Table 3 Numbers of participants by subcohort for informed consent items 1–5 at baseline survey and at 6 months

	Basic survey		Basic survey + genetic analysis		p value (2-tailed) comparison between subcohorts		
	Adogawa	Shin-asahi	Takashima	Makino	4 areas	2 areas without genetic analysis	2 areas with genetic analysis
Total	2213	953	1065	1130			
Men	812	277	344	438			
Women	1401	676	721	692			
At baseline							
Item 1: basic survey:							
Total (%)	2053 (92·8)	885 (92·9)	938 (88·1)	945 (83·6)	<0·0001	NS	0·0033
Men (%)	765 (94·2)	266 (96·0)	306 (89·0)	372 (84·9)	<0·0001	NS	NS
Women (%)	1288 (91·9)	619 (91·6)	632 (87·7)	573 (82·8)	<0·0001	NS	0·0107
Item 2: preservation of blood samples for future use							
Total (%)	2038 (92·1)	878 (92·1)	926 (86·9)	942 (83·4)	<0·0001	NS	0·0187
Men (%)	760 (93·6)	266 (96·0)	304 (88·4)	372 (84·9)	<0·0001	NS	NS
Women (%)	1278 (91·2)	612 (90·5)	622 (86·3)	570 (82·4)	<0·0001	NS	NS
Item 3: examination of medical records and death certificate							
Total (%)	2025 (91·5)	875 (91·8)	917 (86·1)	938 (83·0)	<0·0001	NS	0·0373
Men (%)	758 (93·3)	264 (95·3)	304 (88·4)	372 (84·9)	<0·0001	NS	NS
Women (%)	1267 (90·4)	611 (90·4)	613 (85·0)	566 (81·8)	<0·0001	NS	NS
Item 4: genetic analysis							
Total (%)			919 (86·3)	938 (83·0)			0·0378
Men (%)			304 (88·4)	372 (84·9)			NS
Women (%)			615 (85·3)	566 (81·8)			NS
Item 5: preservation of DNA samples for future analysis							
Total (%)			911 (85·5)	938 (83·0)			NS
Men (%)			300 (87·2)	372 (84·9)			NS
Women (%)			611 (84·7)	566 (81·8)			NS
After 6 months							
Item 1: basic survey							
Total (%)	2045 (92·4)	881 (92·4)	909 (85·4)	941 (83·3)	<0·0001	NS	0·0059
Men (%)	764 (94·1)	266 (96·0)	299 (86·9)	371 (84·7)	<0·0001	NS	NS
Women (%)	1281 (91·4)	615 (91·0)	610 (84·6)	570 (82·4)	<0·0001	NS	0·0197
Item 2: preservation of blood samples for future use							
Total (%)	2030 (91·7)	874 (91·7)	897 (84·2)	938 (83·0)	<0·0001	NS	0·0345
Men (%)	759 (93·5)	266 (96·0)	297 (86·3)	371 (84·7)	<0·0001	NS	NS
Women (%)	1271 (90·7)	608 (89·9)	600 (83·2)	567 (81·9)	<0·0001	NS	NS
Item 3: examination of medical records and death certificate							
Total (%)	2017 (91·1)	871 (91·4)	888 (83·4)	934 (82·7)	<0·0001	NS	NS
Men (%)	757 (93·2)	264 (95·3)	297 (86·3)	371 (84·7)	<0·0001	NS	NS
Women (%)	1260 (89·9)	607 (89·8)	591 (82·0)	563 (81·4)	<0·0001	NS	NS
Item 4: genetic analysis							
Total (%)			890 (83·6)	934 (82·7)			NS
Men (%)			297 (86·3)	371 (84·7)			NS
Women (%)			593 (82·2)	563 (81·4)			NS
Item 5: preservation of DNA samples for future analysis							
Total (%)			882 (82·8)	934 (82·7)			NS
Men (%)			293 (85·2)	371 (84·7)			NS
Women (%)			589 (81·7)	563 (81·4)			NS

NS, not significant.

Participation in Item 1 (basic survey), item 2 (preserving blood samples for future use), and item 3 (examination of medical records and death certificate)

At baseline

In the non-genetic subcohorts of Adogawa and Shin-asahi, participation rates for items 1–3 were all more than 90%, and there was no statistical difference between these areas. In the genetic subcohorts of Takashima and Makino, however, participation rates for items 1–3 were significantly lower: about 86–88% in Takashima ($p < 0·0001$, $p < 0·0001$, $p < 0·0001$, respectively, compared with those in Adogawa) and around 83% in Makino ($p < 0·0001$, $p < 0·0001$, $p < 0·0001$, respectively). However, Takashima had significantly higher participation rates than Makino for items 1–3 ($p = 0·0033$, $p = 0·0187$, $p = 0·0373$, respectively).

Six months after baseline

Each subcohort had withdrawals by 6 months after the baseline survey, thus reducing the participation rates. Takashima experienced a seven times higher withdrawal rate than the other three areas, lowering its participation rate to 82–85%, close to that in Makino. Takashima still had statistically higher participation rates compared with Makino for item 1 ($p = 0·0059$) and item 2 ($p = 0·0345$), but not for item 3.

Participation in item 4 (genetic analysis) and item 5 (preserving DNA samples for future analysis)

Takashima, where standard methods of providing information were used, showed a significantly higher participation rate at baseline for item 4 compared with Makino, where participants were exposed to extensive information

Table 4 Effect of genetic analysis: odds ratios of participation between a non-genetic subcohort (Adogawa) and a genetic subcohort (Takashima) at baseline and at 6 months

		At baseline		After 6 months	
Dependent variable	Independent variables	OR	95%CI	OR	95%CI
Participation in basic survey	Gender†	0·69*	0·53 to 0·91	0·69*	0·52 to 0·90
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Genetic analysis‡	0·77**	0·68 to 0·88	0·76**	0·67 to 0·86
Participation in blood sample preservation for future use	Gender†	0·68*	0·52 to 0·88	0·67*	0·51 to 0·87
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Genetic analysis‡	0·77**	0·68 to 0·87	0·76**	0·67 to 0·85
Participation in examination of medical records and death certificate	Gender†	0·64*	0·50 to 0·83	0·63*	0·49 to 0·82
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Genetic analysis‡	0·62**	0·49 to 0·78	0·60**	0·48 to 0·76

*$p < 0.05$; **$p < 0.001$ (2-tailed).
†Male = 0; female = 1.
‡No = 0, Adogawa; yes = 1, Takashima.

($p = 0.0378$). However, there was no statistical difference between these two areas for item 5. On the other hand, Takashima had a total of 29 withdrawals at 6 months, while Makino had only four, resulting in the participation rates for items 4 and 5 being no longer statistically different.

Odds ratio of participation in and withdrawal from consent items

Effect of demographic differences between areas

Demographic factors were the only differences between the non-genetic subcohorts. The rates of both participation in and withdrawal from items 1–3 showed no differences between non-genetic subcohorts, neither at baseline nor 6 months later.

Effect of genetic analysis

The ORs for participation in and withdrawal from each consent item for a study implementing genetic analysis are given in tables 4 and 5. The only difference in study design between Takashima and Adogawa (control group) was that Takashima involved genetic research, but Adogawa did not. Takashima had significantly lower participation rates for items 1–3 than Adogawa both at baseline and at 6 months (table 4). As a result, the ORs for participation in the study implementing genetic analysis were 0·77 (95% CI 0·68 to 0·88) for item 1 (basic survey) at baseline, 0·77 (95% CI 0·68 to 0·87) for item 2 (preserving blood samples for future use), and 0·62 (95% CI 0·49 to 0·78) for item 3 (examination of medical records and death certificate). Six months later the ORs were 0·76 (95% CI 0·67 to 0·86), 0·76 (95% CI 0·67 to 0·85), and 0·60 (95% CI 0·48 to 0·76) for items 1–3 respectively. The ORs for withdrawal from the study implementing genetic analysis were 7·72 (95% CI 3·51 to 16·97), 7·75 (95% CI 3·52 to 17·05), and 7·76 (95% CI 3·53 to 17·08) for items 1–3 respectively (table 5).

Effect of providing extensive information

For the two genetic subcohorts, table 6 presents the ORs for participation in each consent item at baseline and at 6 months, and table 7 the ORs for withdrawal from each consent item. Before deciding whether or not to take part in the study, potential participants in Makino were exposed to more information and offered more opportunities than those in Takashima to learn and understand the relationships between genes and lifestyle related diseases, and about the nature of the proposed genetic research. All participation rates in Makino were revealed to be significantly lower than those in Takashima. Thus, at baseline the ORs for participation in the study providing extensive preliminary information were 0·63 (95% CI 0·49 to 0·81) for item 1 (basic survey), 0·69 (95% CI 0·54 to 0·87) for item 2 (preserving blood samples for future use); 0·71 (95% CI 0·56 to 0·90) for item 3 (examination of medical records and death certificate), 0·70 (95% CI 0·55 to 0·89) for item 4 (genetic analysis), and 0·74 (95% CI 0·59 to 0·94) for item 5 (preserving DNA samples for future analysis). Six months later the ORs were 0·65 (95% CI 0·51 to 0·83), 0·70 (95% CI 0·55 to 0·90), 0·73 (95% CI 0·57 to 0·93), 0·72 (95% CI 0·57 to 0·91), and 0·76 (95% CI 0·60 to 0·97) for items 1–5 respectively (table 6). The ORs for withdrawal from the study implementing extensive preliminary information were 0·15 for all five items (table 7).

Effect of gender and age

Female gender and older age were factors for non-participation, but not for withdrawal (tables 4–7).

Table 5 Effect of genetic analysis: odds ratio of withdrawal between a non-genetic (Adogawa) and a genetic (Takashima) subcohort

Dependent variable	Independent variables	OR	95%CI
Withdrawal from basic survey	Gender†	2·07	0·93 to 4·61
	Age (years)	1·03	0·99 to 1·05
	Genetic analysis‡	7·72**	3·51 to 16·97
Withdrawal from blood sample preservation for future use	Gender†	2·09	0·94 to 4·07
	Age (years)	1·02	0·99 to 1·05
	Genetic analysis‡	7·75**	3·52 to 17·05
Withdrawal from examination of medical records and death certificate	Gender†	2·02	0·95 to 4·69
	Age (years)	1·02	0·99 to 1·05
	Genetic analysis‡	7·76**	3·53 to 17·08

*$p<0.05$, **$p<0.001$ (two-tailed).
†Male = 0; female = 1.
‡No = 0, Adogawa; yes = 1, Takashima.

Table 6 Effect of providing extensive preliminary information: odds ratios of participation between the two genetic subcohorts at baseline and after 6 months

		At baseline		After 6 months	
Dependent variable	Independent variables	OR	95%CI	OR	95%CI
Participation in basic survey	Gender†	0·79	0·61 to 1·03	0·79	0·61 to 1·02
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Extensive information‡	0·63**	0·49 to 0·81	0·65*	0·51 to 0·83
Participation in blood sample preservation for future use	Gender†	0·77*	0·59 to 0·99	0·76*	0·59 to 0·98
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Extensive information‡	0·69*	0·54 to 0·87	0·70*	0·55 to 0·90
Participation in examination of medical records and death certificate	Gender†	0·73*	0·56 to 0·94	0·72*	0·56 to 0·93
	Age (years)	0·98**	0·98 to 0·99	0·98**	0·98 to 0·99
	Extensive information‡	0·71*	0·56 to 0·90	0·73*	0·57 to 0·93
Participation in genetic analysis	Gender†	0·73*	0·57 to 0·94	0·73*	0·56 to 0·94
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Extensive information	0·70*	0·55 to 0·89	0·72*	0·57 to 0·91
Participation in DNA sample preservation for future analysis	Gender†	0·75*	0·58 to 0·96	0·74*	0·58 to 0·95
	Age (years)	0·98**	0·97 to 0·99	0·98**	0·97 to 0·99
	Extensive information‡	0·74*	0·59 to 0·94	0·76*	0·60 to 0·97

*p<0·05, **p<0·001 (two-tailed).
†Male = 0; female = 1.
‡No = 0, Takashima; yes = 1, Makino.

DISCUSSION

In this population based cohort study involving genetic research, we found that people in the genetic subcohorts were less likely to participate in the entire study (4·7–9·3% lower crude participation rates) than those in the non-genetic subcohorts. However those in the latter group seemed to understand the non-genetic aspects well and had a more cooperative attitude towards them, as demonstrated by their participation rates being remarkably high at more than 90%. This finding suggests that the general population has some intrinsically strongly negative attitudes towards human genetic research, which may arise from scepticism, fear, distrust, or aversion to research itself. We also found that providing more preliminary qualitative/quantitative information about the genetic study decreased the initial number of participants, but reduced the number of subsequent withdrawals from the initial consent items. Conversely, although the genetic subcohort not provided with extensive qualitative/quantitative preliminary information produced initially higher participation rates, there were many more subsequent withdrawals from the study and the resulting participation rates became equal.

Fortunately, we noted unusually high participation rates in the genetic subcohort that had received more qualitative/quantitative information. However, this should be considered an unusual exception and wholly a result of our previous efforts. It has taken decades to improve our confidence and establish a close relationship with residents in these research areas through various community medical services and health care education. We believe this has raised the number of potentially highly cooperative participants in these areas. However, we do take seriously that, of these potentially cooperative participants, 10% dissented from the genetic research. Without existing good relationships with the residents, we would have failed to achieve high participation rates even in the non-genetic subcohorts.

The history of population based human genetic research indicates that it remains in a precarious situation. Any carelessness in protecting personal genetic profiles and people's privacy could have serious repercussions, sparking strong opposition to genetic research by the public and perhaps even leading to halting the research itself.[15 16] In order to form a relationship of mutual trust between genetic researchers and the general population, investigators therefore need to find better ways of ensuring protection of participants' rights, and obtaining higher quality informed consent. Specifically, potential research participants should be accurately, effectively, and sufficiently educated about the research in which they are being asked to take part.[17]

Table 7 Effect of providing extensive preliminary information: odds ratio of withdrawal between the two genetic subcohorts

Dependent variable	Independent variables	OR	95%CI
Withdrawal from basic survey	Gender†	1·75	0·78 to 3·96
	Age (years)	1·02	0·99 to 1·06
	Extensive information‡	0·15**	0·05 to 0·43
Withdrawal from blood sample preservation for future use	Gender†	1·77	0·78 to 4·00
	Age (years)	1·02	0·99 to 1·05
	Extensive information‡	0·15**	0·05 to 0·43
Withdrawal from examination of medical records and death certificate	Gender†	1·79	0·79 to 4·03
	Age (years)	1·02	0·99 to 1·05
	Extensive information‡	0·15**	0·05 to 0·43
Withdrawal from genetic analysis	Gender†	1·79	0·79 to 4·03
	Age (years)	1·02	0·99 to 1·05
	Extensive information‡	0·15**	0·05 to 0·43
Withdrawal from DNA sample preservation for future analysis	Gender†	1·78	0·79 to 4·01
	Age (years)	1·02	0·99 to 1·05
	Extensive information‡	0·15**	0·05 to 0·42

**p<0·001 (two tailed).
†Male = 0; female = 1.
‡No = 0, Takashima; yes = 1, Makino.

Investigators have also observed that efforts to educate participants and ensure protection of their rights by means of consent documents may ironically result in them having an inadequate understanding of what they are consenting to and may interfere with their later recall about the nature of their consent.[18] Healthy volunteers tend to remember the risk information rather than the procedures, purposes or benefits of research.[19] Furthermore, as Cassileth *et al* have reported, even patients who are not healthy and want more information before consenting do not even read the consent form from the beginning before signing it.[20] Our finding that the Takashima genetic subcohort had the highest withdrawal rate implied that, for some participants, the mere distribution of consent documents and the document itself, even when accompanied by oral explanations, would not provide them with adequate information for fully informed consent. As a result, we believe that their potential anxieties, distrust, misunderstanding, or incomprehension remained unaddressed, so that these participants would later change their minds and withdraw their initial consent.

The key lesson that we learned is that informed consent is not simply a form,[21] but a long-term process of educating people and constructing a genuine partnership based on mutual trust. Hence, distributing consent documents should not be the only way of informing and educating participants, but rather one of several auxiliary steps used to achieve higher quality informed consent. In their article on a clinical trial, Lynöe *et al* noted that the interval between providing information and asking for consent is an important factor in the consent process: too short a time to consider the procedure and its consequences may make it difficult for people to decide freely whether or not to participate in the proposed research.[4] This observation would also be true in population based genetic research. The extensive information methods adopted in the Makino genetic subcohort, which included conducting several educational lectures and explanatory meetings in advance, may have enabled participants successfully to make free and definitive informed consent decisions, resulting in there being many fewer withdrawals in Makino compared with Takashima, where only the usual information methods were employed.

Investigators and participants are all prone to view informed consent as a legal or ethical requirement, or as a mere explanation of the research, rather than as an educational process.[20 21] Many medical research studies appear to include only a limited educational component to their informed consent process. Indeed, in some studies, an educational consent process may not be necessary when the study objectives and methods are very familiar to the participants and easy to understand. It could also be argued on scientific grounds that employing an educational informed consent process in observational research would represent an intervention that not only could change participants' future behaviours but also may threaten the ability of researchers to generalise prospective data and findings to a broader population.[22] This idea does have some validity in a purely scientific context. Nonetheless, we believe that educational consent processes should be used in surveys such as genetic research that are less familiar to the population, where understanding may be difficult, and where there is less direct benefit to the participants. Otherwise, the role of genetic research in public health could fail to be either properly recognised or appreciated, and thus not receive support from the general population, however important such studies may be in the protection of public health.

This ethical position should therefore have priority over scientific concerns, even if this may have some adverse effects on the study results. Population based genetic research is only in its infancy, trapped between expectations for it to contribute to public health and scepticism regarding its value, so it is crucial that genetic researchers should utilise an informative and educational consent process worthy of the public trust.

CONCLUSION

The general population responds sceptically towards participation in genetic research when actually faced with the decision-making process. In addition, the distribution of consent documents is insufficient by itself for the provision of information about genetic research, and thus not good enough as a basis for the general population to give fully informed consent. Rather, it should be thought of as an auxiliary step towards a more informed consent. For informed consent to be adequate, and for proper appreciation and support by the general population of the scientific roles of genetic research in public health the consent process should be a systematic educational process instead of a mere ethical form or procedure.

Limitation of the analyses

Our comparative analyses may have a potential limitation because they assume that the rates of participation and withdrawal among subcohorts would be equivalent if the other conditions and method designs were all the same. To prove this assumption would be extremely difficult and consume excessive time and expense. However, the comparisons between the non-genetic subcohorts provide evidence supportive of this assumption as they demonstrate that area differences hardly affect participation rates or withdrawal rates, at least when geographical, socioeconomic, historical, and cultural characteristics among study areas are uniform, and when the populations are homogeneous.

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K Matsui designed the study and the consent forms for the Takashima study, and contributed to the consent process, data collection, interpretation of results, statistical analysis, and writing of the manuscript. Y Kita managed the Takashima study and contributed to the consent process, data collection, statistical review, and critical revision of the manuscript. H Ueshima designed the concept and protocols for the Takashima study, and contributed to the statistical review and critical revision of the manuscript.

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Notice

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事業所勤務者における高コレステロール血症の認識（awareness）・治療・コントロール状況（HIPOP-OHP study）

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【目的】 高コレステロール血症は虚血性心疾患やアテローム血栓性脳梗塞の重要な危険因子である。高コレステロール血症の有所見者が生活習慣の改善や服薬治療を開始するための契機として、有所見者自らが危険因子を保有しているということを認識している必要がある。しかし、本邦における高コレステロール血症に関する自己認識や治療の状況は明らかではなく、既存の研究の多くは横断的もしくは思い出しによるものが多い。本研究は、複数の事業所勤務者における高コレステロール血症の自己認識及び治療の状況を前向き調査によって明らかにすることを目的とした。

【対象と方法】 本研究の対象者は「青・壮年者を対象とした生活習慣病予防のための長期介入研究」(The High-risk and Population Strategy for Occupational Health Promotion study (HIPOP-OHP study)) に参加の全国 12 事業所に勤務する 6186 名（男性 4903 名、女性 1283 名）である。ベースライン時（1999～2000 年）の定期健康診断で高コレステロール血症の定義を満たした対象者を追跡し、一年後の高コレステロール血症の認識状況及び治療状況について分析した。総コレステロール値の測定を実施する検査機関については CDC-CRMLN の精度管理を通じて国際的な標準化を行った。高コレステロール血症は ATP Ⅲの基準に従い総コレステロール値が 240 mg/dℓ以上または脂質降下剤服用中のものとした。自己認識の状況や治療の状況については質問紙で把握した。また、コントロール良好者は一年後の健診で総コレステロール値が 240 mg/dℓ未満の者とした。なお本研究では最初の 1 年間は観察期間とし、介入は実施していない。

【結果】 ベースライン時の高コレステロール血症の有所見者は男性 461 人（12.2%）、女性 99 人（12.6%）であった。このうち一年後の調査で「今までに高コレステロール血症と言われたことがない」と回答したものは男性 204 人（44.3%）、女性 41 人（41.4%）であった。治療状況については、未治療者（「高コレステロール血症と認識していない者」および「放置（非服薬かつ非生活療法）」）が男性で 281 人（61.0%）、女性で 56 人（56.6%）を占めた。服薬及び生活療法のいずれかまたは両方を行っている「治療群」におけるコントロール良好者は男性で 83 人（46.1%）、女性で 20 人（46.5%）であった。

【考察】 前年度の健康診断で高コレステロール血症を指摘されているにもかかわらず、自身の高コレステロール血症を認識していない者が男女とも約 4 割認められた。また高コレステロール血症有所見者の半数以上が未治療者であり、さらに「治療群」の半数以上が総コレステロール値を十分にコントロールできていないことが明らかになった。これらの結果は同じ集団で検討した高血圧に関する分析結果と比べて認識度・コントロールともに不良であることが示された（田中他、第 25 回日本高血圧学会抄録集 p.78）。今後、健康診断結果の通知方法や事後指導方法の改善、診断基準や治療目標の一般への普及・啓発が必要と考えられた。

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第51回 日本栄養改善学会学術総会講演集

栄養改善50年の軌跡と次代への懸け橋
－人と自然と文化の石川から－

平成16年10月20日（水）・21日（木）・22日（金）
石川県金沢市（石川県立音楽堂・金沢全日空ホテル・金沢都ホテル）

PF02-26 青・壮年者を対象とした生活習慣病予防のための長期介入研究（第12報）—弁当給食への介入—

○井手　真美[1]、由田　克士[2]、多田　賢代[3]、田中　太一郎[1]、千葉　良子[4]、玉置　淳子[5]、菊池　有利子[6]、武林　亨[6]、門脇　崇[1]、岡村　智教[1]、上島　弘嗣[1]
（滋賀医科大学　福祉保健医学[1]、国立健康・栄養研究所[2]、美作大学　生活科学部　食物学科[3]、つくば国際短大　人間生活[4]、近畿大・医・公衛[5]、慶応義塾大・医・衛生公衛[6]）

【目的】前年度の本学会にて、職域内に給食施設がなく多くの従業員が外部からの配達弁当を利用している事業所における一連の栄養介入について報告した。その後も介入を継続し、その状況、特に配達弁当の栄養改善への効果について報告する。【対象と方法】兵庫県内に所在する本事業所は、従業員数約540人の現業系事業所である。給食施設を有しない食堂（テーブルと椅子、湯茶設備のみ）を従業員の約８割が利用し、その多くは特定業者の配達弁当を昼食に利用している。食堂を利用する従業員に対する栄養介入としては、減塩や野菜摂取量の増加を目的としたイベント（料理レシピの紹介と試食）を実施し、健康一口メモによる情報提供を継続している。同時に配達弁当に対する介入として、弁当業者の複数化、主食（米飯）の測定、汁物の塩分濃度測定、弁当の栄養分析（専門分析機関による）、業者に対する分析結果の説明と要望等実施した。弁当利用者に対するアンケートも実施し、その結果も業者へ報告した。【結果】２業者による販売は、業者自身独自の特徴を意識した弁当の内容となり、利用者が嗜好や体調により選択出来るようになった。本年の弁当の栄養分析結果では、エネルギーの適正化、炭水化物量の減少、カリウム量の増加がみられ、分析結果をフィードバックさせることで、より客観的な根拠に基づく要望や提案が行え、業者側の理解が深まり、要望や提案を受け入れようとする姿勢がみられた。弁当利用者に対するアンケート結果では、価格重視の意見も見られたが、ごはん量や野菜量に対する要望もあり、業者側の弁当の内容を改善する契機となった。【考察】弁当の内容も生きた教材として栄養介入の一翼を担えるよう試みたが、弁当の栄養分析という客観的根拠の提示など業者に対する介入と、弁当利用者の食への意識の改善を測る介入の両者に対する栄養介入により、食習慣改善の取り組みが実際に遂行されることが確認された。

PF02-27 青・壮年者を対象とした生活習慣病予防のための長期介入研究（第13報）—４年の介入経過—

○多田　賢代[1]、由田　克士[2]、田中　太一郎[3]、井手　真美[3]、千葉　良子[4]、玉置　淳子[5]、菊池　有利子[6]、武林　亨[6]、門脇　崇[3]、岡村　智教[3]、上島　弘嗣[3]
（美作大学　食物学科[1]、国立健康・栄養研究所[2]、滋賀医科大学　福祉保健医学[3]、つくば国際短大　人間生活[4]、近畿大・医・公衛[5]、慶應義塾大・医・衛生公衛[6]）

【目的】ある現業系事業所で社員食堂を活用した食事バランスに関する継続的な取り組みを行っている。ここでは栄養介入のほか、運動、喫煙など健康づくり全般についての介入を４年間行ってきた。本報では、介入効果の評価として、生活習慣に関する調査と健診成績の関連を報告する。【対象と方法】福井県のＢ社（従業員数約900人）には、社員食堂が設置されており、01年３月から従来のメニュー表示方法を改め、毎食主食、主菜、副菜の３品を揃えて摂り、バランスのとれた食事を心がけるよう働きかけた。また、「あなたのお食事拝見キャンペーン」などの継続的なイベントの開催や卓上一口健康メモ等による情報提供も実施し、４年間の栄養介入を行った。生活習慣に関する調査は、介入前とその後の４年間実施した。【結果】介入開始から４年経過後時点まで継続して健診と生活習慣に関する調査結果が得られた人は、774人であった。これらの対象者の４年後の健診成績を初年度と比較すると、BMI、総コレステロールは増加がみられたが、これは加齢の影響と考えられる範囲のものであった。中性脂肪は、４年経過後も変化がみられなかった。平均赤血球容積（MCV）は、加齢と共に増加するとされるが、本調査では減少がみられた。脂質については、LDL－コレステロールには変化がみられず、HDL－コレステロールは増加がみられた。生活習慣に関する調査では、塩分の取り過ぎ、脂肪の取り過ぎに注意すると回答する人が増え、１週間に魚や大豆・大豆製品を食べる頻度も増える結果となった。また尿中塩分排泄量も減少傾向を示した。【考察】長期間の社員全体を対象とした介入により、HDL－コレステロールの増加や塩分排泄量の減少等を認め、Population strategy の重要性が示された。

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A Cross-sectional Study of Alcohol Drinking and Health-related Quality of Life among Male Workers in Japan

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Abstract: A Cross-sectional Study of Alcohol Drinking and Health-related Quality of Life among Male Workers in Japan: Isao SAITO, *et al.* Department of Public Health, Nara Medical University— *Background*: Although light and moderate alcohol drinkers are likely to have better subjective health, the sub-scales for subjective health have not been well documented. *Methods*: We studied 4,521 male workers aged 25 yr and older with no history of cancer or cardiovascular disease, in 12 occupational groups in Japan. Data were from the High-risk and Population Strategy for Occupational Health Promotion Study (HIPOP-OHP). Drinking status was classified according to daily alcohol intake or frequency of drinking. We assessed the health-related quality of life (HRQOL) based on scores for five scales of the SF-36. *Results*: Decreased odds ratios of sub-optimal HRQOL conditions, defined as less than the median SF-36 scores, for Role-Physical and General Health were found among persons who consumed 1.0 to 22.9 g/d of alcohol. Odds ratios for sub-optimal Vitality conditions were lowered according to increased levels of alcohol intake. Role-Emotional scores were not associated with alcohol drinking. People who drank 5 to 6 d/wk had higher levels of Role-Physical and Vitality, and those who drank 1 to 2 d/wk had better Vitality and Mental Health scores than non-drinkers. When adjusted for age, marital status, working hours, physical activity at work, self-reported job stress, smoking, regular exercise, hypertension, hyperlipidemia, and diabetes, the associations were almost unchanged except for General Health. *Conclusions*: Associations of drinking patterns with subjective health varied in five sub-scales of the SF-36. Overall, alcohol drinkers rated their health as good in comparison with non-drinkers. *(J Occup Health 2005; 47: 496–503)*

Key words: Alcohol drinking, Epidemiology, Health-related quality of life, SF-36, Subjective health

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It is widely known that light and moderate alcohol intake are associated with decreased risk of incident cardiovascular disease[1–3] and all-cause mortality[4–6]. The mechanism for this protective effect has been postulated to be due to the modification of high-density lipoprotein[7] and platelet aggregability[8, 9] and lowered fibrinogen levels[10].

Several epidemiological studies have indicated that people with higher levels of self-rated health[11–14] or good health practices[15, 16] are at low risk of mortality and cardiovascular disease. Moreover, a few studies have suggested that light and moderate drinkers rate their health as good[17–20]. Among Japanese employees, it was documented that men who consumed 25 to 35 or 49 g/d or more of alcohol had a significantly lower risk of self-rated ill health compared with non-drinkers[20]. This Japanese study equated ill health with the response of "poor" on the self-reported questionnaire and did not separate abstainers in the analysis, but only 4.8% of the study participants were in this category. Therefore, the inverse association might be due to a selection bias for healthy people who consumed a lot of alcohol. Furthermore, previous studies on this issue did not consider sub-scales for subjective health. So, it is important to better understand the effect of alcohol on subjective physical and mental health as measured in a health-related quality of life (HRQOL) assessment.

The Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36) is one of the generic HRQOL instruments. SF-36 is based on a conceptual model consisting of physical and mental health constructs, and it is designed to measure perceived health status and daily functioning. It consists of 36 items that are scored in the following eight domains: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. The score on each scale ranges from 0 to 100, with a low score indicating poor health or great disability. SF-36 is widely used and is available in many languages, including Japanese[21, 22].

In the present study, we examined the association between alcohol drinking patterns and the HRQOL among male workers, controlling for working environment, health practices, and burden of common chronic diseases.

Methods

Population

We analyzed baseline data from the High-risk and Population Strategy for Occupational Health Promotion (HIPOP-OHP) intervention study[23]. This study population consisted of 12 companies (one life insurance company, two chemical companies, one electrical appliance company research laboratory, and eight electrical appliance manufacturers). There were 5,002 male workers, aged 25 yr and over, who responded to an assessment of drinking habits at the baseline examination during 1999–2000. The response rate was 92% (5,002/5,442), and there were no differences among companies. We selected 4,521 male workers, after exclusion of those who did not reply to an answer on alcohol consumption (n=307), those who had a history of cancer or cardiovascular disease (n=96), and those who did not complete the SF-36 questionnaire (n=106). In all, 481 men were excluded from our analysis (28 overlapped) due to our exclusion criteria. Their mean age (42.4 y) was slightly higher than the mean age of the other. Adjusted for age, a higher proportion of current smokers (57.6%) and a lower proportion of those who did regular exercise (58.9%) were listed among them. However, there were no differences in proportions of married persons, daytime workers, persons with heavy physical activity at work, persons perceiving job stress, and people with obesity, hypertension, hyperlipidemia, and/or diabetes, between excluded and analyzed subjects.

Written informed consent was obtained from the subjects for individual intervention. Since the HIPOP-OHP study was designed as an occupational community-based intervention by means of population strategy, we did not think it necessary to obtain written informed consent from all individuals. However, we informed them that the data were being used in our study and individual information was strictly protected under the privacy policy. Furthermore, approval for this study was obtained from the Institutional Review Board of Shiga University of Medical Science (No. 10–16).

Measurements

In the HIPOP-OHP study, we used the same questionnaire to get health information from all companies in accordance with the common protocol described elsewhere[23]. At each company, after a 5-min rest timed with an hourglass, subjects' blood pressure was measured twice using an automatic sphygmomanometer. The mean of these two values was used. Hypertension was defined as systolic blood pressure (SBP) of 140 mmHg or higher or diastolic blood pressure (DBP) of 90 mmHg or higher. Serum gamma-glutamyl-transpeptidase activity (γ-GTP) was measured using a colorimetric method. Lipid measurements, including HDL (high-density lipoprotein) cholesterol, were standardized according to the protocol of the U.S. Cholesterol Reference Method Laboratory Network (CRMLN) of the Centers for Disease Control and Prevention to compare values among laboratories participating in the study. Subjects with hyperlipidemia and diabetes were defined as those who had ever been diagnosed by a physician, regardless of treatment status. Body mass index (BMI) was calculated using measured weight (kg) divided by the square of the height (m^2).

Each subject's drinking habits were assessed using a previously published method[24]. First, we asked them the following: "Could you choose the appropriate description of your alcohol consumption in the previous month: (1) never drank, (2) drank in the past, or (3) current drinker?" In the case of current drinkers, we asked them, "How many times per week do you usually drink alcohol? Which alcoholic beverages do you drink on a typical occasion?" and "Please describe the typical quantity of each beverage." The frequency of alcohol consumption during a week and the total alcohol intake on each occasion were determined and used to calculate the alcohol intake per week. We defined the ethanol concentration of each major alcoholic beverage as follows: beer 5%, *sake* 16%, whiskey 40%, *shochu* 25%, and wine 12%. *Happo-shu*, which has a taste and ethanol concentration similar to that of beer but includes less malt as a raw material, was calculated as beer. The ethanol concentration of other minor beverages was defined individually. This value was then divided by 7 to obtain the average alcohol intake per day. Drinkers were defined as those consuming more than 0.3 *gou* a week (1.0 g/d of ethanol), as in previous cohort studies in Japan[2, 3]. So, self-described current drinkers were re-classified as non-drinkers if they reported consuming less than 0.3 *gou* a week. The reason why we used frequency of alcohol drinking as a variable was that it was considered to be an important marker indicating drinking behavior, and the

frequency itself has been significantly associated with cardiovascular disease events[1]. We classified the responses into six groups, i.e., non-drinker, ex-drinker, and four categories of current drinkers according to alcohol intake per day: 1.0 to 22.9 g, 23.0 to 45.9 g, 46.0 to 68.9 g, and 69.0 g and over. These groups correspond to the categories related to incidents of coronary heart disease and stroke among Japanese[3].

We assessed individuals' marital status, working hours, physical activity at work, self-reported job stress, smoking status, and regular exercise and added these variables to the multivariate models as confounders.

The assessment of HRQOL was done with version 2.0 of the SF-36 questionnaire form and scoring program[25]. The Japanese version of the SF-36 has been validated in previous studies[26]. Missing data were complemented in the validated algorithm of calculation. In addition, we calculated scores by the norm based scoring (NBS) method, which was set at 50 for Japanese means based on the normal distribution of the scores derived from the SF-36 national survey in 2002. The first step in the NBS consists of standardizing each SF-36v2 scale using a z-score transformation. A z-score for each scale is computed by subtracting the 2002 general Japanese population mean for each SF-36 scale and dividing the difference by the corresponding scale standard deviation from the 2002 general Japanese population. The second step involves transforming each SF-36v2 z-score to the NBS (50, 10). This is accomplished by multiplying each z-score from Step 1 by 10 and adding the resulting product to 50.

Although the SF-36 has eight sub-scales, we used only the five sub-scales of Role-Physical, General Health, Role-Emotional, Mental Health, and Vitality, because the HIPOP-OHP study basically was conducted for healthy workers without physical disability and they were mostly middle-aged or younger men; the other three sub-scales (Bodily Pain, Social Functioning, and Physical Functioning) were not investigated[23].

Higher levels of Role-Physical and Role-Emotional represent the conditions where people can work usually without physical and psychological problems, respectively. General Health is assessed by self-perceived health status; for example, "I am as healthy as anybody I know." Higher scores of Vitality indicate conditions in which people have a lot of energy or are not exhausted at all. Mental Health reflects feelings of depression, nervousness, and happiness. Each sub-scale score consisted of three to five questions in the SF-36.

Overall, the SF-36 sub-scales were divided into two domains representing physical and mental health. In a validation study of the Japanese version, Role-Physical was interpreted as a condition of physical health, and Mental Health and Vitality were valid scales representing mental health. General Health and Role-Emotional scales were not consistent with hypotheses, but the validation study suggested that General Health reflected both physical and mental conditions, and Role-Emotional was closely related to the physical component[27]. We defined sub-optimal HRQOL as less than the median score of all subjects for each SF-36 sub-scale.

To test the internal consistency reliability, we computed Cronbach's alpha for each SF-36 sub-scale. These ranged between 0.75 and 0.91. All coefficients were satisfied with criteria (>0.7) that were considered to be reliable for the use of group level comparison.

Data Analysis

Means of alcohol consumption and the frequency of drinking were computed by the levels of alcohol consumption. Also, we calculated the proportions of married persons, daytime workers, persons with heavy physical activity at work, persons perceiving job stress, current smokers, those who did regular exercise, and people with obesity, hypertension, hyperlipidemia, and/or diabetes. Means of scores of the original SF-36 and the NBS by sub-scales and standard deviations were computed by drinking status.

Age-adjusted and multivariate logistic models were done. The risk of sub-optimal HRQOL based on SF-36 was calculated according to alcohol consumption and frequency of alcohol drinking in comparison with non-drinkers. The odds ratios were adjusted for age in model 1. In model 2, marital status (married, other), working hours (daytime, other), physical activity at work (heavy, other), self-reported job stress (yes, no), smoking status (current smoker, other), and regular exercise (yes, no) were added using dummy variables. Finally, we added factors indicating obesity, hypertension, hyperlipidemia, and diabetes to model 2. This became model 3. All analyses were done using SAS software, version 8.2 (SAS Institute, Inc., Cary, North Carolina).

Results

Among 4,521 male workers (mean age, 39.4 y), 60.4% were current drinkers. Table 1 shows the characteristics of our subjects by group. Frequency of drinking increased as the amount of alcohol consumption increased. Compared to non-drinkers and ex-drinkers, subjects who consumed the lowest amount of alcohol had better health practices, i.e., lower prevalence of smoking and higher proportion of regular exercise. High percentages of obesity and diabetes were seen among ex-drinkers. Means of HDL-cholesterol were clearly elevated in accordance with alcohol consumption levels. People who reported consumption of 1.0 to 22.9 g/d of alcohol had higher scores in the areas of Role-Physical, whereas ex-drinkers tended to have low scores, especially in General Health. Vitality scores were higher among men who drank more. The NBS scores by sub-scales are presented.

Table 1. Population characteristics by alcohol consumption among male workers in the HIPOP-OHP Study

Variables	Non-drinker	Ex-drinker	Current drinkers by alcohol consumption, g/d			
			1.0–22.9	23.0–45.9	46.0–68.9	69.0 and over
Number, n	1,497	291	1,408	703	359	263
Mean age, y	37.8	39.0	38.6	41.3	43.4	42.5
Mean (SD§) alcohol consumption, g/d	–	–	12.1 (5.8)	33.2 (6.5)	54.8 (6.2)	93.6 (26.0)
Frequency of alcohol drinking, d/wk	–	–	4.0	5.8	6.4	6.6
Married, %	67.1	72.0	76.7	79.6	83.4	83.0
Working hours, % daytime	60.3	61.9	73.3	69.5	71.3	61.1
Physical activity at work, % heavy	6.9	9.4	6.3	8.6	9.0	6.6
Self-reported job stress, % yes	22.6	23.0	22.5	24.3	23.5	21.5
Current smokers, %	49.3	56.8	46.3	59.8	60.7	71.4
Regular exercise, %	58.9	60.2	64.7	64.5	66.1	56.9
Obesity*, %	23.6	30.9	20.5	19.8	24.2	26.6
Hypertension**, %	10.2	16.8	13.7	15.3	24.3	19.9
Hyperlipidemia†, %	12.6	13.8	11.1	14.6	15.7	16.4
Diabetes†, %	4.8	10.4	5.3	6.3	7.6	7.7
Mean HDL-cholesterol‡ (SD§), mg/dL	52.2 (12.6)	51.9 (12.5)	55.7 (13.6)	59.0 (13.9)	59.0 (13.4)	60.3 (14.9)
Mean SF-36 scores (SD§) by scales						
Role-Physical	86.6 (19.1)	83.6 (21.0)	89.0 (17.2)	86.5 (20.0)	87.6 (17.8)	87.4 (18.8)
General Health	58.2 (16.9)	54.9 (15.2)	60.3 (16.3)	59.4 (16.2)	57.9 (15.9)	60.6 (16.6)
Vitality	52.2 (18.9)	52.3 (17.5)	53.9 (18.2)	54.5 (17.8)	55.7 (18.3)	56.4 (18.9)
Role-Emotional	85.8 (20.0)	84.4 (21.6)	87.5 (18.0)	86.3 (19.7)	87.0 (18.6)	87.2 (19.2)
Mental Health	65.4 (17.3)	64.7 (17.1)	66.8 (16.8)	66.0 (17.3)	65.9 (17.6)	67.0 (17.1)
Mean SF-36 NBS scores‖ (SD§) by scales						
Role-Physical	48.9 (10.4)	47.3 (11.5)	50.2 (9.4)	48.9 (10.9)	49.5 (9.7)	49.4 (10.2)
General Health	46.9 (9.1)	45.1 (8.2)	48.0 (8.8)	47.5 (8.7)	46.7 (8.6)	48.2 (8.9)
Vitality	45.2 (9.3)	45.2 (8.6)	46.0 (8.9)	46.3 (8.8)	46.9 (9.0)	47.3 (9.3)
Role-Emotional	49.3 (10.2)	48.6 (11.0)	50.2 (9.2)	49.6 (10.0)	50.0 (9.5)	50.0 (9.8)
Mental Health	46.7 (9.2)	46.3 (8.9)	47.4 (8.9)	47.0 (9.2)	46.9 (9.4)	47.5 (9.1)

*Defined as body mass index ≥25 kg/m^2. **Defined as systolic blood pressure ≥140 mmHg, diastolic blood pressure ≥90 mmHg, or current use of antihypertensive medication. †Defined as those who had been told by doctors. ‡Data were available for 3,310 subjects. §Standard deviation. ‖NBS (Norm-based scoring) scores, which were set at 50 as Japanese means, were based on the total distribution from the SF-36 national survey[25].

Compared with Japanese means, which were set at 50, our population of SF-36 means in each sub-scale were below 50.

Age-adjusted and multivariate odds ratios, according to daily consumption of alcohol, for sub-optimal health are shown by SF-36 sub-scales in Table 2. The age-adjusted odds ratio for General Health was 1.69 (95% confidence interval, 1.29–2.20) in ex-drinkers. The group that consumed 1.0 to 22.9 g/d of alcohol had a low risk for sub-optimal scores in Role-Physical, General Health, and Vitality. Those for Vitality were lowered in accordance with increasing levels of alcohol intake. Among those who reported heavy drinking (69.0 g/d and over), the odds ratio did not increase at all. In models 2 and 3, after addition of confounding factors, alcohol drinkers who consumed 1.0 to 22.9 g/d were more likely to have a good HRQOL; however, the odds ratio for General Health was not statistically significant after the adjustment. Inverse association of alcohol consumption with Vitality scores still remained significant in models 2 and 3.

Table 3 shows age-adjusted and multivariate odds ratios for sub-optimal HRQOL by the frequency of alcohol drinking per week. Alcohol consumption levels by four drinking frequency categories corresponded with 9.9, 18.7, 30.8, and 45.8 g/d. Individuals who consumed alcohol 1 to 2 d/wk had higher HRQOL levels for General Health, Vitality, and Mental Health, and those who consumed alcohol on 5 to 6 d/wk were in good condition as determined by Role-Physical. People who drank alcohol 3 to 4 or 5 to 6 d/wk had good HRQOL Vitality scores. When the odds ratios were adjusted for several factors in models 2 and 3, the association was almost the same.

Table 2. Age- and multivariate-adjusted odds ratios for suboptimal health† based on the SF-36 scales by alcohol consumption in the HIPOP-OHP Study

Model‡	SF-36 scales	Non-drinker	Ex-drinker	Current drinkers by alcohol consumption, g/d			
				1.0–22.9	23.0–45.9	46.0–68.9	69.0 and over
Model 1	Role-Physical	1.00	1.18 (0.92–1.52)	0.84 (0.72–0.97)*	0.94 (0.79–1.13)	0.94 (0.74–1.19)	0.86 (0.66–1.12)
n=4,521	General Health	1.00	1.69 (1.29–2.20)**	0.83 (0.72–0.96)*	0.94 (0.78–1.12)	1.21 (0.95–1.53)	0.86 (0.66–1.11)
	Vitality	1.00	0.94 (0.73–1.22)	0.82 (0.70–0.94)**	0.79 (0.66–0.95)*	0.69 (0.55–0.88)**	0.70 (0.54–0.91)**
	Role-Emotional	1.00	0.98 (0.76–1.26)	0.97 (0.84–1.12)	1.05 (0.88–1.26)	0.97 (0.77–1.23)	0.89 (0.67–1.17)
	Mental Health	1.00	1.15 (0.90–1.48)	0.87 (0.75–1.01)	1.04 (0.87–1.25)	1.10 (0.87–1.39)	0.89 (0.68–1.16)
Model 2	Role-Physical	1.00	1.15 (0.89–1.49)	0.86 (0.74–1.00)	0.93 (0.77–1.12)	0.92 (0.72–1.17)	0.84 (0.63–1.11)
n=4,415	General Health	1.00	1.76 (1.34–2.33)**	0.90 (0.77–1.04)	0.98 (0.81–1.19)	1.28 (1.00–1.64)	0.83 (0.63–1.10)
	Vitality	1.00	0.96 (0.73–1.25)	0.86 (0.74–1.01)	0.79 (0.65–0.96)*	0.68 (0.53–0.88)**	0.67 (0.50–0.89)**
	Role-Emotional	1.00	0.96 (0.74–1.25)	0.98 (0.84–1.14)	1.04 (0.86–1.25)	0.93 (0.73–1.20)	0.95 (0.71–1.26)
	Mental Health	1.00	1.13 (0.86–1.48)	0.92 (0.79–1.08)	1.04 (0.85–1.26)	1.10 (0.85–1.41)	0.87 (0.65–1.16)
Model 3	Role-Physical	1.00	1.18 (0.91–1.54)	0.85 (0.73–0.997)*	0.93 (0.77–1.12)	0.92 (0.72–1.18)	0.84 (0.64–1.12)
n=4,333	General Health	1.00	1.68 (1.27–2.22)**	0.89 (0.76–1.04)	0.97 (0.80–1.17)	1.23 (0.96–1.59)	0.80 (0.60–1.06)
	Vitality	1.00	0.97 (0.74–1.28)	0.86 (0.73–1.01)	0.77 (0.63–0.94)*	0.69 (0.53–0.90)**	0.67 (0.50–0.90)**
	Role-Emotional	1.00	1.02 (0.78–1.34)	0.99 (0.85–1.16)	1.04 (0.86–1.26)	0.97 (0.76–1.25)	0.97 (0.73–1.29)
	Mental Health	1.00	1.11 (0.84–1.46)	0.91 (0.78–1.07)	1.03 (0.84–1.26)	1.13 (0.87–1.46)	0.88 (0.65–1.18)

*p<0.05, **p<0.01. †Suboptimal health was defined as less than median SF-36 on each scale. ‡Model 1 was adjusted for age. Model 2 was adjusted for age plus marriage status (married, other), working hours (daytime, other), physical activity at work (heavy, other), self-reported job stress (yes, no), smoking status (current smoker, other), and regular exercise (yes, no). Model 3 was adjusted for factors in model 2 plus obesity, hypertension, hyperlipidemia, and diabetes.

Table 3. Age- and multivariate-adjusted odds ratios for suboptimal health† based on the SF-36 scales by frequency of alcohol drinking in the HIPOP-OHP Study

Model‡	SF-36 scales	Non-drinker	Ex-drinker	Current drinkers by frequency of alcohol drinking per week, d/wk			
				1–2	3–4	5–6	Every day
Model 1	Role-Physical	1.00	1.18 (0.92–1.51)	0.88 (0.72–1.09)	0.93 (0.76–1.13)	0.82 (0.69–0.99)*	0.88 (0.75–1.04)
n=4,521	General Health	1.00	1.68 (1.29–2.20)**	0.78 (0.63–0.96)*	1.04 (0.85–1.27)	0.86 (0.72–1.03)	0.93 (0.79–1.09)
	Vitality	1.00	0.95 (0.73–1.22)	0.76 (0.61–0.94)**	0.78 (0.64–0.96)*	0.68 (0.57–0.82)**	0.87 (0.74–1.02)
	Role-Emotional	1.00	0.98 (0.76–1.26)	0.96 (0.78–1.19)	1.09 (0.89–1.34)	0.91 (0.76–1.09)	0.99 (0.84–1.16)
	Mental Health	1.00	1.15 (0.90–1.48)	0.78 (0.63–0.96)*	1.00 (0.82–1.23)	0.89 (0.74–1.07)	1.03 (0.88–1.21)
Model 2	Role-Physical	1.00	1.15 (0.89–1.49)	0.93 (0.75–1.15)	0.96 (0.78–1.18)	0.81 (0.67–0.98)*	0.87 (0.74–1.03)
n=4,415	General Health	1.00	1.76 (1.34–2.32)**	0.83 (0.67–1.03)	1.11 (0.90–1.37)	0.90 (0.74–1.09)	0.97 (0.82–1.15)
	Vitality	1.00	0.96 (0.73–1.26)	0.77 (0.62–0.97)*	0.84 (0.67–1.04)	0.70 (0.57–0.85)**	0.88 (0.74–1.05)
	Role-Emotional	1.00	0.96 (0.74–1.25)	0.95 (0.76–1.18)	1.13 (0.92–1.40)	0.90 (0.74–1.09)	0.99 (0.83–1.17)
	Mental Health	1.00	1.13 (0.86–1.48)	0.78 (0.62–0.97)*	1.08 (0.87–1.34)	0.93 (0.76–1.13)	1.04 (0.88–1.25)
Model 3	Role-Physical	1.00	1.18 (0.91–1.54)	0.93 (0.74–1.15)	0.96 (0.77–1.18)	0.82 (0.68–0.99)*	0.86 (0.73–1.02)
n=4,333	General Health	1.00	1.68 (1.26–2.22)**	0.81 (0.65–1.02)	1.11 (0.90–1.38)	0.87 (0.72–1.06)	0.96 (0.81–1.14)
	Vitality	1.00	0.98 (0.74–1.28)	0.76 (0.61–0.96)*	0.84 (0.67–1.05)	0.69 (0.57–0.85)**	0.87 (0.73–1.04)
	Role-Emotional	1.00	1.02 (0.78–1.33)	0.95 (0.76–1.18)	1.16 (0.94–1.44)	0.93 (0.76–1.13)	1.00 (0.84–1.18)
	Mental Health	1.00	1.11 (0.84–1.46)	0.76 (0.60–0.95)*	1.08 (0.87–1.35)	0.94 (0.77–1.15)	1.03 (0.87–1.24)

*p<0.05, **p<0.01. †Suboptimal health was defined as less than median SF-36 on each scale. ‡Model 1 was adjusted for age. Model 2 was adjusted for age plus marriage status (married, other), working hours (daytime, other), physical activity at work (heavy, other), self-reported job stress (yes, no), smoking status (current smoker, other), and regular exercise (yes, no). Model 3 was adjusted for factors in model 2 plus obesity, hypertension, hyperlipidemia, and diabetes.

Since it was possible that our data were biased by heavy or frequent drinkers who had poor health due to alcoholic liver disease, we re-analyzed the data excluding subjects with levels of γ-GTP greater than 100 IU/L. Furthermore, considering effects of common chronic diseases, such as obesity, hypertension, hyperlipidemia, and diabetes, we examined the data among only healthier men without the diseases. Regardless of chronic disease conditions, we found similar associations to those shown in Tables 2 and 3 (data not shown).

Discussion

In the present study, we used the baseline dataset of an intervention trial (HIPOP-OHP study)[23]. The population strategy of the HIPOP-OHP study was conducted in three fields, i.e., nutrition, physical activity, and smoking from 1999 to 2004. Although intervention for alcohol intake was defined as one part of the population strategy for the nutrition field, there was no announcement regarding alcohol intervention, at least in the baseline survey in all companies. Accordingly, our results were not affected by the intervention process.

We found that people who consumed 1.0 to 22.9 g/d of alcohol scored high in HRQOL conditions: Role-Physical, General Health, and Vitality. Also, vitality conditions were better in accordance with increased levels of alcohol intake. The risks for sub-optimal health did not increase even among heavy drinkers (69.0 g/d and over). Ex-drinkers were at increased risk of poorer general health. This association, however, may have been due to former drinkers who had quit because of ill health.

Looking at the frequency of alcohol drinking, men who drank fewer days per week had higher HRQOL levels for General Health, Vitality, and Mental Health. The Vitality score was also good for those who drank 3 to 4 and 5 to 6 d/wk. Although the association of the amount of alcohol consumption and its frequency with the HRQOL scales were slightly different, alcohol drinkers were more likely to rate their health as good in comparison with non-drinkers.

The HIPOP-OHP study demonstrated that alcohol drinking patterns were clearly associated with blood pressure levels[24]. Mean HDL-cholesterol levels were positively associated with alcohol consumption, which can have a protective effect on atherosclerosis[2, 3]. The reliability of the drinking assessment was moderate (kappa=0.76) for subjects who reported drinking status at two separate times in one year. Since it was possible that abstainers from alcohol drinking had a health problem, we analyzed them separately. But when several confounders, including ill health related to obesity, hypertension, hyperlipidemia, and diabetes were considered, the significant association of alcohol drinking with HRQOL was unchanged.

In the present study, we made the definition of sub-optimal HRQOL as less than the median score for each SF-36 sub-scale, similar to a previous study that considered "average," "rather poor," or "very poor" of five subjective health grades to be sub-optimal health[17]. When SF-36 HRQOL scores were divided into quartiles and the lowest category was considered sub-optimal health, the associations of sub-optimal health with alcohol drinking were similarly demonstrated.

Our findings, based on the results of the physical and mental scales of the SF-36, were largely consistent with previous conclusions[17, 18]. That is, light and moderate alcohol drinking might have effects that modify the subjective experience of physical and mental health. Not only levels of alcohol consumption but also the frequency was similarly associated with the SF-36 scales, except for Role-Emotional. In the SF-36 validation study, scales of both Mental Health and Vitality were highly associated with mental conditions[27]. However, the Vitality condition remained at higher levels among men who drank more frequently.

The Japanese SF-36 validation study indicated that Role-Emotional represented physical condition rather than mental condition, as hypothesized, and its association with mental condition was dependent on the levels of psychiatric impairment[27]. Given the difficulty in the interpretation of Role-Emotional, it is unclear why only Role-Emotional sub-scales were not associated with drinking status in our population.

Heavy drinkers were not at increased risk of sub-optimal health in the present study, a finding contrary to the results from a general population study[17]. This may be explained by our population characteristics, in which occupational health was well managed. People with health problems were likely to quit or reduce drinking alcohol under intensive health management. Significant increased odds ratio of sub-optimal General Health for ex-drinkers supported in part this reasoning.

The strength of our study is the large population, which consists of mainly manufacturing and related company subjects/employees. This relatively homogeneous population helped us to interpret the effects of alcohol drinking on subjective health, including numerous factors related to working circumstances, carefully standardized in risk assessments. Nonetheless, several limitations should be considered. First, a cross-sectional study design does not prove causality. It can be argued that the data were biased by individuals who did not drink alcohol due to health problems, such as liver dysfunction. So, we separated abstainers from the analysis and presented the risks for sub-optimal health for the rest of the population. Furthermore, when we excluded subjects with levels of γ-GTP greater than 100 IU/L to rule out liver dysfunction, the associations remained. Second, the SF-36 NBS scores of our population were somewhat low in comparison with the national survey for SF-36

standardization in 2002. Because subjective health is affected by socioeconomic status[28], we hypothesize that people with sub-optimal health may be over-represented due to the economic recession in Japan, especially for a workplace population such as in the present study. Third, reporting bias should be considered in the interpretations of the SF-36 sub-scales. For example, if people with favorable HRQOL levels are likely to underestimate their alcohol intake, our findings may have been to some extent affected by the bias. Nevertheless, it is impossible to rule it out from the present study design.

Although light and moderate alcohol consumption has often been reported to be most beneficial for cardiovascular disease and total mortality[1-5], alcohol drinking patterns also may provide benefits for subjective health, explained by the HRQOL sub-scales: Role-Physical, General Health, Vitality, and Mental Health. Nonetheless, a longitudinal study will be needed to clarify the potential causality of association between alcohol consumption and HRQOL conditions.

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Appendix

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働き盛りの農村住民、都市部勤務者の循環器疾患危険因子の比較研究

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【目的】60歳未満の働きざかりの男性を対象として、農村部住民と都市部勤務者を対象として、飲酒、喫煙、塩分摂取量などの生活習慣、循環器疾患の危険因子を比較し、各集団の健康管理上の問題点を明らかにする。
【方法】研究対象とする農村地域は滋賀県X郡とし、東京・大阪近郊の大企業3社の勤務者集団（大都市勤務者）と各種健康指標の比較を実施した。各集団間でデータの相互比較を可能とするために、生活習慣や健康意識把握のための共通問診票を導入し、さらに健診時の検査内容についても精度管理を行った。比較する検査所見としては、血圧、血清脂質、耐糖能異常、喫煙、飲酒、塩分排泄量など主要な循環器疾患の危険因子とその薬物療法、非薬物療法等の実施状況である。X郡住民60歳未満男性 552人（平均年齢 48歳）、大都市（東京、大阪）企業勤務者 60歳未満男性 2,168人（平均年齢 38歳）について健診等の標準化を行なった。両群の年齢構成に大きな差があるため、年齢層がほぼ重複する 40～55歳（X郡住民 266人、都市部勤務者 817人、平均年齢は49歳、47歳）を分析対象とした。
【結果】共分散分析で年齢を調整すると、収縮期血圧値はX郡住民で124mmHg、大都市勤務者で128mmHg、拡張期血圧値はそれぞれ82mmHg、78mmHgと有意差を認めた。1日尿中塩分排泄量は13グラムと9グラム、喫煙率は 56%と 52%でいずれもX郡住民のほうが有意に高かった。また血清総コレステロール値、HDL コレステロール値も、X郡住民、大都市勤務者でそれぞれ、210mg/dl と 204mg/dl、54mg/dl、56mg/dl でX郡住民のほうが、脂質プロフィールが悪い傾向を示した。高血圧、高コレステロール血症、糖尿病の服薬率は両群で差を認めなかったが、それぞれの食事療法、運動療法を実施している者の割合は、大都市勤務者のほうが有意に高かった。BMI は両群で差を認めず、随時血糖値（対数変換）は都市部勤務者のほうが高かった。線形重回帰分析の結果、両群の収縮期血圧値の差のうち1.5mmHg（約 40%）は塩分排泄量（摂取量）の差に起因することが示された。
【結論】働き盛りの男性において農村と大都市勤務者の危険因子には明らかな差が認められ、今後の農村部の健康管理に課題があることが明らかとなった。引き続き非都市的地域の事業所を加えて更なる比較を実施する予定である。

資　料

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