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	Page1/Line5-6	Title
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page2/Line10-30	Abstract/Paragraph2-3
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page3/Line13-Page4/Line9	Introduction/Paragraph 1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page4/Line9-12	Introduction/Paragraph 2
Methods				
Study design	4	Present key elements of study design early in the paper	Page4/Line19	Methods/Paragraph1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page4/Line19-22	Methods/Paragraph1
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	Page4/Line22-Page5/Line2	Methods/Paragraph1
		(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	Page6/Line10-13	Baseline patient characteristics/Paragraph1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page5/Line3-7	Methods/Paragraph1
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	Page5/Line16-22	Methods/Paragraph2
Bias	9	Describe any efforts to address potential sources of bias	Page5/Line29-30	Methods/Paragraph3
Study size	10	Explain how the study size was arrived at	Page6/Line8-14	Baseline patient characteristics/Paragraph1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page5/Line16-22	Methods/Paragraph3

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page5/Line26-Page6/Line2	Methods/Paragraph3
		(b) Describe any methods used to examine subgroups and interactions	N/A(not involved)	N/A(not involved)
		(c) Explain how missing data were addressed	N/A(no missing data)	N/A(no missing data)
		(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	Page5/Line18-21	Methods/Paragraph2
		(e) Describe any sensitivity analyses	Page6/Line1-2	Methods/Paragraph3
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	Page6/Line9-13	Baseline patient characteristics/Paragraph1
		(b) Give reasons for non-participation at each stage	Page6/Line8-10	Baseline patient characteristics/Paragraph1
		(c) Consider use of a flow diagram	Figure 1	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page6/Line15-32	Baseline patient characteristics/Paragraph1
		(b) Indicate number of participants with missing data for each variable of interest	N/A(no missing data)	N/A(no missing data)
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	Page7/Line27	PFS and OS/Paragraph1
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Page6/Line10-14	Baseline patient characteristics/Paragraph1
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N/A(no Case-control study)	N/A(no case-control study)
		Cross-sectional study—Report numbers of outcome events or summary measures	N/A(Cross-sectional study)	N/A(cross-sectional study)
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	Page7/Line27-Page8/Line23	PFS and OS/Paragraph1-4
		(b) Report category boundaries when continuous variables were categorized	N/A(not involved)	N/A(not involved)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A(Not applicable)	N/A(Not applicable)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page8/Line26,32-Page9/Line1,15-19,24-32	Efficacy/Paragraph12, Safety/Paragraph1
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page9/Line17-22	Discussion/Paragraph1
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	Page11/Line17-22	Discussion/Paragraph7

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page9/Line23-Page11/Line16	Discussion/Paragraph2-6
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page11/Line26-30	Conclusions/Paragraph1
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	Page12/Line4-8	Funding/Paragraph1

*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.