

PROCESS 2023 guidelines.

Topic	Item	Item description	Page number(s)
Title	1	The phrase 'case series' is included <ul style="list-style-type: none"> • The focus of the research study is mentioned (e.g. patient population, setting, diagnosis, intervention, outcome etc.) 	1
Keywords	2	Include three to six keywords that identify what is covered in the case series (e.g. patient population, setting, diagnosis, intervention, outcome etc.) <ul style="list-style-type: none"> • Include 'case series' as one of the keywords • Include the surgical subspeciality the case series pertains to as a keyword 	Uploaded with article
Abstract	3a	Introduction – briefly describe: <ul style="list-style-type: none"> • Background • Scientific rationale for this study • Overarching theme of the case series • Aims and objectives 	1
	3b	Methods – briefly describe: <ul style="list-style-type: none"> • Sample size • Timeframe of research • Characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.) 	1
	3c	Outcomes <ul style="list-style-type: none"> • Describe the outcomes of the intervention and management strategy 	1-2
	3d	Conclusion – briefly describe: <ul style="list-style-type: none"> • Key findings and take-home messages • Impact on future clinical practice • Direction of future research 	2
	3e	Present a structured abstract <ul style="list-style-type: none"> • Informal case series – introduction, case presentations (brief description of each case) and discussion/conclusion • Formal case series – introduction, methods, results and discussion/conclusion 	1-2
Highlights	4	Convey the key findings of the research study in 3 to 5 bullet points	n/a

Introduction	5	<p>Introduction – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	2-3
Methods	6a	<p>Registration</p> <ul style="list-style-type: none"> • 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, for example, ResearchRegistry.com, ClinicalTrials.gov, or ISRCTN. • If a protocol already 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 	6
	6b	<p>Ethical approval</p> <ul style="list-style-type: none"> • State whether ethical approval was needed or not, with reason(s) • If appropriate, state name of body giving ethical approval and approval number 	6
	6c	<p>Study design</p> <ul style="list-style-type: none"> • State that the study is a case series • Describe key characteristics of study design (e.g. prospective/retrospective, single-/multicentre, informal/formal, consecutive/nonconsecutive, exposure-/outcome-based sampling, clinical/population-based etc.) 	3
	6d	<p>Setting and timeframe – comprehensively describe:</p> <ul style="list-style-type: none"> • 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.) • Relevant dates (e.g. recruitment, intervention, follow-up, data collection etc.) 	3
	6e	<p>Participants – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	3-4 + Figure 1

		<ul style="list-style-type: none"> • Approach to selecting patients (e.g. consecutive/nonconsecutive, exposure-/outcome-based, formal/informal etc.) • Methods used to ensure de-identification of patient information 	
	6f	<p>Recruitment – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	4
	6g	<p>Preintervention patient optimisation:</p> <ul style="list-style-type: none"> • Lifestyle (e.g. weight loss, nutritional support, exercise, smoking cessation etc.) • Medication review (e.g. anticoagulation, oral hypoglycemics, insulin, oral contraceptive pill etc.) • Presurgical stabilisation/preparation (e.g. treating hypothermia/-volemia/-tension, ICU care, nil by mouth, bowel preparation etc.) • Other (e.g. psychological support, preoperative education/counselling etc.) 	3-4
	6h	<p>Interventions – comprehensively describe:</p> <ul style="list-style-type: none"> • 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.) 	3-4
	6i	<p>Intervention specifics – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	3-4
	6j	<p>Operator details – comprehensively describe:</p> <ul style="list-style-type: none"> • Relevant training, specialisation and operator’s experience (e.g. average number of the relevant procedures performed annually, independent, needs direct/indirect 	3

		supervision etc.) <ul style="list-style-type: none"> • Learning curve for technique • Requirement for additional training 	
	6k	Quality control – comprehensively describe: <ul style="list-style-type: none"> • 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 	n/a
	6l	Postoperative care and follow-up – comprehensively describe: <ul style="list-style-type: none"> • Postoperative care (e.g. patient education, postoperative medications, early mobilisation, targeted physiotherapy, early enteral nutrition, early removal of catheters/drains, psychological therapy etc.) • Follow-up time-frames (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 	3-5
Results	7a	Participants – comprehensively describe: <ul style="list-style-type: none"> • 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 • Include table showing baseline patient characteristics 	6 + Table 2
	7b	Deviation from the initial management plan – comprehensively describe: <ul style="list-style-type: none"> • Any changes to the planned intervention with rationale • If appropriate, include a suitable schematic diagram 	n/a
	7c	Outcomes and follow-up – comprehensively describe: <ul style="list-style-type: none"> • Expected versus attained clinician assessed outcome, providing reference to scientific 	7-8 + Tables

		<p>literature used to inform expected outcomes (e.g. core outcome set)</p> <ul style="list-style-type: none"> • If appropriate, include patient-reported outcomes (e.g. quality-of-life) • Percentage of patients lost to follow-up with rationale 	1, 3, 4, 5, 6, 7
	7d	<p>Intervention adherence and compliance – comprehensively describe:</p> <ul style="list-style-type: none"> • Assessment of patient’s adherence and tolerability of intervention and postoperative instructions (e.g. avoiding heavy lifting/strenuous activity, tolerance of chemotherapy/pharmacological agents etc.) • Impact on long-term applicability of intervention in clinical practice 	n/a
	7e	<p>Complications and adverse events – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 appropriate, 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 postoperative and long-term morbidity/mortality • State if there were no complications or adverse events 	7-8 + Tables 1, 3, 4, 5, 6, 7
Discussion	8a	<p>Key results – comprehensively describe:</p> <ul style="list-style-type: none"> • Key results with relevant raw data • Include table showing key results 	8
	8b	<p>Scientific context and implications – comprehensively describe:</p> <ul style="list-style-type: none"> • Relevant literature and if appropriate, similar published studies • Implications for clinical practice and guidelines (e.g. NICE) • Comparison to current gold standard of care 	9-11

		<ul style="list-style-type: none"> • Relevant hypothesis generation 	
	8c	<p>Strengths – comprehensively describe:</p> <ul style="list-style-type: none"> • Strengths of the study • Any multidisciplinary or cross-speciality relevance 	8-11
	8d	<p>Weaknesses and limitations – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	11-12
	8e	<p>Directions for future research – comprehensively describe:</p> <ul style="list-style-type: none"> • 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 	8-12
	8f	<p>Cost – comprehensively describe:</p> <ul style="list-style-type: none"> • Cost of intervention • Justify cost if intervention more expensive than current gold standard of care • Any cheaper alternatives 	n/a
Conclusions	9a	<p>Key conclusions</p> <ul style="list-style-type: none"> • Outline the key conclusions from this study 	12
	9b	<p>Rationale</p> <ul style="list-style-type: none"> • Explain the rationale behind those conclusions 	12
	9c	<p>Future work – briefly describe:</p> <ul style="list-style-type: none"> • Any questions arisen from the study • Any differences in approach to patient diagnosis or management which authors might adopt in future similar studies 	12
Patient and/or Carer Perspective	10	<p>Where appropriate, the patients 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)</p>	n/a
Informed Consent	11	<p>The authors must provide evidence of consent, where applicable, and if requested by the journal</p> <ul style="list-style-type: none"> • 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) 	n/a

		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	6
	12b	State any sources of funding (e.g. grant details) <ul style="list-style-type: none"> • Role of funder 	6
	12c	Other relevant disclosures <ul style="list-style-type: none"> • State any author contributions and acknowledgements • 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 	6, 13
Clinical Images and Videos	13	Where relevant and available, include clinical images to help demonstrate the cases pre-, peri- and postintervention (e.g. radiological, histopathological, patient photographs, intraoperative images etc.) <ul style="list-style-type: none"> • 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 	n/a
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	3