Minimally important change on the Roland Morris Disability Questionnaire

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Background

- At an individual level, the imprecision of the Roland Morris Disability Questionnaire (RMDQ) exceeds its minimally important change (MIC)
- Using the minimal detectable change (MDC) for an individual as a proxy for MIC leads to spurious results; too few patients achieve such large magnitudes of change
- Following a review of both properties, there is consensus that five points or 30% change from baseline is an appropriate threshold by which to judge individual responders to treatment
- This was intended to be re-evaluated as further data become available
- Different methodologies exist for estimating MIC using ROC curves
- We estimated MIC and MDC for the RMDQ, using data from the UK Back Pain Exercise and Manipulation (BEAM) a large trial of physical therapies for low back pain

• Objectives

- To estimate MIC (improvement and deterioration) and MDC for the RMDQ
- To compare two suggested methods for estimating MIC:

  $min\{sens - spec\}$ versus $min\{1\text{-}sens +1\text{-}spec\}$

Materials and methods

- Data from the 1,334 patients enrolled in the UK BEAM trial who completed the RMDQ at baseline, and three months
- MIC estimated for improvement and deterioration, using ROC curves and a seven-point transition question
- Heteroskedasticity of SE explored as a function of bootstrap replications, then CIs estimated from 2500 replications
- Sub-analyses for bands of baseline severity and adjustment for regression to the mean (RTM) using Yudkin and Stratton's method
- TQ validity explored using correlation and regression
- MDC estimated as the square root of within person error variance of stable participants (identified by TQ) repeated measurements between baseline and four weeks

Results

MIC standard error (SE) by number of bootstrap replications

Source: UK BEAM one year RMDQ change scores
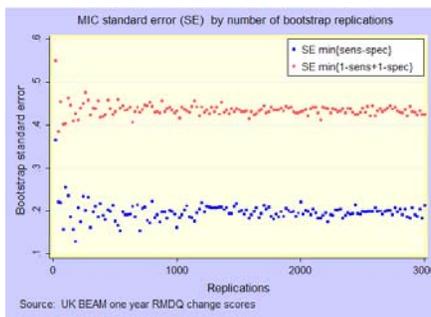
MIC (improvement and deterioration) with 95% CI using $min\{sens\text{-}spec\}$

RMDQ	MIC	95% CI	MIC$_{det}$	95% CI
Three months				
Whole group	4	3.35 to 4.64	1	0.24 to 1.76
Low disability (4 to 10)	4	3.94 to 4.06	0	-1.11 to 1.11
Medium disability (11 to 17)	7	6.16 to 7.83	2	-0.02 to 4.02
High disability (18 to 24)	14	13.10 to 14.90	2	-3.84 to 7.84
Twelve months				
Whole group	5	4.57 to 5.42	1	-0.04 to 2.04
Low disability (4 to 10)	4	3.94 to 4.06	1	0.22 to 2.22
Medium disability (11 to 17)	8	6.97 to 9.03	2	0.58 to 3.42
High disability (18 to 24)	14	*	0	-2.20 to 2.19

* No estimate could be produced. Only three participants with high RMDQ disability improved on the TQ.

MIC (improvement and deterioration) with 95% CI using $min\{1\text{-}sens+1\text{-}spec\}$

RMDQ	MIC	95% CI	MIC$_{det}$	95% CI
Three months				
Whole group	4	3.31 to 4.68	2	0.50 to 3.5
Low disability (4 to 10)	4	3.18 to 4.81	1	-1.19 to 3.19
Medium disability (11 to 17)	8	6.94 to 9.05	1	-2.0 to 4.0
High disability (18 to 24)	14	13.09 to 14.91	2	-6.37 to 10.37
Twelve months				
Whole group	4	3.08 to 4.92	0	-1.12 to 1.12
Low disability (4 to 10)	4	3.01 to 4.98	1	0.76 to 2.76
Medium disability (11 to 17)	7	4.68 to 9.31	2	-0.94 to 4.94
High disability (18 to 24)	14	*	3	-0.62 to 6.62

* No estimate could be produced. Only three participants with high RMDQ disability improved on the TQ.

MIC (improvement) adjusted for RTM

RMDQ	MIC *Three months*	MIC *Twelve months*
Whole group	†	†
Low disability (4 to 10)	†	†
Medium disability (11 to 17)	4.8	5.7
High disability (18 to 24)	9	8.8

MIC method min{sens-spec}
† Group contains the mean

Correlation and regression models

Correlation	r	Regression model	β	R^2
TQ_{3m} and baseline	0.17***	$RMDQ_{3m}$ on TQ_{3m}	0.144***	0.33
TQ_{12m} and baseline	0.22***	addition of baseline	-0.056***	0.35
TQ_{3m} and $RMDQ_{3m}$	0.57***	$RMDQ_{12m}$ on TQ_{12m}	0.178***	0.45
TQ_{12m} and $RMDQ_{12m}$	0.67***	addition of baseline	-0.058***	0.47
TQ_{3m} and $RMDQ_{change}$	0.49***			
TQ_{12m} and $RMDQ_{change}$	0.57***			

*** $P < 0.001$
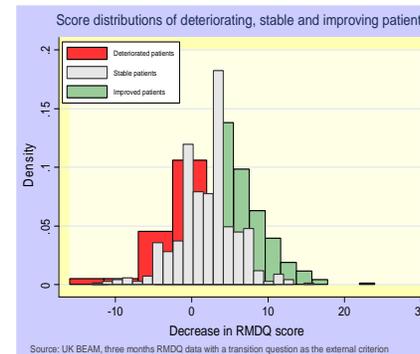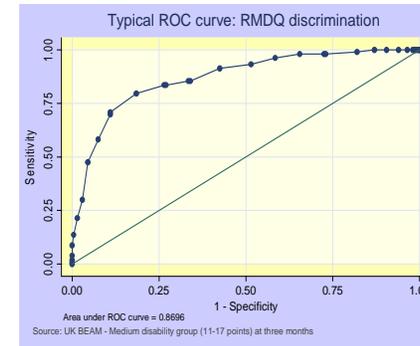
Minimal detectable change

> **At a group level ≈ 0·4 RMDQ points (1.7%)**
> **At an individual level, MDC = 8.1 RMDQ points (33·8%)**

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MIC software for STATA at:

www.robertfroud.info

Typical ROC curve: RMDQ discrimination

Area under ROC curve = 0.8696
Source: UK BEAM - Medium disability group (11-17 points) at three months

Score distributions of deteriorating, stable and improving patients
- Deteriorated patients
- Stable patients
- Improved patients

Source: UK BEAM, three months RMDQ data with a transition question as the external criterion

Discussion

- Values obtained fall within the range considered by the consensus team and ranges reported by authors using similar methods
- Higher MICs were observed for more disabled patients; at least partially an artefact of regression to the mean
- In our population patients required more than 30% change from baseline to improve
- Participants indicating deterioration on the TQ tended to improve on the RMDQ: although their LBP worsened, they may have learned to cope better with their disability
- The Five RMDQ point consensus seems a reasonable threshold by which to judge responders to treatment
- Proportional change from baseline may be more population-specific than previously thought
- Transition question did not measure change in disability
- MIC estimates from ROC curves depend on methodology used. We prefer $min\{sens - spec\}$ as it cannot favour sensitivity or specificity and is associated with a lower SE (less covariance)

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