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Perception of Breakthrough Pain in Patients with Chronic Painful Conditions

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Background

- Breakthrough pain has been defined as *"a transitory increase in pain to greater than moderate intensity, which occurs on a baseline pain of moderate intensity or less in a patient receiving chronic opioid therapy"*[1]
- However, pain flares may also be experienced by patients with medical conditions that are not routinely treated with opioids
- An understanding of how patients characterize their pain flares will improve the scientific and clinical communities' ability to communicate with this population

1. Portenoy RK, Hagen NA. Breakthrough pain: Definition, prevalence, and characteristics. *Pain* 11990;41:273-81.

Objective

- To understand how patients with chronic non-cancer pain define and describe pain flares

Study Design

- A 3-month prospective, observational study of outpatients at a large U.S. tertiary care center
- Follow-up consisted of a 1 week diary administered at baseline, then a monthly telephone survey for 3 consecutive months

Methods

Sample Population

- Patients who had chronic pain due to one or more of the following medical conditions:
  - Musculoskeletal problems (back, knee, shoulder, neck, and other areas)
  - Rheumatological diseases (arthritis, lupus, and others)
  - Chronic headache
  - Sickle cell anemia

Eligibility Criteria

- Inclusions
  - Patients with chronic pain meeting the following definition: "*Chronic pain is pain that continues a month or more beyond the usual recovery period for an injury or illness or that goes on for months or years due to a chronic condition. The pain is usually not constant, but can interfere with daily life at all levels.*"[2]
  - Age ≥18 years
- Exclusions
  - Patients who were not able to communicate in English sufficiently well to complete the required follow-up
  - Patients deemed to be inappropriate for participation by their physician

2. American Chronic Pain Association. Definition of Chronic Pain. Available at: http://www.theacpa.org

Data

- A Pain Flare Definitions Questionnaire was administered at baseline
  - A short-two item instrument developed by United BioSource Corporation
  - Patients were asked to choose a term that best describes a pain flare and a definition of the term they selected
- Pain scores were captured using a 10-point scale
  - 0 = "No Pain"; 10 = "Worst Pain Imaginable"

Pain Flare Definitions Questionnaire

Directions: Please answer the following questions, which will help us to better understand your perspective on pain flares.

1) What term best describes your pain flare?
Check one of the following terms:
- o Breakthrough pain
- o Acute pain episode
- o Pain crisis
- o Sudden new pain episode
- o Pain flare

2) How would you best define the term you checked above?
Check one of the definitions listed below:
- o Brief episode of pain more intense than your usual pain
- o A period of intense pain worse than usual normal pain
- o An episode of pain worse than your controlled pain
- o An intense pain worse than your regular pain
- o Sudden pain more than your chronic pain

Results

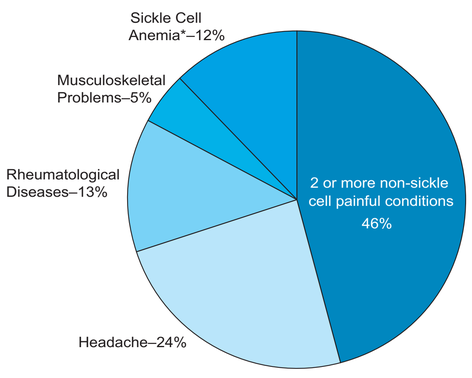
Demographics

A total of 161 participants completed the diary. Most were female (79%), Caucasian (68%), and experienced at least 1 pain flare during the diary week (88%).

Gender	n	%
Females	127	79%
Males	34	21%
Ethnicity	**n**	**%**
Caucasian	106	68%
African American	45	29%
Hispanic	4	3%
Asian	1	1%
Other	1	1%
At Least 1 Pain Flare During Diary Week	**n**	**%**
Yes	141	88%
No	15	9%

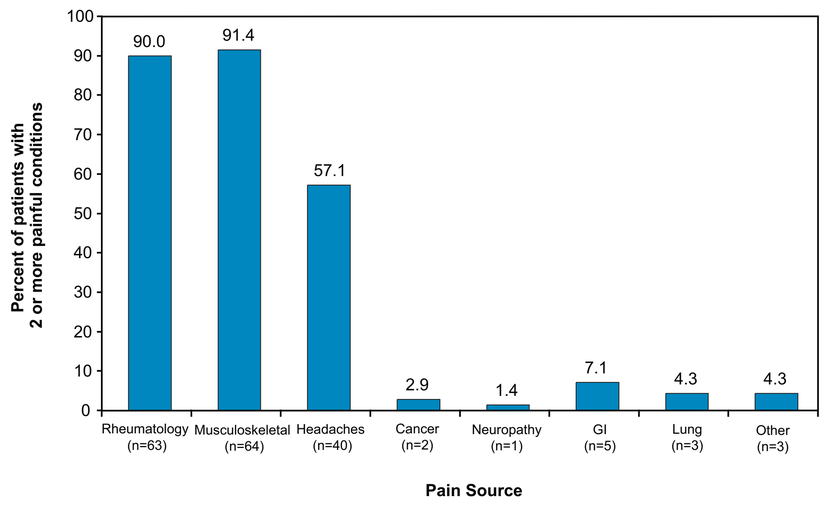
Enrollment by Pain Source (n=151)

Among the 161 patients enrolled, 151 answered both pain flare definition questions. Of these, 36 suffered from headache, 19 from rheumatological diseases, 8 from musculoskeletal problems, 18 from sickle cell anemia, and 70 with 2 or more painful non-sickle cell conditions



*Patients with sickle cell anemia and other painful conditions

Sources of Pain Among Patients with 2 or More Painful Conditions (n=70)*



*Patients can have two sources of pain that fall into the same category.

Demographics

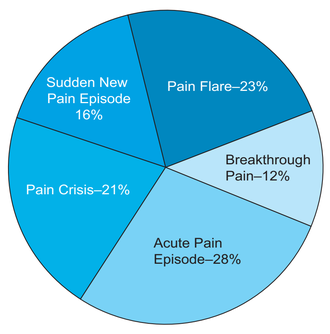
The mean pain level reported during the diary week was 6, and the mean age was 47 years.

	n	Mean	Median	SD	Range
Pain Level*	159	5.77	6	2.1	0.0-10.0
Age (years)	161	47.44	48	14.34	18.0-83.0

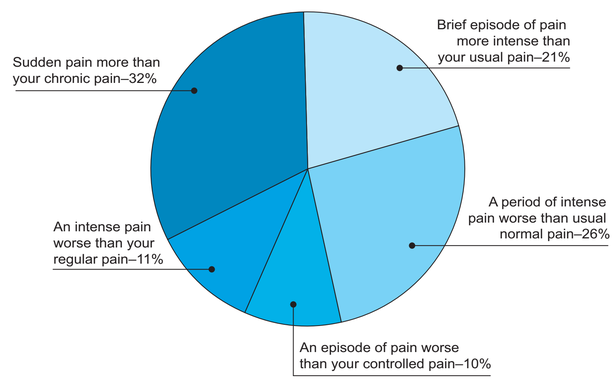
*Pain scores based on 10-point scale with 0 described as "No Pain" and 10 described as the "Worst Pain Imaginable"

Term Preferred to Describe a Pain Flare (n=155)

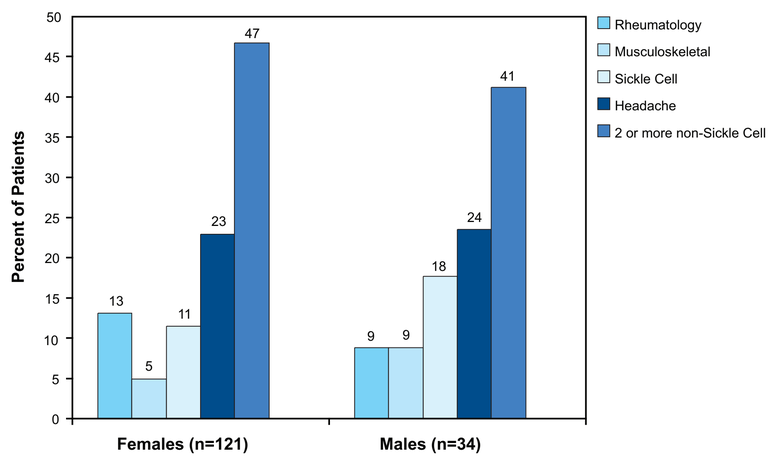
The most common terms used to describe a pain flare were "Acute Pain Episode" (28%), "Pain Flare" (23%), and "Pain Crisis" (21%)



How Patients Defined a "Pain Flare" (n=154)

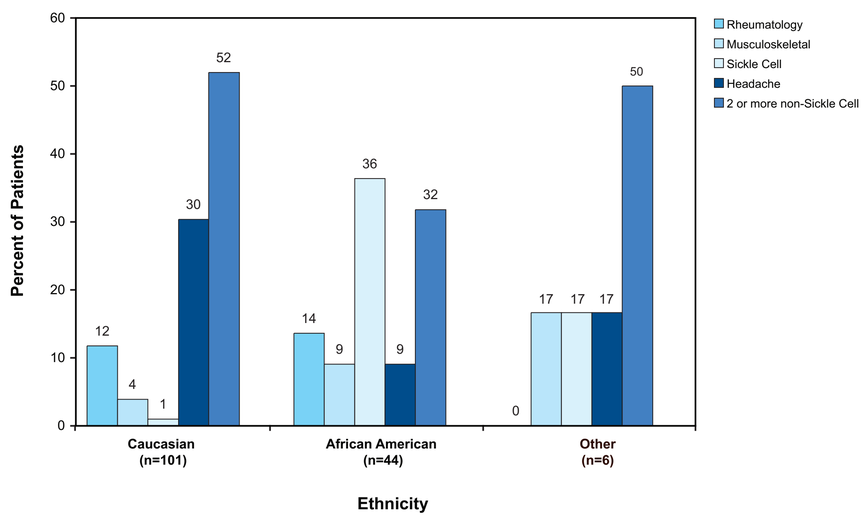


Pain Source by Gender*



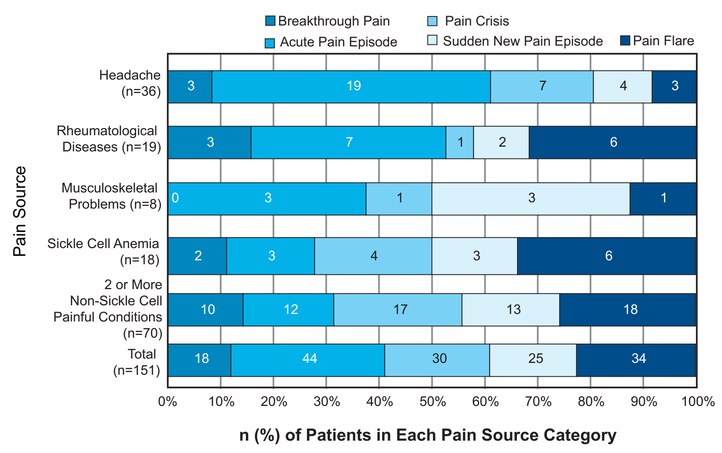
*Percent of patients within each gender group with specified pain source

Pain Source by Ethnicity*

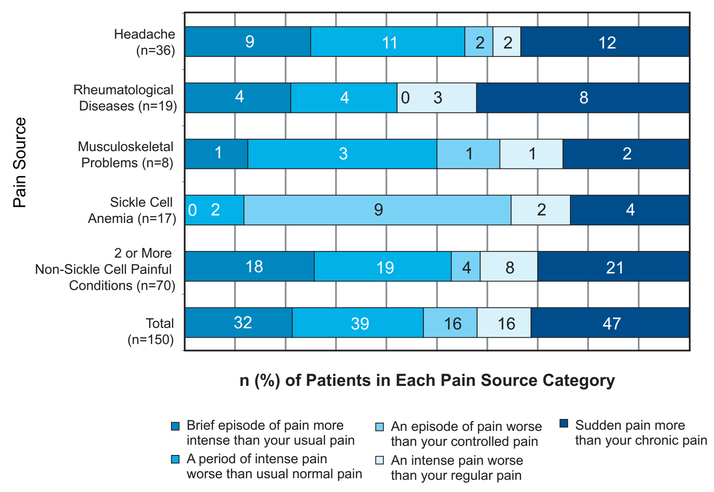


*Percent of patients within each ethnicity group with specified pain source

Term Preferred to Describe a Pain Flare, by Pain Source (n=151)



Definition of a "Pain Flare" By Pain Source (n=150)



Limitations

- Patients appear to have severe disease and therefore are not representative of all patients with these conditions
- Analyses are limited by small Pain Source groups
- Study fails to capture patients with neuropathic pain, another important source of chronic non-cancer pain
- Additional analyses of participants with 2 or more sources of pain would be worthwhile to examine whether their perceptions are consistent with the single-source pain groups

Conclusions

- Participants did not prefer to use the term "Breakthrough Pain" when referring to a pain flare
  - They preferred the terms "Acute Pain Episode" and "Pain Crisis" or simply "Pain Flare"
- Chronic headache patients appeared to prefer the term "Acute Pain Episode"
- The concepts of "Sudden", "Period", and "Brief" appear to be important when defining a pain flare
- Results will be helpful to outcomes researchers who study pain and to clinicians who treat patients with these conditions

Disclosure

- This study was funded through an Investigator Sponsored Research grant from Cephalon, Inc.
- Results reflect slight changes to numbers presented in the published abstract because poster analyses are limited to those who responded to both items in the Pain Flare Definitions Questionnaire

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