Published on Figshare May 10th 2019

Does occupational lifting affect the risk of hypertension, and are those using antihypertensive drugs and of older age particularly vulnerable?
- A study protocol.

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Background

As previously described by Korshøj and colleagues (1), hypertension is a major risk factor for cardiovascular disease (2, 3), the prevalence varies across occupational groups and is thought to be affected by differences in the working environment, such as lifting (4, 5). Lifting heavy burdens acutely rises the blood pressure (6), and due to the long duration and high frequency of lifts during occupational hours among some workers, an increased blood pressure may follow (7). The relation between occupational lifting and blood pressure was investigated in the Copenhagen City Heart Study (8). The overall results showed weak positive relations both in cross-sectional and prospective analyses, while secondary explorative prospective analyses showed that those using antihypertensive drugs experienced major increases in systolic blood pressure (16 mmHg) when exposed to heavy occupational lifting. Also, among participants aged ≥ 50 years, exposure to heavy occupational lifting indicated a tendency of increased incidence of hypertension (OR 1.30, 95% CI 0.97 - 1.73). Both the age-dependent stiffening of the arteries as well as the hypertension and related endothelial damage, among use of antihypertensive drugs, may correspond to a lowered elasticity of the arteries leading to increases in the total peripheral resistance and thereby also increased blood pressures (9, 10).

Thus, the aim of this study is to explore associations between heavy occupational lifting and hypertension in the Copenhagen General Population Study. Associations will be investigated in a cross-sectional design among all randomly selected citizens from two districts of Copenhagen, Denmark, and in groups stratified by use of antihypertensive drugs as well as age.

Methods

This study will use data from the Copenhagen General Population Study, which have been collected via health examinations and questionnaires in an examination conducted from 2004 to 2015. The sample consists of approximately 110,000 people in the age interval 20 – 80+ years. The response rate was 42%. The data set contains person-based information on health as well as a large variety of biological, environmental and life-style related factors.

The protocol for inclusion of participants, processing of data and statistical analysis are similar to the analysis performed in the Copenhagen City Heart Study (1). Thus, this study will try to replicate the cross-sectional results from the previous study preformed in the Copenhagen City Heart Study (8). However, in the previous study several measures per person were collected and therefore analyses were conducted using generalized estimation equation, in this study the analyses will be conducted by use of maximum likelihood due to the fact that this sample only hold one measure per participant, besides this the cross-sectional analyses will be the same. Below, the protocol is briefly described.

The primary null-hypothesis is that there is no association between heavy occupational lifting and hypertension across the general population of workers, secondary an investigation of interaction between use of antihypertensive drugs and occupational lifting as well as an interaction between age and occupational lifting are planned based on the previous findings of these groups to be more vulnerable to rises in blood pressure by exposure to occupational lifting (8). Due to the multiple hypothesis tested a confidence interval of 99% were chosen.

Inclusion criteria

The criteria for inclusion will be participation in the BP measurement and having provided answers to the questions regarding level of occupational physical activity (also including heavy lifting), antihypertensive drug usage, as well as being aged ≤70 years old at the time of data collection.

We believe that potential effects of heavy occupational lifting on BP may be concealed, reversed or otherwise distorted by effects from antihypertensive drugs, and therefore will a secondary analysis stratify on the use of those drugs.

Assessment of exposure

The self-reported information on level of occupational physical activity was obtained by use of the question: "Please describe your level of occupational physical activity within the past year" with the following response categories:"1) predominantly sedentary; 2) sitting or standing, some walking; 3) walking, some handling of material; 4) heavy manual work". If answering 3 or 4, an additional question regarding heavy occupational lifting was applied. The question was: "Do you lift heavy burdens?" with the response categories: "1) yes; 2) no". Participants will be classified as exposed to heavy occupational lifting by answering "yes" to the question concerning heavy burdens, and those participants answering 1, 2 and 3 or 4 in combination with not lifting heavy burdens will be classified as the reference group.

In the examination, 72,273 participants answered the question regarding occupational physical activity, use of antihypertensive drug use and were aged ≤70 years old at the time of data collection; of those 16,819 answered level 3 or 4 and 15,662 answered the question regarding heavy occupational lifting.

Assessment of outcome

The primary outcomes will be systolic blood pressure and hypertensive status. Participants will be classified as hypertensives if they use antihypertensive drugs and/or they had a measured SBP ≥ 140 mmHg or DBP ≥ 90 mmHg.

In addition, secondary analyses will be conducted with pulse pressure (pulse pressure = SBP – DBP), mean arterial pressure (mean arterial pressure = (2*DBP + SBP)/3)) and mid BP (½ SBP + ½ DBP) as outcomes [14].

Assessment of covariates

Previously a number of factors have been shown to be associated both with occupational workload and BP. Thus, those factors will be included as covariates: sex (male/female) (11, 12); age (categories of <40; 50-59; 60-70 years) (13); body mass index (BMI) (categories of <18.5; 18.5 – 24.9; 25.0 – 29.9; ≥30kg/m^2) (14, 15) calculated from objectively measured body height and weight; smoking (categories of nonsmoking; currently smoking)(16, 17); level of leisure time physical activity (LTPA)(categories of *mainly sedentary* "you spend most of your leisure time performing sedentary tasks"; *light physical active* "you go for a walk, use your bicycle a little or perform activity for at least 4 hours per week"; *moderate physical active* " you are an active athlete, for at least 3 hours/week; *strenuous physical active* "you take part in competitive sports, or perform moderate to vigorous activity more than 4 hours/week (18), mental stress (are you feeling stressed? yes/no) (19), length of education in total years (20, 21); and occupational group (categories of self-employed, vocational trained, no education/training, official/civil servant, house wife, un-employed/retired) (22).

Criteria for statistical significance

Five hypotheses will be tested. The overall significance level will be set at 0.05. A Bonferroni correction will be applied. Hence, each of the five primary hypotheses will be tested at the significance level 0.01. Secondary analyses will be regarded as exploratory and will therefore not be tested for statistical significance, but the precision will be reported by 99% confidence interval (CI), as they may influence the interpretation of the primary analyses.

Primary statistical analyses

The analysis will be controlled for sex, age, BMI, smoking, LTPA, mental stress, years of education, and occupational group. The significance test will be based on the empiric standard error and the Wald Statistic. The odds ratio (OR) between the exposed and the non-exposed will be calculated and presented with a 99% confidence interval (CI). The CI will be based on the empiric standard error.

Statistical power

All statistical analysis will be performed in the statistical software SAS, version 9.4 (SAS Institute, Cary, NC, USA). Table 1 gives the expected numbers of observations, participants and "cases" that will be included in the primary analyses.

Table 1. Number of observations, participants and estimated cases that we expect to include in the primary analyses.

Analysis	**Number of observations**	**Number of participants**	**Estimated number of cases**
Cross-sectional	72,273	72,273	18,068

The statistical powers of the primary hypotheses are given in Figures 1 - 5. The calculations are based on statistics given in Table 3, a median age at 50 years, a standard deviation of systolic blood pressure at 17 mm Hg (23), the propagation of error formulas, the central limit theorem, and a two-tailed significance level at 0.01, for each of the five hypotheses.

Primary analyses

1. *Linear regression on systolic blood pressure*

It has been suggested that each mmHg increase in resting SPB is associated with an approximately 3.5% increased risk of death due to stroke and IHD (24). It has moreover been suggested that the relative effect of a one mmHg increase is quite independent of the level of SBP, a change in SBP from 120 to 121 would, for example, cause the same relative risk increase as a change from 139 to 140 (24). From this viewpoint it would be of interest to estimate the expected effect of heavy occupational lifting on resting SBP in a linear regression model and thereby obtain an estimate that could be directly translated into relative risks of death due to stroke or IHD.

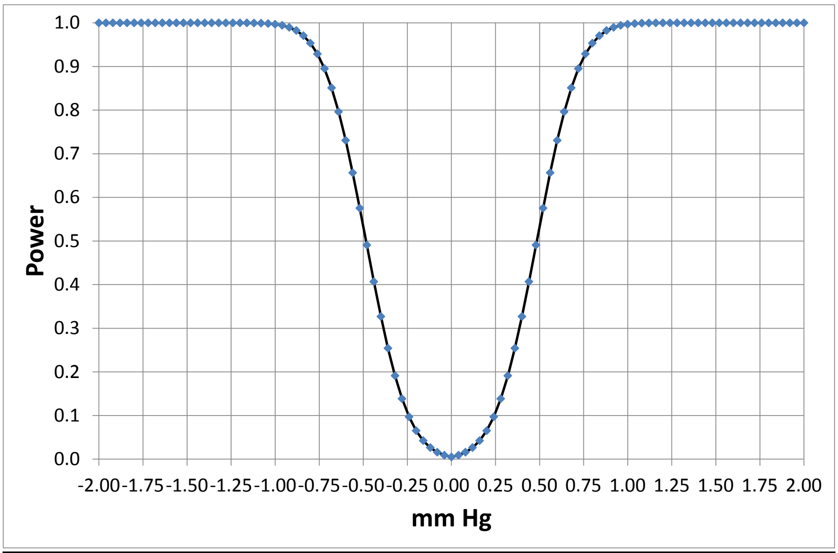

Figure 1. Statistical power of detecting an association between heavy occupational lifting and systolic blood pressure (SBP), as a function of the difference in mean SBP among exposed versus unexposed people in the target population.

2. Odds for hypertension

The odds for being hypertensive among those exposed and not exposed to occupational lifting, will be estimated by use of maximum likelihood and logistic regression.

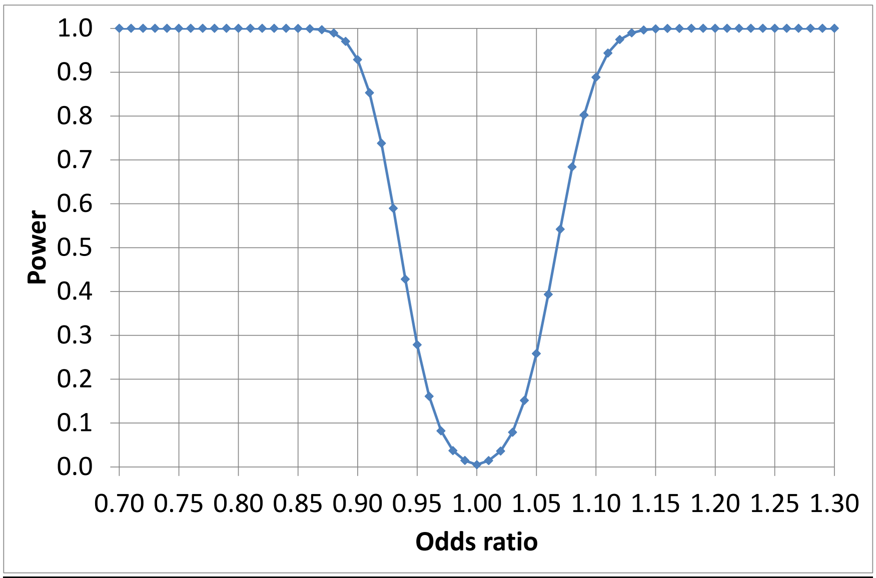

Figure 2. Statistical power of detecting an association between heavy occupational lifting and hypertension, as a function of the underlying odds ratio for hypertension among exposed versus unexposed people in the target population.

3. Stratification by age

A potential effect of occupational exposures might be more pronounced among older people who are likely to have been occupationally active throughout a longer time span. Also, increasing age leads to decreases of aerobic capacity (25, 26) and thus a higher strain from occupational lifting than among younger workers (27), this in combination with the gradually loss of arterial compliance (2, 9) could lead to greater peaks in BP during occupational lifting among older than younger workers. Therefore an age-stratified analysis similar to the primary linear regression analysis will be performed. Also, the ORR ratio for the interaction of age and occupational lifting will be estimated by the dividing the OR among both older (>= 50 years) and younger (< 50 years) participants to estimate the interaction effect of age*occupational lifting.

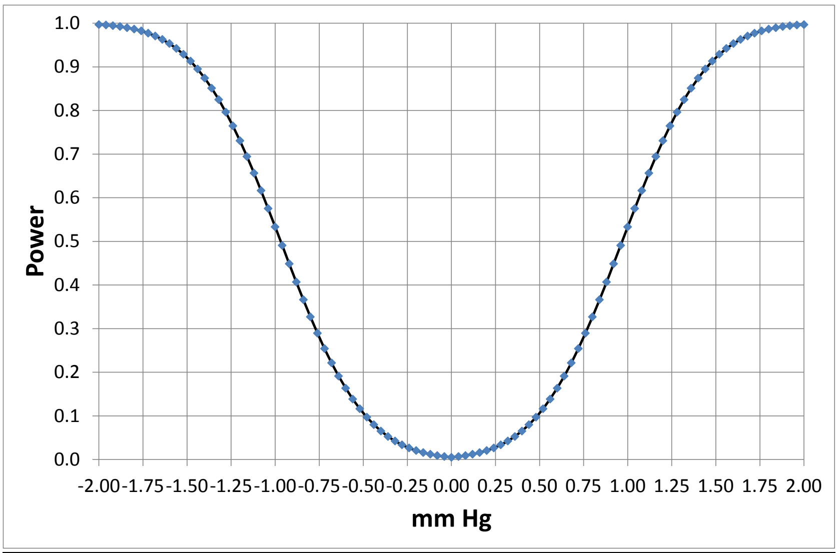

Figure 3. Statistical power of detecting an effect of interaction between age (<50 vs >= 50 years) and heavy occupational lifting (Yes vs No) on systolic blood pressure (SBP), as a function of the difference between the age group-specific differences in mean SBP among exposed versus unexposed people in the target population.

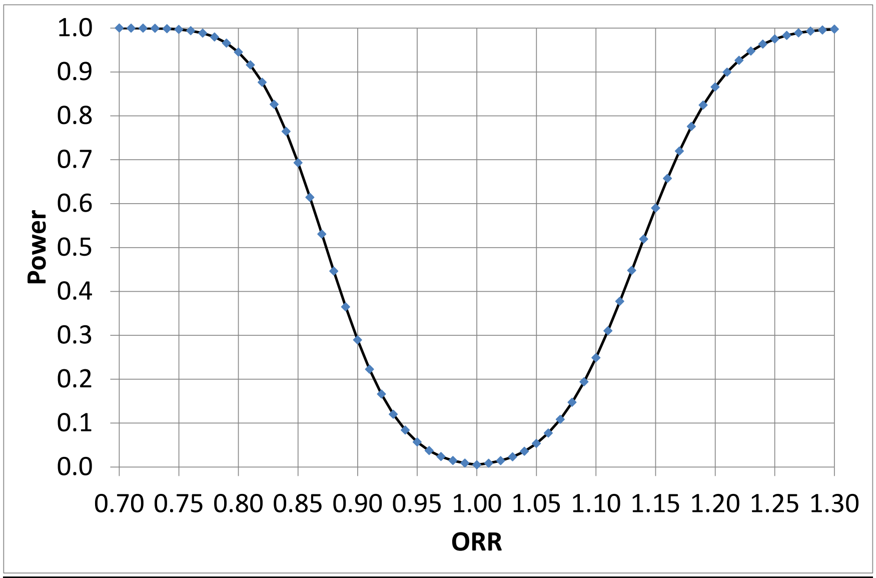

Figure 4. Statistical power of detecting an effect of interaction between age (<50 vs >= 50 years) and heavy occupational lifting (Yes vs No) on the risk of hypertension, as a function of the ratio of the age-group specific odds ratios for hypertension among exposed versus unexposed people in the target population.

4. Stratification by use of antihypertensive drugs

Due to the previous findings of users of antihypertensive drugs being more vulnerable to rises in BP by exposure to occupational lifting (8) we plan to investigate the interaction between occupational lifting and use of antihypertensive drugs. The expected difference between the exposed and the non-exposed in the stratified groups will be estimated by a linear regression and presented with a 99%CI, based on the empiric standard error.

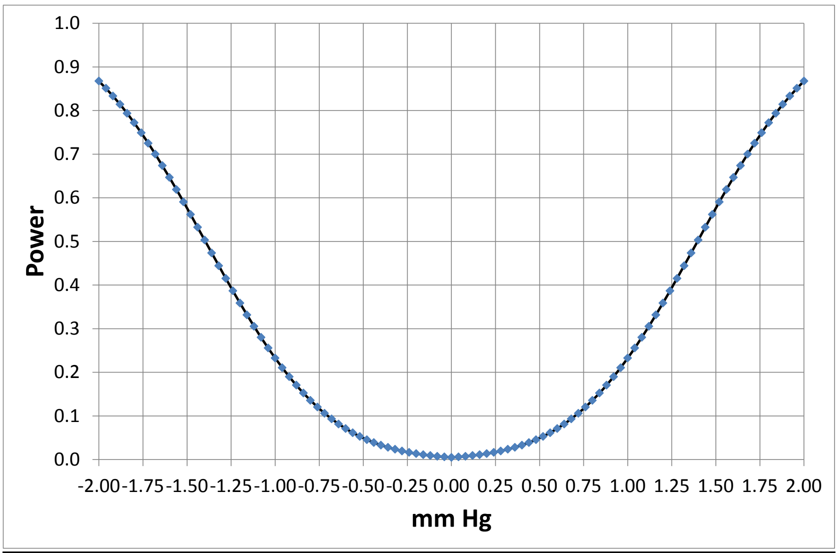

Figure 5. Statistical power of detecting an effect of interaction between use of antihypertensive drugs (Yes vs No) and heavy occupational lifting (Yes vs No) on systolic blood pressure (SBP), as a function of the difference between the concerned differences in mean SBP among exposed versus unexposed people in the target population.

The power calculations are based on statistics given in Table 3, a median age at 50 years, a standard deviation of systolic blood pressure at 17 mm Hg, the propagation of error formulas, the central limit theorem, and a two-tailed significance level at 0.01, for each of the five hypotheses.

Secondary analyses

1. Linear regression on other types of blood pressure measurements

It is presently not known if and how a person's resting BP is influenced by occupational lifting activities. It is therefore of interest to also regard potential effects of occupational lifting on mean arterial pressure, DBP, and pulse pressure. For this reason we will repeat the linear regression analyses described above on each of these outcomes.

2. Sensitivity to choice of comparison group

Our assessment of exposure includes that the exposed group would consist of participants whose work entailed heavy occupational lifting combined with walking, some handling of material or heavy manual work, while the comparison group would consist of the rest of the occupationally active participants, regardless of their type of occupational activity. We want to know how sensitive our analyses are to the choice of comparison group after adjustment for the included covariates. To shed some light on this issue, we will perform an additional set of linear regressions on SBP. In these particular analyses, we will split the comparison group into three different sub groups and thereby create an exposure variable with four instead of two categories. The statistical models, covariates and inclusion criteria will otherwise be the same as they are in our previously defined linear regression analyses. The results will be presented as outlined in table 2.

Table 2. Dummy table for the reporting of results of linear regressions on systolic blood pressure (SBP) as a function of occupational physical activity.

Occupational physical activity	**Cross-sectional differences in SBP**		
	N	**Diff.**	**99% CI**
Heavy lifting		Ref.	-
Walking, some handling of material or heavy manual work, but no heavy lifting			
Sitting or standing, some walking			
Predominantly sedentary work			

N = Number of observations; Diff. = Difference in mmHg; CI = Confidence interval; Ref. = Reference group

3. Sensitivity to the definition of hypertension

In our primary analysis we will define hypertension as use of antihypertensive drugs and/or a measured consultation SBP ≥140 mmHg or DBP ≥90 mmHg (28). We recognise, however, that the cut-points could have been defined differently, e.g. SBP ≥160 mmHg or DBP ≥100 mmHg (28); SBP ≥180 mmHg or DBP ≥110 mmHg (28, 29) or SBP ≥130 mmHg or DBP ≥80 mmHg (30).

We want to know if the OR for hypertension as a function of heavy occupational lifting is sensitive to the definition of hypertension. We will therefore conduct two additional logistic regression analyses, which will be performed in the same way as the primary analysis but with the cut-points SBP ≥160 mmHg or DBP ≥100 mmHg and SBP ≥130 mmHg or DBP ≥80 mmHg instead of the traditional SBP ≥140 mmHg or DBP ≥90 mmHg.

Optional sub-analyses of interest

In addition to the abovementioned secondary analysis, investigations of associations between occupational lifting and BP in subgroups based on combinations of levels of occupational and leisure time physical activities could be of interest due to previous findings of differences in ambulatory BP across these sub-groups (7) explained by the differing health effects described in the health paradox of leisure time and occupational physical activity (31). Also, due to the previous findings of users of antihypertensive drugs to be vulnerable to BP raises when exposed to occupational lifting (8), and the previously reported differing effects on BP due to levels of leisure time physical activity it would be of interest to investigate associations between occupational lifting and BP in subgroups based on levels of leisure time physical activity and use of antihypertensive drugs. Furthermore, investigations of the possible buffering effect on BP from leisure time physical activity among users of antihypertensive drugs exposed to occupational lifting would be of interest for future preventive initiatives and clinical guidelines.

Results

The response rate was 42% in the examination running from 2004 – 2015. Based on the inclusion criteria of answering on the level of occupational physical activity 32,604 observations were excluded. Hence, the final populations for the cross-sectional analysis are assumed to include less than 72,273 participants (figure 3), due to the additional inclusion criteria of measured BP and use of antihypertensive drugs. The information on BP and use of antihypertensive drugs will be provided after this protocol paper is uploaded.

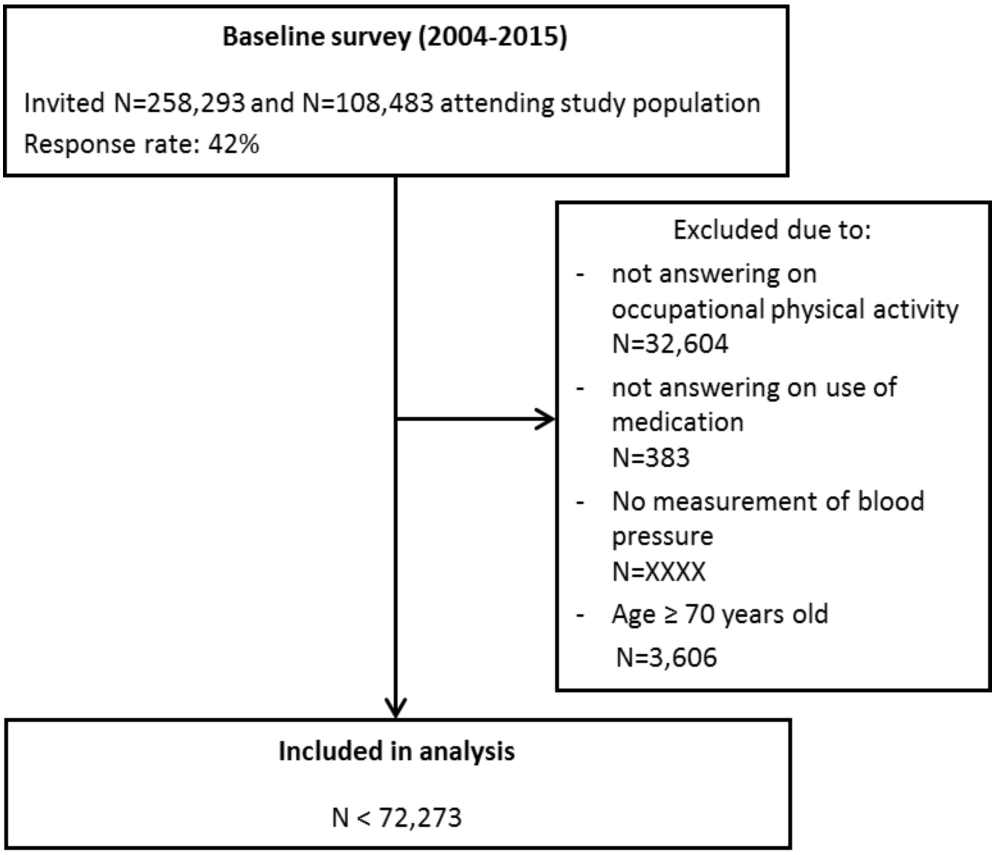

Figure 6. Flow of the observations and participants in the examination of the Copenhagen General Population Study.

Descriptive information of the included population

The population which will be included in the analysis will be set by the criteria for inclusion, described previously. Therefore it is assumed that fewer participants will be included in the analysis than the amount of participants answering on the level of occupational physical activity and use of medication, described in the following descriptive table.

Table 3. Baseline characteristics of the participants answering on the level of occupational physical activity and use of medication including 72,273 participants.

	Mean	SD	%	range
Age (years)	51.29	9.58		20.12 to 69.99
Sex (%female)			55%	
BMI (kg/m^2)	25.93	4.25		14.17 to 91.79
Smoking (%current smokers)			18%	
Using medication			14%	
Total year of school and education	11.22	1.67		0.00 to 14.00
Occupational physical activity				
Predominantly sedentary			44%	
Sitting or standing, some walking			33%	
Walking, some handling of material			20%	
Heavy manual work			4%	
Occupational heavy lifting (%yes)			13%	
Feeling stressed (% yes)			27%	

Discussion

This study aims to contribute to the knowledge about the risk for hypertension from heavy occupational lifting by building further on previous findings in the CCHS (8), and possibly thereby contribute to the prevention of cardiovascular disease.

Study population

Some differences were seen between the participants answering on the level of occupational physical activity and those attending at the data collection. Participants answering on the level of occupational physical activity were 6.7 years younger (mean age 51.3 years among the participants answering on the level of occupational physical activity and 58.0 years among the attending), and none of the participants answering on the level of occupational physical activity stated to be unemployed or retired, whereas 29.3% of the attending participants stated to be unemployed or retired. Among the participants answering on the level of occupational physical activity there was 9.9% less medication use than in the attending participants (14.0% used medication among the participants answering on the level of occupational physical activity and 23.9% among the attending).

These differences between participants attending and those also answering on the level of occupational physical activity may affect the prevalence of hypertension. The difference in age might lower the prevalence of hypertension among those answering on the level of occupational physical activity (10), this assumption is supported by the lower fraction of using medication and thus indicating less prevalence of disease in general. Furthermore, the higher proportion stating to be unemployed or retired among the attending participants may affect the prevalence of hypertension to be higher than among those answering on the level of occupational physical activity, both due to increased age (10), but also employment status (32).

Methodological challenges

These analyses hold both strengths and limitations.

The strengths cover the limited risk of classification of participants as false negative hypertensives due to the determination of hypertension based on both use of antihypertensive drugs and the casual BP in mmHg and the high number of randomly selected participants in the study population.

The limitations cover the single measurement of a casual BP, shown to have a lower prognostic value than ambulatory BP or BP monitored during sleep (33, 34) and the self-rated exposure to occupational lifting that could be biased by recall (35, 36) and duration of working hours, as exposure to occupational lifting seems to affect the odds for prolonged working hours (37).

Perspectives of the proposed findings

The Eurofound survey observes one third of the European workforce to be exposed to occupational lifting (6^{th} survey in Eurofound) and hypertension is classified as a major risk factor for cardiovascular disease and mortality (3, 5, 38). Therefore, a positive association between occupational lifting and risk for hypertension would indicate a prevention-potential for hypertension by minimizing occupational lifting exposures. For example, minimizing occupational lifting could be achieved by introduction of automatization of manual work tasks and assistive devices currently requiring manual material handling, as a positive association would be assumed to reflect a physiological mechanism across common workers. On the other hand, a reflection of a physiological mechanism would not be assumed in negative associations until such association is verified in study populations not working under the Danish restrictive occupational lifting regulations.

These proposed analyses will be based on a randomly selected adult population in Denmark and are therefore considered to be generalizable to the fraction of the Danish workforce exposed to occupational lifting.

Acknowledgments

The project is funded by the Danish tax payers, via the Danish Work Environment Research Foundation, grant number 20150067515.

Conflicts of Interest

None declared.

Abbreviations

BMI: body mass index
BP: blood pressure
CI: confidence interval
DBP: diastolic blood pressure
IHD: ischemic heart disease
OR: Odds ratio
RR: rate ratio
SBP: systolic blood pressure

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