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| The STROCSS 2019 Guideline |
| Item no. | **Item description** | **Page** |
| TITLE |
| 1 | Title:* The word cohort or cross-sectional or case-controlled is included
* The area of focus is described (e.g. disease, exposure/intervention, outcome)
* Key elements of study design are stated (e.g. retrospective or prospective)
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| ABSTRACT |
| 2a | Introduction: the following points are briefly described* Background
* Scientific Rationale for this study
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| 2b | Methods: the following areas are briefly described* Study design (cohort, retro-/prospective, single/multi-centred)
* Patient populations and/or groups, including control group, if applicable
* Interventions (type, operators, recipients, timeframes)
* Outcome measures
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| 2c | Results: the following areas are briefly described* Summary data (with statistical relevance) with qualitative descriptions, where appropriate
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| 2d | Conclusion: the following areas are briefly described* Key conclusions
* Implications to practice
* Direction of and need for future research
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| INTRODUCTION |
| 3 | Introduction: the following areas are described in full* Relevant background and scientific rationale
* Aims and objectives
* Research question and hypotheses, where appropriate
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| METHODS |
| 4a | Registration and ethics * Research Registry number is stated, in accordance with the declaration of Helsinki\*
* All studies (including retrospective) should be registered before submission

\*"*Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject*" (this can be obtained from: ResearchRegistry.com or ClinicalTrials.gov or ISRCTN) |  |
| 4b | Ethical Approval: the following areas are described in full* Necessity for ethical approval
* Ethical approval, with relevant judgement reference from ethics committees
* Where ethics was unnecessary, reasons are provided
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| 4c | Protocol: the following areas are described comprehensively* Protocol (*a priori* or otherwise) details, with access directions
* If published, journal mentioned with the reference provided
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| 4d | Patient Involvement in Research* Describe how, if at all, patients were involved in study design e.g. were they involved on the study steering committee, did they provide input on outcome selection, etc.
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| 5a | Study Design: the following areas are described comprehensively* ‘Cohort’ study is mentioned
* Design (e.g. retro-/prospective, single/multi-centred)
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| 5b | Setting: the following areas are described comprehensively* Geographical location
* Nature of institution (e.g. academic/community, public/private)
* Dates (recruitment, exposure, follow-up, data collection)
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| 5c | Cohort Groups: the following areas are described in full* Number of groups
* Division of intervention between groups
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| 5d | Subgroup Analysis: the following areas are described comprehensively* Planned subgroup analyses
* Methods used to examine subgroups and their interactions
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| 6a | Participants: the following areas are described comprehensively* Eligibility criteria
* Recruitment sources
* Length and methods of follow-up
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| 6b | Recruitment: the following areas are described comprehensively* Methods of recruitment to each patient group
* Period of recruitment
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| 6c | Sample Size: the following areas are described comprehensively* Margin of error calculation
* Analysis to determine study population
* Power calculations, where appropriate
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| INTERVENTION AND CONSIDERATIONS |
| 7a | Pre-intervention Considerations: the following areas are described comprehensively* Patient optimisation (pre-surgical measures)
* Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications)
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| 7b | Intervention: the following areas are described comprehensively* Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological)
* Aim of intervention (preventative/therapeutic)
* Concurrent treatments (antibiotics, analgaesia, anti-emetics, NBM, VTE prophylaxis)
* Manufacturer and model details where applicable
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| 7c | Intra-Intervention Considerations: the following areas are described comprehensively* Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time)
* Pharmacological therapies include formulation, dosages, routes and durations
* Figures and other media are used to illustrate
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| 7d | Operator Details: the following areas are described comprehensively* Training needed
* Learning curve for technique
* Specialisation and relevant training
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| 7e | Quality Control: the following areas are described comprehensively* Measures taken to reduce variation
* Measures taken to ensure quality and consistency in intervention delivery
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| 7f | Post-Intervention Considerations: the following areas are described comprehensively* Post-operative instructions and care
* Follow-up measures
* Future surveillance requirements (e.g. imaging, blood tests)
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| 8 | Outcomes: the following areas are described comprehensively* Primary outcomes, including validation, where applicable
* Definitions of outcomes
* Secondary outcomes, where appropriate
* Follow-up period for outcome assessment, divided by group
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| 9 | Statistics: the following areas are described comprehensively* Statistical tests, packages/software used, and interpretation of significance
* Confounders and their control, if known
* Analysis approach (e.g. intention to treat/per protocol)
* Sub-group analysis, if any
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| RESULTS |
| 10a | Participants: the following areas are described comprehensively* Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons)
* Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences)
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| 10b | Participant Comparison: the following areas are described comprehensively* Table comparing demographics included
* Differences, with statistical relevance
* Any group matching, with methods
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| 10c | Intervention: the following areas are described comprehensively* Changes to interventions, with rationale and diagram, if appropriate
* Learning required for interventions
* Degree of novelty for intervention
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| 11a | Outcomes: the following areas are described comprehensively* Clinician-assessed and patient-reported outcomes for each group
* Relevant photographs and imaging are desirable
* Confounders to outcomes and which are adjusted
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| 11b | Tolerance: the following areas are described comprehensively* Assessment of tolerance
* Loss to follow up, with reasons (percentage and fraction)
* Cross-over with explanation
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| 11c | Complications: the following areas are described comprehensively* Adverse events described
* Classified according to Clavien-Dindo classification\*
* Mitigation for adverse events (blood loss, wound care, revision surgery should be specified)

\*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 |  |
| 12 | Key Results: the following areas are described comprehensively* Key results, including relevant raw data
* Statistical analyses with significance
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| DISCUSSION |
| 13 | Discussion: the following areas are described comprehensively* Conclusions and rationale
* Reference to relevant literature
* Implications to clinical practice
* Comparison to current gold standard of care
* Relevant hypothesis generation
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| 14 | Strengths and Limitations: the following areas are described comprehensively* Strengths of the study
* Limitations and potential impact on results
* Assessment of bias and management
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| 15 | Implications and Relevance: the following areas are described comprehensively* Relevance of findings and potential implications to clinical practice are detailed
* Future research that is needed is described, with study designs detailed
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| CONCLUSION |
| 16 | Conclusions:* Key conclusions are summarised
* Key directions for future research are summarised
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| DECLARATIONS |
| 17a | Conflicts of interest* Conflicts of interest, if any, are described
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| 17b | Funding* Sources of funding (e.g. grant details), if any, are clearly stated
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