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| **TITLE** | 1 | - 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, analgesia, 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)


### 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

### Strengths and Limitations: the following areas are described comprehensively
#### 14
- Strengths of the study
- Limitations and potential impact on results
- Assessment of bias and management

### Implications and Relevance: the following areas are described comprehensively
#### 15
- 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