

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Location/details
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	Study design details included in the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	All items included in Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Paragraphs 1 and 2 in the Introduction cover the scientific background for this study and paragraph 3 covers the rationale
Objectives	3	State specific objectives, including any prespecified hypotheses	Paragraph 2 lists the specific aims of the study
Methods			
Study design	4	Present key elements of study design early in the paper	All items included in the Methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Details of the data source are described in the <i>study design and data source</i> section of the Methods
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Specifics of sample collection, including periods of recruitment, eligibility criteria and follow-up are described in the <i>study sample collection</i> section of the Methods
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed	NA
		<i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Study outcomes (baseline demographics and comorbidities, annual all-cause healthcare resource use and annual all-cause healthcare costs) are detailed in the Methods

Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Details of methods of assessment of all variables are provided in the <i>statistical analysis</i> section of the Methods.
Bias	9	Describe any efforts to address potential sources of bias	<p>To address potential sources of bias, stringent exclusion criteria were applied to ensure that a clean cohort of NASH patients were formed, thereby preventing misclassification bias as much as possible. The exclusion criteria are detailed in Supplementary Figure 1.</p> <p>A multivariate generalized estimating equation model was conducted to account for confounding factors caused by comorbidities. Details of the multivariate analysis are provided in the <i>statistical analysis</i> section of the Methods</p> <p>To minimize prevalence bias, incident cohorts were derived for healthcare resource utilization and cost estimation.</p>
Study size	10	Explain how the study size was arrived at	Arrival at study size is described in the <i>study sample selection</i> section of the Methods. Patients aged ≥ 18 years with ≥ 1 inpatient or verified outpatient claim for diagnosis of NAFLD or NASH between January 1, 2011 and December 31, 2016 were included.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Details of the multivariable analysis (using generalized estimation equation models) are described in the <i>statistical analysis</i> section of the Methods.
Statistical methods	12	<p>(a) Describe all statistical methods, including those used to control for confounding</p> <hr/> <p>(b) Describe any methods used to examine subgroups and interactions</p>	<p>The Student's t-test and the asymptotic Pearson chi-squared test was used for the comparison of continuous and categorical variables, respectively.</p> <hr/> <p>NA</p>

(c) Explain how missing data were addressed	NA
(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	Details of how loss to follow-up was addressed are provided in the <i>study sample selection</i> section of the Methods
<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	
<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
(e) Describe any sensitivity analyses	NA

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Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Study participant numbers are described in the <i>study sample selection</i> section of the Results
		(b) Give reasons for non-participation at each stage	Patient attrition is described in the <i>sample selection</i> section of the Results
		(c) Consider use of a flow diagram	A simplified and a detailed patient attrition flowchart (figure 1 and supplementary figure 1 respectively) explaining the various exclusion criteria are provided
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Baseline demographics of study participants are fully described in the Results
		(b) Indicate number of participants with missing data for each variable of interest	Patient attrition is described in the <i>sample selection</i> section of the Results
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Follow-up details (pre vs post index) are fully described for all outcomes throughout the Results
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	Outcome data are fully detailed in the Results
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	<p>Figure 2 provides unadjusted annual all-cause healthcare cost estimates</p> <p>Figure 3 and Table 3 provide adjusted annual all-cause healthcare post-index cost estimates reporting 95% confidence intervals and odds ratios</p> <p>Common comorbidities prevalent among NASH patients were adjusted for along with age, sex, and region. Metabolic conditions like CVD, hypertension, hyperlipidemia, renal disease, type 2 diabetes</p>

mellitus are known to have a bidirectional nature with NAFLD/NASH and were therefore included.

		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Annual all-cause healthcare resource utilization and costs stratified by the presence and absence of common comorbidities are provided in the Supplementary material
Discussion			
Key results	18	Summarise key results with reference to study objectives	Key findings are summarized in paragraph 1 of the Discussion
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Limitations of the study are discussed in paragraph 5 of the Discussion
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	A cautious conclusion based on the study findings in the context of previous research is provided in paragraph 7 in the Discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	Generalisability (external validity) of the study results are discussed in paragraph 5 of the Discussion “The analyses were restricted to the InGef research database, which may not be representative of the whole German population.
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	The source of funding and the role of the funders is provided on the Title page of the article

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

Article information: <http://dx.doi.org/10.21037/atm-20-7179>

*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version.