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Risk of developmental delay: Comparison of late preterm and full term Canadian infants at age 12 months

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ABSTRACT

Background: Late preterm ($34^{0/7}$ to $36^{6/7}$ weeks gestation) infants may experience developmental delays greater than those found in term (≥ $37^{0/7}$ weeks gestation) infants.
Aim: The aim of this study was to compare the risk of developmental delay between late preterm and full-term Canadian born infants at age 12 months, and to determine infant and maternal factors associated with risk of delay.
Methods: A descriptive comparative study was conducted from data available from the All Our Babies community-based, prospective, pregnancy cohort in Calgary, Alberta. Participants were a sample of mothers of 52 infants born late preterm and 156 randomly selected mothers of term infants, matched for infant sex; eligible infants were singleton births. Mothers completed a developmental screening tool, the Ages and Stages Questionnaire, version 3 (ASQ-3), when their infant was age 12 months. Corrected age (CA) was used for preterm infants.
Results: Both late preterm and term infants who required neonatal intensive care (NICU) were more likely to demonstrate risk of developmental delay. Compared to term infants, there was a trend for late preterm infants to be at risk of communication and gross motor delay at age 12 months CA that was attenuated to the null when adjustments were made for NICU admission and other covariates.
Conclusions: Infants born between 34 and 41 weeks who are admitted to NICU are at increased risk of developmental delay. Early identification of risk provides an opportunity for referral for developmental assessment and early intervention programming.

1. Introduction

Worldwide in 2010, 11.1% of live births were preterm (< $37^{0/7}$ weeks gestation), an estimated 14.9 million infants [1]. In Canada, 7.7% of live births were preterm [2]. Approximately 75% of preterm infants were born between $34^{0/7}$ to $36^{6/7}$ weeks gestation [3], or late preterm (LP) [4]. Based on recent reviews [5–9], LP infants have a greater risk of short- and longer-term morbidity as compared to their term counterparts (≥ $37^{0/7}$ weeks gestation). During the birth hospitalization, LP infants have greater risk of respiratory distress syndrome (relative risk [RR], 17.3), apnea (RR, 15.7), feeding difficulties (RR, 6.5), hypoglycemia (RR, 7.4), hyperbilirubinemia (RR, 2.8), sepsis (RR, 5.6), and intraventricular hemorrhage (RR, 4.9) [6], which are attributed to physiological immaturity [10]. These morbidities are associated with increased rates of admission to NICU [11], increased length of hospital stay [4,12] and re-hospitalization [4,13,14]. Compared to their full term counterparts, LP infants are suggested to be at increased risk of poorer longer-term outcomes [7,8,15,16]. Under the age of 6 years, evidence suggests that children born LP are at increased risk of developmental delay [17–19], cerebral palsy [20], and behavioral and emotional problems [21]. At school age, LP children are more likely to have poorer cognitive, language and mathematics scores [15,22], be enrolled in special education programs [23–25], and have cerebral palsy [26] and behavioral problems [15]. At school start, the risk of poor school achievement increased as gestational age decreased [25,27]. However, one recent review suggests that school age outcomes for these children may be more varied than previously believed [15]. A large USA study that followed 1298

Abbreviations: LP, late preterm; NICU, neonatal intensive care unit; ASQ-3, Ages and Stages Questionnaires 3rd edition; CA, corrected age.

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children ($n = 53$ LP) from birth to age 15 years found no significant differences between children born LP and full term on cognitive, achievement, social, behavioral, and emotional outcomes [21]. Similarly, in a retrospective USA cohort, there were no differences between children born LP ($n = 256$) versus full term ($n = 4419$) in the incidence of learning disabilities and attention deficit/hyperactivity disorder followed to age 19 years [28].

Despite what is known about the increased risk of potentially adverse outcomes during perinatal, preschool and school ages, there is limited research focused on the early development of LP infants up to 12 months of age in more contemporary cohorts. Studies that addressed development at this age present ambiguous results using prospective cohort [29] and comparison study designs [30–34]. Ambiguous results may be related to inconsistent use of corrected age (CA; chronological age minus the number of weeks born early). For example, studies that compared LP and term infants reported no developmental differences when using CA [30–32], but found significant differences [31,32] when using chronological age at 12 month assessment. Results were further limited by (1) heterogeneity of outcomes, (2) small sample sizes, (3) use of developmental screeners versus assessments, and (4) failure to control for covariates. When LP infants and very preterm infants (≤ 32 weeks) who required NICU admission were compared, no significant differences in developmental outcomes [34] were reported after controlling for co-morbidities and the risk of requiring developmental intervention at age 12 months was the same [33]. Yet, required NICU admission as a predictor of increased developmental risk for LP infants as compared to term or very preterm infants has not been fully investigated [7]. Also poorly understood are the factors and comorbidities associated with early developmental delay in LP infants. Further investigation of the early risks and predictors of developmental delay in LP infants is warranted to inform early intervention and improve outcomes.

The objectives of the current study were to compare the risk of developmental delay between LP and term Canadian infants at age 12 months, and to determine infant and maternal factors associated with risk of delay. The research questions were: (1) Compared to term infants, do LP infants have a greater risk of developmental delay as measured by the domains (Communication, Gross Motor, Fine Motor, Problem-Solving, and Personal-Social) on the Ages and Stages Questionnaires 3rd edition (ASQ-3) (35) at age 12 months CA? (2) Controlling for infant and maternal characteristics selected based on the literature, what is the association between LP birth status and risk of delay at age 12 months CA?

2. Methods

2.1. Participants

A descriptive comparative study design was used with data collected for the All Our Babies (AOB) community-based, prospective, pregnancy cohort [36]. Women in the AOB study were recruited between May 2008 and December 2010 at <25 weeks gestation in Calgary, Alberta. Eligible women were ≥ age 18 years, understood spoken and written English, and had a singleton pregnancy. The response rate was 85% (McDonald et al., 2013b). In the current study, the sample was 52 LP infants and 156 out of 1185 randomly selected term infants, matched 1:3 on infant sex, with mother-completed questionnaires at age 12 months CA ± 2 weeks. Exclusion criteria applied to both groups were: (1) infant born small for gestational age (< 10th percentile,) and/or with a genetic disorder or congenital anomaly, and (2) non-English speaking mother.

2.2. Procedures

Mothers completed mailed questionnaires at <25 weeks, between 34 and 36 weeks, and postnatal ages 4 and 12 months. Maternal demographic characteristics were collected at intake. For infants, the ASQ-3 was administered at 12 months (± 2 weeks) using CA for preterms and chronologic age for terms. The gestational age of LP infants was verified against health records. Term and LP infants were matched on sex because being a male has been associated with poorer developmental outcomes [37]. This study was approved by the Conjoint Health Research Ethics Board at the University of Calgary. Participants provided consent at enrolment.

2.3. Measures

2.3.1. Ages and Stages Questionnaire - Third Edition (ASQ-3) (35)

This parent-completed screening instrument for children aged 1 to 66 months has 30 age-appropriate items that address five developmental domains: communication, gross motor, fine motor, problem-solving, and personal-social. Each item describes a skill, ability, or behavior to which a parent responds "yes" (10 points), "sometimes" (5), or "not yet" (0). A score is calculated for each domain and categorized as: (1) above cut-off (typical development), (2) monitoring zone (score between one and two standard deviations below the mean), and (3) referral zone (score less than two standard deviations below the mean). Between 2% and 7% of children in the normative population of 18,572 American children scored in the referral zone. Families approximated American census proportional estimates for education, economic and ethnic diversity in the normative sample. The American normative sample is the best available evidence for North American comparisons given there is no Canadian normative sample. For preterm infants, ASQ developers recommend using CA up to 24 months. The ASQ-3 was written at a 5th grade level and takes 10 to 15 min to complete. Intra-parental agreement was 92% over a 2-week interval. Parent and trained examiners agreement was 93%. Cronbach's alphas across age intervals and developmental domains ranged from 0.51 to 0.87. The ASQ-3 has moderate to high agreement with delay classifications on the Battelle Developmental Inventory [38] and moderate agreement with the Bayley-III [39] in term and preterm infants. In the 2 to 12 month age band, sensitivity was 0.85 and specificity was 0.91 [35]. In addition to strong psychometric properties, the ASQ-3 screener was selected because of its ease of use, low cost, and widespread adoption within the local community.

2.4. Statistical analyses

Up to two missing values on a domain were replaced by the mean score for that infant [35]. Infants were classified in the monitoring/referral zone when they scored <1 standard deviation below the mean of the normative ASQ data in accordance with the user's manual [35]. Frequencies and percentages were used to describe maternal and infant demographic characteristics and birth outcomes. Sample characteristics were compared for LP versus term infants using Pearson's chi-square test (or Fisher's exact test when expected cell counts were <5). Bivariate associations between maternal and infant characteristics, including term status (LP versus term) and ASQ-3 domain classifications were conducted using Pearson's chi-square test (or Fisher's exact test when expected cell counts were <5) and unadjusted odds ratios (uOR) and 95% confidence intervals (CI).

Multivariable logistic regression was used to estimate adjusted differences in each ASQ-3 domain between LP and term infants (aOR). Co-linearity was evaluated prior to analysis and all correlations were deemed adequate. All multivariable models controlled for potential confounders identified in the literature including maternal education, method of delivery, NICU admission or non-admission, and breastfeeding status to allow comparison with other research studies [37], [40,41]. Matching on infant sex allowed for control of this confounding variable in the design stage. Significance was set at $p < 0.05$. Analyses were conducted with Statistical Package for Social Sciences (SPSS) – Version 22 (IBM Corp., Armonk, New York, USA).

3. Results

See Table 1 for demographic characteristics and birth outcomes of mothers and infants. On average LP infants weighed 2703 (SD = 398) grams at birth, with a gestational age 35.4 (SD = 0.8) weeks; and term infants were 3430 (SD = 463) grams at birth with a gestational age of 39.2 (SD = 1.2) weeks. There were more male (61%) than female infant participants, which reflects the 1:3 matching for LP to controls, and the increased number of LP infants who were male ($n = 30$ male vs. $n = 19$ female). LP infants (59.2%) were significantly more likely to be admitted to NICU especially younger gestational aged infants at 34 and 35 weeks. The majority of term infants (94.5%) did not require NICU care. While not statistically significant, compared to mothers of term infants, more mothers of LP infants were over the age of 35 years, more were partnered, fewer were born in Canada, and fewer breastfed for >8 weeks.

3.1. Comparison between LP and term infants on risk of developmental delay

LP and term infant ASQ-3 domain classifications and proportions that scored at risk of delay at 12 months are provided in Table 2. In bivariate analysis, LP infants were at significantly greater risk of developmental delay as measured by the ASQ-3 in the communication (13.5 versus 4.5%, $p < 0.05$; uOR = 3.31, 95% CI 1.10, 9.94) and gross motor domains (34.6 versus 20.5%, $p < 0.05$; uOR = 2.05, 95% CI 1.03, 4.09) (uOR, see Tables 3 and 4). There were no significant differences between LP and term infants on fine motor, problem solving and personal-social domains.

Table 1
Sample characteristics for total sample, and stratified by gestational age.

Characteristic	Total Sample $N = 208$	Late Preterm $n = 52$	Term $n = 156$	
DEMOGRAPHICS	*n* (%)	*n* (%)	*n* (%)	*p* value
Maternal age[a]				
34 years old or less	161 (78.2)	38 (74.5)	123 (79.4)	0.468
35 years old or more	45 (21.8)	13 (25.5)	32 (20.6)	
Marital status[b]				
Married/Common-law	196 (94.7)	50 (98.0)	146 (93.6)	0.300[c]
Other	11 (5.3)	1 (2.0)	10 (6.4)	
Education				
Less than post-secondary	39 (18.8)	9 (17.3)	30 (19.2)	0.758
Completed post-secondary or greater	169 (81.3)	43 (82.7)	126 (80.8)	
Born in Canada[b]				
Yes	172 (83.1)	40 (78.4)	132 (84.6)	0.306
No	35 (16.9)	11 (21.6)	24 (15.4)	
Sex of child[d]				
Male	125 (61.0)	30 (61.2)	95 (60.9)	0.967
Female	80 (39.0)	19 (38.8)	61 (39.1)	
Gestational age				
34 weeks	8 (3.8)	8 (15.4)	0 (0.0)	<0.001
35 weeks	15 (7.2)	15 (28.8)	0 (0.0)	
36 weeks	29 (13.9)	29 (55.8)	0 (0.0)	
37 weeks or greater	156 (75.0)	0 (0.0)	156 (100.0)	
BIRTH OUTCOMES				
Parity [e]				
No previous births	99 (48.5)	22 (45.8)	77 (49.4)	0.669
Previous birth to a fetus (at least once)	105 (51.5)	26 (54.2)	79 (50.6)	
Method of delivery[d]				
Vaginal	161 (78.5)	38 (77.6)	123 (78.8)	0.847
C-section	44 (21.5)	11 (22.4)	33 (21.2)	
NICU admission (infant)[f]				
Yes	37 (19.0)	29 (59.2)	8 (5.5)	<0.001
No	158 (81.0)	20 (40.8)	138 (94.5)	
Breastfeeding status[g]				
Did not breastfeed or ≤8 weeks	33 (16.3)	27 (17.6)	6 (12.2)	0.373
Greater than >8 weeks	169 (83.7)	126 (82.4)	43 (87.8)	

[a]Two missing values; [b]One missing value; [c]Fisher's exact test was used; [d]Three missing values; [e]Four missing values; [f]Thirteen missing values; [g]Six missing values.

Table 2
ASQ-3 domain scores and proportions that scored at risk of delay by late preterm and term status.

ASQ-3 domain	Total Sample Late preterm $n = 52$	Total Sample Term $n = 156$	NICU-admitted Late preterm $n = 29$	NICU-admitted Term $n = 8$
Communication				
On track, n(%)	45 (86.5)	149 (95.5)	23 (79.3)	7 (87.5)
Monitoring/referral, n(%)	7 (13.5)	7 (4.5)	6 (20.7)	1 (12.5)
Gross motor				
On track, n(%)	34 (65.4)	124 (79.5)	18 (62.1)	6 (75.0)
Monitoring/referral, n(%)	18 (34.6)	32 (20.5)	11 (37.9)	2 (25.0)
Fine motor				
On track, n(%)	46 (88.5)	144 (92.3)	23 (79.3)	8 (100.0)
Monitoring/referral, n(%)	6 (11.5)	12 (7.7)	6 (20.7)	0 (0.0)
Problem-solving				
On track, n(%)	40 (76.9)	130 (83.3)	21 (72.4)	8 (100.0)
Monitoring/referral, n(%)	12 (23.1)	26 (16.7)	8 (27.6)	0 (0.0)
Personal-social				
On track, n(%)	43 (82.7)	136 (87.2)	22 (75.9)	6 (75.0)
Monitoring/referral, n(%)	9 (17.3)	20 (12.8)	7 (24.1)	2 (25.0)

3.2. Factors associated with risk of developmental delay

After controlling for infant and maternal characteristics that were selected based on the literature (maternal education, method of delivery, NICU admission or non-admission, and breastfeeding status), the multivariable logistic regression models indicated that LP birth status was not significantly associated with delay in any ASQ developmental domain at 12 months (see Tables 3 and 4). However, LP and term infants, who required NICU admission were at greater risk of communication delay (aOR = 8.44, 95% CI 1.52, 46.95) (see Table 3).

4. Discussion

Primary findings from this study provide evidence that NICU admission was the most significant factor associated with the risk of communication delay in LP and term infants, after adjusting for maternal and infant factors. To the best of our knowledge, this is the first study to compare both NICU admitted and non-NICU admitted LP and term infants. Three other comparison studies have reported that neonatal risk factors, defined as NICU admission, are associated with threats to the development of LP infants, only. Baron and colleagues identified that NICU admitted LP infants had significantly poorer outcomes in visuospatial and verbal fluency skills at 3 years than did healthy term infants based on a 2004–2005 birth cohort [42]. Further research by Baron and colleagues affirmed poorer cognitive outcomes in preschoolers born LP that had experienced an NICU admission as compared to clinically stable, non-NICU admitted LP and term infants in a 2004–2006 birth [43]. By contrast, McGowan and colleagues found that developmental outcomes between NICU admitted and non-NICU admitted LP infants that were born in 2006, were similar at 3 years, within the same gestational age range and with a larger sample size [44]. The contrary nature of these findings may be explained by lack of controlling for covariates. None of these studies included both NICU admitted and non-NICU admitted term infants as comparators for LPs, as in our study. Further research is required to unravel how neonatal risk factors and NICU admission during a period of rapid brain development may contribute to greater risk of developmental delay.

Secondary findings are specific to communication and gross motor development. Unadjusted comparisons between LP and term infants,

Table 3
Associations between demographic characteristics and development on the ASQ-3 Communication domain scores.

Characteristic	On Track[a] $n = 194$	Monitoring/Referral Zone[b] $n = 14$			
DEMOGRAPHICS	*n* (%)	*n* (%)	*p* value	uOR (95% CI)	aOR (95% CI)
Education					
Less than post-secondary	36 (92.3)	3 (7.7)	0.729[c]	1.20	1.18
Completed post-secondary or greater	158 (93.5)	11 (6.5)		(0.32, 4.51)	(0.13, 10.78)
BIRTH OUTCOMES					
Method of delivery					
Vaginal	152 (94.4)	9 (5.6)	0.483[c]	1.69	2.65
C-section	40 (90.9)	4 (9.1)		(0.50, 5.77)	(0.64, 10.96)
Term status					
Late preterm	45 (86.5)	7 (13.5)	0.048[c]	3.31	1.05
Term	149 (95.5)	7 (4.5)		(1.10, 9.94)	(0.20, 5.70)
NICU admission (infant)					
Yes	30 (81.1)	7 (18.9)	0.001[c]	8.98	8.44
No	154 (97.5)	4 (2.5)		(2.48, 32.61)	(1.52, 46.95)
Breastfeeding status					
Did not breastfeed or ≤ 8 weeks	31 (93.9)	2 (6.1)	1.000[c]	1.08	1.93
Greater than >8 weeks	158 (93.5)	11 (6.5)		(0.23, 5.11)	(0.35, 10.71)

[a]On track, typical development; [b] Monitoring/Referral Zone, <1 standard below the mean; [c]Fisher's exact test was used; uOR, unadjusted odds ratio; aOR, adjusted odds ratio.

suggest an increased risk of communication delay in LP infants at 12 months CA (uOR = 3.31) that was attenuated to the null in the multivariable model (aOR = 1.05). Only LP and term infants who required NICU admission remained at significant risk of communication delay (aOR = 8.44). Nepomnyaschy and colleagues [18] reported increased risk of language delay at two and four years of age in non-NICU admitted LP as compared to term infants, based on parent-report and controlling for confounders. In addition, Kerstjens and colleagues [17] found that 4-year old children born at 32 to 35 weeks gestation had lower ASQ communication scores, but higher than those born at earlier gestations. Although this study included infants born at a younger gestational age than in our study, their findings indicate that communication delay may be longer lasting, and the risk increases with decreasing gestational age. Typically, studies to date have not addressed early risk of communication delay [17,18,29,32], as in our study. Screening for risk of communication delay remains clinically important for all infants who experience NICU care, and particularly for the LP infant until further evidence emerges. Earlier screening may enable early intervention that could mitigate future risks for language, reading and cognitive delays.

Based on unadjusted comparisons, our study suggests that LP infants may be identified at greater risk of gross motor delay. The finding was attenuated to the null in the multivariate model, although the odds ratio of 1.83 remains in the direction of increased risk. Similarly, Romeo and colleagues [29] found early differences in the motor development of LP infants admitted to the NICU between 2000 and 2004, specifically less optimal reflexes and hypotonicity at 12 months CA as compared to term infants. Our results however, differ from other studies conducted in the first year of life that reported LP infants had similar motor development to healthy term infants at 6 months [31] and 12 months [30], as measured by the Alberta Infant Motor Scale and Bayley-II- Psychomotor Development Index, respectively. At 24 months chronological age, Woythaler and colleagues [19] reported that LPs had significantly lower psychomotor scores than term infants on the Bayley-II, although without controlling for NICU admission. In contrast, at 4 years of age, Kerstjens and colleagues [17] found no differences in gross motor development between moderate preterm ($32–35^{6/7}$ weeks) and term infants as measured by the ASQ. Discordant findings in reporting motor development may be related to measurement bias (parent-report versus assessment) and variability in timing

Table 4
Associations between demographic characteristics and development on the ASQ-3 Gross Motor domain scores.

Characteristic	On Track[a] $n = 194$	Monitoring/Referral Zone[b] $n = 14$			
	n (%)	*n* (%)	*p* value	uOR (95% CI)	aOR (95% CI)
DEMOGRAPHICS					
Education					
Less than post-secondary	32 (82.1)	7 (17.9)	0.323	0.64	1.95
Completed post-secondary or greater	126 (74.6)	43 (25.4)		(0.26, 1.56)	(0.62, 6.12)
BIRTH OUTCOMES					
Method of delivery					
Vaginal	125 (77.6)	36 (22.4)	0.495	1.30	1.37
C-section	32 (72.7)	12 (27.3)		(0.61, 2.78)	0.62, 3.04)
Term status					
Late preterm	34 (65.4)	18 (34.6)	0.039	2.05	1.83
Term	124 (79.5)	32 (20.5)		(1.03, 4.09)	(0.73, 4.59)
NICU admission (infant)					
Yes	24 (64.9)	13 (35.1)	0.053	2.13	1.23
No	126 (79.7)	32 (20.3)		(0.98, 4.65)	(0.45, 3.39)
Breastfeeding status					
Did not breastfeed or ≤ 8 weeks	28 (84.8)	5 (15.2)	0.228	1.85	0.75
Greater than >8 weeks	127 (75.1)	42 (24.9)		(0.67, 5.10)	(0.26, 2.14)

[a]On track, typical development; [b]Monitoring/Referral Zone, <1 standard below the mean.
uOR, unadjusted odds ratio; aOR, adjusted odds ratio.

of measurement, sample size, infant sex, NICU admission status, and heterogeneity of study participants. Alternatively, discordant findings may indicate that early gross motor delays, as detected in our study and others [19,29], may resolve over time [17].

The risk of communication delay observed in this study for LP infants could be related to the interruption of critical brain growth and development in the last six weeks of gestation as hypothesized by Kugelman and Colin [45]. The alternate explanation is that delays in development could be secondary to neonatal risk factors [6]; factors that required NICU admission as reported for LP and term infants in this study. Although not confirmed in LP infants, evidence from studies of moderate and very preterm infants support the explanation that neonatal risk factors adversely impact developmental outcomes [5,16,46].

Few previous studies have addressed early developmental outcomes in LP infants in the first year of life. The strengths of the current study included prospective data collection, use of a standardized developmental screening measure, and comparison of singleton LP infants with term infants while controlling for maternal and infant factors. This study has a number of limitations. First, risk of developmental delay was measured using a parent-report screening tool (ASQ-3) rather than direct assessment as in aforementioned studies [42–44]. The use of a screening measure can result in over reporting of developmental risk (i.e., increased false positive). This risk is offset however, by the advantages that the ASQ-3 is less expensive, more efficient to administer and directly engages parents in understanding development. The ASQ-3 cut-off scores are based on a sample of American children that may not accurately represent Canadian children. Secondly, our findings at 12 months of age cannot be definitely confirmed without direct neurodevelopmental assessment and follow-up to two years of age. Thirdly, maternal participants in the AOB cohort study had higher income levels than the average Canadian mother, and those unable to speak English were excluded. Infant participants were disproportionately male (61%) as compared to the ASQ-3 reference population (50%) because of the 1:3 matching for LP to controls. The present study findings can be generalized only to populations with similar characteristics, including those who benefit from universal health care coverage as in Canada. Lastly, our study included a heterogeneous population of both NICU admitted and non-NICU admitted LP infants and term infants. Information about maternal pregnancy complications, reasons for NICU admission, and infant neuroimaging or follow-up assessments were unavailable for this study. Subgroup analyses were not possible due to our small sample. Additional, prospective longitudinal research that differentiates between NICU admitted and non-admitted LP infants and term infants is warranted in order to advance our understanding of the relationship between risk associated with gestational age at delivery compared to risk associated with NICU care. Clinical implications are derived from the study's findings and indicate that the ASQ-3 can be used for early detection of developmental risk in LP and term infants as early as 12 months.

Conflict of interest statement

We declare that all authors made substantial contributions for conception and design of the study, acquisition of data, or analysis and interpretation of data; drafting and revising the manuscript; and have approved the final submitted version.

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