Research Article

Time to recognition, aetiology, antibiotic sensitivity pattern and outcome of sepsis (sepsis 2 definition) in a tertiary care hospital in Sri Lanka

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Abstract

Introduction: Patients with sepsis or severe sepsis usually present to the Emergency Department (ED). The overall mortality rate for patients admitted with severe sepsis is 35% - approximately five times higher than that of ST-elevation myocardial infarction. Prompt recognition and treatment are essential to improve survival. Our aim was to study the time to recognition, identify aetiology, and obtain antibiotic sensitivity patterns and outcome of patients presenting with suspected sepsis.

Methodology: A prospective observational study including all patients suspected of having sepsis was carried out from July 1, 2016, to June 30, 2017, at the Emergency Department (ED) of the Provincial General Hospital Kurunegala, Sri Lanka. The study instrument was a data sheet comprising of the surviving sepsis guidelines (Sepsis 2) of the United Kingdom and demographics and background information from patient records. All the patients were followed up for one month.

Results: One hundred and four patients (Age:61 ±17, 54.8% males) were studied. Blood culture results were available in 94 patients (90.4%) of which 19 (20%) were positive. The most common organisms identified were coagulase-negative *Staphylococcus* (CoNS) (42%) and *Escherichia coli* (42%). Door to blood culture time was 38.6 ± 26.7 minutes with 98% having blood cultures taken within 45 minutes of admission. Door to antibiotic time was 43.3 ±27.2 minutes. The most common primary foci of infection were pneumonia (34.6%) and cellulitis (28.8%). All CoNS were sensitive to teicoplanin and vancomycin, while all *Escherichia coli*

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isolates were sensitive to meropenem. The median (IQR) duration of hospital stay was 6 (3 to 9.1) days.

The in-hospital mortality was 30 (28.9%) and 30-day mortality was 36 (34.6%). There was no statistical significance regarding mortality among blood culture positive and negative patients.

Conclusion: The sepsis bundle had been activated within 45 minutes in most of our patients. The outcome of sepsis at our hospital is better than data published from other centres around the world.

Keywords: *Sepsis, early recognition, antibiotic sensitivity, Emergency department, Sri Lanka*

Introduction

Over the years, understanding of sepsis has improved and so has the ability to define sepsis. "Sepsis 1" defined sepsis based on the presence of features of systemic inflammatory response syndrome (SIRS) as a result of suspected or proven infection. "Sepsis 2" upgraded this definition by elaborating and defining the features suggestive of infection while "sepsis 3" recognized sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection and introduced the SOFA and qSOFA scores.[1,2]

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At the time of initiating this study, "sepsis 2" consensus was in use. "Sepsis 2" defined sepsis as the presence of two or more of the SIRS criteria along with suspected or proven infections.[3] The overall mortality rate for patients admitted with sepsis is 40% - approximately 5 times higher than for ST-elevation in myocardial infarction or a stroke. Sepsis is responsible for approximately 37,000 deaths and 100,000 hospital admissions per year in the United Kingdom.[4] Annually, 750,000 cases of sepsis occur in the United States of America.[5] In Asia, hospital mortality was 44.5%.[6] Compliance rates for the resuscitation and management bundles were 7.6% and 3.5% respectively.[6]

The majority of patients with sepsis will present to the ED. Early recognition and treatment with instituting a bundle of care will simplify and improve the outcome.[7] 'Bundle' when implemented as a group, has an effect beyond implementing individual elements alone and has proved to be effective in the survival of patients with sepsis in intensive care units of high-income countries. Similarly, the same can be applied in a resource-limited setting with minimum or no extra cost.

All patients presenting with physiological disturbances that meet the SIRS criteria, or with signs and symptoms compatible with an infective illness, should be formally screened for sepsis. At each opportunity, a binary decision should be reached for all patients screened: (a) this patient could have sepsis or (b) this patient does not have sepsis.[4]

Suspicion of an infective cause is all that is required, i.e., ED staff do not need positive cultures, swabs, or other investigations. Once a patient is suspected of having sepsis, the patient should be seen immediately, ideally in the resuscitation area of the ED, and sepsis screening should be started.

As the study was based on guidelines before 2016 (sepsis 2), the key immediate intervention that took place in our study was sepsis six which consists of three diagnostic and three therapeutic steps – all to be delivered within one hour ('Golden hour') of the initial diagnosis of sepsis.[8] These steps consist of delivering high flow oxygen, taking blood cultures, administering empiric intravenous antibiotics, measuring serum lactate and performing a full blood count, starting intravenous fluid resuscitation, and commencing accurate urine output measurement.[8,9]

Investigations such as a chest x-ray, urinalysis, and culture of urine and any other relevant specimens should be undertaken as required.

An increasing trend in antimicrobial resistance in healthcare settings has been observed and demonstrated in Sri Lanka with the improvement of microbiological services in the country. Although studies have been carried out in different localities giving the prevalence of resistance, and an upward trend in antimicrobial resistance in pathogenic microorganisms noted, data to demonstrate it is scarce.[10]

Achieving sepsis six will place an ED well on the road to the provision of excellent sepsis management.

The objective of the study was to identify the time taken to detect sepsis, identify the aetiology with causative organisms, obtain results of antibiotic sensitivity testing, and determine the outcome of sepsis with 30-day mortality in a tertiary care hospital in Sri Lanka.

Method

A prospective observational study was carried out in the Emergency Department (ED) of the Provincial General Hospital, Kurunegala, Sri Lanka, from 1.7.2016 to 30.6.2017 (one year period). All patients above the age of 18 who presented with suspected sepsis[3] [tachycardia (>90/min), tachypnoea (>20/min), fever (>38.3 ºC) or temperature <35.6 ºC, leukocytosis (>12x10^9/L) or leukopaenia (4x10^9/l), or >10% immature (band) forms] from 1.7.2016 to 30.6.2017 and who consented were enrolled in the study. They were monitored by co-investigators without disturbing the relevant unit management, till discharge/death in the hospital and all were followed up for 30 days. Patients with major trauma and pregnant women were excluded.

All patients admitted to the study were managed according to the surviving sepsis guidelines 2012 on admission and subsequently with the hospital antibiotic policy in intensive care units and relevant wards. Patients who were discharged were followed up for one month. This was done in clinics and by telephone conversations with the patients and their families.

The study instrument included the data sheet (page 11) which included the surviving sepsis 2 guidelines of the United Kingdom and NICE guidelines,[11,12] and used for decision making and recording of key events. In addition, demographic background information, such as age, sex and previous co-morbidities, severity of illness, the aetiology of sepsis, the interval between admission and obtaining blood for culture and initiation of the first dose of antibiotic (door to first dose) were obtained.

On admission, according to the SIRS criteria, temperature >38.3 ^{o}C or <36 ^{o}C, pulse rate (PR) >90/minute, respiratory rate (RR) >20min, new confusion/drowsiness, systolic blood pressure (SBP) <90 mmHg, capillary blood glucose (CBS) >7.7mmol/L in the absence of known diabetes, white blood cells (WBC) >12 or <4 x109/L, and lactate >2.0 mmol/L were recorded. According to the findings, patients were categorized into five categories: septic shock, severe sepsis, red flag sepsis, uncomplicated sepsis, and no current evidence of sepsis.[1]

In addition to the above investigations, while the patient was in the ED, to define the rest of organ dysfunction criteria, chest X-rays were done when there was low oxygen saturation (<90%) and signs of pneumonia, and blood for serum creatinine, international normalized ratio (INR) and bilirubin were sent as initial investigations. Additionally, they were given initial treatment according to the surviving sepsis guidelines (bundle of six).

Empirical antibiotics according to the national antibiotic guidelines[13] was given within the golden hour with relevant resuscitation (hydration, vasopressors, inotropes, oxygen, insulin). Ceftriaxone was the empirical antibiotic used in the ED while ciprofloxacin was used if a history of allergy to penicillin was obtained.

Once a patient was admitted to the relevant ward/ICU, the remainder of the investigations and treatment were initiated and continued. Their clinical records, including known chronic conditions, vital signs, Glasgow Coma Scale (GCS), fluid challenge, administration of oxygen and other drugs including antibiotics, laboratory tests, and initial diagnoses made by attending clinicians and diagnosis on discharge were recorded. Subsequent targeted treatment was provided by the attending clinicians and their team. These were documented in the datasheet by trained doctors (co-investigators) on a day-to-day basis from the time of admission with the supervision of principal investigator.

Patients were followed up while in the ward and one month after discharge. This was done by reviewing the patient's records and lab results. The 30-day mortality was evaluated via telephone contact/clinic if the patients were no longer hospitalized or had been discharged.

Statistical analysis

Data were analysed using the Statistical Package for Social Sciences 21. Appropriate statistical tests were applied for the comparison of variables. For comparison of continuous variables, a t-test was used while the chi-square test was used to compare discrete variables.

Ethical considerations

Ethical approval was obtained from the Ethical Review Committee of the Provincial General Hospital, Kurunegala (ERC/2016/04/R02). Permission was obtained from the Director and all the attending specialists in intensive care units and relevant wards.

Informed written consent was obtained from all the participants before their inclusion in the study. In situations that involved the critically ill, elderly, and disabled, who were unable to give consent, consent was obtained from a legally acceptable representative (LAR). All the data was obtained anonymously and confidentially was assured at all times.

The electronic databases were kept password protected and both hardcopy data sheets and soft copy databases were stored securely.

Results

One hundred and four patients were enrolled with a mean age of 61 (SD16) years of whom 54.8% were males with a mean age of 59.7 (SD17) years. The mean age of females was 63.8 (SD16) years. Fever (n=25;24%) and confusion (n=14;13.5%) were the most common presenting symptoms, but the majority presented with symptoms of both fever and confusion (n=59;56.7%). Associated co-morbidities were present in 69 (66.3%) patients. The most commonly associated co-morbidity was diabetes mellitus (n=40;38.5%), followed by hypertension (n=30;28.8%), chronic obstructive pulmonary disease/bronchial asthma (COPD) (n=14;13.5%), chronic kidney disease (n=13;12.5%), ischaemic heart disease/heart failure (n=9;8.6%), stroke (n=8;7.7%), chronic liver cell disease (n=5;4.8%) and malignancy (n=1;0.9%). In terms of categories of sepsis, 24 (23.1%) were identified as septic shock. (Table 1).

Table 1 – Category of sepsis

Category of sepsis	Frequency (n=104)	Percentage (%)
Septic shock	24	23.1
Severe sepsis	21	20.2
Red flag sepsis	39	37.5
Uncomplicated sepsis	20	19.2
Total	**104**	**100.0**

Door to blood culture time was 38.6 (SD 26.7) minutes and 99 (95%) had blood taken for culture within 45 minutes of admission. Door to antibiotic time was 43.27 (SD 27.7) minutes. Fifty-eight (56%) patients were given fluid boluses on admission and all were started on normal saline infusion before they were moved out of the ED. Nine (8.6%) were started on inotropes at the ED. Eighty-three (79.8%) patients were given oxygen. Soluble insulin was given to 21 (20%) patients on admission. Ninety (86.5%) patients were sent to wards, 11 (10.6%) were sent to ICUs and three (2.9%) died in the ED.

Table 2 - Haematological parameters

Haematological parameter	Range	Frequency (n=104)	Percentage (%)
Hb (g/dL)	<7 g/dL	4	3.8
	7-11	63	60.6
	>11	37	35.6
WBC ($\times 10^9$/L)	<4×10^9/L	5	4.8
	4-11.9	35	33.6
	12-19.9	44	42.3
	20-29.9	19	18.3
	>30	1	0.9
Platelets ($\times 10^9$/L)	<50×10^9/L	6	5.8
	50-100	6	5.8
	100-150	14	13.5
	>150	72	69.2
	>450	6	5.8

Thirty patients (28.8%) underwent surgical procedures of whom 21 (70%) underwent wound toilet, cleaning, dressing and drainage of abscesses, 2 (1.9%) had below-knee amputations, and one each (0.9%) had arthroscopy, dynamic hip screw, total abdominal hysterectomy, empyema drainage, and appendicectomy.

Only one patient had a white blood cell count (WBC) higher than 30 x 109/L, while 63 (60.6%) patients had a WBC of ≥12 x 109/L (Table 2). When categorised according to SIRS,

leukocytosis or leucopenia was noted in 69 (66.3%) of patients. A low haemoglobin (<11g/dL) was found in 67% of the patients and four had haemoglobin of less than 7g/dL (Table 2).

Blood cultures were not performed on five patients and five blood cultures could not be traced. Of the remaining 94 (90.4%), 19 (20%) were positive.

The most common organisms isolated from blood cultures were CoNS (n=8;42%) and *E coli* (n=8;42%). Among the patients from whom CoNS was isolated, seven had comorbidities.

The 3 remaining isolates were Group A Streptococcus, Enterococcus and Methicillin Resistant *Staphylococcus aureus* (MRSA) which was sensitive only to linezolid, teicoplanin and vancomycin.

All CoNS were sensitive to clarithromycin, linezolid, teicoplanin and vancomycin but resistant to cloxacillin, cefuroxime, ciprofloxacin, erythromycin and cefotaxime. All *E coli* were sensitive to meropenem. The most commonly used antibiotics were ceftriaxone (n=57;54.8%), meropenem (n=27;26%) and clarithromycin (n=20;19.2%).

The commonest primary foci of infection were pneumonia (n=37;35.6%) followed by cellulitis (n=30;28.8%) and other less common foci as shown in Table 3.

Table 3 - Diagnosis

Diagnosis (n=104)	**Frequency**	**Percentage (%)**
Pneumonia	37	35.6
Cellulitis	30	28.8
Lower UTI and pyelonephritis	19	18.3
Septic arthritis	5	4.8
Meningitis/meningoencephalitis	4	3.8
Gastroenteritis	3	2.9
Cholecystitis	2	1.9
Tubo-ovarian abscess	1	1.0
Septic abortion	1	1.0
Necrotizing fasciitis	1	1.0
Appendicitis	1	1.0
Total	**104**	**100.0**

Radiological evidence of pneumonia was confirmed in 25 (24%) patients. Urine cultures were positive in four patients, three of whom had the same organism in their blood cultures.

One patient had more than eight antibiotics during the course of stay in the ICU and recovered. A majority were managed with one (n=41: ICU 3 and ward 38) or two antibiotics (n=40: ICU 4 and ward 36). Three antibiotics were used in two ICU patients and nine ward patients. There was a significantly higher antibiotic use in the wards than in the ICU (p=0.03). There was no significant difference in mortality with the number of antibiotics used in treatment.

Duration of hospital stay was a minimum of one and a maximum of 37 days. The median (IQR) duration of hospital stay was 6 (3 to 9.1) days. The in-hospital mortality was 30 (28.9%) and 30-day mortality was 36 (34.6%). There was no statistical difference in mortality among blood culture positive and negative patients. A generalised linear model was used in comparing the mortality rates of patients with comorbidities. There was significant mortality (p=0.027) in patients with ischaemic heart disease but not with any other comorbidities. An independent chi-

square test revealed that the percentage of deaths in the ICU (63.6%) was significantly higher (p=0.003) than that of the ward which was 21.5%.

Discussion

Sepsis is a significant burden to the world. When comparing countries with good health care indicators, Sri Lanka has a good healthcare status despite limited resources. This study is an eye-opener, that even within a limited setting, outcome can be improved by implementing a methodical system.

In the current study, more males were identified with sepsis and a similar finding was reported in an Indian study in 2016.[14] Although the incidence of sepsis is higher in men than women, it is controversial that a gender difference is associated with mortality and further studies are needed.[15]

Fever and confusion were found to be the most common presenting symptoms in our study, whereas it was only fever in the same Indian study.[14] The most common comorbidity was diabetes in both studies as well as in a descriptive study done in Sri Lanka.[16] This may be due to the fact that people with diabetes have an increased risk of infections and both sepsis and diabetes are on the rise globally.

In the majority of patients in the current study, door to blood culture time and door to antibiotic time was within an hour which is in keeping with the surviving sepsis guideline standards. Additionally, blood cultures were taken in 94% of the patients (n=99) before administering antibiotics. In a Hong Kong ED study in 2017 before and after introducing the sepsis guidelines, obtaining blood for culture increased from 29% to 72.9%, and antibiotic administration within one hour increased from 38.7% to 72.9%.[17] In a Korean study in 2019, 69.7% and 38.9% were administered antibiotics and intravenous fluid on time.[18] A study in New Delhi in 2020 found that door to antibiotic time was 155 minutes.[19] In the current study, door to blood culture time was 38.6 minutes and door to antibiotic time was 43.27 minutes with blood cultures done in 95% of the patients in the study. This is mainly due to the action protocol given to the recognition and management of sepsis and the staff awareness.

In this current study, all patients were started on crystalloids and fluid boluses were given where indicated. Unavailability of onsite blood gas facilities led to a lack of arterial blood gas determination on admission. This is the only action we were unable to perform. The septic bundle was initiated in almost all the patients whereas adherence to the septic bundle was poor in previous studies done in Sri Lanka and India.[16,19] Adherence to the management bundle was 95% in our study which is exceptionally high compared to the descriptive study done in Sri Lanka and in the MOSAIC study.[6,16] Availability of the sepsis identification protocol at ED may have been the reason for this.

With quick recognition of sepsis, the current study identified 25% of patients were in septic shock on admission. Mortality rate at the ED on arrival was 3% and the in-hospital mortality rate was 29% with a 30-day mortality of 35%. This is better than the MOSAIC study which showed a

44% mortality rate in Asia and an in-hospital mortality of 43.2% and 18.5% in patients with and without shock respectively in a Korean study.[18]

In this study, the majority (94%) had their blood taken for culture on admission, before administrating antibiotics. However, blood cultures were positive in only 20% of cases of sepsis and 80% of patients with sepsis did not have microbiological confirmation of infection. Though microbiological confirmation of respiratory tract infection was challenging in both diagnosis and management, clinical findings and radiological evidence were supportive. This may explain the early recognition of sepsis in the ED.

White blood counts were also supportive as 69 (66%) patients had white cell counts of above 12 x 109/L, or below 4 x 109/L, indicating that full blood count can continue to be used as a supportive guide in recognition of sepsis. Gram-positive and negative organisms were equally isolated from blood cultures in this study in contrast to Gram negatives in the Indian study.[14] However, respiratory illnesses were common in both. In a sepsis study in a tertiary care hospital in Peshawar, among bacterial isolates, *Staphylococcus aureus* was found in 37.5%, *E coli* in 11.4%, CoNS in 2.3% and MRSA in 14.8% of patients. In the current study, CoNS and *E. coli* were isolated in 40% each. CoNS commonly live on a person's skin and are typically considered as harmless. However, they can cause septicaemia in patients with prosthetic devices. In this study none of the patients had a prosthetic device, 6 were immunocompromised and 4 (50%) died (3 with comorbidities and one without comorbidities). Three died with pneumonia and one with a septicaemia following cellulitis. CONS could also be a contaminant where the actual pathogen was either masked or not isolated.

Interpretation of CONS in blood cultures is difficult, especially when blood is taken for culture in a busy ED. The high mortality in patients from whom CoNS was isolated in our study and where blood for culture was taken on arrival to ED, suggests that CONS may not be a contaminant but the causative agent of sepsis.

Limitation

Recognition of sepsis would have been higher if this study was done using sepsis 3 criteria.

Conclusion

The mortality rate due to severe sepsis is 44% in Asia, compared to 29% as documented in this study. This is mainly due to adherence to management bundles in this unit and using the protocol with a data sheet to recognise the signs of sepsis.

The isolation rate in blood cultures was low and determining the reason(s) for the low isolation rates and/or finding alternative ways of identifying the causative agent are needed. Most of the organisms isolated were sensitive to meropenem and ceftriaxone, which is helpful in choosing an empirical antibiotic for initial treatment of sepsis in this setting. Further studies with larger sample numbers are required to confirm this finding.

The results of this study represent a single centre study that cannot be generalized. However, the findings of this study do suggest that the establishment of a similar environment would be

helpful in recognition and appropriate early management of sepsis in all emergency units around the country.

Disclosure

The abstract of this paper was presented in the Annual Academic Sessions in Ceylon College of Physicians in September 2018. Also, it was presented as an e-poster in Innovation in Medicine 500 years, Annual Conference Royal College of Physicians, London, June 2018, which subsequently published the abstract in Supplementary Clinical Medicine e-Journal Royal College of Physicians, London, in March 2019 (Clin Med March 2019 (Suppl 2):47).

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Jayasekera MMPT, corresponding author and principal investigator, developed the research concept and was involved in the supervision of data collection, the verification of the accuracy of data, funding, statistical analysis, and the preparation of the final document.
De Costa NDP, Senarathne MCJ Gunarathne WMMKB, Malkanthi KMS aided with data collection and verified the accuracy of the data.

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Data sheet **Sepsis**

Date

Serial No

BHT Age Sex Time of arrival

Temperature >38.3 °C or >36 °C	☐
Pulse >90/min	☐
RR>20	☐
New confusion/drowsiness	☐
Systolic Blood Pressure <90	☐
Blood Glucose >7.7mmol/L in the absence of known diabetes	☐
WCC >12 or <4 x109/L	☐
Lactate >2.0mmol/L	☐

Recording

Septic shock	(SBP<90/MABP<65/no improvement after fluid bolus)	☐
Severe sepsis	(2/8 as mentioned above (Sepsis)+organ dysfunction)	☐
Red flag sepsis	(HR>130, RR>25, AVPU<alert)	☐
Uncomplicated sepsis		☐
No current evidence of sepsis		☐

The Sepsis Six

1. Administer high-flow oxygen	☐
2. Take blood cultures and consider infective source	☐
3. Administer intravenous antibiotics	☐
4. Give intravenous fluid resuscitation (30 mL/kg of crystalloid fluid rapidly)	☐
5. Check haemoglobin and serial lactates	☐
6. Commence hourly urine output measurement	☐

7. Hand over - Ward ICU Time…….