Predictive Accuracy of Procalcitonin in Diagnosing Bacteraemia in Adult Patients in a Tertiary Hospital in Madurai, India

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ABSTRACT

BACKGROUND

Bacteraemia is the presence of bacteria in the bloodstream that are alive and capable of reproducing. The incidence of bloodstream infections (BSI) either of the community-acquired origin or of hospital-acquired origin has dramatically increased. Identifying patients with high risk of bacteraemia in emergency department (ED) using predictive models is needed. The present study was conducted to evaluate the efficacy of procalcitonin as well as other biomarkers as diagnostic, predictive markers of bacteraemia in an adult patient population in India.

METHODS

A descriptive observational study was conducted at the ED of a tertiary care hospital in India. Fifteen years or older patients who were ready to give at least two samples of blood for blood culture were recruited. Data on demographic variables, predisposing conditions, clinical presentations, laboratory tests, and presumptive diagnosis was analysed using SPSS and P value of 0.05 was considered statistically significant. A logistic model was built using an iterative procedure which was later simplified into a coefficient-based scoring system.

RESULTS

Out of 78 patients, (66.67 %) from the emergency department and (33.33 %) from out-patient department (OPD) were enrolled. Among the study population, 40 (51.28 %) were with bacteraemia, and the remaining 38 (48.72 %) had no bacteraemia. There was no statistically significant difference in levels of procalcitonin, pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure, SPO2, total count, MCV, RDW, MPV, albumin, urea, creatinine between bacteraemia and no bacteraemia. (P value > 0.05). The mean procalcitonin was 33.02 ± 43.46.

CONCLUSIONS

Although, increased PCT levels can be useful as predictors of bacteremias in the emergency department, interpretation should be made carefully when deciding the prescription of antibiotics.

KEYWORDS

Procalcitonin, Bacteraemia, PCT levels

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DOI: 10.18410/jebmh/2021/323

How to Cite This Article:
Joena V. Predictive accuracy of procalcitonin in diagnosing bacteremia in adult patients in a tertiary hospital in Madurai, India. J Evid Based Med Healthc 2021;8(21):1711-1716. DOI: 10.18410/jebmh/2021/323

Submission 03-07-2020,
Peer Review 13-07-2020,
Acceptance 08-04-2021,
Published 24-05-2021.

BACKGROUND

The presence of bacteria in the bloodstream that are alive and capable of reproducing is known as bacteraemia. The range of occurrence of bloodstream infections (BSI) either of the community-acquired origin or of hospital-acquired origin has dramatically increased. It is mainly due to an imbalance between the invading microorganisms and the host defence mechanisms. Bacteraemia causes a high mortality rate of 16 % of the world population and 21 % of the world global burden of the diseases.[1] Recent worldwide laboratory-based surveillance report said that an attributable mortality rate of 35 – 50 % from bacteraemia alone despite the emergence of newer antibiotics and improvement in supportive care.[2] With advancements in the medical field, even now, the morbidity and mortality in the rural population are under-reported in most of the developing countries including India.

Detection of bacteraemia is needed as quickly as possible.[3] The gold standard for bacteraemia is blood culture which takes between 24 - 48 hours, within which the patients can develop fatal septicaemia. Several protocols such as white blood cell counts and serum C-reactive protein (CRP), along with various biomarkers have been tested to determine the cause of bacteraemia so that it can be diagnosed at the earliest. Though, an ideal biomarker is missing.

Serum procalcitonin (PCT) is a 116-amino-acid peptide, and elevated levels of this peptide are strongly associated with systemic bacterial infections.[4] Serum PCT measurement relies on a quick and routine lab test that takes only 2 to 6 hours to be detected and confirm the presence of bacteremia.[5] Likewise, it's been reported that the extent of elevated PCT is firmly correlated with outcome in critically ill patients.

In this study, we intend to evaluate the efficacy of procalcitonin as well as other biomarkers as diagnostic, predictive markers of bacteraemia in an adult patient population in India.

METHODS

The following descriptive observational study was approved by the research and ethics committee of a tertiary hospital in India. Seventy-eight patients of both genders, suffering SIRS, sepsis, severe sepsis or septic shock according to the criteria established by the ACCP/SCCM Consensus Conference, were included in this study.[6] The sample size was calculated using convenience sampling for the feasibility of the study. Procalcitonin, CRP and microbiological cultures were obtained for each blood sample within the same time (± 24 hours). Patients on antibiotics at the time of blood collection or immunosuppressive drugs or patients with major trauma, severe burns or recent surgery were excluded. Patients diagnosed with small cell lung cancer or thyroid carcinoma (C-cell) were also excluded.

Procalcitonin Measurement and Interpretation

To prepare the blood samples for PCT measurement, EDTA-plasma was separated from whole blood by centrifugation. PCT was measured semi-quantitatively using the "PCT-Q" (BRAHMS Diagnostica, Berlin, Germany). Six drops of plasma were dropped into the round cavity of the assay and left for 30 minutes of incubation at room temperature. Once the incubation period is complete, the validity of the test is determined by checking that the control band is visible. To determine the PCT concentration, the colour intensity of the test band is compared to the colour blocks of the reference card supplied with the kit. The colour intensity of the test band corresponds to the PCT concentration as four categories provided by the reference scale. The interpretations and risk of progression to severe sepsis for each category is shown in Table 1.

Risk of Progression to Severe Systemic Infection (Severe Sepsis)	Interpretation	PCT
Low	The local bacterial infection is possible Systemic infection (sepsis) is not likely	< 0.5 µg/L
Moderate	Systemic infection (sepsis) is possible, but various conditions are known to induce PCT as well	0.5 2 µg/L
High	Systemic infection (sepsis) is likely High risk for progression to severe systemic infection (severe sepsis)	2 - 10 µg/L
High likelihood of severe sepsis or septic shock	Important systemic inflammatory response, almost exclusively due to severe bacterial sepsis or septic shock	> 10 µg/L

Table 1. Interpretation of PCT-Q (BRAHMS) Values and Risk of Progression to Severe Sepsis, Adapted from Meisner et al.[7]

Outcomes

The primary outcome of this study was a clinically significant positive blood culture as independently assessed by three investigators. The definitions of true bacteraemia were adopted from the CDC and MacGregor and Beaty guidelines as one or more of the following[8,9]

1. Two sets of positive blood culture obtained from separate sites;
2. One set positive for a gram-negative bacterial pathogen; or
3. One set positive for a gram-positive pathogen in a patient with an intravascular device and compatible clinical characteristics.

Patients who did not fit for the above criteria were considered to be false bacteraemic and were classified into the non-bacteraemic group for analysis.

Statistical Methods

Culture report was considered as the primary outcome variable. Clinical parameters, sensorium of the patient, nasogastric tube, urinary catheters, central vein catheters, hemodynamic parameters, etc., considered explanatory variables. Descriptive analysis for quantitative variables was represented as mean and standard deviation and frequency and proportion for categorical variables. All quantitative

variables were checked for normality distribution using visual inspection of histograms, Q-Q plots and Shapiro-Wilk test. P value of > 0.05 was considered as a normal distribution. Independent sample t-test (2 groups) was used to compare the mean values between the study groups. Categorical outcomes were compared between study groups using chi square test. Univariate binary logistic regression analysis was performed to test the association between the explanatory variables and outcome variables. Unadjusted odds ratio along with 95 % CI was presented. The utility of procalcitonin in predicting culture was assessed by Receiver Operative curve (ROC) analysis. Area under the ROC curve along with its 95 % CI and P value were presented. The sensitivity, specificity, predictive values and diagnostic accuracy of the screening test with the decided cut off values along with their 95 % CI were presented value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.[10]

RESULTS

Seventy-eight subjects were considered in final analysis. The mean age was 48.24 ± 18.66 years. The minimum age was 1.5 year, and the maximum was 85 years. 41 (52.56 %) were male, and 37 (47.44 %) were female. 52 (66.67 %) were admitted in the emergency department, and 26 (33.33 %) were admitted through OPD. (Table 2)

	Variables	Frequency
	Age	48.24 ± 18.66 (1.5 to 85)
Gender	Male	41(52.56 %)
	Female	37(47.44 %)
OPD/Emergency Admission	Emergency	52(66.67 %)
	OPD	26(33.33 %)

Table 2. Distribution of Baseline Parameters in the Study Population (N = 78)

	Variables	Frequency
Sensorium of patient	Conscious	72 (92.31 %)
	Altered	6 (7.69 %)
First culture sent from	Blood	65 (83.33 %)
	Urine	12 (15.38 %)
	Catheter tip	1 (1.28 %)
Nasogastric tube	Present	9 (11.54 %)
	Absent	69 (88.46 %)
Urinary catheters	Present	25 (32.05 %)
	Absent	53 (67.95 %)
Central vein catheters	Present	9 (11.54 %)
	Absent	69 (88.46 %)
Peripheral vein catheters	Present	74 (94.87 %)
	Absent	4 (5.13 %)
Other artificial devices	ET	4 (5.13 %)
	ICD	1 (1.28 %)
	Antibiotic given (Mean ± SD)	1.77 ± 2.73 (0 to 22)
Antibiotic started after culture	Yes	67 (85.90 %)
	No	11 (14.10 %)
Antibiotic taken before admission	Yes	10 (12.80 %)
	No	68 (87.20 %)
Recent surgery is done < 30 days	Yes	12 (15.40 %)
	No	66 (84.60 %)
c-reactive protein	Present	1 (1.28 %)
	Absent	77 (98.72 %)
Chills	Present	25 (32.05 %)
	Absent	53 (67.95 %)
Culture report	Bacteraemia	40 (51.28 %)
	No bacteraemia	38 (48.72 %)

Table 3. Distribution of Clinical Parameters in the Study Population (N = 78)

Among the study population, 72 (92.31 %) had conscious sensorium and 6 (7.69 %) had altered sensorium. Among the study population, 65 (83.33 %) patients culture sent from blood, 12 (15.38 %) culture sent from urine and remaining one participant culture sent from the catheter tip. Among the study population, 9 (11.54 %) had a nasogastric tube. Among the study population, 25 (32.05 %) had urinary catheters. Among the study population, 9 (11.54 %) had central vein catheters. Among the study population, 74 (94.87 %) had peripheral vein catheters. Among the study population 4 (5.13 %) ET devices and 1 (1.28 %) had ICD devices. The mean antibiotic given was 1.77 ± 2.73 ranges from 0 to 22. Among the study population, 67 (85.90 %) were started antibiotic after culture. Among the study population, 10 (12.80 %) were taken antibiotics before admission. Among the study population, 12 (15.40 %) has surgery recently < 30 years. Among the study population, 25 (32.05 %) had chills. Among the study population, 40 (51.28 %) were with bacteraemia and the remaining 38 (48.72 %) had no bacteraemia. (Table 3)

Variable	Mean ± SD	Minimum	Maximum
Temperature (N = 27)	101.37 ± 1.52	99.0	105.0
Pulse rate	96.51 ± 20.1	66.0	152.0
Respiratory rate	18.78 ± 3.51	11.0	33.0
Systolic BP (mmHg)	125.27 ± 20.86	80.0	170.0
Diastolic BP (mmHg)	78.33 ± 11.78	60.0	110.0
Spo2	96.59 ± 4.24	68.0	100.0
Total count / µL	12850.64 ± 7787.68	1000.00	34200.00
Mean corpuscular volume (fl)	87.08 ± 8.88	59.20	116.30
Red cell distribution width (%)	17.31 ± 12.54	12.20	123.60
MPV	8.25 ± 0.95	6.30	10.60
Albumin (g / dl)	3.28 ± 0.53	1.90	4.80
Urea (mg / dl)	64.01 ± 64.04	10.00	302.00
Creatinine (mg / dl)	2.43 ± 4.41	0.40	25.00
Procalcitonin (N = 25)	33.02 ± 43.46	0.1	100.0

Table 4. Distribution of Clinical Parameters in the Study Population

The mean temperature was 101.37 ± 1.52. The mean pulse rate was 96.51 ± 20.1. The mean respiratory rate was 18.78 ± 3.51. The mean systolic BP was 125.27 ± 20.86 mmHg. The mean diastolic BP mmHg was 78.33 ± 11.78 ranges from 60 to 110. The mean SPO2 was 96.59 ± 4.24 ranges from 60 to 100. The mean total count was 12850.64 ± 7787.68. The mean MCV was 87.08 ± 8.88. The mean RDW was 17.31 ± 12.54. The mean MPV was 8.25 ± 0.95. The mean albumin was 3.28 ± 0.53. The mean urea was 64.01 ± 64.04. The mean creatinine was 2.43 ± 4.41. The mean procalcitonin was 33.02 ± 43.46. (Table 4)

	Variable	Frequency
Pulse rate	> 90	41 (52.46 %)
	< = 90	37 (47.44 %)
Respiratory rate	> 20	13 (16.67 %)
	<= 20	65 (83.33 %)
Total count	> 11000	45 (57.69 %)
	<= 11000	33 (42.31 %)
Spo2	< 95	11 (14.10 %)
	>= 95	67 (85.90 %)
SBP	>= 80	78 (100 %)
Albumin	< 3.50	48 (61.54 %)
	>= 3.50	30 (38.46 %)
Creatinine	> 1.5	22 (28.21 %)
	<= 1.5	56 (71.79 %)
RDW	> 14	54 (69.20 %)
	<= 14	24 (30.80 %)
MCV	> 100	5 (6.40 %)
	<= 100	73 (93.60 %)
MPV	<= 11	78 (100 %)

Table 5. Distribution of Lab Parameters in the Study Population (N = 78)

Among the study population, 41 (52.46 %) had pulse rate > 90 and 37 (47.44 %) had <=90. Among the study population, 13 (16.67 %) had respiratory rate > 20 and 65 (83.33 %) had <=20. Among the study population, 45 (57.69 %) had total cell count > 11000 and 33 (42.31 %) had <=11000.

Among the study population, 11 (14.10 %) had spo2 and 67 (85.90 %) had >=95. Among the study population, 78 (100 %) had systolic blood pressure >=80. Among the study population, 48 (61.54 %) had albumin < 3.50 and 30 (38.46 %) had albumin >=3.50.

Among the study population, 22 (28.21 %) had creatinine > 1.5 and 56 (71.79 %) had <=1.5. Among the study population, 54 (69.20 %) had RDW > 14 and 24 (30.80 %) had <=14. Among the study population, 5 (6.40 %) had MCV > 100 and 73 (93.60 %) had <=100. Among the study population, all 78 (100 %) had MPV <=11. (Table 5)

The univariate logistic regression analysis had shown a statistically significant association with bacteraemia culture with only one parameter (antibiotic started after culture) as presented in table 6-the mean age in 49.51 ± 18.3 years. The difference in age between culture was statistically not significant. (P value 0.539).

In bacteraemia group majority, 23 (57.5 %) were male participants and shown statistically not a significant association between culture P value 0.371. There was no statistically significant difference in OPD/emergency admission between cultures with P value of 0.873. Among bacteraemia group, majority of 38 (95 %) conscious sensorium and shown statistically insignificant with P value of 0.370.

There was no statistically significant difference in a nasogastric tube, urinary catheters, central vein catheters, peripheral vein catheters, other artificial devices between culture (P value >0.05).

Among bacteraemia group, 31 (77.5 %) were started antibiotics after culture and shown a statistically significant association between culture (P value 0.029). Among bacteraemia group, 5 (12.5 %) were taken antibiotics before admission and shown a statistically insignificant association between culture (P value 0.931).

There was no statistically significant difference in pulse rate, respiratory rate, spo2, lab parameters like total count, albumin, urea, creatinine, CRP, RDW, MCV between culture (P value > 0.05). (Table 6).

There was no statistically significant difference in pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure, SPO2, total count, MCV, RDW, MPV, albumin, urea, creatinine and procalcitonin between bacteraemia and no bacteraemia. (P value >0.05). (Table 7)

	Parameter	Culture Report		Unadjusted Odds Ratio (95 % CI)	P Value
		Bacteraemia (N = 40)	No Bacteraemia (N = 38)		
	Age Mean ± SD	49.51 ± 18.3	46.89 ± 19.18	1.008 (0.984 to 1.032)	0.539
Gender (Baseline=female)	Male Female	23 (57.5 %) 17 (42.5 %)	18 (47.37 %) 20 (52.63 %)	1.503 (0.615 to 3.674)	0.371
OPD/Emergency admission (Baseline=OPD)	Emergency OPD	27 (67.5 %) 13 (32.5 %)	25 (65.79 %) 13 (34.21 %)	1.080 (0.421 to 2.77)	0.873
Sensorium of patient (Baseline=Altered)	Conscious Altered	38 (95 %) 2 (5 %)	34 (89.47 %) 4 (10.53 %)	2.235 (0.385 to 12.98)	0.370
Nasogastric tube (Baseline=Absent)	Present Absent	4 (10 %) 36 (90 %)	5 (13.16 %) 33 (86.84 %)	0.733 (0.181 to 2.965)	0.663
Urinary catheters (Baseline=Absent)	Present Absent	13 (32.5 %) 27 (67.5 %)	12 (31.58 %) 26 (68.42 %)	1.043 (0.403 to 2.702	0.931
Central vein catheters (Baseline=Absent)	Present Absent	5 (12.5 %) 35 (87.5 %)	4 (10.53 %) 34 (89.47 %)	1.214 (0.300 to 4.909)	0.785
Peripheral vein catheters (Baseline=Absent)	Present Absent	37 (92.5 %) 3 (7.5 %)	37 (97.37 %) 1 (2.63 %)	0.33(0.033 to 3.353)	0.351
Other artificial devices (Baseline=Nil)	ET ICD	1 (2.5 %) 0 (0 %)	3 (7.89 %) 1 (2.63 %)	0.288 (0.029 to 2.91) 0.0	0.292 1.0
Antibiotic started after culture (Baseline=No)	Yes No	31 (77.5 %) 9 (22.5 %)	36 (94.74 %) 2 (5.26 %)	0.191 (0.038 to 0.953)	0.029
Antibiotic taken before admission (Baseline=No)	Yes No	5 (12.5 %) 35 (87.5 %)	5 (13.16 %) 33 (86.84 %)	0.943 (0.250 to 3.557	0.931
Recent surgery done < 30 days (Baseline=No)	Yes No	8 (20 %) 32 (80 %)	4 (10.53 %) 34 (89.47 %)	2.215 (0.583 to 7.748)	0.253
Pulse rate (Baseline <=90)	>90 <=90	24 (60 %) 16 (40 %)	17 (44.74 %) 21 (55.26 %)	1.853 (0.754 to 4.55)	0.179
Respiratory rate (Baseline <=20)	>20 <=20	7 (17.5 %) 33 (82.5 %)	6 (15.79 %) 32 (84.21 %)	1.131 (0.343 to 3.733)	0.839
Total count (Baseline <=11000)	>11000 <=11000	25 (62.5 %) 15 (37.5 %)	20 (52.63 %) 18 (47.37 %)	1.500 (0.608 to 3.7)	0.379
Spo2 (Baseline>=95)	<95 >=95	7 (17.5 %) 33 (82.5 %)	4 (10.53 %) 34 (89.47 %)	1.803 (0.482 to 6.74)	0.376
Albumin (Baseline>=3.50)	<3.50 >=3.50	24 (60 %) 16 (40 %)	24 (63.16 %) 14 (36.84 %)	0.875 (0.351 to 2.182)	0.775
Urea (Baseline <=40)	>40 <=40	18 (45 %) 22 (55 %)	18 (47.37 %) 20 (52.63 %)	0.909 (0.373 to 2.216)	0.834
Creatinine (Baseline<=1.5)	>1.5 <=1.5	12 (30 %) 28 (70 %)	10 (26.32 %) 28 (73.68 %)	1.200(0.446 to 3.227)	0.718
RDW (Baseline<=14)	>14 <=14	27 (67.5 %) 13 (32.5 %)	27 (71.05 %) 11 (28.95 %)	0.846 (0.323 to 2.219)	0.734
MCV (Baseline<=100)	>100 <=100	3 (7.5 %) 37 (92.5 %)	2 (5.26 %) 36 (94.74 %)	1.459 (0.230 to 9.225)	0.688

Table 6. Factors Associated with Culture Report Univariate Logistic Regression (N=78)

Univariate logistic regression analysis was applied (P value >0.05), * Due to 0 subjects in the cells No statistical test was applied

Clinical Parameters	Culture Report Median (IQR) Bacteraemia (N = 40)	No bacteraemia (N = 38)	Mann Whitney U Test (P Value)
Pulse rate	99 (82,116.5)	90 (80,99)	0.099
Respiratory rate	19 (18,20)	18 (16,20)	0.147
Systolic BP	125 (110,134.5)	125 (110,140)	0.363
Diastolic BP	75 (70,90)	80 (70,90)	0.244
SPO2	97.5 (96,98)	98 (96,99)	0.154
Total count / µL	12600 (7800,17475)	11350 (6225,15150)	0.280
Mean corpuscular volume (fl)	85.25 (82.15,88.7)	87.45 (83.95,90.08)	0.204
Red cell distribution width (%)	15.75 (13.65,17.93)	14.8 (13.98,17.13)	0.631
MPV (N=78)	8.3 (7.55,8.85)	8.05 (7.58,8.83)	0.579
Albumin (g / dl)	3.15 (2.83,3.68)	3.25 (3.08,3.53)	0.756
Urea (mg / dl)	39.5 (25.25,77.75)	38 (20.5,68.5)	0.596
Creatinine (mg / dl)	1.1 (0.6,1.85)	1.1 (0.6,2.11)	0.787
Procalcitonin (N = 25)	11.93 (0.75,100)	2.42 (0.61,89.24)	0.544

Table 7. Comparison of Median Lab Parameters between Cultures (N = 78)

DISCUSSION

Bacteremia, in simplest terms, refers to viable bacteria in the blood. Asymptomatic bacteremia can occur in normal daily activities such as conducting oral hygiene procedures and after minor medical procedures.[11] These clinically benign infections are transient and do not cause further consequences in healthy persons. However, when immune response mechanisms fail or become overwhelmed, bacteremia becomes a bloodstream infection that can proceed to life-threatening septicemia.

The clinical appearance in a bacteremic patient is the existence of a fever. Studies have found that the rate of undiagnosed episodes of bacteremia or sepsis in febrile patients ranges from 15 % to 50 %.[12-14] Chills and /or rigours do not need to present. However, the presence of these signs can indicate that a febrile patient is now bacteremic.

In this study, we found that there was no statistically significant difference in pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure, SPO2, total count, MCV, RDW, MPV, albumin, urea, creatinine between bacteremia and no bacteremia indicating that these parameters cannot be used as predictors of bacteremia.

Blood parameters and microbiological diagnosis in patients with bacteremia are important for effective antimicrobial therapy.[15] Although blood culture is known as the gold standard for the diagnosis of bacteremia, there are some problems, such as differentiating true infection from contamination, interpreting of the results of polymicrobial culture, interpreting the importance of microorganisms that normally has low virulence, etc.[16] Hence, a fast biological marker with high sensivity ans speificity is needed for the identification of bacteremia that which helps to tackle the necessity of experienced staff and a long time for blood culture together with false negative and false positive results. Nowadays, procalcitonin and C-reactive protein are being widely used to predict bacteremia.

Procalcitonin, the precursor of the hormone calcitonin, is produced by C-cells of the thyroid gland or neuroendocrine cells in the lung or intestine.[17,18] Very few PCT molecules are released into circulation in a normal state, serum PCT concentrations increase in patients with bacterial and viral infections.[19] PCT concentration has been reported to be useful for the early diagnosis of bacteraemia and decisive initial antimicrobial therapy. It has been reported that PCT can differentiate bacteraemia from inflammatory sepsis in 77 % of cases with other clinical parameters.[20] Likewise, the present study revealed that PCT levels increased exclusively in bacteraemia cases. Procalcitonin levels were shown to be significantly higher in patients with positive blood cultures and were a better predictor of bacterial sepsis than CRP and other blood parameters.[21] As a result, we consider that further research is needed using multicentric studies to explore the clinical and predictive value of PCT in concluding bacteraemia.

A major limitation in our study is small sample size. This is due to short supply of PCT-Q assays and patient's enrolment was stopped after achieving statistical significance. Further prospective studies are required to generalize our study findings.

CONCLUSIONS

The study concluded that patients' clinical status, PCT and other laboratory markers shuould be evaluated carefully in early assessment of bacteremia. Although, increased PCT levels can be useful as predictors of bacteremias in the emergency department, interpretation should be made carefully when deciding the prescription of antibiotics.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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