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Perception of Breakthrough Pain in Patients with Chronic Painful Conditions

L. T. Pizzi Thomas Jefferson University, laura.pizzi@jefferson.edu

S. P. Lee Thomas Jefferson University

D. Richardson Thomas Jefferson University

N. Cobb Thomas Jefferson University

B. Leas Thomas Jefferson University

See next page for additional authors

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Authors

L. T. Pizzi, S. P. Lee, D. Richardson, N. Cobb, B. Leas, R. Toner, V. Pracilio, S. K. Ballas, A. Ashkenazi, C. T. Derk, D. Wang, and E. DeSousa



Perception of Breakthrough Pain in Patients with Chronic Painful Conditions

LT Pizzi¹, SP Lee¹, D Richardson¹, N Cobb¹, B Leas¹, R Toner¹, V Pracilio¹, SK Ballas², A Ashkenazi³, CT Derk³, D Wang³, E DeSousa³

¹Department of Health Policy, Jefferson Medical College, Philadelphia PA, USA ²Cardeza Foundation, Department of Medicine, Jefferson Medical College, Philadelphia, PA, USA ³Jefferson University Physicians, Philadelphia PA, USA

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

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

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"

1. Portenov 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

Results

- 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 \geq 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

Pain Flare Definitions Questionnaire

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

- 1) What term <u>best</u> describes your pain flare? Check one of the following terms:
 - o Breakthrough pain
 - Acute pain episode
 - Pain crisis
 - Sudden new pain episode
 - o Pain flare
- 2) How would you <u>best</u> 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

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%).

							90 -						
Gender	n	%	questi		Musculoskeletal	5	80 -						
emales	127	79%		ese, 36 suffered headache, 19	Problems-5%	SU							
lales	34	21%		rheumatological		di≦i	70 -						
Ethnicity	n	%	diseas	ses, 8 from	Rheumatological		60 -	57.1	l				
Caucasian	106	68%		uloskeletal	Diseases–13% 2 or more non-sickle cell painful conditions 46%	of patier painful c	50 -						
African American	45	29%		ems, 18 from cell anemia, and		e pa	40 -						
lispanic	4	3%		th 2 or more		lo zo	30 -						
Asian	1	1%		ul non-sickle cell									
Other	1	1%	condit	tions	Headache-24%		20 -						
At Least 1 Pain Flare During Diary Week	n	%			Treaddorne=2470		10 -		2.9	1.4	7.1	4.3	4.3
/es	141	88%					-	/ Musculoskeletal Headach (n=64) (n=40		Neuropathy (n=1)	GI (n=5)	Lung (n=3)	Other (n=3)
No	15	9%					(11 00)		, ()	()	(11 0)	(11 0)	(11-0)
							Pain Source						
			*Patients	with sickle cell anemia and other p	ainful conditions	*Patients can h	*Patients can have two sources of pain that fall into the same category.						
					Term Preferred to Describe a Pa			Patients Def	inod a "	Dain Ela	pro" (n-	_15/1)	 1
mographics					(n=155)		11000	ratients Der	incu a		ne (n-	-134)	
	2 d P												
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nean pain level reported du d the mean age was 47 yea		ek was			The most common terms used to describe a pain flare w Pain Episode" (28%) "Pain Flare" (23%) and "Pain Cris								
			SD Ra	ange	The most common terms used to describe a pain flare w Pain Episode" (28%), "Pain Flare" (23%), and "Pain Cris						Brief episode o more intens		
	ars.	an Median		ange)-10.0				pain more than pnic pain–32%			Brief episode o more intens your usual pair	se than	

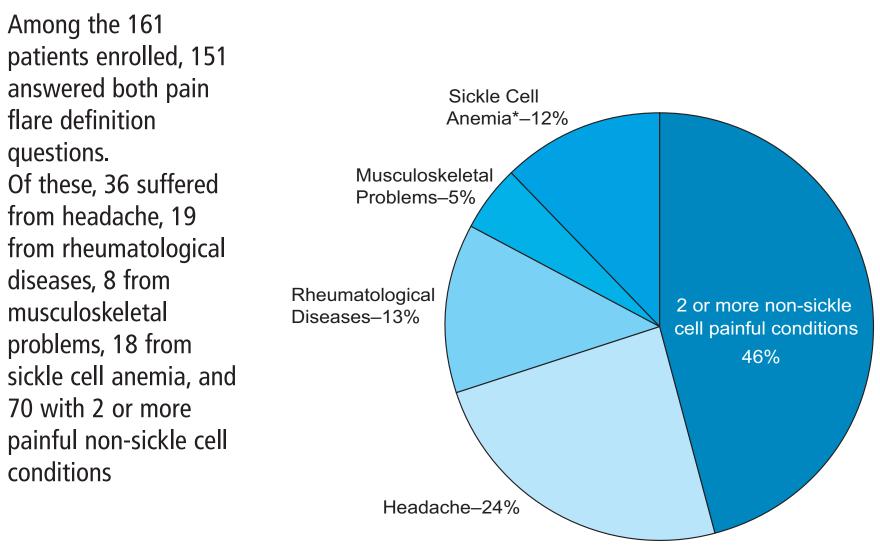
udden New

Pain Episode

16%

Pain Crisis-21%

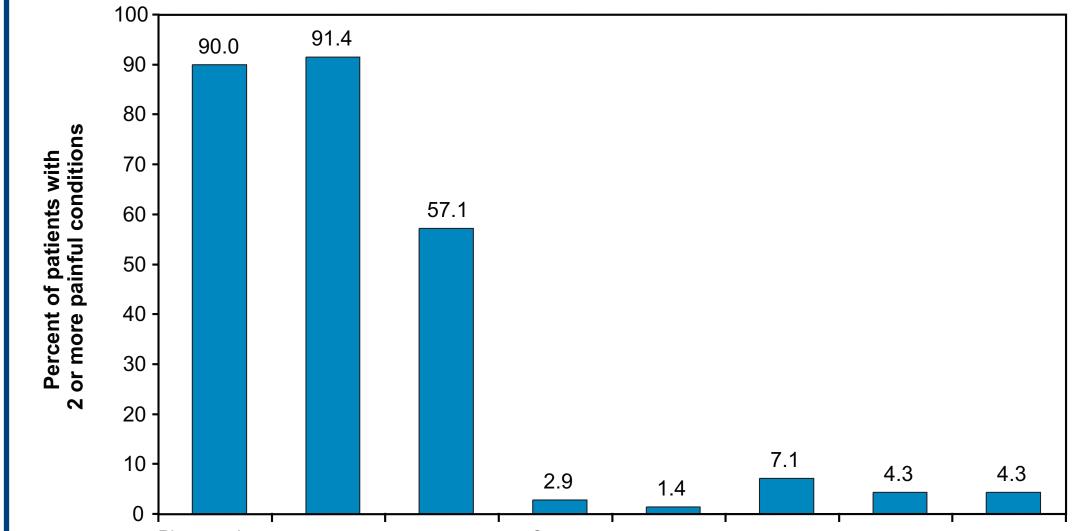
Enrollment by Pain Source (n=151)



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

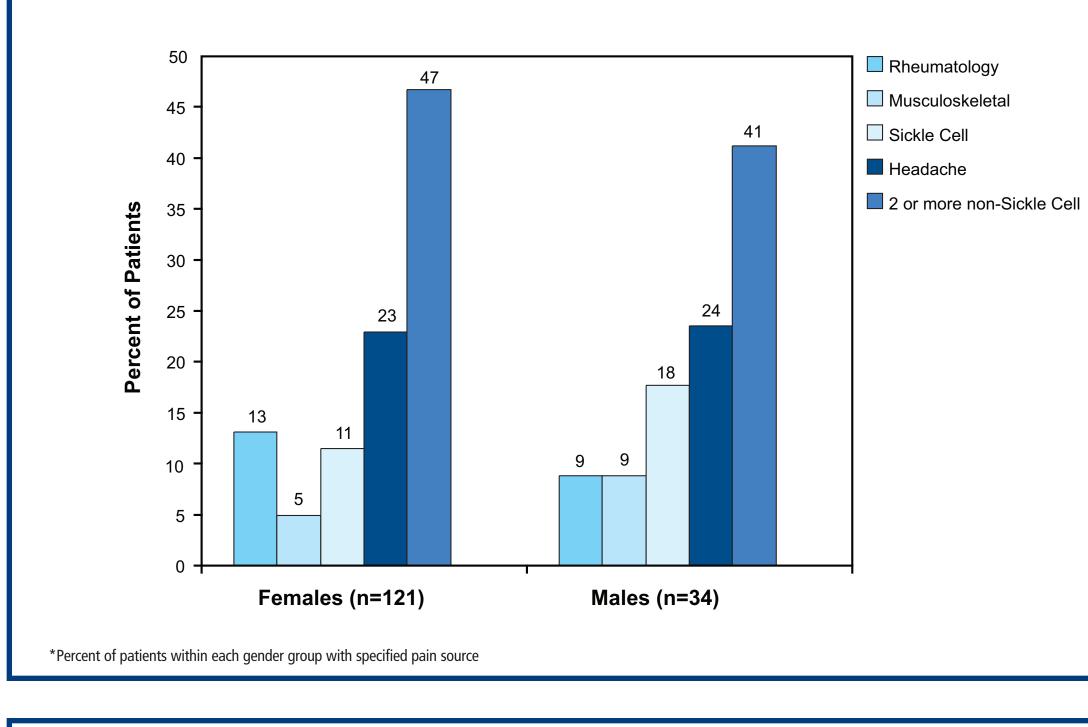
An intense pain

worse than your regular pain–11%



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

Pain Source by Gender*



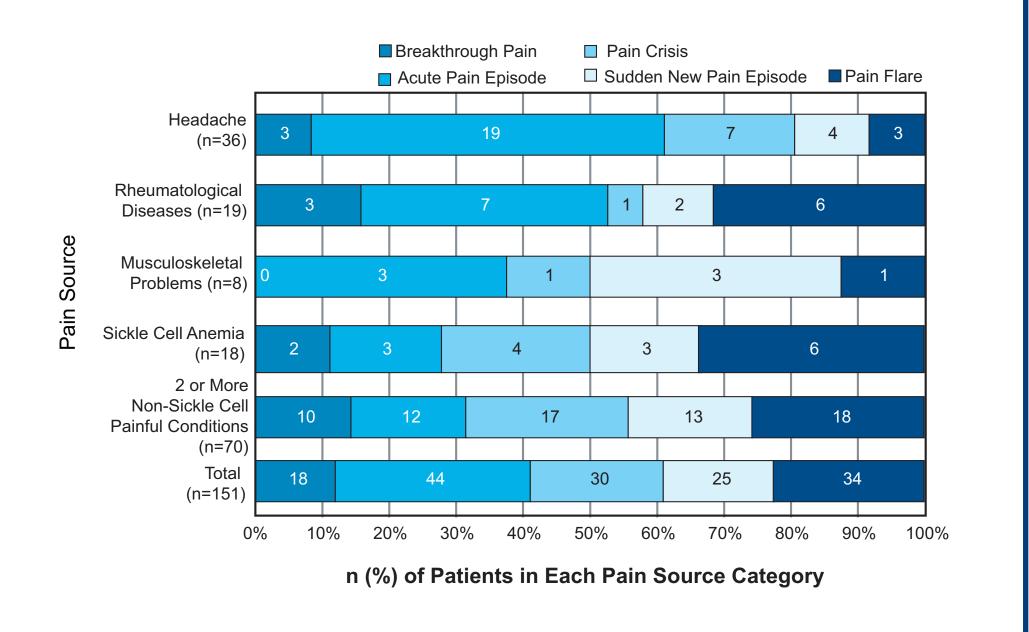
Acute Pain Episode-28%

Pain Flare-23%

Breakthrough

Pain–12%

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



Limitations

An episode of pain worse

than your controlled pain–10%

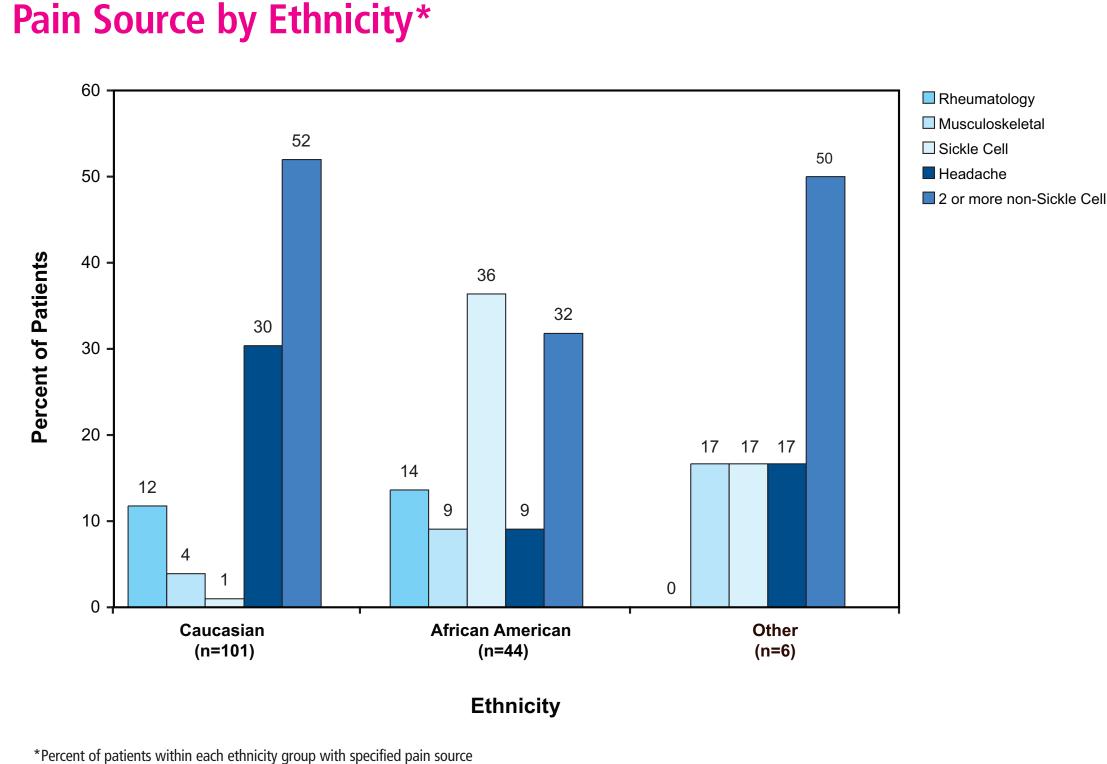
• Patients appear to have severe disease and therefore are not representative of all patients with these conditions

A period of intense

normal pain-26%

pain worse than usual

- Analyses are limited by small Pain Source groups
- Study fails to capture patients with neuropathic pain, another important source of chronic



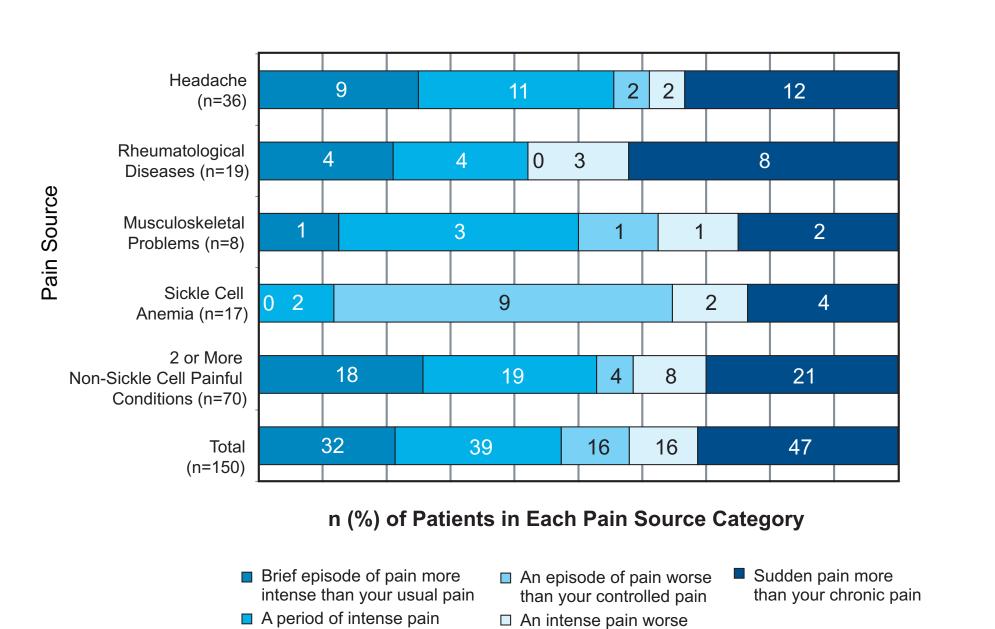
Disclosure

- 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**

Acknowledgements

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- We also appreciate the assistance of Angela Yin-Chieh Yu, PharmD candidate, in developing the poster

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



than your regular pain

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

Presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 10th Annual European Congress, Dublin Ireland, October 20-23, 2007 (Poster Number PPN9)

worse than usual normal pain