World Society of Emergency Surgery

WSES

WSES prognostic score for patients with cIAIs severity

A prospective validation study

WISS Study (WSES cIAIs Score Study)

Study protocol

Rationale

Intra-abdominal infections (IAIs) include several different pathological conditions, ranging from uncomplicated appendicitis to faecal peritonitis [1].

IAIs are usually classified into uncomplicated and complicated.

In complicated IAIs (cIAIs), the infectious process extends beyond the organ, and causes either localized peritonitis or diffuse peritonitis. The treatment of patients with complicated intra-abdominal infections involves both source control and antibiotic therapy.

Complicated intra-abdominal infections are an important cause of morbidity and are frequently associated with poor prognosis, particularly in higher risk patients.

The term complicated intra-abdominal infections describes a wide heterogeneity of patient populations, making difficult to suggest a general treatment regimen and stressing the need of an individualized approach to decision making.

Early prognostic evaluation of complicated intra-abdominal infections is important to assess the severity and decide the aggressiveness of treatment.

Many factors influencing the prognosis of patients with cIAIs have been described including advanced age, poor nutrition, pre-existing diseases, immunosuppression, extended peritonitis, occurrence of septic shock, poor source control, organ failures, prolonged hospitalization before therapy, and infection with nosocomial pathogens [2-9].

Identifying a new clinical score to assess the severity the cIAIS would be clinically relevant in order to modulate the aggressiveness of treatment according the type of infection and the clinical characteristics of the patients.

In the last years the World Society of Emergency Surgery designed the CIAO Study and the CIAOW Study [10-11]

The CIAO Study ("Complicated Intra-Abdominal infection Observational" Study) is a multicenter investigation performed in 68 medical institutions throughout Europe during a 6-month observational period (January-June 2012).

The study included patients undergoing surgery or interventional drainage to address cIAIs.

2,152 patients with a mean age of 53.8 years (range: 4-98 years) were enrolled in the study. 46.3% of the patients (996) were women and 53.7% (1156) were men.

The overall mortality rate of patients was 7,6% (163/2152).

According to univariate statistical analysis of the data, severe sepsis and septic shock upon hospital admission were both predictive of patient mortality. The setting of acquisition (healthcare associated infection versus community acquired infection) was also a variable found to be predictive of patient mortality. Among the various sources of infection, colonic non-diverticular

perforation, complicated diverticulitis, and small bowel perforation were significantly correlated with patient mortality.

According to stepwise multivariate analysis, the independent variables predictive of mortality, included patient age, the presence of an intestinal non-appendicular source of infection, a delayed initial intervention (delay over 24 hours), severe sepsis and septic shock in the immediate post-operative period, and ICU admission .

Given the interesting results of the CIAO Study, a prospective observational study investigating the management of cIAIs in a worldwide context was designed.

The CIAOW study (Complicated intra-abdominal infections worldwide observational study) is a multicenter observational study underwent in 68 medical institutions worldwide, over the course of a six-months period (October 2012-March 2013). The study included patients, older than 18 years undergoing surgery or interventional drainage to address cIAIs.

2020 cases were collected. 122 cases did not meet the inclusion criteria. 1898 patients with a mean age of 51.6 years (range 18-99) were enrolled in the CIAOW study. 777 patients (41%) were women and 1,121 (59%) were men.

The overall mortality rate of patients was 10,5% (199/1898).

The variables predictive of patient mortality were similar to those of the CIAO Study.

According to univariate statistical analysis of the data, the setting of acquisition (healthcare-associated infections versus community acquired infection) was a variable found to be predictive of patient mortality. Among the various sources of infection, colonic non-diverticular perforation, complicated diverticulitis, small bowel perforation and post-operative infections were significantly correlated with patient mortality. Mortality rates did not significantly differ among patients who received adequate source control and those who did not. However, a delayed initial intervention (over 24 hours) was associated with an increased mortality rate.

Also comorbidities were associated to patient mortality (Malignancy, immunosuppression: and serious cardiovascular disease) .

According to stepwise multivariate analysis, the independent variables predictive of mortality included patient age, the presence of small bowel perforation, a delayed initial intervention (over 24 hours), ICU admission and patient immunosuppression .

All the risk factors for occurrence of death during hospitalization were evaluated and discussed within an international panel of experts. The most significant variables, adjusted to clinical criteria, were used to create a severity score for patients with cIAIs.

Risk factors for occurrence of death during hospitalization were studied, and the most significant variables, adjusted to clinical criteria, were used to create a prognostic score for severity of cIAIs

WSES cIAIs Score

Clinical condition at the admission

- Severe sepsis (acute organ dysfunction) at the admission **3 score**
- Septic shock (acute circulatory failure characterized by persistent arterial hypotension. It always requires vasopressor agents) at the admission **5 score**

Origin of the IAIs

- Colonic non-diverticular diffuse peritonitis **2 score**
- Small bowel diffuse peritonitis **2 score**
- Diverticular diffuse peritonitis **2 score**
- Post traumatic peritonitis **2 score**
- Post-operative diffuse peritonitis **3 score**

Delay in source control

- Delayed initial intervention (a delay exceeding 24 hours) **2 score**

Age

- Age 70-80 years **1 score**
- Age>80 **2 score**

Immunosuppression

- Immunosuppression (chronic glucocorticoids, immunosuppresant agents, chemoteraphy, lymphatic diseases, virus) **3 score**

Severity classification based on the total score (the sum of the aforementioned scores)

< = 3 Low severity

4 - 6 Intermediate severity

= >7 High severity

Methods

The purpose of the WISS study (WSES cIAIs Score Study) is both to value the variables predictive of in-hospital death in patients with complicated intra-abdominal infections and to validate the WSES Score for severity of patients with cIAIS.

Study population

This prospective multicenter observational study will be performed in various medical institutions worldwide over a 4-month period (October, 15, 2014 - February, 15, 2015). Patients older than 18 years, undergoing surgery or interventional drainage to assess complicated IAIs, will be included in the database. Patients with pancreatitis, primary peritonitis from cirrhosis, or ascites will be excluded from the study.

Study design

This observational study will not attempt to change or modify the laboratory or clinical practices of the participating physicians, and neither informed consent nor formal approval by an Ethics Committee will be required.

The study will meet and conform to the standards outlined in the Declaration of Helsinki and Good Epidemiological Practices.

It will be conducted under the supervision of WSES board.

Data collection

In each centre, the coordinator will collect and compile data in an online case report system.

Statistical analysis

Following data entry into a computerized database. The primary endpoint will be the validation of the WSES score, with any eventual minor modifications.

Inclusion Criteria

Patients older than 18 years

Patients undergoing surgery or interventional drainage to assess complicated IAIs

Exclusion Criteria

Age under 18 years

Pancreatitis

Primary peritonitis.

Definitions

Complicated intra-abdominal infections

In cIAIs, the infectious process proceeds beyond the organ, and causes either localized peritonitis/abscess or diffuse peritonitis.

Severe sepsis

According to the new International guidelines of Surviving Sepsis Campaign for Management of Severe Sepsis and Septic Shock [12] severe sepsis is defined as sepsis-induced tissue hypoperfusion or organ dysfunction

One of these organ dysfunctions caused by infection defines severe sepsis

- Sepsis-induced hypotension
- Lactate above upper limits laboratory normal
- Urine output < 0.5 mL/kg/hr for more than 2 hrs despite adequate fluid resuscitation
- Acute lung injury with PaO2/FIO2 < 250 in the absence of pneumonia as infection source
- Acute lung injury with PaO2/FIO2 < 200 in the presence of pneumonia as infection source
- Creatinine > 2.0 mg/dL (176.8 μmol/L)
- Bilirubin > 2 mg/dL (34.2 μmol/L)
- Platelet count < 100,000 μL
- Coagulopathy (international normalized ratio > 1.5)

Septic Shock

It is defined as acute circulatory failure characterized by persistent arterial hypotension due to the infection. It always requires vasopressor agents [13].

Delayed initial intervention

Delayed initial intervention is defined as a delay exceeding 24 hours in controlling source of infections or a preoperative duration of (localized or diffuse) peritonitis > 24 hours

Immunosuppression

Immunosuppression is defined as:

- Chronic treatment with glucocorticoids,
- Treatment with immunosuppressive agents
- Chemoteraphy
- Patients with lymphatic diseases
- Virus related immunosuppression (i.e. HIV).

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