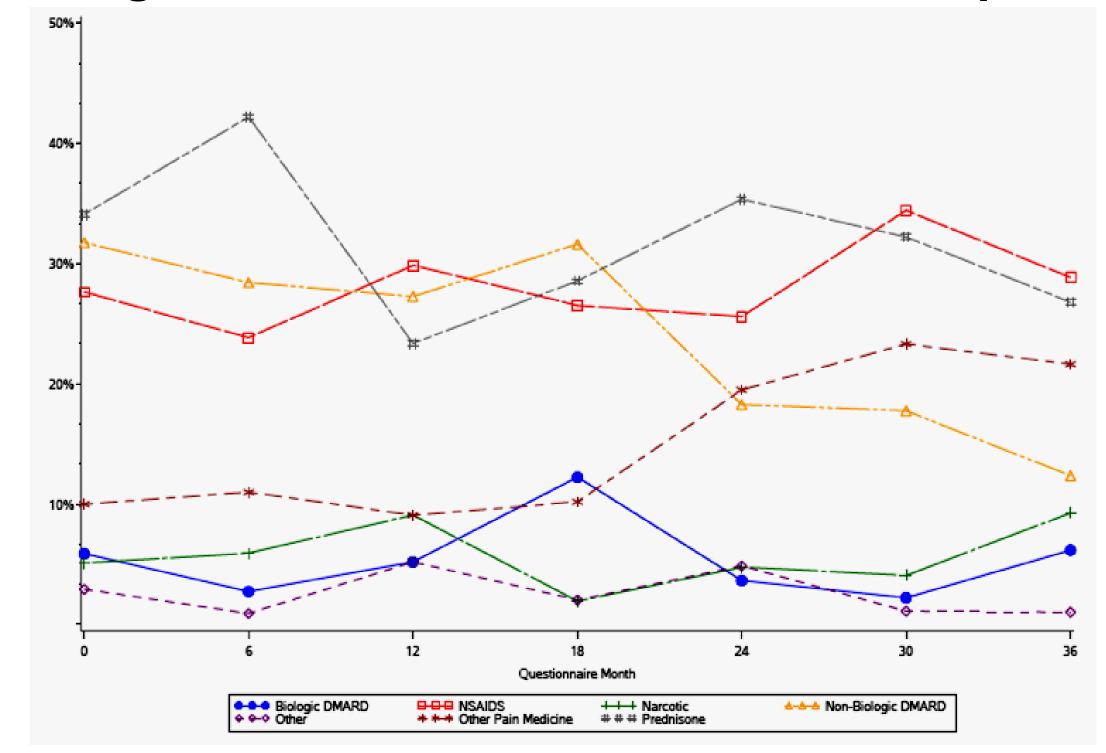


Table 1. Baseline Characteristics –Patients Reporting Flares vs. No Flares

|                                 | Flare (SE) | No Flare (SE) | P-Value |
|---------------------------------|------------|---------------|---------|
| Age                             | 56.3 0.6   | 57.9 1.1      | 0.1780  |
| Female                          | 85.1 0.02  | 85.4 0.03     | 0.9280  |
| Disease Duration (years)        | 13.9 0.6   | 15.6 1.0      | 0.1217  |
| Caucasian (%)                   | 93.3 0.01  | 93.7 0.02     | 0.8717  |
| Tender Joint Count (0-28)       | 9.3 0.4    | 7.2 0.6       | 0.0078  |
| Swollen Joint Count (0-28)      | 8.2 0.4    | 7.5 0.6       | 0.3269  |
| Physical Function (0-3) (MDHAQ) | 0.7 0.03   | 0.4 0.03      | <.0001  |
| Pain Scale (0-100) (MDHAQ)      | 40.5 1.4   | 21.4 1.8      | <.0001  |
| Physician Global Scale (0-100)  | 38.2 1.1   | 24.7 1.6      | <.0001  |
| Patient Global Scale (0-100)    | 34.5 1.2   | 19.9 1.6      | <.0001  |
| CRP (mg/L)                      | 9.9 1.0    | 6.7 0.9       | 0.0708  |
| RF/CCP (%)                      | 73.5 0.02  | 74.3 0.04     | 0.8540  |

Table 2. Variables which predict a flare over the next 6 months \*

| Multivar | riate | Regress | sion)         |
|----------|-------|---------|---------------|
|          |       |         | <b>5.0.</b> , |

| Model 1 - All Measures:            |            |              |              |         |
|------------------------------------|------------|--------------|--------------|---------|
| Variable                           | Odds Ratio | Lower 95% CI | Upper 95% CI | P value |
| Age                                | 0.9889     | 0.977        | 1.001        | 0.0716  |
| CRP                                | 0.9964     | 0.9877       | 1.0053       | 0.4298  |
| <b>Emotional Distress FSM15</b>    | 0.9879     | 0.9787       | 0.9973       | 0.0119  |
| Patient Global (MDHAQ Scale)       | 0.9951     | 0.9863       | 1.0039       | 0.2733  |
| Pain (MDHAQ Pain Scale)            | 1.0131     | 1.0046       | 1.0218       | 0.0026  |
| Tender Joint Count (0-28)          | 0.974      | 0.9434       | 1.0056       | 0.1061  |
| Physician Global                   | 1.0137     | 1.0041       | 1.0234       | 0.0052  |
| AM Stiffness                       | 1.3999     | 1.0241       | 1.9138       | 0.0349  |
| Swollen Joint count (0-28)         | 1.0065     | 0.9749       | 1.0392       | 0.6889  |
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#### **Model 2 - Patient Reported Measures:**

| Variable                        | Odds Ratio | Lower 95% CI | Lower 95% CI | P value |
|---------------------------------|------------|--------------|--------------|---------|
| Age                             | 0.9873     | 0.9758       | 0.999        | 0.0339  |
| <b>Emotional Distress FSM15</b> | 0.9896     | 0.9807       | 0.9987       | 0.0246  |
| Patient Global (MDHAQ scale)    | 0.9968     | 0.9885       | 1.0051       | 0.4453  |
| Pain                            | 1.014      | 1.006        | 1.022        | 0.0006  |
| AM Stiffness                    | 1.5421     | 1.134        | 2.0971       | 0.0058  |
|                                 |            |              |              |         |

#### Model 3 - Physician Measures:

| Variable                  | Odds Ratio | Lower 95% CI | Lower 95% CI | P value |
|---------------------------|------------|--------------|--------------|---------|
| Age                       | 0.9856     | 0.9758       | 0.9954       | 0.0041  |
| CRP                       | 1.0051     | 0.9985       | 1.0117       | 0.1297  |
| Tender Joint Count (0-28) | 0.9946     | 0.9738       | 1.0158       | 0.6158  |
| Physician Global          | 1.0198     | 1.013        | 1.0267       | <.0001  |
| Swollen Joint count (28)  | 0.9964     | 0.9749       | 1.0183       | 0.7426  |

<sup>\*</sup> Odds Ratios by GEE

#### Limitations

- Patients' information on flare is subject to recall bias
- Patients with active disease may be more likely to report flare

#### Conclusions

- Patient self reported flares are frequent in RA
- Over 50% last at least 1 week
- Patients who flare are more likely to use steroids, pain medications and or narcotics
- Patient pain VAS, physician global and TJC best reflect flare in patients with RA
- When considering PROs, only pain independently associates with flare over time

# Acknowledgements

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