Outpatient Versus Hospitalization Management for Uncomplicated Diverticulitis

A Prospective, Multicenter Randomized Clinical Trial (DIVER Trial)

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Objective: We compare the results of 2 different strategies for the management of patients with uncomplicated left colonic diverticulitis and to analyze differences in quality of life and economic costs.

Background: The most frequent standard management of acute uncomplicated diverticulitis still is hospital admission both in Europe and United States. **Methods:** This multicenter, randomized controlled trial included patients older than 18 years with acute uncomplicated diverticulitis. All the patients underwent abdominal computed tomography. There were 2 strategies of management: hospitalization (group 1) and outpatient (group 2). The first dose of antibiotic was given intravenously to all patients in the emergency department and then group 1 patients were hospitalized whereas patients in group 2 were discharged. The primary end point was the treatment failure rate of the outpatient protocol and need for hospital admission. The secondary end points included quality-of-life assessment and evaluation of costs.

Results: A total of 132 patients were randomized: 4 patients in group 1 and 3 patients in group 2 presented treatment failure without differences between the groups (P = 0.619). The overall health care cost per episode was 3 times lower in group 2, with savings of €1124.70 per patient. No differences were observed between the groups in terms of quality of life.

Conclusions: Outpatient treatment is safe and effective in selected patients with uncomplicated acute diverticulitis. Outpatient treatment allows important costs saving to the health systems without negative influence on the quality of life of patients with uncomplicated diverticulitis. Trial registration ID: EudraCT number 2008-008452-17.

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D iverticular disease of the colon has become a common problem over the last decades and ranks as the fifth most important gas-

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trointestinal disease in terms of direct and indirect health care costs in Western countries with similar frequency in men and women.^{1–3} The prevalence rises with age affecting up to two-thirds of individuals by the age of 80 years. Similarly, the incidence of diverticulitis increases in young patients.⁴

Symptomatic diverticular disease may be observed in up to 25% of all cases during lifetime. In the absence of complications such as perforation, fistula, obstruction, or bleeding, a localized inflammatory process or phlegmon of the colon is termed "uncomplicated diverticulitis" which accounts for 75% of diagnosed symptomatic diverticular disease.⁵

Various professional organizations have published guidelines⁶⁻⁸ for the treatment of sigmoid diverticulitis. Even if they state that oral antibiotic treatment is feasible depending on the patient's health status, recommendations on outpatient management of uncomplicated diverticulitis are vague. Also, an important number of patients is still admitted to the hospital for diverticular disease without perforation or abscesses.⁹

Once the diagnosis of uncomplicated diverticulitis is reliably confirmed by radiological imaging, most frequently by abdominal computed tomography (CT),¹⁰ little is known on whether patients with uncomplicated sigmoid diverticulitis benefit from outpatient treatment, because evidence from prospective studies or randomized trials is lacking. Moreover, the majority of patients admitted with acute diverticulitis present uncomplicated diverticulitis and are treated medically, with less than 15% of patients requiring surgical intervention during the same admission.^{1,11}

Based on the hypothesis that outpatient care of patients with uncomplicated diverticulitis would be as safe and effective as hospitalization, the aim of this study is to compare the results of 2 different strategies of management of patients with uncomplicated left colonic diverticulitis. Besides, quality of life and differences in economic costs were analyzed.

METHODS

Study Design and Participants

This was a multicenter, 2-arm, parallel, 1:1, randomized controlled trial. After having obtained signed informed consent, participating patients with acute uncomplicated diverticulitis were randomly allocated to the hospitalization group (group 1) with usual treatment or to the outpatient group (group 2) in which case they were discharged from the emergency department and contacted daily for 5 consecutive days by the study investigators in each center.

The study was approved by the ethical committees of all participating institutions and followed the Declaration of Helsinki guidelines. Permission from the Spanish Agency for Drugs and Health Products (AEMPS) was obtained.

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Hospital and Vall d'Hebron Hospital, Barcelona; Josep Trueta Hospital, Girona; Clinic Hospital, Valencia; and Virgen del Camino Hospital, Pamplona) recruited patients between October 1, 2009 and October 31, 2011.

All patients admitted to the emergency department (24 h/d, 7 days a week) with clinical suspicion of diverticulitis, with fever, and acute lower abdominal pain with tenderness were screened for potential eligibility. Chest and abdominal plain radiographies excluded differential surgical or medical diagnoses and were followed by an abdominal CT, the standard diagnostic tool, with intravenous contrast administration and with water-soluble contrast enema, if necessary. Diverticulitis grade was classified according to the modified Hinchey classification^{12,13} (Table 1).

Inclusion criteria were patients older than 18 years of age, with uncomplicated diverticulitis able to tolerate oral intake, and with good response to first treatment measures in emergency (improvement of pain and fever) and willing to continue treatment at home under supervision.

Uncomplicated diverticulitis was defined as pericolic phlegmon (grade I a, modified Hinchey classification).

Exclusion criteria were complicated colonic diverticulitis (grade I b: confined pericolic abscess; grade II: pelvic, intraabdominal, or retroperitoneal abscess; grade III: generalized purulent peritonitis; and grade IV: fecal peritonitis); absence of symptom relief (maintenance of tenderness, fever, or/and persistence or worsening of acute pain after analgesic and first doses of antibiotics); pregnancy or breastfeeding; intake of antibiotic for colonic diverticulitis in the month previous to actual diagnosis; colorectal cancer suspicion at computed tomographic findings; concomitant unstable comorbid conditions; immunosuppression (cortisone or immunosuppressive drug intake, transplantation, chronic renal failure with hemodialisis, acquired or congenital immunodeficiency, active malignant neoplasm)¹⁴; cognitive, social, or psychiatric impairment; intolerance to oral intake and persisting vomiting; and patients' rejection of written consent.

Adverse events were considered untoward medical occurrence, not necessarily with a causal relationship with the treatment, suffered by any patient included in the study. In case of adverse events, patients discontinued participation in the study.

Data of each patient were collected by the investigator surgeon of each center in a proforma. Data were sent after inclusion of patient, evolution and final visit, to the central registry, in Bellvitge University Hospital, and held by the monitor of the study.

Study End Points

The primary end point of the trial was the treatment failure rate of the outpatient management for patients with uncomplicated diverticulitis compared with that of hospitalized patients. Treatment failure was defined as persistence, increase, or recurrence of abdominal pain and/or fever, inflammatory bowel obstruction, need for radiological abscess drainage or immediate surgery due to complicated diverticulitis, need for hospital admission, and mortality during the first 60 days after discharge. This period suffered a deviation from protocol because initially it had been considered to be the first 30 days.

The secondary end points included a quality-of-life assessment by the SF-12 questionnaire on days 14 and 60 after discharge and the evaluation of costs for both management strategies.^{15,16} Eight health profile dimensions (physical function, physical role, bodily pain, general health, vitality, social function, role emotional, and mental health) were constructed through the answers to the 12 questions of the questionnaire and from these 2 final components summary: physical and mental.

To avoid difficulties related to the variability of each autonomous community health system involved in the study, cost analysis was performed only in the coordinator hospital (Bellvitge University Hospital). The financial department of the hospital provided the cost data according to in-hospital expenses by the accounting system, including variable and fixed costs. Costs were attributed to each treatment strategy according to the services for diagnostics, treatments, and follow-up. Costs of bed areas were calculated on the basis of the mean hospital stay of the hospitalized patients in group 1.

Randomization and Interventions

Randomization was performed by using a computer-generated random code and stratified by center. The random code was held centrally in a sealed envelope and distributed to each center by the monitor of the study. Surgeons on call in the different centers (in most cases, not the study investigator) were responsible for recruitment and randomization. All patients received detailed written information about their diagnosis and their treatment plan and an emergency contact telephone number for emergency consultation to the investigator physician.

All patients in the study protocol were randomized to hospitalization (group 1) or to outpatient management (group 2). The first dose of antibiotic treatment was given intravenously to all patients of both groups in the emergency department. The intravenous antibiotic treatment of choice was amoxicillin and clavulanic acid (1g per 125 mg) every 8 hours. In case of a history of penicillin allergy, the alternative treatment was ciprofloxacin 200 mg every 12 hours and metronidazole 500 mg every 8 hours. After the first dose of antibiotic, patients of group 1 were admitted to the ward and administered intravenous antibiotics and fluids for at least 36 to 48 hours until oral feeding was tolerated. Patients of group 2 were discharged from the hospital and given oral amoxicillin and clavulanic acid (875 mg per 125 mg every 8 hours) or, in case of penicillin allergy, the combination of ciprofloxacin (500 mg per 12 hours) and metronidazole (500 mg per 8 hours). Antibiotic treatment in both arms was discontinued after 10 days.

Diet recommendations were given in the detailed written information sheets and explained to the patient by the investigation physicians during daily telephone call for patients at home or during ward rounds for the hospitalized patients. Oral intake for outpatients

Hinchey Classification ¹²			Modified Hinchey Classification ¹³		
Stage		Stage			
-		0	Mild clinical diverticulitis		
Ι	Pericolic abscess or phlegmon	Ia	Confined pericolic inflammation-phlegmon		
		Ib	Confined pericolic abscess		
II	Pelvic, intra-abdominal, or retroperitoneal abscesses	II	Pelvic, intra-abdominal, or retroperitoneal abscesses		
III	Generalized purulent peritonitis	III	Generalized purulent peritonitis		
IV	Generalized fecal peritonitis	IV	Generalized fecal peritonitis		

started with a liquid diet with electrolyte-balanced drinks for 2 days and then stepwise increased to a complete low fiber diet. Pain control was achieved with paracetamol (1000 mg per 8 hours), if needed, for no more than 10 days. In case of allergy or intolerance, metamizole was the alternative analgesic.

Follow-up

Patients assigned to outpatient care were contacted daily by telephone for 5 consecutive days by the study investigator in each center to assess temperature, diet progression and bowel movement confirmation, pain control, and general conditions.

Similarly, hospitalized patient were assessed daily by the attending surgeon and by at least 1 investigator till tolerance of a complete low-fiber diet. Physicians were advised to discharge patients when their initial clinical condition was stabilized, oral intake was tolerated, and pain controlled.

Before discharge in emergency department, patients were instructed to control temperature regularly 3 times a day, to progress diet according to tolerance and bowel movements, and to record pain as improvement or worsening from the previous day. A standard scale for pain was not used.

All patients were appointed with an investigator physician close to day 14 after discharge in the outpatient clinic. Diverticulitis was considered cured at this visit in the absence of abdominal pain and fever and if complete diet and regular movements were normalized. At the final visit on day 60, the patient was seen again in the outpatient clinic to confirm the presence of diverticular disease and to exclude an underlying malignant neoplasm by colonoscopy performed between 45 and 60 days from discharge.

Although nurse follow-up was considered suitable for ambulatory control, within the study context it was decided to focus telephone call on the investigator due to lack of availability of nurse cooperation in every center.

Sample Size and Statistical Analysis

The sample size calculation was based on results from previous published studies.^{10,17} No randomized clinical trials were found. The failure rate of the outpatient treatment for no complicated diverticulitis was 5.0% in 1 prospective study.¹⁷ In a retrospective series,¹⁰ 7.1% of patients admitted for grade Ia diverticulitis presented no response to conservative treatment.

Assuming a rate of no medical treatment failure of 95% in the control group (group 1) and a no inferiority limit of 10%, with an α risk of 5% and a β risk of 20%, 59 patients were needed in each group. Believing in an anticipated dropout rate of 10%, the total sample of patients will include 66 patients per group.

To evaluate the primary end point, noninferiority limit of 10%, method based on confidence interval of the unilateral difference of 95% of the percentage of nonrelapse between the 2 groups was used. Intention-to-treat analyses were done.

Comparative analyses of the quantitative data were performed using nonparametric test (Mann-Whitney U test). The χ^2 test for proportions or Fisher exact test was used in the analysis as appropriate.

To compare the results of quality of life with the SF-12 test, analyzing the effect of both time and group of treatment, a linear mixed-effects model was performed.

RESULTS

Recruitment and Patients' Characteristics

During the study period, 453 patients were treated for colonic diverticulitis. According to the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement,¹⁸ the flow of participants from group assignment to final analysis is shown in Figure 1.

One hundred thirty-two patients met the inclusion criteria and were randomized. Sixty-six patients were allocated in each group. The distribution of patients in the 5 hospitals was similar, without differences between group 1 and 2 randomization.

Three hundred twenty-one patients were not randomized: 35 patients underwent emergency operations, 160 patients presented complicated diverticulitis at abdominal CT, and 126 patients, even if eligible, did not meet the inclusion criteria. After randomization, 3 patients in group 1 and 1 patient in group 2 refused to follow the assigned treatment of the assigned management. Despite deviation from the protocol and according to the intention-to-treat analysis, these patients were analyzed in the assigned group. Two patients were lost for follow-up, 1 in each group.

Distribution per hospital, age, sex, American Society of Anesthesiologists status, type of abdominal pain (localized or diffuse) at the admission, leukocytes levels, and antibiotic treatment are reported in Table 2. No differences were observed between the 2 groups.

Three patients discontinued participation in the study, I patient in group 1 for violation of protocol and 2 patients in group 2 for adverse events.

Primary Outcome

Seven patients (5.3%) of all the series were readmitted because of failure of medical treatment: 4 patients (6.1%) in group 1 and 3 patients (4.5%) in group 2. No differences were observed between the 2 groups (P = 0.619). No patients needed emergency surgery as a consequence of readmission and no mortality was observed.

Secondary Outcomes

Quality-of-life assessment by the SF-12 questionnaire, for physical health and mental health components summary, shows differences inside of each group between the first and the second visits (Table 3). However, no differences were observed between the groups at the visits of days 14 and 60 (Figs. 2 and 3).

Table 4 shows the costs related to each group. The overall health care cost per episode was 3 times lower in group 2 compared with group 1, with savings of \notin 1124.70 per outpatient. This cost is the sum of the total cost of all health care processes including oral antibiotics with which the patient was discharged.

DISCUSSION

Statement of Principal Findings

This study on management of acute uncomplicated colonic diverticulitis demonstrated that outpatient treatment with oral antibiotics and diet is as safe and effective as hospitalization with endovenous treatment. Moreover, important saving cost has been observed in outpatients with similar quality of life compared with hospitalized patients.

Strengths and Weakness of the Study

One of the strengths of the study is that it is the first multicenter randomized clinical trial dealing with this question. Moreover, in reference to the primary end point, the difference of proportions between experimental group and control was 1.5% and the confidence interval of difference (-7.3%; 10.5%) did not exceed the limit of no inferiority. As a consequence, and due to the current variability of the treatment of uncomplicated diverticulitis among physicians and hospitals, this study contributes to create a high-level scientific evidence that helps in the decision-making process of the management of mild diverticulitis.

A weakness of this study is related to the high number of patients who were not suitable of randomization. Patients with diverticulitis with pericolic abscesses of 2 cm or less (stage Ib)

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CONSORT 2010 Flow Diagram



FIGURE 1. CONSORT 2010 flow diagram.

could probably have been included in the trial thus increasing the studied population. To our knowledge, there are few studies that have examined stage Ib diverticulitis, and those analyze a small number of patients.¹⁹ Moreover, about 19% of admitted patients with stage Ib diverticulitis do not present improvement with medical treatment and an urgent resection is needed.¹⁰ Based on the lack of evidence, and due to the heterogeneity of patients affected by diverticulitis, the trial aimed to avoid potential bias to provide clear guidelines for admission versus outpatient treatment. It was decided to focus on a homogeneous group of patients with uncomplicated diverticulitis that represents the most frequent stage of colonic diverticulitis.

Local factors could have influence to some extent the difference between the 2 protocols. Despite tendencies in hospital management toward ambulatory care and surgery and high bed turnover, those processes are not always implemented straightforward. Reluctance to changes and feeling of worse control between physicians and patients have only been overcome after objective evidence of improvement. In fact, within the study centers, some did not have a previous short-stay policy for uncomplicated diverticulitis and others have shortened their hospital length of stay for patients who were admitted.

Another limitation of this study relates to the important number of patients who refused to be included in the trial. The most frequent reason for rejection was that patients with an acute abdominal process had concern to be treated at home. Therefore, creating robust evidence on this topic allows emergency physicians to make decisions on the management of diverticulitis with a clear-cut, quality-supporting evidence and reassuring recommendations to the patients selected for the outpatient treatment.

Interpretation With Reference to Other Studies

Since 1998, oral hydration and oral antibiotics have been proposed in patients with mild diverticulitis by different authors.⁷ Various professional organizations have published guidelines on diverticulitis⁷⁻⁸ that state that an oral antibiotic treatment in an

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		Group 1 Hospitalized	Group 2 Outpatient	
	All the Series	(n = 66)	(n = 66)	Р
Hospital				
Valencia	12 (9.1)	3 (4.5)	9 (13.6)	
Girona	15 (11.4)	7 (10.6)	8 (12.1)	0.375*
Bellvitge	49 (37.1)	24 (36.4)	25 (37.9)	
Vall Hebron	30 (22.7)	17 (25.8)	13 (19.7)	
Pamplona	26 (19.7)	15 (22.7)	11 (16.7)	
Age		. ,	· /	
Mean (SD)	56.3 (13.0)	56.8 (12.8)	55.9 (13.4)	0.604†
Sex	× /			
Female	60 (45.5)	28 (42.4)	32 (48.5)	0.484^{*}
Male	72 (54.5)	38 (57.6)	34 (51.5)	
ASA status		. ,	· /	
Ι	53 (40.2)	23 (34.8)	30 (45.5)	0.450*
II	65 (49.2)	35 (53.0)	30 (45.5)	
III	14 (10.6)	8 (12.1)	6 (9.1)	
Abdominal pain	× /			
Localized	123 (93.2)	61 (92.4)	62 (93.9)	1.000 [‡]
Diffuse	9 (6.8)	5 (7.6)	4 (6.1)	·
Leukocytes levels	× /			
Mean (SD)	11.1 (3.3)	11.5 (3.5)	10.7 (3.1)	0.173†
Antibiotic treatment	× /	× /	~ /	
Amoxicillin and clavulanic acid	104 (78.8)	56 (84.8)	48 (72.7)	0.089*
Ciprofloxacin + metronidazole	28 (21.2)	10 (15.2)	18 (27.3)	
Number of previous episodes	. /			
Mean (SD)	0.47 (0.9)	0.39 (1.0)	0.55 (0.9)	0.057†

TABLE 2. Characteristic of the Patients Included in the Randomization

Values within parentheses are percentages unless otherwise indicated (SD).

*Chi-square test

†U de Mann-Whitney

‡Fisher exact test.

ASA indicates American Society of Anesthesiologists.

TABLE 3. Quality of Life Assessment by the SF-12 Questionnaire at the 14th and 60th Day Visits

		Mean (SD)	P *
Physical Health			
Hospitalized	14 days	45.9 (8.1)	Time $P < 0.001$
	60 days	49.6 (8.7)	
Outpatient	14 days	43.9 (8.5)	Group $P = 0.590$
1	60 days	50.3 (7.2)	•
Mental Health		× /	
Hospitalized	14 days	49.7 (12.7)	Time $P = 0.012$
1	60 days	52.6 (9.5)	
Outpatient	14 days	48.9 (9.4)	Group $P = 0.989$
*	60 days	53.0 (8.6)	*
*Linear mixed-ef	fects model.		

outpatient setting is feasible depending on the grade of diverticulitis and the patient's health status. Nevertheless, recommendations on outpatients management such as "uncomplicated diverticulitis may be managed as an outpatient for those without appreciable fever, excessive vomiting, or marked peritonitis, as long as there is the opportunity for follow-up" by Rafferty et al⁸ are quite vague. Indeed, the most frequent standard management of acute uncomplicated diverticulitis still is hospital admission both in Europe and United States.^{20,21} In a recent publication, Mills and colleagues²¹ observed that among 207,838 patients discharged for acute diverticulitis, only 19.5% were admitted for complicated diverticulitis whereas the rest presented with an uncomplicated stage. In a Dutch study, 259 of 364 patients



FIGURE 2. Physical health—component summary measure.

(71.2%) with uncomplicated colonic diverticulitis were hospitalized for treatment. $^{\rm 20}$

Surveys among American Society of Colorectal Surgeons members²² and, more recently, among general surgeons from the United Kingdom²³ observed a large variety in the management of not complicated diverticulitis in the routine clinical practice.

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Hinchey classification aims to stratify patients with acute diverticulitis into different severity categories. However, the system does not differentiate between patients with small pericolic abscesses and mesenteric phlegmon that may present different clinical stages.¹⁰ A new classification¹³ was used to better stratify subcategories of diverticulitis by abdominal CT.

Diverticulitis has become a priority health problem in developed countries being, at present, 1 of 5 gastrointestinal pathologies more burdensome to the health care system. In Finland, cases of complicated diverticulitis have increased by 50% over the past 2 decades, having attributed the increase to an aging population and a decline in fiber intake.²⁴ Based on the National Inpatient Sample database, in the United States, rate increase by 9.5% has recently been observed in the emergent admission rate. From a total of 1,073,397 patients with diverticulitis admitted, 85.92% were treated with medical treatment.²⁵ The literature on this topic^{17,19,26–29} shows that outpatient treat-

The literature on this topic^{17,19,26–29} shows that outpatient treatment is safe and effective in 93% to 97% of patients and applicable in most of the patients who present for urgent evaluation. In a retrospective analysis²⁷ among a cohort of patients who were referred for outpatient treatment, free fluid on computed tomographic scan was related to a higher risk for treatment failure. Alonso et al²⁸ recently observed that ambulatory treatment of uncomplicated acute divertic-





ulitis is applicable to 73% of patients. Exclusion criteria were intolerance to oral intake, no appropriate family support, and presence of comorbid conditions such as diabetes mellitus, heart failure, renal insufficiency, and chronic obstructive pulmonary disease. In the present trial, of 258 patients eligible for inclusion, 77 patients presented exclusion criteria and 181 (132 allocated and 49 refused) (70.2%) could have been treated as outpatients. Overall treatment failure rate was 5.3%, whereas treatment was effective in 95.5% of outpatient group and without differences when compared with hospitalized patients.

In a recent multicenter randomized trial,³⁰ it has been shown that antibiotic treatment of acute uncomplicated diverticulitis neither accelerates recovery nor prevents complications or recurrence. It should be kept in mind that all the patients of both groups in the Swedish trial were admitted to the hospital, the aim being assessing the role of antibiotics in the management of diverticulitis. In this study, aiming to save costs by avoiding hospitalization, all patients received antibiotics. Outpatient management without antibiotics has not been assessed.

Improve the efficiency of health systems and reduce health care costs is an objective that has to be taken into account when a treatment strategy is planned.³¹ The burden of care and health costs due to diverticular disease has increased steadily in recent years. According to data from the National Hospital Discharge Survey, diverticular disease is responsible for 314,000 hospital admissions per year³² in the United States, and the estimated annual cost in 1998 was about \$2.6 billion.²

The outpatient protocol of this study is applicable to a selected group of patients with uncomplicated diverticulitis. But, even if it is a selected group of patients, due to the prevalence of diverticulitis, this strategy could reduce health care costs. In this trial, outpatient management helped reduce health care costs by 67% over a hospital admission with average stay of 4 days.

CONCLUSIONS AND RECOMMENDATIONS

This study showed that outpatient management is safe and effective in patients with uncomplicated acute diverticulitis who do not present concomitant unstable comorbid conditions; immunosuppression; cognitive, social, or psychiatric impairment; and intolerance to oral intake. Outpatient management allows important cost saving to the health systems without negative influence on the quality of life of

	Hospitalization Group 1		Outpatient Treatment Group 2		Costs Saving	
	Cost	Total	Cost	Total	Cost	Total
Physician	73.87	141.89*	95.25	164.77*	21.38	22.88*
Nurse	58.74		58.74		0.00	
Personnel variable	9.28		10.78		1.50	
Medical supplies	5.20	5.51	5.20	5.51	0.00	0.00
Variable	0.31		0.31		0.00	
Drugs	27.74	29.40	8.31	8.81	19.43	20.59
Variables	1.66		0.50		1.17	
Diagnosis tools	318.53	337.00	318.53	337.00	0.00	0.00
Variable	18.47		18.47		0.00	
Bed cost	265.83†	1063.33‡	0.00	0.00	265.83	1063.33
Nonmedical personnel, administrative work	94.63	94.63	30.96	30.96	63.66	63.66
Total cost		1671.75		547.05		1124.70

ABLE 4. Costs of Treatment for Each Patient (All Numbers Are Values in Euros)	
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‡Bed cost calculated according to the mean hospital stay of the group 1.

patients with uncomplicated diverticulitis. Further research is needed to study the safety and efficacy of outpatient management in selected patients with acute colonic diverticulitis complicated by small size abscesses.

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