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 2, line 54	Abstract/ para 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2, lines 54 – 68	Abstract/ para 2-3
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3-4, lines 89-120	Background/ para 1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4, lines 122-127	Background/ para 4
Methods				
Study design	4	Present key elements of study design early in the paper	Page 5-7, lines 132-134, 141-147, 150-153, 163-166, 176-181, 184-190, 192-193	Methods/ para 1-3, 5-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, lines 132-139	Methods/ para 1
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	Page 5, lines 132-138 & 147	Methods/ para 1 & 2
		(b) ***Cohort study***—For matched studies, give matching criteria and number of exposed and unexposed	Page 7, lines 183-190	Methods/ para 7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 & 7 & 8, lines 141-147, 184-185 & 189-190, 214-215	Methods/ para 2, 7 & 9

Data sources/ measureme	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 5-8, lines 141-143, 150-153, 163-166, 168-181, 192-207	Methods/ para 2, 3, 5, 6& 8
Bias	9	Describe any efforts to address potential sources of bias	Not applicable – 100 serial patients were followed with the stated exclusions (page 5, lines 134-138), no specific adjustments for bias occurred	
Study size	10	Explain how the study size was arrived at	Page 5, lines 132-133	Methods/ para 1
Quantitat ive variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8, lines 210-215	Methods/ para 8

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 5, 7 & 8, lines 150-151, 178-181, 184-190, 192-207, 210-215	Methods/ para 3 & 6-9
		(b) Describe any methods used to examine subgroups and interactions	Page 7 & 8, lines 184-190, 192-207	Methods/ para 7 & 8
		(c) Explain how missing data were addressed	N/A; as a prospective observation study, we did not have 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	N/A, there was no loss to follow-up	
		(e) Describe any sensitivity analyses	N/A, we did not perform sensitivity analysis	
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 8, lines 221-223	Results/ para 1
		(b) Give reasons for non-participation at each stage	Page 8, lines 221-223	Results/ para 1

		(c) Consider use of a flow diagram	N/A – with 100 consecutive patients and the noted exclusions without losses to follow-up, the value of a flow diagram was felt to be limited	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9, lines 225-230	Results/ para 2
		(b) Indicate number of participants with missing data for each variable of interest	N/A – no missing data for variables of interest	
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	N/A – no follow-up	
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Page 9 & 10, lines 239 (Table1), 244-249	Results/ para 3, 4
		Case-control study—Report numbers in each exposure category, or summary measures of		
		Cross-sectional study—Report numbers of outcome events or summary measures		
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 9-10, lines 232-237, 245-249, 252-258, 260-265	Results/ para 2, 3, 5, 6, 7
		(b) Report category boundaries when continuous variables were categorized	Page 5, lines 152-153	Methods/ para 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful		
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 10 & 11, lines 268-278, 281-290	Results/ para 8& 9
Discussion				

Key results	18	Summarise key results with reference to study objectives	Page 13-16, lines 321-328, 338-342, 344-359, 361-368, 370-375, 377-383, 385-392	Conclusions/ para 4, 6-11
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 402-413	Conclusions/para 13

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 14-16, lines 338-342, 361-368, 394-400	Conclusion/ para 6, 8, 12
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 17, lines 415-425	Conclusion/ Para 14
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	N/A, no 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.