

The minimal important change of the PRAFAB-questionnaire in women with stress urinary incontinence:

Erik Hendriks

Department of Epidemiology and Caphri Research School &
Centre of Evidence Based Physiotherapy (CEBP) and guidelines
Maastricht University

Evidence based Physiotherapy

- **Development of EB – guidelines (1996 -)**
(state of the art of diagnostic procedures, optimal interventions and outcome measures)
- **Implementation (2000 -)**
- **Evaluation (2002 -)**

Evaluation of outcome measures

Development of the Questionnaire (1989)

(Vierhout, 1990; Mulder and Vierhout, 1990)

- 5 items (min-max 1-4 points)
- Total score (min-max = 5-20)

The PRAFAB-Questionnaire

Protection

1. I never use protection for urine loss
2. I use protection sometimes, or I have to change my underwear because of urine loss
3. I normally use protection, or I change my underwear several times a day because of urine loss
4. I always have to wear protection because of urinary incontinence

Amount

1. The amount of urine lost is just a drop
2. Sometimes I loose a small quantity of urine
3. Urine loss is so great that it wets my protective pad or clothing noticeably
4. Urine loss is so great that my protective pad is soaked or leaks

Frequency

Involuntary loss of urine occurs:

1. Once a week or less
2. More than once but less than three times a week
3. More than three times a week, but not every day
4. Every day

Adjustment

Implications of urine loss:

1. My normal daily activities have not been restricted
2. I have stopped some activities, such as some sports and some physically demanding activities
3. I have stopped most physical activities that cause involuntary urine loss
4. I almost never go out

Body (or self) image

1. I do not worry about urine loss
2. I think urine loss is annoying and troublesome, but I am not greatly bothered by it
3. I find urine loss disgusting
4. I am disgusted by myself because of my urine loss

Total Score:

Vierhout, 1990
Mulder& Vierhout 1990

Global Perceived Effect

Jaeschke 1989

“How is your current condition compared to how it was before you started physiotherapy treatment?”

1. very much improved
2. much improved
3. moderately improved
4. slightly improved
5. unchanged
6. slightly worse
7. moderately worse
8. much worse
9. very much worse

Ratings of 4 to 6 are considered as no meaningful change

Previous study-1

Vierhout, 1990; Mulder and Vierhout, 1990

Psychometric study (N= 50 / 30)

- Acceptable inter-rater reliability (?)
- Discriminates between non-severe and severe urine loss (2 gram per hour [Inco-test]) with a score ≥ 14 points
 - The positive predictive value of 'severe' UI = 83%
 - The negative predictive value = 61%

Previous study-2 (self-report)

Hendriks et al, 2007

Psychometric study (N= 99 [stress / urgency UI])

Test-retest reproducibility (at 10 days) = 0.93 [ICC]

Internal consistency = 0.82

Construct validity:

Good discrimination:

- between UI groups

- improved vs. not improved (ROC AUC=0.96)

Correlation PRAFAB-Q - patients' perceived benefit (0.86-0.91)

Responsiveness

TABLE V. Patient's Perception of Change on the Global Rating Score (GRS) and the Mean Changes and Percentage (%) of Change on the PRAFAB-Score at 12 Weeks

GRS-score	Baseline mean (SD)	12 weeks Mean (sd)	N (%)	Change ^a Mean (SD)	%	ES	SRM
Stress UI group (n=56)							
1. Very much better	12.5 (1.9)	5.9 (0.8)	20 (35.7)	-6.6 (1.5)	-88	-3.5	-4.4
2. Much better	13.3 (2.9)	7.5 (1.8)	12 (21.4)	-5.8 (1.9)	-70	-2.0	-3.1
3. Moderately better	12.0 (2.8)	8.7 (1.6)	6 (10.7)	-3.3 (1.4)	-47	-1.2	-2.3
4. Stable	10.8 (3.1)	10.4 (2.8)	15 (26.8)	-0.4 (1.1)	-7	-0.1	-0.4
5. Moderately worse	7.0 (0.0)	10.3 (2.3)	3 (5.4)	3.3 (2.3)	+65	—	1.4
Spearman's r^b		0.86	0.91				
Improved	12.6 (2.4)	6.8 (1.7)	38 (67.9)	-5.8 (2.0)	-76.3	-2.4	-2.9
Unchanged	10.9 (3.1)	10.4 (2.9)	15 (32.1)	-0.5 (1.1)	-8.5	0.2	-0.5
Urgency UI group (n=31)							
1. Very much better	11.0	6.0	1 (3.2)	-5.0 —	-83	—	—
2. Much better	13.2 (2.3)	8.8 (1.6)	12 (38.7)	-4.4 (0.9)	-54	-1.9	-4.9
3. Moderately better	14.3 (3.1)	11.3 (2.8)	6 (19.4)	-3.0 (0.9)	-33	-1.0	-3.3
4. Stable	12.6 (3.0)	11.5 (3.6)	8 (25.8)	-1.1 (1.3)	-14	-0.4	-0.8
5. Moderately worse	11.0 (0.82)	12.3 (2.1)	4 (13.0)	1.3 (1.7)	+22	1.5	0.8
Spearman's r^b		0.90	0.93				
Improved	13.4 (2.5)	9.4 (2.4)	19 (61.3)	-4.0 (1.1)	-47.6	-1.6	-3.6
Unchanged	12.1 (2.6)	11.8 (3.0)	8 (38.7)	-0.3 (1.8)	-4.2	-0.12	-0.2

Abbreviations: ES, effect size; SRM, standardized response mean.

^aCorrected for the minimum PRAFAB-Q score of five points (Min-Max = 5-20; Range = 16): [Change score/(Baseline score - 5) × 100%].

^bSpearman's correlation coefficients between the changes on the total PRAFAB-Q score (from baseline and at 12 weeks) and patient's perceived benefit assessed by the GRS.

Methods

to determine MIC-values?

- **Mean change method ***
 - Improved vs. Not improved
 - Moderately to very much improved vs no change incl. slightly better/worse
- **‘Moderately’ improved**
 - as defined on the GRS
- **ROC – method**
- **SDC (SEM)**

MIC-estimates

TABLE VII. The Minimally Important Change, Including Stratified Analysis, Assessed by the Mean Change Scores on the Total PRAFAB-Q Defined as “Moderately to Very Much” Improved (vs. Unchanged), “Moderately” Improved on the Global Rating Scale (GRS) and Optimal Cut-Off Point Determined by ROC-Method

	Stress UI Mean change (95% CI)	Urgency UI Mean change (95% CI)
Total group	N=56	N=31
Mean total	11.7 (11.1; 12.5)	13.0 (12.0; 13.8)
1. Mean change (SD) ^a	-5.8 (-6.4; -5.1)	-4.0 (-4.5; -3.4)
2. GRS “moderately” improved	-3.3 (-4.8; -1.9)	-3.0 (-3.9; -2.1)
3. Optimal cut-off point	-3.0	-3.0
Range	-3.0 to -5.8	-3.0 to -4.0
Stratified analysis ^b		
Low scores (<14) ^b	N=40	N=22
Mean total	11.3 (10.5; 12.1)	11.5 (10.9; 12.1)
1. Mean change (SD) ^a	-4.6 (-5.3; -4.0)	-3.4 (-4.1; -2.9)
2. GRS “moderately” improved	-2.8 (-3.4; -2.2)	-2.5 (-3.8; 3.8)
3. Optimal cut-off point	-2.5	-2.5
Range	-2.5 to -4.6	-2.5 to -3.4
High scores (≥14) ^b	N=16	N=9
Mean total	16.0 (15.2; 16.8)	16.3 (15.7; 16.9)
1. Mean change (SD) ^a	-7.0 (-9.1; -5.1)	-4.4 (-4.9; -3.8)
2. GRS “moderately” improved ^c		
3. Optimal cut-off point	-4.5	-4.0
Range	-4.5 to -7.0	-4.0 to -4.4
SDC	-1.8 (-2.1; -1.4)	-1.9 (-2.8; -1.4)

^aBased on the dichotomised groups: “Improved” (moderately to very much improved) vs. “Unchanged” (including slightly worse or better). Patients who were deteriorated were excluded from the analysis.

^bStratified analysis on dichotomised groups in low (<14) versus high (≥14) total PRAFAB-Q scores.

^cData not presented because of the small numbers in the stress (n=2) and urge (n=1) UI group.

Conclusions

High responsiveness

Effect size statistics $ES / SRM > 1.0$

MIC: non-severe = -3.0 (to -5.0)*

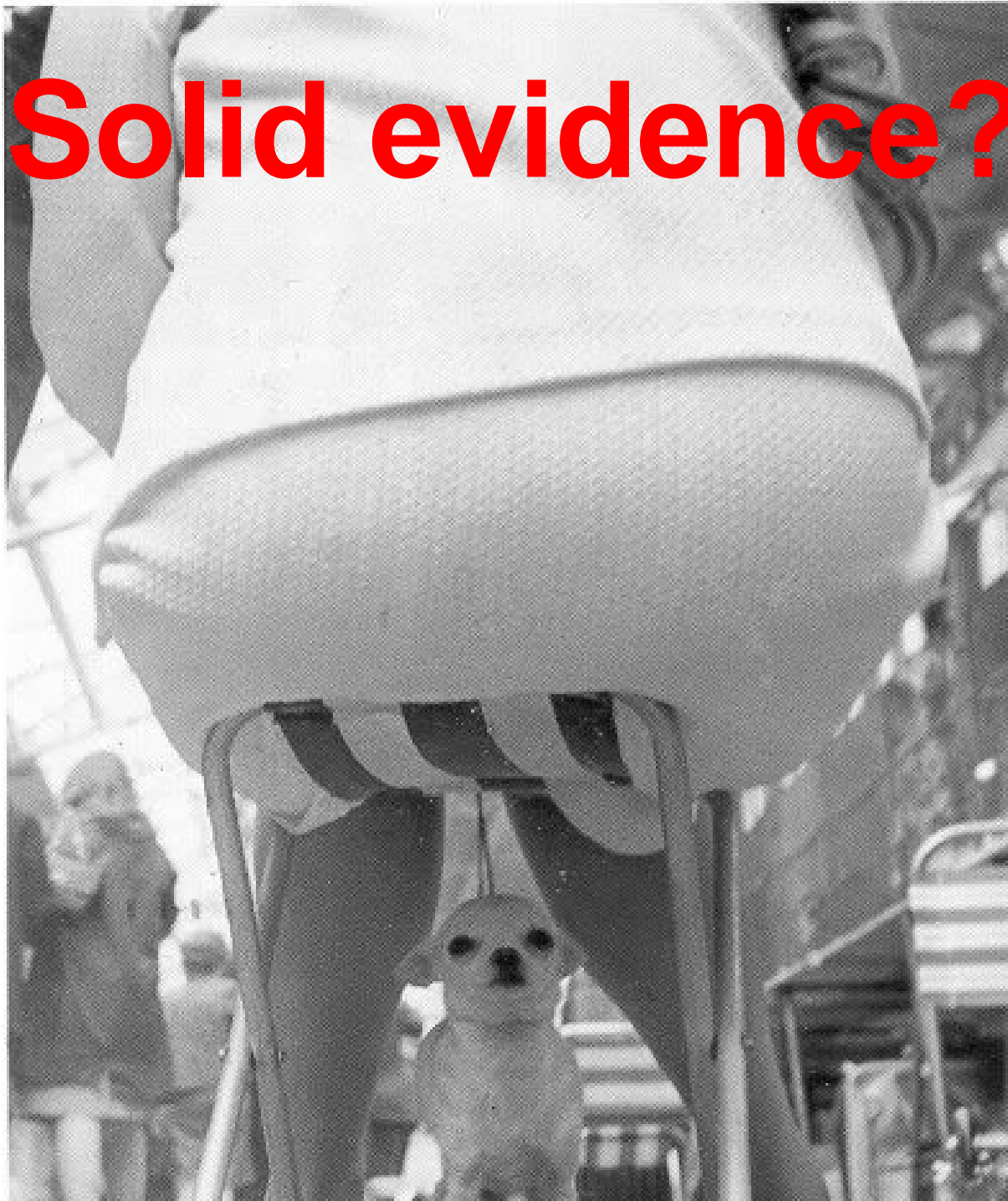
MIC: severe = -5.0 (to -7.0)

SDC: = -1.8

* Overestimation (mean change method)



Solid evidence?



Replication study

Purpose:

- To estimate the MIC-values of the total PRAFAB questionnaire score in women referred for physiotherapy intervention following primary or recurrent episodes of stress urinary incontinence
- MIC values could be applied to individual patients and used as a threshold by which practitioners decide to continue, change or end a specific intervention

Methods

N = 279 mainly Caucasian women

MIC values were determined by:

- (1) the mean change method (Jaeschke, 1989) *
 - Mean moderately better (GRS 3) – unchanged (4-6)
- (2) the ROC method
- (3) the 95% limit cut-off point
 - Mean change + 1.96 SD (or + /- 1.645 SD)

- MIC values were compared to SDC.
- Effect of initial baseline scores on the MIC
- Visualized by the anchor-based MIC distribution

Responsiveness

TABLE III. The Mean Differences of the Total PRAFAB Questionnaire Scores by Global Rating Scale (GRS) at the 12 Weeks Follow-Up for the Total Group and Stratified Groups in Non-Severe and Severe Stress Urinary Incontinence

	GRS categories		Baseline total PRAFAB-Q score		12 weeks total PRAFAB-Q score		Change scores ^a	
	N	(%)	Mean	(SD)	Mean	(SD)	Mean (SD)	%
Total group	279	(100)	11.9	(2.6)	8.7	(3.1)	-3.2 (2.8)	-46
1. Very much better	78	(28.0)	11.9	(2.3)	5.8	(0.9)	-6.1 (2.0)	-88
2. Much better	40	(14.3)	11.2	(2.2)	7.1	(1.0)	-4.1 (1.4)	-66
3. Moderately better	43	(15.4)	11.8	(2.9)	8.4	(1.6)	-3.4 (1.4)	-50
4. Unchanged ^b	114	(40.8)	12.3	(2.7)	11.4	(2.7)	-0.9 (1.3)	-12
5. Moderately worse	4	(1.4)	11.0	(2.8)	14.8	(1.5)	3.8 (1.5)	62
Spearman's r ^c							0.87	
Non-severe (<14)	198	(100)	10.7	(1.8)	7.9	2.4	-2.8 (2.5)	-49
1. Very much better	58	(29.3)	11.0	(1.7)	5.7	0.8	-5.3 (1.7)	-88
2. Much better	35	(17.7)	10.7	(1.8)	6.9	0.9	-3.8 (1.3)	-67
3. Moderately better	32	(16.2)	10.4	(1.6)	7.9	1.1	-2.5 (0.7)	-46
4. Unchanged ^b	69	(34.8)	11.0	(1.9)	10.4	1.9	-0.6 (1.3)	-11
5. Moderately worse	4	(2.0)	11.0	(2.8)	14.8	1.5	3.8 (1.5)	63
Spearman's r ^c							0.88	
Severe (≥ 14)	81	(100)	15.0	(1.2)	11.2	3.5	-3.9 (3.3)	-39
1. Very much better	20	(24.7)	14.7	(1.1)	6.4	1.3	-8.3 (1.2)	-86
2. Much better	5	(6.1)	14.6	(0.9)	8.4	1.1	-6.2 (0.5)	-65
3. Moderately better	11	(13.6)	15.9	(1.4)	10.5	1.0	-5.4 (0.7)	-50
4. Unchanged ^b	45	(55.6)	15.0	(1.5)	14.2	1.3	-1.3 (1.4)	-13
5. Moderately worse	—		—		—		—	
Spearman's r ^c							0.94	

^aCorrected for the minimum total PRAFAB questionnaire score of five points (Min–Max = 5–20; range 16): [Change score/(Baseline score – 5) × 100%].

^bDefined as slightly better, about the same and slightly worse and considered as 'not importantly improved.'

^cSpearman correlation coefficients between the changes on the total PRAFAB questionnaire scores (from baseline and at 12 weeks) and patient's perceived benefit assessed by the GRS.

MIC-estimates

TABLE IV. Summary of all Methods Used to Determine the MIC, Including Stratified Analysis^a and Absolute Scores^b to Correspond to Each Individual Score on the PRAFAB Questionnaire

	Mean change (SD) [abs] ^b
Total group	N = 279
1. Change method (Jaeschke et al. ²)	2.5
2. ROC optimal cut-off point	2.5
3. 95% limit cut-off point	3.2
Range (min-max) ^c	0.7 (2.5-3.2) [3-4]
SDC	2.1
Stratified analysis ^a	
Non-severe (<14)	N = 198
1. Change method (Jaeschke et al. ²)	1.9
2. ROC optimal cut-off point	2.0
3. 95% limit cut-off point	2.7
Range (min-max) ^c	0.8 (1.9-2.7) [2-3]
SDC	1.6
Severe (≥14)	N = 81
1. Change method (Jaeschke et al. ²)	4.1
2. ROC optimal cut-off point	4.0
3. 95% limit cut-off point	3.6
Range (min-max) ^c	0.5 (3.6-4.1) [4-5]
SDC	2.3

^aStratified analysis on dichotomized groups in low (<14) versus high (≥14) total PRAFAB questionnaire scores.

^bThe MIC range in absolute [abs] scores.

Results

- Results of all methods to define the MIC:
- Non-severe: range = 1.9 - 2.7 (SDC = 1.6)
- Severe: range = 3.6 - 4.1 (SDC = 2.3)

MIC estimates were larger than the SDC.

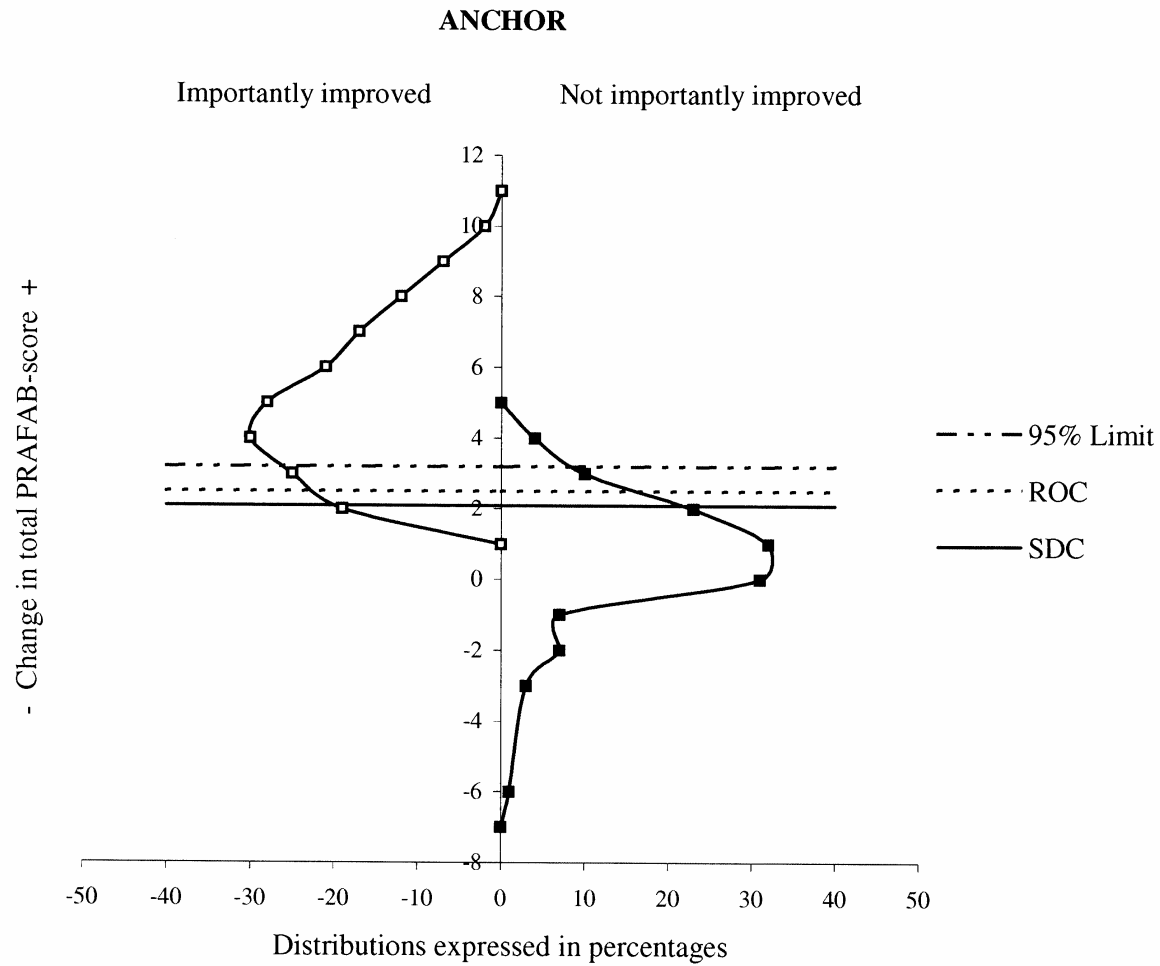
Results

- Results of all methods to define the MIC:
- Non-severe: range = 1.9 - 2.7 (SDC = 1.6) [3.0]*
- Severe: range = 3.6 - 4.1 (SDC = 2.3) [5.0]*

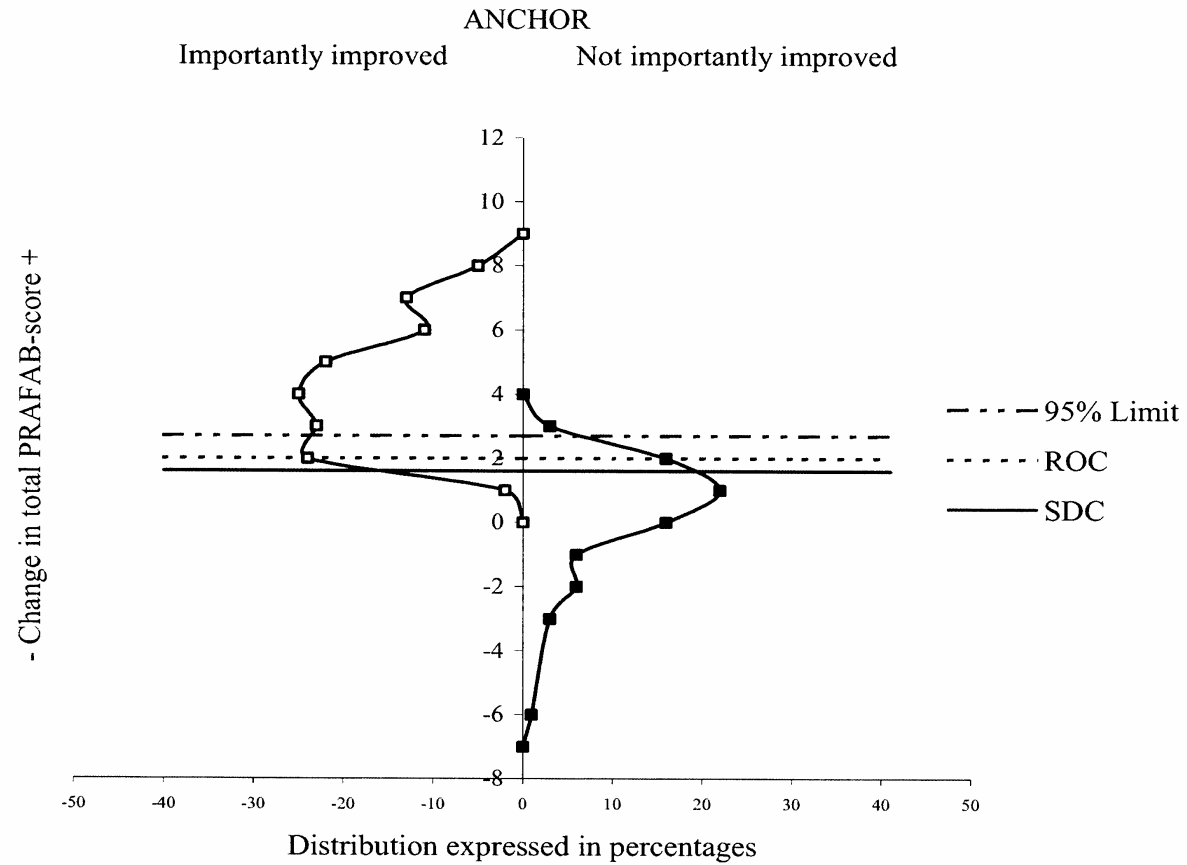
MIC estimates > SDC (1.6 and 2.3 points)

* Comparison previous study

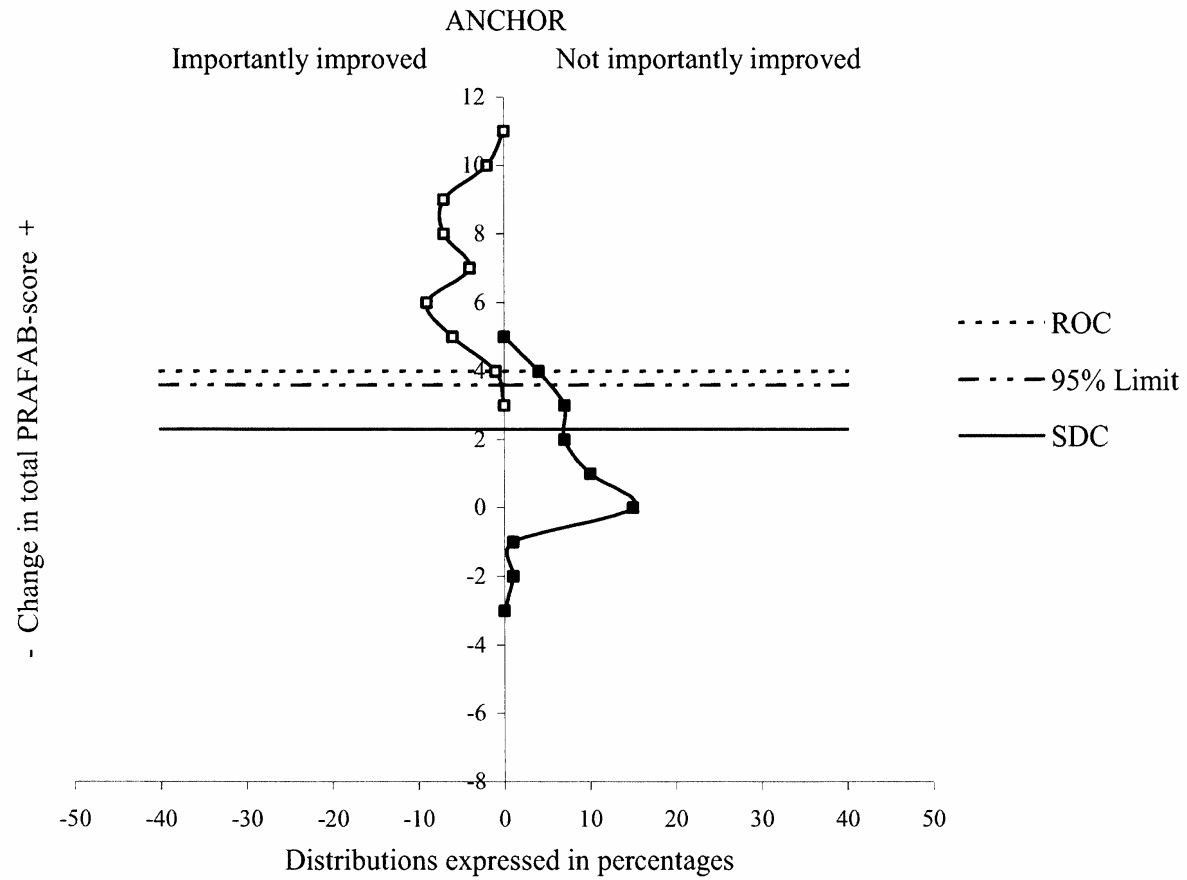
Anchor Based – MIC distribution



Anchor Based – MIC distribution



Anchor Based – MIC distribution



Conclusions

- The total PRAFAB-Q score is a brief and simple outcome measure that easily can be used to monitor progress and to interpret meaningful improvement in individual women with stress UI



Thank you for your kind attention



