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ORIGINAL ARTICLE

Evaluation of the BD GeneOhm StaphSR assay for detection of *Staphylococcus aureus* in patients in intensive care units

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KEYWORDS

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Screening

Background: *Staphylococcus aureus* is the major nosocomial pathogen and rapid detection of colonized patients with subsequent precaution is needed to prevent transmission. A new assay, the BD GeneOhm™ SaphSR assay (BD GeneOhm™, San Diego, CA, USA), is a multiplex real-time polymerase chain reaction (PCR) for rapid detection of both methicillin-sensitive *S aureus* (MSSA) as well as methicillin-resistant *S aureus* (MRSA).

Methods: Anterior nasal swab specimens of 273 pediatric and adult patients hospitalized in intensive care units at Chang Gung Memorial Hospital were collected for this assay in parallel with conventional cultures as standard.

Results: Overall, 71 (26.0%) patients were colonized with *S aureus* by conventional culture and MRSA accounted for 67.6% of all isolates. For the detection of MRSA, 79 patients (28.9%) were positive by PCR and 48 (17.6%) were positive by conventional cultures. The sensitivity, specificity, and positive and negative predictive values were 95.9%, 85.3%, 58.5%, 99.0%, respectively. For the detection of MSSA, 48 patients (17.6%) were positive by PCR and 23 (8.4%) were positive by conventional culture. The sensitivity, specificity, and positive and negative predictive values were 91.3%, 89.2%, 43.8%, and 99.1%, respectively.

Conclusion: As a screening method, the BD GeneOhm™ StaphSR assay could rapidly detect and differentiate between MRSA and MSSA colonization. A negative result of the assay could almost exclude *S aureus* colonization.

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Introduction

Staphylococcus aureus, regardless of methicillin-resistance (MRSA) or methicillin-susceptibility (MSSA), is among the major nosocomial pathogens worldwide, including in Taiwan.¹ They can cause wide spectrum of infections from systemic infections, such as sepsis and catheter-related infections, to local infections, such as skin and soft tissue infections or surgical site infections. Patients colonized with *S. aureus*, especially MRSA, may spread to other patients and can serve as reservoirs for subsequent infections.^{2,3} Compared with MSSA, infections caused by MRSA are associated with higher mortality, hospital stay, and costs.^{4,5}

In recent years, hospital infection controls have put emphasis on rapid detection of MRSA-colonized patients to improve patient care. Some reports had showed that active surveillance of MRSA colonization might decrease relevant mortality and morbidity,^{6,7} and these measures had become a part of new guidelines by Center for Disease Control and Prevention of the United States.⁸ In many European countries, recommendations are made for MRSA screening on cultures from nares, skin, or mucosa.⁹ In the Netherlands, the "search-and-destroy" methods even had decreased the MRSA prevalence of all staphylococcal infections to less than 1%.¹⁰

To detect MRSA/MSSA colonization, conventional culture requires 48–96 hours. Some selective agars, such as CHRO-Magar MRSA medium (BD Diagnostics, Sparks, MD, USA), MRSA ID (bioMerieux, Portland, USA), MRSAselect (Bio-Rad Laboratories, CA, USA) could shorten turnaround time within 18–24 hours.^{11,12} Because early detection of MRSA/MSSA colonization would facilitate identification of carriers and therefore allow early intervention to prevent spread or infections, several nucleic acid amplification-based assays, such as BD GeneOhm MRSA real-time polymerase chain reaction (PCR) assay (BD GeneOhm, San Diego, CA, USA), hplex StaphyloResist multiplex PCR-ELISA system (BAG, Lich, Germany), GenoType MRSA Direct (Hain Lifescience, Nehren, Germany), and IDI-MRSA assay (Infecto Diagnostics, Inc., Sainte-Foy, Quebec, Canada) have been developed and can yield results within 2 hours.^{13–15} However, these assays could only identify MRSA but could not identify MSSA.

A new assay, called BD GeneOhm™ StaphSR assay (BD GeneOhm, San Diego, CA, USA), is a multiplex real-time PCR method that uses primers specific for various staphylococcal cassette chromosome (SCC) *mec* right-extremity sequences and a probes and primers specific for the *S. aureus* chromosomal *orfX* gene to the right of the SCC *mec* insertion site.^{14,15} This assay is the first product that offers not only rapid detection of *S. aureus* but also differentiation between MRSA and MSSA. Preliminary results^{16–18} showed fair value in rapidly differentiating bacteremia caused by MRSA and MSSA from bloodstream samples. However, additional specimen claims, including nasal or wound samples, are under study. In this article, we evaluated the performance of this assay in parallel with conventional cultures as standard for detection of MRSA and MSSA from anterior nares specimens of pediatric and adult patients hospitalized in intensive care units (ICUs) to determine the usefulness for rapid screening.

Material and methods

This study was conducted at Chang Gung Memorial Hospital, a 4000-bed, university-affiliated teaching hospital and was approved by the Institutional Review Board.

Patients

A total of 273 patients, including 167 adults (80 in surgical ICUs and 87 in medical ICUs), 15 children in pediatric ICUs, and 91 newborns in neonatal ICUs, hospitalized in ICUs at Chang Gung Memory Hospital were screened for MRSA/MSSA nasal colonization. Patients who had very unstable vital signs or those with pulmonary tuberculosis were excluded. These patients were not known to previously be colonized or infected with MRSA/MSSA.

Specimen collection

In each patient, nasal swab specimen was collected from the anterior nares using two separate dry Copan Transystem Liquid Stuart swabs (Venturi Transystem; Copan Diagnostics, Corona, CA, USA). Each swab was rubbed inside the anterior nares, first into one side and then into the other, ensuring that each swab contained specimens of both nares of each patient. These swabs were then transported at room temperature and processed within 4 hours.

Conventional culture and broth enrichment

One of two swabs from each patient was inoculated into trypticase soy agar with 5% sheep blood (TSA II 5% SB) plate (Becton, Dickinson and Company, Sparks, MD, USA) for conventional culture. Isolates of *S. aureus* and MRSA identification by oxacillin susceptibility with the disc diffusion methods were confirmed according to the recommendations of Clinical and Laboratory Standards Institute.

Another swab from the same patient was sent for BD GeneOhm StaphSR assay. If the results showed positive for MRSA or MSSA, this swab would be put into Mueller Hinton Broth (Becton, Dickinson and Company, Sparks, MD, USA) in CO₂ incubator at 37°C overnight and then was subcultured into TSA II 5% SB plate and identified using same methods.

BD GeneOhm StaphSR assay

The BD GeneOhm StaphSR assay uses the same primers and probes for MRSA detection as the BD GeneOhm MRSA real-time PCR assay. These primers and probes have been described in details previously.¹⁹ The MRSA assay uses primers specific for various SCC*mec* right-extremity sequences and a primer and probes specific for the *S. aureus* chromosomal *orfX* gene located to the right of the SCC*mec* insertion site.

Specimen preparation

The assay was performed according to the manufacturer's instructions. One of two swabs from one patient was inoculated into 1 mL of buffer in a tube labeled with sample number. The sample buffer tube was subjected to a vortex at high speed for 1 minute, and 600–700 µL of cell suspension

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