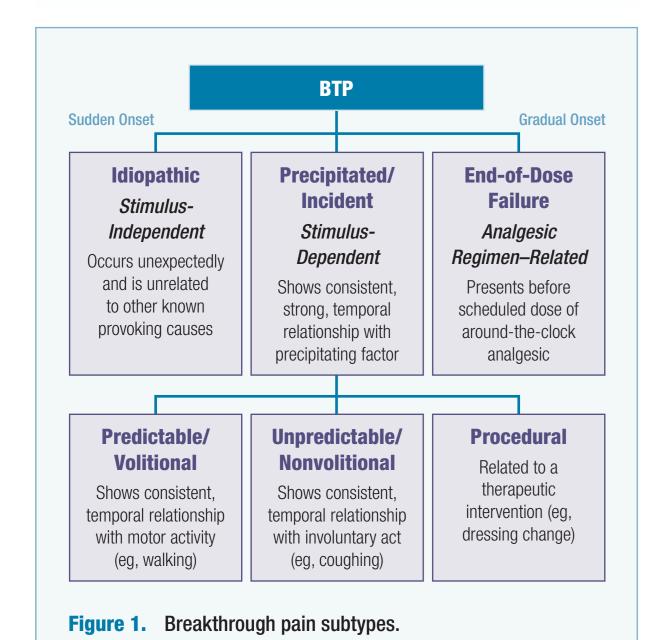
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INTRODUCTION

Chronic pain is a disease of the central and peripheral nervous systems with unpleasant, recurring, and often debilitating consequences. An inherently labile and subjective experience, chronic pain has two components: persistent pain and breakthrough pain (BTP).¹ Persistent pain occurs around-the-clock (ATC) and represents a baseline condition, whereas BTP is a transitory episode of moderate to severe pain in patients with otherwise well-controlled baseline pain. Epidemiologic data indicate that BTP is widely prevalent and similar in patients with chronic cancer-related or noncancer pain.²-6

BTP can be classified into several subtypes based on precipitants and predictability (**Figure 1**).^{5,7} Idiopathic BTP subtype is unrelated to an identifiable cause, occurs unexpectedly, and usually has a rapid onset. Incident BTP, another subtype, is attributed to precipitating factor(s) that are either volitional or nonvolitional. Medical treatment may in some patients cause procedural BTP. And finally, end-of-dose failure is a common BTP subtype that emerges as ATC medication falls below analgesic levels.^{5,7}

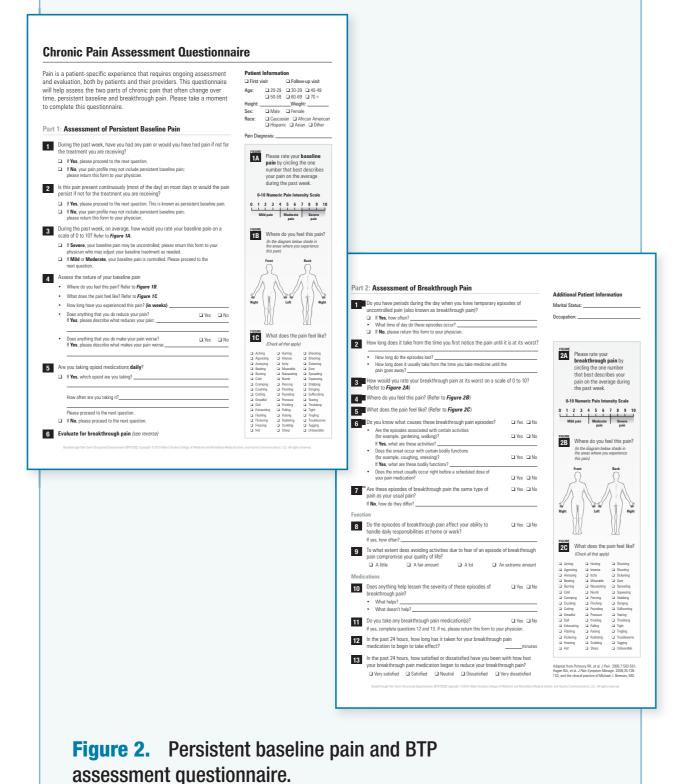
Appropriate management of chronic pain requires comprehensive initial and ongoing assessment. Structured around clinical interviews, patient history, and physical examination, assessment necessarily evaluates pain pathogenesis as well as patient function, comorbidities, and treatment goals. Patient self-reports provide critical insights into the pain profile, particularly the severity and adverse effects of the pain experience, which vary considerably within and between patients. Clinicians and patients would benefit from strategies and resources that help capture the dynamics of chronic pain and the factors that may precipitate, perpetuate, or palliate



its symptoms. Although validated tools are available to assess chronic pain in general, few, if any, specifically distinguish persistent baseline pain from BTP. Accordingly, we have developed a preliminary Persistent and Breakthrough Pain Semi-Structured Questionnaire (BTP/SSQ). Results presented here reflect initial efforts to develop a tool broadly applicable to diverse chronic pain patient populations encountered in academic and community-based pain clinics. Iterative refinement of the questionnaire—stressing, in particular, the layout, word choices, syntax, and intent and value of each question—is ongoing.

METHODS

Peer-reviewed literature, expert opinion, and clinical experience were synthesized to develop this preliminary questionnaire. Structured to help characterize the patient-specific temporal dynamics of chronic pain, 4,5,8,9 Part 1 of the BTP/SSQ addresses persistent baseline pain, while Part 2 addresses breakthrough pain (**Figure 2**). We evaluated the BTP/SSQ based in part on its ability to improve dialogue between the clinician and the patient, and to discriminate controlled from uncontrolled pain as well as persistent baseline pain from BTP. To this end, 112 chronic pain patients from private practices and academic teaching and community-based hospitals completed the BTP/SSQ, data from which were then consolidated and evaluated according to traditional statistical methods.



RESULTS

The BTP/SSQ respondents were predominantly white and middle-aged, with slightly more women than men represented (**Table 1**). Respondents were diagnosed with a wide range of chronic pain conditions—prominently including chronic low back pain and osteoarthritis—that spanned the cancer and noncancer spectrum (**Table 2**).

Characteristics	Patients
Race/Ethnicity, n (%) [80 respondents]	
/hite	71 (88.8)
ispanic	6 (7.5)
Asian	2 (2.5)
Other	1 (1.2)
ge (mean), y	51
Sex, n (%) [86 respondents]	
Men .	39 (45.3)
Vomen	47 (54.7)

Etiology	n (%) [112 Respondents]
Musculoskeletal pain	9 (8.0)
Osteoarthritis	16 (14.3)
Chronic low back pain	64 (57.1)
Fibromyalgia	13 (11.6)
Cancer pain	4 (3.6)
Neuropathic pain	6 (5.4)

Approximately two-thirds of respondents (69%) had their persistent pain controlled, most commonly with opioids (81%) (**Table 3**). BTP was reported by nearly 86% of respondents (**Table 4**). Consistent with peer-reviewed literature, the episodes occurred most frequently 1 to 3 times daily, with durations from 30 minutes to 3 hours. Most patients (78%) rated their BTP episodes as severe, with time to peak intensity ranging from immediately to 6 hours after onset. Further, 65% of respondents described their BTP as "similar" to their persistent pain, and 87% reported that their BTP significantly diminished their ability to perform daily activities. More than half (57%) of the respondents stated that their BTP markedly reduced their quality of life. Of note, 4 of every 5 patients (80%) indicated that pharmacologic as well as nonpharmacologic modalities such as heat or massage reduced their BTP severity. Moreover, 70% of patients reported medication use for their BTP, with an average of 40 minutes required for onset of analgesia.

Table 3. Persistent (baseline) pain characteristics

Controlled – prevalence, n (%) [104 respondents]	72 (69.2)
Duration of chronic pain	1 week – 32 years
Daily opioid use, n (%) [78 respondents]	63 (80.8)
Does anything aggravate the chronic pain? YES; n (%) [93 respondents]	83 (89.2)
Aggravating factors, n (%) [83 respondents]
Sitting	21 (25.3)
Walking	19 (22.9)
Standing	17 (20.5)
General activity	16 (19.3)
Lifting	15 (18.1)
Bending	11 (13.3)
Work	4 (4.8)

Table 4. BTP characteristics

Prevalence, n (%) [99 respondents]	85 (85.9)
Same type as persistent pain, n (%) [80 respondents]	52 (65.0)
Intensity	
"Severe" prevalence, n (%) [88 respondents]	69 (78.4)
Temporal	
Frequency, episodes/day	1-3
Duration, min	30-180
Time to peak intensity, min	0-360
Function	
Impact on daily activity, n (%) [87 respondents]	76 (87.4)
"A lot"/"extreme" impact on quality-of-life, n (%) [85 respondents]	48 (56.5)
Management	
Able to identify modalities to lessen severity, n (%) [80 respondents]	64 (80.0)
Medication use, n (%) [79 respondents]	55 (69.6)
Time to analgesia (mean), min	40
Subtypes	
Incident	
Volitional, n (%) [75 respondents]	55 (73.3)
Nonvolitional, n (%) [76 respondents]	17 (22.4)
End-of-dose failure, n (%) [37 respondents]	27 (73.0)
Could not identify a precipitant, n (%) [75 respondents]	32 (42.7)

The questionnaire also facilitated differentiation between various BTP subtypes: 73% of patients reported volitional incident pain, 22% nonvolitional incident pain, and 73% end-of-dose failure, the latter underscoring the need for continual assessment of ATC dosing strategies. About 43% of patients reported that they could not identify a precipitant for their BTP. Although varying in intensity, similar descriptors were used by patients to characterize their persistent pain and BTP experiences (**Table 5**). The most commonly reported locations of persistent pain and BTP are described in **Table 6**.

Descriptor	Persistent Pain, n (%) [106 Respondents]	BTP, n (%) [70 Respondents]
Aching	63 (59.4)	39 (55.7)
Agonizing	33 (31.1)	19 (27.1)
Annoying	39 (36.8)	16 (22.9)
Burning	31 (29.2)	16 (22.9)
Hurting	48 (45.3)	23 (32.9)
Intense	42 (39.6)	25 (35.7)
Miserable	31 (29.2)	16 (22.9)
Radiating	37 (34.9)	17 (24.3)
Sharp	45 (42.5)	25 (35.7)
Shooting	29 (27.4)	24 (34.3)
Sore	35 (33.0)	16 (22.9)
Stabbing	37 (34.9)	24 (34.3)
Throbbing	37 (34.9)	23 (32.9)
Unbearable	23 (21.7)	16 (22.9)

Location	Persistent Pain, n (%) [104 Respondents]	BTP, n (%) [80 Respondents]
Neck	14 (13.5)	11 (13.8)
Back	54 (51.9)	50 (62.5)
Lower back	43 (41.3)	40 (50.0)
Hip	27 (26.0)	15 (18.8)
Shoulder	23 (22.1)	16 (20.0)
Leg	53 (51.0)	47 (58.8)
Abdomen	11 (10.6)	5 (6.3)

CONCLUSIONS

This BTP/SSQ is designed to meet an as yet unaddressed clinical need—namely, an assessment tool predicated on the volatility of the chronic pain experience, even when well controlled, and its validated separation into two distinct though interrelated temporal components: persistent baseline pain and BTP. As noted in an accompanying poster, much of our preliminary work was aided by an IRB-reviewed educational outcomes study, results from which highlight the need for this BTP screening instrument. Although limited, the data presented here support findings from peer-reviewed studies over the past two decades.

Pending further evaluation, the BTP/SSQ may improve patient education on such abstract issues as temporal variations in pain and the corresponding need to continually monitor analgesia effectiveness. Further, the BTP/SSQ may help clinicians and patients alike characterize persistent pain and BTP, and provide both with improved strategies for multimodal treatment. Further psychometric evaluation is planned in subsequent studies.

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DISCLOSURES

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