The appropriateness of an improved diary for the assessment of pre-menstrual mastalgia.

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Abstract
Current mastalgia assessment diaries are effective in reporting severity and frequency, however recent literature suggests that these diaries assess mastalgia more comprehensively establishing severity, frequency, timing and location. This study aimed to assess validity, reliability, acceptability and minimal detectable change (MDC) of an improved mastalgia diary. Twenty premenopausal females who self-reported pre-menstrual mastalgia completed the diary once a day using paper, email or mobile formats, over one menstrual cycle. Predictive validity was assessed comparing pain pre- and post-menstruation. Test-retest and internal consistency established reliability. Acceptability was assessed using evaluation questions. MDC was calculated using a previously established method using the SEM to a 95% confidence interval. Results showed pre-menstrual mastalgia was significantly higher than post-menstrual, demonstrating diary validity. Reliability tests determined high test-retest reliability (ICC>0.90) and internal consistency (α=0.89). The diary was acceptable for >90% of participants. MDC determined change of 1 on each question would be > measurement error and therefore representing ‘real’ change. This improved mastalgia diary is a more comprehensive, valid, reliable, and acceptable tool for assessing mastalgia.

Key Words
Mastalgia, diary, reliability, validity
**Introduction**

Accurately assessing mastalgia is important for clinicians in order to prescribe appropriate treatment advice to patients. Tavaf-Motamen, Ader and Brown (1) reported that up to 15% of premenopausal women could have clinically significant cyclical mastalgia and therefore patients need to be accurately assessed in order to diagnose this. Diaries are recommended for use in reporting various health conditions in order to gain the most comprehensive information from patients (2). The Cardiff Breast Pain Chart (3) was developed to monitor mastalgia (3). More recently, Pearlman and Griffin (2010) suggest that severity, frequency, timing and location of pain should be considered when assessing mastalgia. Whilst the Cardiff Breast Pain Chart (3) is beneficial and has been widely used, aspects can be developed further based on the areas suggested by Pearlman and Griffin, (2010) and other pain diaries. Recently a new mastalgia diary has been presented (5) improving on aspects associated with the Cardiff Breast Pain Chart; currently the Cardiff Breast Pain Chart (3) does not allow for the reporting of mastalgia during menstruation. The new study by Gautam (5) allows for this as the authors have separated the diary into a chart to report pain intensity and a chart for reporting the menstrual cycle.

Alongside the content of the diary, it is also important that the diary is valid and reliable. Like the Cardiff Breast Pain Chart, the new diary proposed by Gautam (5) have yet to be assessed for reliability and validity and currently there has been no assessment of reliability or validity of any previous mastalgia diaries.

Pre-menstrual mastalgia occurs in the luteal phase (mid cycle onwards) (3), and reduces following menstruation onset, and thus predictive validity of the diary can be assessed as mastalgia occurrence can be predicted (6). Reliability can be assessed using a test-retest method and the Cronbach’s Alpha statistic, to measure internal consistency. Previous studies have also assessed the acceptability of pain diaries using satisfaction questions at the end of the study (7). The Minimum Detectable Change (MDC) is also an important consideration if the diary is used to determine change (for example, after an intervention). This measure determines whether a change in score over time is due to measurement error or the effect of an intervention (8).

This study aimed to determine the appropriateness of an improved mastalgia diary for the monitoring of pre-menstrual mastalgia. Appropriateness was assessed by investigating diary compliance, validity, reliability, acceptability and MDC. It was hypothesised that pain in the pre-menstruation phase would be significantly worse than the post-menstruation phase. It was also hypothesised that the diary would show high internal consistency significantly high reliability for the test-retest data (9).
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Methods

Participants
Following institutional ethical approval and informed consent, twenty premenopausal female participants (mean age 35 ±9 years) who self-reported mastalgia every month, had a regular menstrual cycle, were not currently pregnant, had not been pregnant or breast feeding in the past year and had not had breast surgery, were recruited and completed the diary, in either electronic (email (n=10), mobile (n=4)), or paper (n=6) formats, in full.

Diary Development
Based on Pearlman and Griffin’s (2010) recommendations two pain severity ratings were included in the diary; 0 to 10 rating scale (used in many studies investigating pain) (10–12) and the Present Pain Index (PPI) (mild/discomforting/distressing/horrible/excruciating) (13). To assess pain frequency the diary was implemented on a daily basis, similar to the Cardiff Breast Pain Chart (3) and the pattern/frequency of pain during each day was assessed. This was to determine whether the severity ratings (NRS) recorded on a certain day related directly to the frequency of pain, for example, pain that lasted all day (e.g. continuous pain) or acute pain (e.g. shooting pains). Time point in the menstrual cycle was assessed. Finally, mastalgia location was not included in the diary as it is a constant measure with no scale, and pain moving from one location to another cannot be determined as an improvement.

Procedures
Participants completed a short mastalgia survey at the beginning of the study to ascertain demographic information and their current mastalgia experience. Participants then selected their preferred diary format and were instructed to complete the diary daily, prior to sleep. Each evening, prompts were sent to participants using the electronic methods. To assess test-retest reliability, once a week participants completed the diary twice in one day with a one hour gap. Participants completed the diary for 35 days to cover a full menstrual cycle. At the end of the study participants completed a short survey on the clarity, usefulness, ease of use and format of the diary.

Data Analysis
Data were coded (Excel 2010); pain severity - numeric, PPI; 0=no pain, 1=mild, 2=discomforting, 3=distressing, 4=horrible and 5=excruciating, frequency; 0=no pain, 1=once, 2=every couple of hours, 3=every hour and 4=all day, menstruation status; 1=no and 2=yes.
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Validity: Participants were excluded if they had an unequal number of completed pre- (six days prior to menstruation) and post-menstrual (six days post-menstruation; Freeman et al., 1996) days to compare. Scores were calculated by establishing the sum of the responses for each of the questions over the 6 days pre- and 6 days post-menstruation. Shapiro-Wilks tests determined a violation of parametric assumptions (IBM SPSS Statistics 21), so Wilcoxon Signed Rank Tests compared pre and post-menstrual scores for severity, PPI and frequency of pain ($\alpha = 0.05$). Reliability: Using all compliant data ICCs ($r > 0.90$ - strong, 0.80 to 0.89 – moderate, 0.70 to 0.79 - questionable (9)) and Cronbach’s alpha test for internal consistency ($\geq 0.90$ (15)) were calculated. Acceptability: evaluation questions; reported as percentages. Minimum Detectable Change (MDC): Minimum detectable change was calculated with the test-retest data using equation 2 (8);

$$MDC = 1.96 \times \sqrt{2} \times SEM \quad (Equation \ 2)$$

This allows the MDC to be calculated within 95% confidence intervals. Standard Error of Measurement (SEM) was calculated using equation 3 (16);

$$SEM = SD(diff) \times (\sqrt{1 - r}) \quad (Equation \ 3)$$

Where SD(diff) is the difference between the standard deviation of the test and retest data and $r$ is the test-retest reliability coefficient from the ICC’s.

Results

Participants

*Insert Table 1 here*

Validity

Severity data ($n=14$) showed that breast pain was significantly greater within the pre-menstrual phase (score; $\Sigma=189$) compared to the post-menstrual phase (score; $\Sigma=87; Z=-2.453, p=0.011$). Significant differences were also seen in the PPI data (pre-menstrual score $\Sigma=96$, post-menstrual $\Sigma=41; Z=-2.773, p=0.003$) and the frequency of breast pain (pre-menstrual score $\Sigma=160$, post-menstrual score $\Sigma=86; Z=-2.167, p=0.028$). These results showed that the pre-menstrual phase was significantly more painful for participants than the post-menstrual phase.
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Reliability

Test-retest reliability (ICC) was high across all questions (Severity = 0.96, PPI = 0.92 and Frequency = 0.93). Cronbach’s α was calculated on the test-retest days only using only the initial diary completion and was 0.89.

Acceptability

Participants (95%) found the diary easy to use and the questions clear and 85% like the format of the diary and found keeping the diary useful. Within the open question, a participant reported she did not find keeping the diary useful, because she was aware of her mastalgia already. The key feedback was that the diary was not complex enough for the pain experienced as multiple types of pain were experienced during the day. Another suggested that having the option to look over past diary entries may help to assess pain. Two participants reported that they were more aware of their pain as a result of completing the diary, with one stating that she felt her pain was less now she had time to consider the pain.

Minimum Detectable Change

The minimum detectable change for each question was ±0.27 out of 10 (severity), ±0.28 out of five (PPI) and ±0.43 out of four (frequency).

Discussion

This is the first study to assess the reliability and validity of a mastalgia diary. With pre-menstrual mastalgia peaking in the luteal phase of the cycle (mid cycle) (3), validity tests showed mastalgia scores for the pre-menstrual phase were significantly greater than the post-menstrual phase, supporting Freeman et al. (1996) and accepting hypothesis one, that the diary has predictive validity. Cronbach’s α statistics (0.89) was higher than the 0.7 required for a measurement tool to be used within research, however, it was lower than the value of 0.9, which was considered appropriate for clinical decision making (rejecting hypothesis two) (15). Test-retest reliability showed ICC values of ≥0.9 (9) for each question suggesting reliability and accepting hypothesis three. Participants reported that the diary was easy to use, clear, appropriately formatted and useful, suggesting acceptability in its current form. Additional feedback suggests that an open question may be useful to provide an opportunity to add additional details. The participant who experienced multiple types of mastalgia during the day was considered to not understand the aim of the diary as it was to assess average pain each day and not variations of pain. The MDC calculated for severity was 0.27, this means on the NRS (0 to 10 scale) a change of 1 point would show a change beyond that due to measurement error, a change of 1 point was also the value calculated for the PPI and frequency.
An improved diary for the assessment of mastalgia questions. This demonstrates that any responses to treatment that occur during intervention based studies using this diary are changes that have occurred directly due to the intervention and not due to measurement error. It is recognised that a threshold for MDC to be considered clinically relevant is controversial and debated, however the results of this study were always greater than the MDC reported in this study.

Although the results suggest that this diary is appropriate for use within mastalgia research, it is not without limitations. Mastalgia was assessed over one menstrual cycle (35 days); the pain experienced within this time may not be representative of participants continued mastalgia. A strength of the Cardiff Breast Pain Chart is that it has trans-national applicability, and as of yet this diary has not been assessed for this. A strength of the diary developed in this study however is its ability to be used electronically as well as on paper. The electronic method was also deemed reliable, valid and accepted by the participants who chose to use this method to record their mastalgia.

This diary can be introduced in to breast clinics so that patients reporting with mastalgia can be monitored reliably, using a valid method and over a longer duration. A diary is a form of ecological momentary assessment as the condition (mastalgia), is reported by the patient as they go through everyday life and not in the setting of a breast clinic where their recall may be biased. Broderick et al (2006) is cited by Shiffman, Stone and Hufford (17) as reporting that pain is typically exaggerated by patients if they are experiencing pain when asked to report it. Conversely patients under-exaggerate their pain experience if they are not experiencing pain on the day they are asked to report it. The ability to recall information is also variable between people, so this mastalgia diary also allows for a reliable method of monitoring of mastalgia across patients (17).

**Conclusion**

To conclude, this is the first comprehensive mastalgia diary that has been assessed for validity, high reliability, acceptability and MDC. The diary was found to be both valid (predictive validity) and reliable and also accepted for use by sufferers. The MDC calculation established the degree of change needed to ensure the measurement taken was not due to error. This study presents an improved mastalgia diary that provides additional data beyond severity and prevalence, and is deemed appropriate for further breast health research.

**References**

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