

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

2 Emma Sharland, Jenny Burbage and Joanna Wakefield-Scurr

3 **Abstract**

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

17 **Key Words**

18 Mastalgia, diary, reliability, validity

19 **Introduction**

20 Accurately assessing mastalgia is important for clinicians in order to prescribe appropriate treatment advice to
21 patients. Tavaf-Motamen, Ader and Brown (1) reported that up to 15% of premenopausal women could have
22 clinically significant cyclical mastalgia and therefore patients need to be accurately assessed in order to diagnose
23 this. Diaries are recommended for use in reporting various health conditions in order to gain the most
24 comprehensive information from patients (2). The Cardiff Breast Pain Chart (3) was developed to monitor
25 mastalgia (3). More recently, Pearlman and Griffin (2010) suggest that severity, frequency, timing and location
26 of pain should be considered when assessing mastalgia. Whilst the Cardiff Breast Pain Chart (3) is beneficial and
27 has been widely used, aspects can be developed further based on the areas suggested by Pearlman and Griffin,
28 (2010) and other pain diaries. Recently a new mastalgia diary has been presented (5) improving on aspects
29 associated with the Cardiff Breast Pain Chart; currently the Cardiff Breast Pain Chart (3) does not allow for the
30 reporting of mastalgia during menstruation. The new study by Gautam (5) allows for this as the authors have
31 separated the diary in to a chart to report pain intensity and a chart for reporting the menstrual cycle.

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

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

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

47 **Methods**

48 **Participants**

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

53 **Diary Development**

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

63 **Procedures**

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

70 **Data Analysis**

71 Data were coded (Excel 2010); pain severity - numeric, PPI; 0=no pain, 1=mild, 2=discomforting, 3=distressing,
72 4=horrible and 5=excruciating, frequency; 0=no pain, 1=once, 2=every couple of hours, 3=every hour and 4=all
73 day, menstruation status; 1=no and 2=yes.

74 Validity: Participants were excluded if they had an unequal number of completed pre- (six days prior to
75 menstruation) and post-menstrual (six days post-menstruation; Freeman et al.,1996) days to compare. Scores were
76 calculated by establishing the sum of the responses for each of the questions over the 6 days pre- and 6 days post-
77 menstruation. Shapiro-Wilks tests determined a violation of parametric assumptions (IBM SPSS Statistics 21), so
78 Wilcoxon Signed Rank Tests compared pre and post-menstruation scores for severity, PPI and frequency of pain
79 ($\alpha = 0.05$). Reliability: Using all compliant data ICCs (r of >0.90 - strong, 0.80 to 0.89 – moderate, 0.70 to 0.79 -
80 questionable (9)) and Cronbach's alpha test for internal consistency (≥ 0.90 (15)) were calculated. Acceptability:
81 evaluation questions; reported as percentages. Minimum Detectable Change (MDC): Minimum detectable change
82 was calculated with the test-retest data using equation 2 (8);

83
$$MDC = 1.96 * \sqrt{2} * SEM \text{ (Equation 2)}$$

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

86
$$SEM = SD(diff) * (\sqrt{1} - r) \text{ (Equation 3)}$$

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

89 **Results**

90 **Participants**

91 ***Insert Table 1 here***

92 **Validity**

93 Severity data ($n=14$) showed that breast pain was significantly greater within the pre-menstrual phase (score;
94 $\Sigma=189$) compared to the post-menstrual phase (score; $\Sigma=87$; $Z=-2.453$, $p=0.011$). Significant differences were
95 also seen in the PPI data (pre-menstrual score $\Sigma=96$, post-menstrual $\Sigma=41$; $Z=-2.773$, $p=0.003$) and the frequency
96 of breast pain (pre-menstrual score $\Sigma=160$, post-menstrual score $\Sigma=86$; $Z=-2.167$, $p=0.028$). These results showed
97 that the pre-menstrual phase was significantly more painful for participants than the post-menstrual phase.

98 **Reliability**

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

101 **Acceptability**

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

109 **Minimum Detectable Change**

110 The minimum detectable change for each question was ± 0.27 out of 10 (severity), ± 0.28 out of five (PPI) and
111 ± 0.43 out of four (frequency).

112 **Discussion**

113 This is the first study to assess the reliability and validity of a mastalgia diary. With pre-menstrual mastalgia
114 peaking in the luteal phase of the cycle (mid cycle) (3), validity tests showed mastalgia scores for the pre-menstrual
115 phase were significantly greater than the post-menstrual phase, supporting Freeman et al. (1996) and accepting
116 hypothesis one, that the diary has predictive validity. Cronbach's α statistics (0.89) was higher than the 0.7
117 required for a measurement tool to be used within research, however, it was lower than the value of 0.9, which
118 was considered appropriate for clinical decision making (rejecting hypothesis two) (15). Test-retest reliability
119 showed ICC values of ≥ 0.9 (9) for each question suggesting reliability and accepting hypothesis three. Participants
120 reported that the diary was easy to use, clear, appropriately formatted and useful, suggesting acceptability in its
121 current form. Additional feedback suggests that an open question may be useful to provide an opportunity to add
122 additional details. The participant who experienced multiple types of mastalgia during the day was considered to
123 not understand the aim of the diary as it was to assess average pain each day and not variations of pain. The MDC
124 calculated for severity was 0.27, this means on the NRS (0 to 10 scale) a change of 1 point would show a change
125 beyond that due to measurement error, a change of 1 point was also the value calculated for the PPI and frequency

126 questions. This demonstrates that any responses to treatment that occur during intervention based studies using
127 this diary are changes that have occurred directly due to the intervention and not due to measurement error. It is
128 recognised that a threshold for MDC to be considered clinically relevant is controversial and debated, however
129 the results of this study were always greater than the MDC reported in this study.

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

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

144 **Conclusion**

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

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