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Associations between Workplace Factors and Carpal Tunnel Syndrome: A Multi-site Cross Sectional Study

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Abstract

Background: Few large epidemiologic studies have used rigorous case criteria, individual-level physical exposure measurements, and appropriate control for confounders to examine associations between biomechanical factors and risk of carpal tunnel syndrome (CTS).

Methods: Pooling data from six independent research studies, we assessed associations between the prevalence of CTS and estimates of force, repetition, posture and composite measures of biomechanical factors, while adjusting for confounders using multivariable logistic regression.

Results: Personal factors of older age, female gender, obese, and medical conditions (diabetes mellitus, rheumatoid arthritis, thyroid disease, pregnancy) and workplace measures of forceful hand activity (analyst or worker related Borg CR-10 and the Threshold Limit Value for Hand Activity Level) were related to CTS prevalence.

Conclusions: In this cross-sectional study of production and service workers, CTS prevalence was associated with personal and work related factors.

Keywords

musculoskeletal disorders; physical work load; workers; individual-level assessment; confounders

Introduction

Carpal tunnel syndrome (CTS) is characterized by numbness, tingling, burning or pain in the thumb, index and long fingers of the hand and slowing of median nerve conduction at the wrist due to entrapment of the median nerve in the carpal tunnel [Moore, 1992; Stevens, 1997]. CTS cases related to occupational exposures result in a substantial burden of worker's compensation claims, lost work time and productivity, and disability [Foley, et al., 2007; Manktelow, et al., 2004; Silverstein and Adams, 2007]. Due to differences in populations studied, risk factors examined, study design, and CTS case definition, there are wide ranges in the reported prevalence and incidence of electrophysiologically-confirmed CTS [ACOEM, 2011; Descatha, et al., 2011; Rempel, et al., 1998]. Prevalence of CTS in working populations ranges from 1.7% to 21% [Armstrong, et al., 2008; Dale, et al., 2013; Gorsche, et al., 1999; Maghsoudipour, et al., 2008; Roquelaure, et al., 2001] and are generally higher than the rates of 1% to 4.9% observed among members of the general population [Atroshi, et al., 1999; de Krom, et al., 1992; Stevens, et al., 1988; Tanaka, et al., 1994]. Similarly, the incidence of CTS in workers (0.23 to 11 per 100 person-years) [Gorsche, et al., 1999; Roquelaure, et al., 2008; Silverstein and Adams, 2007; Bonfiglioli et al., 2013] is higher than that in the general population (0.18 to 0.28 per 100 person-years) [Bongers, et al., 2007; Mondelli, et al., 2002].

Previous studies have reported risk factors for CTS that include personal, psychosocial, and job physical exposures. Personal factors include older age [Atroshi, et al., 1999; Stevens, et al., 1988], female gender [Geoghegan, et al., 2004; Shiri, et al., 2007; Silverstein and Adams, 2007; Solomon, et al., 1999; Tanaka, et al., 1994], obesity [Boz, et al., 2004; Geoghegan, et al., 2004], diabetes mellitus [Geoghegan, et al., 2004], thyroid disease [Roquer and Cano, 1993; Tanaka, et al., 1994], inflammatory arthritis [Geoghegan, et al., 2004; Solomon, et al., 1999] and pregnancy [Zyluk, 2013]. A few studies have assessed the role of occupational psychosocial factors, reporting associations between incident CTS and high job demand, high job strain, and psychosocial distress [Harris-Adamson, et al., 2013; Roquelaure, et al., 2001; Silverstein, et al., 2010]. Work-related CTS has also been associated with high hand force (forceful pinch or power grip) often in combination with high repetition, and hand-arm vibration [Shiri, et al., 2009; Silverstein, et al., 2009; Silverstein, et al., 2010; Werner, 2006; Bonfiglioli et al. 2013; Burt et al. 2013].

Some studies of CTS risk factors have been criticized for use of imprecise or unreliable exposure measures (e.g. job title), small samples sizes, retrospective methods, inadequate control of confounders, and samples that were not representative of workers and industries [Frost, et al., 1998; Gell, et al., 2005; Hegmann and Oostema, 2008; Roquelaure, et al., 2008]. To date, few large epidemiologic studies used rigorous case criteria, individual-level physical exposure measurements, and appropriate control of confounding by personal and psychosocial factors when exploring associations between biomechanical factors and risk of CTS [Violante, et al., 2007; Bonfiglioli et al. 2013].

The current manuscript presents the results from analyses of baseline pooled data collected by six prospective studies of upper extremity disorders among US production and service workers. We assessed the associations between prevalence of CTS at study inception and estimates of force, repetition, posture and composite measures of biomechanical factors, while adjusting for historical and important confounding factors. Findings of the prospective analyses of the incident CTS cases are presented in a other papers.

Methods

Study design and participants

As part of a consortium of National Institute of Occupational Safety and Health (NIOSH)-funded studies of risk factors for upper extremity MSDs in industry, baseline data were pooled from six independent prospective epidemiological studies conducted at 50 US companies with workers employed in production, agriculture, construction and service sectors. Each of the six datasets included a uniform CTS case definition for dominant-hand, personal and psychosocial factors, and individual-level measurements of job physical exposure. Details on the study designs, the process of pooling data, and baseline CTS prevalence are provided elsewhere [Dale, et al., 2013; Harris-Adamson, et al., 2013]. Briefly, for all six studies, similar questionnaires were administered to participants at study enrollment to collect information on work history, demographics, medical history, musculoskeletal symptoms, and psychosocial work environment. In addition, electrodiagnostic studies (EDS) of the median and ulnar nerves at the wrist were collected at baseline by clinicians blinded to exposure status [Harris-Adamson, et al., 2013].

Of the 4,321 participants pooled from the six studies, we excluded 58 persons who met electrophysiological criteria for polyneuropathy [Dale, et al., 2013] and 1,282 subjects who had incomplete demographic or exposure data. Therefore, this cross-sectional analysis included 2,981 workers.

Study outcome

The study outcome was CTS in the dominant hand at the time of enrollment. The CTS case definition required (i) dominant hand symptoms that met study criteria (described below) and (ii) EDS results consistent with median nerve mono-neuropathy at the wrist [Gerr and Letz, 1998; Rempel, et al., 1998]. The symptom criteria were numbness, tingling, burning, and/or pain in the thumb, index finger, or long finger. Median nerve mono-neuropathy was defined as temperature adjusted: (1) peak median sensory latency >3.7ms or onset median sensory latency >3.2ms at 14cm, (2) motor latency >4.5ms, (3) transcarpal sensory difference of > 0.8ms (the difference in sensory latencies between the median and ulnar nerves across the wrist), and/or (4) an unobtainable latency value consistent with an abnormal NCS (Dale et al., 2013). Workers with prior CTS surgery were also included as baseline cases (N=32).

Physical exposure factors

Details on the collection of workplace physical exposure measures from each site as well as methods used for pooling physical exposure data are reported elsewhere [Kapellusch, et al., 2013]. Briefly, all sites ensured that measures of hand force, repetition, posture and vibration were collected at the task level [Chiang, et al., 1993; Fung, et al., 2007; Garg, et al., 2012; Maghsoudipour, et al., 2008; Silverstein, et al., 1987]. Specifically, hand force ratings (Borg CR-10 scale, Borg 1982) were assessed by both workers and analysts. Duty cycle was quantified for all hand exertions and as well as for only forceful hand exertions from video tape analysis. Forceful hand exertion was defined as greater than ≥ 10N pinch force or ≥ 45N of grip force. Repetition was assessed by trained analysts using the 10-point American Conference of Governmental Industrial Hygienists (ACGIH) Hand Activity Level (HAL) scale. The analyst TLV for HAL was calculated using the analyst's peak force rating and analyst HAL rating. Posture was quantified from videotapes of participants doing their job tasks as the percent time spent in >30° wrist extension and the percent time spent in >30° wrist flexion. Hand/arm vibration (yes/no) was recorded by task if there was visible hand/arm vibration or use of vibratory hand-tools; this information was collected by 4 of the 5 sites.

Workers typically performed one to two tasks but could have up to eight tasks. For workers whose job involved more than one task, task level exposures were combined to produce a job level exposure. Specifically, for each worker, exposure was assessed at the job level by combining task level data using three summary measures: 1) peak exposure (e.g. highest force, highest frequency of exertion, worst posture), 2) typical exposure (i.e. exposure from the task performed most of the time) and 3) time-weighted average exposure across all tasks. There were high correlations between job level exposure measures (e.g. peak, typical, and time-weighted average), with Spearman correlation coefficient rho=0.85 to 0.97. Time-weighted average measures, therefore, were used for this analysis.

Personal and Psychosocial Factors

Information about age, gender, body mass index (BMI), race/ethnicity, education, smoking status, hand dominance, and co-morbid medical conditions such as rheumatoid arthritis, diabetes mellitus, thyroid disease, and pregnancy status was collected by questionnaire from all study participants. The total number of hours spent per week in recreational hand intensive and aerobic activities and the self-reported years worked at the current employer at enrollment were also collected. The occupational psychosocial factors assessed were co-worker or supervisor support, job demand, decision latitude, physical or mental exhaustion after work, and job satisfaction [Bigos, et al., 1991; Karasek, et al., 1998]. Of these psychosocial factors, data on co-worker or supervisor support were available from three sites and the other psychosocial variables were available from four research sites. Therefore, the sample sizes for these analyses are less than other analyses.

Statistical analysis

Multivariable logistic regression models were used to estimate associations between each of the 11 physical exposure variables and prevalent CTS while adjusting for age, gender, obesity, research site and other covariates. For each model, the physical exposure variables (measures of force, repetition, duty cycle and posture) were converted to categorical values using cut points by tertiles based on the distribution in the pooled study population. TLV for HAL scores were categorized into three levels by the Action Limit (0.56) and Threshold Limit Value (TLV) (0.78) [Garg, et al., 2012].

Potential confounding by personal and psychosocial factors was evaluated empirically. Specifically, those covariates associated with the outcome ($p \le 0.20$), that were not thought to be on the pathway from exposure to response, and had less than 10% missing data were initially included in each multivariable model. Covariates that changed the effect estimate of the primary exposure by more than 10% were retained in the final models.

All analyses were conducted using SAS (v9.3) statistical software (SAS, 2010).

Results

Of the 2,981 participants, 9.6% (N=287) met the criteria for CTS at baseline. Of these prevalent CTS cases, 32 (11.1%) had been previously diagnosed by a physician as having CTS (data not shown). Compared to the non-cases, CTS cases were older (>35 years-old), more likely to be female, obese, had other medical conditions (diabetes mellitus, rheumatoid arthritis, thyroid disease, and pregnancy), reported previous distal upper extremity disorders, and were past smokers (Table 1). There were no statistically significant differences between the CTS cases and non-cases on race/ethnicity, education, and general health status (Table 1).

CTS prevalence was increased among workers who reported spending more than 3 hours/ week on recreational hand intensive and aerobic activities than those who spent less than 3 hours/week on these activities after adjusting for age, gender, obesity and research sites (Table 2). There was a significant association between being moderately to severely physically exhausted after work and CTS prevalence. Workers who were dissatisfied with their jobs had higher prevalence of CTS than those who were very satisfied, OR 1.56 (95% CI 1.09–2.24). Job demand, decision latitude, supervisor or co-worker support, mentally exhausted after work, job tenure, work shift, and job training were not significantly related to CTS prevalence.

Six job physical exposure measures were significantly associations with CTS prevalence after adjusting for age, gender, obesity, medical conditions and research site: percent time in forceful hand exertions (duty cycle), worker rated hand exertion (Borg CR-10), analyst rated hand exertion (Borg CR-10), forceful repetition rate, analyst rated TLV for HAL, and working with vibrating tools (Table 3). In contrast, total percent time in all hand exertion (duty cycle), total hand repetition rate, analyst’s HAL rating (repetition), wrist extension ≥30°, and wrist flexion ≥30° were not significantly related to CTS prevalence.

Discussion

Jobs requiring high hand forces were associated with prevalent cases of CTS in this cross-sectional, multisite study. Overall, forceful hand activities as assessed by various measures, e.g., duty cycle, worker or analyst ratings, and repetition rate for forceful exertions, was observed to be consistently and strongly associated with CTS after adjusting for covariates. On the other hand, total hand repetition rate and wrist posture were not. The composite index, that combines force and repetition, the ACGIH TLV© for HAL, was associated with CTS. Being older, female, obese, having another medical condition (diabetes mellitus, rheumatoid arthritis, thyroid disease, or pregnancy), having a previous upper extremity disorder, and doing recreational activities were also associated with an increased prevalence of CTS.

The observed association between higher hand force measures and CTS prevalence is consistent with previous studies. Forceful gripping greater than 1kg was associated with CTS in both a case-control [Roquelaure, et al., 1997] and a cross sectional study [Maghsoudipour, et al., 2008] and sustained forceful movement of the wrist was a risk factor for CTS in a case-control study [Fung, et al., 2007]. Peak hand force was found to predict risk of CTS in two prospective studies [Werner, et al., 2005; Bonfiglioli, et al., 2013].

Measures of hand repetition have been associated with CTS in some prior studies [Bonfiglioli, et al., 2006; Chiang, et al., 1990; Maghsoudipour, et al., 2008; Roquelaure, et al., 2001; Silverstein, et al., 1986; Bonfiglioli et al., 2013] but not others [McCormack, et al., 1990; Moore and Garg, 1994; Nathan, et al., 2005]. We found no statistically significant association between CTS and measures of total hand repetition based on video analysis of tasks or based on analyst estimates of repetition using the HAL scale. In contrast, CTS was related to hand repetition rate if repetition rate only considered forceful hand exertions (e.g., ≥ 10N pinch force or ≥ 45N grip force). The video analysis for total hand repetition rate counted all wrist and finger motions whether an external force was applied or not. In most prior studies it has not been specified what the minimal hand exertion level should be to be counted as a repetition. Since the composite index of analyst's TLV for HAL ratings were the combination of the HAL repetition measure and force rating by analysts, the significant associations between TLV for HAL and the prevalence of CTS appear to be primarily due to the contribution from the force rating. Thus, these results and those of others [McCormack, et al., 1990; Moore and Garg, 1994; Nathan, et al., 2005] suggest that repetition per se may not be as potent a risk factor as force.

There was a significant association between use of vibrating tools and CTS prevalence after adjusting for age, gender, obesity, medical conditions, and research sites. This finding is compatible with previous studies of quarry/rock drillers, stonemasons, and forestry workers exposed to hand-arm vibration [Bovenzi, 1994; Farkkila, et al., 1988; Barcenilla et al. 2012].

Many previous epidemiologic studies of CTS that have assessed hand-wrist posture have failed to observe significant associations between posture and CTS [Moore and Garg, 1994; Nordstrom, et al., 1998; Roquelaure, et al., 1997; Silverstein, et al., 1986; Silverstein, et al., 1987]. However, some cross-sectional or case-control studies have identified posture such as bending or twisting of the hands or wrists over 30 degrees [Maghsoudipour, et al., 2008] or frequent flexion or extension [de Krom, et al., 1990; Fung, et al., 2007] as risk factors. In our study, neither video assessed time in wrist extension ≥ 30° nor wrist flexion ≥ 30° was significantly associated with CTS prevalence. However, the average percent time that subjects were in wrist flexion was small (< 3%).

A number of personal factors have been reported as risk factors for CTS. Our findings on age >50 and obesity add to the large body of epidemiological evidence demonstrating associations between CTS and age [Atroshi, et al., 1999; Stevens, et al., 1988; Harris et al., 2013] and BMI [Boz, et al., 2004; Geoghegan, et al., 2004; Nordstrom, et al., 1997]. Although the association between CTS and female gender has been observed in previous studies, [Shiri, et al., 2007; Solomon, et al., 1999; Tanaka, et al., 1994] some authors have reported that the strength of the association was attenuated after adjusting for occupational hand activities [Franklin, et al., 1991; Nordstrom, et al., 1997]. In our analysis, however, the effect of female gender persisted even after adjusting for other important personal and physical exposure factors (data not shown). Some medical conditions have been associated with CTS in previous cross-sectional studies, e.g., diabetes mellitus [Geoghegan, et al., 2004], thyroid disease [Roquer and Cano, 1993; Tanaka, et al., 1994], inflammatory arthritis [Geoghegan, et al., 2004; Solomon, et al., 1999] and pregnancy [Zyluk, 2013].

Relatively few studies have assessed psychosocial factors as a risk for CTS and no consistent associations have been identified [Leclerc, et al., 2001; Nordstrom, et al., 1997; Werner, et al., 1998]. High job strain and low supervisor and co-worker support were observed to increase the risk of incident CTS in the prospective component of our study [Harris-Adamson, et al., 2013] but that association was not observed in this cross-sectional component. In the prospective analyses of our pooled data set job satisfaction was not associated with CTS [Harris-Adamson, et al., 2013] but in this cross-sectional analysis it was. This seemingly contradictory finding suggests that job satisfaction is not be a predictor of CTS but instead is related to the impact of CTS symptoms on ability to perform the job or the response of the employer to the report of symptoms. Job satisfaction was only collected by four research sites.

Some of the personal and psychosocial variables were not included in the final models for workplace physical factors because they either had missing data >10% (recreational hand intensive or aerobic activities) or were considered to be intermediate variables on the causal pathway between physical exposure and CTS (i.e., previous distal upper extremity disorders and self-reported physically exhaustion after work).

The strength of the current analyses include a large sample size, multi-site collection of data, rigorous CTS case criteria, individual-level physical exposure measures, and control for many confounders of associations between biomechanical risk factors and the CTS prevalence. Pooling data from multiple research sites allowed for wide job exposure variances among a diverse group of industries and occupations. Therefore, the findings are generalizable to a broad range of workplaces.

A few important limitations of these analyses are worth noting. First, these are cross-sectional analyses of baseline variables only. Even though the results provide a better understanding of potential risk factors, we were unable to evaluate the temporal relationships between exposures and outcome. It is possible that some persons who experienced CTS moved from higher exposure to lower exposure (i.e., selective survival), thereby attenuating the strength of some associations. Second, methodological differences between sites in physical exposure data collection and/or analysis may lead to some non-differential misclassification of exposure category in the pooled analysis. However, this type of misclassification is likely to bias the findings toward the null. Third, while the intent of pooling data from multiple research sites was to increase the statistical power, there were practical problems resulting from variations in the prevalence of CTS and some missing data from the individual research sites. The psychosocial data was not collected by all sites and one site did not collect information on vibrating hand tools. So for these variables the sample sizes were smaller. As a result, the multivariable regression models assessing the role of these variables were conducted for a subset of pooled data.

Conclusion

In this large multi-site cross-sectional study, we found that jobs requiring high hand force were associated with an increased CTS prevalence after adjusting for important confounders. Overall, hand force was observed to be consistently and strongly associated with the prevalence of CTS, while repetition per se and wrist posture were not.

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Table 1.

Demographics and personal factors

Total N=2981	**N**	**CTS Cases**	**OR**	**95% CI**
Age (years)				
50+	709	90	**3.07**	**(1.97–4.79)**
35–50	1675	170	**2.38**	**(1.57–3.62)**
<35	597	27	1.00	
Gender				
Female	1572	191	**1.89**	**(1.46–2.44)**
Male	1409	96	1.00	
Race/Ethnicity				
Hispanic	579	45	0.77	(0.55–1.10)
African American	231	28	1.27	(0.83–1.95)
Asian	164	9	0.53	(0.27–1.07)
Other	88	11	1.31	(0.68–2.52)
Caucasian	1549	152	1.00	
Education				
Some High school or less	566	43	0.74	(0.53–1.04)
High school Graduate or above	2381	237	1.00	
Obese (BMI≥30)				
Yes	1058	154	**2.29**	**(1.79–2.93)**
No	1906	132	1.00	
General Health				
Fair or Poor	342	42	1.21	(0.83–1.77)
Good	1059	118	1.08	(0.82–1.43)
Excellent or Very Good	1051	109	1.00	
Medical Conditions *				
Yes	362	59	**2.04**	**(1.49–2.78)**
No	2614	228	1.00	
Previous Distal Upper Extremity Disorder				
Yes	335	76	**3.48**	**(2.56–4.73)**
No	1877	146	1.00	
Smoking Status				
Current	787	74	1.10	(0.82–1.48)
Previous	573	71	**1.50**	**(1.11–2.03)**
Never	1601	138	1.00	

* Diabetes Mellitus, Rheumatoid Arthritis, Thyroid Disease, or Pregnancy

Bold indicates statistically significant at 5% error.

Table 2.

Binary analyses on recreation, psychosocial, and work factors[*]

	N	Cases	OR	95% CI
Recreational Hand Intensive Activity				
>3 hours/week	1590	165	**1.64**	**(1.18–2.28)**
<=3 hours/week	812	54	1.00	
Recreational Aerobic Activity				
>3 hours/week	626	89	**1.43**	**(1.03–1.98)**
<=3 hours/week	1126	84	1.00	
Workplace Factors				
Years Worked at Enrollment				
<=1	389	33	1.15	(0.75–1.76)
1 to <=7	1269	114	0.91	(0.69–1.20)
7+	1297	133	1.00	
Job demand				
High	917	71	1.12	(0.78–1.61)
Low	906	63	1.00	
Decision latitude				
Low	810	61	1.29	(0.90–1.86)
High	1062	74	1.00	
Supervisor or co-worker support				
Low	410	17	0.94	(0.45–1.97)
High	351	14	1.00	
Physically Exhausted after Work				
Moderate to Severely Exhausted	961	137	**1.66**	**(1.28–2.15)**
None to Slightly Exhausted	1580	135	1.00	
Mentally Exhausted after Work				
Moderate to Severely Exhausted	682	84	1.21	(0.91–1.60)
None to Slightly Exhausted	1875	194	1.00	
Job Satisfaction				
Poorly Satisfied	420	60	**1.56**	**(1.09–2.24)**
Satisfied	1349	129	0.95	(0.71–1.27)
Very Satisfied	827	85	1.00	
Receiving Job Training				
None to Little	291	29	1.22	(0.78–1.90)
Some to A lot	1224	103	1.00	
Work shift				
Day	2467	257	1.79	(0.77–4.18)
Swing	311	19	1.50	(0.58–3.91)

	N	Cases	OR	95% CI
Rotating or Night	118	6	1.00	

[*] Odd ratios (OR) adjusted for age, gender, obesity, and research sites.

Bold indicates statistically significant at 5% error.

Table 3.

Multivariable analyses on physical exposures at job level[*]

	Cutpoints	CTS Cases	% Cases	OR	95% CI
Duty cycle					
Forceful exertions, % time					
	>32	85	9.0	**1.50**	**(1.06–2.12)**
	>11 to ≤32	111	11.4	**1.69**	**(1.23–2.32)**
	≤11	82	9.1	1.00	
All exertions, % time					
	>76	94	10.8	0.91	(0.66–1.26)
	>60 to ≤76	92	11.4	1.08	(0.78–1.48)
	≤60	92	10.7	1.00	
Force					
Worker Borg CR-10					
	>4	112	14.0	**2.04**	**(1.45–2.88)**
	>2.5 to ≤4	88	10.4	1.23	(0.86–1.75)
	≤2.5	65	7.5	1.00	
Analyst Borg CR-10					
	>4	88	9.0	1.32	(0.96–1.82)
	>2.5 to ≤4	88	12.3	**1.42**	**(1.04–1.96)**
	≤2.5	102	8.8	1.00	
Repetition					
Repetition, Forceful exertions (per min)					
	>10	110	10.0	**1.45**	**(1.03–2.04)**
	>3 to ≤10	90	10.9	1.21	(0.89–1.64)
	≤3	78	8.7	1.00	
Repetition, All exertions (per min)					
	>25	100	11.3	1.33	(0.93–1.91)
	>13 to ≤25	95	11.9	1.13	(0.82–1.57)
	≤13	83	9.7	1.00	
Analyst HAL rating					
	>6	62	12.3	1.33	(0.96–1.82)
	>4 to ≤6	119	10.3	1.12	(0.80–1.57)
	≤4	98	8.1	1.00	
Composite indexes					
Analyst HAL-TLV					
	>0.78	90	10.2	**1.74**	**(1.27–2.39)**
	>0.56 to ≤0.78	64	11.4	1.36	(0.91–2.02)
	≤0.56	119	8.7	1.00	

	Cutpoints	CTS Cases	% Cases	OR	95% CI
Posture					
Wrist Extension ≥30°, % time					
	>14	99	10.5	1.03	(0.71–1.48)
	>1.5 to ≤14	87	10.3	1.30	(0.91–1.86)
	≤1.5	91	9.0	1.00	
Wrist Flexion ≥30°, % time					
	>3	80	10.4	1.09	(0.8–1.49)
	>0 to ≤3	75	8.3	1.25	(0.9–1.74)
	=0	122	10.8	1.00	
Vibration					
	Yes	127	13.8	**1.71**	**(1.28–2.29)**
	No	131	8.2	1.00	

[*] Time weighted avearge. Odd ratios (OR) adjusted for age, gender, obesity, medical conditions and research sites.

Bold indicates statistically significant at 5% error.