Descriptive and correlational study of the epidemiological, clinical and etiological characteristics of peritonitis in the surgical department of the HUEH during the period from January 2013 to December 2018

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Study Protocol

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Lists of abbreviations

ANOVA ..... *Analysis of variance*
APACHE ..... Acute physiology and chronic health evaluation
FMP ..... Faculty of Medicine and Pharmacy
Hb..... *hemoglobin*, *Hemoglobin*
HR..... *Heart rate*, *Heart rate*
HUEH .....Hospital of the State University of Haiti (, Hospital of the State University of Haiti
LABMES *Laboratory of Ethical Medicine and Societies*, Laboratory of Ethical Medicine and Societies
MPI ..... Mannheim peritonitis index
RR ..... *Respiratory rate*, *Respiratory rate*
SAPS ..... Simplified acute physiology score
SSS..... Sepsis severity score
T *Temperature*, *Temperature*
UEH .....State University of Haiti
WBC ..... *white blood cell count*, white blood cell

Research Synopsis

Study title	**Descriptive and correlational study of the epidemiological, clinical and etiological characteristics of peritonitis in the surgical department of the HUEH during the period from January 2013 to December 2018**
Study Population	All patients diagnosed, hospitalized and operated on in the peritonitis ward during January 2013 to December 2018
Study Design	correlational descriptive study, retrospectively carried out over a period of 6 years, from January 2013 to December 2018 in the surgical department of the HUEH
General Objective	To study the prevalence, etiology, and factors associated with the severity of peritonitis and its complications in the department of surgery at HUEH.
Specific Objectives	¬ Identify epidemiological characteristics. ¬ Describe the main etiologies encountered in the service ¬ Measure the time required for treatment and its consequences on the evolution of peritonitis.
Sample Size	91 patients
Study Duration	January 2013 to December 2018

Introduction

Background

Generalized secondary peritonitis is one of the most common emergencies encountered in surgical departments (1). It is a major surgical condition with a mortality of up to 20% and classified as the third most common cause of surgical abdomens after appendicitis and intestinal obstruction (2). Despite advances in surgical techniques, its management remains difficult and complex and it has been reported as one of the most lethal non traumatic conditions in the department emergency around the world (3,4). Several factors such as: age, sex, failing organs, malignancy, peritonitis extension, type of contamination, site of perforation, surgery, co-morbidities, severity of sepsis, treatment delay and immunosuppression, are known to influence mortality and morbidity (4). There is an etiological disparity between developed and developing countries. It was noted that infectious peritonitis dominates the picture in developing countries while perforation cases are the majority in developed countries (5,6). Infectious peritonitis dominates the picture in developing countries while perforation cases are the majority in developed countries, generally the observations show patients in low-income countries tend to have perforations of the proximal intestine, while in the western world they are more often affected by perforations of the large intestine (4,7). Delays in surgical management are known as conditions that increase mortality and generally the three main sources of delay in surgery are: delays in seeking care after the onset of symptoms, delays in arriving at the hospital in a timely manner, and delays in surgical management (8). While early prognostic assessment of peritonitis is essential for the objective classification of the severity of the disease, the late presentation of the majority of patients to health facilities affects this situation, further complicating effective management and promoting the occurrence of complications (9). Muralidhar observed that mortality was 5% in patients who presented within 24 hours, 13% in patients who presented between 2 to 5 days and 50% in patients who presented after 5 days. (10) Thus, as the delay is significant, the risk of mortality becomes greater. It has been observed that classifying the severity of peritonitis has a major contribution to decision-making and improves management (10). Many scoring systems have been designed and successfully used to assess the severity of acute peritonitis, including: Acute physiology and chronic health evaluation (APACHE) II score, Simplified acute physiology score (SAPS), Sepsis severity score (SSS), Ranson score, Imrite score, Mannheim peritonitis index (MPI). The Mannheim Peritonitis Index (MPI) is a specific score, which is highly accurate and allows clinical parameters to be easily manipulated, allowing the individual prognosis of patients with

peritonitis to be predicted. It is an independent, objective and effective rating system for predicting mortality and has advantages over the other rating systems described above (10,11).

Rationale

Knowing these characteristics, namely the importance of delays and the severity score, will help to better manage the disease and its progression both in terms of diagnosis and therapy. Hence the interest of this study in our environment, where coming to the hospital is often the last choice of patients due to lack of resources sometimes, but especially because of a lack of information particularly on surgical pathologies. In Haiti, few studies on surgical pathologies are available, and with regard to peritonitis, only two thesis works have been listed on the subject, including one carried out at the Justinian University Hospital of Cap-Haitien on 176 patients by Dr. Jacques JULMICE, who presents the main etiologies of peritonitis over a 5-year period[a]. And the other one carried out at the Albert Schweitzer Hospital by Dr. Moise ARISTIDE, still on the etiological factors of peritonitis[b]. These two studies are carried out outside the country's metropolitan region (the most populated region) and that they only explored the different etiologies without taking into account the time required for treatment and the gravity factors of peritonitis.

Aim

1) Our study aims to explore the demographic, clinical and etiological characteristics of peritonitis in the main referral hospital in the metropolitan region of the Haiti
2) Evaluate the main delays (onset of symptoms, pre-op, post-op and stay time at hospital) and its relationship with the severity of the disease by measuring the MPI score.

Objectives of the project

Primary objective:

To study the prevalence, etiology, and factors associated with the severity of peritonitis and its complications in the service of HUEH Surgery.

[a] Dr. Jacques JULMICE. ETUDE SUR LES PARTICULARITES ETIOLOGIQUES DE LA PERITONITE SECONDAIRE A L'HOPITAL UNIVERSITAIRE JUSTINIEN ,DR JACQUES JULMICE(ETUDE RETROSPECTIVE JANVIER 2003-DECEMBRE 2007) - Unpublished manuscript [Internet]. 2010 [cited 2019 Apr 15]. Available from: http://atelier.rfi.fr/profiles/blogs/etude-sur-les-particularites

[b] ARISTIDE M. Facteurs étiologiques des péritonites infectieuses généralisées, Unpublished manuscript. Université notre dame d'Haïti, Faculté de médecine et des sciences de la santé. Université notre dame d'Haïti; 2013.

Secondary objectives:

¬ Identify epidemiological characteristics.

¬ Describe the main etiologies encountered in the service

¬ Measure the time required for treatment and its consequences on the evolution of peritonitis.

Methodology

Study Type and Design

It is a correlational descriptive study, retrospectively carried out over a period of 6 years, from January 2013 to December 2018 in the surgical department of the HUEH

The study is being conducted in the Surgery Department of the Hospital of the State University of Haiti (HUEH). It is a university hospital, the main training center of the Faculty of Medicine and Pharmacy (FMP) of the State University of Haiti (UEH).

Study Population

The study population is composed of all patients diagnosed, hospitalized and operated on in the peritonitis ward during the study period.

Inclusion Criteria

¬ Patients whose peritonitis diagnosis was made and operated on in the department during the period.

¬ Patient whose record is identified (with age, sex) with at least the clinical and etiological diagnosis identified in the operating protocol.

Exclusion Criteria

¬ Patients with incomplete records.

¬ Cases of post-operative peritonitis.

¬ Patient under 10 years of age

Sample Size

Sampling is probabilistic, simple random sampling. The sample size is randomly determined from Epi Info 7. To estimate the sample size, we considered the peritonitis prevalence of an African study on the particularity of peritonitis in tropical environments, an environment that reflects our reality in ecological, demographic and epidemiological terms, namely 19% (5). The standard error rate chosen was 5%. This allows us to estimate our sample at 88 with a confidence interval of 97%. Given the possibility of finding missing files at HUEH, our sample was adjusted to 20% (standard non-response rate), by the formula: (Adjusted sample) = (Initial sample) + (Probable non-response). Thus the Adjusted sample becomes 106. The sample was listed on a unit list consisting of all files recorded during the study period. The files were numbered from 1, the numbers were chosen at random, from the batches of 10 the first 106 were chosen randomly. (annexes)

Study Duration and Timeline

Protocol writing and reviewed from: August 2018 to December 2018

Data collection from: March 2019 to May 2019

Data Analysis from: May 2019 to August 2019

Correction and reviewing from: September 2019 to November 2019

Presentation and Publication from: November 2019 to December 2019

Statistical Analysis Plan

An individual collection sheet, prepared on the Epi Info 7 software, was used, which contains a part for demographic and identity data, a part for vital signs, another part for clinical and para-clinical data and a part for intraoperative data. Data collection was conducted in the surgical department's archive room, according to the principles mentioned above in the ethical consideration. A file is considered complete (and therefore accepted) if it contains: demographic data, clinical diagnosis and operating protocol. Identity information is taken from the first record recorded for the patient. The information concerning the clinical diagnosis is taken from the admission note and the vital signs considered are those found in this first note. For the data of the para clinical examinations only the first examinations, i.e. the closest to the date of admission, were considered. Intraoperative diagnostic data are collected directly from the operating protocol. For complications and management, only information from the progress notes closest to the date of the intervention was considered. Quantitative variables are measured by calculating the mean, and quartiles, and categorical variables by calculating frequencies and percentages. other quantitative variables were transformed into qualitative variables such as: heart rate with 3 modalities (bradycardia if HR < 60 ; normal between 60-100 and tachycardia if > 100); respiratory rate (bradypnea if RR < 12 ; normal between 12-20 and tachypnea if > 20) ; temperature (hypothermia if T < 3 6.5; normal between 36.5 - 75.5 and hyperthermia if >37.5); hemoglobin level (normal if Hb > 12 gram; abnormal if < 12 gram); white blood cell count (leukopenia if WBC < 5000 ; normal between 5000- 10000 ; leukocytosis if > 10000) ; urea (normal between 20-40 mg/dl) creatinine (normal between 0.4-1.40 mg/dl). For the qualitative variables, they were presented according to several modalities such as: sex according to two modalities (Male, Female); marital status according to three modalities (Married, single, not mentioned); academic level according to five modalities (elementary, student, university, illiterate, not mentioned); address according to five modalities (Port-au-Prince commune, Carrefour commune, Delmas commune, Petion-ville commune, outside the

capital). Vital signs were mentioned in two ways (yes, no), including the surgical techniques used. And the durations according to 3 modalities (less than 3 days, between 3-8 days, more than 8 days). The age will be grouped by interval of 10 years, with 10 groups of 11-20 years 21-30 years. The dependent variables are: etiological diagnosis, complications and changes. The independent variables are: age, MPI score, pre-op duration, post-op duration, length of stay, onset of symptoms. The relationship between length of hospital stay and length of post-op, pre-op and pre-hospital stay and time to hospital arrival was analyzed as well as the MPI severity score. Pearson's correlation with $p<0.05$ was used as the significance threshold and the correlation of complications and duration of management by Spearman's correlation to assess the relationship between sex, age group, complications and length of hospital stay. The correlation is estimated as perfect if $r=1$; very strong if $r>0.8$; strong if r [0.5-0.8]; medium if r [0.2-0.5] and low if $r<0.2$. A multiple linear regression will be done for the most significant correlations. The comparison of the means was made by the Z test (for samples >30), with $\alpha<$ 0.05 as the significance threshold, and the student T test (Independent T Test) for variables with two modalities such as complication. The ANOVA test was used to cross-reference dependent and independent variables with more than 2 modalities, and the Pearson chi-square test for qualitative variables with etiological and demographic diagnoses. The results are presented on tables and graphs. The data are collected from the sheets and then entered into the Epi Info software and processed by the PSPP and SPSS 20, Software.

Risk and benefit to study participants

This study does not present any direct benefit to the participants. However, the study does provide a better understanding of the disease/condition studied in our community.

Ethics of Study

The work is carried out under the supervision of the Faculty's LABMES (Laboratory of Ethical Medicine and Societies). First we submitted the work protocol to LABMES, which after analysis and corrections gave us permission to request a letter from the vice deanery of the Faculty addressed to the head of the hospital. A coding system made with the first letters of patients' first and last names as well as the first digit of the admission date, was used to keep anonymity and the data was collected in the department itself, then stored on my personal online account Dropbox.

Informed Consent/Assent Process

As it is a retrospective study we cannot have access to the patient for an informed consent. So we assumed that the head medical directory of the hospital gives us the permission to use the data information.

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Publication Policy

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published

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