Received: 28 January 2024 | Revised: 30 March 2024 | Accepted: 11 April 2024

DOI: 10.1111/codi.17014

STUDY PROTOCOLS

Global International Society of University Colon and Rectal Surgeons in collaboration with European Society of Coloproctology audit on office-based and surgical treatment of haemorrhoidal disease: Study protocol

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Abstract

Aim: Haemorrhoidal disease (HD) is one of the most common anal disorders in the adult population. Despite that, treatment options differ among different countries and specialists, even for the same grade of HD. The aim of this study is to evaluate the differences in patient demographics, surgeon preference for the treatment option, outcomes as well as patient satisfaction rate for the procedure using an office-based or surgical approach for the treatment of HD among International Society of University Colon and Rectal Surgeons (ISUCRS) and European Society of Coloproctology (ECSP) fellows.

Method: A panel of the ISUCRS and ECSP members will answer questions that are included in a questionnaire about the treatment of HD. The questionnaire will be distributed electronically to ISUCRS and ECSP fellows included in our database and will remain open from 1 April 2024 to 31 May 2024.

Conclusion: This multicentre, global prospective audit will be delivered by consultant colorectal and general surgeons as well as trainees. The data obtained will lead to a better understanding of the incidence of HD, treatment and diagnostic possibilities. This snapshot audit will be hypothesis generating and inform areas the need future prospective study.

KEYWORDS
audit, haemorrhoidal disease, office-based procedures, surgical treatment

Audrius Dulskas and Dovile Cerkauskaite contributed equally to this article

INTRODUCTION

Haemorrhoidal disease (HD) is one of the most common anal disorders in the adult population, especially in those between 45 and 65 years of age, and it affects between 4.5% and 36% of the general population [1–3]. It is the fourth most common outpatient gastrointestinal disorder in the United States, followed by a prevalence in Australia of up to 39% of the Australian population, 13%–36% in the United Kingdom and up to 15% in Korea [2, 4–6]. The exact statistics for worldwide prevalence are unknown because most patients are asymptomatic (Grades 1 and 2 disease) and HD can then be found only during endoscopic procedures [7].

There are several treatment options, including conservative, office-based and invasive or surgical treatments, which depend on the degree of haemorrhoidal prolapse, the severity of symptoms, special situations (i.e. comorbidities) as well as surgeon preference and experience. There are many guidelines for the management of HD in different countries [8–11]. The majority agree that lifestyle modification is the first-line therapy for symptomatic HD. Phlebotonics are also frequently used as a part of conservative treatment and they have a beneficial effect for symptomatic HD [8, 9, 11, 12]. Other medical management options, such as local anaesthetics, corticosteroids, antiseptics and astringents, which can relieve symptoms of pruritus and discomfort, improve symptoms in the short term. However, their long-term beneficial effect is debatable [13]. When the effect of conservative treatment is not sufficient, office-based procedures can be performed; these include rubber band ligation, infrared coagulation and three types of sclerotherapy injections, namely endoscopic injection sclerotherapy, cap-assisted endoscopic sclerotherapy or transanal sclerotherapy via an anoscope using three different sclerosant agents such as aluminium potassium sulphate and tannic acid, 3% polidocanol foam and phenol in almond oil. There are several studies showing different results for office-based procedures for treating advanced HD of Grades 3 and 4 [13, 14]. Most try to find the best procedure for the patient with the lowest postprocedure complication and disease recurrence rates.

When symptoms of the disease are severe, or office-based procedures fail, more invasive surgical treatment options are necessary; these include excisional haemorrhoidectomy [Ferguson or closed haemorrhoidectomy (CH) or Milligan–Morgan open haemorrhoidectomy OH)], stapled haemorrhoidopexy (SH), transanal haemorrhoidal dearterialization, Doppler-guided haemorrhoidal arterial ligation and transanal haemorrhoidal dearterialization with mucopexy [15]. OH is more popular and widely used in Europe and the United Kingdom [16, 17]. While it was developed mainly for Grade 2–4 HD, it was recently considered to be the most effective surgical treatment for Grade 3–4 HD [18]. CH was developed in the United States where it is widely used, mainly for Grade 3–4 HD [19].

Patients who present with acutely thrombosed or strangulated haemorrhoids require urgent haemorrhoidectomy [13].The results of urgent haemorrhoidectomy are mostly the same as for an elective haemorrhoidectomy when it is performed by an expert [2].

Despite plenty of publications on different types of treatment options for HD, the results are debatable as they vary depending on author, country, year of publication and the grade of the disease they are used for. In 2019, the European Society of Coloproctology (ESCP) developed a core outcome set (COS) for HD based on a systematic review of the literature and an international Delphi study. The COS for HD may enhance the ability to compare future studies in order to produce treatment guidelines [20].

Our aim for this study is to evaluate the treatments of HD and compare the success rate of treatment procedures in follow-up in different countries as well as to compare results with those published in the ECSP COS international Delphi study among health care professionals in 2019 [20].

OBJECTIVES

The primary objective is to evaluate the differences in patient demographics, the most important symptoms, surgeon preference for the treatment option, outcomes as well as the patient satisfaction rate for the procedure using office-based or surgical approaches for the treatment of HD among International Society of University Colon and Rectal Surgeons (ISUCRS) and ECSP members.

Other objectives are: (1) to assess the proportion of patients with office-based treatment of HD, (2) to assess the proportion of patients with surgical treatment of HD, (3) to compare the operative results between these two groups and (4) to compare the results with the results of the ESCP COS for HD published in the 2019 international Delphi study among health care professionals [20].

METHODS AND ANALYSIS

Study design

This is a multicentre ISUCRS collaboration with ECSP audit of office-based and surgical treatment of HD.

The main objective of this audit is to e valuate the tendency to use the different treatment options for the management of HD by different specialists from different countries in selected patients. Moreover, the outcomes, the main complications and the patient satisfaction rate will be assessed. This will be accomplished by collecting general information about the physician (personal colorectal involvement, age, years of practice), patient demographics (sex, age, past medical history, previous treatment of HD, risk factors, complaints, pretreatment investigation, grade of disease), treatment choice for HD (office-based or surgical treatment, duration of procedure, type of anaesthesia, the main reason for choosing the specific type of treatment), length of hospitalization, intraoperative and postoperative (30 days) complications and follow-up results, as well as patient satisfaction [Haemorrhoidal Impact and Satisfaction Score (PROM-HISS) and Haemorrhoidal disease symptom score (HDSS)] [21, 22]. The questionnaire used in this audit will be reviewed,

discussed and corrected in collaboration with patients before the start of the audit.

Study population

All specialists who belong to ISURCRS and ECSP and specialize in the treatment of HD will be approached by e-mail inviting them to participate in this audit. All members will need the agreement of patients who meet the eligibility criteria to participate in this study.

Eligibility criteria

Inclusion criteria:

1. subjects with a definite diagnosis of HD with no associated ongoing anorectal pathology
2. adult patients (>18 years old)
3. agreement to participate in the study.

Exclusion criteria:

1. patients with medical or psychiatric conditions that compromise the their ability to give informed consent or comply with the audit protocol
2. pregnancy or breastfeeding
3. immunosuppression.
4. diagnosed with inflammatory bowel disease (IBD) [Crohn's disease or ulcerative colitis (ICD codes K50–59)]
5. anal tuberculosis.
6. anal cancer.
7. rectal cancer.
8. history of external beam radiation to the pelvis.
9. anal fistula or fissure.

Centre eligibility

All hospitals/units/private clinics/cabinets seeing proctology patients with HD will be eligible to join this audit. There are no unit size or case throughput stipulations. Countries outside Europe can also participate in this audit.

All participating centres will be required to register their details with the ESCP cohort study office and will be responsible for their own local approvals prior to the start of the data collection period.

Centres should ensure that they have appropriate pathways and staff to include all consecutive eligible patients during the study period and provide >95% completeness of data entry before locking data to the database.

Recruitment

All specialists who belong to ISURCRS and ECSP and specialize in the treatment of HD will be eligible to participate in this audit. Patients who have HD and meet the inclusion criteria (including agreement to participate in this audit) will be recruited to the study.

Patient follow-up

No follow-up will be required.

Informed consent

Informed consent will be gained from all patients.

DATA COLLECTION AND MANAGEMENT

Data collection

During this study, general information about the physician (personal colorectal involvement, age, years of practice), patient demographics (sex, age, past medical history, previous treatment of HD, risk factors, complaints, pretreatment investigation, grade of disease), treatment of HD (whether office-based or surgical treatment was used, duration of procedure, type of anaesthesia, the main reason for choosing the specific type of treatment), length of hospitalization, intraoperative and postoperative (30 days) complications and follow-up results, as well as patient satisfaction rate before and after the procedure (PROM-HISS and HDSS) will be collected.

Data management

All information will be recorded in electronic documents created specifically for this study (https://form.123formbuilder.com/6636020/office-based-patient-information and https://form.123formbuilder.com/6636008/surgical-procedures-form). No patient-identifiable data (name, surname, date of birth, address, etc.) will be collected or recorded. During the running of audit, only the local data will be available to participants; other sites' data will not be accessible.

The data will be processed in a computerized manner, with storage of electronic research documents and password-protected data. Access codes will be known only to the main authors. All data will be analysed and reported in summary format. No individual will be identifiable.

Data will be stored securely on encrypted and certified servers for a minimum of 5 years under the governorship of the ESCP and ISUCRS. The data may be used for future research, although it

should be noted that the anonymized nature of the database means that individual patients will not be reverse-identifiable in the future.

Publication of data

Data will be published as a pool from all participating units. Subgroup analyses by disease, treatment technique or outcome variables may be presented, but no hospital-level or surgeon-level data will be published whereby an individual unit or surgeon could be identified. If local investigators would like a breakdown of their own unit's data for benchmarking purposes and local presentation/discussion this will be available after the end of the study.

Confidentiality

During this audit, patients' personal information, including name and surname, date of birth, address and phone number, will not be collected. If the law does not provide otherwise, only the doctor conducting the study and the research staff will be able to become acquainted with the confidential data revealing the name and surname.

AUTHOR CONTRIBUTIONS

Audrius Dulskas: Conceptualization; methodology; project administration; supervision; writing – review and editing; investigation. **Dovile Cerkauskaite:** Writing – original draft; validation; visualization; formal analysis; data curation. **Joseph Nunoo-Mensah:** Supervision; data curation; project administration; writing – review and editing; conceptualization. **Richard Fortunato:** Conceptualization; investigation; methodology; validation; formal analysis; supervision. **Gaetano Gallo:** Data curation; software; validation; investigation; writing – review and editing. **Alaa El Hussuna:** Validation; writing – review and editing; data curation; resources. **Varut Lohsiriwat:** Resources; supervision; formal analysis; writing – review and editing; investigation. **Tomas Aukstikalnis:** Resources; formal analysis; validation; funding acquisition. **Narimantas E. Samalavicius:** Investigation; validation; project administration; data curation; writing – review and editing.

FUNDING INFORMATION

No funding received.

CONFLICT OF INTEREST STATEMENT

No.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This work will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines [23]. The study will be reviewed and approved by the Institutional Review Board according to individual countries' legal regulations.

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How to cite this article: Dulskas A, Cerkauskaite D, Nunoo-Mensah J, Fortunato R, Gallo G, El Hussuna A, et al. Global International Society of University Colon and Rectal Surgeons in collaboration with European Society of Coloproctology audit on office-based and surgical treatment of haemorrhoidal disease: Study protocol. Colorectal Dis. 2024;00:1–5. https://doi.org/10.1111/codi.17014