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DEVELOPMENT OF A PROTOCOL FOR EPIDEMIOLOGICAL STUDIES OF WHOLE-BODY VIBRATION AND MUSCULOSKELETAL DISORDERS OF THE LOWER BACK

M. L. MAGNUSSON[†] AND M. H. POPE[†]

Iowa Spine Research Center, The University of Iowa, Iowa City, IA52242-1088 USA

C. T. J. HULSHOF

Coronel Institute for Occupational and Environmental Health, Academic Medical Center, University of Amsterdam, Amsterdam, NL-105 AZ, The Netherlands

AND

M. BOVENZI

Institute of Occupational Medicine, University of Trieste, Trieste 34129, Italy

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It seems evident from a large number of studies that there is a positive relationship between exposure to whole body vibration (WBV) and the occurrence of low back pain. There are existing standards for evaluating the human exposure to WBV, which are based on other factors than the effect of musculoskeletal disorders. Several national and international standards also exist for evaluating human exposure to WBV. The exposure limit values or health guidance caution zones included in some of these standards are not or only to a limited extent based on systematic epidemiological investigations. It has not yet been possible to establish a clear exposure–response relationship. There are many confounding or contributing factors which influence the hazards to workers caused by exposure to WBV. Reliable methods for the detection and prevention of injury due to vibration exposure at work, alone or in combination with other risk factors, need to be implemented. The aim of this paper was to design a protocol and a questionnaire for conducting collaborative studies of WBV and musculoskeletal back disorders. The protocol will be tested in a pilot study before it will be used in multi-center studies.

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1. BACKGROUND

Millions of workers throughout the world are exposed to mechanical vibration, transmitted to the whole body through the seats of industrial vehicles. Exposure to whole-body vibration (WBV) can cause musculo-skeletal disorders of the spinal system. The most frequently reported adverse effects are low back pain (LBP), early degeneration of the spine and herniated intervertebral discs. Several national and international standards exist for evaluating human exposure to WBV. The exposure limit values or health guidance caution zones included in some of these standards are not or only to a limited extent based on systematic epidemiological investigations. Existing epidemiological surveys strongly suggest a relationship between WBV and the development of LBP. However, a clear

[†]Also at University of Patras, Patras, Greece.

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exposure–response relationship has not yet been established. Many confounding and contributing factors are involved in the hazards to workers exposed to WBV. Reliable exposure data are needed to establish dose–response curves. A general agreement on diagnostic classification, in particular of the majority of the cases that lack objective signs is another problem. For this reason, it has been suggested that epidemiology of back conditions be restricted to studies of sciatica or disc herniations, where the definitions are easier and the criteria more uniform [1, 2]. The multifractorial etiology and pathophysiology of LBP is in most patients not well understood. Nevertheless, the prevailing weight of evidence suggests a link between vibration and LBP and pathologic changes to the spine.

The aim of this paper is to describe the steps for developing a protocol for conducting epidemiological multi-center studies of WBV and musculo-skeletal spinal disorders in order to advance methods for the detection and prevention of injury due to vibration exposure at work, alone or in combination with other risk factors.

2. METHODOLOGY

2.1. RATIONALE

There are several problems with currently published epidemiological studies of musculoskeletal problems. In particular, no disorder is uniquely associated with vibration. In addition, there are many confounding or contributing factors in the relationship between WBV and LBP disorders. Besides, vibration and shock exposures are complex and often not known.

Several recent epidemiological studies have shown strong evidence of a relationship between WBV and musculoskeletal health effects [3–11]. Two reviews [12, 13] critically discussed the evidence from epidemiological data on different work-related risk factors for low back disorders and concluded that there was evidence for a relationship between exposure to WBV and back disorders.

As a starting point for developing a protocol for epidemiological studies, a recent review of the relationship between exposure to WBV and LBP by Bovenzi and Hulshof [14] was considered. In this review 37 papers published between 1986 and 1996 were evaluated. A scoring procedure was used to evaluate the quality of each study according to criteria concerning the assessment of vibration exposure, assessment of health effects, and methodology. Sixteen articles reached adequate score on each of the criteria, and were included in the final review. The results showed that occupational exposure to WBV is associated with an increased risk of LBP, sciatic pain, and degenerative changes in the spinal system. However, the evidence was not sufficient to prove an exposure-response relationship between WBV and low back disorders.

New epidemiological multi-center studies should meet criteria such as outlined in the review by Bovenzi and Hulshof (see Table 1 in reference [14]). Accordingly, the present protocol suggests (1) that unified methods of assessment of (a) WBV exposure and (b) effects of WBV and confounding factors be developed and (2) to apply methods to assess occupational exposures of high risk groups such as agricultural tractors, forest machines, fork lifts, etc., and controls, (3) to develop guidelines for risk, and (4) assessing risk (cause and effect).

2.2. STUDY DESIGNS

Various groups of occupational drivers may be identified for being important targets of cohort or cross-sectional studies. Cohort studies can be either retrospective or prospective. The prospective cohort study is the preferred study design, that, when well conducted, produces results in terms of exposure-response relationships and allows the development of hypothesis for disease aetiology. In this type of study, subjects are enrolled at the time of exposure onset and followed forward in time. Because it may take years for a disease to develop, prospective studies are seldom feasible due to cost and practical reasons. Therefore, the majority of cohort studies in the field of occupational health are retrospective. In retrospective cohort studies, existing records of health status and exposure to causal factors in the past are used. In this case, the exposure and possibly the disease happened before the study was conducted. The following driving groups may be considered for cohort studies: drivers of industrial lorries, mining vehicles, long distance lorries, construction vehicles, public transport, test drivers, and military vehicle drivers. Control groups might include people with prolonged seated occupation including low intensity WBV exposure such as taxi drivers and policemen. The reason for choosing control groups with some vibration exposure is that, in today's society, it is difficult to find groups with no or very little vibration exposure. People utilizing agricultural machines, aircraft, and small fast boats may be suitable for cross-sectional studies. Compared to a longitudinal study design, cross-sectional studies have a lower validity. However, cross-sectional studies have several pragmatic advantages: groups that have previously had little study can be reviewed less expensively in cross-sectional studies than in cohort studies and the investigative instruments can be field tested. Both the cohort and the cross-sectional studies require the enrollment of a large number of subjects and, in the cohort study, many years of follow-up.

ASSESSMENT

3.1. ASSESSMENT OF VIBRATION EXPOSURE

In most epidemiological studies of occupational drivers there is a shortage of data on the relationship between WBV exposure and back disorders. The information from most studies, until recently, has been limited because of poor assessment of WBV exposure.

Vibration measurements should be performed according to the guidelines of ISO 2631 document (International Organization for Standardization) [15], which takes into consideration intensity, frequency, direction, and duration of vibration exposure. The measurements should be performed on the seat-pan during typical driving. Furthermore, detailed questions about type of vehicle, ground surface, environment, driving style, seat, back support, armrests should be assessed. For assessing long-term exposure, days or hours per week, months and year, as well as number of years of exposure must be recorded. A measure of lifetime cumulative WBV dose is suggested in the recent review by Bovenzi and Hulshof [14].

Earlier exposure data may be gathered by questionnaire and where it is possible an estimate of overall exposure should be made. A subjective evaluation by the driver of current and past exposures may be also of interest for the investigators.

3.2. Assessment of health effect

According to the relevant literature, particularly the Agency of Health Care Policy Research (AHCPR) guidelines, LBP is a symptom not necessarily related to a specific diagnosis. The symptoms can only sometimes be linked to a specific malfunction and to a pathological diagnosis with a high degree of certainty, but acute, chronic and recurrent LBP can originate from a large number of disorders with different aetiology. Because of the difficulties in determining the origin of the LBP even when sophisticated clinical methods are used, it is difficult to define the underlying disease. The weakness of most existing studies is that there is an inadequate diagnosis and, therefore, common criteria for assessing disorders must be developed.

In Germany [16] vibration induced spinal disorders have been added to the list of occupational diseases, effective from January 1993 [17]. The instruction leaflet [17] for the new occupational disease also included a list of diseases, which "under certain circumstances can be caused by the effect of seated WBV". This list includes: (i) "local lumbar syndrome", with irritation of the posterior ligament originating from intradiscal mass shift, the joint capsule or the vertebral periosteum as the underlying pathogenetic mechanism; clinical findings include localized area of pain in a vertebral segment, restriction of mobility, pain radiation and neurological irritation to the segment; (ii) "mono- and polyradicular lumbar syndrome" originating from a mechanical irritation of the nerve roots L3 to S1 due to degenerative changes of the lumbar discs such as protrusion and prolapse, loosening and a change in volume of the intervertebral discs, and instability in the motion segment; the main symptom of this syndrome is pain radiating into one or both legs; (iii) "cauda equina syndrome", which is a special form of the polyradicular syndrome, with a complex of symptoms attributable to a lesion of several lumbosacral nerve roots.

Most of the effects in epidemiological studies have been assessed by questionnaires or interviews and by clinical observations (mostly radiological findings). When the assessment has been based on only subjective symptoms, it is almost impossible to distinguish the exposure factor as an aetiologic factor from an aggravating or modifying factor. Also, imaging examinations have limited value due to the poor correlation between LBP and degenerative findings seen on radiographs. Clinical tests, although important, are somewhat limited in this context since they are more related to the severity of pain at the time of testing than the underlying disease. It may turn out that it is not very fruitful to link a certain restricted disease entity to WBV.

Ideally, the initial assessment of a patient with LBP consists of a focused medical history and physical examination. The primary purpose should be to rule out a serious underlying spinal condition unrelated to WBV exposure such as tumor or fracture. Referred back symptoms due to non-spinal conditions should be assessed (e.g., abdominal, vascular, urinary or pelvic pathology) as some literature supports a relationship of these conditions with WBV exposure [18]. The use of the Quebec Task Force [18] scheme may be of help for the classification of LBP syndromes. For patients with radicular symptoms (self reported), clear radiographic and clinical documentation of a herniated disc is needed. For patients with sciatica, MRI or CT may be useful to provide evidence of a herniated nucleus pulposus (HNP). HNP has been linked to WBV exposure by Kelsey *et al.* [19]. Other severe degenerative disorders of the spinal column (such as stenosis or root compression syndromes, etc.) should be subjected to radiographic and clinical documentation. Suspected spinal stenosis can be identified by myelography or CT.

3.3. Assessment of confounding factors

The most important confounding factors, except for those attributed to individual, social, and lifestyle factors, that need to be assessed in a protocol for occupational driving, are posture and lifting. In fact, posture may also be regarded as a contributing factor as it is always present with any WBV exposure. These risk factors have been associated with LBP and are directly connected with driving occupations [20–22]. These factors need to be assessed as detailed as possible, such as description of posture, weight of burdens, frequency, and duration.

Psychosocial factors have been suggested by some authors to have a more important role than any physical factors in the development of LBP [23]. However, it has also been shown that there were no psychosocial disturbances present in LBP sufferers who were still at work, indicating that LBP exists without psychosocial impact [24]. Clearly, one must differentiate between pain and disability. Pain originates from injured tissues, whereas psychosocial factors, such as work satisfaction can have an influence on disability [25]. Work satisfaction is an important issue for the completeness of environmental factors and should be addressed using a validated instrument.

4. PROTOCOL

A questionnaire was developed based on validated tools as well as clinical and epidemiological experience. It is important that a questionnaire is validated and tested against other instruments. Background factors, such as anthropometry, social status and educational level were included. Some lifestyle factors that have been linked to the risk of musculoskeletal ill health were also included. These factors give an idea of the person's responsibility of his/her health. It was considered meaningful to ask questions about smoking and alcohol consumption as well as exercise habits only if they are fairly specified in terms of units per day. Including the annual amount of driving in this section encompasses some important confounding factors.

In assessing health effects, special emphasis was focused on musculoskeletal problems. LBP, neck, and shoulder pain are the most frequently reported problems among occupational drivers both in terms of incidence rates and of disability. In order to get meaningful information for establishing an exposure–response relationship of back, neck and shoulder pain the questionnaire includes detailed questions of symptoms, aggravating triggers, severity of pain, disability, and pain history. In addition, questions about previous trauma to the back, neck and shoulder, that have required the intervention of a physician or physiotherapist, were included. The questionnaire also seeks information about presence of herniated cervical or lumbar discs, which have been documented by radiologic examinations. For grading the severity of chronic pain, the pain intensity and disability scales suggested by von Korff [26] will be used. In addition, the validated Quebec Pain Disability Scale [27] will be used for the assessment of functional disability. For the completeness, questions about other disorders (such as hypertension, bladder/bowel problems, etc.), known as being more common among drivers than in a general population, have been included.

The protocol includes the assessment of long-term exposure to vibration using detailed questions about the type of vehicle, amount of driving, ground surface, driving environment and conditions, seat suspension, and back support. Confounding and contributing factors like posture and lifting and previous back pain are included as well. A new instrument (PAW), validated for internal consistency and reliability, will be used for the assessment of Psychosocial Aspects of Work [28]. The instrument is based on the 7-item Work APGAR described by Bigos *et al.* [29], which was mainly concerned with job satisfaction. The 15 statements on the PAW reflect attitudes towards three specific aspects of work: general job satisfaction, social support from colleagues/managers, and the mental stress of work. Finally, the Fear-Avoidance Beliefs Questionnaire (FABQ) is a validated instrument that concentrates on the individual's beliefs about physical activity or work activity being a cause of their trouble, and on their fears about the dangers of such activities when they have an episode of pain [30].

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TABLE 1

Outline of	an	epid	emiol	logic	protocol	for	assessing	exposure	and	effect	of	occupational	w	hol	e
body vibration															

I.	Assessment of Vibration Exposure Recording site (seat floor)	III.	Assessment of Health Effects Musculoskeletal Problems
	Measurement method intensity frequency direction duration Driving conditions road speed vehicle seat suspension Longterm exposure hours/week, weeks/month, months/year	IV.	neck pain shoulder pain (low) back pain herniated disc aggravating triggers trauma pain assessment disability assessment Other disorders Confounding Factors Background Factors anthropometry
II.	Contributing Factors Posture time sitting/standing awkward posture (twisting & bending) unsupported posture seat, backrest Lifting weights frequency History of back pain		educational level Lifestyle Factors smoking alcohol consumption exercise habits Annual Driving Psychosocial Factors

5. DISCUSSION

Several epidemiological studies on WBV and health effects have been performed, which have led to the understanding that a relation exists. The problem with many of these earlier studies is that they are mostly not comparable for different reasons. In a critical review, Hulshof *et al.* [31] found that no study so far reached high quality scores for drawing any firm conclusions. During the past decade, however, there has been a number of well designed controlled studies which have shown strong evidence of a relationship between long-term WBV and LBP. However, an exposure–response relationship has not yet been established.

Exposure to WBV can indeed cause musculoskeletal disorder of the spinal system. Apart from personal pain and annoyance, these symptoms and disorders result in the loss of very many working days, with consequent loss of industrial production and increased welfare payments by governments. They are also producing a growing number of claims for compensation from employers. There are no harmonized methods for either regular health surveillance or the evaluation of compensation claims, which can be applied by occupational health workers across Europe. Therefore, the design of a standardised protocol for the assessment of WBV and musculoskeletal disorders is an essential requirement for conducting multi-center epidemiological studies.

Before developing the epidemiological protocol, the problems with existing epidemiological studies of WBV and musculo-skeletal disorders have to be identified. According to the recent critical evaluation of the literature on health effects in long-term exposure to WBV by Bovenzi and Hulshof [14], the main concerns are the study design, the appropriate and reliable definition of disorders, how to address confounding factors,

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and how to measure exposure. An extensive review of validated tools for the assessment of health effects indicates that a questionnaire must be quite thorough to be meaningful for assessing effect variables. Assessment of exposure and confounding variables should be comprehensive, both in terms of a correct measuring technique and in terms of additional information in order to assess long-term exposure and to control for confounders.

With a multi-center approach, a more comprehensive survey can be achieved with account taken also of the differences in health and compensation systems in different countries. Another advantage of multi-center studies is that the cohorts to be studied can be spread between the centers. Using the same protocol would enhance direct comparisons between groups. The multi-center design will accelerate the data collection of different groups and facilitate the data handling in a central base. The difficulties, however, include the control of compliance of the groups taking into account the costs. It is essential to test the protocol in a pilot study before initiating a multi-center study and to test the language translations in small pilot studies.

Several studies have been performed with the ambition to establish the health risks of certain occupational vibration exposed groups. Although some strong evidence has been shown of adverse health effects, a reliable exposure–response relationship has not been established. These occupational driving groups may be suitable for a cohort study design. Other groups, not yet identified as high risk groups, and/or representing a relatively small group, may be investigated in cross-sectional studies.

In this paper, as controls the authors propose occupational groups exposed to a lesser amount of WBV, such as occupational drivers of personal cars, rather than non-vibration exposed seating groups. The main reason being the assumption that most people will have some vibration exposure in daily life irrespective of occupation. Thus, the choice of a lower exposure occupational group takes into account the control for non-occupational vibration exposure as a confounding factor.

The length of the questionnaire could be debated. People of course hesitate to answer too lengthy protocols. On the other hand, the main critique of previous studies has been the poor or inadequate assessment of exposure. Therefore, emphasis was made to design the protocol such that it can provide the necessary information for establishing reliable measures of vibration exposure. Likewise, in the assessment of outcomes or effects the emphasis was put upon more detailed than normal for questionnaires information, in order to meet the criteria of defining certain disorders. The length of the questionnaire can be altered by assessing only LBP or including also neck, shoulder and other musculoskeletal problems as well as other medical problems that can be related to WBV.

The results of the proposed multi-center study may provide useful exposure and epidemiological data for the development of future ISO and CEN standards concerned with (i) the evaluation of exposures to WBV, (ii) guidance on exposure–effect relationships for WBV, (iii) diagnostic tests for vibration injuries, and (iv) the testing of protective equipment.

The main objective of the above-mentioned study is to advance methods for the detection and prevention of injury due to WBV exposures at work, alone or in combination with other risk factors. Specific issues to be addressed are (i) development of common methods for health surveillance, including the development of improved methods for the detection and diagnosis of disorders, (ii) establishment of relationships between vibration exposures and injury, through collaborative epidemiological research, and (iii) improvement of methods for preventing disorders, including consideration of current standard methods for hazard surveillance and for testing the protection provided by seats.

In this paper the authors have described the challenges and the methodologies to be utilised to address the assessment of exposure and effect variables.

The protocol will be field validated for understanding before being implemented as pilot studies. After evaluation and modification, it will be used in multi-center studies and data collected and analysed in a data base. Follow-ups should be undertaken yearly over a 10-year period or more. Further examination of those who report LBP, neck and shoulder pain will include measurement of range of motion and muscle function. Muscle function measurement should include the flexion-relaxation phenomenon, strength, endurance and response to sudden loads, using EMG.

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