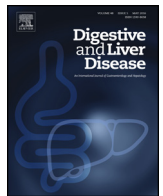




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Alimentary Tract

Economic burden of diverticular disease: An observational analysis based on real world data from an Italian region

F.S. Mennini^{a,b}, P. Sciattella^{a,f}, A. Marcellusi^c, B. Toraldo^d, M. Koch^{e,*}

^a Economic Evaluation and HTA (CEIS-EEHTA)—IGF Department, Faculty of Economics, University of Rome “Tor Vergata”, Italy

^b Institute for Leadership and Management in Health—Kingston University London, London, UK

^c National Research Council (CNR), Institute for Research on Population and Social Policies (IRPPS), Rome, Italy

^d Alfa Wassermann Italia, Italy

^e Complex Unit of Gastroenterology and Hepatology, San Filippo Neri Hospital, Italy

^f Department of Statistical Sciences, “Sapienza” University of Rome, Rome, Italy

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ABSTRACT

Introduction: Diverticular disease (DD), a herniation of the colonic mucosa through the muscle layer, covers a wide variety of conditions associated with the presence of diverticula in the colon. The most serious form is an acute episode of diverticulitis, which can lead to hospitalization and surgery with various types of consequences. The main aim of this study is to evaluate the economic burden of hospitalizations arising from acute episodes of diverticulitis using data from the administrative databases used in the Marche region in Italy and, as a secondary objective of this real-world data analysis, to study patient outcome variables following initial hospitalization for diverticulitis.

Method: A deterministic linkage was performed at individual user level between the different administrative sources of the Marche region through anonymous ID number for a period of analysis between 1 January, 2008 and 31 December, 2014. We enrolled all patients with at least one hospitalization for “diverticulitis of the colon without mention of haemorrhage” (ICD-9-CM code 562.11) or “diverticulitis of the colon with haemorrhage” (ICD-9-CM code 562.13) as primary or secondary diagnosis. For each patient we assessed the cost of hospitalization, of medicines and of specialist services considering a time-scale of one year or cohort analysis 365 days after first admission.

Results: The total number of residents in the Marche region who had at least one hospitalization for diverticulitis in the period 2008–2014 was 2987 (427 patients a year, corresponding to about 35 patients per 100,000 adult residents); the total number of admissions was 3453 (just over 490 a year). The direct healthcare costs incurred by the Marche region for episodes of diverticulitis in 2008–2014 amounted to approximately €11.4 million (€1.6 million a year), of which €10.9 million (95.5%) for the hospitalizations, € 246,000 (2.1%) for pharmaceutical treatment and €270,000 (2.4%) for specialist outpatient services. The average annual cost per patient was €3826, of which €3653 was for hospitalization, while pharmaceutical expenditure and specialist services accounted for €83 and €90, respectively. The cohort of patients undergoing a first admission for diverticulitis between 2010 and 2013 was made up of 1729 people (54.4% women, mean age 68.9 years), of whom 1500 (86.8%) did not undergo surgery while in hospital. Hospital mortality, recorded only for the over-65 age class, averaged 1.2%; for patients not receiving surgery during the initial hospitalization it was 0.5%, reaching 5.2% in patients undergoing surgery. The percentage of patients with one or more readmissions for diverticulitis within a year of the first was on average 7.8% and in 48% of cases this resulted in surgery.

Conclusions: Our study is the first analysis in Italy to use real-world data to measure the financial impact of diverticular disease. Assuming that the diagnostic and therapeutic behaviour identified in the Marche region could be representative of the situation nationwide, the estimated annual number of hospitalizations in Italy for acute episodes of diverticulitis is 19,000. The total amount of economic resources needed to treat patients suffering from acute episodes of diverticulitis is estimated at €63.5 million a year.

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* Corresponding author at: San Filippo Neri Hospital, Complex Unit of Gastroenterology and Hepatology Rome, Via G. Martinotti, 20, 00135 Rome, Italy.

E-mail address: kochmaurizio@gmail.com (M. Koch).

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1. Introduction

Diverticular disease (DD) covers a wide variety of conditions associated with the presence of diverticula in the colon (herniation of the colonic mucosa through the muscle layer). Of these, the most serious condition is an acute episode of diverticulitis that, depending on its severity, can lead to hospitalization, surgery and may even result in the patient's death.

Traditionally, three factors are associated with the pathogenesis of DD: age, diet and bowel motility. In recent years, this list has expanded to six with the addition of genetic factors, intestinal innervation and microbiota.

The incidence of diverticula is correlated with increasing age: Peery et al.'s study shows 16% of subjects are under the age of 40 rising to over 63% among the over 70s [1].

Alterations of the connective tissue, such as greater cross-linking of collagen fibrils or altered expression of matrix metalloproteinases, may help to increase the onset of diverticula with age [2].

DD has also been correlated with Western lifestyle and lack of physical activity [3].

Focus on DD is increasing exponentially, as reflected also in the number of publications devoted to it.

Most diverticulosis cases remain asymptomatic for life: only about 4% of patients with an endoscopic diagnosis of diverticulosis develop diverticulitis [4]. Of these patients, around 15–30% undergo a relapse and about 15% develop complications. Admissions for diagnosis code diverticulitis without haemorrhage (562.11) are very much on the increase: in the USA alone, the increase in the admissions rate was +21% compared to 2003, with a hospital mortality rate of 0.5% [5].

Over the years, different ways of reducing the risk of occurrence and recurrence of diverticulitis have been explored, with the most promising ones including the use of non-absorbable antibiotics. Prevention of acute episodes of diverticulitis as well as improvements to DD patient management should reduce the number of hospitalizations and, consequently, the direct costs arising from DD-related complications. An evidence-based review on the natural history of DD and the role of treatment has just been published [6].

In the United States, according to data in the literature, annual costs of diverticular disease are between 2.2 and 2.6 billion dollars, making it the fifth most costly gastrointestinal disorder in terms of direct and indirect costs [5].

Despite the significant epidemiological burden, in Italy there are currently no financial evaluations available on a representative sample of the population regarding the costs of diverticular disease and its complications.

The aim of this study is to evaluate the financial impact generated by complications of diverticular disease using real-world data from the Marche region's administrative database and to quantify the patient outcome variables in the period following the index admission for diverticulitis.

2. Data source and methods

2.1. Data source

Admissions for diverticulitis were selected from the Marche region's Hospital Information System, which records all admissions to accredited public and private hospitals in the region. The discharge records include the patient's demographic (gender, age, education, residence) and clinical information, the diagnosis and the main and secondary procedures (5 fields) as set out in the International Classification of Diseases (ICD-9-CM).

Drug prescriptions were extracted from the Marche region's Pharmaceutical Prescription Information System, containing all prescriptions sent to municipal and private pharmacies within the region and reimbursed by the Italian National Health Service.

Specialist outpatient care was selected from the Marche region's Specialist Service Information System, containing all outpatient appointments for diagnostic and therapeutic services in the region.

A deterministic linkage was performed at individual user level between the different administrative sources through anonymous ID number for a period of analysis between 1 January, 2008 and 31 December, 2014.

3. Methods

Prevalent cases of diverticulitis per year were identified by selecting all persons residing in the Marche region with at least one admission for "diverticulitis of the colon without mention of haemorrhage" (ICD-9-CM code 562.11) or "diverticulitis of the colon with haemorrhage" (ICD-9-CM code 562.13) as primary diagnosis, or else as secondary diagnosis where, however, the main diagnosis was one of the diverticulitis-related diagnoses (see Annex).

For these subjects, we identified all prescriptions of intestinal antibiotics (ATC A07AA), intestinal anti-inflammatory drugs (ATC A07EC) and metronidazole (ATC J01XD01; P01AB01) as well as all specialist outpatient services (see Annex) correlated with the disease which took place during the calendar year of admission.

The annual cost of diverticulitis was estimated by assigning a value to each admission based on the Marche region's tariff for hospital services in force during the year of discharge, the cost of drugs was estimated using the regional reimbursement price current at the time of dispensing and outpatient specialist care was calculated using the current regional price in the year of provision of the service.

Longitudinal analysis was performed by identifying the cohort of patients admitted for diverticulitis in the three-year period from 2010–2013 with no prior admissions for diverticulitis in the previous two years. If a patient had more than one admission during these three years, their first admission was selected as the index admission (Fig. 1).

Subjects were stratified by surgical procedure (large intestine, small intestine or rectal resection) during the index admission; the procedure was identified using the DRG attributed on discharge (see Supplementary Table S2).

Only subjects of legal age living in the Marche region at the time of index admission were considered.

All enrolled subjects, once discharged from the index admission, were followed for one year, and all subjects requiring re-admission and/or surgery for diverticulitis during follow-up have been identified. Annual costs were thus estimated taking into account the cost of the index admission and any possible subsequent admissions occurring during the year of observation (Table 1).

4. Results

The total number of subjects resident in the Marche region who had at least one hospitalization for diverticulitis in the period 2008–2014 was 2987 (427 patients a year, corresponding to 35 per 100,000 adult residents) whereas the total number of admissions was 3453 (just over 490 a year).

The number of hospitals of Marche region from which data have been collected is 44. The number of admissions for each hospital varied from 1 to 218.

On average, 75% of patients received at least one drug prescription, from a list of drugs related to diverticular disease and granted by the national health service (see Supplementary Table S3) in

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