ISRCTN82669637 https://doi.org/10.1186/ISRCTN82669637

Prognostic value of excessive perineal descent for the surgical outcome of obstructed defecation syndrome

Submission date
11/11/2024

Recruitment status
No longer recruiting

Registration date
22/01/2025

Overall study status
Completed

Last Edited
27/11/2024

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

This observational retrospective case-control study investigates the prognostic value of excessive perineal descent (PD) for the surgical outcome of obstructed defecation syndrome (ODS). This syndrome is a clinical condition with a multifactorial and still debated pathogenesis. It may be secondary to functional disorders, which are amenable to medical and rehabilitative therapy, and/or to anatomical abnormalities of the rectum (e.g., rectal intussusception and rectocele) and urogenital tract (e.g., urogenital prolapse) that may require surgical correction. PD is also associated with ODS, as excessive and repetitive straining can weaken the pelvic floor muscles, promoting PD. This, in turn, necessitates even greater straining for defecation, potentially leading to further deterioration of the pelvic floor, thus establishing a vicious cycle. PD appears to play a significant role in the pathogenesis of ODS, being almost invariably present in patients with long-standing ODS and, unlike associated morphological rectal abnormalities, showing a strong correlation with symptom severity. Nevertheless, the surgical procedures currently proposed for the treatment of ODS are almost exclusively aimed at correcting rectal anatomical abnormalities such as intussusception (RI) and/or rectocele, without addressing the coexisting issue of excessive PD. In light of these considerations, the primary objective of this study is to evaluate the impact of excessive PD on the medium- and long-term outcomes of surgery for ODS. The hypothesis is that excessive PD may serve as a negative prognostic factor for the surgical outcomes of patients undergoing correction of rectal and urogenital anatomical abnormalities associated with ODS. The secondary objective of this study is to assess the presence of additional risk factors for poor surgical outcomes following ODS surgery. This will specifically focus on key demographic and clinical characteristics of the patients, such as age, sex, comorbidities, duration of symptoms, history of pregnancy, and the type and extent of pelvic organ morphological abnormalities identified in preoperative radiological examinations.

Who can participate?

All patients with ODS resistant to medical therapy and who underwent resective or suspensive surgery at the participating centers between January 2010 and January 2020 will be eligible for inclusion.

What does the study involve?
The present study focuses on preoperative data and medium- to long-term follow-up of a large cohort of patients who, over the past 10 years, underwent surgery for ODS at leading specialized centers affiliated with the Italian Society of Coloproctology (SIUCP). The ODS-S (Obstructed Defecation Syndrome-Score) is a tool used to measure symptoms of obstructed defecation syndrome (ODS). It includes five items: excessive straining, feeling like you haven't completely emptied your bowels, using enemas or laxatives, needing to use your fingers to help with bowel movements, and abdominal discomfort due to difficulty in passing stool. Each item is scored from 0 to 5, with a total score ranging from 0 (no symptoms) to 20 (severe symptoms). During tests like defecography and dynamic pelvic MRI, doctors will look at factors such as the presence and size of rectocele, recto-rectal and recto-anal intussusception, and other pelvic organ prolapses. They will also measure excessive PD by checking the distance between the anorectal junction and the pubococcygeal line during maximum straining, which is consistent whether the patient is sitting or lying down.

What are the possible benefits and risks of participating?
The benefits of participation include a greater and clearer understanding of the predictive factors for negative outcomes after surgery for ODS. This knowledge could influence therapeutic strategies, potentially avoiding the need for additional surgeries for patients and guiding them toward rehabilitative therapy or an alternative surgical approach.

There are no risks associated with participating in the study.

Where is the study run from?
Department of Medicine, Academy of Applied Medical and Social Sciences-AMiSNS: (Akademia Medycznych I Spolecznych Nauk Stosowanych), Poland

When is the study starting and how long is it expected to run for?
July 2024 to March 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Luigi Marano, l.marano@amisns.edu.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Antonio Brillantino

ORCID ID
https://orcid.org/0000-0002-0198-8511

Contact details
Via Cardarelli 9
Naples
Italy

80138
+393290119127
antonio.brillantino@aocardarelli.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
012024

Study information

Scientific Title
Impact of excessive perineal descent on surgical outcomes in patients with obstructed defecation syndrome: a multicenter retrospective case-control study comparing long-term outcomes of patients undergoing surgical correction of rectal and urogenital abnormalities

Study objectives
The primary hypothesis of this observational study is that excessive perineal descent (PD) negatively impacts long-term surgical outcomes in patients undergoing corrective surgery for obstructed defecation syndrome (ODS). Specifically, we hypothesize that patients with significant PD will experience higher rates of surgical failure compared to those without excessive PD.

Additionally, the study aims to identify demographic and clinical risk factors, such as age, symptom duration, history of pregnancy, and the presence of other pelvic anatomical abnormalities, which may further contribute to poor postoperative outcomes in patients treated for ODS.

This study is being conducted to address the current gap in the understanding of how excessive PD influences surgical success rates and to provide evidence for tailoring surgical interventions that take into account coexisting pelvic floor dysfunctions, potentially leading to improved patient management and outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2024, Ethical Committee "Campania 2" - AOU "L. Vanvitelli" (Piazza Miraglia 3, Naples, 80138, Italy; +39081 5665067; comitato.etico@policliniconapoli.it), ref: 20240024103

Study design
Multicenter observational retrospective case-control study

Primary study design

Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructed defecation syndrome (ODS)

Interventions
During defecography and dynamic pelvic MRI, key parameters assessed will include the presence and size of rectocele, recto-rectal and recto-anal intussusception, colpocele, uterocele, enterocele, sigmoidocele, cystocele, and excessive perineal descent. Excessive perineal descent will be evaluated by measuring the perpendicular distance between the anorectal junction during maximum straining and the pubococcygeal line, a parameter found to be consistent regardless of patient position (sitting or supine) during the examination.

The Obstructed Defecation Syndrome-Score (ODS-S) is a validated symptom score designed specifically for ODS, comprising 5 items (excessive straining, sensation of incomplete rectal evacuation, use of enemas and/or laxatives, vaginal-anal-perineal digital assistance, and abdominal discomfort due to obstructed defecation), with each item scored from 0 to 5, and a total score ranging from 0 (no symptoms) to 20 (severe symptoms).

Data Collection
All demographic, clinical, and surgical data will be collected in a database using online forms on the Google Drive platform. Each local collaborator will receive a link to access the Google Drive form. Each clinical center will be assigned a unique ID by the study coordinator before data collection begins. Local collaborators will coordinate patient inclusion, data collection, and entry into the database, ensuring anonymity and data protection. Only the principal investigator will have access to the anonymized and password-protected database.

For each enrolled patient, the following parameters will be analyzed: age, sex, comorbidities (diabetes, heart disease, lung disease, connective tissue disorders, autoimmune diseases), duration of symptoms, the severity of preoperative symptoms (using ODS-S), pelvic morphological abnormalities identified on defecography or dynamic pelvic MRI (rectocele, recto-rectal and recto-anal intussusception, colpocele, uterocele, enterocele, sigmoidocele, cystocele, and PD), type of surgery performed, and postoperative symptom follow-up using the ODS-S. Clinical follow-up data will be collected at 1, 2, and 3 years post-surgery, as well as long-term data using the longest available follow-up at each center, with the median follow-up.

Statistical Analysis
Statistical analysis will be performed using SPSS® software for MAC OSX (version 22; SPSS Inc., Chicago, IL, USA). Categorical data will be presented as absolute numbers with percentages, and continuous data will be reported as medians with ranges or as means ± standard deviations, depending on data distribution. Based on postoperative GCS-S scores, patients will be categorized into two groups: Group 1 with GCS > 9 (indicative of surgical failure) and Group 2 with GCS < 9 (indicative of surgical success). The two groups will be compared across all demographic and clinical variables mentioned earlier. Categorical data will be compared using the Chi-square test, and continuous data will be compared using the Kruskal-Wallis test with Dunn’s Multiple Comparison Test. The association between surgical failure (dependent variable)

and patients' demographic and clinical characteristics (independent variables) will be evaluated using multiple logistic regression analysis. A p-value < 0.05 will be considered statistically significant.

Sample Size and Expected Outcomes
The study aims to assess the impact of excessive perineal descent on clinical outcomes in patients undergoing surgery for ODS. Considering that the prevalence of perineal descent in the general ODS population is approximately 80%, the minimum sample size needed to detect a 20% increase in the prevalence of perineal descent in patients with unfavorable surgical outcomes was calculated to be 495 patients using a chi-square test with $\alpha = 0.05$ (two-tailed) and a power $(1 - \beta)$ of 0.95. We anticipate that excessive perineal descent will be a significant risk factor for poor outcomes following ODS surgery. Additionally, other risk factors for negative prognosis are expected to include age, symptom duration, and history of pregnancy.

Ethical Considerations
This is a retrospective observational study that will not alter the clinical practices of the participating investigators. All surgeons involved in patient recruitment will be responsible for obtaining local ethics committee approval. Data collection will be anonymized, and no sensitive information (e.g., hospital names, patient names, nationalities) will be recorded or reported. The study will adhere to the standards outlined in the Declaration of Helsinki and good epidemiological practices.

Informed Consent
This retrospective observational study will not attempt to change or modify the clinical practices of participating surgeons. All enrolled patients will be informed about the study and will have provided prior written consent for surgery and the collection, processing, storage, and use of their personal data for scientific purposes.

Dissemination of Results and Publication Policy
The study results will be presented at clinical conferences. The study is a collaborative effort, and all contributors will be acknowledged as collaborators in all publications utilizing the study data.

Intervention Type
Not Specified

Primary outcome(s)
Impact of excessive perineal descent (PD) on the medium- and long-term outcomes of surgery for obstructed defecation syndrome (ODS), measured by comparing the prevalence of excessive perineal descent (cm) in patients with ODS-S (Obstructed Defecation Syndrome-Score) > 9 (considered as failure of surgery) and < 9 (considered as success of surgery) at the 3-year follow-up point after surgery. The prevalence of excessive perineal descent will be compared between groups using the Chi-square test.

Key secondary outcome(s))
The presence of additional risk factors for poor surgical outcomes following ODS surgery, measured by comparing, between the two groups, the median age, sex, median duration of symptoms, prevalence of diabetes, heart disease, connective tissue disorders, neurological conditions, and the prevalence of various pelvic morphological abnormalities identified through

defecographic or defeco-MRI examinations. Statistical comparisons will be performed using the Chi-square test or the Kruskal-Wallis test, depending on the characteristics of the variables considered (categorical or continuous).

Completion date
14/03/2025

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Clinically assessed preoperatively using the Obstructed Defecation Syndrome-Score (ODS-S)
3. Evaluated preoperatively with imaging studies (X-ray defecography or dynamic pelvic MRI)
4. Underwent postoperative clinical evaluation at least 3 years after surgery using the ODS-S

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Are aged <18 years
2. Did not undergo the required preoperative imaging studies (X-ray defecography and/or dynamic pelvic MRI)
3. Were not evaluated pre- and postoperatively using the ODS-S
4. Had prior anorectal surgery
5. Had a clinical follow-up shorter than 3 years after surgery

Date of first enrolment
01/10/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment

Italy

Poland

Study participating centre
U.O.C. Surgery 3, Department of General Surgery and Women's Health, A. Cardarelli Hospital
Via Cardarelli 9
Naples
Italy
80131

Study participating centre
Minimally Invasive Surgery Unit, Buon Consiglio Fatebenefratelli Hospital
Via Manzoni 220
Naples
Italy
80123

Study participating centre
Department of General Surgery, Minimally Invasive Surgery, and Obesity, University of Campania "Luigi Vanvitelli"
Via Pansini 5
naples
Italy
80138

Study participating centre
General Surgery Unit - Villa Esther Clinic
Via Due Principati 169
Avellino
Italy
83100

Study participating centre
U.O.C. Surgery and Pelvic Floor Center, PAUSL-IRCCS
Via Amendola 2
Reggio Emilia
Italy
42122

Study participating centre
U.O.C. General Surgery, Humanitas Gavazzeni/Castelli Hospital
Via Gavazzeni 21
Bergamo
Italy
24125

Study participating centre
U.O.C. Surgery and Pelvic Floor Center, Humanitas San Pio X Hospital
Via Nava 31
Milan
Italy
20159

Study participating centre
Department of General Surgery and Surgical Oncology, "Saint Wojciech" Hospital, "Nicolaus Copernicus" Health Center
Aleja Jana Pawła II n. 50
Gdansk
Poland
53-100

Sponsor information

Organisation
University of Campania "Luigi Vanvitelli"

ROR
https://ror.org/02kqnpp86

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes