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DOI: 10.17235/reed.2020.6884/2020
Link: PubMed (Epub ahead of print)

Please cite this article as:
Moreno Sánchez Nadia, Paredes José María, Ripollés Tomas, Sanz de la Vega Javier, Latorre Patricia, Martínez María Jesús, Richart José , Vizuete José, Moreno-Osset Eduardo. Treatment of abdominal fistulas in Crohn's disease and monitoring with abdominal ultrasonography. Rev Esp Enferm Dig 2020. doi: 10.17235/reed.2020.6884/2020.

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OR 6884

Treatment of abdominal fistulas in Crohn's disease and monitoring with abdominal ultrasonography

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Received: 23/01/2020

Accepted: 04/05/2020

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Ethical statement: all authors of the manuscript declare that they have no conflicts of interest.

The approval of our center's Ethics Committee was obtained in order to conduct the study. Prior to their inclusion in the study, patients were informed of its nature and gave their written consent. The work has not been funded by any entity.

ABSTRACT

Objective: to assess the usefulness of medical treatment to achieve closure of internal fistulas detected on abdominal ultrasound in a series of patients with fistulizing Crohn's disease.

Material and methods: a retrospective analysis was performed of the medical records of patients with Crohn's disease with a fistula detected on abdominal ultrasound from 2010 to 2018. The study included patients who received medical treatment after the

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diagnosis of this complication and underwent ultrasonographic monitoring of the therapeutic response. The factors associated with the response to medical treatment or the need for surgery were investigated.

Results: forty-six patients were included in the study. Enteromesenteric (69.6 %) was the most common type of fistula and associated abscesses were found in 14 (30.4 %) patients. Fistulas were classified as complex in 20 patients. Treatment with immunosuppressants was started in 14 (30.4 %) cases and a biologic drug was added in 18 (39.1 %) patients. Complete closure of the abdominal fistula was observed with ultrasonography in 24 (52.2 %) of the 46 patients. The only factor related to fistula closure was the type of fistula and was more likely to occur in patients with an enteromesenteric fistula. Thirteen (28 %) of the 46 patients needed a surgical resection. The only factor with a significant correlation with a lower need for surgery was fistula closure after treatment (8.3 % *vs* 50 %, p = 0.002).

Conclusion: medical treatment achieves internal fistula closure in more than half of cases and almost a third require surgical treatment. Abdominal ultrasound can detect abdominal fistulas at an earlier stage and allow prompt treatment changes.

Keywords: Crohn's disease. Abdominal fistulas. Abdominal ultrasound.

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INTRODUCTION

The clinical course of Crohn's disease (CD) is often complicated by the development of fistulas, consisting of abnormal tracts formed between the intestine and other anatomical structures (1). Fistulas are classified as internal or external, depending on where they terminate. Internal fistulas include enteroenteric, gastrocolic, enterovaginal, enterovesical and enteromesenteric fistulas (also called "sinus tracts") and external fistulas are termed enterocutaneous or perianal (2). A population study reported 88 fistulas in 51 patients with CD; 61 % were external and 39 % internal (3).

Both enterocutaneous and internal fistulas are considered as abdominal fistulas because they originate in the abdominal cavity and can cause limiting symptoms. In the case of internal fistulas, these symptoms can become severe, depending on their location and the amount of bowel bypassed (1). Internal fistulas are difficult to diagnose when endoscopy and barium X-rays are used for the study of CD and were usually detected incidentally during surgery (1,4). Cross-sectional imaging techniques give a clearer picture of the intestinal wall and adjacent anatomical structures and are now the techniques of choice for the initial assessment and monitoring of these complications (5).

Despite the availability of more effective drugs for the treatment of CD, little is known about their therapeutic efficacy in abdominal fistulas. Nearly all studies to date have focused on the management of external fistulas, primarily perianal (6-8). There are few reports in the literature about the benefits of treating internal fistulas (1,9-13).

The main objective was to assess the usefulness of medical treatment to achieve closure of internal fistulas in a series of patients with abdominal fistulas detected on abdominal ultrasound (AUS). The secondary objectives were to evaluate the need for surgical treatment in patients with abdominal fistulas and to identify the factors associated with response to medical treatment or the need for surgery.

MATERIAL AND METHODS

Study characteristics

A descriptive, observational and retrospective study of data collected from the computerized medical records of patients with CD treated in our center was performed. Data was only included from patients with a fistula detected on imaging studies and who received medical treatment after a diagnosis of this complication.

Patient selection criteria

Inclusion criteria were: diagnosis of CD based on the Lennard-Jones criteria (14), age over 18 years and at least one abdominal fistula detected using imaging studies and treatment for their bowel pathology that lasted at least 12 weeks.

Approval was obtained from our center's Ethics Committee in order to perform the study. Prior to their inclusion in the study, patients were informed of its nature and gave their written consent.

Clinical assessment/data collection

All patients who met the selection criteria, with available data from January 2010 (when electronic clinical records were introduced in our center) until June 2018, were included. Patient demographics and epidemiological data, disease-related clinical data recorded at the time of detecting the fistula, prior treatment, treatment given after diagnosing the fistula, the need for abscess drainage and a morphological description of the fistulas were collected.

Radiological evaluation

Diagnosis and follow-up of fistulas were performed using the imaging techniques routinely used in the clinical practice in our center for the study of CD. This included AUS as a first choice technique and magnetic resonance enterography (MRE) when there was a doubt with the initial exploration about the diagnosis of the fistula or to discard an associated collection.

The protocol for AUS and MRE have been previously described (15,16). AUS is usually the first imaging technique performed and MRE is performed if the presence of the

complication is unclear.

In both AUS and MRE, an abdominal fistula was defined as a tubular tract extending from the affected intestinal wall to other anatomical structures (abdominal wall, mesentery or other viscera). On ultrasound, these are seen as hypoechoic tracts with fluid or air trapping (17,18). On MRE, they are seen as linear tracts that are enhanced on T1 sequences with contrast and hyperintense on T2 due to their liquid content (19).

The fistulas were classified according to their anatomical structure: enterocutaneous (connected to the abdominal wall), enteromesenteric (sinus tract or mesenteric inflammatory mass), enteroenteral (between two intestinal loops), enterocolonic (between the small intestine and colon) and enterovesical (between the intestine and bladder). They were also classified as complex if they had several tracts, involved several intestinal loops, or if a structured collection that encompassed intestinal loops and fistulas was observed (18).

On AUS, inflammatory masses were defined as hypo- or anechoic lesions in the mesenteric fat. Second-generation ultrasound contrast was administered (Sonovue®, Bracco) to distinguish between a phlegmon and an abscess (20). On MRE, an abdominal abscess was defined as a mass with liquid or a heterogeneous content, with wall enhancement after contrast injection (17). Closure of internal fistulas was defined as the disappearance of the tract that was observed during follow-up in ultrasonography studies.

Statistical study

Basic descriptive statistics were used, which included the mean and standard deviation for continuous variables and the absolute frequency and percentages for qualitative variables. The Chi-squared test or Fisher's exact test (when necessary) were used to compare the proportions between independent samples, and the odds ratio (OR) and 95 % confidence interval were calculated.

RESULTS

Forty-six patients were included in the study and table 1 shows the demographic and clinical characteristics at the time of diagnosis of the abdominal fistula. The diagnosis of a fistula was made as a complication of a previously diagnosed CD in 31 patients (67.4 %). In these patients, the median time between diagnosis and fistula detection was 88 months (range 2-348). In 15 (32.6 %) cases, the fistula was detected at the time of diagnosis of the disease. When the abdominal fistula was diagnosed, 60.9 % of patients presented abdominal mass on palpation, 67.4 % presented moderate-severe disease on the Harvey-Bradshaw index and 78.2 % presented elevated C-reactive protein levels (> 10 mg/dl). None of the patients were receiving biologic drugs at the time of diagnosis of the abdominal fistula.

Imaging study findings

The fistula was detected with AUS performed during the initial diagnostic workup in the 15 patients who debuted with the fistula. In the remaining 31 (67.4 %) patients in whom the fistula was diagnosed during the course of the disease, the indication to perform the imaging study was a change in clinical status. In 16 (34.7 %) patients, MRE was performed after AUS to rule out deep abscesses in the abdominal cavity or other associated complications. MRE confirmed the presence of a fistulous track described on AUS in all cases and additional transmural complications were not found. Table 2 describes the radiological findings at the time of detecting the abdominal fistula.

The most common (69.6 %) type of fistula (Fig. 1) was enteromesenteric. Inflammatory masses associated with the fistula were detected in 32 (69.6 %) patients, of which 14 (30.4 %) were abscesses and nine (64.3 %) had a diameter greater than 3 cm. The remaining inflammatory masses were diagnosed as phlegmon. Enteromesenteric fistulas were most commonly associated with an abdominal abscess (62.5 % of cases). Fistulas were classified as complex in 20 patients, which was due to the presence of multiple tracts in 14 (30.4 %) and due to the involvement of multiple intestinal loops in six cases (13.0 %).

Medical treatment

Fistulas were treated with antibiotic therapy in all patients and the abscess was initially drained in nine (19.6 %) patients. Thirty-two (69.6 %) patients received corticosteroids after the septic symptoms were resolved.

Treatment with immunosuppressants (thiopurine in ten patients and methotrexate in four patients) was started at the time of diagnosis of the abdominal fistula in 14 (30.4 %) cases. A biologic drug was added (infliximab in eight patients and adalimumab in ten) in 18 (39.1 %) patients who were already taking immunosuppressants (15 thiopurine and three methotrexate). At the time of diagnosis of the abdominal fistula, eight (17.5 %) patients were started on a combination of immunosuppressants and biologics. Infliximab and methotrexate was used in one patient, infliximab and thiopurine in six patients and adalimumab and thiopurine in one patient. Furthermore, six patients (13.0 %) were given a biologic as monotherapy (two infliximab and four adalimumab). AUS was repeated to confirm the resolution of the abscess in all patients prior to the starting the biologic therapy.

Clinical and radiological response to medical treatment

Complete closure of the abdominal fistula during follow-up of a median of 30 (range 4-48) months was observed in 24 (52.2 %) of the 46 patients (Fig. 2). The mean time to fistula closure was six months (range 3-12 months).

Table 3 shows the percentage of fistula resolution after medical treatment. In terms of the type of fistula, all three (100 %) enterocutaneous fistulas, 20 of the 32 (62.5 %) enteromesenteric and one of the eight (12.5 %) enteroenteric fistulas closed after medical treatment. None of the enterocolonic or enterovesical fistulas closed. With regard to the treatment given, no correlation was observed between the rate of fistula closure and treatment with corticosteroids. Furthermore, there were no significant differences between patients receiving combination therapy (immunosuppressants and biologics) *vs* monotherapy with immunomodulators (37.5 % closure) or biologics (66.6 % closure).

The only factor related to fistula closure was the type of fistula (Table 3). Fistula closure was more likely to occur in patients with an enteromesenteric type and those with an abscess at the time of diagnosis (usually associated with enteroenteric fistulas) compared to those with other types of fistulas. By the end of the follow-up, radiological findings had normalized in only six (13 %) patients (intestinal wall thickness less than 3 mm with no evidence of fistulas).

Need for surgery

Thirteen (28 %) of the 46 patients needed a surgical resection during follow-up. The mean time from fistula diagnosis to the need for surgery was nine months (standard deviation ± 3.7 months). The only factor with a significant correlation with a lower need for surgery was fistula closure after treatment (8.3 % *vs* 50 %, p = 0.002; OR 0.09 [0.01-0.48]). Two patients with a fistula closure after treatment required bowel resection during follow-up, due to the appearance of intestinal stenosis with symptoms of obstruction.

All enterocolonic and enterovesical fistulas required surgical treatment. The analysis of the surgical pieces confirmed the presence of the fistula described in the AUS, except in one case that showed a deep fissure and phlegmon.

DISCUSSION

In our center, cross-sectional imaging techniques (mainly AUS) are used to classify the disease phenotype at the time of diagnosis, monitor response to treatment and for re-examination in the event of changes in the patient's clinical status. This fact partly explains the high percentage of enteromesenteric fistulas found in our series (69 %). Other series published before the use of AUS and MRE in CD reported a lower percentage of enteromesenteric fistulas (25 % of all fistulas detected in 51 patients) (2). However, a series published at the beginning of 2000 showed that AUS detected more enteromesenteric fistulas (36 %) when findings were compared with the surgical specimen (21). Some authors claim that fistulizing into the mesentery is an

initial stage of penetrating disease (18). Therefore, we believe that the high percentage of enteromesenteric fistulas in our study was due to early and more frequent use of cross-sectional imaging techniques in CD.

There is no prior clinical suspicion in up to 50 % of cases in which fistulizing disease was diagnosed using imaging techniques (22). In our series, although a high percentage of patients presented signs of inflammatory activity, fistulizing disease was not suspected after abdominal palpation in one third of all cases. All this highlights the importance of using imaging techniques to detect complications, both at the time of diagnosis and when monitoring treatment, even when there are no clinical changes.

It is also important to identify abscesses in order to control the septic process prior to starting treatment with immunosuppressants (23). In our series, abscesses were detected in 14 of 46 (30.4 %) patients, which is similar to that reported by Maconi (36.1 %) (21). Nine of the 14 patients had abscesses measuring over 3 cm in diameter and required percutaneous drainage. No signs of abdominal septic complications or disease worsening were observed during treatment in patients with abdominal abscess or phlegmon. Although anti-TNF therapy has traditionally been contraindicated in patients with an abdominal abscess (20), two recent series used these drugs safely in patients with abdominal abscesses measuring less than 2 cm in diameter (24,25).

In our series, fistula closure was achieved with prescribed medical treatment in 52 % of patients. Internal fistulas are known to respond poorly to medical treatment (12,26). However, there is little information on the effectiveness of medical treatment for abdominal fistulas. A large number of patients with perianal disease have been included in trials with anti-TNF drugs in fistulizing CD, but very few of these (7 %) had enterocutaneous fistulas (6-8). A recent study evaluated clinical outcomes in patients with enterocutaneous fistulas and reported a closure rate of 33 % with anti-TNF drugs (13). Only three enterocutaneous fistulas were included in our series and all three closed after the prescribed treatment. A large recently published study evaluated the treatment of enterovesical fistulas and reported a sustained remission. Among the patients treated with anti-TNF drugs, 45 % presented fistula closure (27)

that was confirmed by imaging studies (MRE or computed tomography). However, in our study, there was only an enterovesical fistula that did not close with treatment.

The most common fistulas in our study were enteromesenteric, which also responded best to the treatment. This is probably because they represent an earlier stage of fistulizing disease (16), although this hypothesis should be confirmed in prospective studies with a larger number of cases. In our study, fistula type was the only factor that correlated significantly with the closure rate. There was no correlation between closure rate and treatment given (monotherapy *vs* combination and anti-TNF *vs* immunomodulators), probably due to the small size of the subgroups.

Despite these good outcomes with medical treatment, the surgery rate (bowel resection) was high. Almost one third of our patients needed a bowel resection relatively early during follow-up (median 30 months). These results are consistent with the findings of two recent series in which anti-TNF drugs were frequently used to treat abdominal, enterocutaneous and enterovesical fistulas, with a high surgery rate (54 % and 81 %, respectively) (13,27). Interestingly, very few patients achieved normalization of ultrasound findings (transmural healing) (13 %). This is lower than the rate reported in other series where the predominant phenotype was inflammatory (28).

The limitations of this study include the small sample size of the treatment subgroups. Another limitation is the relatively short follow-up period to evaluate the rate of surgery. Although the median follow-up was 30 months, only 23 (50 %) patients were followed up for three to four years. Follow-up time in the remaining patients was 1-2 years, which was insufficient to confirm a good outcome.

In conclusion, medical treatment achieves internal fistula closure in more than half of patients with CD. However, almost a third require surgical treatment during follow-up. AUS can detect abdominal fistulas at an earlier stage and allow prompt treatment changes in many patients. Furthermore, they can also be used to monitor the response to medical treatment.

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Table 1. Demographic and clinical characteristics of the 46 patients included in the study

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Variables	*Frequencies* *n (%)*
Females	26 (56.5)
Age (years) (median and range)	40.0 (22-67)
Location	
Ileum	34 (74.0)
Colon	2 (4.3)
Ileum and colon	10 (21.7)
Behavior at the time of diagnosis	
Inflammatory	29 (63.0)
Fistulizing	17 (37.0)
Age at diagnosis	
< 16 years (A1)	3 (6.5)
17-40 years (A2)	40 (87.0)
> 40 years (A3)	3 (6.5)
Perianal involvement	4 (11.1)
Previous surgery	11 (30.6)
Harvey index (score) (median and range)	6.0 (0-11)
Serum C-reactive protein (mg/dl) (median and range)	20.0 (4-91)
Baseline treatment	
No treatment	15 (32.6)
Corticosteroids	13 (28.3)
Immunomodulators	18 (39.1)

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Table 2. Radiological findings of abdominal fistulas detected in 46 patients included in the study

Variables	*Frequencies* n (%)
Type of fistula	
Enteromesenteric	32 (69.6)
Enteroenteric	8 (17.4)
Enterocutaneous	3 (6.5)
Enterocolonic	2 (4.3)
Enterovesical	1 (2.2)
Fistula classification	
Simple	26 (56.5)
Complex	20 (43.5)
Collections	32 (69.6)
Phlegmon	18 (39.1)
Abscess	14 (30.4)
Abscess in enteromesenteric fistulas	12 (37.5)
Abscess in fistulas other than enteromesenteric fistulas	2 (14.3)

Table 3. Factors associated with abdominal fistula closure in 46 patients included in the study

Factor	*Closure*	*Odds ratio (95 % confidence interval)*	*p*
Disease < 2 years	50.0 %	1.1 (0.36-3.74)	0.79
Disease > 2 years	53.8 %		
Fistula at diagnosis	40.0 %	2.0 (0.59-7.28)	0.25
Fistula as a complication	48.3 %		
Associated abscess	78.5 %	5.3 (1.24-23.04)	0.01
No abscess	40.6 %		
Enteromesenteric fistula	62.5 %	4.1 (1.06-16.27)	0.03
Non-enteromesenteric fistula	28.5 %		
Simple fistula	57.6 %	0.6 (0.18-1.94)	0.39
Complex fistula	45.0 %		
Corticosteroid therapy	50.0 %	0.7 (0.21-2.65)	0.65
No corticosteroid therapy	57.1 %		
Combination therapy	60.0 %	2.0 (0.61-6.49)	0.24
Monotherapy	42.8 %		

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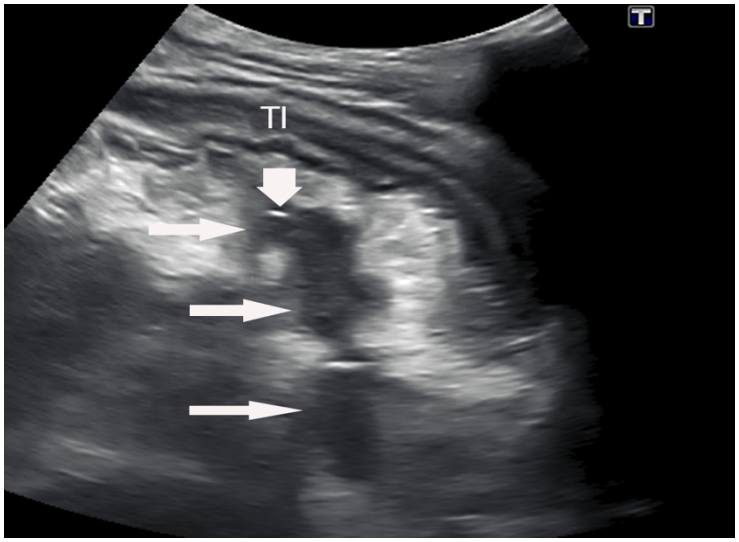

Fig. 1. A 27-year-old male with Crohn's disease. Longitudinal AUS scan of the right lower quadrant shows a blind-end hypoechoic tract (arrows) originating from the thickened terminal ileum (TI), which represents a fissure penetrating the mesentery. Note the hyperechoic bubbles of extraluminal gas in the tract (arrowhead).

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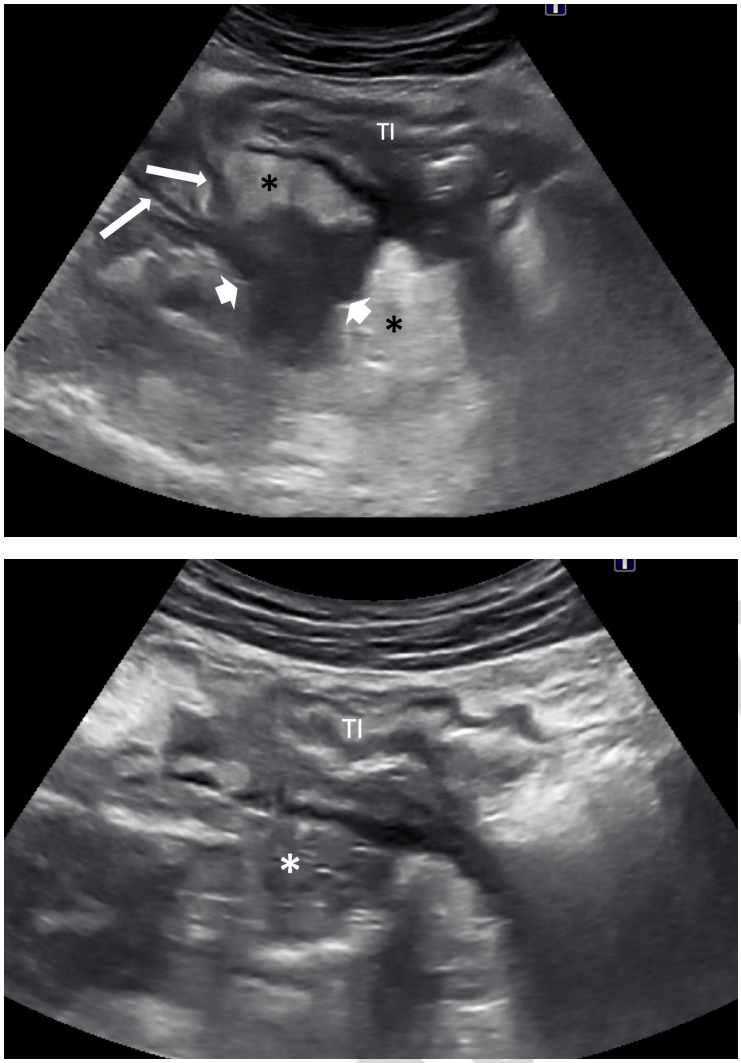

Fig. 2. A 31-year-old female recently diagnosed with Crohn's disease. A. Transversal AUS scan of the right lower quadrant depicts an irregular inflammatory hypoechoic mass (short arrows) originating from the thickened terminal ileum (TI), penetrating the echogenic hypertrophied mesentery (*). Note another two lineal hypoechoic sinus tracts (long arrows) penetrating the echogenic mesenteric fat. B. Transversal AUS scan of the right lower quadrant after six months of treatment showing persistence of the thickening of TI but normal fat echogenicity (*), without transmural complications.