PROCESS 2023 guidelines		
Topic	**Item**	**Item description**
Title	**1**	● The phrase 'case series' is included ● The focus of the research study is mentioned (e.g. patient population, setting, diagnosis, intervention, outcome etc.)
Key Words	**2**	● Include three to six keywords that identify what is covered in the case series (e.g. patient population, setting, diagnosis, intervention, outcome etc.) ● Include 'case series' as one of the keywords ● Include the surgical subspecialty the case series pertains to as a keyword
Abstract	**3a**	Introduction – briefly describe: ● Background ● Scientific rationale for this study ● Overarching theme of the case series ● Aims and objectives
	3b	Methods – briefly describe: ● Sample size ● Timeframe of research ● Characteristics of study design (e.g. prospective/retrospective, single-/multi-centre, informal/formal, consecutive/non-consecutive, exposure-/outcome-based sampling, clinical/population-based etc.) ● Inclusion and exclusion criteria
	3c	Results – briefly describe: ● Outcomes of the intervention/management strategy ● Analysis - narrative or statistical (report any statistical testing, although mostly inappropriate in case series studies)

	3d	Conclusion – briefly describe: ● Key findings and take-home messages ● Impact on future clinical practice ● Direction of future research
	3e	Present a structured abstract ● Informal case series – introduction, case presentations (brief description of each case) and discussion/conclusion ● Formal case series – introduction, methods, results and discussion/conclusion
Highlights	**4**	● Convey the key findings of the research study in 3 to 5 bullet points
Introduction	**5**	Introduction – comprehensively describe: ● Relevant background and scientific rationale for case series with reference to key scientific literature ● Overarching theme (e.g. common patient population, setting, diagnosis, intervention, outcome etc.) ● Aims and objectives
Methods	**6a**	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.) ● All retrospective studies should be registered before submission; it should be stated that the research was retrospectively registered **"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject"*

	6b	Protocol ● If a protocol exists, state the corresponding registration number and access directions (e.g. website or journal, and include a hyperlink that is publicly accessible) ● It must be written in the English language
	6c	Ethical approval ● State whether ethical approval was needed or not, with reason(s) ● If appropriate, state name of body giving ethical approval and approval number
	6d	Study design ● State that the study is a case series ● Describe key characteristics of study design (e.g. prospective/retrospective, single-/multi-centre, informal/formal, consecutive/non-consecutive, exposure-/outcome-based sampling, clinical/population-based etc.)
	6e	Setting and timeframe – comprehensively describe: ● Geographical location ● Nature of setting(s) where the patient was managed (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.) ● Volume of similar cases presenting to the institution ● Relevant dates (e.g. recruitment, intervention, follow-up, data collection etc.)

	6f	Participants – comprehensively describe: ● Relevant participant characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants (e.g. COVID-19) ● Subsequent inclusion and exclusion criteria with clear definitions ● Approach to selecting patients (e.g. consecutive/non-consecutive, exposure-/outcome-based, formal/informal etc.) ● Methods used to ensure de-identification of patient information
	6g	Recruitment – comprehensively describe: ● Sources of recruitment (e.g. physician referral, electronic health record etc.) ● Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided
	6h	Pre-intervention patient optimisation: ● Lifestyle (e.g. weight loss, nutritional support, exercise, smoking cessation etc.) ● Medication review (e.g. anticoagulation, oral hypoglycemics, insulin, oral contraceptive pill etc.) ● Pre-surgical stabilisation/preparation (e.g. treating hypothermia/-volemia/-tension, ICU care, nil by mouth, bowel preparation etc.) ● Other (e.g. psychological support, pre-operative education/counselling etc.)

	6i	Interventions – comprehensively describe: ● Type of intervention (e.g. pharmacological, surgical, physiotherapy, psychological etc.) ● Aim of intervention (preventative/therapeutic) ● Concurrent treatments (e.g. antibiotics, analgesia, antiemetics, venous thromboembolism prophylaxis etc.)
	6j	Intervention specifics – comprehensively describe: ● Rationale for the treatment offered ● Techniques involved in the administration of the intervention ● Time to intervention ● For pharmacological therapies, include details such as formulation, dosage, strength, route and duration ● For surgical intervention, include details on anaesthesia, patient positioning, preparation used, equipment needed, devices, sutures, surgical stage etc. ● Degree of novelty of surgical technique/device (e.g. 'first in human' or 'first in this context') ● Manufacturer and model of any medical devices used
	6k	Operator details – comprehensively describe: ● Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually, independent, needs direct/indirect supervision etc.) ● Learning curve for technique ● Requirement for additional training ● Collaboration with other specialities (e.g. hybrid cardiac surgery)

	6l	Quality control – comprehensively describe: ● Measures taken to reduce inter- or intra-operator/operation variation, ensure quality and maintain consistency between cases (e.g. independent observers, lymph node counts, standard surgical technique etc.) ● Any specific disparities between cases
	6m	Post-operative care and follow-up – comprehensively describe: ● Post-operative care (e.g. patient education, post-operative medications, early mobilisation, targeted physiotherapy, early enteral nutrition, early removal of catheters/drains, psychological therapy etc.) ● Follow-up timeframes (e.g. first follow-up post-discharge, follow-up duration at the time of submission etc.) and frequency ● Follow-up setting (e.g. home via phone/video consultation, primary care, secondary care etc.) ● Follow-up method (e.g. history, clinical examination, blood tests, imaging etc.) ● Follow-up personnel (e.g. operating surgeon) ● Any specific long-term surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair, clinical/ultrasound examination of regional lymph nodes for skin cancer etc.) ● State if any participants were lost to follow-up and why

	6n	Analysis ● Narrative or statistical (report any statistical testing, although mostly inappropriate in case series studies)
Results	**7a**	Participants – comprehensively describe: ● Number of patients involved ● Patient characteristics (e.g. demographics, comorbidities, ASA score, severity of surgery, urgency of surgery, smoking status, tumour staging etc.) and if relevant, exposure(s) of the participants (e.g. COVID-19) ● Include table showing baseline patient characteristics
	7b	Deviation from the initial management plan – comprehensively describe: ● Any changes to the planned intervention with rationale ● If appropriate, include a suitable schematic diagram
	7c	Outcomes and follow-up – comprehensively describe: ● Expected versus attained clinician assessed outcome, providing reference to scientific literature used to inform expected outcomes (e.g. core outcome set) ● If appropriate, include patient-reported outcomes (e.g. quality-of-life) ● Use of validated outcome measures ● Time of outcome occurrence ● Percentage of patients lost to follow-up with rationale

	7d	Intervention adherence and compliance – comprehensively describe: ● Assessment of patient's adherence and tolerability of intervention and post-operative instructions (e.g. avoiding heavy lifting/strenuous activity, tolerance of chemotherapy/pharmacological agents etc.) ● Impact on long-term applicability of intervention in clinical practice

	7e	Complications and adverse events – comprehensively describe: ● Precautionary measures taken to prevent complications (e.g. antibiotic/venous thromboembolism prophylaxis) ● Complications and adverse events (e.g. blood loss, wound infection, deep vein thrombosis, pulmonary embolism etc.), categorised in accordance with the Clavien-Dindo classification ● Timing of adverse events ● Mitigation for adverse events (e.g. blood transfusion, wound care, re-exploration/revision surgery etc.) ● If relevant, whether complications or adverse events were discussed locally (e.g. morbidity and mortality meetings) ● If appropriate, whether complications or adverse events were reported to the relevant national agency or pharmaceutical company ● Specify time to discharge following completion of intervention and whether this was within the expected timeframe or not (if not, why not) ● Where applicable, specify the 30-day post-operative and long-term morbidity/mortality ● State if there were no complications or adverse events

Discussion	**8a**	Key results – comprehensively describe: ● Key results ● Include table showing key results
	8b	Scientific context and implications – comprehensively describe: ● Relevant literature and if appropriate, similar published studies ● Implications for clinical practice and guidelines (e.g. NICE) ● Comparison to current gold standard of care ● Relevant hypothesis generation
	8c	Strengths – comprehensively describe: ● Strengths of the study ● Any multidisciplinary or cross-speciality relevance
	8d	Weaknesses and limitations – comprehensively describe: ● Weaknesses and limitations of the study, with potential impact on results and their interpretation ● Deviations from protocol, with reasons ● For novel techniques or devices, outline any contraindications/alternatives and potential risks/complications if applied to a larger population

	8e	Directions for future research – comprehensively describe: ● Impact on future research and clinical practice ● Questions that have arisen as a result of the study ● Alternative study design(s) best suited to address these questions
	8f	Cost – comprehensively describe: ● Economic implication(s) ● Justify cost if intervention more expensive than current gold standard of care ● Any cheaper alternatives
Conclusions	**9a**	Key conclusions ● Outline the key conclusions from this study
	9b	Rationale ● Explain the rationale behind those conclusions
	9c	Future work – briefly describe: ● Any questions arisen from the study ● Any differences in approach to patient diagnosis or management which authors might adopt in future similar studies
Patient and/or Carer Perspective	**10**	● Where appropriate, the patient(s)/carers(s) should be given the opportunity to share their perspective on the intervention(s) they received (e.g. sharing quotes from a consented, anonymised interview or questionnaire)

Informed Consent	**11**	● The authors must provide evidence of consent, where applicable, and if requested by the journal ● State the method of consent at the end of the article (e.g. verbal or written) ● If not provided by the patients, explain why (e.g. death of patient and consent provided by next of kin). If the patients or family members were untraceable then document the tracing efforts undertaken.
Additional Information	**12a**	● State any conflicts of interest
	12b	● State any sources of funding (e.g. grant details) ● Role of funder
	12c	Other relevant disclosures ● State any author contributions and acknowledgments ● If appropriate, give details of institutional review board and ethical committee approval ● Disclose whether the case has been presented at a conference or regional meeting
Clinical Images and Videos	**13**	● Where relevant and available, include clinical images to help demonstrate the cases pre-, peri- and post-intervention (e.g. radiological, histopathological, patient photographs, intraoperative images etc.) ● Where relevant and available, include a link (e.g. Google Drive, YouTube etc.) to the narrated operative video to highlight specific techniques or operative findings ● Ensure all media files are appropriately captioned and indicate points of interest to allow for easy interpretation

Referencing the Checklist	**14**	• Include reference to the PROCESS 2023 publication by stating: 'This case series has been reported in line with the PROCESS Guideline' at the end of the methods section and include citation in the references section