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ONIS-STOMA: An observational multicentre prospective protocol study of stoma patients ☆

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ABSTRACT

Approximately 70,000 Italians live with urinary or intestinal stomas, primarily due to cancer, chronic inflammatory intestinal diseases, and trauma. These individuals face physical, psychological, and social challenges, reducing their quality of life. No study has yet mapped this situation in Italy. The ONIS-STOMA study aims to collect sociodemographic, clinical, health status, and quality of life data from patients with stomas to identify pathways and interventions for improving clinical outcomes and overall quality of life. This multicenter observational prospective study will involve at least four centers and adhere to the Strengthening the Reporting of Observational Studies in Epidemiology Checklist. Eligible participants are adults with temporary or permanent intestinal or urinary stomas attending specialized outpatient clinics. Data will be collected via ONIS, a dedicated online platform. Descriptive and correlation analyses will be conducted, targeting a sample size of 3,000–6,000 patients.

- The study will provide valuable insights into the lives of patients with stomas in Italy, guiding personalized interventions.
- The number of patients with stomas is expected to increase due to the aging population and rising prevalence of chronic conditions.
- The registry could enroll patients to monitor their progress and provide decision-makers with information on the overall health status of this population.

Specifications table

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Ethics:	The ethics committee of Brescia will be notified of the protocol and study documents before starting any study procedure. Before data collection, each participating center will obtain approval for the observational study from its ethics committee. Any modifications to the protocol will be communicated to each ethics committee for their awareness and updating. All patients will be invited to participate voluntarily in the study. They will be provided with an explanation of the study's purpose and procedures. They will also have the opportunity to address any doubts or uncertainties by asking questions and receiving clear and satisfactory answers whenever necessary. After reviewing the study information, patients will have ample time to decide whether to proceed with signing the informed consent form. Patients will have the freedom to withdraw from the study at any time without providing any specific justifications.
Value of the Protocol:	The number of patients with stomas is expected to increase in the future due to the aging population and increasing prevalence of chronic conditions. The registry could enroll patients to monitor their progress and provide decision-makers with information on the overall health status of patients with stomas. The study aims to collect data on patients with stomas to identify clinical, care, and educational pathways and interventions for improving clinical outcomes and overall quality of life.

Background

Approximately 70,000 Italians ([1]; Federazione delle Associazioni Incontinenti e Stomizzati [2], 2018), 700,000 Europeans [3], and 1 million Americans [4] live with urinary or intestinal stomas. The principal causes of stomas are cancer, chronic inflammatory intestinal diseases, intestinal volvulus, trauma, bowel obstruction, and familial adenomatous polyposis [1,5]. In Italy, more than 48,000 new cases of colorectal carcinoma and 28,000 new cases of bladder carcinoma were detected in 2020 [6]. People who undergo ostomy surgery experience significant changes in their daily lives, including physical (e.g., bowel and urinary dysfunction, sexual difficulties, and stoma-related complications), psychological (e.g., negative body image and depression), and social (e.g., isolation, loneliness, anxiety, and impaired relationships) consequences, leading to a reduced quality of life [7,8–10,11,12]. Currently, it is not possible to map this situation in Italy, as there is no tool available for collecting data on patients with stomas. Each year, stoma and pelvic floor rehabilitation clinics produce summary reports on the services provided during the period. These summary reports contain aggregated and anonymous data on education and counseling activities, clinical information on individuals attending the clinic, and monitoring data on health status. This represents an enormous amount of information, most of which remains within healthcare institutions and is neither shared externally nor used for development, innovation, and research purposes in the field. Additionally, there is currently no national study planned in Italy to collect these data, resulting in a lack of information and support that prevents an accurate and detailed overview of the situation.

The FAIS [2] advocates the development and implementation of a national study to collect data on patients with stomas, intending to describe their sociodemographic and clinical characteristics and health status to identify personalized intervention pathways and procedures aimed at improving clinical outcomes and overall quality of life. In addition to these data, this study will also collect information on the structural and organizational characteristics of involved stoma outpatient centers.

Description of protocol

Design

The ONIS-STOMA study is a prospective observational study based on a registry containing clinical and instrumental data collected from patients with stomas attending specialized outpatient clinics in participating centers. It involves a total of 11 centers. The study protocol follows the Strengthening the Reporting of Observational Studies in Epidemiology Checklist [13]. This checklist ensures high-quality reporting of observational studies and maintains rigorous standards in their conduct [13,14].

Aim

The ONIS-STOMA study aims to collect sociodemographic, clinical, health status, and quality of life data from patients with stomas to identify clinical, care, and educational pathways and interventions for improving clinical outcomes and overall quality of life.

Expected results

The collected data will aim to describe the following:

a) Clinical and sociodemographic characteristics of people living with stomas;
b) Level of self-care and quality of life of people living with stomas and their predictive factors; and
c) Structural characteristics and outpatient services of participating centers.

Setting

Participating centers will primarily consist of those affiliated and registered with the Società Italiana di Chirurgia [15]. At least four centers will be included, with the Istituto Ospedaliero Fondazione Poliambulanza di Brescia as the coordinating center.

Population

The ONIS-STOMA study will include adults (≥18 years old) living with temporary or permanent intestinal stomas (ileostomy or colostomy) and/or urinary stomas (ureterocutaneostomy or ureterocutaneoileostomy).

Eligibility criteria

Inclusion criteria

The study will include the following:

a) Patients with intestinal stomas (ileostomy or colostomy) and/or urinary stomas (ureterocutaneostomy or ureterocutaneoileostomy) attending the specialized outpatient clinics of participating centers;
b) Patients at their first outpatient clinic visit after ostomy surgery;
c) Patients living with stomas attending their follow-up visits; and
d) Patients providing their written informed consent for participation in the study.

Exclusion criteria

The study will exclude the following:

a) Pediatric patients (<18 years old) and
b) Patients unable to understand the risks and benefits of the study or provide consent for participation and data collection.

Patient registration

Each center will register every patient by completing a paper data collection form, and a progressive numerical code will be assigned to each patient to generate an anonymization code. This code will be combined with a string defined by the coordinating center, which is specific to each center. The resulting alphanumeric code will be entered into the study database and utilized as the unique identification code for each patient.

Data collection

The ONIS-STOMA study does not involve clinical examinations or procedures for participants that differ from the standard practices of each involved center. Stoma nurses, nurses with specialized training in stoma therapy who typically oversee the outpatient clinic where patients with stomas are treated, will identify potential candidates meeting the inclusion criteria. They will then introduce the study to these candidates, provide them with information, and request their consent to participate.

Data quality and management

Stoma nurses at each center will conduct the data collection process. Data will be collected and entered into a dedicated platform owned by the FAIS, which meets all requirements for the protection and preservation of privacy. The research team will train each stoma nurse to use the data collection platform. Each stoma nurse will have access to the project website (https://www.onisitalia.net) and will be able to log in using their user IDs and passwords. The website will allow for registration upon first access, and in case of any problems, a function will be available to recover login information.

Upon logging in, stoma nurses will have access to an informative section containing data relevant to the ONIS-STOMA study pertaining to the affiliated institution's structure. They may also enter new information relevant to the study. The platform meets appropriate privacy and anonymity requirements as outlined in the General Data Protection Regulation (GDPR) European Union (EU) 2016/679 [16]. Only authorized users will be able to access the study data. The data in the study database can be accessed via the web with a graphical interface that allows information to be viewed as a table, histogram, or geolocated graph.

Sample size

The exact number of patients to be included in the study cannot be accurately predicted. All eligible patients will be recruited from participating centers for 36 months. According to epidemiological data currently available in Italy [17], approximately 70,000 patients have stomas, including 10,000 children. It can be hypothesized that the present study will be able to identify at least 5–10% of all patients registered in healthcare facilities across the national territory. Therefore, the total number of patients recruited by the study from all participating centers nationwide over the years at a steady state could range from 3000 to 6000.

Potential participant risks and benefits

There are no potential risks associated with the study and its procedures.

Endpoint and outcome

Table 1
Endpoint and outcome.

Primary outcome	
	Prevalence of patients living with stomas according to the type of stoma (colostomy, ileostomy, or urostomy)
Primary endpoint	
	Association between the type of stoma and the related sociodemographic and clinical characteristics, level of self-care, and quality of life to identify patient profiles
Secondary outcomes	
	Structural characteristics of the outpatient clinic of each participating center Number and characteristics of services provided Comorbidity index Level of self-care Quality of life

Statistical analysis

Descriptive statistics including measures of central tendency and dispersion (i.e., means, medians, standard deviations, and interquartile ranges) will be used to present the quantitative variables. Conversely, frequencies and percentages will be utilized to describe the categorical variables. Correlation analyses will be conducted using linear and generalized linear models, depending on the distribution of the variables under study. Classification and/or stratification techniques (i.e., multivariate statistical techniques and machine learning [ML] methods) will be applied to identify patient profiles. The hypothesized sample size (n = 3000–6000) will allow for the valid and robust application of ML techniques [18]. However, a formal definition of the sample size for such techniques is still being established and strongly depends on the type of approach or technique applied. Recent studies [18,19] have evaluated the performance of various ML techniques in terms of accuracy and effect size, finding that sample sizes larger than 2000–2500 can achieve good to excellent performance, even with low-quality data (i.e., unrepresentative samples and/or small effect sizes). The proposed sample size is sufficiently large to apply even the most computationally complex ML techniques.

Ethical considerations

This study will be conducted in accordance with the described protocol, the International Council for harmonisation–Good Clinical Practice guidelines [20], and the principles of the Declaration of Helsinki [21]. The study protocol and all other necessary documents will be submitted to the relevant authorities. Any amendments and new versions of the protocol will be promptly shared with the ethics committee. This study will be conducted in accordance with the protocol described by the investigators.

Ethics committee approval

The ethics committee of ASST Spedali Civili di Brescia approved the study protocol (Project Code: NP 5721 – STUDIO ONIS-STOMA) on March 28, 2023.

Patient information and consent

All patients will be invited to participate voluntarily in the study. They will be provided with an explanation of the study's purpose and procedures. They will also have the opportunity to address any doubts or uncertainties by asking questions and receiving clear and satisfactory answers whenever necessary. After reviewing the study information, patients will have ample time to decide whether to proceed with signing the informed consent form. Patients will have the freedom to withdraw from the study at any time without providing any specific justifications.

Ethics committee approval

The ethics committee of Brescia will be notified of the protocol and study documents before starting any study procedure. Before data collection, each participating center will obtain approval for the observational study from its specific ethics committee. Any modifications to the protocol will be communicated to each ethics committee for their awareness and updating.

Data quality and database management

The research team will be responsible for managing the data, conducting quality control, and maintaining data integrity. The data will be collected on the ONIS platform using a centralized web system that can be accessed through any standard browser with an internet connection. The collected data will be recorded, processed, managed, and stored in both paper and computerized formats for the exclusive purposes of the research, in compliance with the GDPR (EU) 2016/679 [16]. The principal investigator will be responsible for managing the data.

Data confidentiality and privacy

The privacy of participants will be fully protected, and their data will be treated confidentially, in accordance with Italian laws, and European Regulation No. 679 of 2016 [16]. The data collected during the study will be kept anonymous and processed for scientific purposes only. Individual data will not be published; they will be combined with data from all other participants to produce descriptive analysis results. The investigators will ensure participant confidentiality by identifying participants only with an identification number in the study database. All documents will be securely stored and accessible only to the investigators and other authorized personnel.

Data ownership

The FAIS (the promoter) owns all data related to the study, including its execution and results, in accordance with the Legislative Decree of December 17, 2004. Each participating center can access and use the data related to its own area. The coordinating center (Istituto Ospedaliero Fondazione Poliambulanza di Brescia) will be responsible for data management and storage in compliance with current regulations.

Data publication

The research results will be made available to the public and all interested parties through presentations at conferences, congresses, and symposia as well as articles in national and international scientific journals. The research team must approve and coordinate any studies arising from the subgroup analyses. They will also prepare the study's final report, which will be presented at a meeting and include a list of all participating centers and their contact persons. Authorship will be determined based on each investigator's involvement and contribution. The study promoter must be listed in all papers and mentioned in the acknowledgement section.

Record retention

The principal investigator will keep all information about study participants, documentation related to submissions and approvals by the European Commission, and regulatory documentation in the archives of the surgery department.

Protocol validation

The ONIS-STOMA study aims to collect sociodemographic, clinical, health status, and quality of life data from patients with stomas to identify clinical, care, and educational pathways and interventions to improve clinical outcomes and overall quality of life. The collected data will aim to describe the following: clinical and sociodemographic characteristics of people living with stomas; level of self-care and quality of life of people living with stomas and their predictive factors; and structural characteristics and outpatient services of participating centers. The number of patients with stomas is expected to increase in the future due to the aging population and rising prevalence of chronic conditions. The registry has the potential to enroll patients to monitor their progress and provide decision-makers with information on the overall health status of this population.

Limitations

There are some limitations to the design of this study. The enrollment of patients with stomas depends on participating centers; most centers are located in the north-central part of Italy, while few are located in the south. Furthermore, the data refer to patients with stomas attending outpatient clinics. Although the outpatient network in Italy is fairly widespread, some regions lack this service, forcing patients to travel long distances. This can hinder patients' ability to maintain continuous follow-up with their outpatient centers.

Funding

The study is not for profit. Due to the observational nature of the study, insurance coverage will only be provided if necessary.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Danila Maculotti: Methodology, Writing – original draft. **Giulia Villa:** Conceptualization, Methodology, Writing – original draft. **Andrea Poliani:** Writing – original draft. **Nicola Angelo Caione:** Methodology, Writing – original draft. **Pier Raffaele Spena:** Conceptualization, Methodology, Writing – original draft. **Duilio Fiorenzo Manara:** Supervision, Writing – review & editing.

Data availability

No data was used for the research described in the article.

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