PROCESS Checklist

Section/Topic	Item No	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	1	The words “case series” and the area of focus should appear in the title (e.g. disease, exposure/intervention or outcome).	Page 1/Line 1-3	Title
Abstract	2a	Introduction - what is the unifying theme of the case series.	Page 2, Line 2-3	Abstract/Paragraph 1
	2b	Methods - describe what was done, how and when was it done and by whom.	Page 2, Line 8-14	Abstract/Paragraph 2
	2c	Results - what was found.	Page 2, Line 15-23	Abstract/Paragraph 3
	2d	Conclusion - what have we learned and what does it mean	Page 2, Line 24-27	Abstract/Paragraph 4
Introduction	**3**	Explain the scientific background and rationale for the case series. What is the unifying theme - common disease, exposure, intervention and outcome, etc. Why is this study needed?	Page 3	Introduction/Paragraph 1-2
Methods	4a	Registration and ethics - state the research registry number in accordance with the declaration of Helsinki - "Every research study involving human subjects must be registered in a publicly accessible database" (this can be obtained from; ResearchRegistry.com or ClinicalTrials.gov or ISRCTN). State whether ethical approval was needed and if so, what the relevant judgement reference was?	Page4, Line 1-7	Methods/Patient Criteria/Paragraph 1
	4b	Study design - state the study is a case series and whether prospective or retrospective in design, whether single or multi - centre and whether cases are consecutive or non-consecutive.	Page 3, Line 30	Methods/Patient Criteria/Paragraph 1
	4c	Setting - describe the setting(s)and nature of the institution in which the patient was managed; academic, community or private practice setting? Location(s), and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page4, Line2-4	Methods/Patient Criteria/Paragraph 1
	4d	Participants - describe the relevant characteristics of the participants (comorbidities, tumour staging, smoking status, etc). State any eligibility (inclusion/exclusion) criteria and the sources and methods of selection of participants. Describe length and methods of follow-up.	Page 4, Line 8-10 Page 5, Line 16-24	Methods/Patient Criteria/Paragraph 2 Methods/Postoperative complications and follow-up/Paragraph 1-2
	4e	Pre-intervention considerations e.g. Patient optimisation: measures taken prior to surgery or other intervention e.g. treating hypothermia/hypovolaemia/hypotension in burns patients, ICU care for sepsis, dealing with anticoagulation/other medications and so on.	Page 4, Line 12-15	Methods/Interventional procedure/Paragraph 1
	4f	Types of intervention(s) deployed and reasoning behind treatment offered (pharmacological, surgical, physiotherapy, psychological, preventive) and concurrent treatments (antibiotics, analgesia, anti-emetics, nil by mouth, VTE prophylaxis, etc). Medical devices should have manufacturer and model specifically mentioned.	Page 4 Line 12-Page5, Line14	Methods/Interventional procedure/Paragraph 1

	4g	Peri-intervention considerations - administration of intervention (what, where, when and how was it done, including for surgery; anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc). Pharmacological therapies should include formulation, dosage, strength, route and duration).	Page 4 Line 12-Page5, Line14	Methods/Interventional procedure/Paragraph 1
	4h	Who performed the procedures - operator experience (position on the learning curve for the technique if established, specialisation and prior relevant training).	Page 4 Line 12-Page5, Line14	Methods/Interventional procedure/Paragraph 1
	4i	Quality control - what measures were taken to reduce inter or intra-operator variation. What measures were taken to ensure quality and consistency in the delivery of the intervention e.g. independent observers, lymph node counts, etc	NA	
	4j	Post-intervention considerations e.g. post-operative instructions and place of care. Important follow-up measures - diagnostic and other test results. Future surveillance requirements - e.g. imaging surveillance of endovascular aneurysm repair (EVAR) or clinical exam/ultrasound of regional lymph nodes for skin cancer.	Page 5, line 20-24	Methods/Postoperative complications and follow-up/Paragraph 2
Results	5a	Participants - reports numbers involved and their characteristics (comorbidities, tumour staging, smoking status, etc).	Page 6.Line 1-19	Results/Paragraph 1
	5b	Any changes in the interventions during the course of the case series (how has it evolved, been tinkered with, what learning occurred, etc) together with rationale and a diagram if appropriate. Degree of novelty for a surgical technique/devi ce should be mentioned and a comment on learning curves should be made for new techniques/ devices.	Page 6.Line20-23	Results/Paragraph 2
	5c	Outcomes and follow-up - Clinician assessed and patient- reported outcomes (when appropriate) should be stated with inclusion of the time periods at which assessed. Relevant photographs/radiological images should be provided e.g. 12 month follow-up.	Page 6.Line24- Page 6,Line11	Results/Paragraph 3
	5d	Where relevant - intervention adherence/compliance and tolerability (how was this assessed). Describe loss to follow-up (express as a percentage) and any explanations for it.	Page 7.Line7-11	Results/Paragraph 3
	5e	Complications and adverse or unanticipated events. Described in detail and ideally categorised in accordance with the Clavien- Dindo Classification. How they were prevented, diagnosed and managed. Blood loss, operative time, wound complications, re- exploration/revision surgery, 30-day post-op and long-term morbidity/mortality may need to be specified.	Page 7.Line3-7	Results/Paragraph 3
Discussion	6a	Summarise key results	Page7.Line24-28	Discussion/Paragraph 1
	6b	Discussion of the relevant literature, implications for clinical practice guidelines, how have the indications for a new technique/device been refined and how do outcomes compare with established therapies and the prevailing gold standard should one exist and any relevant hypothesis generation.	Page7-9	Discussion/Paragraph 2 -6
	6c	Strengths and limitations of the study	Page9, line28-Page10, Line 2	Discussion/Paragraph 7
	6d	The rationale for any conclusions?	Page 7 line29-Page8 li ne12	Discussion/Paragraph 2

Conclusions	7a	State the key conclusions from the study	Page 10,Line4-6	Conclusion/Paragraph 1
	7b	State what needs to be done next, further research with what study design.	Page 10,Line7-9	Conclusion/Paragraph 1
Additional Information	8a	State any conflicts of interest	Page 10,Line20-21	Footnote/ COI
	8b	State any sources of funding	Page 10,Line13-16	Acknowledgments/Funding

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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.