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RESEARCH ARTICLE

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Global validation of the WSES Sepsis Severity Score for patients with complicated intra-abdominal infections: a prospective multicentre study (WISS Study)

Massimo Sartelli^{1*}, Fikri M. Abu-Zidan², Fausto Catena³, Ewen A. Griffiths⁴, Salomone Di Saverio⁵, Raul Coimbra⁶, Carlos A. Ordoñez⁷, Ari Leppaniemi⁸, Gustavo P. Fraga⁹, Federico Coccolini¹⁰, Ferdinando Agresta¹¹, Ashraf Abbas¹², Saleh Abdel Kader¹³, John Agboola¹⁴, Adamu Amhed¹⁵, Adesina Ajibade¹⁶, Seckin Akkucuk¹⁷, Bandar Alharthi¹⁸, Dimitrios Anyfantakis¹⁹, Goran Augustin²⁰, Gianluca Baiocchi²¹, Miklosh Bala²², Oussama Baraket²³, Savas Bayrak²⁴, Giovanni Bellanova²⁵, Marcelo A. Beltràn²⁶, Roberto Bini²⁷, Matthew Boal⁴, Andrey V. Borodach²⁸, Konstantinos Bouliaris²⁹, Frederic Branger³⁰, Daniele Brunelli³¹, Marco Catani³², Asri Che Jusoh³³, Alain Chichom-Mefire³⁴, Gianfranco Cocorullo³⁵, Elif Colak³⁶, David Costa³⁷, Silvia Costa³⁸, Yunfeng Cui³⁹, Geanina Loredana Curca⁴⁰, Terry Curry⁶, Koray Das⁴¹, Samir Delibegovic⁴², Zaza Demetrashvili⁴³, Isidoro Di Carlo⁴⁴, Nadezda Drozdova⁴⁵, Tamer El Zalabany⁴⁶, Mushira Abdulaziz Enani⁴⁷, Mario Faro⁴⁸, Mahir Gachabayov⁴⁹, Teresa Giménez Maurel⁵⁰, Georgios Gkiokas⁵¹, Carlos Augusto Gomes⁵², Ricardo Alessandro Teixeira Gonsaga⁵³, Gianluca Guercioni⁵⁴, Ali Guner⁵⁵, Sanjay Gupta⁵⁶, Sandra Gutierrez⁵⁷, Martin Hutan⁵⁸, Orestis Ioannidis⁵⁹, Arda Isik⁶⁰, Yoshimitsu Izawa⁶¹, Sumita A. Jain⁶², Mantas Jokubauskas⁶³, Aleksandar Karamarkovic⁶⁴, Salla Kauhanen⁶⁵, Robin Kaushik⁵⁶, Jakub Kenig⁶⁶, Vladimir Khokha⁶⁷, Jae Il Kim⁶⁸, Victor Kong⁶⁹, Renol Koshy⁴⁴, Avidyl Krasniqi⁷⁰, Ashok Kshirsagar⁷¹, Zygimantas Kuliesius⁷², Konstantinos Lasithiotakis⁷³, Pedro Leão⁷⁴, Jae Gil Lee⁷⁵, Miguel Leon⁷⁶, Aintzane Lizarazu Pérez⁷⁷, Varut Lohsiriwat⁷⁸, Eudaldo López-Tomassetti Fernandez⁷⁹, Eftychios Lostoridis⁸⁰, Raghuvver Mn⁸¹, Piotr Major⁸², Athanasios Marinis⁸³, Daniele Marrelli⁸⁴, Aleix Martinez-Perez⁸⁵, Sanjay Marwah⁸⁶, Michael McFarlane⁸⁷, Renato Bessa Melo⁸⁸, Cristian Mesina⁸⁹, Nick Michalopoulos⁹⁰, Radu Moldovanu⁹¹, Ouadii Mouaquit⁹², Akutu Munyika⁹³, Ionut Negoii⁹⁴, Ioannis Nikolopoulos⁹⁵, Gabriela Elisa Nita¹⁰, Iyiade Olaoye⁹⁶, Abdelkarim Omari⁹⁷, Paola Rodríguez Ossa⁷, Zeynep Ozkan⁹⁸, Ramakrishnapillai Padmakumar⁹⁹, Francesco Pata¹⁰⁰, Gerson Alves Pereira Junior¹⁰¹, Jorge Pereira¹⁰², Tadeja Pintar¹⁰³, Konstantinos Pougouras⁸⁰, Vinod Prabhu¹⁰⁴, Stefano Rausei¹⁰⁵, Miran Rems¹⁰⁶, Daniel Rios-Cruz¹⁰⁷, Boris Sakakushev¹⁰⁸, Maria Luisa Sánchez de Molina¹⁰⁹, Charampos Seretis¹¹⁰, Vishal Shelat¹¹¹, Romeo Lages Simões⁹, Giovanni Sinibaldi¹¹², Matej Skrovina¹¹³, Dmitry Smirnov¹¹⁴, Charalampos Spyropoulos¹¹⁵, Jaan Tepp¹¹⁶, Tugan Tezcaner¹¹⁷, Matti Tolonen⁸, Myftar Torba¹¹⁸, Jan Ulrych¹¹⁹, Mustafa Yener Uzunoglu¹²⁰, David van Dellen¹²¹, Gabrielle H. van Ramshorst¹²², Giorgio Vasquez¹²³, Aurélien Venara³⁰, Andras Vereczkei¹²⁴, Nereo Vettoretto¹²⁵, Nutu Vlad¹²⁶, Sanjay Kumar Yadav¹²⁷, Tonguç Utku Yilmaz¹²⁸, Kuo-Ching Yuan¹²⁹, Sanoop Koshy Zachariah¹³⁰, Maurice Zida¹³¹, Justas Zilinskas⁶³ and Luca Ansaloni¹⁰

* Correspondence: massimosartelli@gmail.com

¹Department of Surgery, Macerata Hospital, Macerata, Italy

Full list of author information is available at the end of the article



Abstract

Background: To validate a new practical Sepsis Severity Score for patients with complicated intra-abdominal infections (cIAIs) including the clinical conditions at the admission (severe sepsis/septic shock), the origin of the cIAIs, the delay in source control, the setting of acquisition and any risk factors such as age and immunosuppression.

Methods: The WISS study (WSES cIAIs Score Study) is a multicenter observational study undertaken in 132 medical institutions worldwide during a four-month study period (October 2014-February 2015). Four thousand five hundred thirty-three patients with a mean age of 51.2 years (range 18–99) were enrolled in the WISS study.

Results: Univariate analysis has shown that all factors that were previously included in the WSES Sepsis Severity Score were highly statistically significant between those who died and those who survived ($p < 0.0001$). The multivariate logistic regression model was highly significant ($p < 0.0001$, $R^2 = 0.54$) and showed that all these factors were independent in predicting mortality of sepsis. Receiver Operator Curve has shown that the WSES Severity Sepsis Score had an excellent prediction for mortality. A score above 5.5 was the best predictor of mortality having a sensitivity of 89.2 %, a specificity of 83.5 % and a positive likelihood ratio of 5.4.

Conclusions: WSES Sepsis Severity Score for patients with complicated Intra-abdominal infections can be used on global level. It has shown high sensitivity, specificity, and likelihood ratio that may help us in making clinical decisions.

Keywords: Intra-abdominal, Infections, Sepsis, Septic shock

Background

Intra-abdominal infections (IAIs) include several different pathological conditions [1] and 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 IAIs are an important cause of morbidity and may be associated with poor prognosis. However the term “complicated intra-abdominal infections” describes a wide heterogeneity of patient populations, making it 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 crucial 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 [2–10].

Recently the World Society of Emergency Surgery (WSES) designed a global prospective observational study (CIAOW Study) [11, 12]. All the risk factors for occurrence of death during hospitalization were evaluated and then discussed with an international panel of experts. The most significant variables, adjusted to clinical criteria, were used to create a severity score for patients with cIAIs including the clinical conditions at

admission (severe sepsis/septic shock), the origin of the cIAIs, the delay in source control, the setting of acquisition and any risk factors such as age and immunosuppression (Appendix).

There may be different causes of sepsis, health care standards, and differences in underlying health status, economical differences that make prediction of sepsis on global level difficult. The WSES addressed this issue in the present study which aims to validate a previous score on a global level.

Methods

Ethical statement

The study met the standards outlined in the Declaration of Helsinki and Good Epidemiological Practices. This study did not change or modify the laboratory or clinical practices of each centre and differences of practices were kept as they are. The data collection was anonymous and identifiable patient information was not submitted.

Individual researchers were responsible for complying with local ethical standards and hospital registration of the study.

Study population

This multicenter observational study was run in 132 medical institutions from 54 countries worldwide during a four-month period (October 2014-February 2015). Inclusion criteria were patients older than 18 years with complicated intra-abdominal sepsis (cIAIs) who had surgical management or interventional radiological drainage. cIAIs was defined as an infectious process that proceeded beyond the organ, and caused either localized peritonitis/abscess or diffuse peritonitis [13]. Patients who were younger than 18 years, or those

who had pancreatitis, or primary peritonitis were excluded from the study. Severe sepsis was defined as sepsis-induced tissue hypoperfusion or organ dysfunction (any of the following thought to be due to the infection): hypotension ($<90/60$ or $MAP < 65$), lactate above upper limits laboratory normal, Urine output <0.5 mL/kg/h for more than 2 h despite adequate fluid resuscitation, Creatinine >2.0 mg/dL (176.8 $\mu\text{mol/L}$), Bilirubin >2 mg/dL (34.2 $\mu\text{mol/L}$), Platelet count $<100,000$ μL , Coagulopathy (international normalized ratio >1.5), Acute lung injury with $Pao_2/Fio_2 < 250$ in the absence of pneumonia as infection source. Septic shock was defined as severe sepsis associated with refractory hypotension ($BP < 90/60$) despite adequate fluid resuscitation [14].

WSES Sepsis Severity Score for patients with complicated Intra-abdominal infections is shown in Appendix.

Data monitoring and collection

The study was monitored by the coordination center, which investigated and verified missing or unclear data submitted to the central database. This study was performed under the direct supervision of the Board of Directors of WSES. In each centre, the coordinator collected and compiled data in an online case report system. Data were entered directly through a web-based computerized database. Data were entered either by a drop menu for categorical data like the source of infection or numbers for continuous variables such as age. Data collected included demographic data of the patient and disease characteristics, demographical data, type of infection (community- or healthcare-acquired), severity criteria and origin of infection and surgical procedures performed.

Statistical analysis

Sepsis status was coded as ordinal data for testing the logistic regression (not for scoring) as follows: no sepsis = 0, sepsis = 2, severe sepsis = 3, septic shock = 4). The source of sepsis was analysed as categorical data in the logistic regression, and the age as continuous data, while healthcare associated infection, delay in management, and immunosuppression as binomial data. The variables used in this scoring system in the patients who survived and those who died were compared using univariate analysis. This included Fisher's exact test or Pearson Chi-Square as appropriate for categorical data and Mann-Whitney U-test for continuous or ordinal data. Significant factors were then entered into a direct logistic regression model. A p value of ≤ 0.05 was considered significant. Data were analyzed with PASW Statistics 21, SPSS Inc, USA.

Results

Four thousand six hundred fifty-two cases were collected in the online case report system. One hundred twenty-nine cases did not meet the inclusion criteria. Four thousand five hundred thirty-three patients with a mean age of 51.2 years (range 18–99) were enrolled in the WISS study. One thousand nine hundred thirty-five patients (42.7 %) were women and 2598 (57.3 %) were men.

Among these patients, 3966 (87.5 %) were affected by community-acquired IAIs while the remaining 567 (12.5 %) suffered from healthcare-associated infections. One thousand six hundred twenty-seven patients (35.9 %) were affected by generalized peritonitis while 2906 (64.1 %) suffered from localized peritonitis or abscesses. Seven hundred ninety-one patients (17.4 %) were admitted in critical condition (severe sepsis/septic shock). The various sources of infection are outlined in Table 1. The most frequent source of infection was acute appendicitis; 1553 cases (34.2 %) involved complicated appendicitis.

The overall mortality rate was 9.2 % (416/4533).

Table 2 shows the univariate analysis comparing patients with complicated intra-abdominal infection who survived and those who died. The analysis shows that all factors included in the Sepsis Severity Score were highly significantly different between those who died and those who survived ($p < 0.0001$ in all variables). Accordingly all factors were entered into a direct logistic regression model (Table 3). The direct logistic regression model was highly significant ($p < 0.0001$, $R^2 = 0.54$) and showed that all factors included in the Sepsis Severity Score were significant independent

Table 1 Source of infection in 4553 patients from 132 hospitals worldwide (15 October 2014–15 February 2015)

Source of infection	Number (%)
Appendicitis	1553 (34.2 %)
Cholecystitis	837 (18.5 %)
Post-operative	387 (8.5 %)
Colonic non diverticular perforation	269 (5.9 %)
Gastro-duodenal perforations	498 (11 %)
Diverticulitis	234 (5.2 %)
Small bowel perforation	243 (5.4 %)
Others	348 (7.7 %)
PID	50 (1.1 %)
Post traumatic perforation	114 (2.5 %)
Missing	
Total	4553 (100 %)

PID pelvic inflammatory disease

Table 2 Univariate analysis of patients with complicated intra-abdominal infection comparing patients who survived ($n = 4117$) and patient who died ($n = 416$)

Variable	Survived (%) $n = 4117$	Died (%) $n = 416$	p value
Sepsis status			<0.0001
No sepsis	1914 (46.5 %)	23 (5.5 %)	
Sepsis	1725 (41.9 %)	80 (19.2 %)	
Severe sepsis	404 (9.8 %)	157 (37.7 %)	
Septic shock	74 (1.8 %)	156 (37.5 %)	
Healthcare associated infection	433 (10.5 %)	134 (32.2 %)	<0.0001
Source of infection			<0.0001
Appendicitis	1536 (37.3 %)	17 (4.1 %)	
Cholecystitis	809 (19.7 %)	28 (6.7 %)	
Colonic non diverticular perforation	204 (5 %)	65 (15.6 %)	
Diverticulitis	203 (4.9 %)	31 (7.5 %)	
Gastro-duodenal perforation	431 (10.5 %)	67 (16.2 %)	
PID	50 (1.2 %)	0 (0)	
Postoperative	415 (10.1 %)	86 (20.7 %)	
Small bowel perforation	174 (4.2 %)	69 (16.6 %)	
Post-traumatic	104 (2.5 %)	10 (2.4 %)	
Others	259 (6.3 %)	53 (12.7 %)	
Delay in source control	2015 (48.9 %)	341 (82 %)	<0.0001
Median age years (range)	48 (18–97)	79 (18–99)	<0.0001
Immunosuppression	292 (7.1)	120 (28.8 %)	<0.0001
Sepsis severity score	3 (0–17)	10 (0–17)	<0.0001

Data presented as median range or number percentage as appropriate

PID pelvic inflammatory disease

p value = Fisher's exact test, Pearson Chi-Square, or Mann Whitney U test as appropriate

Table 3 Direct logistic regression model with factors affecting mortality of patients complicated intra-abdominal infection, global study of 132 centres, ($n = 4553$)

Score variable	B	S.E.	Wald test	P value	OR	OR 95 % C.I.	
						Lower	Upper
Sepsis status	1.57	0.08	365.59	<0.0001	4.81	4.09	5.65
Setting of infection acquisition	0.6	0.18	10.49	0.001	1.81	1.27	2.6
Source of infection ^a			59.38	<0.0001			
Colonic non-diverticular perforation	-0.26	0.27	0.97	0.33	0.77	0.46	1.3
Diverticulitis diffuse peritonitis	-0.26	0.34	0.51	0.48	0.78	0.40	1.54
Postoperative diffuse peritonitis	-0.005	0.29	0	0.99	1.00	0.56	1.76
Remaining sources	-1.2	0.21	32.47	<0.0001	0.30	0.20	0.46
Delay in management	1.47	0.17	78.53	<0.0001	4.33	3.13	5.99
Age	0.04	0.004	103.58	<0.0001	1.04	1.04	1.05
Immunosuppression	1.24	0.17	55.79	<0.0001	3.46	2.5	4.79
Constant	-7.52	0.41	342.24	<0.0001	0.001		

OR odds ratio

^aCompared with small bowel perforation

Table 4 Direct logistic regression model showing the ability of WSES Sepsis Severity Score in predicting mortality of patients complicated intra-abdominal infection, global study of 132 centres, (n = 4553)

Variable	B	S.E.	Wald	P value	OR	OR 95 % C.I.	
						Lower	Upper
WSESSCORE	0.58	0.02	639.59	<0.0001	1.784	1.706	1.866
Constant	-5.79	0.19	958.74	<0.0001	.003		

OR odds ratio

predictors of mortality. Accordingly the ability of the score to predict mortality was tested by a direct logistic regression which is shown in Table 4. Again, this model using only the sepsis severity score was highly significant ($p < 0.0001$, $R^2 = 0.5$). The odds of death increased by 0.78 by an increase on one score which is remarkable.

Figure 1 shows that WSES Sepsis Severity Score had a very good ability of distinguishing those who survived from those who died. The overall mortality rate was 9.2 % (416/4533). This was 0.63 % for those who had a score of 0–3, 6.3 % for those who had a score of 4–6, and 41.7 % for those who had a score of ≥ 7 . The receiver operating characteristic curve showed that the best cutoff point for predicting mortality was a Sepsis Severity Score. 5.5 was the best predictor of mortality having a sensitivity of 89.2 %, a specificity of 83.5 % and a positive likelihood ratio of 5.4 (Fig. 2).

Discussion

Complicated intra-abdominal infections remain an important source of patient morbidity and may be frequently associated with poor clinical prognosis. Treatment of patients with cIAIs, has been usually described to achieve satisfactory results if adequate management is established [15]. However, results from published clinical trials may not be representative of the true morbidity and mortality rates of such severe infections. First of all, patients who have perforated appendicitis are usually over-represented in clinical trials. Furthermore patients with intra-abdominal infection enrolled in clinical trials have often an increased likelihood of cure and survival. In fact the trial eligibility criteria usually restrict the inclusion of patients with co-morbid diseases that would increase the death rate of patients with intra-abdominal infections [16]. In the WISS study we enrolled all the patients older than 18 years old with complicated intra-abdominal infections in the study-period and the overall mortality rate was 9.2 % (416/4533). Stratification of the patient's risk is essential in order to optimize the treatment plan. Patients with intra-abdominal infections are generally classified into low risk and high risk. "High risk" is generally intended to describe patients with a high risk for treatment failure and mortality. In high risk patients the increased mortality associated with inappropriate management cannot be reversed by subsequent modifications. Therefore early prognostic

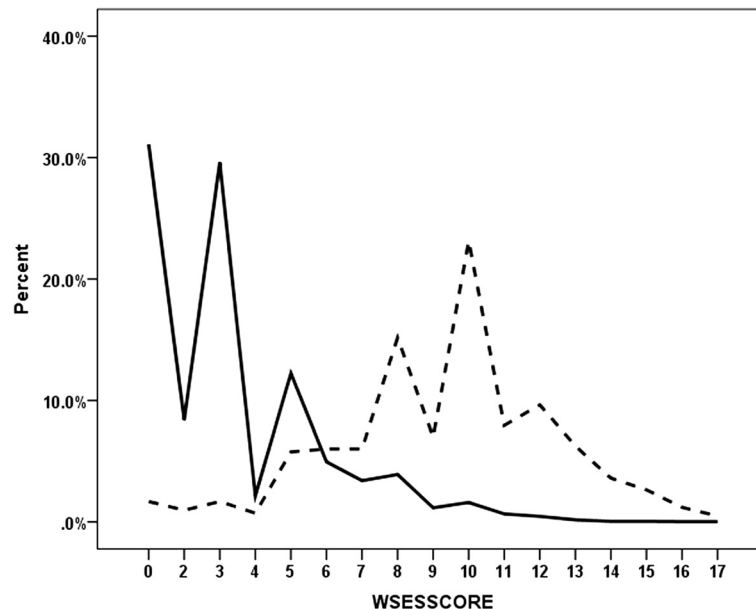


Fig. 1 Distribution of the percentile WSES Sepsis Severity Score of complicated intra-abdominal infection patients for those who survived (solid line) (n = 4117) and those who died (interrupted line) (n = 416)

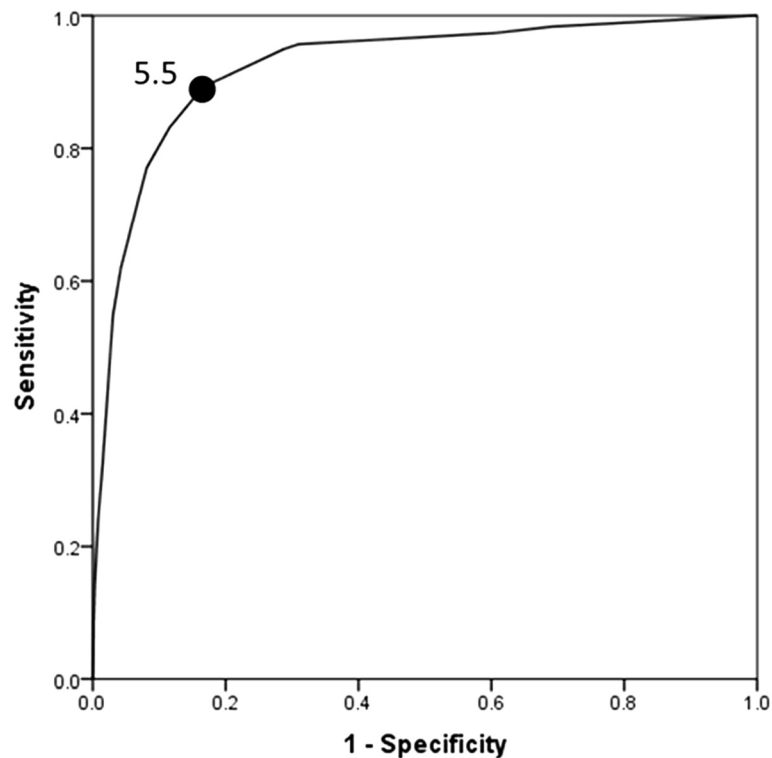


Fig. 2 Receiver operating characteristic curve for the best WSES Sepsis Severity Score that predicted mortality in patients having complicated intra-abdominal infection, global study of 132 centres, ($n = 4553$)

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

Scoring systems can be roughly divided into two groups: disease-independent scores for evaluation of serious patients requiring care in the intensive care unit (ICU) such as APACHE II and Simplified Acute Physiology Score (SAPS II) and peritonitis-specific scores such as Mannheim Peritonitis Index (MPI) [17].

Although considered a good marker, APACHE II value in peritonitis has been questioned because of the difficulty of the APACHE II to evaluate interventions despite the fact that interventions might significantly alter many of the physiological variables. Moreover it requires appropriate software to be calculated [18].

The MPI is specific for peritonitis and easy to calculate. MPI was designed by Wacha and Linder in 1983 [19]. It was based on a retrospective analysis of data from 1253 patients with peritonitis. Among 20 possible risk factors, only 8 proved to be of prognostic relevance and were entered into the Mannheim Peritonitis Index, classified according to their predictive power. After 30 years, 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.

WSES Sepsis Severity Score is a new practical clinical severity score for patients with complicated intra-abdominal infections. It is specific for cIAIs and easy to calculate, even during surgery. It may be relevant in order to modulate the aggressiveness of treatment particularly in higher risk patients.

The score is illustrated in Appendix. The statistical analysis shows that the sepsis severity score has a very good ability of distinguishing those who survived from those who died. The overall mortality was 0.63 % for those who had a score of 0–3, 6.3 % for those who had a score of 4–6, 41.7 % for those who had a score of ≥ 7 . In patients who had a score of ≥ 9 the mortality rate was 55.5 %, those who had a score of ≥ 11 the mortality rate was 68.2 % and those who had a score ≥ 13 the mortality rate was 80.9 %.

Conclusions

Given the sweeping geographical distribution of the participating medical centers, WSES Sepsis Severity Score for patients with complicated Intra-abdominal infections can be used on global level. It has shown high sensitivity, specificity, and likelihood ratio that may help us in making clinical decisions.

Appendix

Table 5 WSES sepsis severity score for patients with complicated Intra-abdominal infections (Range: 0–18)

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
Setting of acquisition	
• Healthcare associated infection	2 score
Origin of the IAIs	
• Colonic non-diverticular perforation peritonitis	2 score
• Small bowel perforation peritonitis	3 score
• Diverticular diffuse peritonitis	2 score
• Post-operative diffuse peritonitis	2 score
Delay in source control	
• Delayed initial intervention [Preoperative duration of peritonitis (localized or diffuse) > 24 h]	3 score
Risk factors	
• Age > 70	2 score
• Immunosuppression (chronic glucocorticoids, immunosuppressant agents, chemotherapy, lymphatic diseases, virus)	3 score

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MS designed the study and wrote the manuscript. FMA-Z performed statistical analysis. All authors participated in the study. All authors read and approved the final manuscript.

Author details

¹Department of Surgery, Macerata Hospital, Macerata, Italy. ²Department of Surgery, College of Medicine and Health Sciences, UAE University, Al-Ain, United Arab Emirates. ³Department of Emergency Surgery, Maggiore Hospital, Parma, Italy. ⁴General and Upper GI Surgery, Queen Elizabeth Hospital, Birmingham, UK. ⁵Department of Surgery, Maggiore Hospital, Bologna, Italy. ⁶Department of Surgery, UC San Diego Medical Center, San Diego, USA. ⁷Fundación Valle del Lili, Universidad del Valle, Cali, Colombia. ⁸Abdominal Center, University Hospital Meilahti, Helsinki, Finland. ⁹Division of Trauma Surgery, Hospital de Clinicas, School of Medical Sciences, University of Campinas, Campinas, Brazil. ¹⁰General and Emergency Surgery, Papa Giovanni XXIII Hospital, Bergamo, Italy. ¹¹General Surgery, ULSS19 del Veneto, Adria, RO, Italy. ¹²Department of Surgery, Mansoura University Hospital, Mansoura, Egypt. ¹³Department of General Surgery, Al Ain Hospital, Al-Ain City, United Arab Emirates. ¹⁴Department of Surgery, Kwara State General Hospital, Ilorin, Nigeria. ¹⁵Department of Surgery, Ahmadu Bello University Teaching Hospital Zaria, Kaduna, Nigeria. ¹⁶Department of Surgery, LAUTECH Teaching Hospital, Osogbo, Nigeria. ¹⁷Department of General Surgery, Training and Research Hospital of Mustafa Kemal University, Hatay, Turkey. ¹⁸Department of Surgery, King Fahad Medical City, Riyadh, Saudi Arabia. ¹⁹Primary Health Care Centre of Kissamos, Chania, Greece. ²⁰Department of Surgery, University Hospital Center, Zagreb, Croatia. ²¹Clinical and Experimental Surgery, Brescia Civil Hospital, Brescia, Italy. ²²Trauma and Acute Care Surgery Unit, Hadassah Hebrew University Medical Center, Jerusalem, Israel. ²³Department of Surgery, Bizerte Hospital, Bizerte, Tunisia. ²⁴Department of General Surgery, Istanbul Training and Research Hospital,

Istanbul, Turkey. ²⁵Surgical II Division, S. Chiara Hospital, Trento, Italy. ²⁶Department of General Surgery, Hospital San Juan de Dios de La Serena, La Serena, Chile. ²⁷Department of General and Emergency Surgery, SG Bosco Hospital, Turin, Italy. ²⁸Emergency Surgery Department, 1st Municipal Hospital, Novosibirsk State Medical University, Novosibirsk, Russian Federation. ²⁹Department of Surgery, University Hospital of Larissa, Larissa, Greece. ³⁰Visceral Surgery, CHU, Angers, France. ³¹Chirurgia Generale, Ospedale di Città di Castello, Città di Castello, Italy. ³²Department of Emergency Surgery, Umberto I Hospital, "La Sapienza" University, Rome, Italy. ³³Department of Surgery, Kuala Krai Hospital, Kelantan, Malaysia. ³⁴Department of Surgery, Regional Hospital, Limbe, Cameroon. ³⁵General and Emergency Surgery, Policlinico Paolo Giaccone, Palermo, Italy. ³⁶Department of General Surgery, Samsun Education and Research Hospital, Samsun, Turkey. ³⁷Department of General and Digestive Tract Surgery, Alicante University General Hospital, Alicante, Spain. ³⁸Department of Surgery, CHVNG/E, EPE, Vila Nova de Gaia, Portugal. ³⁹Department of Surgery, Tianjin Nankai Hospital, Tianjin, China. ⁴⁰Department of General Surgery, Emergency Municipal Hospital Pascani, Pascani, Iasi, Romania. ⁴¹Department of Surgery, Numune Training and Research Hospital, Adana, Turkey. ⁴²Department of Surgery, University Clinical Center, Tuzla, Bosnia and Herzegovina. ⁴³Department General Surgery, Kipshidze Central University Hospital, Tbilisi, Georgia. ⁴⁴Department of Surgery, Hamad General Hospital, Doha, Qatar. ⁴⁵Department of Surgery, Riga East Clinical University Hospital, Riga, Latvia. ⁴⁶Department of Surgery, Bahrain Defence Force Hospital, Manama, Bahrain. ⁴⁷King Fahad Medical City, Riyadh, Saudi Arabia. ⁴⁸Division of General and Emergency Surgery, Hospital Estadual Mario Covas, ABC School of Medicine, Santo André, Brazil. ⁴⁹Department of Surgery 1, Vladimir City Clinical Hospital of Emergency Medicine, Vladimir, Russian Federation. ⁵⁰Cirurgia General y Digestiva, Hospital Universitario Miguel Servet, Zaragoza, Spain. ⁵¹2nd Department of Surgery, Aretaieio University Hospital, Athens, Greece. ⁵²Department of Surgery, Hospital Universitário Terezinha de Jesus, Faculdade de Ciências Médicas e da Saúde de Juiz de Fora, Juiz de Fora, Brazil. ⁵³Department of Surgery, Hospital Escola Padre Albino, Catanduva, Brazil. ⁵⁴Department of Surgery, Ascoli Piceno Hospital, Ascoli Piceno, Italy. ⁵⁵Department of General Surgery, Trabzon Kanuni Training and Research Hospital, Trabzon, Turkey. ⁵⁶Department of Surgery, Government Medical College and Hospital, Chandigarh, India. ⁵⁷Hospital Universitario del Valle, Universidad del Valle, Cali, Colombia. ⁵⁸2nd Surgical Department of Medical Faculty Comenius University, University Hospital Bratislava, Bratislava, Slovakia. ⁵⁹2nd Surgical Department, General Hospital of Kavala, Kavala, Greece. ⁶⁰Department of Surgery, Mengucek Gazi Training Research Hospital, Erzincan, Turkey. ⁶¹Department of Emergency and Critical Care Medicine, Jichi Medical University, Shimotsuke, Japan. ⁶²Department of Surgery, S M S Hospital, Jaipur, India. ⁶³Department of Surgery, Hospital of Lithuanian University of Health Sciences, Kaunas, Lithuania. ⁶⁴Clinic for Emergency Surgery, Medical Faculty University of Belgrade, Belgrade, Serbia. ⁶⁵Division Digestive Surgery and Urology, Turku University Hospital, Turku, Finland. ⁶⁶3rd Department of General Surgery, Jagiellonian University Collegium Medium, Kraków, Poland. ⁶⁷Department of Emergency Surgery, City Hospital, Mozyr, Belarus. ⁶⁸Department of Surgery, Ilсан Paik Hospital, Inje University College of Medicine, Goyang, Republic of Korea. ⁶⁹Department of Surgery, Edendale Hospital, Pietermaritzburg, South Africa. ⁷⁰Department of Surgery, University Clinical Center of Kosovo, Pristina, Kosovo. ⁷¹Department of General Surgery, Krishna Hospital, Karad, India. ⁷²Department of General Surgery, Republican Vilnius University Hospital, Vilnius, Lithuania. ⁷³Department of Surgery, York Teaching Hospital NHS Foundation Trust, York, UK. ⁷⁴General Surgery/Colorectal Unit, Braga Hospital, Life and Health Sciences Research Institute (ICVS), School of Health Sciences, University of Minho, Braga, Portugal. ⁷⁵Department of Surgery, Yonsei University College of Medicine, Seoul, South Korea. ⁷⁶Department of Surgery, Hospital La Paz, Madrid, Spain. ⁷⁷Cirurgia de Urgencias, Hospital Universitario Donostia, Donostia, Spain. ⁷⁸Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. ⁷⁹Department of Surgery, Insular University Hospital of Gran Canaria, Las Palmas, Spain. ⁸⁰1st Department of Surgery, Kavala General Hospital, Kavala, Greece. ⁸¹Department of General Surgery, Mysore Medical College and Research Institute, Government Medical College Hospital Mysore, Mysore, India. ⁸²2nd Department of Surgery, Jagiellonian University Medical College, Krakow, Poland. ⁸³First Department of Surgery, Tzaneio Hospital, Piraeus, Greece. ⁸⁴Department of General Surgery and Surgical Oncology, Le Scotte Hospital, Siena, Italy. ⁸⁵Department of Surgery, University Hospital, Valencia, Spain. ⁸⁶Department of Surgery,

- Post-Graduate Institute of Medical Sciences, Rohtak, India. ⁸⁷Department of Surgery, Radiology, University Hospital of the West Indies, Kingston, Jamaica. ⁸⁸General Surgery Department, Centro Hospitalar de São João, Porto, Portugal. ⁸⁹Second Surgical Clinic, Emergency Hospital of Craiova, Craiova, Romania. ⁹⁰3rd Department of Surgery, Haepa University Hospital, Thessaloniki, Greece. ⁹¹Department of Surgery, CH Armentieres, Arras, France. ⁹²Surgery Department, University Hospital Hassan II, Fez, Morocco. ⁹³Department of Surgery, Onandjokwe Hospital, Ondangwa, Namibia. ⁹⁴Department of Surgery, Emergency Hospital of Bucharest, Bucharest, Romania. ⁹⁵Department of General Surgery, Lewisham & Greenwich NHS Trust, London, UK. ⁹⁶Department of Surgery, University of Ilorin Teaching Hospital, Ilorin, Nigeria. ⁹⁷Department of Surgery, King Abdalla University Hospital, Irbid, Jordan. ⁹⁸Department of Surgery, Elazig Training and Research Hospital, Elazig, Turkey. ⁹⁹Department of Laparoscopic and Metabolic Surgery, Sunrise Hospital, Kochi, India. ¹⁰⁰Department of Surgery, Sant'Antonio Abate Hospital, Gallarate, Italy. ¹⁰¹Division of Emergency and Trauma Surgery, Ribeirão Preto Medical School, Ribeirão Preto, Brazil. ¹⁰²Surgery 1 Unit, Centro Hospitalar Tondela Viseu, Viseu, Portugal. ¹⁰³Department of Surgery, UMC Ljubljana, Ljubljana, Slovenia. ¹⁰⁴Department of Surgery, Bharati Medical College and Hospital, Sangli, India. ¹⁰⁵Department of Surgery, Insubria University Hospital, Varese, Italy. ¹⁰⁶Abdominal and General Surgery Department, General Hospital Jesenice, Jesenice, Slovenia. ¹⁰⁷Department of Surgery, Hospital de Alta Especialidad de Veracruz, Veracruz, Mexico. ¹⁰⁸General Surgery Department, Medical University, University Hospital St George, Plovdiv, Bulgaria. ¹⁰⁹Department of Surgery, Fundación Jimenez Díaz, Madrid, Spain. ¹¹⁰Department of Surgery, Good Hope Hospital, Heart of England NHS Foundation Trust, Birmingham, UK. ¹¹¹Department of General Surgery, Tan Tock Seng Hospital, Novena, Singapore. ¹¹²Department of Surgery, Fatabenefratelli Isola Tiberina Hospital, Rome, Italy. ¹¹³Department of Surgery, Hospital and Comprehensive Cancer Centre Novy Jicin, Novy Jicin, Czech Republic. ¹¹⁴Department of General Surgery, Clinical Hospital at Chelyabinsk Station of OJSC "Russian Railroads", Chelyabinsk, Russian Federation. ¹¹⁵3th Department of Surgery, Iaso General Hospital, Athens, Greece. ¹¹⁶Department of Surgery, North Estonia Medical Center, Tallin, Estonia. ¹¹⁷Department of Surgery, Baskent University Ankara Hospital, Ankara, Turkey. ¹¹⁸General Surgery Service, Trauma University Hospital, Tirana, Albania. ¹¹⁹1st Department of Surgery - Department of Abdominal, Thoracic Surgery and Traumatology, General University Hospital, Prague, Czech Republic. ¹²⁰Department of General Surgery, Sakarya Teaching and Research Hospital, Sakarya, Turkey. ¹²¹Department of Renal and Pancreas Transplantation, Manchester Royal Infirmary, Manchester, UK. ¹²²Department of Surgery, Red Cross Hospital, Beverwijk, Netherlands. ¹²³Emergency Surgery, Arcispedale S. Anna Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy. ¹²⁴Department of Surgery, Medical School University Pecs, Pecs, Hungary. ¹²⁵Department of Surgery, Montichiari Hospital, Ospedali Civili Brescia, Brescia, Italy. ¹²⁶1st Surgical Clinic, St. Spiridon Hospital, Iasi, Romania. ¹²⁷Department of Surgery, Rajendra Institute of Medical Sciences, Ranchi, India. ¹²⁸Department of Surgery, Kocaeli University Training and Research Hospital, Kocaeli, Turkey. ¹²⁹Trauma and Emergency Surgery Department, Chang Gung Memorial Hospital, Taoyuan City, Taiwan. ¹³⁰Department of Surgery, MOSC Medical College Kolenchery, Cochin, India. ¹³¹General and Digestive Surgery Department, Teaching Hospital Yalgado Ouedraogo, Ouagadougou, Burkina Faso.
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