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Evaluation of the diagnostic accuracy of microalbuminuria in predicting mortality among elderly patients with sepsis

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ABSTRACT

Background: Sepsis is a common cause of morbidity and mortality among geriatrics. **Aims and Objectives:** The objective of study was to find the clinicomicrobiological profile of elderly inpatients (≥60 years) with sepsis and to evaluate the diagnostic accuracy of urine albumin to creatinine ratio (ACR) or microalbuminuria in predicting mortality. **Materials and Methods:** A prospective observational study was conducted among 50 geriatric patients admitted with sepsis in the ward or intensive therapy unit under medicine department of a tertiary care center for a period of 1 year. Baseline clinicomicrobiological profile was noted. Urine ACR values were measured at admission, day 4, and day 7 and geriatrics were followed up for 28 days to see the outcome. Receiver operator characteristic curve analysis was performed to evaluate the area under the curve for microalbuminuria on the 3 days and to determine the optimum cut-off points to predict mortality. **Results:** The mortality rate within 28 days was 64%. Urine microalbuminuria on day 1, day 4, and day 7 of admission was significantly higher among the non-survivors compared to survivors ($P \leq 0.001$, $P \leq 0.001$, and $P = 0.006$, respectively). Microalbuminuria levels (in mcg/mg) of 143.0, 60.05, and 42.6 on day 1, 4, and 7 of admission, respectively, can be used as the cut-off to predict the death of geriatric sepsis inpatients with overall diagnostic accuracy of 83.0%, 83.4% and 86.1%, respectively, sensitivity as 93.75%, 87.50%, and 100.0%, respectively, and specificity as 44.44%, 72.22%, and 72.22%, respectively. **Conclusion:** Microalbuminuria can be a potential biomarker to predict death among geriatric septic inpatients, which can further help in improving the treatment strategy.

Key words: Area under curve; Biomarkers; Health services for aged; Receiver operator characteristics curve; Sensitivity and specificity, sepsis

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INTRODUCTION

The world is aging rapidly at an unprecedented pace. The number of people aged 65 years or older worldwide is projected to more than double, rising from 761 million in 2021 to 1.6 billion in 2050.[1] China (265 million) and India (149 million) currently have the largest numbers of older persons in the world as on 2022.[2] The share of the population aged 60 or over in India is projected to increase from 10.5% in 2022 to 20.8% (347.6 million) by 2050.[3] This emphasizes even more the necessity for the country to be ready to address the difficulties of rapidly aging societies.

Sepsis is an important cause of morbidity and mortality among elderly patients.[4] It is a syndromic response to infection and is frequently a final common pathway to death from many infectious diseases worldwide.[5] An estimated 49 million cases of sepsis and 11 million potentially avoidable, sepsis-related deaths occurred worldwide in 2017, accounting for approximately 20% of all-cause deaths globally and with the highest incidence and mortality

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rates in lower-middle-income countries (LMICs).[5,6] Sepsis incidence was biphasic; it peaked in early childhood and again in elderly adults.[5] Among adults, the hospital-treated sepsis and intensive care unit (ICU)-treated sepsis had mortality rates of 26.7% and 42.0%, respectively.[5] Sepsis mortality is often related to suboptimal quality of care, an inadequate health infrastructure, poor infection prevention measures in place, late diagnosis, and inappropriate clinical management.[5] Sepsis is a potentially life-altering illness and can cause severe morbidities and sequelae, even in those who survive.[5] Combating sepsis is not only costly but also an integral part of realizing sustainable development goals.[5] There are limited data worldwide on the best approaches for minimizing disability due to sepsis and improving long-term outcomes.[5] Furthermore, there is paucity of data on sepsis in the old age cohort, particularly in LMICs.

A rapid, accurate diagnosis of sepsis improves clinical outcomes and represents a priority for both surveillance and clinical management.[5] Existing diagnostic modalities are either too costly or technology-dependent to be relevant in LMICs.[5] Biomarkers have been an area of intense research among sepsis investigators, but they are not affordable or sufficiently relevant so far.[5] Microalbuminuria can be an important potential biomarker for improving timely and targeted treatment in sepsis.[7,8] However, there are limited data in our country that explored the potential utility of this low-cost affordable biomarker in predicting mortality among older patients. With this background, the current study was done with an overall aim to assess the clinicomicrobiological profile and diagnostic evaluation of urine albumin to creatinine ratio (ACR) or microalbuminuria in predicting mortality in hospital or ICU-treated elderly sepsis inpatients. Early prediction of outcome might help in timely and targeted treatment, further improving the prognosis of sepsis patients.

Aims and objectives

The objective of the study was to find out the clinicomicrobiological profile of elderly inpatients (age 60 and above) with sepsis and to evaluate the diagnostic accuracy of urine ACR or microalbuminuria in predicting the mortality among geriatric inpatients with sepsis.

MATERIALS AND METHODS

Study design and study participants

An institutional-based observational study with longitudinal design was conducted for a period of 1 year among the elderly patients aged 60 years or above[9] with sepsis and admitted in medicine ward or intensive therapy unit (ITU) under the Department of General Medicine of a tertiary-level hospital in West Bengal, India. Study settings included the three departments of the tertiary-level hospital of West Bengal, i.e., general medicine, microbiology, and biochemistry.

Inclusion and exclusion criteria

Those elderly patients who were admitted in the medicine ward or ITU within 24 h of diagnosis of sepsis and gave consent for the study were included. Whereas, those who had pre-existing malignancy, chronic kidney disease, anuria, macroscopic hematuria, pregnancy and those who had taken several days of antibiotic therapy were excluded from the study.

Operational definition of sepsis

Sepsis is defined by suspected (or documented) infection and an acute increase in ≥2 sequential (sepsis related) organ failure assessment (SOFA) score.[5,10] SOFA score is a 24-point measure of organ dysfunction that uses six organ systems (renal, cardiovascular, pulmonary, hepatic, neurologic, hematologic), where 0–4 points are assigned per organ system.[10]

Sample size and sampling technique

Considering sensitivity of microalbuminuria to predict mortality in sepsis to be more clinically relevant in this scenario, sample size was computed using the formula for sensitivity,[11] $n = \frac{[Z^2_{\alpha/2} Sn (1 - Sn)]}{(d^2 P)}$, where P is the prevalence (or probability) of the condition (here death) among the geriatric patients admitted with sepsis, taken as 50%[12] Z_{α}=1.96 at 95% confidence level, anticipated sensitivity (Sn) of microalbuminuria to detect sepsis was 90.7% based on Omar and Elsayed,[7] minimum clinically desired precision (d) was taken to be 12% and further adjusted for 10% attrition rate. Final sample size after adjustment for attrition came out to be fifty. Fifty consecutive geriatric patients with sepsis were selected based on their eligibility criteria.

Study tools, technique, and data collection procedure

Study was conducted using interview, observation, clinical examination, laboratory investigations, and record review techniques. Detailed histories such as age, sex, presenting symptoms, comorbidities, thorough clinical examination including general survey, and detailed systemic examination were done in all cases using the predesigned pretested structured schedule, sphygmomanometer, stethoscope, thermometer, etc. Laboratory investigations included complete hemogram, serum creatinine, serum bilirubin, serum sodium, and urine routine examination in all cases. Blood culture, urine culture sputum culture, etc. were done using standard protocol and instruments as indicated. Microalbuminuria is defined as the presence of albumin in urine above the normal range (currently defined as <30 mg/d) but below the detectable range with conventional

dipstick methodology (>300 mg/day) and it is commonly presented as ACR to correct for changes in urine flow.[7] Spot urine was collected on the 1st, 4th, and 7th day of admission for testing microalbumin by immunoturbidimetric method and urinary creatinine by modified kinetic Jaffe reaction. Then, urine microalbumin: creatinine (urine ACR) ratio was determined. The microalbuminuria, expressed as ACR in mg/g of creatinine, is defined as ACR of <300 mg/g.[13] The ratio has a conventional cutoff value of 30 mg/g in the healthy reference population.[13]

All patients initially enrolled were followed up for a period of 28 days.

Outcome measures

Outcome was death or survival up to 28 days. Death was determined clinically. Those who died within these 28 days of admission were labeled as non-survivors, while the rest were considered as survivors.

Statistical analysis

The data were entered in Microsoft Excel and analyzed using SPSS statistics for Windows, version 16.0 (SPSS Inc., Chicago, Ill., USA). Results were expressed in terms of numbers, percentages, mean, median, interquartile range standard deviation, etc. Chi-square test was done to find the association between two categorical variables. Shapiro–Wilk test and QQ plots were done for urine ACR values, which showed non-normal distribution. For determining the association between median urine ACR values across the sepsis outcomes, Mann–Whitney *U*-test was applied. Receiver operator characteristics curve analysis was done to determine the diagnostic accuracy and the cut-off points of urine ACR values on day 1, day 4, and day 7 of admission for predicting mortality among geriatric inpatients with sepsis. For all statistical purposes, the $P<0.05$ was considered significant.

Ethical considerations

Study was approved by the Institutional Ethics Committee of Calcutta National Medical College and Hospital, Kolkata, India and conducted after obtaining written informed consent from the study participants and their caregivers. Study adhered to the ethical guidelines of Helsinki Declaration. Anonymity and confidentiality of the study participants were maintained.

RESULTS

The mean age of the elderly patients admitted with sepsis was 69.38±6.85 years with a range from 60 to 84 years. Maximum study participants belonged to 60–69 years (58.0%) followed by 70–79 years (30.0%) and 80–89 years (12.0%). Males (52.0%) were slightly higher than females. They presented with one or more symptoms concomitantly such as altered sensorium (48.0%), fever (24.0%), respiratory distress (14.0%), urinary incontinence (10.0%), increased urinary frequency (8.0%), and cough (2.0%). Likewise, majority (94.0%) of the elderly had one or more comorbidities. Maximum geriatrics had diabetes mellitus (42.0%) as the comorbidity followed by stroke (26.0%), hypertension (24.0%), chronic obstructive pulmonary disease (14.0%), benign hyperplasia of prostate (8.0%), dementia (8.0%), coronary artery disease (6.0%), etc.

Clinical profile of the study participants at admission is shown in Table 1. Some (12.0%) of the geriatrics were in septic shock, and a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities is associated with a greater risk of mortality than with sepsis alone.[10] The source of infection in majority of cases was urinary tract

Table 1: Baseline clinical profile of geriatric patients admitted with sepsis (n=50)

Clinical profile	Number (%)	Mean±SD
Body temperature (°F)		99.71±1.66
<96.8	2 (4.0)	
96.8–100.4	30 (60.0)	
>100.4	18 (36.0)	
Tachycardia (pulse rate/min)		113.44±18.24
Present (pulse rate >90/min)	40 (80.0)	
Absent (pulse rate ≤90/min)	10 (20.0)	
Tachypnea (respiratory rate/min)		30.46±6.55
Present (>24 breaths/min)	40 (80.0)	
Absent (≤24 breaths/min)	10 (20.0)	
Systolic blood pressure (mm of hg)		114.48±27.84
<90	10 (20.0)	
90–39	27 (54.0)	
≥140	13 (26.0)	
Total leukocyte count (per µL)		$21.62*10^3$±$24.42*10^3$
<4000 (leukopenia)	1 (2.0)	
4000–12000	2 (4.0)	
12000–20000	26 (52.0)	
≥20000 (leukocytosis)	21 (42.0)	
Serum creatinine (mg/dL)		1.89±0.65
≤1.2	4 (8.0)	
>1.2	46 (92.0)	
Serum bilirubin (mg/dL)		2.82±1.95
≤1.2	18 (36.0)	
>1.2	32 (64.0)	
Urine output (mL/day) after 24 h of admission		822.00±442.29
<400 (oliguria)	14 (28.0)	
≥400 (normal)	36 (72.0)	
Serum sodium (mEq/L)		135.59±6.09
<135 (hyponatremia)	14 (28.0)	
135–145 (normal)	34 (68.0)	
>145 (hypernatremia)	2 (4.0)	

(54.0%), followed by respiratory (34.0%) and skin and soft tissue (12.0%). *Escherichia coli* (34.0%) and *Klebsiella* spp. (14.0%) were the most common microorganisms found. Blood culture turned out to be positive in 22.0% of the patients, of whom 63.7% had infection with Gram-negative bacteria while remaining had infection with Gram-positive bacteria. The microbiological profile of the elderly patients admitted with sepsis has been represented in Table 2.

The patients were followed up for a period of 28 days, during which 64% patients could not survive. Of those geriatrics with sepsis who could not survive, one-fourth died within 4 days of admission, more than half (53.1%) died between 5 and 7 days of admission and less than one-fourth (21.9%) died beyond 7 days of admission. The mortality rate was significantly higher in males (76.9%) in comparison to females (50.0%) (χ^2=3.9263, df=1, P=0.0475).

Mann–Whitney *U*-test was performed separately on three different days to evaluate whether microalbuminuria differed by outcomes of sepsis. The results indicated that the geriatric non-survivors had significantly higher microalbuminuria levels than survivors across days 1, 4, and 7 of admission, U=98.00, P≤0.001, U=71.50, P≤0.001, and U=17.50, P=0.006, respectively (Table 3 and Figure 1).

Microalbuminuria on days 1, 4, and 7 of admission, all had excellent discrimination (area under curve [AUC] - 0.8–0.9) to predict the outcome (death or survival) of geriatric inpatients with sepsis. Microalbuminuria on day 7 followed by day 4 and day 1 will be able to predict with an overall diagnostic accuracy of 86.1%, 83.4%, and 83.0%, respectively, to distinguish between death and survival as possible outcomes in geriatric patients admitted with sepsis (Figure 2).

A microalbuminuria level (in mcg/mg) of 143.0 on day 1, 60.05 on day 4, and 42.6 on day 7 of admission can be used as the cut-off to predict the outcome of geriatric sepsis inpatients with sensitivity and specificity and other characteristics are shown in Table 4.

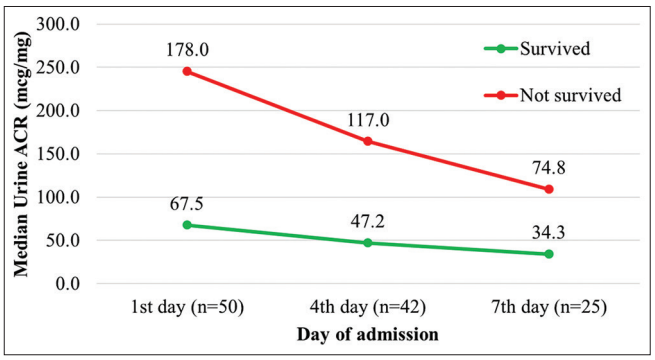

Figure 1: Line diagram showing trend of median urine albumin-to-creatinine ratio (mcg/mg) values or microalbuminuria at days 1, 4, and 7 of admission among the survivors and non-survivors of geriatric inpatients with sepsis

Table 2: Microbiological profile of geriatric patients admitted with sepsis in medicine ward and intensive therapy unit (n=50)

Microorganisms	Urine culture	Sputum culture/ pleural fluid	Skin or soft tissue	Total	Positive blood culture (admission)
	n (%) 27 (54.0)	n (%) 17 (34.0)	n (%) 6 (12.0)	n (%) 50 (100.0)	n (%) 11 (22.0)
Escherichia coli	17 (100.0)	-	-	17 (100.0)	3 (27.3)
Klebsiella spp.	3 (42.9)	3 (42.9)	1 (14.3)	7 (100.0)	3 (27.3)
Streptococcus pneumoniae	-	7 (100.0)	-	7 (100.0)	1 (9.1)
Staphylococcus aureus	1 (16.7)	2 (33.3)	3 (50.0)	6 (100.0)	3 (27.3)
Pseudomonas aeruginosa	2 (40.0)	2 (40.0)	1 (20.0)	5 (100.0)	1 (9.1)
Acinetobacter baumannii	1 (33.3)	2 (66.7)	-	3 (100.0)	-
Proteus spp.	2 (100.0)	-	-	2 (100.0)	-
*Others**	1 (33.3)	1 (33.3)	1 (33.3)	3 (100.0)	-

*Others: *Enterococcus faecalis, Enterobacter aerogenes, Candida* spp.

Table 3: Comparison of microalbuminuria (urine ACR values) across the outcomes of the geriatric patients admitted with sepsis (n=50)

Days of admission	Urine ACR (mg/g)				Test statistics Mann–Whitney U, P-value
	Survivors		Non-survivors		
	Median (IQR)	n	Median (IQR)	n	
Day 1	67.50 (64.5)	18	178.00 (176.5)	32	98.00, <0.001
Day 4	47.15 (44.33)	18	117.00 (123.25)	24	71.50, <0.001
Day 7	34.30 (28.88)	18	74.80 (15.60)	7	17.50, 0.006

ACR: Albumin-to-creatinine ratio

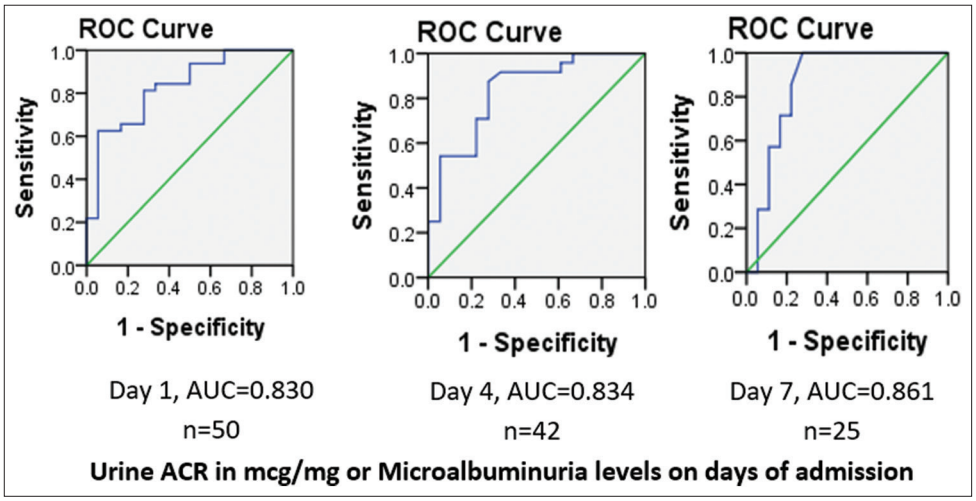

Figure 2: Receiver operator characteristics curve of urine albumin-to-creatinine ratio (in mcg/mg) or microalbuminuria levels on day 1, day 4, and day 7 after admission of geriatric inpatients with sepsis

Table 4: Comparison of diagnostic performance of microalbuminuria (mcg/mg) on day 1, day 4, and day 7 of admission in predicting outcome (survival or death) of sepsis among geriatric inpatients

Parameters All values are with 95% CI	Microalbuminuria Day 1 (n=50)	Microalbuminuria Day 4 (n=42)	Microalbuminuria Day 7 (n=25)
Cut off value	143	60.05	42.6
AUC	0.830 (0.712–0.947)	0.834 (0.710–0.959)	0.861 (0.717–1.000)
Significance	<0.001	<0.001	0.006
Sensitivity	93.75 (79.19–99.23)	87.50 (67.64–97.34)	100.00 (59.04–100.00)
Specificity	44.44 (21.53–69.24)	72.22 (46.52–90.31)	72.22 (46.52–90.31)
Positive likelihood ratio	1.69 (1.11–2.58)	3.15 (1.47–6.74)	3.60 (1.71–7.58)
Negative likelihood ratio	0.14 (0.03–0.59)	0.17 (0.06–0.52)	0.00
Disease prevalence	64.00 (49.19–77.08)	57.14 (40.96–72.28)	28.00 (12.07–49.39)
Positive predictive value	75.00 (66.28–82.07)	80.77 (66.26–89.98)	58.33 (39.93–74.68)
Negative predictive value	80.00 (48.71–94.40)	81.25 (59.14–92.84)	100.00
Accuracy	76.00 (61.83–86.94)	80.95 (65.88–91.40)	80.00 (59.30–93.17)

AUC: Area under curve

DISCUSSION

An observational study was conducted among the geriatric patients admitted with sepsis in medicine ward and ITU under the Department of General Medicine of tertiary level hospital with an overall aim to find their clinicomicrobiological profile and to determine the effectiveness of microalbuminuria as a prognostic marker in predicting the outcomes of geriatric patients admitted with sepsis. In the current study, majority (60%) of elderly were in the age group of 60–69 years, males (52%) were slightly more than females (48%). Females are less susceptible to sepsis and recover more effectively compared to males.[14] Incidence of sepsis was more in males than females and was also revealed from Lakbar et al., study and other studies.[14-16]

It is difficult to diagnose sepsis in older adults due to atypical symptoms. In the current study, the geriatric patients presented with altered sensorium (46%), fever (24%), respiratory distress (14%), urinary incontinence (10%), urinary hesitancy (8%), and cough (2%). Similarly, Sharda et al. found that fever (73.52%) and cough (56.86%) were the most common presenting symptoms. The respiratory system was affected in 76.47% patients, followed by renal involvement in 64.70% patients.[15] In another study, it was similarly found that 58% of the study population had delirium.[16] Rowe and McKoy also concluded that older patients can present with atypical symptoms making diagnosis difficult.[17]

The presence of comorbidities can increase the susceptibility to sepsis or may worsen the prognosis of the older patients with sepsis. In the current study, it was found that the older patients admitted with sepsis had one or more comorbidities such as diabetes (38%), cerebrovascular accidents (26%), hypertension (24%), chronic obstructive pulmonary disease (14%), benign prostatic hyperplasia (8%), dementia (8%), and coronary artery disease (6%). Similarly, Omar and Elsayed found diabetes (56%) as the

most common comorbidity.[7] Longitudinal aging study in India study also revealed that the occurrence of non-communicable diseases, including heart disease, stroke, chronic respiratory disorders, cancer, and dementia, added to the burden of disease in older age in a significant way.[9]

The most common source of infection in the current study was urinary (54%) followed by respiratory (34%) and skin and soft tissue (12%). Shukeri et al. revealed most common site of infection as the lungs followed by urinary tract and abdomen and then soft tissue.[4] The variations represented the heterogeneity of the varied presentations at different area. Blood culture was positive in 22% cases in the current study with Gram-negative organism found in 63.7% cases.

The current study revealed 28-day mortality rate to be 64.0% among elderly septic inpatients. Globally, mortality due to sepsis was reported as 57.5% in 2017.[6] Another study reported 50.0% of elderly died within 30 days of admission.[4] However, a recent systematic review of literature revealed 27.0% hospital mortality rate of adult sepsis, and 42% mortality rate in intensive care adult patients treated for sepsis.[5] These differences were observed because the review was mainly a representation from high-income countries with limited representation from LMICs, which was mentioned as limitations for the global sepsis estimates by the WHO.[5]

The current study revealed that geriatric non-survivors had significantly higher microalbuminuria levels than survivors across days 1, 4, and 7 of admission. Similarly, Omar and Elsayed[7] found that ACR was significantly higher in non-survivors in comparison to survivors. High microalbuminuria after admission can be a warning sign to direct the treatment so that survivability rates may be improved. Microalbuminuria on days 1, 4, and 7 of admission, all had excellent discrimination (83.0%, 83.4%, and 86.1%, respectively) to predict death of geriatric inpatients with sepsis as revealed by the current study. Moreover, microalbuminuria level (in mcg/mg) of 143.0 on day 1 of admission can be used as the cut-off to predict the outcome (survival or death) of geriatric sepsis inpatients with a sensitivity of 93.75% and specificity of 44.44% with total accuracy of 76.0% and AUC of 0.830 (CI 0.712–0.947). However, Omar and Elsayed reported that ACR≥40 (mg/gm creatinine) as the cut-off point for predicting mortality with a sensitivity of 90.7% and specificity of 71.8% with total accuracy of 66% and AUC 0.75 (CI 0.62–0.88).[7] These differences could be probably due to inclusion of all adult patients above 18 years and admitted to ICU in the later study in contrast to the current study where only elderly patients were recruited. More so, our study also determined cut-off points on day 4 and day 7 of admission to predict mortality in the study subjects but despite best effort authors could not find the utility of this potential biomarker in predicting the outcome of sepsis in old age from other studies. Hence, there is a need to evaluate the utility of this biomarker in future studies in large scale and better designs.

The factors predicting the mortality in septic patients were not explored in the current study that has been explored in other studies.

Limitations of the study

The study had some limitations like, anaerobic organisms could not be isolated and secondly diabetes and hypertension could itself be independent cause of microalbuminuria.

CONCLUSION

Despite the fact that day 7 microalbuminuria is the better predictor of outcome of sepsis among elderly followed by day 4 and day 1, microalbuminuria on day 1 can still be an acceptable test to predict survivability or death among geriatric inpatients with sepsis which may save time and improve outcome by early aggressive management.

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