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

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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 (α=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 ($\geq$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    $MDC = 1.96 * \sqrt{2} * SEM$ (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    $SEM = SD(diff) * (\sqrt{1} - r)$ (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    $\sum$=189) compared to the post-menstrual phase (score; $\sum$=87; Z=-2.453, *p*=0.011). Significant differences were

95   also seen in the PPI data (pre-menstrual score $\sum$=96, post-menstrual $\sum$=41; Z=-2.773, *p*=0.003) and the frequency

96   of breast pain (pre-menstrual score $\sum$=160, post-menstrual score $\sum$=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 **<u>Discussion</u>**

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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