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Short Communication

Does the socioeconomic status differ between users of potentially NDMA-contaminated generic valsartan and users of brand-name valsartan in Germany?

Unterscheiden sich Nutzer von potenziell NDMA-kontaminierten Valsartan-Generika und Nutzer von Valsartan-Originalpräparaten in Deutschland hinsichtlich des sozioökonomischen Status?

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Abstract

A recently published study from Germany suggested an increased risk of liver cancer among NDMA-contaminated generic valsartan users. However, studies from the US showed that generic versus brand-name drug users differ regarding socioeconomic characteristics. If also true for Germany, this might have biased the results on NDMA-contaminated valsartan given that the socioeconomic status was not considered in the analysis. We, therefore, investigated for the first time whether users of brand-name versus generic preparations in Germany differ by socioeconomic status. Based on a large claims database (GePaRD), we conducted a cross-sectional study including individuals with ≥1 valsartan dispensation in 2017. Among 495,832 individuals, we observed no meaningful differences between generic versus brand-name valsartan users regarding educational level or socioeconomic deprivation. Our results suggest brand-name versus generic drug users in Germany to be comparable regarding the socioeconomic status, thus, supporting the validity of findings on harmful effects of NDMA-contaminated valsartan exposure.

Keywords: pharmacoepidemiology, drug utilization, valsartan, generic drugs, socioeconomic factors

Zusammenfassung

Eine kürzlich publizierte Studie aus Deutschland zeigte Hinweise auf ein erhöhtes Leberkrebsrisiko bei Nutzern von NDMA-kontaminierten Valsartan-Generika. Studien aus den USA hingegen zeigten, dass sich Generika-Nutzer von Nutzern der Originalpräparate hinsichtlich sozioökonomischer Charakteristika unterscheiden. Sollte dies auch für Deutschland zutreffen, könnte dies zu einer Verzerrung der Ergebnisse zu NDMA-kontaminiertem Valsartan geführt haben, da der sozioökonomische Status in den Analysen nicht berücksichtigt wurde. Daher untersuchten wir erstmals, ob sich Generika- und Originalpräparat-Nutzer in Deutschland hinsichtlich des sozioökonomischen Status unterscheiden. Basierend auf einer großen Datenbank mit Abrechnungsdaten (GePaRD) führten wir eine Querschnittsanalyse durch, die Personen mit mindestens einer Valsartan-Abgabe in 2017 umfasste. Bei 495.832 Personen beobachteten wir keine bedeutsamen Unterschiede zwischen Generika-Nutzern und Nutzern von Originalpräparaten hinsichtlich des Bildungsniveaus oder der sozioökonomischen Deprivation. Unsere Ergebnisse weisen darauf hin, dass Nutzer von Originalpräparaten und Generika-Nutzer in Deutschland hinsichtlich des sozioökonomischen Status vergleichbar sind, was die Gültigkeit der Ergebnisse zu den schädlichen Auswirkungen einer NDMA-kontaminierten Valsartan-Exposition unterstützt.

Introduction

Following the detection of a contamination with the probable carcinogen N-nitrosodimethylamine (NDMA), certain valsartan generics were withdrawn from the market in 2018 – seven years after their distribution had been initiated in Germany. In May 2021, novel results on long-term carcinogenic effects of potentially NDMA-contaminated valsartan intake derived from an analysis of German statutory health insurance (SHI) claims data were published suggesting an increased risk of liver cancer (adjusted hazard ratio 1.16 [95% CI 1.03–1.31]) among individuals exposed to potentially NDMA-contaminated versus uncontaminated valsartan [1]. Results were adjusted for important confounders (e.g. age, sex, comorbidities, co-medications) while the socioeconomic status (SES) was not taken into account – likely because it was not available in the data [1]. Low SES is considered to be associated with an unhealthy lifestyle potentially entailing risk factors for liver cancer (e.g. obesity, high alcohol consumption) [2]. Studies on US data have demonstrated that generic versus brand-name drug users are not comparable with regard to the SES [3], [4]. If this also holds true for Germany, the SES and, accordingly, unhealthy lifestyle factors would not be balanced across the groups compared in the aforementioned analysis (generic versus brand-name valsartan) [1].

Further knowledge on differences with regard to the SES in generic versus brand-name drug users in Germany is needed in order to assess whether unmeasured confounding by the SES might have biased the findings on harmful effects of NDMA-contaminated valsartan exposure in Germany [1]. However, individual-level information on the SES is often lacking in pharmacoepidemiological research databases. Our group has previously established and indirectly validated an algorithm to estimate the SES both at an individual (using information on education) and at an aggregate level (using information on the district of residence linked to the German Index of Socioeconomic Deprivation (GISD)) based on data of the German Pharmacoepidemiological Research Database (GePaRD) [5]. To enhance interpretability of the findings on long-term carcinogenic effects of potentially NDMA-contaminated valsartan intake [1], we aimed to describe and compare the SES in individuals represented in GePaRD who are using generic versus brand-name valsartan.

Methods

For this study, we used GePaRD which is based on claims data from four SHI providers in Germany and currently includes information on approximately 25 million persons who have been insured with one of the participating providers since 2004 or later. In addition to demographic data, GePaRD contains information on drug dispensations as well as outpatient (i.e., from general practitioners and specialists) and inpatient services and diagnoses. Per data year, there is information on approximately 20% of the general population and all geographical regions of Germany are represented. In GePaRD, the Anatomical Therapeutic Chemical (ATC) code is used to identify drugs dispensed in the outpatient setting. The valsartan-containing drugs relevant for this study were identified based on the ATC codes C09CA03, C09DA23, C09DB01, C09DX01 and C09DX04.

We conducted a cross-sectional population-based analysis of individuals in GePaRD who used valsartan in 2017. To be included in the analysis, individuals had to have valid information on age and sex, at least one day of insurance coverage in 2017 and at least one valsartan dispensation in 2017. Based on the type of dispensed valsartan in 2017 as identified through the pharmaceutical registration number, individuals were categorized into the following two groups:

1. at least one dispensation of a generic preparation of valsartan, i.e. potentially exposed to NDMA-contamination,
2. only dispensations of brand-name (or reimport) preparations of valsartan, i.e. not affected by potential NMDA-contamination.

The two groups were described and compared with regard to the SES. Results were further stratified by age groups and sex. At an individual level, the SES was measured based on information on school education using a 3-level variable:

1. higher education, i.e. (technical) university entrance qualification (German: (fachgebundene) Hochschulreife),
2. (basic) secondary degree (German: Hauptschulabschluss oder mittlere Reife),
3. unknown/no degree.

This information was obtained from the so-called occupation key (German: Tätigkeitsschlüssel) available in GePaRD. Employers provide this occupation key to the health insurance. The key contains information on occupation, occupational status, and education. The use of earlier data years allowed to identify past periods of employment in individuals already retired in 2017. We assumed individuals covered by the insurance of a family member to have the same educational status as the respective primary insurance holder. In case of discrepant information from different data years, we considered the highest documented level of education [5]. At an aggregate level, information on the district of residence available in GePaRD was linked to the GISD developed by the Robert Koch Institute. The index reflects the extent of deprivation of districts based on the three dimensions income, education, and occupation. The GISD was categorized into previously specified quintiles with reference to nationwide German data. Increasing quintiles indicate increasing deprivation [6].

The distribution of continuous variables was summarized as mean (± standard deviation) while categorical variables were expressed as frequency counts (percentages). To facilitate the comparison of variable distributions between

Table 1: Description of valsartan users according to type of dispensations (generic versus brand-name dispensation)

		Any dispensation of a generic preparation of valsartan (n=425,794, 85.9%)	Only dispensations of brand-name preparations of valsartan* (n=70,038, 14.1%)	SD
Age [mean ± standard deviation]		67.3 ± 12.8	67.0 ± 12.3	0.03
Sex [n (%)]	Female	234,471 (55.1)	29,150 (41.6)	0.27
Individual-level socioeconomic status				
Education[1] [n (%)]	Unknown / No degree	6,194 (3.1)	1,095 (3.2)	0.01
	(Basic) Secondary degree	104,478 (51.7)	17,928 (52.1)	
	Higher education	91,505 (45.3)	15,393 (44.7)	
Aggregate-level socioeconomic status				
Deprivation index[2] [n (%)]	Quintile 1	83,597 (19.8)	13,507 (19.4)	0.14
	Quintile 2	79,785 (18.9)	11,452 (16.4)	
	Quintile 3	105,578 (24.9)	15,462 (22.2)	
	Quintile 4	74,667 (17.6)	12,366 (17.7)	
	Quintile 5	79,713 (18.8)	16,913 (24.3)	

* Including reimport dispensations
[1] Available for n=236,593 observations, percentages are referring to observations with available data
[2] Available for n=493,040 observations, percentages are referring to observations with available data. Analysis based on the German Index of Socioeconomic Deprivation (GISD) which was categorized into pre-specified quintiles with reference to nationwide German data. Increasing quintiles indicate increasing deprivation. Education, occupation and income are the three central dimensions of the GISD [6].
Abbreviations: SD, standardized differences

groups, standardized differences (SD) were calculated. A SD<0.1 was considered to indicate the absence of differences between groups. We conducted all statistical analyses using the software SAS version 9.4.

Results

A total of 495,832 eligible valsartan users in 2017 were identified, with the majority having at least one generic dispensation (n=425,794; 85.9%). Compared to the brand-name group, individuals using a generic were more likely to be female (55.1% versus 41.6%; SD=0.27). Mean age was 67 years in both groups (generic: 67.3 ± 12.8 years versus brand-name: 67.0 ± 12.3 years; SD=0.03). The distribution of educational levels was comparable across groups: 45.3% of generic and 44.7% of brand-name users had higher education, respectively (SD=0.01). Among generic users, a smaller fraction was represented in the quintile of highest socioeconomic deprivation compared to brand-name users (18.8% versus 24.3%) while we observed no obvious trend across further quintiles (SD=0.14, Table 1). Simultaneous stratification by age, sex and the respective SES variable did not change meaningfully the above described patterns (Table 2, Table 3), neither did comparisons between three groups of valsartan users (only generic users versus only brand-name users versus individuals using both; data not presented).

Discussion

In a large and unselected cohort of valsartan users, we did not find a meaningful difference between users of generic versus brand-name valsartan with regard to the SES. Among generic users, a smaller fraction was represented in the quintile of highest socioeconomic deprivation compared to brand-name users (18.8% versus 24.3%) with a marginally elevated SD of 0.14. No obvious trend across further quintiles was observed. Also within levels of age and sex, generic versus brand-name valsartan users were comparable regarding the SES. When interpreting the stratified results, low availability of information on the educational status for higher age groups needs to be taken into account.

Our data included individuals covered by SHI, which made our cohort closely comparable to the one used by Gomm and colleagues to investigate the effects of NDMA-contaminated valsartan generic exposure [1]. Also, our cohort was greatly representative of the overall German population as in 2017 approximately 87% of the German population were covered by SHI [7].

We investigated whether users of brand-name and users of generic preparations in Germany differ with regard to the SES as there are both arguments supporting differences and similarities between the two groups. In general, the German SHI system is characterized by solidarity and universal access to healthcare. However, some services – including certain medications – may only be accessible

Table 2: Description of valsartan users according to type of dispensations (generic versus brand-name dispensation) stratified by age groups and sex: individual-level socioeconomic status

Age group	Education[1] [n (%)]	FEMALES (n= 263,621, 53.2%)			MALES (n= 232,211, 46.8%)		
<50 years		Any dispensation of a generic preparation of valsartan (n=15,686; 90.7%)	Only dispensations of brand-name preparations of valsartan* (n=1,614; 9.3%)	SD	Any dispensation of a generic preparation of valsartan (n=20,440; 84.1%)	Only dispensations of brand-name preparations of valsartan* (n=3,852; 15.9%)	SD
	Unknown / No degree	341 (2.3)	46 (3.1)	0.08	319 (1.7)	83 (2.3)	0.08
	(Basic) Secondary degree	8,141 (55.5)	876 (58.5)		8,356 (43.7)	1,679 (46.9)	
	Higher education	6,175 (42.1)	575 (38.4)		10,448 (54.6)	1,818 (50.8)	
≥50 and <60 years		Any dispensation of a generic preparation of valsartan (n=41,046; 89.4%)	Only dispensations of brand-name preparations of valsartan* (n=4,851; 10.6%)	SD	Any dispensation of a generic preparation of valsartan (n=40,784; 81.8%)	Only dispensations of brand-name preparations of valsartan* (n=9,058; 18.2%)	SD
	Degree unknown	958 (2.6)	116 (2.7)	0.06	664 (1.8)	128 (1.6)	0.10
	(Basic) Secondary degree	21,464 (58.7)	2,629 (61.4)		15,418 (42.5)	3,790 (47.7)	
	Higher education	14,126 (38.7)	1,535 (35.9)		20,184 (55.7)	4,029 (50.7)	
≥60 and <70 years		Any dispensation of a generic preparation of valsartan (n=58,285; 88.6%)	Only dispensations of brand-name preparations of valsartan* (n=7,520; 11.4%)	SD	Any dispensation of a generic preparation of valsartan (n=51,663; 81.2%)	Only dispensations of brand-name preparations of valsartan* (n=11,974; 18.8%)	SD
	Degree unknown	1,457 (3.9)	204 (4.3)	0.06	993 (2.6)	235 (2.7)	0.04
	(Basic) Secondary degree	23,037 (61.8)	3,070 (64.3)		16,849 (43.9)	4,018 (45.7)	
	Higher education	12,757 (34.2)	1,497 (31.4)		20,518 (53.5)	4,537 (51.6)	
≥70 and <80 years		Any dispensation of a generic preparation of valsartan (n=71,905; 88.5%)	Only dispensations of brand-name preparations of valsartan* (n=9,308; 11.5%)	SD	Any dispensation of a generic preparation of valsartan (n=51,430; 82.4%)	Only dispensations of brand-name preparations of valsartan* (n=10,951; 17.6%)	SD
	Degree unknown	560 (8.2)	86 (10.1)	0.09	790 (6.3)	181 (7.0)	0.04
	(Basic) Secondary degree	4,422 (64.5)	515 (60.6)		6,468 (51.9)	1,299 (50.3)	
	Higher education	1,875 (27.3)	249 (29.3)		5,196 (41.7)	1,102 (42.7)	
≥80 years		Any dispensation of a generic preparation of valsartan (n=47,549; 89.0%)	Only dispensations of brand-name preparations of valsartan* (n=5,857; 11.0%)	SD	Any dispensation of a generic preparation of valsartan (n=27,006; 84.2%)	Only dispensations of brand-name preparations of valsartan* (n=5,053; 15.8%)	SD
	Degree unknown	37 (17.4)	5 (17.2)	0.00	75 (16.7)	11 (12.2)	0.23
	(Basic) Secondary degree	110 (51.6)	15 (51.7)		213 (47.5)	37 (41.1)	
	Higher education	66 (31.0)	9 (31.0)		160 (35.7)	42 (46.7)	

* Including reimport dispensations
[1] Available for n=236,593 observations, percentages are referring to observations with available data
Abbreviations: SD, standardized differences

Table 3: Description of valsartan users according to type of dispensations (generic versus brand-name dispensation) stratified by age groups and sex: aggregate-level socioeconomic status

Age group	Deprivation index[1] [n (%)]	FEMALES (n=263,621, 53.2%)			MALES (n=232,211, 46.8%)		
<50 years		Any dispensation of a generic preparation of valsartan (n=15,686; 90.7%)	Only dispensations of brand-name preparations of valsartan* (n=1,614; 9.3%)	SD	Any dispensation of a generic preparation of valsartan (n=20,440; 84.1%)	Only dispensations of brand-name preparations of valsartan* (n=3,852; 15.9%)	SD
	Quintile 1	2,841 (18.2)	290 (18.1)	0.13	4,065 (20.0)	786 (20.5)	0.13
	Quintile 2	2,840 (18.2)	249 (15.5)		3,610 (17.8)	642 (16.7)	
	Quintile 3	4,102 (26.3)	406 (25.3)		5,339 (26.3)	878 (22.9)	
	Quintile 4	2,859 (18.3)	277 (17.3)		3,535 (17.4)	649 (16.9)	
	Quintile 5	2,944 (18.9)	380 (23.7)		3,738 (18.4)	881 (23.0)	
≥50 and <60 years		Any dispensation of a generic preparation of valsartan (n=41,046; 89.4%)	Only dispensations of brand-name preparations of valsartan* (n=4,851; 10.6%)	SD	Any dispensation of a generic preparation of valsartan (n=40,784; 81.8%)	Only dispensations of brand-name preparations of valsartan* (n=9,058; 18.2%)	SD
	Quintile 1	7,493 (18.4)	843 (17.4)	0.16	7,759 (19.1)	1,741 (19.3)	0.14
	Quintile 2	7,445 (18.2)	816 (16.9)		7,436 (18.3)	1,475 (16.4)	
	Quintile 3	10,630 (26.1)	1,077 (22.3)		10,564 (26.0)	2,081 (23.1)	
	Quintile 4	7,337 (18.0)	865 (17.9)		7,362 (18.2)	1,590 (17.6)	
	Quintile 5	7,900 (19.4)	1,231 (25.5)		7,439 (18.3)	2,131 (23.6)	
≥60 and <70 years		Any dispensation of a generic preparation of valsartan (n=58,285; 88.6%)	Only dispensations of brand-name preparations of valsartan* (n=7,520; 11.4%)	SD	Any dispensation of a generic preparation of valsartan (n=51,663; 81.2%)	Only dispensations of brand-name preparations of valsartan* (n=11,974; 18.8%)	SD
	Quintile 1	10,480 (18.1)	1,305 (17.4)	0.16	8,976 (17.5)	2,017 (16.9)	0.17
	Quintile 2	10,413 (18.0)	1,166 (15.6)		9,355 (18.2)	1,813 (15.2)	
	Quintile 3	14,596 (25.2)	1,694 (22.6)		12,964 (25.2)	2,570 (21.6)	
	Quintile 4	10,426 (18.0)	1,270 (17.0)		9,603 (18.7)	2,306 (19.4)	
	Quintile 5	12,053 (20.8)	2,053 (27.4)		10,492 (20.4)	3,211 (26.9)	

(Continued)

Table 3: Description of valsartan users according to type of dispensations (generic versus brand-name dispensation) stratified by age groups and sex: aggregate-level socioeconomic status

Age group	Deprivation index[1] [n (%)]	FEMALES (n=263,621, 53.2%)			MALES (n=232,211, 46.8%)		
≥70 and <80 years		Any dispensation of a generic preparation of valsartan (n=71,905; 88.5%)	Only dispensations of brand-name preparations of valsartan* (n=9,308; 11.5%)	SD	Any dispensation of a generic preparation of valsartan (n=51,430; 82.4%)	Only dispensations of brand-name preparations of valsartan* (n=10,951; 17.6%)	SD
	Quintile 1	14,783 (20.7)	1,835 (19.8)	0.16	10,358 (20.2)	2,164 (19.9)	0.13
	Quintile 2	13,380 (18.7)	1,496 (16.1)		9,844 (19.2)	1,839 (16.9)	
	Quintile 3	17,258 (24.1)	1,934 (20.9)		12,260 (24.0)	2,356 (21.6)	
	Quintile 4	12,334 (17.2)	1,632 (17.6)		9,159 (17.9)	1,969 (18.1)	
	Quintile 5	13,754 (19.2)	2,368 (25.6)		9,530 (18.6)	2,568 (23.6)	
≥80 years		Any dispensation of a generic preparation of valsartan (n=47,549; 89.0%)	Only dispensations of brand-name preparations of valsartan* (n=5,857; 11.0%)	SD	Any dispensation of a generic preparation of valsartan (n=27,006; 84.2%)	Only dispensations of brand-name preparations of valsartan* (n=5,053; 15.8%)	SD
	Quintile 1	11,058 (23.4)	1,370 (23.5)	0.10	5,784 (21.6)	1,156 (23.0)	0.11
	Quintile 2	9,850 (20.8)	1,065 (18.3)		5,612 (20.9)	891 (17.8)	
	Quintile 3	11,413 (24.2)	1,332 (22.9)		6,452 (24.0)	1,134 (22.6)	
	Quintile 4	7,506 (15.9)	954 (16.4)		4,546 (16.9)	854 (17.0)	
	Quintile 5	7,423 (15.7)	1,106 (19.0)		4,440 (16.5)	984 (19.6)	

* Including reimport dispensations

[1] Available for n=493,040 observations, percentages are referring to observations with available data. Analysis based on the German Index of Socioeconomic Deprivation (GISD) which was categorized into pre-specified quintiles with reference to nationwide German data. Increasing quintiles indicate increasing deprivation. Education, occupation and income are the three central dimensions of the GISD [6].

Abbreviations: SD, standardized differences

at additional charges. For example, reimbursements of certain drugs are capped by reference prices which are defined by the National Association of SHI Funds for groups of comparable preparations [7]. In addition, German SHI providers may conclude rebate contracts with pharmaceutical suppliers for certain medications – in many cases involving generic preparations. Still, patients may request from their physician or pharmacist to be prescribed or dispensed a specific preparation not covered by an agreement of their provider, such as the brand-name preparation [8]. However, they will have to pay themselves for any additional costs beyond the reference price. Based on the example of valsartan, our results suggest that potential additional charges for brand-name preparations did not lead to an imbalance between brand-name and generic drug users with regard to the SES in Germany.

In conclusion, we were the first to investigate whether users of brand-name versus generic preparations in Germany differ by the SES. Our results suggest users of brand-name versus generic preparations to be comparable with regard to the SES. Our findings, thus, support the validity of the previously published results on cancer risk associated with potentially NDMA-contaminated valsartan generic exposure [1] as we provided evidence pointing towards the absence of confounding by the SES.

Notes

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Ethics statement

In Germany, the utilization of health insurance data for scientific research is regulated by the Code of Social Law. All involved health insurance providers as well as the German Federal Office for Social Security and the Senator for Health, Women and Consumer Protection in Bremen as their responsible authorities approved the use of GePaRD data for this study. Informed consent for studies based on claims data is required by law unless obtaining consent appears unacceptable and would bias results, which was the case in this study. According to the Ethics Committee of the University of Bremen studies based on GePaRD are exempt from institutional review board review.

Competing interests

All authors are working at an independent, non-profit research institute, the Leibniz Institute for Prevention Research and Epidemiology – BIPS. Unrelated to this study, BIPS occasionally conducts studies financed by the pharmaceutical industry. Almost exclusively, these are post-authorization safety studies (PASS) requested by health authorities. The design and conduct of these studies as well as the interpretation and publication are not influenced by the pharmaceutical industry. The study presented was not funded by the pharmaceutical industry and was performed in line with the ENCePP Code of Conduct.

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