# Feasibility and safety of an Ileus Management Protocol for postoperative ileus

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# Feasibility and safety of an Ileus Management Protocol for postoperative ileus

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**Short title:** Algorithm for postoperative ileus

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**Abbreviation:** POI – postoperative ileus, NGT – nasogastric tube, ERP – Enhanced recovery pathway, I-MAP: Ileus MAnagement Protocol, LOS: Length of stay, WSC: Water soluble contrast

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## Abstract

### Background

Postoperative ileus (POI) remains one of the most frequent complications after gastrointestinal surgery with only limited options for prevention and treatment. Management of POI shows wide variation due to limited evidence. The aim was to establish a standardized treatment algorithm for POI and to study its feasibility and safety.

### Methods

The core team developed a comprehensive and pragmatic treatment algorithm to standardize management of POI (POI algorithm). This pathway was then studied in a single-center prospective cohort study including consecutive patients developing POI and requiring nasogastric tube (NGT) insertion after abdominal surgery. Primary outcome measure was compliance with the pathway.

### Results

In 9 months, 60 patients with POI were screened for eligibility and 47 were included in the trial. 40 patients were treated according to the protocol (compliance 85%) and 39/40 (98%) were successfully treated conservatively. Median NGT time was 2 (IQR 2-3) days, and 3 patients required NGT reinsertion (10%) after prior removal. Median hospital stay was 12 (IQR 8-16) days and 13.1 (IQR 5.5-15) days after surgery and insertion of NGT, respectively. One bronchoaspiration was documented in this prospective cohort.

### Conclusions

The suggested POI algorithm proved to be feasible and safe. Its superiority compared with best physician’s choice needs to be confirmed through a multicenter randomized trial.

This study has been registered by the Research Ethics Commission on human beings of the Canton de Vaud (CER-VD) (2022-01420)

**Key words:** postoperative ileus, gastrointestinal surgery, hospital stay, treatment algorithm

## Introduction

Postoperative ileus (POI) affects between 10-20 % of patients after gastrointestinal surgery and is associated with an overall increase in morbidity, hospital stay and costs (1,2). Multiple definitions exist and only recently, some consensus has been reached to come to a common language (3–5). So far, preventive measures have not convincely reduced POI and even enhanced recovery pathways (ERP) could not reduce the incidence but only advance resolution of POI (6). The treatment of POI underlies wide variation and the evidence for the management of the nasogastric tube (NGT) is very limited with regards to indication for insertion, duration, safe removal, and clamping trials (7,8). Therefore, treatment of POI is delivered in most hospitals case-by-case upon discretion of the treating physician. This lack of standardization for management of one of the most frequent complications in gastrointestinal surgery is concerning, especially given that standardization in itself has been shown to improve outcomes even in fields with limited evidence (9,10).

The aim of this feasibility study was therefore to elaborate a standardized treatment algorithm for POI and to test its feasibility and safety in a prospective cohort of patients.

## Materials and Methods

### *Study Design*

This is a single-center prospective cohort study aiming to assess feasibility and safety of a standardized treatment algorithm for POI (I-MAP: Figure 1). The study was approved by the Research Ethics Commission on human beings of the Canton de Vaud (CER-VD) (2023-00759). The study adhered to the ethical principles of the Declaration of Helsinki and the principles and procedures for integrity in scientific research involving human beings (STROBE statement, **Table S1)**. All participants provided general consent (11).

### *Participants*

Eligible were consecutive adult patients who underwent abdominal surgery and developed post-operative ileus within 30 days. Exclusion criteria were preoperative bowel obstruction, anastomotic leak, prophylactic nasogastric tube (NGT) placement, pregnancy, and lack of general consent.

### *Intervention*

The treatment algorithm was elaborated by the study group based on the available evidence, clinical judgement and practical considerations **[Figure 1].** The implementation of the algorithm was carried out in collaboration with a multidisciplinary team of experts within our institution composed of surgeons, clinical nurses and nurse practitioners, and pharmacists. It was first presented during an educational symposium to the entire divisional medical staff in March 2023, and subsequently to nursing heads and staff during dedicated sessions in May 2023. Adaptations were then discussed among stakeholders until final agreement. Pocket cards summarizing the algorithm were printed and distributed to each caregiver (residents and nurses) in the visceral surgery department.

Postoperative ileus (POI) was defined as insertion of a nasogastric tube (NGT) at any time after surgery due to symptoms such as persistent nausea, vomiting, abdominal distension, or inability to tolerate oral intake. This objective definition was chosen as a hard endpoint to reflect clinical practice and to reduce interobserver variability (3,12). Resolution of POI was defined as tolerance of the institutional refeeding policy (light diet within 24 hours after NGT removal, normal diet thereafter).

Management decisions were mainly based on NGT output over the last 12 hours assessed at 8 a.m., coinciding with shift changes of the nursing team. Depending on NGT output, Water Solution Contrast (WSC) was applied through the NGT as therapeutic and diagnostic management tool with re-assessment of patients 4 hours after administration (NGT clamp test). If WSC was not tolerated, a CT-scan or x-Ray was performed. The decision to perform a CT scan or x-Ray was made by the operating surgeon based on clinical presentation and lab results. A CT scan was the preferred modality when small bowel obstruction was suspected. Neostigmine® as a prokinetic medication was administered only after small bowel obstruction was ruled out (13,14). The WSC used at our institution was TELEBRIX® gastro sol (Guerbet AG, Zürich, CH), containing ioxitalamic acid 300 mg/ml. ROBINUL Neostigmine® sol inj (Sintetica SA, Ticino, CH) containing Neostigmine metilsulfate (2.5 mg) diluted in 500 mL NaCl 0.9% was injected over 5 hours. It was administered on the ward without need for cardiac monitoring in patients without relative contraindications (including bronchospasm, bradycardia, hypertension, congestive heart failure, thyrotoxicosis, epilepsy, warranting cardiac monitoring in the intermediate care unit) after careful patient, followed by clinical monitoring at one-hour intervals.

*Outcomes/study endpoints*

The primary endpoint for the present study was the feasibility of the I-MAP algorithm, measured by the ratio of patients treated according to the algorithm to the total number of eligible POI patients during the study period. A protocol adherence rate of 85% was defined as minimal threshold to demonstrate feasibility (15). Feasibility of the I-MAP protocol was assessed on a patient level and defined as adherence to all key steps of the algorithm. Deviations were systematically recorded and categorized as either major (omission of WSC, failure to clamp NGT, premature administration of neostigmine) or minor (delays not affecting treatment flow, variations based on patient fragility or surgeon discretion). Only patients with major deviations were considered non-adherent. Minor deviations were tolerated if the overall treatment sequence remained consistent within the protocol's intent. The rate of adherence was calculated as the proportion of patients who followed the algorithm without major deviation. In addition, the most frequently deviated algorithm components were recorded to identify areas requiring refinement.

Secondary outcomes included NGT reinsertion, total time with NGT, length of stay (LOS), conservative treatment failure, and complications such as pneumonia, bronchoaspiration and other adverse events related to POI.

*Data synthesis and analysis*

Categorical variables were expressed as frequencies and percentages, and continuous variables as median (range) and mean (±SD). Data analysis was performed using Microsoft Excel 365, (Microsoft Corporation, Redmond, WA, USA Software Group, Chicago, IL, USA).

## Results

### *Patients*

Between June 15, 2023 and March 1, 2024, 60 patients with POI were screened for eligibility and 47 were included in the trial **[Figure 2].** Out of the initially 60 screened patients, six refused study consent, five met an exclusion criterion as they were monitored in the intensive care unit, one had a maintained NGT at the end of surgery and one presented with a state of delirium impeding study participation. The remaining 47 patients constituted the final study cohort.

Patient characteristics and surgical details of the study cohort are summarized in **Table 1**. POI occurred a median of 3 (IQR 2-3) days after surgery.

### *Primary outcome*

In total, 40 out of 47 were treated per protocol (compliance rate 85%) and 39/40 (98%) were successfully treated conservatively **[Figure 2]**. One patient required re-operated for adhesive small bowel obstruction.

Reasons for protocol deviation were: administration of WSC was intentionally delayed by the senior surgeon (n=3); neostigmine was voluntarily initiated as a first place treatment by the senior surgeon (n=2); NGT was not clamped before removal despite 300-1000 ml of drainage (n=1) related to a medical error; delay of several days before WSC administration for safety reasons in a fragile patient upon clinical judgment by a senior surgeon (n=1).

### *Secondary outcomes*

NGTs were inserted on at a median of postoperative day (POD) 3 (range 1-17), with drainage of a median of 640 ml (range 0-2200ml) of gastric content after insertion. The median time of NGT drainage was 2 days (range 0-12).

Three patients required NGT reinsertion on days 0, 3, and 16 after initial removal. The first patient on day 0 because of an evisceration, the second on day 3 due to adhesive small bowel obstruction, the third on day 16 due to bilioma leading to recurrent paralytic ileus. None of them required reoperation, while one experienced bronchoaspiration before NGT reinsertion, and one developed pneumonia without signs of bronchoaspiration 4 days after NGT reinsertion. Three patients received neostigmine, allowing NGT removal the day after administration, with no drug-related side effects. Two patients needed surgery during POI treatment, one for evisceration (POD 6) and one for small bowel obstruction due to an epiploic adherence (misdiagnosed POI, POD 7).

The median length of stay in the hospital from the index operation was 12 days (IQR 8-16), however, this included the waiting time until transfer to a rehabilitation facility. The median length of stay from the onset of POI until discharge was 9 days (IQR 5-12).

Out of the 47 patients included in the study, the protocol was not followed in 7 patients (15%). Among them, 3 were in the ICU, where it was challenging to apply the protocol for logistic reasons. In 2 cases, neostigmine was immediately administered according to requests of the senior surgeon to bypass the protocol. The remaining 2 patients were transferred to the ward with a postoperative NGT in place.

## Discussion

This pragmatic POI pathway proved to be feasible and safe in our institutional practice and can be used in clinical practice to standardize patient care. Clinical superiority, compared to case-by-case decisions, needs to be confirmed through multicenter RCTs.

Standardized care pathways help to simplify clinical decision making, timely launch therapeutic strategies and, ultimately, to improve and expedite patient care (16). Postoperative ileus is one of the most common complications after abdominal surgery and lacks standardized management. Our institutional algorithm is an attempt to facilitate decision-making for medical and nursing staff. This is of particular importance in academic hospitals with regular turnover of junior staff. The proposed algorithm was based on a comprehensive review of current literature and guidelines, also considering institutional experience and logistic feasibility in our center (17). A recent meta-analysis revealed limited evidence concerning pharmacological prevention and therapy of POI, while emphasizing the importance of opioid sparing concepts, reduction of sympathetic hyperactivity and laxatives into multimodal perioperative approaches (18). Longstanding ERP experience with focus on preventive measures including early mobilization, stringent fluid management and early resumption of an oral diet to mitigate the inflammatory stress response and promote bowel recovery are integral part of perioperative care in our center (19–21).

Pharmacological attempts to treat POI within ERPs include alvimopan, neostigmine, lidocaine and other prokinetics(22). Alvimopan has demonstrated its efficacy in enhancing gastrointestinal recovery following bowel resection surgeries and is approved for use in the United States (23). However, despite its clinical benefits, it remains unavailable in the European Union due to regulatory and market constraints.

Conversely, Neostigmine has shown promising results in small-scale studies, but broader validation is lacking. While WSCA appears to be beneficial in enhanced care pathways, it is unlikely to provide a direct therapeutic benefit and should rather be considered a supportive element in postoperative protocols than an active pharmacological agent (24).

Definitions of POI remain inconsistent across studies, despite efforts to standardize (7). A systematic review of randomized controlled trials revealed close to 800 different outcomes and 73 measures related to POI with a wide heterogeneity of definitions (25). While POI relates to “prolonged POI” in most studies, it should be distinguished from the “obligatory POI” referring to the physiological ileus that follows all GI surgeries to a certain extent. A nested methodological study protocol to assess gastrointestinal recovery in cases of POI and small bowel obstruction was initiated in 2019 (26). A core outcome set with focus on patient reported outcomes (PROMs) was established recently through a consensus meeting (27). The aim was to provide a universal framework to evaluate the effectiveness of clinical interventions to reduce POI, ultimately helping to facilitate informed decision-making.

Our protocol focused on an easily reproducible and pragmatic decision framework, mainly focusing on drainage volumes to initiate further actions. Water-soluble contrast (WSC, gastrografin) was integral part of the algorithm and timely launched, mainly for its therapeutic purpose through a hyperosmolar effect to counteract gut wall edema (28). As a distinctive feature, our protocol suggested repeated WSC administration every morning at fixed hours depending on drainage thresholds until POI resolution, with imaging studies 4 to 8 hours after administration, mainly to exclude an obstructive ileus component. Neostigmine as a parasympathomimetic drug enhancing smooth muscle tone was used as a second line treatment due to the

beneficial effect on bowel recovery revealed in a recent systematic review (28). This medication needs to be embedded in an opioid-sparing analgesia strategy for the best possible results. Patients were advised to report abdominal cramps during the 5-hour administration, and particular caution was warranted in patients with preexisting pneumopathy, given the low risk of pulmonary bronchospasm, edema and respiratory failure (30). An x-Ray after WSC administration (to confirm WSC advancement to the colon) or CT-scan at the surgeon's discretion was mandatory before neostigmine administration to rule out a mechanical obstructive component needing surgical management. The limited use of this drug in our study—administered to only three patients—along with the need for precautions such as avoiding use in elderly patients and monitoring those with cardiopulmonary conditions, reflects a cautious approach. This hesitance suggests that a more systematic application may require further protocol refinement.

Our proposed algorithm incorporated simple measures launched according to predefined NGT drainage cut-offs assessed at periodic intervals, allowing for periodic decision-making involving the entire care team. Feasibility of our algorithm was confirmed through high adherence to the protocol (85%), facilitated by involvement of all caregivers. Taken together, the algorithm has proven its utility for our clinical practice.

The algorithms' safety has also been demonstrated, considering pulmonary complications and bronchoaspiration, frequent POI-related events, occurred rarely in the present cohort (31). Surgery required in two patients for evisceration and small bowel obstruction was potentially related to or misdiagnosed as POI.

Future research should focus on validating this algorithm in larger, multi-center studies to further establish its efficacy and generalizability. Additionally, ongoing

education and engagement of healthcare providers and patients will be crucial in maintaining high compliance rates and optimizing postoperative outcomes.

Several limitations of the present study need to be addressed. The study was powered to assess feasibility without a control group. A former institutional series focusing on POI occurrence however demonstrated a lack of standardization, a slightly longer LOS and WSC use in only 35% of cases (32). The LOS in the present study may also be overestimated due to logistic drawbacks (delayed transfer to rehabilitation facilities). Hence, conclusions regarding clinical efficacy are not possible at this stage. The underlying treatment algorithm was based on limited available evidence also including logistic considerations and subjective clinical judgment of the core team. Lengths of stay were long, also due to important delays related to patients awaiting transfer to rehabilitation facilities. Detailed functional recovery parameters including resumption of an oral diet were not assessed in the setting of this study. These metrics are presently assessed in the setting of an institutional prospective observational protocol (project Recovery (CER-VD 2024-00706)). Finally, despite appearing safe and feasible in our practice, the next step to assess the protocol consists of an in-depth comparative evaluation.

In conclusion, the proposed standardized treatment algorithm for POI can be safely used in clinical routine and may, due to its simplicity, also work in other hospitals and settings. Further assessment of clinical impact and potential refinements will require prospective multi-center evaluation with specific focus on time to ileus resolution, NGT reinsertion, total length of hospital stay, and patient satisfaction.

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**Statement of Authorship**

Study conception and design: DC, DH, FG, MH

Acquisition of data: DC, GH, ND, MTT

Analysis and interpretation of data: DC, GH, MH, FG

Drafting of manuscript: MTT, DC, FG

Critical revision of manuscript: all authors

Maria Teresa Torres and Chappalley Dimitri share first authorship

**All authors have no conflict of interest to declare.**

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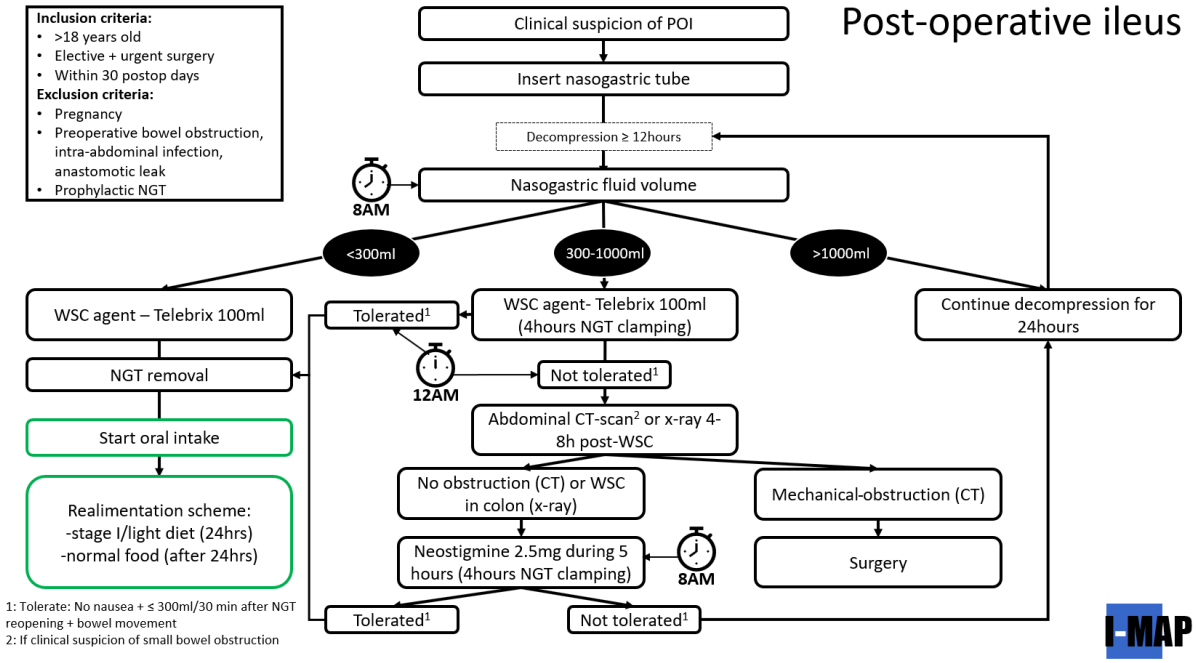
**TABLE 1** Baseline characteristics

| **Item** | | |
|---|---|---|
| Number of patients, n | 47 | |
| Age (years), median (range) | 67 | (28-92) |
| Gender (female), n (%) | 20 | (42) |
| **Comorbidities** | N=47 | |
| Diabetes, n (%) | 2 | (4) |
| Active smoker, n (%) | 11 | (23) |
| Alcohol abuse, n (%) | 2 | (4) |
| ASA classification (<3), n (%) | 23 | (49) |
| Cardiopathy, n (%) | 10 | (21) |
| COPD, n (%) | 1 | (2) |
| Cirrhosis, n (%) | 2 | (4) |
| BMI (kg/m$^2$), median (range) | 24.4 | (15.7-37.2) |
| **Surgical specifics** | N=47 | % |
| Cancer Surgery, n (%) | 21 | (45) |
| Emergency Surgery, n (%) | 15 | (30) |
| Surgical duration (min), median (range) | 168 | 192.5 (59 – 600) |
| Laparotomy, n (%) | 32 | (68) |
| MIS, n (%) | 15 | (32) |
| Contamination class | | |
| Clean or clean-contamined, n (%) | 36 | (77) |
| Contamined, n (%) | 11 | (23) |
| **Type of colorectal surgery** | N=47 | |
| Left colectomy | 10 | (21) |
| Right colectomy | 10 | (21) |
| Rectal resection | 6 | (14) |
| Small bowel resection | 8 | (18) |

| | | |
|---|---|---|
| Appendectomy | 3 | (6) |
| Other colorectal | 3 | (6) |
| **Other type of surgery** | N=47 | |
| - Debulking without colorectal resection | 3 | (6) |
| - HPB | 1 | (2) |
| - Hernia surgery | 2 | (4) |
| - Nephrectomy | 1 | (2) |

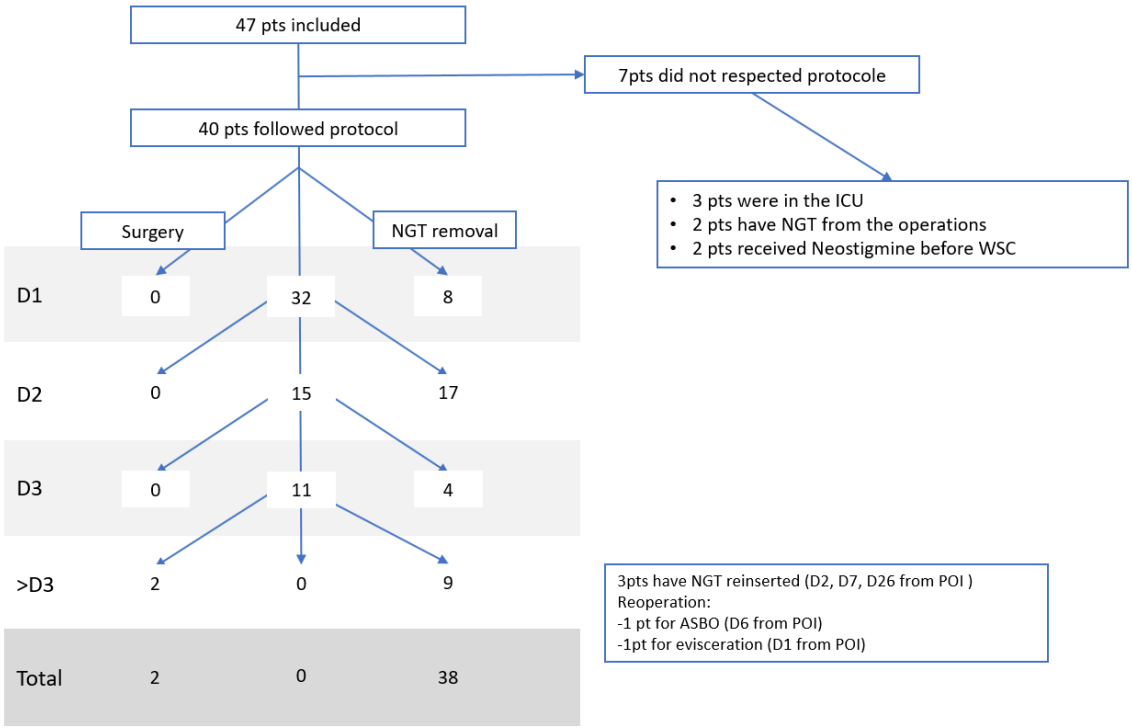
Table 1: ASA – American Society of Anaesthesiologist score, COPD – chronic obstructive pulmonary disease, BMI – body mass index, MIS – minimally invasive surgery, HPB – hepatobiliary and pancreatic surgery

**Figure 1** I-MAP protocol




I-MAP – Ileus management protocol, POI – postoperative ileus, NGT – nasogastric tube, WSC – water-soluble contrast, CT – computed tomography

**Figure 2** Management of POI




POI – postoperative ileus, NGT – nasogastric tube

1 **TABLE S1** STROBE Statement—Checklist of items that should be included in reports of cohort studies

| | Item No. | Recommendation | Page No. | Relevant text from manuscript |
|---|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 1,2 | |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 | |
| **Introduction** | | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 | |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 4 | |
| **Methods** | | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5-6 | |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5-6 | |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 5-6 | |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | - | |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *6* | |
| Bias | 9 | Describe any efforts to address potential sources of bias | - | |

| | | | | |
|---|---|---|---|---|
| Study size | 10 | Explain how the study size was arrived at | 5 | |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6 | |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 6 | |
| | | (b) Describe any methods used to examine subgroups and interactions | - | |
| | | (c) Explain how missing data were addressed | 6 | |
| | | (d) Cohort study—If applicable, explain how loss to follow-up was addressed | - | |
| | | (e) Describe any sensitivity analyses | - | |
| **Results** | | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 | |
| | | (b) Give reasons for non-participation at each stage | 8 | |
| | | (c) Consider use of a flow diagram | 8 | |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 8 | |
| | | (b) Indicate number of participants with missing data for each variable of interest | 8 | |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | 8 | |
| Outcome dats | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | *8-9* | |

| | | | | |
|---|---|---|---|---|
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 8-9 | |
| | | (*b*) Report category boundaries when continuous variables were categorized | 8-9 | |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | - | |
| | | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 8-9 | |
| **Discussion** | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 10-11-12 | |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12-13 | |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 10-11-12-13 | |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | - | |
| **Other information** | | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | | |

**Table S1:** STROBES Checklist