STROCSS 2021: Strengthening the reporting of cohort, cross-sectional and case-control studies in surgery

Item no.	Item description	Reported on Page Number/Line Number	Reported on Section/Paragraph
TITLE			
1	**Title**		
	- The word cohort or cross-sectional or case-control is included*	NA	NA
	- Temporal design of study is stated (e.g. retrospective or prospective)	NA	NA
	- The focus of the research study is mentioned (e.g. population, setting, disease, exposure/intervention, outcome etc.)	NA	NA
ABSTRACT			
2a	**Introduction** – briefly describe:		
	- Background	1/31-40	Introduction/1
	- Scientific rationale for this study	1/35-39	Introduction/1
	- Aims and objectives	1/39-40	Introduction/1
2b	**Methods** - briefly describe:		
	- Type of study design (e.g. cohort, case-control, cross-sectional etc.)	1/41-46	Methods/1
	- Other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.)	1/41-46	Methods/1
	- Patient populations and/or groups, including control group, if applicable	1/41-46	Methods/1
	- Exposure/interventions (e.g. type, operators, recipients, timeframes etc.)	1/41-46	Methods/1
	- Outcome measures – state primary and secondary outcome(s)	1/41-46	Methods/1
2c	**Results** - briefly describe:		
	- Summary data with qualitative descriptions and statistical relevance, where appropriate	41/47-56	Results/1
2d	**Conclusion** - briefly describe:		
	- Key conclusions	1/57-58	Conclusion /1
	- Implications for clinical practice	1/57-58	Conclusion /1
	- Need for and direction of future research	1/57-58	Conclusion /1

INTRODUCTION			
3	**Introduction** – comprehensively describe:		
	- Relevant background and scientific rationale for study with reference to key literature	3/65-119	Introduction/1-3
	- Research question and hypotheses, where appropriate	4/65-100	Introduction/2
	- Aims and objectives	5/113-119	Introduction/3
METHODS			
4a	**Registration**		
	- In accordance with the Declaration of Helsinki#, state the research registration number and where it was registered, with a hyperlink to the registry entry (this can be obtained from ResearchRegistry.com, ClinicalTrials.gov, ISRCTN etc.)	5-6/122-128	Method/1
	- All retrospective studies should be registered before submission; it should be stated that the research was retrospectively registered	5-6/122-128	Method/1
4b	**Ethical approval**		
	- Reason(s) why ethical approval was needed	5-6/122-128	Method/1
	- Name of body giving ethical approval and approval number	5-6/124-125	Method/1
	- Where ethical approval wasn't necessary, reason(s) are provided	5-6/123-125	Method/1
4c	**Protocol**		
	- Give details of protocol (*a priori* or otherwise) including how to access it (e.g. web address, protocol registration number etc.)	NA	NA
	- If published in a journal, cite and provide full reference	NA	NA
4d	**Patient and public involvement in research**		
	- Declare any patient and public involvement in research	7/159-165	Method/3
	- State the stages of the research process where patients and the public were involved (e.g. patient recruitment, defining research outcomes, dissemination of results etc.) and describe the extent to which they were involved.	7/159-165	Method/3
5a	**Study design**		
	- State type of study design used (e.g. cohort, cross-sectional, case-control etc.)	7/130-142	Method/4
	- Describe other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.)	7/130-142	Method/4

5b	**Setting and timeframe of research** – comprehensively describe:		
	- Geographical location	5-6/122-128	Method/1
	- Nature of institution (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.)	5-6/124-125	Method/1
	- Dates (e.g. recruitment, exposure, follow-up, data collection etc.)	5-6/122-128	Method/1
5c	**Study groups**		
	- Total number of participants	9/241-242	Result/1
	- Number of groups	8/195-207	Method/6
	- Detail exposure/interventionallocated to each group	8/188-207	Method/5-6
	- Number of participants in each group	8/188-207	Method/5-6
5d	**Subgroup analysis** – comprehensively describe:		
	- Planned subgroup analyses	10-11/271-281	Result/5
	- Methods used to examine subgroups and their interactions	10-11/271-281	Result/5
6a	**Participants** – comprehensively describe:		
	- Inclusion and exclusion criteria with clear definitions	7/166-174	Method/3
	- Sources of recruitment (e.g. physician referral, study website, social media, posters etc.)	6/130-142	Method/2
	- Length, frequency and methods of follow-up (e.g. mail, telephone etc.)	NA	NA
6b	**Recruitment** – comprehensively describe:		
	- Methods of recruitment to each patient group (e.g. all at once, in batches, continuously till desired sample size is reached etc.)	8/188-207	Method/6-7
	- Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided	NA	NA
	- Nature of informed consent (e.g. written, verbal etc.)	NA	NA
	- Period of recruitment	NA	NA
6c	**Sample size** – comprehensively describe:		
	- Analysis to determine optimal sample size for study accounting for population/effect size	NA	NA
	- Power calculations, where appropriate	NA	NA
	- Margin of error calculation	NA	NA

METHODS - INTERVENTION AND CONSIDERATIONS			
7a	**Pre-intervention considerations** – comprehensively describe:		
	- Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.)	6-7/130-157	Method/2
	- Pre-intervention treatment (e.g. medication review, bowel preparation, correcting hypothermia/-volemia/-tension, mitigating bleeding risk, ICU care etc.)	6-7/130-157	Method/2
7b	**Intervention** – comprehensively describe:		
	- Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.)	8/188-207	Method/5-6
	- Aim of intervention (preventative/therapeutic)	7-8/176-186	Method/4
	- Concurrent treatments (e.g. antibiotics, analgesia, antiemetics, VTE prophylaxis etc.)	NA	NA
	- Manufacturer and model details, where applicable	NA	NA
7c	**Intra-intervention considerations** – comprehensively describe:		
	- Details pertaining to administration of intervention (e.g. anaesthetic, positioning, location, preparation, equipment needed, devices, sutures, operative techniques, operative time etc.)	8/188-207	Method/5-6
	- Details of pharmacological therapies used, including formulation, dosages, routes, and durations	8/188-207	Method/5-6
	- Figures and other media are used to illustrate	NA	NA
7d	**Operator details** – comprehensively describe:		
	- Requirement for additional training	NA	NA
	- Learning curve for technique	NA	NA
	- Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually)	NA	NA
7e	**Quality control** – comprehensively describe:		
	- Measures taken to reduce inter-operator variability	NA	NA
	- Measures taken to ensure consistency in other aspects of intervention delivery	NA	NA
	- Measures taken to ensure quality in intervention delivery	NA	NA
7f	**Post-intervention considerations** – comprehensively describe:		
	- Post-operative instructions (e.g. avoid heavy lifting) and care	NA	NA
	- Follow-up measures	NA	NA
	- Future surveillance requirements (e.g. blood tests, imaging etc.)	NA	NA

8	**Outcomes** – comprehensively describe:		
	- Primary outcomes, including validation, where applicable	6/177	Method/4
	- Secondary outcomes, where appropriate	6//177-178	Method/4
	- Definition of outcomes	6-7/143-157	Method/2
	- If any validated outcome measurement tools are used, give full reference	NA	NA
	- Follow-up period for outcome assessment, divided by group	NA	NA
9	**Statistics** – comprehensively describe:		
	- Statistical tests and statistical package(s)/software used	8-9/209-238	Statistics/1-2
	- Confounders and their control, if known	8-9/209-238	Statistics/2
	- Analysis approach (e.g. intention to treat/per protocol)	8-9/209-238	Statistics/2
	- Any sub-group analyses	8-9/225-229	Statistics/2
	- Level of statistical significance	8-9/209-238	Statistics/2
RESULTS			
10a	**Participants** – comprehensively describe:		
	- Flow of participants (recruitment, non-participation, crossover and withdrawal, with reasons). Use figure to illustrate.	NA	NA
	- Population demographics (e.g. age, gender, relevant socioeconomic features, prognostic features etc.)	9-10/241-246	Result/1
	- Any significant numerical differences should be highlighted	NA	NA
10b	**Participant comparison**		
	- Include table comparing baseline characteristics of cohort groups	10/271-281	Result/5
	- Give differences, with statistical relevance	NA	NA
	- Describe any group matching, with methods	NA	NA
10c	**Intervention** – comprehensively describe:		
	- Degree of novelty of intervention	NA	NA
	- Learning required for interventions	NA	NA
	- Any changes to interventions, with rationale and diagram, if appropriate	NA	NA

11a	**Outcomes** – comprehensively describe:		
	- Clinician-assessed and patient-reported outcomes for each group	9-11/241-281	Result/1-5
	- Relevant photographs and imaging are desirable	9-11/241-281	Result/1-5
	- Any confounding factors and state which ones are adjusted	9-11/241-281	Result/1-5
11b	**Tolerance** – comprehensively describe:		
	- Assessment of tolerability of exposure/intervention	NA	NA
	- Cross-over with explanation	NA	NA
	- Loss to follow-up (fraction and percentage), with reasons	NA	NA
11c	**Complications** – comprehensively describe:		
	- Adverse events and classify according to Clavien-Dindo classification†	NA	NA
	- Timing of adverse events	NA	NA
	- Mitigation for adverse events (e.g. blood transfusion, wound care, revision surgery etc.)	NA	NA
12	**Key results** – comprehensively describe:		
	- Key results with relevant raw data	10/248-253	Result/2
	- Statistical analyses with significance	10/255-269	Result/3-4
	- Include table showing research findings and statistical analyses with significance	10/248-253	Result/2
DISCUSSION			
13	**Discussion** – comprehensively describe:		
	- Conclusions and rationale	11/284-289	Discussion /1
	- Reference to relevant literature	14-16/373-448	Reference/1
	- Implications for clinical practice	11-13/290-350	Discussion /2-5
	- Comparison to current gold standard of care	NA	NA
	- Relevant hypothesis generation	11-13/290-350	Discussion /2-5

14	**Strengths and limitations** – comprehensively describe:		
	- Strengths of the study	12-13/325-341	Discussion /4
	- Weaknesses and limitations of the study and potential impact on results and their interpretation	13/342-350	Discussion /5
	- Assessment and management of bias	NA	NA
	- Deviations from protocol, with reasons	NA	NA
15	**Relevance and implications** – comprehensively describe:		
	- Relevance of findings and potential implications for clinical practice	12-13/325-341	Discussion /4
	- Need for and direction of future research, with optimal study designs mentioned	13/342-350	Discussion /5
CONCLUSION			
16	**Conclusions**		
	- Summarise key conclusions	13/352-358	Conclusions/1
	- Outline key directions for future research	13/352-358	Conclusions/1
DECLARATIONS			
17a	**Conflicts of interest**		
	- Conflicts of interest, if any, are described	14/367	Footnote/1
17b	**Funding**		
	- Sources of funding (e.g. grant details), if any, are clearly stated	13/360-362	Acknowledgments/1
	- Role of funder	13/360-362	Acknowledgments/1
17c	**Contributorship**		
	- Acknowledge patient and public involvement in research; report the extent of involvement of each contributor	1-2/25-29	Contributorship/1

* STROCSS 2021 guidelines apply to cohort studies as well as other observational studies (e.g. cross-sectional, case-control etc.).

"*Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject*".

† Dindo D, Demartines N, Clavien P-A. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. 2004; 240(2): 205-213.

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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.