Mesenteric Ischemia in the ICU: A Prospective Observational Study Across Estonian Regional Hospitals

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Summary

Title: Mesenteric ischemia in the ICU: a prospective observational study across Estonian regional hospitals

Protocol number: 7

Study design/Methodology: Prospective observational study

Study duration: Recruitment period 06.06.2022 – 05.06.2026, and follow-up will end in 05.09.2026.

Objectives:
The primary objective is to identify independent predictors of transmural NOMI among ICU patients with suspected acute mesenteric ischemia.

The secondary objective is to describe demographics, acute and chronic health conditions, symptoms, laboratory variables, diagnostics, management, and outcomes among ICU patients with NOMI, other forms of AMI, and those with suspected, but not confirmed AMI.

Subjects: all consecutive patients admitted to study sites during the study period in whom suspicion of AMI is raised during their ICU stay.

Eligibility criteria: all patients aged 18 and older, in whom clinical suspicion of acute mesenteric ischemia is raised during their ICU stay.

Background

The current study is a local continuation of a prospective observational multicenter study: Incidence, diagnosis, management and outcome of acute mesenteric ischemia (AMESI Study), focusing on patients within the ICU [1].

Acute mesenteric ischemia (AMI) is a rare but life-threatening condition that is difficult to diagnose due to its non-specific clinical presentation and the lack of reliable biomarkers. In the largest prospective observational study focusing on AMI patients, the AMESI study, the AMI occurred in 0.038% of adult admissions in participating hospitals [1]. Furthermore, a subsequent editorial letter highlighted that, within the AMESI study, a significant number of patients initially admitted with non-AMI diagnoses were later diagnosed with AMI, and non-occlusive mesenteric ischemia (NOMI) was identified in only 13 of 32 participating sites [2]. These findings underscore major challenges associated with the diagnosis of this infrequent condition.

The AMESI study focused on AMI as a one entity including all subtypes, and of 418 patients with AMI, only 61 were in the ICU at the time of diagnosis [1]. Overall, the data specifically focusing on critically ill patients with AMI, and especially NOMI, remains limited [3,4]. A detailed description of patients with AMI in the ICU is scarce in the literature, whereas it is most warranted for future improvement in the recognition, management, and outcomes of this lethal condition.

NOMI is a subtype of AMI where insufficient mesenteric perfusion occurs without occlusion of large mesenteric arteries [5]. NOMI is notoriously difficult to diagnose because of its nonspecific clinical presentation and the limited diagnostic value of a contrast-enhanced computed tomography (CTA) compared with arterial occlusive mesenteric ischemia. A recent systematic review showed that although CTA offers a high sensitivity and specificity in diagnosing AMI, its accuracy is lower in NOMI. The reduced performance might be explained by the absence of vascular signs in NOMI. However, the review also emphasized that none of the non-vascular CT features alone are sufficiently reliable for diagnosing AMI or for detecting progression to transmural necrosis [6]. In line with this, a prospective observational study by Bourcier et al. found that 30% of patients with intestinal necrosis had no non-vascular signs on CT [3]. Importantly, the systematic review by Reintam Blaser et al. noted that the evidence for CTA accuracy in NOMI is based on only two studies, highlighting

a significant gap in current knowledge [6]. This underlies the need for studies that compare CT findings in confirmed versus suspected NOMI.

The critically ill patients are at greatest risk of NOMI. Vasopressors are frequently used during resuscitation and may be linked to the development of NOMI [7–10]. Since this correlation is derived from retrospective studies, it is challenging to determine if there is a causative relationship. There is some conflicting evidence; for instance, a study by Topolsky et al. noted more frequent abdominal organ infarctions in NOMI patients treated with vasopressors. However, it found no correlation between the presence and extent of radiological bowel features indicating acute intestinal ischemia among NOMI patients who received vasopressors compared to those who did not [11]. Furthermore, studies by Topolsky et al. and Yu et al. found no relationship between vasopressor usage and mortality in NOMI patients [11,12]. A systematic review by Brennan et al. published in 2021 found no randomized controlled trials that address vasoactive drug use in NOMI patients [13]. Although there is probably a causative effect of vasopressors on the development of NOMI, the relationship is not entirely clear. Understanding the patterns of vasopressor use in patients with suspected versus confirmed NOMI could provide valuable clinical insights into their potential role as risk factors, helping to refine clinical suspicion in the ICU setting.

According to the World Society of Emergency Surgery Guidelines, the cornerstone of NOMI management is the treatment of the underlying precipitating cause. Fluid resuscitation, optimization of cardiac output, and elimination of vasopressors remain important primary measures [14]. Some patients might benefit from endovascular, either direct or indirect, vasodilatory therapy, but unfortunately, the evidence is mostly based on one nationwide observational study [15]. The decision to intervene surgically is based on the presence of peritonitis, bowel perforation, or overall worsening of the patient's condition [14]. Currently, there is no clear understanding of how to distinguish patients in whom conservative therapy alone is sufficient (non-transmural intestinal damage) from those requiring surgery (transmural intestinal damage). A characterization of management and outcomes in NOMI patients may assist in identifying subgroups more likely not to progress to transmural intestinal necrosis and, accordingly, potentially survive without surgery. This information is needed to plan prospective observational studies and ultimately enhance decision-making.

The study aims to compare the clinical characteristics of ICU patients with confirmed transmural NOMI to those with suspected but not confirmed AMI, with the goal of

identifying factors associated with the development of transmural NOMI. Furthermore, we aim to describe the clinical characteristics, diagnostics, management, and outcomes in patients with NOMI and other forms of AMI.

Study objectives

Primary objective:

1. To identify factors predicting irreversible bowel ischemia in NOMI.

Secondary objectives:

2. To compare baseline demographics, acute and chronic health conditions, symptoms, time factors, laboratory profiles, diagnostics, management (excluding AMI-specific management), and outcomes between ICU patients with NOMI (irreversible bowel ischemia) and no AMI.
3. To compare baseline demographics, acute and chronic health conditions, symptoms, laboratory profiles, diagnostics, management, and outcomes between ICU NOMI patients with irreversible bowel ischemia and reversible bowel ischemia.
4. To compare baseline demographics, acute and chronic health conditions, symptoms, time factors, laboratory profiles, diagnostics, management, and outcomes between ICU patients with NOMI (irreversible bowel ischemia) and AMI of other subtypes (irreversible bowel ischemia)
5. To compare CT findings in ICU patients with NOMI (irreversible bowel ischemia) and no AMI.

Study design and methods

This is a prospective observational study that extends an international multicenter study, conducted at Estonian sites. It will include all patients treated in the ICUs of Tartu University Hospital and North Estonian Medical Center who are suspected of having acute mesenteric ischemia. The study will include patients from the start of the AMESI study in June 2022 until the completion of the AMESI-EST study in June 2026.

Inclusion criteria

- Adult ICU patients in whom clinical suspicion of acute mesenteric ischemia is raised during their ICU stay.

Exclusion criteria

- Patients who develop acute mesenteric ischemia outside of the intensive care unit,
- Confirmed strangulating bowel obstruction,
- Individuals younger than 18 years,
- Chronic mesenteric ischemia without an acute event.

Definitions

- *Suspicion of acute mesenteric ischemia* is based on clinical judgment by local investigators.
- *Occlusive acute mesenteric ischemia*. Decreased mesenteric blood flow due to acute high-grade stenosis or occlusion of mesenteric vessels. Arterial and venous AMI are classified separately. Arterial occlusive AMI comprises arterial embolism and thrombosis.
    - Confirmation will be verified by one or more of the following: CT angiography, mesenteric angiography, endoscopy, surgery, histology, or autopsy.
- *Acute mesenteric ischemia in specific conditions*. Acute intestinal ischemia secondary to aortic dissection, abdominal aortic aneurysm repair, intra-aortic balloon pump or other forms of mechanical cardiac support.
    - Confirmation will be verified by one or more of the following: CT angiography, mesenteric angiography, endoscopy, surgery, histology, or autopsy.
- *Non*-occlusive *mesenteric ischemia*. Acute severe ischemia of the intestine developing without acute thromboembolic high-grade stenosis or occlusion.
    - Confirmation will be verified by one or more of the following: CT angiography, mesenteric angiography, endoscopy, surgery, histology, or autopsy.
- *No acute mesenteric ischemia*. Patients with initial clinical suspicion of AMI in whom subsequent diagnostic workup will not confirm AMI.

Each AMI subtype will be categorized into two subcategories: transmural or non-transmural bowel ischemia.

- Bowel ischemia will be defined as irreversible if the patient:
    - underwent initial or secondary bowel resection,
    - did not undergo bowel resection due to the bowel being deemed non-salvageable,

    - was transitioned to palliative care due to progression of ischemia after any initial curative-intent treatment (including endovascular or conservative approaches), or
    - was assigned to end-of-life care as an initial management decision.

- Bowel ischemia will be defined as reversible if the patient:

    - was treated endovascularly without requiring secondary bowel resection,
    - underwent surgical revascularization without bowel resection (initially or secondarily),
    - underwent explorative laparoscopy or laparotomy without the need for bowel resection (initially or secondarily), or
    - received only conservative treatment without the need for secondary bowel resection.

Group allocation

- *No AMI.*
- *NOMI*. This group will be further divided based on irreversible and reversible bowel ischemia.
- *Other AMI*. This group includes all other subtypes of AMI. This group will be further divided based on irreversible and reversible bowel ischemia.

Ethical considerations

The study has been approved by the Ethics Committee of Tartu University, reference number: 376M-6.

VARIABLES INCLUDED IN THE STUDY

Demographic description

- Sex
- Age (in years)
- Body mass index (BMI)

Chronic health conditions

- Smoking (yes/no/former)
- Atrial fibrillation
- Atherosclerotic disease
- Arterial hypertension
- Previous myocardial infarction
- Age-adjusted Charlson Comorbidity Index
- Chronic mesenteric ischemia

Acute health conditions

- Initial diagnosis leading to hospitalization
- APACHE II score
- SOFA score
- New atrial fibrillation prior to diagnosis/suspicion of AMI
- Cardiac arrest within 72 hours prior to diagnosis/suspicion of AMI
- Mechanical ventilation within 72 hours prior to diagnosis/suspicion of AMI
- Maximum intra-abdominal pressure within the 72 hours prior to diagnosis/suspicion of AMI
- RRT prior to suspicion/diagnosis of AMI
- Cardiac surgery prior to suspicion/diagnosis of AMI
- Aortic surgery prior to suspicion/diagnosis of AMI
- Any other surgery prior to suspicion/diagnosis of AMI
- Enteral nutrition within 48 hours prior to suspicion of AMI
    - Amount in ml during this period
- Vasopressor use within 72 hours prior to diagnosis/suspicion of AMI
    - What type of vasopressor was used
    - Use of multiple vasopressors
    - Maximum dose of each vasopressor

Symptoms supporting suspicion of AMI

- Acute abdominal pain
- Diarrhea
- Bloody stool
- Shock
- Vomiting

- GRV > 500 ml at one point during the 48 hours prior to suspicion/diagnosis of AMI

Laboratory values

- White blood cell count (WBC)
- C-reactive protein (CRP)
- Procalcitonin (PCT)
- Creatinine
- eGFR
- Aspartate aminotransferase (AST)
- Troponin T
- pH
- Base excess (BE)
- D-dimers
- Lactate
    - The maximum value 0 – 12 hours prior to diagnosis/suspicion of AMI
    - The maximum value 12 – 24 hours prior to diagnosis/suspicion of AMI
    - The maximum value 24 – 48 hours prior to diagnosis/suspicion of AMI
    - The maximum value 48 – 72 hours prior to diagnosis/suspicion of AMI

Time factors

- Time from ICU hospitalization to AMI suspicion (days)
- Time from symptoms to any treatment (endovascular or surgical) (hours)
- Time from suspicion to any treatment (endovascular or surgical) (hours)

Diagnostics

- Was AMI confirmed/excluded by/at:
    - CT scan
    - Angiography
    - Endoscopy
    - Surgery
    - Autopsy
    - Histology
- Was AMI suspicion mentioned in the referral for the first study?
- Was there a CT scan performed?

    - No contrast media used
    - Arterial +/- portal venous phase
- Did the radiologist diagnose/suspect AMI?
- Presence of the following signs on the CT scan:
    - Bowel dilatation (small bowel > 3 cm, large bowel > 6 cm, caecum/sigmoid > 9 cm)
    - Bowel wall enhancement on portal venous phase (absence or decreased enhancement; normal enhancement; increased enhancement)
    - Pneumatosis intestinalis (yes/possible/no)
    - Gas in the mesenteric or portal veins (yes/no)
    - Thickening of the bowel wall (small bowel > 3 mm, large bowel > 3 mm if distended or > 5 mm if not distended)
    - Thinning of the bowel wall (paper-thin wall - yes/no)

Management

- Initial management
    - Surgery
    - A combination of surgical and endovascular
    - Endovascular
    - Conservative
    - End-of-life care
- Surgical management
    - Explorative laparoscopy
    - Explorative laparotomy
    - Therapeutic laparotomy
    - Gastrointestinal surgical management
        - No need
        - Resection with primary anastomosis
        - Resection with stoma formation
        - Damage control
        - None, unsalvageable bowel
- Total number of operations
- Resection of the small bowel only
- Resection of the large bowel only

- Combined small and large bowel resection
- Use of open abdomen following initial surgery (yes/no)
- Later treatment
    - Did bowel necrosis develop after initial management (yes/no)
    - Was a secondary bowel resection performed after initial treatment (yes/no)
    - End-of-life care introduced after initial management (yes/no)

ICU management

- Maximum vasopressor dose during the first 48 hours of AMI management
    - Norepinephrine dose
    - Epinephrine dose
    - Vasopressin dose
    - Multiple (combination of at least two) vasopressor use
- Total i/v fluids administered during the first 48 hours of AMI management
- Maximum cumulative fluid balance during the first 48 hours of AMI management
- Mechanical ventilation after initial treatment of AMI
- Renal replacement therapy during the first 48 hours after the initial treatment of AMI
- Nutrition after the initial treatment of AMI
    - 0 – 12 hours
    - 24 – 48 hours
    - 48 – 72 hours
- When was oral or enteral nutrition started (day)
- Anticoagulation use
    - Prophylactic
    - Therapeutic
- Antiaggregation use
    - Single
    - Double

Outcomes

- ICU survival (alive/dead)
- Hospital survival (alive/dead)
- Hospital length of stay (days)

- ICU length of stay (days)
- Duration of mechanical ventilation
- Need for renal replacement therapy during hospital stay (yes/no)
- Duration of parenteral nutrition (days)
- Stoma at discharge (yes/no)
- Parenteral nutrition at hospital discharge (yes/no)
- 30-day survival
- 90-day survival

Study objective analysis

1. To identify factors predicting irreversible bowel necrosis in NOMI.

NOMI patients with irreversible bowel ischemia and no AMI will be included in the analysis. Medians and interquartile ranges will be used to present the data. Categorical data will be represented as n (%). To compare the two groups, the chi-square test, Fisher's exact test, or the Mann-Whitney U test will be employed. Statistical significance will be defined as $p < 0.05$.

To identify the potential predictors for irreversible bowel ischemia in NOMI patients, we will enter all variables listed below into a univariable logistic regression model. All variables showing p-values < 0.1 will be entered into a multivariable logistic regression model to determine the independent associations. Variables showing p-value < 0.05 will be considered independent predictors of irreversible bowel ischemia in NOMI patients.

The following variables will be included in the analysis: age-adjusted Charlson comorbidity index [16], SOFA score [17], GRV > 500 ml at some point within the 48 hours prior to suspicion of AMI [18], presence of bloody stool [18], cardiac arrest [19], need for renal replacement therapy prior to suspicion of AMI [18], highest WBC levels within 72 hours prior to suspicion of AMI [20], highest CRP levels within 72 hours prior to suspicion of AMI [21], highest lactate values 0-12 hours prior to suspicion of AMI [20], pneumatosis intestinalis on the CT [22], decreased bowel wall enhancement on the CT [22].

2. To compare baseline demographics, acute and chronic health conditions, symptoms, time factors, laboratory profiles, diagnostics, management (excluding AMI-specific management), and outcomes between ICU patients with NOMI (irreversible bowel ischemia) and no AMI.

NOMI patients with irreversible bowel ischemia and no AMI will be included in the analysis. Medians and interquartile ranges will be used to present the data. Categorical data will be represented as n (%). To compare the two groups, the chi-square test, Fisher's exact test, or the Mann-Whitney U test will be employed. Statistical significance will be defined as $p < 0.05$.

All variables under the following subsections will be included in the analysis: demographic description, chronic health conditions, acute health conditions, symptoms supporting suspicion of AMI, laboratory values, time factors, diagnostics, management, ICU management, and outcomes.

3. To compare baseline demographics, acute and chronic health conditions, symptoms, laboratory profiles, diagnostics, management, and outcomes between ICU NOMI with irreversible and reversible bowel ischemia.

Patients with confirmed NOMI will be included in the analysis. Medians and interquartile ranges will be used to present the data. Categorical data will be represented as n (%). To compare the two groups, the chi-square test, Fisher's exact test, or the Mann-Whitney U test will be employed. Statistical significance will be defined as $p < 0.05$.

All variables under the following subsections will be included in the analysis: demographic description, chronic health conditions, acute health conditions, symptoms supporting suspicion of AMI, laboratory values, diagnostics, management, ICU management, and outcomes.

4. To compare baseline demographics, acute and chronic health conditions, symptoms, time factors, laboratory profiles, diagnostics, management, and outcomes between ICU patients with NOMI (irreversible bowel ischemia) and AMI of other subtypes.

Patients with NOMI and AMI of other subtypes with irreversible bowel ischemia will be included in the analysis. Medians and interquartile ranges will be used to present the data. Categorical data will be represented as n (%). To compare the two groups, the chi-square test,

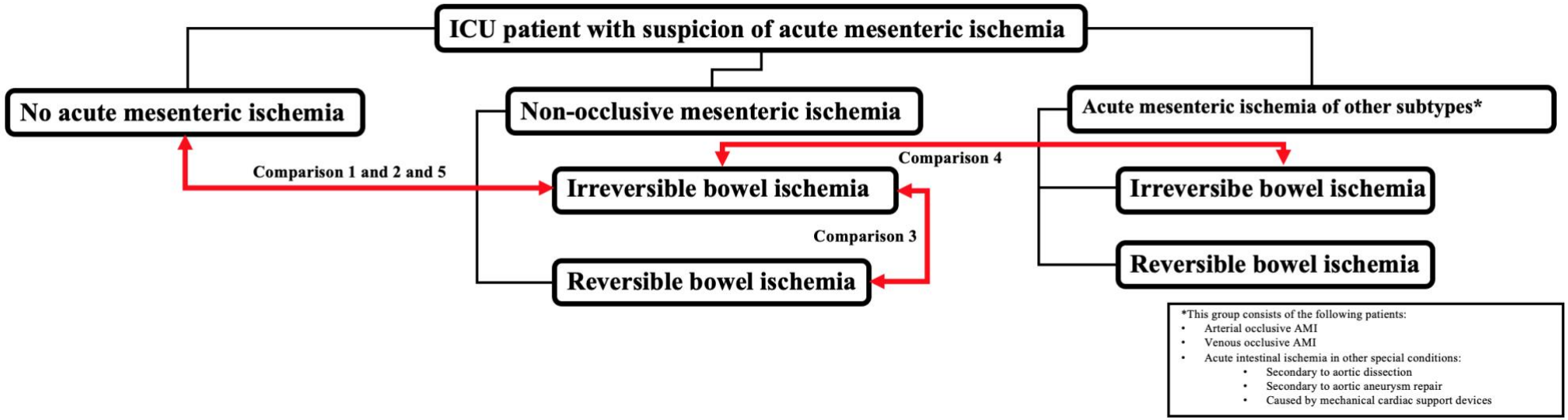
Fisher's exact test, or the Mann-Whitney U test will be employed. Statistical significance will be defined as $p < 0.05$.

All variables under the following subsections will be included in the analysis: demographic description, chronic health conditions, acute health conditions, symptoms supporting suspicion of AMI, laboratory values, time factors, diagnostics, management, ICU management, and outcomes.

5. To compare CT findings in ICU patients with NOMI (irreversible bowel damage) and no AMI.

Patients with transmural NOMI and those with no AMI will be included in the analysis. The abdominal CT scans of both groups will be analyzed with a focus on the following CT signs: presence of bowel dilatation, pathological bowel wall enhancement, presence of pneumatosis intestinalis, presence of gas in the mesenteric or portal venous system, and thickening or thinning of the bowel wall. Categorical data will be presented as n (%). To compare two groups, a chi-square test will be used. Statistical significance will be defined as $p < 0.05$.

Furthermore, we will test the accuracy of AMESIradiol score in detecting irreversible bowel necrosis in ICU patients transmural NOMI to those with no AMI.



Primary objective:

Comparison 1.

The following variables will be included:

- Age-adjusted Charlson comorbidity index
- SOFA score
- Cardiac arrest prior to suspicion
- GRV > 500 ml
- Presence of bloody stool
- Need for RRT
- Highest WBC values
- Highest lactate values
- Highest CRP values
- Pneumatosis intestinalis on CT
- Decreased bowel wall enhancement on CT

All variables showing p-values <0.1 will be included in the multivariable regression model to find independent predictors of transmural NOMI.

Secondary objectives

Comparison 2.

All variables from the following subsections will be included:

- Demographic description
- Chronic health conditions
- Acute health conditions
- Symptoms supporting suspicion of AMI
- Laboratory values
- Time factors
- Diagnostics
- Management
- ICU management
- Outcomes

Comparison 3.

All variables from the following subsections will be included:

- Demographic description
- Chronic health conditions
- Acute health conditions
- Symptoms supporting suspicion of AMI
- Laboratory values
- Time factors
- Diagnostics
- Management
- ICU management
- Outcomes

Comparison 4.

All variables from the following subsections will be included:

- Demographic description
- Chronic health conditions
- Acute health conditions
- Symptoms supporting suspicion of AMI
- Laboratory values
- Time factors
- Diagnostics
- Management
- ICU management
- Outcomes

Comparison 5.

The following abdominal CT-scan variables will be included:

- Presence of bowel dilatation
- Bowel wall enhancement
- Presence of pneumatosis intestinalis
- Presence of gas in the mesenteric or portal venous system
- Thickening or thinning of the bowel wall

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