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Alimentary Tract

Quality of care indicators in inflammatory bowel disease in a tertiary referral center with open access and objective assessment policies

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ABSTRACT

Background: In the management of inflammatory bowel diseases, there is considerable variation in quality of care.

Aims: The aim of this study was to evaluate structural, access/process components and outcome quality indicators in our tertiary referral IBD center.

Methods: In the first phase, structural/process components were assessed, followed by the second phase of formal evaluation of access and management on a set of consecutive IBD patients with and without active disease (248CD/125UC patients, median age 35/39 years).

Results: Structural/process components of our IBD center met the international recommendations. At or around the time of diagnosis usual procedures were full colonoscopy in all patients, with ileocolonoscopy/gastroscopy/CT/MRI in 81.8/45.5/66.1/49.6% of CD patients. A total of 86.7% of CD patients had any follow-up imaging evaluation or endoscopy. The median waiting time for non-emergency endoscopy/CT/MRI was 16/14/22 days. During the observational period patients with flares (CD/UC:50.6/54.6%) were seen by specialist at the IBD clinic within a median of 1 day with same day laboratory assessment, abdominal US, CT scan/surgical consult and change in therapy if needed. Surgery and hospitalization rates were 20.1/1.4% and 17.3/3.2% of CD/UC patients.

Conclusion: Our results highlight that structural components and processes applied in our center are in line with international recommendations, including an open clinic concept and fast track access to specialist consultation, endoscopy and imaging.

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1. Introduction

Inflammatory bowel diseases (IBD) are chronic, progressive, disabling conditions affecting mainly young adults and having substantial impact on social functioning and quality of life. Together with rapidly increasing incidence rates they contribute to the high health-economic burden associated to the disease.

The management of IBD has become increasingly complex. Patient management including diagnostic tools, medical and surgical therapy, monitoring and follow-up strategy has changed significantly in the last decade with the advent of biological therapies. New treatment goals have been developed (STRIDE) [1] and became realistic. We moved away from symptomatic improvement to measuring more objective parameters including clinical, biochemical remission and endoscopic healing, leading ultimately to less complications and improved quality of life. To achieve this, we need multidisciplinary approach and optimized patient stratification, reassessment of monitoring and follow-up strategies and re-thinking of care pathways. Besides new treatment strategies and new diagnostic/assessment tools, timing became utmost impor-

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tant. All these are important components in establishing quality of care (QoC) in IBD [1–3].

However, there is considerable variation in the process of care for patients with IBD which may be associated with poor outcomes [3,4]. The IMPACT [5] patient survey of the European Crohn's and Colitis Organization (ECCO), conducted in 27 European countries and sampling responses from almost 5000 IBD patients, highlights a number of gaps in current clinical care. This indicates the need for identifying quality of care indicators (QIs) for IBD that could be used worldwide in specialized IBD and/or gastroenterology units to harmonize and increase the quality of care delivered to patients [5].

QIs may relate to the structure, process, and outcome parameters of care and could be used to develop standards by which the provided QoC can be assessed and measured [6,7]. Multiple QI sets were developed with expert interpretation of literature and multidisciplinary input in both Europe and North-America with the aim to present measurable basic aspects of quality of care that could be used for limiting variation and improving patient care. A set of 11 QIs for best-practice management of inflammatory bowel disease in Canada was reported in 2014. These focus on accurate diagnosis, timely management, disease monitoring, and prevention or treatment of complications [8]. In 2011, the American Gastroenterology Association (AGA) published a set of 10 clinical performance measures for the management of IBD, while a further QI set containing 10 process and 10 outcome parameters was developed by the Crohn's and Colitis Foundation of America (CCFA) [9,10]. The 'NICE—The National Institute for Health and Care Excellence, IBD Quality Standard' recommendation were also proposed in the UK in 2015 determining structure, process and outcome QIs on 4 key recommendation in IBD management [11]. In a Spanish consensus, Calvet et al. selected a core set of 56 QIs, including 12 structure, 20 process and 24 outcome parameters by conducting a web-based survey and including an expert panel of patient representatives (n=4), nurses (n=7), surgeons (n=2) and physicians (n=18) [12].

Complex evaluation of QoC provided by IBD centers or country profiles based on the above measures are still scarce. Even the most recent publications highlight significant gaps and need for improvement in the quality of care [13–15]. The aim of our present study was to evaluate structural, access/process components and outcome quality indicators based on the QI sets developed and published in literature to assess QoC in our tertiary referral IBD center.

2. Materials and methods

The present study was conducted at an academic tertiary referral IBD center of the Gastroenterology Unit at the 1st Department of Internal Medicine, Semmelweis University, Budapest.

In the first phase of the study, structural components (hospital characteristics and infrastructure, personnel and referral professionals, equipment, patient registers) of our IBD center were assessed. This was followed by the formal evaluation of process/access indicators in patient management (including monitoring disease activity and selecting treatment strategies, measures to prevent disease complications and drug adverse events, access to diagnostic tools and procedures, imaging, access to urgent outpatient consultation). Finally, we present selected access and outcome QI measures, such as time to accessing an IBD specialist in patients with flares, evaluation strategy of flares and time to therapeutic decision, hospitalization rates and surgery requirements, documented relapses in disease activity.

In the second phase we evaluated access, monitoring and outcome parameters in a set of consecutive IBD patients who presented

Table 1
Structural components at our IBD center.

Hospital characteristics
<ul style="list-style-type: none">• Dedicated outpatient clinic• Affiliated inpatient ward• Endoscopy unit• Outpatient infusion therapy unit• Emergency department
Personnel and referral professionals
<ul style="list-style-type: none">• 3 consultant gastroenterologists with IBD interest• Histopathologist• Consultant expert colorectal surgeons• Consultant radiologist with IBD interest• Access to dermatologist, rheumatologist, ophthalmologist• Psychologist• Dietician• Stoma therapist• Pharmacist experienced with IBD and biologic drugs• Regular multidisciplinary and transition meetings are held^a

IBD: inflammatory bowel diseases; MDT: multidisciplinary team.

^a Patients can attend the MDT meeting if their case will be discussed.

as out- or in-patients at our IBD center up to 2016 July. Medical records of patients with and without active disease/flare were collected and comprehensively analyzed (n = 248 Crohn's disease (CD) patients/n = 125 ulcerative colitis (UC) patients, 52%/52% female, median age 35/39 years (y), IQR: 27–44 year and 33–50 year). Data regarding frequency of disease flares, access to IBD specialist physician and imaging procedures, hospitalization and surgery rates were collected between the period of 2014 January and 2016 July (n = 163 CD/n = 95 UC). Ileocolonic location, complicated disease behavior and perianal disease was present in 62.1%, 49.6% and 45.9% of CD patients. 72.1% of UC patients had extensive disease.

Statistical analysis: descriptive statistics, frequency distributions were calculated. Medians and interquartile ranges were calculated for continuous variables. Outcomes in patients with and without flares were compared by D-test of Chi² analysis, and logistic regression as appropriate. Statistical analysis was performed using the SPSS software v. 20.0 (Chicago, IL).

2.1. Ethical considerations

The study complies with the principles of the Declaration of Helsinki (6th revision, 2008). The study protocol was approved by the Semmelweis University Regional and Institutional Committee of Science and Research Ethics [TUKÉB] (No.: 142/2010).

3. Results

3.1. Evaluating structural components

Our IBD center includes an outpatient clinic, an affiliated inpatient ward with 10 hospital beds and an endoscopy unit. Further structural components of the center regarding personnel and access to referral specialists and other health care professionals as well are presented in Table 1. Our center cannot provide access to a specialized IBD nurse.

3.2. Process/access quality measures

Process quality indicators were also part of formal standard operational processes of IBD patient care at our center. Process and access quality measures related to our center are presented in Table 2.

Table 2
Process/access quality measures at our IBD center.

Access to provided care:
<ul style="list-style-type: none"> • Each IBD patient is assigned to one of the IBD specialists in charge of his/her clinical care • Urgent outpatient access for patients with suspected flare or complication • Continuous availability (24/7) by e-mail or phone • Fast track access to endoscopic imaging • Fast track access to CT/MRI/MRE/abdominal US imaging
Process of provided care:
<ul style="list-style-type: none"> • Formal assessment of disease activity at each visit (by using clinical scores) • Newly diagnosed patients undergo an extensive evaluation including family history, disease extent, complications and EIMs. Procedures include full ileocolonoscopy and upper GI/small bowel endoscopy and imaging (abdominal US, MRI, CT scan) in CD • Detailed mapping and evaluation of patients at referral, repeating or performing imaging/endoscopy as appropriate • Systematic assessment of EIMs • Assessment of smoking history • Clinical and laboratory monitoring program for all patients including patients on immunosuppressive/biological treatment • At point and random TDM in patients treated with anti-TNFs • Hepatitis B and C testing and hepatitis B vaccinations in patients on immunosuppression or biologicals • Latent TB testing before anti-TNF therapy (Mantoux tuberculin skin test + Interferon-γ release assay + chest X-ray)^a • Pneumococcal and influenza vaccination for patients with immunosuppression or biologicals^a • Clostridium difficile infection is evaluated in patients with disease flares presenting diarrhea • In UC patients with severe activity, rectal biopsies are taken to rule out Cytomegalovirus infection • VTE prophylaxis in hospitalized patients • Colorectal cancer surveillance program in IBD patients with longstanding colonic inflammation • Registry of all IBD patients, and a separate registry of IBD patients receiving biological treatment • Adherence to international guidelines • Continues research in clinical investigator initiated research projects and clinical trials on IBD • Providing oral/written information materials for our patients about disease course, treatment options, anti-TNF therapy, etc.

IBD: inflammatory bowel diseases; CT: computed tomography; MRI: magnetic resonance imaging; MRE: magnetic resonance enterography; EIM: extra intestinal manifestation; US: ultrasound; CD: Crohn's disease; TDM: therapeutic drug monitoring; TNF: tumor necrosis factor; TB: tuberculosis; VTE: venous thromboembolism.

^a TB testing and pneumococcal vaccination is mandatory in Hungary and was universal in our patients before commencing anti-TNFs.

3.3. Outcome quality indicators

We assessed the following parameters at our IBD center considered as outcome measures, presented in [Table 3](#).

3.4. Quality of patient evaluation and distribution of treatment steps

64.5% of CD and 60.8% of UC patients were referred from other hospitals or outpatient units. Detailed medical history was obtained and registered in all IBD patients. All patients of our IBD center underwent at least one full colonoscopy at or around the time of diagnosis. Ileocolonoscopy and gastroscopy was performed in 81.8% and 45.5% of CD patients. CT/MRI was performed in 66.1/49.6% of CD patients while a pelvic MRI in 83.1% of patients with a perianal disease. Ever medication exposure (5ASA: 94.1%, steroids: 79.3%, AZA: 72.9%, and anti-TNF: 47.4%), previous and total surgeries, pregnancies were also registered in all patients.

Table 3
Outcome quality indicators assessed in the present study.

Outcome quality measures
<ul style="list-style-type: none"> • Frequency of disease flares • Time to access for outpatient consultation with an IBD specialist in patients with flares • Time to laboratory and imaging/endoscopy evaluation in patients with flare • Time to therapeutic decision in patients with flare (medical/surgical) therapy • Time to access time for imaging (CT/MRI/abdominal US) in patients without flares • Hospitalization rates • Emergency and elected surgery rates

IBD: inflammatory bowel diseases; CT: computed tomography; MRI: magnetic resonance imaging; US: ultrasound.

Table 4
Access to imaging and endoscopy.

Patients with a procedure during follow-up (%)	Patients with a procedure during follow-up (%)	
	CD patients	UC patients
Endoscopy	45.5	51.5
Abdominal US	49.7	35.9
CT	14.7	2.2
MRI	39.3	3.3

US: ultrasound; CT: computed tomography; MRI: magnetic resonance imaging.

3.5. Frequency and management of patients with flares: access, initial evaluation, change of treatment strategy

50.6% and 54.6% of all CD/UC patients presented with at least one disease flare in the study period between 2014 and 2016 (chronic active patients: 5.5% (n=9/163) and 8.4% (n=8/95) of all CD/UC patients). These patients had an outpatient consultation with a specialist at the IBD clinic (not emergency room) a median of 1 day after request with same day laboratory and same day abdominal US, CT scan and surgical consult if necessary. Same day change in medical therapy was also applied as appropriate. Medical therapy (including initiation of antibiotics, aminosalicylates and local steroids as well) was modified in 51.9/59.4% of all CD/UC patients, and in 94.4/100% of CD/UC patients presenting with flare—initiation of systemic steroids: 46.4/77.3%, azathioprine: 15.9/4.7%, anti-TNF initiation and dose intensification: 32.4/25.6% and 19.4/15.5%.

3.6. Access to imaging and endoscopy, hospitalization and surgery rates

A total of 86.7/61.6% of all CD/UC patients had any imaging evaluation in the period of 2014–2016. Patient access to imaging procedures during our follow-up is presented in [Table 4](#). The median waiting time for non-emergency endoscopy, CT or MRI was 16, 14 and 22 days. Overall hospitalization rates were 17.3/3.2% of all CD/UC patients in 2014–2016. 20.1% of CD patients required any surgery and 1.4% of UC patients underwent colectomy. Detailed hospitalization and surgery rates among patients with isolated flares, chronic active disease and continuous remission are presented in [Table 5](#). 11 pregnancies (6 CD patients and 5 UC patients) were registered during the follow-up period of 2014–2016. All but 2 pregnancies were successful delivered (1 early and 1 late abortion). Our center can provide access to a gynaecologist, who specializes in patients with IBD, as part of the MDT team.

Table 5
Hospitalization and surgery rates.

	Patients with isolated flares	Chronic active patients	Continuous remitting patients
CD	n = 73	n = 9	n = 81
Hospitalization rates	29.4%	22.2%	6.3%
Surgery rates	30.0%	28.6%	6.9%
UC	n = 44	n = 8	n = 43
Hospitalization rates	4.8%	12.5% (n = 1)	0.0%
Surgery rates	0.0%	12.5% (n = 1)	0.0%

4. Discussion

This is the first study reporting on systematic assessment of structural, process and outcome quality of care indicators from an IBD center in East Europe. Major findings of our study were that structural and process indicators of our center meet the requirements of international guidelines and this was coupled with fast track access and objective evaluation of our IBD patients presenting with a flare, in line with the open clinic policy applied by the center. Access to non-emergent visits, endoscopy and imaging was also quick, while the high overall rate of yearly endoscopies and imaging studies confirm that our center is dedicated to objective assessment of disease activity and response.

Quality of care is of utmost importance to improve outcomes in chronic illnesses such as IBD. There is a lack of universally accepted guidelines on the measurement of QoC provided in IBD and it may vary significantly across different healthcare delivery settings [4]. Unequivocal structural, process and outcome QIs are important to better understand where deficiencies in quality care exists and to establish goals for performance competency in IBD care [16,17]. Highly rated process measures include pretreatment screening for latent infections (tuberculosis, hepatitis B), checking for enteric infections (*Clostridium difficile* and cytomegalovirus) in severe steroid-refractory colonic disease and appropriate cancer surveillance in case of longstanding colonic inflammation, etc. Outcome measures include steroid-free clinical remission and current corticosteroid use, assessments of health care utilization (hospitalization days and emergency visits) [9,10,12]. Structure, process and outcome QIs all highlight the need for multidisciplinary management and the continuity of care [10,12].

Recent publications on the operation of IBD centers worldwide suggests that better QoC requires an integrated model of care provided by a multidisciplinary team (MDT), as opposed to a more simplistic biomedical approach which persists at many IBD sites [18–21]. An ideal IBD service should provide timely access to referral professionals, including significant roles of nurses, psychologists and dieticians, and be easily accessible to patients [12,22,23]. The minimal IBD team should include gastroenterologists, radiologist, surgeon, endoscopist and stoma management specialists. IBD centers should be able to provide both outpatient and inpatient care and admission should not break the continuity of care [12,19,21–23].

Our center has applied these standards, structural and process components were developed alongside the above recommendations, with an open clinic concept, as well as fast track access to endoscopy, imaging, second opinion and regular MDT meetings. Structural components of our center met most of the requirements of an “integrated and comprehensive” IBD care unit as proposed in different consensus with the exception of a specialized IBD nurse [12,19,23]. Mikocka-Walus et al. designed a survey to help gather information from health care professionals working in IBD services on current care models [3]. Out of the 135 included respondents, 54% considered their IBD service to apply an integrated model of care and 35% of respondents considered their model favoring biomedical approach in patient care. Specialists involved or timely

accessible at the respondents’ IBD services: IBD nurse 63%, colorectal surgeon 57%, psychologist 33%, pathologist 40%, radiologist 42% [3]. Louis et al. also completed a similar online survey including 142 IBD specialists. Timely access to colorectal surgeon was 87%, IBD nurse 62%, nutritionist 83%, psychologist 66%, imaging specialist to interpret scans/images 85% as reported by the respondents [7].

There are few data on quality measures (access/process/outcome) reported by individual IBD centers [24]. Feuerstein et al. from the United States reviewed charts from 783 consecutive patients with IBD seen at academic, community and also private practices to examine if compliance with the publicized AGA measures were followed [13]. Screening for tobacco abuse was the most frequently assessed core measure at the different IBD centers (89.6%), followed by location of IBD (80.3%), and assessment for corticosteroid-sparing therapy (70.8%). The least-frequently evaluated measures were pneumococcal immunization (16.7%), bone loss (25%), and influenza immunization (28.7%). Compliance of testing for latent TB was 52.7% [13]. There is also considerable variation in the delivery of performance measures among Asian countries, resulted from a questionnaire-based survey including 353 IBD specialists [25]. QIs with a consistently high rate in delivery included testing for latent TB before the initiation of anti-TNF therapy, and proper registries for documentation of IBD patients. Lower ranked performance measures including VTE prophylaxis, pneumococcal and influenza vaccination were comparable to a similarly low compliance in Western countries [13,25,26]. Recent Western survey data suggests that in hospitalized IBD patients the rates of pharmacologic prophylaxis of VTEs is probably less than 40% [25]. There is also significant variation worldwide in routine testing for *Clostridium difficile* infection in patients presenting with flare in IBD (66.9%–92.2%) [14,25].

Calvet et al. also proposed as a QI that IBD centers providing comprehensive care should offer timely access to imaging and offer urgent outpatient consultation when there is a presumption of flare or complication [12]. We applied an open clinic concept and provided an immediate access for an outpatient consultation with a specialist within a median of 1 day after request in patients presenting with a flare, which is important quality indicator. The UK Inflammatory Bowel Disease Audit reported on the organization and structure of IBD services across the United Kingdom in 2011. Over 90% of sites reported that they see relapsing patients within 7 days of contact [27]. Our results are in line with results from the EpiCom inception cohort, where Burisch et al. reported that gastroenterologists were significantly easier to contact by the patients in Eastern Europe, while in Western Europe, other members of the IBD staff (especially the IBD nurse) were easier to be contacted by phone [28]. In addition, the percentage and median waiting time for non-emergency endoscopy/CT/MRI represent also a fast track access and objective monitoring strategy in our IBD center and are in line with the guidance set by the STRIDE initiative and the concept of the objective patient assessment in our IBD center [1,12]. Hospitalization rates and the number of surgical interventions required are important QIs in assessing outcome parameters [10,12]. These however, also represent the severity of the patient population, thus direct comparison among centers is difficult. Nonetheless, measuring time trends in these variables in the given center represents principal QI outcome variables and it is directly linked to the QoC provided by the center [12,29]. There is significant lack of reports from individual centers evaluating outcome quality measures. Based on administrative claims data, Tkacz et al. estimated that only 9.3% of the evaluated IBD centers assessed and reported hospitalization rates [14]. Rejler et al. reported their one-year data including 481 patients from an IBD center in Eskjö, Sweden evaluating patient access, prescription patterns/treatment steps and also hospitalization and surgery rates [29]. In the study

by Feuerstein et al. hospitalization rates were also reported only from a few centers [13].

Although an increasing number of quality indicator sets have been developed by expert groups recently, reports on the implementation and evaluation of these QIs from IBD centers are still scarce. To the best of our knowledge, this study is the first to assess the delivery of structural, access/process and outcome QIs for IBD management in Eastern Europe and Hungary. The strengths of our study include the comprehensive evaluation of structural, process and outcome QIs of our center. A limitation of our study is that it was performed at a single academic tertiary IBD center, and patient characteristics of the center are not representative for general IBD patient populations.

In conclusion, results from the present study confirm that structural components and processes applied in our tertiary referral IBD center were developed in line with international recommendations, including an open clinic concept, fast track access to specialist consultation, endoscopy, imaging or second opinion and regular MDT in patients with and without flares. We believe that prospective continuous tracking and formal evaluation of QIs in IBD centers is important, improving healthcare delivery and efficiency in IBD clinics/centers and ultimately may lead to improved patient outcomes.

Conflict of interest

None declared.

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Institutional review board statement: The study protocol was approved by the Semmelweis University Regional and Institutional Committee of Science and Research Ethics [TUKÉB] (No.: 142/2010).

Informed consent statement: The study complies with the principles of the Declaration of Helsinki. Data collection was performed through chart reviews.

Data sharing statement: No additional data are available.

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