The Establishment of a Minimal Clinically Important Difference (MCID) for Primary Endpoint Questionnaire (PEQ) Used to Evaluate Vaginal Penetration with 3-mo POMPOM data

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Abstract: 65

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OBJECTIVE

- The POMPOM study[1] evaluated the Milli Expanding Vaginal Dilator for the treatment of vaginal muscle tightness (vaginismus) and related painful sex (dyspareunia).
- Successful vaginal intercourse was assessed by the Primary Endpoint Questionnaire (PEQ) item 1, with the total PEQ score used as an exploratory endpoint[2].
- A minimal clinically important difference (MCID) for PEQ has not been established. Defining an MCID is essential for interpreting clinically meaningful treatment benefit.[3]
- This analysis estimated an anchor-based MCID for PEQ using 3-month POMPOM data and concordance with the Pain Numeric Rating Scale (NRS).[4-5]

Date:	**Instructions: Put an "X" in the column that best describes your experience during the last 4 weeks; add the numbers from each column together**			
PEQ Total (0-21):				
Penetration Types	0 = Not Attempted	1 = Attempted, but unsuccessful	2 = Attempted, and sometimes successful	3 = Attempted, and always successful
Full vaginal penetration with the penis of the partner				
Self-insertion in the vagina of one (1) finger by the woman				
Self-insertion in the vagina of two (2) fingers by the woman				
Insertion in the vagina of one (1) finger by the partner				
Insertion in the vagina of two (2) fingers by the partner				
Self-insertion in the vagina of another object (such as a tampon or a dildo) by the woman				
Self-insertion in the vagina of another object (such as a tampon or a dildo) by the partner				

DESIGN

- We analyzed data from 68 participants, primarily menopausal (mean age 50.8±15.4; median 56.5), who completed baseline and 3-month assessments.
- Pain during intercourse was assessed using an 11-point NRS (0–10), and vaginal penetration effectiveness was measured using PEQ.
- We prespecified the pain MCID as a ≥2-point improvement on the NRS. PEQ MCID was derived using NRS responder status as the anchor; a ≥3-point increase from baseline was supported by distribution-based methods.
- Concordance was assessed by cross-tabulation. We evaluated between-group differences using Student's t-test and assessed associations using Pearson correlation.

TABLE 1: Improvement in 3-Month Questionnaire Scores vs. Responder Status

N *Average ± SD* *[Median]{Range}*	Comparative Responder		Testing	
	Yes	No	P-value*	Correlation**
PEQ Improvement	37 2.7±4.5 [2.0](-5, 12}	31 -0.3±3.4 [0](-11, 6}	.0033	.5078
Pain NRS Improvement	22 3.9±3.0 [3.5](-1, 10}	46 1.2±2.9 [1](-10, 10}	.0009	

*Student's t-test | **Pearson correlation coefficient

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RESULTS

- At 3 months, 55% met the Pain NRS MCID and 33% met the PEQ MCID.
- Among PEQ responders, 82% were also Pain responders, while only 6% of Pain nonresponders met the PEQ threshold, indicating high specificity.
- Mean PEQ improvement was greater in Pain responders vs. nonresponders (2.7±4.5 vs −0.3±3.4; p=0.0033).
- Pain improvement also differed (3.9±3.0 vs 1.2±2.9; p=0.0009).
- PEQ and Pain NRS changes showed a moderate correlation (r=0.51).

TABLE 2: 3-Month Responder Concordance Pain NRS vs. Total PEQ

	PEQ Responder	PEQ Non-Responder	Total	Kappa
Pain NRS Responder	18	19	37	.3440
Pain NRS Non-Responder	4	27	31	**McNemar**
Total	22	46	68	.0018

CONCLUSION

- A ≥3-point improvement on the PEQ represents a clinically meaningful threshold that aligns with established pain MCID criteria.
- Concordance with Pain NRS supports PEQ construct validity as an endpoint reflecting meaningful improvement in sexual pain and function.
- Limited discordance highlights the multidimensional nature of sexual function.
- Establishing a PEQ MCID improves the interpretability of treatment response and supports use as a responder definition in clinical trials.
- Limitations of this interim analysis include sample size and reliance on a single anchor; however, complementary distribution-based methods support the results.
- These findings will be extended in a 6-month analysis incorporating additional anchors, including concordance with the Female Sexual Function Index (FSFI) pain domain, to evaluate stability over time and further validate PEQ as a clinically meaningful outcome.

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