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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) |  |
| ABSTRACT | | |
| 2a | Introduction: the following points are briefly described   * Background * Scientific Rationale for this study |  |
| 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 |  |
| 2c | Results: the following areas are briefly described   * Summary data (with statistical relevance) with qualitative descriptions, where appropriate |  |
| 2d | Conclusion: the following areas are briefly described   * Key conclusions * Implications to practice * Direction of and need for future research |  |
| INTRODUCTION | | |
| 3 | Introduction: the following areas are described in full   * Relevant background and scientific rationale * Aims and objectives * Research question and hypotheses, where appropriate |  |
| 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 |  |
| 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 |  |
| 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. |  |
| 5a | Study Design: the following areas are described comprehensively   * ‘Cohort’ study is mentioned * Design (e.g. retro-/prospective, single/multi-centred) |  |
| 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) |  |
| 5c | Cohort Groups: the following areas are described in full   * Number of groups * Division of intervention between groups |  |
| 5d | Subgroup Analysis: the following areas are described comprehensively   * Planned subgroup analyses * Methods used to examine subgroups and their interactions |  |
| 6a | Participants: the following areas are described comprehensively   * Eligibility criteria * Recruitment sources * Length and methods of follow-up |  |
| 6b | Recruitment: the following areas are described comprehensively   * Methods of recruitment to each patient group * Period of recruitment |  |
| 6c | Sample Size: the following areas are described comprehensively   * Margin of error calculation * Analysis to determine study population * Power calculations, where appropriate |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 7d | Operator Details: the following areas are described comprehensively   * Training needed * Learning curve for technique * Specialisation and relevant training |  |
| 7e | Quality Control: the following areas are described comprehensively   * Measures taken to reduce variation * Measures taken to ensure quality and consistency in intervention delivery |  |
| 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) |  |
| 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 |  |
| 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 |  |
| 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) |  |
| 10b | Participant Comparison: the following areas are described comprehensively   * Table comparing demographics included * Differences, with statistical relevance * Any group matching, with methods |  |
| 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 |  |
| 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 |  |
| 11b | Tolerance: the following areas are described comprehensively   * Assessment of tolerance * Loss to follow up, with reasons (percentage and fraction) * Cross-over with explanation |  |
| 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 |  |
| 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 |  |
| 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 |  |
| 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 |  |
| CONCLUSION | | |
| 16 | Conclusions:   * Key conclusions are summarised * Key directions for future research are summarised |  |
| DECLARATIONS | | |
| 17a | Conflicts of interest   * Conflicts of interest, if any, are described |  |
| 17b | Funding   * Sources of funding (e.g. grant details), if any, are clearly stated |  |