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# The MONICA Augsburg Surveys – Basis for Prospective Cohort Studies

*Die MONICA Augsburg Surveys – Grundlage für prospektive Kohortenstudien*

## Zusammenfassung

Als Teil des WHO-MONICA-Projektes sind seit 1984/85 drei bevölkerungsrepräsentative Querschnittsstudien in der Region Augsburg durchgeführt worden, um die zeitlichen Trends der klassischen Risikofaktoren abzubilden. Im Rahmen von KORA wird die Bedeutung der untersuchten Parameter für die sich verändernde kardiovaskuläre Gesundheit erforscht. Für die MONICA-Surveys wurden drei voneinander unabhängige Zufallsstichproben rekrutiert (1984/85 S1: Alter 25–64 Jahre, 1989/90 S2: Alter 25–74 Jahre und 1994/95 S3: Alter 25–74 Jahre). Die nach Alter und Geschlecht stratifizierte 2-stufige Clusterstichprobe bestand aus einer Zufallsauswahl in der Stadt Augsburg und einer nach Wohnortgröße erfolgten zufälligen Auswahl von 16 Kommunen aus den beiden angrenzenden Landkreisen. Durch die Zufallsauswahl wurden einige Personen für mehr als einen Survey ausgewählt, weshalb sich für 13 427 Personen insgesamt 13 818 Studienteilnahmen ergaben. Von 1984 bis 1995 wurden bei Bluthochdruck keine Veränderungen beobachtet. Für Fettstoffwechselstörungen (Ratio von Gesamt-/HDL-Cholesterin  $\geq 5,0$ ) gab es Zunahmen um 15% (Männer) bis 30% (Frauen), während Zigarettenrauchen bei 55- bis 64-jährigen Männern ab- und bei 35- bis 64-jährigen Frauen zunahm. Die Risikoprädiktion für inzidente akute Myokardinfarkte je 100 000 Personenjahre ist am größten für das Zigarettenrauchen (Männer 880, Frauen 360), gefolgt von Blutfettstörungen (Männer 739, Frauen 318) und systolischen Blutdruckwerten größer oder

## Abstract

As part of the WHO MONICA project three population-representative surveys were conducted in the study region of Augsburg since 1984/85 to describe time trends of classical cardiovascular risk factors. These surveys provide relevant baseline-information for prospective health outcome studies. Three independent study populations were recruited in 1984/85 (S1: age 25–64 years), 1989/90 (S2: age 25–74 years), and 1994/95 (S3: age 25–74 years) by a two-stage cluster sampling, with random sampling for the city of Augsburg, and a random selection of 16 communities by community size in the two adjacent counties. In the three surveys, 13,427 persons have had 13,818 study participations, since some subjects were by chance sampled for more than one survey. From 1984 to 1995, no trends in hypertension could be observed, but an increase of 15% (men) resp. 30% (women) in dyslipidaemia (total/HDL cholesterol ratio  $\geq$  five). Cigarette smoking decreased in 55 to 64 year old men and increased in 35 to 64-year old women. The predictive impact for incident Acute Myocardial Infarction (AMI) per 100,000 person years is highest for cigarette smoking (men 880, women 360), followed by dyslipidemia (men 739, women 318) and systolic blood pressure  $\geq$  160 mm Hg (men 658, women 276). By 31st December 2002 1,551 persons (1,031 men, 520 women) had died. The surveys will be used for further gender-specific cross-sectional and longitudinal analyses with special focus on classical, new laboratory and genetic risk factors as determinants of mortality, inci-

### note

The MONICA/KORA study group consists of: KORA: H.-E. Wichmann (speaker), H. Löwel, C. Meisinger, T. Illig, R. Holle, J. John and co-workers who are responsible for the design and conduct of the KORA studies. MONICA: U. Keil (principal investigator), A. Döring, B. Filipiak, H. W. Hense, H. Löwel, J. Stieber and co-workers who were responsible for the design and conduct of the MONICA studies.

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gleich 160 mm Hg (Männer 658, Frauen 276). Bis zum 31.12.2002 waren insgesamt 1551 Personen (1031 Männer, 520 Frauen) verstorben. Die Surveys bildeten die Basis für weitere geschlechtsspezifische Quer- und Längsschnittanalysen mit speziellem Fokus auf die klassischen wie auch neue Labor- und genetischen Risikofaktoren als Determinanten von Mortalität, inzidentem Herzinfarkt und Typ-2-Diabetes für verbesserte Präventionsstrategien.

Schlüsselwörter

MONICA/KORA Projekt Augsburg · kardiovaskuläre Risikofaktoren · Querschnittsstudie · Kohortenstudie · Herzinfarktinzidenz

dent AMI and incident type 2 diabetes, to improve preventive strategies.

Key words

MONICA/KORA-project Augsburg · cardiovascular risk factors · survey · cohort study · incident acute myocardial infarction

Introduction

The MONICA (multinational monitoring trends and determinants in cardiovascular disease) project was initiated in the early 80 s by the World Health Organization (WHO) to study risk factors of premature cardiovascular diseases in regional defined communities of the world by a standardized protocol. Finally, 38 populations from 25 countries and four continents fulfilled the strong quality control criteria [1]. The MONICA Augsburg project was performed in the city of Augsburg and the two adjacent counties Augsburg and Aichach-Friedberg. Risk factors were monitored through three independent cross-sectional population-based surveys at the beginning (S1 1984/85), the middle (S2 1989/90), and the end (S3 1994/95) of the ten years observation period. The age range for the international WHO project was originally 35 to 64 years, but was extended to 25 to 64 years in S1 and to 25 to 74 years in S2, and S3 for the Augsburg region.

In all three surveys, MONICA core information on socio-demographic variables, smoking status and further health behaviour, medication use, and parental history of diseases were gathered by trained medical staff (mainly nurses) during a standardized

face-to-face interview. In addition all participants underwent an extensive standardized medical examination (e.g. blood pressure measurement) including collection of a non-fasting blood sample (e.g. lipid status). The aim of this paper was to demonstrate the enormous relevance of the survey data base for trend analyses and gender-specific prospective health outcome studies with special focus on the three main cardiovascular risk factors.

Study population and sampling frame

The WHO MONICA project focused on international comparability of classical risk factors with special regard to socio-demographic particularities.

For the Augsburg surveys, two-stage cluster sampling was applied. In the city of Augsburg a random sample of 311 subjects was drawn for each ten-year age (25–34, 35–44, 45–54, 55–64, 65–74) and sex group. In the two adjacent counties from a total of 68 communities 16 were randomly selected by population size. Four of these (Friedberg, Gersthofen, Königsbrunn, und Neusäß) have been selected with certainty and the sample

Table 1 Population, sample size, and participants (n = 13,427 persons: 6,725 men, 6,702 women) by age and sex. MONICA Augsburg survey 1984/85, 1989/90, 1994/95

sex	age group	survey 1984/84 (S1)			survey 1989/90 (S2)			survey 1994/95 (S3)		
		population	sample size	participants	population	sample size	participants	population	sample size	participants
men	25–34	39 082	664	464	46 844	664	470	56 390	664	444
	35–44	38 423	664	485	36 482	664	462	43 376	664	457
	45–54	35 602	664	539	41 184	664	520	39 509	664	482
	55–64	25 839	664	535	28 713	664	510	34 344	664	531
	65–74	–	–	–	16 653	661	520	21 635	664	491
	25–64	138 946	2 656	2 023	153 223	2 656	1 962	173 619	2 656	1 914
	25–74	–	–	–	169 876	3 317	2 482	195 254	3 320	2 405
women	25–34	37 967	664	463	44 143	664	476	52 298	664	462
	35–44	35 917	664	523	35 683	664	486	41 411	664	514
	45–54	34 929	664	515	39 081	664	539	37 803	664	510
	55–64	34 520	664	498	31 745	664	503	35 606	664	516
	65–74	–	–	–	28 522	664	454	32 384	664	449
	25–64	143 333	2 656	1 999	150 652	2 656	2 004	167 118	2 656	2 002
	25–74	–	–	–	179 174	3 320	2 458	199 502	3 320	2 451
total		282 279	5 312	4 022	349 050	6 637	4 940	394 756	6 640	4 856

sizes in these towns were proportional to their sizes. The remaining communities (Affing, Aichach, Bobingen, Diedorf, Fischach, Hollenbach, Kutzenhausen, Meitingen, Nordendorf, Schmiechen, Stadtbergen, and Ustersbach) were selected applying a random procedure with probabilities proportional to their size and fixed sample size. In each of the 16 communities an age-sex stratified random sample was drawn. A detailed description of the sampling methods is given elsewhere [2]. In 1989/90 and 1994/95 the two smallest communities (Schmiechen and Ustersbach) were substituted by communities with similar sizes (1989/90 Oberottmarshausen and Scherstetten, 1994/95 Ehingen and again Ustersbach), applying the same sample procedures. In Table 1 the number of residents, study population, and participants were listed by age, sex, and survey.

## Risk factor measurement

### Cigarette smoking (current, former, never)

In the interview the following questions on smoking habits were included:

Do you smoke cigarettes now? Yes/no

If 'yes': Do you smoke regularly or occasionally? (occasionally means usually less than one cigarette per day) regularly/occasionally

If 'regularly': On average, how many cigarettes do you smoke a day? Number

Did you ever smoke cigarettes? Yes/no

### Blood pressure and hypertension

The Hawksley random-zero sphygmomanometer was used for blood pressure (BP) measurement. Three BP recordings were taken after completion of the interview, so that each person had been resting in a sitting position for about 30 minutes before first BP recording was performed. BP was measured under strictly standardized conditions following the MONICA Manual (World Health Organization 1986 [3]) and the American Heart Organization guidelines [4]. There was at least a three minute interval between each measurement. Each time the first, fourth and fifth phase of the Korotkoff sounds and the pulse rate was recorded. Three cuff sizes (bladder size 12 × 23 cm, 12 × 28 cm, 14 × 40 cm) were used, according to the circumference of the right upper arm of the participant. Quality assurance and control procedures included assessment of inter- and intra-observer variation of BP measurements by supervisors with double stethoscopes and audiovisual tapes prior to, and at the end of the survey period. To characterize the population burden of hypertension, the definition of actual hypertension comprises all categories of hypertension and all normotensive people under antihypertensive drug medication given, that they were aware of being hypertensive.

In this paper hypertension is defined by systolic blood pressure (SBP) greater or equal 160 mm Hg and diastolic blood pressure (DBP) greater or equal 95 mm Hg.

## Serum cholesterol and hypercholesterolemia

In all surveys blood samples were drawn in a sitting position with minimal tourniquet use. Most of the participants were in a non-fasting state. Blood was allowed clotting for 45 minutes at room temperature and was refrigerated thereafter. Within 60 to 120 minutes after venipuncture the blood was centrifuged at 4000 u/min. The obtained serum was cooled at 4° C. The analyses were done within the following three days (usually the next day) by the institute of laboratory medicine of the central hospital of Augsburg on an autoanalyzer (S1 and S2 SMAC, Fa. Technicon, S3 Hitachi 717). Cholesterol determinants were done by an enzymatic method (CHOD-PAP method S1 and S2, Boehringer No. 236 961, S3 No. 1 127 578), high density cholesterol (HDL) was measured after precipitation of the apoprotein B-containing lipoproteins with phosphotungstate/Mg<sup>2+</sup> (Boehringer No. 543 00 4). Regular internal and external quality control measurements for total serum cholesterol and HDL were performed prior to and during the data gathering phase of the surveys. The external quality control of all MONICA collaborating centers was performed by the WHO quality control center for lipids in Prague [5].

In the present paper dyslipidemia was defined as the ratio of total cholesterol/HDL greater or equal 5.0.

### Follow-up status 1998 and 2002

For the implementation of prospective analyses, follow-up information of the study participants was gathered. In 1998 and actually in 2002, the vital status was assessed for all sampled persons of the three MONICA surveys through the population registries (Einwohnermeldeämter).

## Results

The three MONICA Augsburg survey populations are presented in Table 1. Overall, 13,427 persons participated in the three surveys. Since same subjects were by chance sampled for several surveys, the total number of study participations was 13,818: 12 persons (6 men, 6 women) were participants of all three surveys, and 367 persons (173 men and 194 women) have participated on two (S1/S2, S1/S3, S2/S3) of the three surveys.

The overall survey-specific response after exclusion of the non-eligible participants aged 25–64 years (S1 men 80.0% and women 78.7%, S2 men 76.4% and women 77.2%, S3 men 74.0% and women 76.8%) were comparable. For the age group 65 to 74 years, response of S2 (men 82.4%, women 72.5%) and S3 (men 76.6%, women 69.3%) reached also high and comparable percentages.

### Time trends in prevalence of classical risk factors

In each survey, regular cigarette smoking decreases with age and actual hypertension shows a continuous increase with age in both genders, whereas dyslipidemia remains stable from the age of 45 years on in men and from the age of 55 years on in women (Fig. 1). Comparing the surveys with regard to the three

main risk factors, smoking shows changes from S1 to S2 with a decreasing prevalence in 55 to 64 year old men and an increasing prevalence in 35 to 64 year old women in S3. In the third survey an up to 15% (men) to 30% (women) higher prevalence of dyslipidemia is observed compared to S1 and S2. In general, all risk factors were less prevalent in women compared to men with the exception of hypertension at age 65 to 74 years.

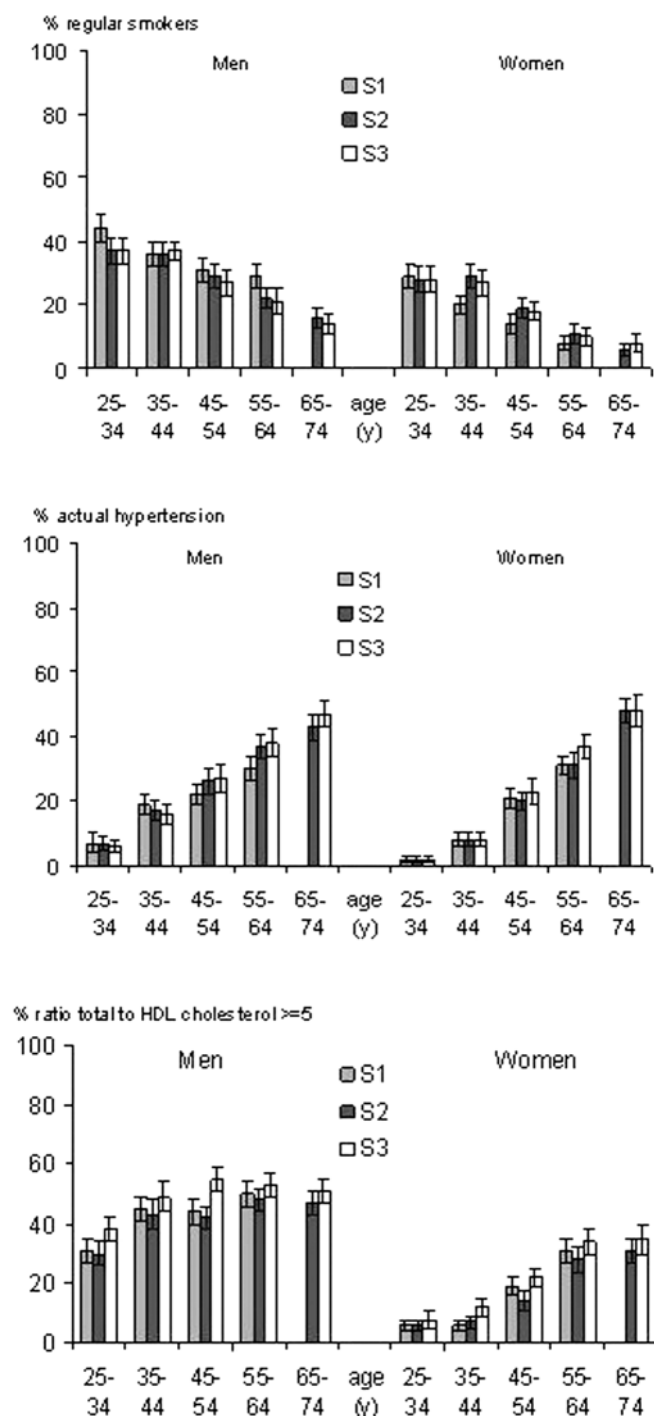


Fig. 1 Time trends of regular smoking ( $\geq 1$  cigarette per day), actual hypertension ( $\geq 160/95$  mm Hg and/or antihypertensive drug medication), and dyslipidemia (ratio of total to HDL cholesterol  $\geq 5.0$ ) by age and sex. MONICA Augsburg Survey 1984/85, 1989/90, 1994/95.

For prospective analyses the risk profile of the pooled MONICA/KORA cohort is shown in Table 2. The most prevalent risk factor in men was dyslipidemia with a prevalence of 45.0% in men; In women it was cigarette smoking with a prevalence of 23.5%.

Table 2 Age-standardized (EU population 1991) prevalences of classical risk factor categories (cigarette smoking, systolic blood pressure [SBP], ratio of total to HDL-cholesterol) in percent by gender and age (25 to 74 years). Pooled MONICA/KORA Augsburg cohort 1984/95, baseline status

	men n = 6,598	women n = 6,471
never smokers	29.2	60.8
ex smokers	38.0	17.7
actual smokers ( $\geq 1$ cigarette per day)	33.8	23.5
SBP < 140 mm Hg	66.2	75.3
SBP 140–159 mm Hg	24.5	17.0
SBP $\geq 160$ mm Hg	9.2	7.7
TC/HDL ratio < 3.5	16.8	43.3
TC/HDL ratio 3.5–4.9	38.2	38.4
TC/HDL ratio $\geq 5.0$	45.0	18.3

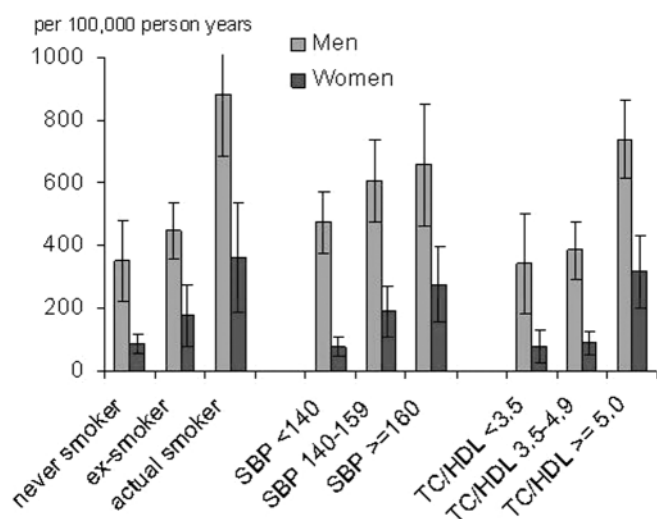
### Incidence of acute myocardial infarction during follow-up 1984 to 1998

The gender-specific age-adjusted incidence of fatal and non-fatal AMI per 100,000 person years among all participants of the three MONICA Augsburg surveys by risk factor categories is presented in Fig. 2. The highest incidence was observed in regular smokers (men 880, women 360 incident cases of AMI per 100,000 person years) followed by dyslipidemia defined as total cholesterol/HDL ratio  $\geq 5$  (men 739, women 318) and systolic blood pressure  $\geq 160$  mm Hg (658 resp. 276). In absence of the respective risk factor, the incidence rate in men was four to six times higher than in women. However, if the respective risk factor was present at baseline the risk in men was only two times higher than in women. The absolute risk difference (attributable risk) between current smokers and ex-smokers in men was 432 events per 100,000 person years. The corresponding incidence difference for the females was 184 per 100,000 person years. The attributable AMI incidence of dyslipidemia defined as TC/HDL ratio  $\geq 5.0$ , compared to people with a TC/HDL ratio < 3.5 was 398 in men and 241 per 100,000 person years in women. Due to the high prevalences of current smoking and dyslipidemia these factors have the highest preventive potentials. Despite the overall lower baseline risk per 100,000 population in women, the attributable risk of SBP  $\geq 160$  mm Hg compared to SBP < 140 mm Hg in females (199 incident AMI) reached the absolute difference of men (184 incident AMI). Considering the same risk factor resulted in a lower AMI incidence in women in comparison to men. Contrary to men, the impact on AMI incidence was relatively higher in women with the respective risk factor than in women without the risk factor. Finally, the high potentials of classical risk factor prevention must be emphasised for both, men and women.

In Table 3 the follow-up status of the participants of each of the MONICA Augsburg surveys is presented. In less than one percent of the pooled populations the survival status was unknown (n=83). Until 31st December 2002 a total of 1.551 persons

**Table 3** Survey participants, deaths during follow-up (n = 1,551 persons: 1,031 men, 520 women), and losses to follow-up (n = 83 persons: 42 men, 41 women) by age and sex. MONICA Augsburg survey 1984/85, 1989/90, 1994/95 with follow up 2002

sex	age group	survey 1984/85 (S1)			survey 1989/90 (S2)			survey 1994/95 (S3)		
		participants	deaths	losses to FU	participants	deaths	losses to FU	participants	deaths	losses to FU
men	25–34	464	17	6	470	12	11	444	2	6
	35–44	485	37	5	462	16	3	457	7	1
	45–54	539	88	2	520	50	2	482	25	1
	55–64	535	243	–	510	118	–	531	54	1
	65–74	–	–	–	520	255	3	491	133	1
	25–64	2 023	385	13	1 962	196	16	1 914	88	9
	25–74	–	–	–	2 482	451	19	2 405	221	10
women	25–34	463	7	8	476	4	5	462	–	8
	35–44	523	20	6	486	5	5	514	2	1
	45–54	515	45	2	539	17	2	510	14	1
	55–64	498	131	–	503	52	1	516	22	–
	65–74	–	–	–	454	141	2	449	76	2
	25–64	1 999	203	16	2 004	78	13	2 002	38	10
	25–74	–	–	–	2 458	219	15	2 451	114	12
total		4 022	588	29	4 940	670	34	4 856	335	22



**Fig. 2** Age-standardized (EU population 1991) incident acute myocardial infarction per 100,000 person years by gender and risk factor status at baseline. MONICA/KORA Augsburg cohort study 1984/1995 with follow-up until 1998.

(1,031 men, 520 women) had died: 588 participants (385 men, 203 women) from S1, 670 participants (451 men, 219 women) from S2, and 335 participants (221 men, 114 women) from S3. These cohort data build the basis for further incidence estimates with special regard to the predictive relevance of a broader range of risk factors.

### Future planning

The baseline and follow-up data of the three MONICA Augsburg surveys allows us to investigate trends in cardiovascular risk factors, and to answer prospective questions concerning the etiol-

ogy of chronic diseases. In the future we will further focus on the incidence of acute myocardial infarction, type 2 diabetes mellitus, total and cardiovascular mortality. In addition, the MONICA/KORA Augsburg studies also provide the possibility to investigate the genetic basis as well as the gene-environment interactions responsible for the development of chronic diseases. Including further new risk factors e. g. inflammation parameters, a population-based Augsburg risk score will be developed for a better individual risk prediction with consequences to tailored strategies of prevention [6].

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The article refers specifically to the following contributions of this special issue of Das Gesundheitswesen: [7–21].



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