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Evaluation of The Maki Method and Sonication for Diagnosing Catheter-Related Infections in ICU Patients with Long-Term Central Venous Catheters

Dr. Chandan Kumar[1*], Dr. S.Srividhya[2]

[1]Associate Professor, General surgery, Indira medical College and Hospitals, Tiruvallur, Tamilnadu, India.

[2]Associate Professor, Indira medical College and Hospitals, Tiruvallur, Tamilnadu, India.

[*]**Corresponding author:**

Dr. Chandan Kumar

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ABSTRACT

Background: Central venous catheters (CVCs) are commonly used in clinical settings but are associated with the risk of catheter-related infections (CRIs), including catheter-related bloodstream infections (CRBSIs). The detection of catheter tip colonization is critical for diagnosing CRIs. This study aims to evaluate the effectiveness of the Maki semiquantitative method and sonication, both individually and in combination, for detecting catheter tip colonization and CRBSIs in ICU patients.

Methods: We conducted a study involving 87 ICU patients with CVCs in place for at least 7 days, which were removed due to suspected CRIs. The diagnosis of CRI was based on the development of sepsis or fever, with the Sepsis-3 Consensus Criteria applied. Catheter tip samples were collected and analyzed using the Maki semiquantitative method and sonication, both separately and in combination. Blood cultures were not collected from patients. Statistical analysis was performed using chi-square tests, Mann-Whitney U tests, Cohen's Kappa test, and receiver operating characteristic (ROC) curves to assess the diagnostic performance.

Results: Of the 94 CVCs analyzed, 23 blood stream infections (BSIs) were identified, with 10 (43.5%) diagnosed as CRBSIs and 13 (56.5%) as bloodstream infections of unknown origin (BSIUOs). The Maki method identified 7 (50%) of the 14 cases of catheter tip colonization, while sonication detected 1 (7.1%) case independently. The combination of Maki and sonication detected 7 (50%) cases. For diagnosing CRBSIs, the Area Under the Curve (AUC) for the combined method was 98%, higher than Maki alone (79%). The combination of methods did not significantly outperform Maki alone for detecting CRBSIs ($p=0.32$). A false-negative rate of 1.1% was found with Maki and sonication for catheter tip colonization.

Conclusion: The Maki method outperformed sonication for detecting both catheter tip colonization and CRBSIs in ICU patients with short-term CVCs. Sonication, although more effective for long-term colonization, did not significantly improve diagnostic performance when used in conjunction with Maki. This study emphasizes the importance of selecting appropriate diagnostic methods based on catheter duration and the patient population, with Maki being a reliable and efficient method for routine clinical diagnostics in ICU settings.

Keywords: *Catheter-related infections (CRIs), Central venous catheters (CVCs), Maki method, Sonication, ICU diagnostics*

1. INTRODUCTION

Central verschiedne Vene Kather (or CVCs) are used in all sorts of clinical tasks, which involve the use of fluids, transfusions of blood derivates, parenteral nutrition, medication delivery and the evaluation of hemodynamics. Nevertheless, the use of such devices poses a substantial threat of catheter-related bloodstream infections (CRBSIs), which cause patient morbidity, mortality as well as healthcare expenses to be increased [1-4].

Semiquantitative technique is one of the most frequently used procedures of detecting colonization on catheter tips, it is also the so called gold standard of this procedure, because it is rather simple. This procedure is able to detect microorganisms on the external portion of the tip of the catheter but it is not able to identify bacteria that can have already attached to the internal surface of the catheter tip, especially when the tip is rolled onto agar. This swiping movement makes the limitations of Maki method to be that the catheter tip colonization would have false-negative results, more so when there is endoluminal colonization that has taken place.

On the other hand, quantitative methods, including sonication and vortexing, that identify colonization by both outer and inner surfaces, could be more feasible than the strategy of Maki due to precise outcomes [6-9]. Although the quantitative techniques have their benefits, their use is time-consuming, which restrains their extensive use in the regular clinical microbiology activities.

When Maki semiquantitative procedure is compared to sonication method used on detection of CRBSI, sonication has proven to be more precise. Both the techniques are deemed to be reliable [10, 12] although sonication has the potential to enhance detection when combined with Maki technique [13].

The American Society for Microbiology (ASM) suggests the combined approach to the diagnosis of catheter-related infections (CII) based on semiquantitative catheter cultures according to the Maki procedure and quantitative segment cultures by ultrasound [14, 15].

In earlier studies, sonication method, as well as Maki method has been evaluated with CVCs of hospitalized patients whose catheters were removed due to various reasons [10-13]. This study has been mostly done when catheters are withdrawn after at least seven days especially when the catheter is withdrawn in ICU or suspected to be infected with CRIs. The effectiveness of sonication and Maki as applied to ICU patients, whose urinary catheters had been removed because of suspected CRIs and had not been in use less than seven days, is the specific focus of the study as well.

2. RESULTANTS AND METHOD OF RESEARCH

We selected ICU patients with a central venous catheter (CVC) that was in use over at least 7 days and that was subsequently removed because a catheter-related infection (CRI) was suspected. The possible existence of CRI was revealed when one of the patients developed sepsis or fever, and to diagnose this, Consensus Criteria Sepsis-3 was applied [16]. Fever was diagnosed as a temperature of 38 C or more.

We gathered diverse variables of every patient, both pre-existing morbidities or diseases like diabetes, asthma, chronic liver disease, smoking, chronic obstructive pulmonary disease (COPD), HIV, hematologic malignancy, and solid tumors, and data on the demographic (sex and age). The indication to admission was also recorded and preceding interventions that included renal replacement therapy, parenteral nutrition, steroid or immunosuppressive therapy were included. We also recorded the corticosteroids, immunosuppressants, parenteral nutrition, propofol, or renal replacement therapy use in case of suspected CRI. We also noted the location, time and outcome of the CVC.

All the patients were sampled with a variety of clinical samples that included paired samples of blood, the catheter tip, and other things. The peripheral vein sample was drawn by taking 10 ml of blood and separated after 15 minutes. In order to collect catheter tip, sterile scissors were involved to remove the tip at the place of insertion and the region was cleaned with 2% chlorhexidine. The tips of the catheters were next run in accordance with the protocol of Maki, using which agar, on which the tips were rolled to, were sonicated and vortexed at a rate of 35,000 Hz and 125 watts respectively in one minute. It was done with semi-quantitative method (Maki) and quantitative sonication method. One milliliter of the sonicated broth was taken and streaked into sheep blood agar plates. It should be mentioned that such patients as those to examine the methods of Maki or sonication (did not include blood culture collections).

According to the European Centre for Disease Prevention and Control (ECDC) standards [17], infections were classified in our work as follows. The colonization of the tip of the catheter was considered meaningful microbial growth on the tip of the catheter with a cut-off limit of 15 colony-forming units (CFU) to the Maki semi-quantitative method [5] or 100 CFU to sonication quantitative method [13]. Catheter-related bloodstream infection (CRBSI) was considered as determination of an antibiotic-resistant pathogen in the blood culture, colonization of CVC tip, as well as the inability to identify an alternative source of infection. Further, bloodstream infections that occurred during the research [it was not determined whether they occurred during the study] were classified as CRBSIs. Some of the bloodstream infections were found to have positive CVC tip colonization when tested by the semi-quantitative or the quantitative colonization method whereas some infections found no positive colonization.

Statistical analysis

The significance of continuous variables was measured using medians and percentiles whereas the significance of categorical variables was measured in frequencies and percentages. We performed chi-square analysis in discrete variables and Mann-Whitney-U test in continuous ones. Cohen kappa test was employed to find out the degree of agreement between the two techniques of diagnosing catheter tip colonization and CRBSI using the Maki method and sonication method, average kappa value was computed.

In the diagnosis of catheter tip colonization and CRBSI, our research researchers used both Maki and sonication and combined method of the same. To compare the area under the ROC curves we used the methodology provided by DeLong et al. [18]. It was a statistical significance when the p-value was less than 0.05. Data analysis was done by SPSS 17.0.

3. RESULTS

Using 87 patients suspected of catheter-related infections (CRI) and 94 central venous catheters (CVCs), we approached the topic under investigation. Of these, 23 blood stream infections (BSIs) were identified of which 10 (43.5) percent were declared as catheter-related blood stream infections (CRBSIs), and 13 (56.5) percent were determined as blood stream infections of unknown origin (BSIUOs). Comparing the characteristics of the patients acquired CRBSIs (n=10) and the patients with no CRBSIs (n=84) (Table 1), there was no difference in the rates of death (p=0.99), the duration of CVC or the position of placement of CVC or otherwise (Figure 2). Comparing such patients with (n=23) and without (n=71) PBSIs did not indicate any significant mortality (p=0.99) or CVC duration differences, positions or other features (Table 1).

COPD= Chronic Obstructive Pulmonary Disease; CVC= central venous catheter

All together 14 cases of catheter- tip colonization were identified, among which CRBSIs 10 cases. With Maki and sonication we found 14 instances of catheter-tip colonization. Of these, 7 (50.0%) were identified in both Maki and sonication methods, 6 (42.9%) in Maki alone and 1 (7.1%) in sonication alone (Table 2). CRBSIs were identified in 10 (40.0%) persons based on both Maki and sonication (60.0%), in 4 (40.0%) persons by Maki alone, but none by sonication alone (Table 2).

Area Under the Curve (AUC) that is used to diagnose CRBSIs was 98 per cent (95 per cent CI = 93 per cent - 99 per cent; P less than 0.001). The AUC of Maki method alone to diagnose CRBSIs was 79% (95% CI = 69% - 87%; $p < 0.001$). The AUC was more distinct when sonicating with Maki than with Maki alone to diagnose CRBSIs (p=0.02) but not the Maki-combined methods (p=0.32).

In the Maki technique, 96 percent of cases correctly diagnosed according to the AUC 95 percent CI 9099 percent, and sonication identified 79 percent. A combination of Maki and sonication correctly diagnosed the cases 100 percent (95 percent confidence interval of 96 percent-100 percent; p less than 0.001). Compared with sonication method, (p=0.002), and compared with Maki method, (p=0.03), the AUC was greater with the combined method on catheter-tip colonization. The AUC of the Maki approach did, however, not differ significantly with the combined approach (p=0.32).

Of the 94 specimens, catheter-tip colonization produced 1 false negative (1.1 % of 94) between the Maki and sonication methods (Cohen Kappa = 0.63, 95 % CI = 0.380.88; $p < 0.001$). In the case of CRBSI, the Maki technique did not have false negative values on 94 specimens (Cohen Kappa = 0.73; 95% CI = 0.48 0.98; p = 0.001). The prevalent pathogen found to have a relation with catheter-tip colonization was Staphylococcus epidermidis, and then others of the specie Staphylococcus epidermidis.

Table 1: Capillary-related bloodstream infections (CRBSI) and primary bloodstream infections (PBSI) developing or not for CVCs

Information	**excluding CRBSIs (n=84)**	**1-10**	**Comparison of CRBSIs and non-CRBSIs**	**71 (non PBSIs)**	**63 (PBSIs)**	**Comparison of PBSIs and non-PBSIs**
by median CVC time (days); (p 25-75)	8 (7-9)	9 (11-13)	1.01	8.5 (7-12)	9:00 (8-12)	1.00
Location of CVC (%)			1.81			0.7
scapular	(18.4)	30 (30)		20 (21.1)	2(6)	
Golf	54 (55.9)	3 (40.1)		37 (52.1)	12 (52.2)	
Peroneal	(25).	3.30 (30.0).		88 (19).	5 (21.7)	
25 to 75 years old	54 to 72	(52-17)	0.74	(64-64)	64 (52-72)	0.80
Male; n (%) Female	24 (27.5)	0	1	2.80 (20)	3 (13.0)	0.17
Diagnostics; n%			38.00			0.07
Healthcare	75 (75.0)	10 (90.0)		51 (71.8)	91.3	

Medical	16.7 (14.1)	0		19 (7.4)	0	
Psychiatry	8.3 (7.0)	1 (10.0)		6 (8.5)	2 (8.7)	
Diabetes mellitus; n (%)	23 (27.4)	4 (40%)	1.37	(33%)	17 (14).	0.20
Before admission, kidney replacement therapy (%)	3.6 (3.80)	10 (10)	1.07	(0.78)	2 (8.7)	0.25
percent (%)	11.9	0	5.99	(10.9)	13 (3)	0.70
Allergic reaction; n (%)	2 (4.6)	2 (10.1)	0.44	4.2 (4.2)	2 (8.7)	1.69
Hepatitis C; n (%)	5 (4.6)	0	1.01	5 (6.8)	0	1
Smoking; nTobacco users (%)	7.6%	(9,0)	1.00	(14,5)	4.00 (4,5)	1.98
Nutritional support prior to admission; n (%)	1.	0	of 1.00	(0.4)	0	1.98
Previous use of corticosteroids; n (%)	2 (3.2)	0	1.00	4 (2.3)	0	1.09
Treatment with immunosuppressive drugs prior to admission; 9 out of 10	(4.8%)	100 (10%)	2.24	5 (6,6)	1.43 (1,3)	1.98
Tumor of the blood; n (%)	0	(10%)	0.11	0	4 (3.3)	1.05
tumors solids; n (%)	1.	0	0.99	1.41	0	99.00
HIV; n (%)	1.	0	0.99	1.41	0	1.01
In cases of sepsis, corticosteroids were administered (%)	14.3%	0	3.05.	11 (3.5)	17 (14).	1.38
In patients with sepsis, immunosuppressive therapy (%)	was 2/2 (2.4)	0	0.99	2.81 (2.88)	0	0.99
Nutritional support in sepsis, n (%)	16 (14).	20 (20).	688.	141.	25.16	0.0021
protopol at sepsis; n (%)	40 (34).	1 (0%).	1.	34 (47.7).	30 (47.3).	0.33
Treatment of sepsis with renal replacement therapy; n (%)	8.3 (7.6)	1/100 (10.2)	1.00	9 (10.0)	4 (3.3)	0.4
Deaths within 30 days (%)	27.3 (23.0)	31	1.98	(38)	26.1 (26)	.941

Table 2: Using maki and sonications to detect infection from catheter tips/bloodstream infections associated with catheters

	Maki +	Maki -	Total
Sonification	8/7	1/1	8/7
Sounding -	7/3	83/84	87/89
Total	15/10	84/85	95/96

Table 3: A bloodstream infection is caused by an organism colonizing the catheter tip. This type of infection can be caused by methods such as Maki/or and Sonication

Microorganism	count in total	Positive results for both techniques	Only positive results for Maki	Sonication positive only
Staphylococcus epidermidis	9/6	1/2	6/4	1/0
Enterococcus faecalis	2/2	2/2	0/0	0/0
Escherichia coli	2/2	2/2	0/0	0/0
Klebsiellaspp.	1/3	1/1	0/0	0/0
Enterobacter cloacae	2/2	2/2	0/0	0/0
Pseudomonas aeruginosa	2/0	2/1	0/0	0/0
TOTAL	18/15	10/10	6/4	1/0

4. DISCUSSION

Past studies that have explored the viability of the Maki and sonication methods of identifying the catheter tip colonization have considered CVCs of either those utilized by patients in hospital settings or the ones that were removed because of various reasons \[10-13]. Certain works evidenced that Maki and sonication approaches can be considered as equally reliable \[10-12], yet other researches point that the mixed use of two methods can have some extra advantages \[13]. Guimbe et al. \[13] reported the use of 252 CVCs and when assessing both methods, i.e. Maki and sonication, they found that 14.3 percent (14) colonization and 15.3 percent (15/ 152) CRBSIs were detected by both methods. Sonication was alone able to detect 6 (16.7%) colonizations and 9 (25.0%) CRBSIs. Among 15 CRBSI cases, it was found that the Maki method with sonication was applied in 11 out of the total (73.3 percent), whereas the sonication method in isolation was done to 4 cases (26.7 percent). They have recommended sonication with samples of patients who have bacteremia of uncertain origin and of negative catheter tip cultures \[13].

Excluding one colonization of the tip of a sonicated catheter, not found on the Maki method, in our study we have found only a single colonization of a non-sonicated catheter tip that was not identified with the Maki method. CRBSI was however not caused by this colonization. Our findings indicated that the AUC of detection of catheter tip colonization and CRBSIs was higher in the Maki method in comparison to sonication and that overall there was no significant difference between the technique of Maki versus the combined techniques of detecting the conditions. Our results also signified that sonication was not found to be beneficial with regards to diagnostic performance of CRBSI used in conjunction with the Maki method.

A possible reason as to why the results of this study compared to that of Guimbe et al. \[13] did not match may be the fact that his study involved a larger number of adults (ICU and non-ICU patients) with a longer catheter (both short and long). Conversely, the present study experimented on patients in the ICU where most of them experienced extraluminal colonization compared to luminal colonization. This is because the sonication method, though more reliable when it comes to testing long-term colonization may have also been less useful to us since we mainly had short-term CVCs in the study which are better tested using Maki because of their ability to detect intraluminal colonization.

Maki or sonication-based semiquantitative and quantitative catheter segment cultures can be regarded as high-quality procedures of diagnosing CRIs. Nonetheless, Maki semi-quantitative method used in our study and other studies was not

found to be profitable in diagnosis of CRBSI, in spite of the fact that it is the method of choice in performing routine microdiology tests in laboratories because of its ease in performing the procedure. This could be the reason why sonication can have few benefits to the ICU patients because of the practice of coagulase-negative staphylococci that are more apt to colonize the outside of the catheter.

We need to mention our research limitations. Other quantitative methods, i.e. vortexing, were not used to diagnose CRBSI with Maki and sonication. Moreover, not every culture (blood, Maki, and sonication) was present, and, therefore, we could not calculate the amount of removed CVCs. Moreover, because of sonication of all catheter tips following Maki technique, sonication may not have been helpful in detecting bacteria already expelled during Maki. Although our study sample size was not high, sonication in combination with other methods was found to have greater effect on the diagnosis compared to subjecting it singly to sonication. The Maki method was also superior to sonication alone when it was used in detecting catheter tip colonization and CRBSI. In case of the catheter colonization at the catheter tip, the CVCs required would be 220 and to detect CRBSI 5,235 were required.

What made our study unique is that it involved only ICU patients that had CVCs which had remained in place at least 7 days and were withdrawn because of possible CRIs. With reference to our findings, we can state that the Maki technique taken together with sonication was unreliable in such cases to diagnose CRBSI.

5. CONCLUSION

This paper has set out to assess how effective the method used by Maki on the .detection of catheter-related infections (CRIs) by using central venous catheters (CVCs) in ICU patients and currently aged 7 days or more, and was removed because doctors suspected CRIs. Although both the procedures were reported to be reliable, our findings revealed that sonication used in conjunction with Maki was not effective in significantly improving the efficacy of a particular method of CRBSIs diagnosis in ICU patients in comparison to Maki technique alone. Maki method performed better diagnostics of both catheter tip colonization and CRBSIs and especially in cases where short-term CVCs, more frequently applied in ICU, were diagnosed earlier than using other methods. An important conclusion of the present research is that sonication, although showing better results in long-term colonization, did not offer any extra advantage to the diagnosis of CRBSI in ICU patients, where extraluminal colonization is more common. It stresses the role of context in the selection of diagnostic techniques because the Maki method, being able to recognize intraluminal colonization, could be more appropriate in short-term CVCs which are more frequently applied in intensive care. The limitations of our study need to be taken into account, i.e., other methods of quantitation were not used, e.g., vortexing, nor the complete data of blood cultures are presented. However, the findings still bring valuable observations as to the comparative effectiveness of Maki and sonication procedures that underline the fact that Maki is a simple and reasonable method, to be used in daily microbiological tests in ICUs. Finally, the study establishes the necessity of diagnostic approaches that are customized to the peculiarities of the patient population and the characteristics of a catheter since the addition of sonication to Maki is insignificantly better than Maki alone regarding diagnosing CRBSI in ICU patients with short-term CVCs.

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