Effectiveness of clinical guidelines in the management of acute sigmoid diverticulitis Results of a prospective diagnostic and therapeutic clinical trial



Ann. Ital. Chir., 2013 84: 171-177 pii: \$0003469X13019118



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BACKGROUND: Evidence-based criteria in the therapeutic choice for sigmoid acute diverticulitis (AD) are lacking. It is necessary to differentiate an acute episode of diverticular disease, not complicated (NCAD) and complicated (CAD) because these stages of diverticular disease needs different approach.

METHODS: In a prospective study on 377 consecutive patients admitted for AD, 265 had NCAD and 112 CAD diagnosed with CT scan. Thirty-six of 265 with NCAD were operated on due to two or more previous episodes of AD. On 188 patients with NCAD followed-up, 35 had further episodes of NCAD and 2 had CAD. On 112 CAD patients, 61 had Hinchey I and were submitted to colonic resection. Twenty-three of 24 patients with Hinchey II were treated with percutaneous drainage. All Hinchey II patients were operated on. All the 13 patients with Hinchey III and IV had emergency surgery.

RESULTS: We had no mortality and respectively 9.8% and 30% morbidity in Hinchey I and II patients. In Hinchey II patients percutaneous drainage was successful in 21 on 23 (91.3%). In 13 Hinchey III and IV patients the mortality rate was 25%. The comparison of CT findings and pathological results showed a sensitivity of 100% and predictive positive value of respectively 94.4, 96.7, 100 and 100% for NCAD, Hinchey I, Hinchey II and Hinchey III-IV.

CONCLUSIONS: The therapeutic approach of diverticular disease needs to differentiate among an acute episode, NCAD and CAD. Evidence-based therapeutic choices can be reached only by homogeneous diagnostic criteria obtained by CT scan.

KEY WORDS: Acute sigmoid diverticulitis, Evidence-based medicine, Surgical therapy

Introduction

In the Western World, diverticulosis of the colon is one of the most common disorders of the gastrointestinal tract, especially in the population above 60 years of age. Indeed, the prevalence of diverticulosis is 30% at age 60, which increases to 50% at age 70, and 60% or higher in those of 80 years or older ¹.

In patients between 50 and 60 years with a diagnosis of diverticulosis, the prevalence of acute diverticulitis (ADC) is about 10%; this rate increases with advancing age and could reach an incidence of $35^{\%}$ ²⁻⁴. In 90% of cases, ADC is located in the sigmoid colon.

Although there have been several attempts to develop specific guidelines for accurate diagnosis and treatment of acute diverticulitis, these efforts have been hampered

Pervenuto in Redazione Marzo 2012. Accettato per la pubblicazione Giugno 2012

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by the fact that there is no consensus in the definition of ADC nor a paradigm for accurate diagnosis and treatment for this disorder.

In fact, many published ADC studies have not shown a clear stratification of ADC cases, and patients with symptoms ranging from just acute lower left quadrant pain to overt signs of infection and radiological evidence of pericolonic or intra-abdominal abscesses have been included ^{1,3}. Such discrepancy in the initial stage of inclusion of cases invariably has distorted the analysis of data, the evaluation of therapeutic outcome, and the criteria for a particular choice of surgical intervention.

The present prospective study started in 1995 and continued for 13 years to evaluate the effectiveness of implementing a careful diagnostic and therapeutic protocol in all suspected cases of ADC admitted to our surgical department.

The specific aim was to see whether the initial results of helicoidal computerized tomography (CT) scans of abdomen and pelvis would correlate with clinical, laboratory and pathologic observations in operated patients. Furthermore, we wanted to see whether the implementation of this protocol would affect the choice of therapeutic approaches, the timing and selection of surgical intervention and the rate of post operative complications and mortality.

Material of Study

From January 1995 to December 2007, all patients with acute lower left quadrant pain who were seen in our service having a previous diagnosis of sigmoid colon diverticulosis established by barium enema and/or colonoscopy, were evaluated for a prospective study according to the following protocol.

The protocol required an initial screening of all patients with lower left abdominal pain seen in our department. All patients with mainly acute abdominal pain localized in lower left quadrant, with or without tenderness, no fever (temperature < 37.5) or tachycardia, no leukocytosis (white blood cell < 10,000) and normal erythrocyte sedimentation rate (ESR), were diagnosed as cases with "acute diverticular pain" (ADP).

ADP cases were followed subsequently by their primary care physicians. In addition, all other cases whose workup showed other types of pathologies, such as colon cancer or IBD, were excluded from this protocol.

All patients with lower left quadrant pain, fever, leukocytosis, and elevated ESR, were asked to participate in this study and, if they agreed, they were recruited and treated according to the protocol. The protocol required that all patient undergo an initial CT scan of the entire abdomen and pelvis. Based on radiological findings, patients were stratified into two main groups: 1) uncomplicated acute diverticulitis (UADC), and 2) complicated acute diverticulitis (CADC).

The UADC group included all patients with abdominal and pelvic CT scan showing diverticulosis of the sigmoid colon with thickening of the main colonic wall and/or of the pericolonic fat layer (fat stranding), but no other abnormal radiological findings.

According to the protocol, the CADC group could be divided into 4 subgroups according to Hinchey's classification ⁵. In patients classified as CADC–Hinchey I subgroup, the CT scan showed pericolonic abscess formation or soft tissue inflammation and phlegmon. In patients classified as CADC-Hinchey II subgroup, the CT scan showed an additional pelvic or retroperitoneal abscess. Finally, in patients classified as CADC-Hinchey's III-IV subgroup, the CT scan showed the presence of free air and endoperitoneal fluid.

All patients in UADC and CADC groups were admitted to our department, asked to remain fasting, and were placed on intravenous (IV) normal saline, and IV cephalosporin and metronidazol, as well as clinical follow-up and radiological control as needed.

In the UADC group, after complete recovery, patients of any age who had history of only one previous episode of ADC, were asked to continue the course of the oral antibiotic treatment at home for up to two weeks, to follow a specific diverticulosis diet (developed by our dietitians), and to be seen every six months in the outpatient setting for the duration of the study.

Patients with history of at least two previous episodes of UADC after complete recovery from an ongoing episode, were subject to further radiological and endoscopical evaluation and were suggested to be submitted to a resection of the sigmoid colon from a proximal area above the colonic wall thickening to a distal area at the upper third segment of rectum, and to a mechanical terminoterminal colo-rectal anastomosis.

Patients in the CADC–Hinchey I subgroup received the usual IV fluids and antibiotic treatment, and those who did not have further complications and recovered within four weeks had a colonic resection as described in above paragraph. However if the patient would not show signs of progressive recovery and a repeated CT scan demonstrated no improvement, then a CT guided percutaneous drainage was placed. In these patients, four weeks after complete recovery, a colonic resection was performed.

Patients in the CADC-Hinchey II subgroup received medical treatment as well as a CT guided drainage of intra-abdominal abscess. The patients who recovered completely, with CT scan showing resolution of abscess, had an elective colon resection within four weeks after recovery. However, all patients in the CADC-Hinchey II subgroup who failed to show signs of improvement following the placement of CT guided drainage, were subject, within a maximum of 8 weeks, to a deferred emergency surgical intervention.

All patients in the CADC-Hinchey III-IV subgroups were subject to emergency surgical intervention, while

receiving adequate IV hydration and antibiotic treatment. In this study, data of Hinchey III-IV patients are reported in one single group, as the CT scan was unable to differentiate them accurately.

Statistical analysis

We calculated the sensibility and positive predictive value (and the respective confidence interval at 5%) of CT scans in the diagnosis of UADC and CADC. These measures were evaluated comparing the radiological diagnosis to surgical and pathological findings. We used the statistical package CIA V2 (with Wilson method).

Results

During a 13 year period, from January 1995 to December 2007, we observed 1310 patients with previous diagnosis of sigmoid colon diverticulosis and acute lower left quadrant pain. Among these, 947 had a diagnosis of ADP, or other acute abdominal or pelvic disorders, and were excluded from this study.

Three hundred and sixty three patients with acute abdominal pain met the criteria for diagnosis of acute diverticulitis, including fever, leukocytosis (range 10500/ml-15900/ml), and elevated ESR (range 13 mm/h-76mm/h, mean: 45 mm/h), had a CT scan of abdomen and pelvis, and were admitted to the surgical in patient service.

Among these 363 patients, a diagnosis of UADC was made in 265 cases (73%). This group included 124 male subjects (age 49-89 years, mean: 74 years) and 141 female patients (age 52-88 years, mean: 77 years). After medical treatment and complete recovery, 36 patients (13.6%) underwent resection of sigmoid colon.

In this latter group, 14 patients (39%) had a history of two episodes of previous diverticulitis, while the remaining 22 (61%) had a history of 3 or more episodes of acute diverticulitis. All these patients had laparotomy with colonic resection followed by termino-terminal mechanical colo-rectal anastomosis. One patient (2.8%) required protective colostomy, as the intraoperative hydropneumatic test of anastomosis integrity was not satisfactory. The patient recovered well. We had no mortality in this group and no anastomotic leakage, and only 3 cases (8.3%) had post surgical complications (two cases of wound infection and one case of pneumonia).

The remaining 229 patients with UADC (86.4%) recovered completely and were discharged. In this latter group we were able to follow 188 patients for a mean period of 7,96 years $\pm 3,5$ SD (range: 0,5 - 15 years). The remaining 41 patients were lost at follow-up.

The follow-up of these 188 patients showed that 35 patients (18.6%) developed only one single episode of UADC and two other patients (1.1%) had recurrent diverticulitis, CADC–Hinckley I. These latter cases

required elective colonic resection. During the follow-up period, no patient required emergency surgery.

Ninety-eight were admitted with diagnosis of CADC according to the established criteria of the protocol. In this group, 61 patients (62,2%) with CADC-Hinchey I (27 male subjects, age 51-82 years, mean: 71 years; 34 females, age 54-83 years, mean: 72 years). All patients had leukocytosis (10300-18100/ml, mean: 15200/ml) and elevated ESR (mean: 57 mm/h). All patients had segmental colonic resection after four weeks of medical treatment and eradication of infection. Among these patients, 59 (96.7%) had one step colon resection with no protective stoma. But two remaining patients required colostomy to protect the anastomosis. There was no postoperative mortality. Post surgical complications were noted in six patients (9.8%): 3 wound infections, 1 pneumonia, 1 myocardial infarction and 1 anastomotic fistula, which was treated medically without the need for surgical intervention.

Twenty four patients (24.5%) were classified as CADC-Hinchey II. This subgroup included 10 male subjects (age 52-86 years, mean: 72 years), and 14 female patients (age 53-87 years, mean: 72 years). Among these patients, 23 (96%) had percutaneous CT scan guided drainage. Only in one case we had to perform surgery immediately due to severe abdominal clinical findings, severe sepsis and elevated co morbidity. In this case, CADC Hinchey II was confirmed at laparotomy and an Hartmann procedure was required.

In 21 cases, the placement of drainage was successful and the intra-abdominal infection was controlled. Following complete recovery, these patients had resection of sigmoid colon, and in 15 (71,4%) cases a colostomy was needed. In two cases we had to operate rather urgently (only after 8 days of medical treatment and percutaneous drainage) because the patients continued to have fever, pain and evidence of sepsis. In these cases we performed segmental colon resection and a protective colostomy was needed.

Only in one case, we had to perform surgery immediately due to severe abdominal clinical findings, severe sepsis and elevated morbidity. In this case, CADC Hinchey II was confirmed at laparotomy and a Hartmann procedure was required.

Overall, in this group of 24 patients we had no mortality but 8 cases (33.3%) of post-operative complications (4 wound infections, 2 pneumonia, 1 acute renal failure and 1 abdominal abscess).

Finally, in the last subgroup, Hinchey III/IV, we had 13 patients with clinical evidence of peritonitis who required emergency surgery.

There were six male subjects (age 57-89, mean: 75 years) and 7 females (age 53-90, mean: 76 years). In all patients leukocytosis (10,100/ml- 27,000/ml, mean: 18,100) and elevated ESR (mean: 68 mm/h) were noted.

Seven patients (53.8%) required segmental resection of the colon, anastomosis as well as colostomy and peri-

toneal wash-out. Among these cases, five patients (71.4%) had major post surgical complications (3 wound infections and pneumonia with pleural effusion and 2 persistent abdominal infections with multiple organ failure); unfortunately two patients deceased (33.3%).

The remaining six patients of Hinchey III/IV subgroup had Hartmann's procedure. In five patients, major post operative complications were seen (83.3%) and two of these patients deceased (mortality 33.3%).

The radiological findings of preoperative CT scan of abdomen and pelvis were compared with surgical and pathological reports of 134 patients who were operated on (36 case of UADC and 98 cases of CADC: 61 Hinchey I, 24 Hinchey II, 13 Hinchey IIII/IV).

The surgical and pathological findings correlated with the CT scan reports in 34 cases of UADC patients (94.4%), in 59 cases of 61 Hinchey I (96.7%) and in all 24 cases of Hinchey II. In the 13 patients classified as Hinchey III/IV, the CT scan accurately diagnosed peritonitis in all cases.

The overall sensitivity of CT scan was 100% and the positive predictive value was 94.4% for UADC, 96.7% for CADC Hinchey I, and 100% for Hinchey II and III/IV.

As these calculations are based on comparing the CT scan findings with surgical and pathological results, the computation of specificity and of negative predictive value of CT scan can not be carried out, because we have no patients with negative pathological findings and negative CT scan.

Discussion

The diagnosis of ADC is based on clinical, laboratory, and radiological findings. The pain and tenderness in lower left quadrant of the abdomen are present in 93-100% of cases, and fever in 57-100% patients, while leukocytosis is seen in 69-83% of ADC cases ^{2,6,7}. Other clinical symptoms such as nausea, abdominal distension, bloating, diarrhea and vomiting are less common.

Barium enema has a reported sensitivity of 94% and a specificity of 77%, and of course does not provide information regarding the presence of intra abdominal abscess (8-10). Abdominal ultra sound has a sensitivity of 84% and specificity of 80%, however the interpretation of results depends on the observer's ability and could be distorted in the presence of obesity ^{3,12,13}.

The CT scan of abdomen and pelvis is reported to have a sensitivity of 95-97% and a specificity of 91-100% ^{12,13}. The level of clinical evidence is III and it is considered the preferred imaging test according to Rafferty J et al ¹. Consequently, an accurate and non invasive diagnosis of ADC is possible only with abdominal CT scan which provides also information regarding associate complication and differentiates UADC from CADC.

Based on CT scan findings, it is possible to decide the

course of treatment and select the patients who need intensive follow-up.

The UADC cases are usually self limited and in 95% of cases respond to medical treatment and do not develop major complications even when they are followed for a prolonged period of time (15-20 years), as reported by Nelson SR et al ¹⁴. In the present study, 98 patients were diagnosed as UADC, treated conservatively, and only two (1%) cases developed CADC (Hinchey I) which required surgery, during a mean follow-up of 6 years.

Although the mean follow up is only 6 years, we estimated the risk of developing CADC in patients who have had one episode of UADC to be only 5% at 10 years, as reported by several authors (4, 15-16). In view of the advanced age of the majority of patients, we think it is justifiable and relatively safe to postpone surgical intervention in UADC cases.

There is significant debate on the relation between the number of episodes of ADC and the decision for surgical intervention. There is really no agreement on a standard paradigm according to published case studies and metanalysis 14, 17. After the first documented episode of UADC, one third of cases may have a second episode and in this latter group one third of patients may have a third event of diverticulitis 17-18. In view of the fact that the majority of patient with UADC are in their first episode, it is estimated that surgical resection of colon would not affect the overall risk of future surgical intervention and eventual mortality related to diverticulitis 17,19-21. Ritz and coll. recently remarked that the risk of free perforation decreases with an increasing number of prior episodes of ADC ²². Accordingly, the mere number of episodes of ADC without objective CT scan criteria does not justify surgical intervention. Therefore we do not completely agree with a still common thought indicating surgery after the second acute episode of diverticular disease ²³.

Even for relatively younger patients with ADC, below age 50, there is no consensus regarding surgery ^{1,7-9,15,23}. Some authors have argued that in such patients the recurrence rate or eventual complication rate may be higher because of longer life expectancy ^{1,15,17-18,22}. However, a large study in the UK by Munikrishnan V et al, has demonstrated that only 6% of patients under age 50 who recovered from ADC eventually required surgical intervention ³.

Moreover Lidor et al. confirmed that ADC in older patients has a low rate of recurrence and rarely need a surgical treatment ²⁴.

Interestingly, there is an almost unanimous agreement regarding the extent of required colonic resection. It is recommended that the resection should be done proximally in a segment of colon without any signs of thickening (even if affected with diverticulosis) and distally at the level of the upper third of the rectum. This type of resection has been reviewed extensively by J Rafferty ¹ and has been given a clinical evidence rating of 3. Regarding the timing for surgical intervention, emergency surgery is needed for Hinchey III and IV, unless a non operative treatment is chosen ^{25, 26}. For cases in Hinchey I and II subgroups, the best time was found to be four weeks after completion of medical treatment and recovery from local infection.

In cases of Hinchey I, a percutaneous drainage is needed only in patients with sepsis persisting more than eight days of conservative therapy. Brand et al ²⁷ reported a 19% failure of conservative therapy in Hinchey I patients. In our experience, we did not need to place a drainage in any of 61 Hinchey I patients before colonic resection.

Vice versa, in Hinchey II patients, the external drainage is needed to reduce the risk of infection, sepsis and leakage, as suggested by a consensus conference ²³. In 23 patients of 24 Hinchey II cases of this study (91%) we used drainage. In 22 cases, the drainage allowed us to obtain complete recovery and perform subsequent elective surgery without any complication. In one single case the drainage failed to improve the patient's clinical state and we had to perform an urgent surgery. In only one of 24 Hinchey II patients we preferred immediate surgery due to the severe abdominal clinical picture and sepsis. Regarding the choice of surgical approach in our study, in 61 Hinchey I cases we were able to perform colonic resection and anastomosis without the use of protective stoma in 59 patients (96.7%). In this group of 59 patients, we had only one anastomotic fistula (1.7%) which recovered with medical treatment and did not require any further surgery. However, in 2 remaining cases, we preferred to a primary derivative colostomy due the positivity of hydropneumatic test. Both cases recovered without complications.

Most authors suggested colonic resection and protective colostomy in Hinchey II cases. We had also a similar result in our present study, and indeed in 24 Hinchey II patients we were able to perform colonic resection and anastomosis with protective colostomy in 23 parents (96%). Only in one patient, we had to perform a Hartmann's procedure (4%).

In conclusion our data show that with adequate medical treatment it is possible to avoid protective colostomy in Hinchey I cases, while in Hinchey II patients a protective colostomy is needed. Our experience shows that in Hinchey I and II cases there is rarely a need for Hartmann's procedure, and confirms the data reported by others ²⁸. Therefore we do not agree with Authors suggesting a wide use of Hartmann procedures in Hinchey II patients ²⁹.

The issue of choice of the type of surgical procedure, particularly the indication to Hartmann's procedure in Hinchey III and IV cases with diffuse peritonitis, perforation and intra-abdominal abscess, is rather extensively debated among various authors (6,30-33). In fact, a variety of scoring systems for the assessment of operative risk and severity of each case is reported without a clear cut paradigm³⁴.

In our present study we needed to perform Hartmann's procedure in 6 of 13 (44%) patients with diffuse peritonitis. Regardless of the different surgical procedures, the mortality remains high: in our study it was 28.5%, and not affected by the type of surgery.

In conclusion, in this study, abdominal CT scan with a care evaluation of sigmoid colon allowed us to differentiate uncomplicated cases of diverticulitis from complicated ones and to reach the appropriate therapeutic decision within an acceptable timetable.

The follow up of 8 years allowed us to develop an algorithm on surgical strategy in patients with UADC and CADC.

The present data confirm that the number of episodes of previous diverticulitis do not offer a precise guideline for indication to perform segmental colonic resection and the patients may not need surgery after the second episode. However, we agree with the majority of authors that in patients below age 50, surgical intervention should be considered after the second episode.

In Hinchey I and II cases, surgical resection is indicated after four weeks of medical treatment. In Hinchey I cases we think colostomy is not needed, while in Hinchey II, this study shows that the majority of cases need a protective colostomy.

Our present data provide a prospective view of patients with diverticulitis without complications and of those with major complications requiring surgery. Obviously, our experience is limited to the laparotomy approach and can not be compared to results reported in cases undergoing laparoscopic surgery. In our opinion, surgical intervention in patients with complicated acute diverticulitis requires significant experience and unfortunate-ly in many cases, when a laparoscopic approach is undertaken, the conversion rate to laparotomy is rather high ³⁵⁻³⁷ and complication rate and quality of life were not always superior ^{38.}

We can conclude that in patients with abdominal pain, fever and leukocytosis, there is strong indication for CT scan of the abdomen and pelvis, careful follow up and medical treatment for four weeks. Any evidence of intraabdominal abscess and or peritonitis requires aggressive invasive approach.

Riassunto

Mancano attualmente criteri basati sull'evidenza per le scelte terapeutiche nei confronti della diverticolite acuta del sigma. Bisogna inoltre fare differenza tra un episodio di diverticolite acuta senza complicanze ed un altro in cui vi siano già delle complicanze, perché questi diversi stadi della malattia diverticolare richiedono scelte diverse.

In uno studio prospettico condotto su 377 pazienti consecutivi ricoverati per diverticolite acuta 265 erano casi non complicati mentre 112 presentavano complicazioni dimostrate con la TAC. Nell'ambito dei 265 casi non complicati 30 pazienti sono stati operati sulla base di due o più precedenti episodi di diverticolite acuta. In 188 casi di questo stesso gruppo posti sotto osservazione 35 andarono incontro a nuovi episodi di diverticolite acuta ma senza complicazioni e 2 pazienti ebbero invece complicazioni.

Dei 112 pazienti che inizialmente presentavano già complicazioni, 61 appartenevano alla classe I di Hinchey e sono stati sottoposti ad una resezione colica; 23 pazienti dei 24 che appartenevano alla II classe di Hinchey sono stati trattati con un drenaggio percutaneo, ma poi tutti e 24 sono stati operati. Tutti i 13 pazienti appartenenti alle classi III e IV di Hinchey sono stati operati con procedura d'urgenza.

Nei pazienti di classe I e II di Hunchey non si è registrata alcuna mortalità, ma 9,8% di morbilità nei pazienti di classe I di Hinchey e una del 30% in quelli appartenenti alla classe II.

Nei pazienti della classe II di Hinchey il drenaggio percutaneo ha avuto successo in 21 su 23 casi, pari al 91,3%. Nei 13 pazienti di classe III e IV di Hinchey l'incidenza della mortalità è stata del 25%.

Il confronto tra i dati della TAC ed il riscontro anatomo-patologico ha mostrato una sensibilità del 100% ed un positivo valore predittivo rispettivamente del 84,4%, del 96,7% e del 100% nei casi non complicati classe Hinchey I, di classe Hinchey II e complessivamente dei casi Hinchey III e IV.

In conclusione l'approccio terapeutico nella malattia diverticolare deve considerare la differenza tra un episodio acuto a seconda che sia privo di complicanze oppure complicato. Scelte terapeutiche basate sull'evidenza possono essere fondate soltanto su criteri diagnostici omogenei basati sui reperti TAC,

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