Minimal important difference of pain numeric rating scale in patients with hidradenitis suppurativa: results from THESEUS

Dear Editor, The THESEUS study[1,2] was a nonrandomized 12-month prospective cohort study set in 10 UK hospitals to describe current UK hidradenitis suppurativa (HS) management pathways. HS is a chronic, painful disease affecting flexures and other skin regions, producing nodules, abscesses and skin tunnels. Patient-reported outcomes collected in THESEUS included current pain numeric rating scale (NRS), a 15-point change in disease severity anchor item, referring to change since the patient was last seen for the study,[3] and Hidradenitis Suppurativa Quality of Life (HiSQOL) score.[4] It is possible to use these data to estimate a minimal important difference (MID) for pain NRS in patients with HS.

The pain NRS change score was calculated as the value at a follow-up visit minus the value at the previous visit, and was calculated only if consecutive visit values were available. Data across follow-up visits were accumulated into a single database and thus it was possible to have a maximum of four rows of data from the same THESEUS participant. The lack of independence between values from the same THESEUS participant meant that only methodologies based on descriptive analyses could be implemented.

To calculate the MID using the anchor-based method, the minimum threshold for the correlation between the anchor and the pain NRS change score was required to be $\geq |0.3|$.[5]

The 15-point disease severity anchor item was split into the following five groups:

- −7 to −4, Large and important negative change;
- −3 to −2, Small but important negative change;
- −1 to +1, No change;
- +2 to +3, Small but important positive change;
- +4 to +7, Large and important positive change.

The sign of the pain NRS change score for those reporting a 'Large and important negative change' or 'Small but important negative change' was reversed, and then the two 'Large and important' categories and the two 'Small but important' categories were combined to create three categories of 'No change', 'Small but important change' and 'Large and important change'. The value of the MID was determined as:

- within the 'Small but important change' group interquartile range;
- close to the median of the 'Small but important change' group;

- the value that jointly maximized the percentage of those in the 'No change' group with a lesser value and the percentage of those in the 'Large and important change' group with the same or a greater value.

To calculate the MID using the distribution-based methods, HiSQOL change scores (HCS) and the SD for the HCS were used to create an anchor:

- HCS > 0.5 SD, Large and important negative change;
- 0.2 SD < HCS ≤ 0.5 SD, Small but important negative change;
- HCS ≤ |0.2 SD|, No change;
- −0.2 SD > HCS ≥ −0.5 SD, Small but important positive change;
- HCS < −0.5 SD, Large and important positive change.

Thereafter, the same algorithmic process for identifying the MID in the anchor-based method was used.

For the anchor-based method, 391 patients had a pain NRS change score and 15-point disease severity anchor item values across the four follow-up visits of the THESEUS study. In the THESEUS population, mean pain scores varied from 3.9 (SD 2.8) at baseline, to 3.7, 3.9, 3.9 and 3.5 after 3, 6, 9 and 12 months, respectively. The correlation between the anchor and the pain NRS change score was $\rho = -0.316$. The interquartile range for the 'Small but important change' group was −1.0 to 2.0, and the median was 0.0. For distribution-based methods, 383 patients had a pain NRS change score and HCS across the four follow-up visits of the THESEUS study. The SD for the HCS was 12.8. The interquartile range for the 'Small but important change' group was −0.5 to 2.0, and the median was 0.0. Therefore, in both cases, the only potential MID values were 1 and 2. The results are provided in Table 1 and show that the best estimate for the pain NRS is a MID of 1, as it provides the best balance across the 'No change' and 'Large and important change' groups, and has a higher overall accuracy compared with the potential MID of 2.

The results presented here estimate a MID of 1 for a current pain NRS in a sample of patients with HS. These analyses have several limitations. One limitation was that the 15-point disease severity anchor item is not specific to pain. Moreover, the 15-point disease severity anchor item was not designed to be an anchor item for responsiveness analyses and therefore the five categories necessary for these analyses have been imposed upon it.

A systematic review of minimum clinically important difference in chronic pain found quite wide variation in values between studies, which were related to the baseline level of pain and possibly to differences between the medical conditions included.[7]

Table 1 Minimal important difference (MID) results for the pain numeric rating scale

Method	Potential MID	Percentage less than the potential MID in the 'No change' group, % (n/M)	Percentage greater than or equal to the potential MID in the 'Small but important change' group, % (n/M)	Percentage greater than or equal to the potential MID in the 'Large and important change' group, % (n/M)	Overall accuracy, % (n/M)	Overall accuracy, 95% CI[a]
Anchor-based method	1	65 (89/137)	54 (63/117)	55 (76/137)	58 (228/391)	53–63
	2	75 (103/137)	37 (43/117)	39 (54/137)	51 (200/391)	46–56
Distribution-based method	1	68 (75/110)	43 (30/69)	63 (129/204)	61 (234/383)	56–66
	2	83 (91/110)	35 (24/69)	51 (104/204)	57 (219/383)	52–62

CI, confidence interval. [a]Binomial proportion was calculated using Wilson's method.[6]

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Data availability: The data underlying this article will be shared on reasonable request to the corresponding author.

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