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

Section/item	Item No	Recommendation	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 3, lines 51-53	Abstract, Paragraph 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3, lines 54-63	Abstract, Paragraphs 2-3
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 4-5, lines 78-112	Introduction, Paragraphs 3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Pages 5-6, lines 113-119	Introduction, Paragraph 5
Methods				
Study design	4	Present key elements of study design early in the paper	Pages 5-6, lines 113-119	Introduction, Paragraph 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6, lines 123-129	Materials and Methods, Patients and sample
Participants	6	(a) ***Cohort study***—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up ***Case-control study***—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 ***Cross-sectional study***—Give the eligibility criteria, and the sources and methods of selection of participants	Page 6, lines 123-129	Materials and Methods, Patients and sample collection, Paragraph 1
		(b) ***Cohort study***—For matched studies, give matching criteria and number of exposed and unexposed ***Case-control study***—For matched studies, give matching criteria and the number of controls per case	NA	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 6-10, lines 140-219	Materials and Methods, Paragraphs 2-8, Table 1
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	Pages 9-10, lines 220-242	Materials and Methods, Paragraphs 9-10, Figure 2
Bias	9	Describe any efforts to address potential sources of bias	Pages 11, 17; lines	Materials and Methods,
Study size	10	Explain how the study size was arrived at	Page 6, lines 123-129	Materials and Methods,
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 7-8,12, lines 163-168, 263-270	Materials and Methods, FISH, Paragraph 3;

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pages 11-12,lines 243-280	Materials and Methods,
		(b) Describe any methods used to examine subgroups and interactions	Pages 11-12,lines 243-280	Materials and Methods,
		(c) Explain how missing data were addressed	Page 6, lines 123-129	Materials and Methods,
		(d) ***Cohort study***—If applicable, explain how loss to follow-up was addressed ***Case-control study***—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study***—If applicable, describe analytical methods taking account of sampling strategy	NA	
		(e) Describe any sensitivity analyses	Pages 10-11, lines	Materials and Methods,
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	Page 13, lines 291-306	Results, Patients, Paragraph 2, Table 1
		(b) Give reasons for non-participation at each stage	Page 6, lines 123-129	Materials and Methods,
		(c) Consider use of a flow diagram	NA	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 13, lines 291-306	Results, Patients, Paragraph 2, Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Page 6, lines 123-129	Materials and Methods,
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	Page 14, lines 318-322	Results, Survival,
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Page 14, lines 322-329	Results, Survival,
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	
		Cross-sectional study—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	Page 14, lines 330-345	Results, Survival, Paragraphs 6-7, Figure 4
		(b) Report category boundaries when continuous variables were categorized	Page 12, lines 262-270	Materials and Methods,
		(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	Pages 12-13, lines	Results, Verification,
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 16, lines 356-361,	Discussion, Paragraphs
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	Page 16, lines 354-361	Discussion, Paragraph 1

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 15-19, lines 346-431	Discussion, Paragraphs 1-4
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 19, lines 432-436	Conclusion
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	Page 20, lines 439-445	Funding

*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.

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*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. In this case, the section/paragraph may be used as an alternative reference.