



Low back pain definitions: effect on patient inclusion and clinical profiles

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Abstract

Introduction: Numerous definitions of acute low back pain (aLBP) exist. The use of different definitions results in variability in reported prevalence or incidence, conflicting data regarding factors associated with the transition to chronic LBP (cLBP), and hampers comparability among studies.

Objective: Here, we compare the impact of 3 aLBP definitions on the number of aLBP cases and participants' characteristics and explore the distribution of participants across definitions.

Methods: A sample of 1264 participants from the Quebec Low Back Pain Study was included. Three definitions of aLBP were used: (1) not meeting the National Institutes of Health (NIH) cLBP definition ("nonchronic"), (2) pain beginning <3 months ago ("acute"), and (3) pain beginning <3 months with a preceding LBP-free period ("new episode").

Results: There were 847, 842, and 489 aLBP cases meeting the criteria for the 3 definitions, respectively. Participants included in the "nonchronic" had lower pain interference, greater physical function scores, and fewer participants reporting >5 years of pain than in the other definitions. Half the participants meeting the "acute" definition and one-third of participants meeting the "new episode" definition were also classified as cLBP based on the NIH definition.

Conclusions: Our results highlight the importance of the definition used for aLBP. Different definitions influence the sample size and clinical profiles (group's characteristics). We recommended that cohort studies examining the transition from aLBP to cLBP ensure that the definitions selected are mutually exclusive (ie, participants included [aLBP] differ from the expected outcome [cLBP]).

Keywords: Acute low back pain, Chronic low back pain, Cohort study

1. Introduction

Low back pain (LBP) is the leading cause of global years-lived-with-disability.¹⁸ The inefficacy of interventions to alleviate pain^{2,15} and transition to chronic LBP (cLBP) explains its enormous socioeconomic burden. When cLBP cannot be explained by another diagnosis and if associated with significant

emotional distress or functional disability, it is now considered a primary disease (chronic primary pain).¹² Thus, it is critical to understand factors underlying the transition to cLBP or recovery after an acute episode of LBP (aLBP).

When examining factors driving the transition to cLBP, the criteria used to define aLBP and cLBP may influence the results. In an expert

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consensus statement, a new episode of aLBP was defined as pain <3 months in duration, preceded by a pain-free period,^{4,6} although some studies do not include a pain-free period.^{1,7,11} Recent studies have used a different aLBP definition based on failure to meet the NIH cLBP definition^{13,17} (ie, “a back pain problem that has persisted at least 3 months and has resulted in pain on at least half the days in the past 6 months”¹⁷). However, failure to meet the cLBP definition is not necessarily equivalent to aLBP. For example, patients having pain for >3 months do not meet the consensus aLBP definition,⁶ and an individual with recurring pain for many years may not meet the NIH cLBP definition. Therefore, use of the newly introduced aLBP definition may artificially inflate sample sizes and confound baseline group characteristics, which could influence discovery of factors related to the transition from aLBP to cLBP. Inconsistent use of aLBP definitions will hinder interpretation and comparisons across studies. Here, we compare the impact of 3 aLBP definitions on the number of aLBP cases and group characteristics using the Quebec Low Back Pain Study.¹⁴

2. Methods

2.1. Participants

The Quebec Low Back Pain Study began recruiting LBP participants in November 2018 (clinicaltrials.gov: NCT04791891). In June 2021, 3367 participants¹⁴ met the inclusion criteria: ≥ 18 years old, fluent in French or English, and suffering from LBP (LBP in the last 4 weeks that is strong enough to limit usual activities or change their daily routine for >1 day⁶). Various recruitment strategies were used: online recruitment (eg, Facebook ads), newspapers ads, leaflets in clinical practices, etc. Data were collected using a survey in REDCap (Research Electronic Data Capture). Participants completed the Canadian adaptation of the minimum NIH dataset for cLBP,¹⁰ the EQ-5D-5L (health-related quality of life), and 4 questions based on the consensus of Dionne et al. (2008) to determine if participants had aLBP.⁶ Demographic characteristics and clinical scores (eg, pain intensity, physical function) were extracted from the minimum dataset.¹⁰ The study was approved by the IRB of McGill University (Project: #A06-M22-18A), in accordance with the Declaration of Helsinki. Participants provided written informed consent.

2.2. Acute LBP definitions

2.2.1. First definition (“nonchronic”)

Participants were considered to have aLBP if they did not meet the NIH cLBP definition,⁵ ie, if they reported (1) the presence of pain for <3 months or (2) the presence of pain for ≥3 months but experienced pain less than half the days in the past 6 months. According to this classification, participants were either aLBP or cLBP based on their responses to 2 questions (see Supplementary material 1, available at <http://links.lww.com/PR9/A154>). This definition was used in a cohort study¹⁷ as a diagnostic criterion for categories of aLBP.¹³

2.2.2. Second definition (“acute”)

Participants were considered to have aLBP if they reported having LBP for <3 months, ie, if they responded “Yes” to the question: “Did your back pain begin less than 3 months ago?” as suggested by Dionne et al.⁶ Here, the presence LBP-free period preceding the current pain episode is not considered, as in some cohort studies.^{1,7,11}

2.2.3. Third definition (“new episode”)

Participants were considered to have a new aLBP episode if they reported having LBP for <3 months (responded “Yes” to “Did your

back pain begin less than 3 months ago?”) and a LBP-free period of at least 3 months (“If yes, was this episode of pain preceded by a period of at least 3 months without pain in your lower back?”).^{4,6}

These 3 definitions were selected to compare the (1) non-consensus, “nonchronic” definition recently used in some studies^{13,17} to the consensus definition (2) with^{4,6,16} and (3) without a pain-free period.^{1,7,11}

2.3. Statistical analysis

Frequencies (n) and proportions (%) were calculated for categorical variables, and central tendency and dispersion measures for continuous variables (SAS version 9.4; SAS Institute). The 95% confidence interval for multinomial proportions and medians were calculated. A Venn diagram (Fig. 1) was used to determine the distribution of participants between definitions. See supplementary material for additional analyses (available at <http://links.lww.com/PR9/A154>).

3. Results

3.1. Number of cases vary by aLBP definition

A total of 1264 participants were classified as having aLBP regardless of the definition (Figs. 1), and 327 (25.9%) of all participants were classified as aLBP by all 3 definitions. The number of aLBP cases varied across definitions: 489 for the third definition (“new episode”) compared with 847 and 842 participants for the first (“nonchronic”) and second definitions (“acute”), respectively.

Noteworthy, 32.9% of all participants concurrently met the criteria of either “acute” or “new episode” and the NIH criteria for cLBP (see supplemental eFigure 1, available at <http://links.lww.com/PR9/A154>). In addition, 422 participants from the “nonchronic” definition had LBP for >3 months (see supplemental eTable 1, available at <http://links.lww.com/PR9/A154>).

3.2. Participant characteristics vary by acute low back pain definition

Table 1 presents comparisons between the 3 definitions. Participants included in the “nonchronic” definition had lower

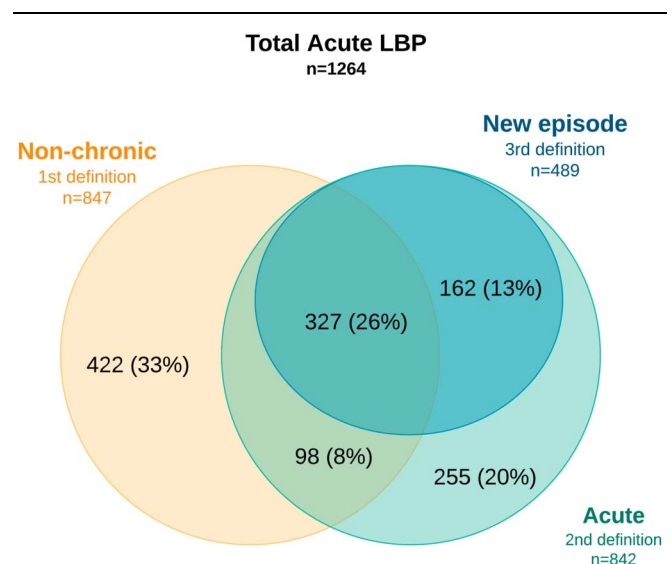


Figure 1. Venn diagram of the 3 acute low back pain (LBP) definitions. Distribution of the total number of participants (n = 1264) identified as having acute LBP across the 3 definitions. Note that only 26% of participants were classified as having acute LBP by the 3 definitions. LBP, low back pain.

pain interference and greater physical function scores compared with those in the “acute” and “new episode” groups. The “nonchronic” participants reported fewer catastrophizing and kinesiophobia thoughts, lower emotional distress or depression, and lower pain impact scores compared with “acute” participants. A higher proportion of the “nonchronic” participants reported pain duration >5 years compared with “new episode,” and fewer participants reported pain duration between 3 and 6 months in the “nonchronic” compared with other definitions.

4. Discussion

The definition used for aLBP classification had an impact both on the number of aLBP cases and on clinical profiles. In addition, our results highlight that the acute or chronic LBP classifications using consensus definitions is neither mutually exclusive nor exhaustive. This may introduce significant bias, especially in studies testing predictors of the acute to cLBP transition.

Participants meeting the “nonchronic” definition had a better clinical profile (eg, better physical function) compared

with participants included in the 2 other definitions, most likely because ~50% of these participants had pain for >3 months (eTable 1, available at <http://links.lww.com/PR9/A154>). Because participants with LBP for >3 months do not meet the consensus aLBP definition,^{4,6} their inclusion inflates study sample size (eg, for prevalence studies), impacts group characteristics, and may confound data related to the transition from acute to cLBP. Importantly, one derived subgroup (“only nonchronic”) met neither of the other 2 aLBP definitions nor the NIH cLBP definition. Thus, using acute or chronic consensus definitions may result in a lack of exhaustiveness (ie, some participants will be classified neither as acute nor chronic).

Although the “nonchronic” definition does not follow the consensus aLBP definition, it has the advantage of producing 2 mutually exclusive groups because participants not meeting the chronic LBP criteria are considered acute.¹⁷ In contrast, we observed nonmutually exclusive groups while using the “acute” and “new episode” definitions. Indeed, half of the participants meeting the “acute” definition and one-third of the participants meeting the “new episode” definition were also classified as

Table 1
Characteristics of the 3 acute low back pain definitions.

Variable	Category	Nonchronic (n = 847)		Acute (n = 842)		New episode (n = 489)	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Age groups (y)	18–40	414	48.9 (44.8–53.0)	353	41.9 (37.9–46.0)	220	45.0 (39.7–50.4)
	41–60	390	46.0 (42.0–50.2)	424	50.4 (46.2–54.5)	242	49.5 (44.1–54.9)
	>60	43	5.1 (3.6–7.2)	65	7.7 (5.8–10.2)	27	5.5 (3.5–8.5)
Sex at birth	Female	442	52.2 (48.1–56.3)	475	56.4 (52.3–60.4)	271	55.4 (50.0–60.7)
	Male	386	45.6 (41.5–49.7)	352	41.8 (37.8–45.9)	211	43.1 (37.9–48.6)
	Missing	19	2.2 (1.3–3.8)	15	1.8 (1.0–3.2)	7	1.4 (0.6–3.4)
Obesity	<30 kg/m ²	491	58.0 (53.9–62.0)	483	57.4 (53.2–61.4)	285	58.3 (52.9–63.5)
	≥30 kg/m ²	314	37.1 (33.2–41.1)	310	36.8 (32.9–40.9)	181	37.0 (32.0–42.4)
	Missing	42	5.0 (3.5–7.1)	49	5.8 (4.2–8.1)	23	4.7 (2.9–7.6)
Smoking status	Never smoked	398	47.0 (42.7–51.3)	359	42.6 (38.4–46.9)	234	47.9 (42.3–53.5)
	Current smoker	150	17.7 (14.7–21.2)	180	21.4 (18.1–25.1)	93	19.0 (15.0–23.8)
	Ex-smoker	272	32.1 (28.2–36.2)	268	31.8 (28.0–36.0)	145	29.7 (24.8–35.0)
	Missing	27	3.2 (2.0–5.1)	35	4.2 (2.7–6.2)	17	3.5 (1.9–6.2)
Pain duration	<1 mo	81	9.6 (7.2–12.6)	79	9.4 (7.1–12.4)	69	14.1 (10.5–18.8)
	1–2 mo	173	20.4 (17.0–24.3)	162	19.2 (15.9–23.1)	135	27.6 (22.6–33.2)
	3–5 mo	29	3.4 (2.1–5.5)*†	69	8.2 (6.0–11.0)*	47	9.6 (6.6–13.7)†
	6–11 mo	43	5.1 (3.4–7.5)	48	5.7 (3.9–8.2)	23	4.7 (2.8–7.9)
	1–5 y	205	24.2 (20.5–28.3)	193	22.9 (19.3–27.0)	83	17.0 (13.0–21.9)
	>5 y	316	37.3 (33.0–41.8)†	291	34.6 (30.4–39.0)	132	27.0 (22.0–32.6)†
Kinesiophobia	Agree	194	22.9 (19.6–26.5)*†	276	32.8 (29.0–36.8)*	157	32.1 (27.3–37.3)†
	Disagree	644	76.0 (72.4–79.4)*†	559	66.4 (62.4–70.2)*	326	66.7 (61.4–71.6)†
	Missing	9	1.1 (0.5–2.3)	7	0.8 (0.3–2.0)	6	1.2 (0.5–3.1)
Catastrophizing	Agree	187	22.1 (18.9–25.7)*†	355	42.2 (38.2–46.3)*‡	158	32.3 (27.5–37.6)†‡
	Disagree	652	77.0 (73.3–80.3)*†	481	57.1 (53.0–61.1)*‡	326	66.7 (61.4–71.6)†‡
	Missing	8	0.9 (0.4–2.1)	6	0.7 (0.3–1.8)	5	1.0 (0.4–2.8)
	Score allowed	n	Mean (SD); median (95% CI)	n	Mean (SD); median (95% CI)	n	Mean (SD); median (95% CI)
Pain intensity	0–10	846	5.6 (2.1); 6.0 (6.0–6.0)	840	6.3 (2.0); 7.0 (6.0–7.0)	488	6.1 (2.0); 6.0 (6.0–7.0)
Pain interference	4–20	832	12.1 (4.1); 12.0 (12.0–12.0)*†	818	13.4 (3.9); 14.0 (13.0–14.0)*	474	13.2 (4.1); 13.0 (13.0–14.0)†
Physical function	4–20	823	15.6 (3.6); 16.0 (16.0–16.0)*†	820	14.3 (3.9); 15.0 (14.0–15.0)*	475	14.5 (3.9); 15.0 (15.0–15.0)†
Emotional distress or depression	4–20	827	8.5 (4.0); 8.0 (8.0–8.0)*	819	9.6 (4.3); 9.0 (9.0–10.0)*	475	9.2 (4.2); 8.0 (8.0–9.0)
Sleep disturbances	4–20	821	12.1 (3.6); 12.0 (12.0–12.0)	802	12.7 (3.6); 13.0 (12.0–13.0)	469	12.5 (3.6); 12.0 (12.0–13.0)
Pain impact score	8–50	811	25 (6.2); 24.0 (24.0–25.0)*	801	26.8 (6.2); 26.0 (26.0–27.0)*	464	26.6 (6.4); 26.0 (25.0–27.0)
Health utility score	–0.148, 0.949	829	0.7 (0.2); 0.8 (0.8–0.8)	828	0.7 (0.2); 0.7 (0.7–0.8)	476	0.7 (0.2); 0.8 (0.7–0.8)

* Significant difference between the “nonchronic” and “acute” definitions.

† Significant difference between the “nonchronic” and “new episode” definition.

‡ Significant difference between the “acute” and “new episode” definition. The groups are not mutually exclusive.

95% CI, 95% confidence interval.

cLBP.⁵ This likely reflects the fluctuating or recurrent nature of LBP⁹; for example, participants may consider their current LBP episode as <3 months (“Did your back pain begin less than 3 months ago?”) even though LBP was an ongoing problem for >3 months (“How long has low-back pain been an ongoing problem for you”). Another advantage of the “nonchronic” definition is the focus on the endpoint (ie, which participants who did not meet the definition of cLBP now meet it?) and it limits the reliance on the selected acute (inclusion criteria) LBP definition. For example, aLBP may be a first episode, a new episode (ie, recurrent pain¹⁶), or even a flare-up.³ Similarly, cLBP (outcomes) varies widely depending on recovery criteria (eg, pain and disability level).⁸

Low back pain definitions may vary depending on study objectives and design. Nevertheless, we recommend the use of definitions in cohort studies that are mutually exclusive (ie, participants included [aLBP] differ from the expected outcome [cLBP]). This will avoid having participants who meet both the aLBP and the cLBP definitions at baseline, which will confound the identification of predictors of transition from acute to cLBP.

Limitations of the current study include the following: (1) the comparison was limited to only 3 potential definitions and (2) the results are based on only one cohort. Thus, future studies are necessary to confirm and extend the current analysis.

5. Conclusion

Our results demonstrate that the choice of LBP definitions affects the sample size, group characteristics and potentially confounds predictors of transition to cLBP if definitions are not mutually exclusive.

Disclosures

The authors have no conflicts of interest to declare.

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Appendix A. Supplemental digital content

Supplemental digital content associated with this article can be found online at <http://links.lww.com/PR9/A154>.

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