

## Measuring episodic abdominal pain and disability in suspected sphincter of Oddi dysfunction

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### Abstract

**AIM:** To evaluate the reliability of an instrument that measures disability arising from episodic abdominal pain in patients with suspected sphincter of Oddi dysfunction (SOD).

**METHODS:** Although several treatments have been utilized to reduce pain and associated disability, measure-

ment tools have not been developed to reliably track outcomes. Two pilot studies were conducted to assess test-retest reliability of a newly developed instrument, the recurrent abdominal pain intensity and disability (RAPID) instrument. The RAPID score is a 90-d summation of days where productivity for various daily activities is reduced as a result of abdominal pain episodes, and is modeled after the migraine disability assessment instrument used to measure headache-related disability. RAPID was administered by telephone on 2 consecutive occasions in 2 consenting populations with suspected SOD: a pre-sphincterotomy population (Pilot I,  $n = 55$ ) and a post-sphincterotomy population (Pilot II,  $n = 70$ ).

**RESULTS:** The average RAPID scores for Pilots I and II were: 82 d (median: 81.5 d, SD: 64 d) and 48 d (median: 0 d, SD: 91 d), respectively. The concordance between the 2 assessments for both populations was very good: 0.81 for the pre-sphincterotomy population and 0.95 for the post-sphincterotomy population.

**CONCLUSION:** The described pilot studies suggest that RAPID is a reliable instrument for measuring disability resulting from abdominal pain in suspected SOD patients.

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**Key words:** Sphincter of Oddi; Abdominal pain; Disability measurement; Reproducibility of results; Pain measurement; Episodic pain

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## INTRODUCTION

The sphincter of Oddi controls the flow of bile and pancreatic secretions into the duodenum through the ampulla of Vater. Dysfunction of the sphincter can result in pain due to back pressure in the pancreas or biliary tree (especially after the gallbladder reservoir has been surgically removed)<sup>[1,2]</sup>. Classically these pains are felt in intermittent episodes, with symptom-free intervals, as emphasized by the Rome III consensus<sup>[3]</sup>. Some of these patients have objective findings on laboratory studies or imaging (e.g. abnormal liver enzymes, or a dilated bile duct), and are categorized by the Milwaukee classification as sphincter of Oddi dysfunction (SOD) Types I and II<sup>[4]</sup>. Many of these are found at endoscopic retrograde cholangiopancreatography (ERCP) to have bile duct stones or fibrotic sphincter stenosis, and are effectively treated by standard endoscopic biliary sphincterotomy.

Patients who have similar symptoms, but who have no demonstrable abnormalities on standard imaging and laboratory tests, are categorized as SOD type III. Presumably these patients suffer from intermittent SOD and related episodes of pain. These patients are very difficult to effectively evaluate and manage<sup>[5]</sup>, given the absence of objective markers of the condition, and because ERCP treatments are not without risk<sup>[6]</sup>.

The intermittent episodes of abdominal pain associated with SOD III can be severe, but the condition is not life-threatening. Pain episodes often interfere with the ability to function in primary roles (e.g. work, homemaker, *etc.*) and have a significant impact on quality of life. Impairment of function in primary roles has been previously shown to be a dominant motivation for seeking care and an outcome of primary concern to both patients and providers<sup>[7]</sup>. Several treatments are used to reduce pain and associated disability. However, measurement tools have not been developed to reliably and validly measure pain severity, frequency of pain episodes, and the impact of pain on function in primary roles.

To advance research in this area, we aimed to define an appropriate clinical measurement of efficacy for SOD treatment, where efficacy is defined as reduced pain-associated disability, also referred to as pain burden. The following describes the development and testing of an instrument to measure the pain burden in this patient population.

An extensive search of the literature did not yield an appropriate and validated instrument to measure pain and related burden for patients with SOD. Published clinical studies of treatment for SOD have used various instruments. Two sham-controlled trials used a global assessment scale<sup>[8,9]</sup>, as have several open-label studies

of sphincterotomy<sup>[10-13]</sup>, and a trial of Botox injection<sup>[14]</sup>. Graded outcome scales (e.g. 5 grades of outcome, from very much improved, to very much worse or simply improved, same or worse) have been reported, but details on the questions and method of administration (e.g. clinic, by telephone, self-administered) were not published. One crossover trial of nifedipine treatment used daily diaries<sup>[15]</sup>, but the study lasted only 16 wk, so the feasibility of daily diary use to assess episodes of pain over a longer follow-up period was not assessed. An extensive report of surgical sphincteroplasty (for a variety of indications) stated outcomes as good or excellent, without specifying criteria for outcomes<sup>[16]</sup>. Finally, a large follow-up study of 313 patients treated endoscopically used the need for re-intervention (at that center) as the primary measure of failure<sup>[17]</sup>. Such an outcome depends on other factors (e.g. access, patient preferences) that are not directly related to the patient's pain experience and that would make it unsuitable for a multicenter trial, particularly if there is not a clearly defined and standardized method of measuring a threshold for re-intervention. This outcome could be made more robust if combined with an outcome measure of a patient's pain experience and related burden.

A review of previous work and literature in other areas outside of gastroenterology revealed several well validated instruments for the assessment of pain and related disability<sup>[18-22]</sup>. Comprehensive reviews, such as the recommendations of the IMMPACT group (Initiatives on Methods, Measurement and Pain Assessment in Clinical Trials)<sup>[23]</sup>, correspondence with numerous published authorities, a thorough search for validated scales that had been developed specifically for the assessment of other intermittent pains and disabilities, such as back pain and arthritis<sup>[24,25]</sup> and review of measures of quality of life (e.g. SF-36) were also conducted. The use of the SF-36 instrument to measure pain burden was deemed to be too general and not sufficiently disease-specific. Hebert *et al.*<sup>[26]</sup> validated and published a Digestive Disease Quality of Life measure (DDQ15) but this instrument covers patients with many digestive diseases, and has not yet been used in practice. A "pain-volume" scale i.e. days of pain episodes in a month multiplied by the average severity of the reported episodes, was also considered, but again the concept does not include assessment of disability due to pain. Daily/weekly pain and disability diaries utilized in other studies were considered, but concerns about compliance over a long follow-up period in the context of pain episodes that are intermittent in nature, and the potential for inconsistent reporting of their number, frequency and severity precluded the use of patient diaries.

An important criterion for the development of a pain burden assessment instrument (unlike a daily diary) is its ability to measure retrospectively baseline pain-related disability over a period of weeks or months prior to any intervention. This is paramount as patients are often referred to tertiary centers from considerable distances, expecting an immediate intervention.

The closest analogy to pain and disability experienced by SOD III patients is in patients with migraine headache. Like SOD pain episodes, onset of migraine headaches is unpredictable, intermittent, and temporarily disabling. Frequency of migraine attacks vary substantially within individuals over time and among individuals. Moreover, migraine can be progressive and evolve to a chronic persistent pain state. The validated migraine disability assessment (MIDAS) questionnaire measures headache-related disability as lost time from paid work or school, household work or non-work activities as a result of headache over the previous 3-mo period. The justification for a 3-mo recall period came from prior studies that illustrated a good correlation between responses from a 90-d recall period and daily patient diaries in this patient population<sup>[27,28]</sup>. MIDAS, widely used in specialty care and available in 5 other languages, defines 4 levels (Grades) of disability ranging from “little or no disability” to “severely limiting disability”<sup>[7,29]</sup>. Based on the MIDAS terms and concepts, the Recurrent Abdominal Pain Intensity and Disability (RAPID) instrument was developed in collaboration with Dr. Stewart. This instrument is comprised of 5 questions, completed by the patient, which records time lost from paid work or school, household work or non-work activities as a result of abdominal pain episodes over the previous 3 mo (Table 1). Two additional questions ask about the average frequency and severity of abdominal pain episodes using a 3-mo recall period. The RAPID score is a 90-d summation of missed days, and days where productivity for paid work or school, household activities and non-work activities are reduced by half as a result of abdominal pain episodes. By analogy with the MIDAS instrument, RAPID grade 1 is a score of 0-5 and indicates little or no disability. Grade 2 is a score of 6-10 and indicates mildly limiting disability. Grades 3 and 4 are 11-20 (moderately limiting disability) and 21 or greater (severely limiting disability), respectively.

## MATERIALS AND METHODS

### Feasibility and reliability studies

Prior to using the newly developed RAPID instrument in a large, multicenter, randomized trial, we assessed its feasibility of administration and used Lin's concordance correlation coefficient to measure test-retest reliability<sup>[30,31]</sup>. Two IRB-approved pilot studies were initiated at the Medical University of South Carolina (MUSC). One study (denoted Pilot I) enrolled a total of 55 SOD III patients from 6 centers in the United States. Potential participants were recruited through existing hospital referral networks. After providing consent, participants were asked to complete the RAPID questionnaire by telephone prior to receiving any treatment by the respective institution. RAPID was administered by telephone on 2 separate occasions at 2-3 wk intervals (Visits 1 and 2) to assess test-retest reliability and to examine the range of RAPID scores in the sample population. The 2-3 wk interval was chosen based on previous work on migraine

**Table 1** Recurrent abdominal pain intensity and disability Instrument

- 1 On how many days in the last 3 mo did you miss work or school because of your episodes of abdominal pain? \_\_\_\_ days
- 2 On how many days in the last 3 mo did you miss work or school because of your episodes of abdominal pain (Do not include days you counted in question 1 where you missed work or school.)? \_\_\_\_ days
- 3 On how many days in the last 3 mo did you not do household work because of your episodes of abdominal pain? \_\_\_\_ days
- 4 On how many days in the last 3 mo was your productivity in household work reduced by half or more because of your episodes of abdominal pain (Do not include days you counted in question 1 where you did not do household work.)? \_\_\_\_ days
- 5 On how many days in the last 3 mo did you miss family, social or leisure activities because of your episodes of abdominal pain? \_\_\_\_ days
- 6 On how many days in the last 3 mo did you have episodes of abdominal pain (If the abdominal pain lasted more than 1 d, count each day.)? \_\_\_\_ days
- 7 On a scale of 0-10, on average, how painful were these episodes of abdominal pain? \_\_\_\_

headaches in which this period was deemed long enough so that respondents did not recall their answers to the previous interview and short enough to ensure that the recall time period was acceptable<sup>[32]</sup>.

The second pilot study (Pilot II) collected the telephone-administered RAPID from 70 consenting adult patients who had undergone a sphincterotomy with a final diagnosis of “papillary stenosis/spasm” at MUSC between January and December 2003. To measure test-retest reliability, RAPID was administered twice by telephone at 2-3 wk intervals, between 6 and 18 mo post-sphincterotomy.

## RESULTS

Of the 55 enrollees in Pilot I, 55% were female, 85% were Caucasian and the average age was 44 years (SD: 16 years). One enrolled patient did not complete the baseline questionnaire and was excluded from the analysis. At Visit 1, the average RAPID score for the 54 participants was 82 (median: 81.5, SD: 64, range: 0-255); average number of pain-days per 3-mo interval (Question 6 on RAPID) was 70 pain-days (SD: 29, range: 3-90); and 65% reported a pain severity level greater than 5 on a 10-point scale (Question 7 on RAPID; median rating: 7). Table 2 illustrates the number of participants in each RAPID grade at Visit 1 and the descriptive statistics of their RAPID score by grade. Thirty-one patients (57%) were contacted by telephone for the second interview (Visit 2). Table 3 illustrates the RAPID scores for the participants who completed both Visits 1 and 2. The test-retest reliability for the RAPID instrument, as measured by Lin's concordance, was 0.81 ( $n = 31$ ).

Of the 70 enrolled participants in the Pilot II study, the average RAPID score at the first visit was 48 (median: 0, SD: 90.76, range: 0-450). The pain episodes (questions 6-7 on RAPID) recorded at the first visit occurred at an

**Table 2** Pilot I recurrent abdominal pain intensity and disability score by migraine disability assessment grade at Visit 1 (*n* = 54)

| RAPID       | <i>n</i> | mean   | SD    | Median | Min   | Max    |
|-------------|----------|--------|-------|--------|-------|--------|
| MIDAS grade |          |        |       |        |       |        |
| 1           | 6        | 1.17   | 1.83  | 0.00   | 0.00  | 4.00   |
| 2           | 2        | 9.00   | 1.41  | 9.00   | 8.00  | 10.00  |
| 3           | 3        | 15.00  | 2.65  | 14.00  | 13.00 | 18.00  |
| 4           | 43       | 101.70 | 57.35 | 103.00 | 21.00 | 255.00 |

RAPID: Recurrent abdominal pain intensity and disability; MIDAS: Migraine disability assessment.

**Table 3** Pilot I recurrent abdominal pain intensity and disability score by Visit (for participants completing both visits)

| RAPID | <i>n</i> | mean  | SD    | Median | Min  | Max    |
|-------|----------|-------|-------|--------|------|--------|
| Visit |          |       |       |        |      |        |
| 1     | 31       | 80.65 | 71.82 | 53.00  | 0.00 | 255.00 |
| 2     | 31       | 75.71 | 79.25 | 53.00  | 0.00 | 300.00 |

RAPID: Recurrent abdominal pain intensity and disability.

average frequency of 31 pain days per 3-mo interval (SD: 39, range: 0-90), with 43% of participants reporting a pain severity level greater than 5 on a 10-point scale. Table 4 illustrates the number of participants in each grade post-treatment and the descriptive statistics of their RAPID score by grade. The RAPID was collected at both interview visits on 56 (80%) participants. RAPID scores at each visit are shown in Table 5. The test-retest reliability as measured by Lin's concordance was 0.95 (*n* = 56).

## DISCUSSION

The RAPID instrument was developed to provide a meaningful measurement of pain severity and related burden experienced by patients with suspected SOD III. This patient population is very similar to patients that suffer from severe headaches with respect to the unpredictable, intermittent, and temporarily disabling episodes of pain. For that reason, the development of RAPID relied on the published experience with the MIDAS instrument which illustrated the reliability, validity, and clinical utility of measuring pain-related disability in the previous 3 mo in patients experiencing severe headaches. The present 2 pilot studies demonstrated the reliability of the RAPID disability measure as measured by Lin's concordance. The high levels of concordance between the RAPID scores indicate that the instrument is consistent within individuals when capturing disability due to abdominal pain in the past 3 mo. The higher test-retest concordance value in Pilot II may result from participants being assessed post-sphincterotomy with several RAPID scores of 0 (no disability due to abdominal pain in the last 3 mo). The discrepancy in the completion rates between the 2 studies

**Table 4** Pilot II recurrent abdominal pain intensity and disability score by migraine disability assessment grade at Visit 1 (*n* = 70)

| RAPID       | <i>n</i> | mean   | SD     | Median | Min   | Max    |
|-------------|----------|--------|--------|--------|-------|--------|
| MIDAS grade |          |        |        |        |       |        |
| 1           | 40       | 0.33   | 1.02   | 0.00   | 0.00  | 4.00   |
| 2           | 4        | 7.00   | 1.15   | 7.00   | 6.00  | 8.00   |
| 3           | 2        | 15.00  | 0.00   | 15.00  | 15.00 | 15.00  |
| 4           | 24       | 137.33 | 109.74 | 115.50 | 26.00 | 450.00 |

RAPID: Recurrent abdominal pain intensity and disability; MIDAS: Migraine disability assessment.

**Table 5** Pilot II recurrent abdominal pain intensity and disability score by Visit (for participants completing both visits)

| RAPID | <i>n</i> | mean  | SD    | Median | Min  | Max    |
|-------|----------|-------|-------|--------|------|--------|
| Visit |          |       |       |        |      |        |
| 1     | 56       | 54.46 | 98.89 | 0.00   | 0.00 | 450.00 |
| 2     | 56       | 53.63 | 89.68 | 3.50   | 0.00 | 450.00 |

RAPID: Recurrent abdominal pain intensity and disability.

(55% Pilot I, 80% Pilot II) most likely arises from limited resources at the various participating sites in Pilot I to repeatedly contact patients after the initial telephone attempt. Despite this limitation, the instrument is easy to administer and the concordance measurements support its reliability for consistently measuring pain disability in a suspected SOD III patient population. Patients with SOD III experience severe episodic pain that is highly disabling. In our studies, 80% of the Pilot I population and 34% of the Pilot II population were classified as having severely limiting disability (Grade 4). The difference in median baseline RAPID scores between the 2 populations (82 and 0 d) provides insight into the validity of the instrument (i.e. ability to measure treatment response) but formal instrument validation studies need to be conducted. Further studies should be conducted to assess how RAPID correlates with other relevant measurements of the impact of episodic abdominal pain in this patient population including quality of life (e.g. SF-36), and depression and anxiety.

SOD is not the only condition associated with intermittent abdominal pain. Further studies are needed to show whether the RAPID instrument is an appropriate measurement tool for pain/burden and the response to treatment in other abdominal conditions, such as irritable bowel syndrome.

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## COMMENTS

### Background

Patients diagnosed with suspected sphincter of Oddi dysfunction (SOD) suffer from intermittent sphincter dysfunction and related episodes of pain. Measurement tools have not been developed to reliably measure pain severity, frequency of pain episodes, and the impact of pain on function in primary roles for these patients.

### Research frontiers

Although several treatments have been utilized to reduce pain and associated disability, measurement tools have not been developed to reliably track patient-related outcomes. In this study, the authors evaluated the feasibility of administration and estimate the test-retest reliability of a newly developed instrument, the recurrent abdominal pain intensity and disability, for the measurement of disability due to episodic abdominal pain in patients with suspected SOD.

### Innovations and breakthroughs

A measurement tool that reliably measures disability due to pain has the potential to improve understanding of the impact of treatments. This manuscript reports the development and reliability testing of an instrument that measures pain severity and related burden experienced by patients with suspected SOD.

### Applications

If shown to be reliable, then future studies can assess the clinical usefulness of this instrument in suspected SOD patients and potentially other similar abdominal conditions such as irritable bowel syndrome.

### Peer review

Professor Durkalski *et al* have performed an interesting pilot study in order to evaluate abdominal pain and disability in patients with suspected sphincter of Oddi dysfunction.

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