

145-1 Characterization of *Staphylococcus hominis* strains isolated in an immunobiological pharmaceutical unit.

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Resumo:

In an immunobiological pharmaceutical industry, it is necessary to prevent microbial contamination that may be present at any stage of the production chain. The processes are accomplished in an aseptic manner to ensure product quality and user safety. However, if there is any contamination, microbiological tests carried out by quality control play a fundamental role in identifying these contaminants and their sources. *Staphylococcus* spp. are among the most isolated bacteria from pharmaceutical production areas. *Staphylococcus hominis* is a coagulase-negative species which is part of the normal flora of human skin but can also be pathogen in skin and soft tissues. Identifying the strains of *S. hominis* can help in the adoption of preventive and corrective actions to avoid products contamination. The microbiological control laboratory of the pharmaceutical unit that was the object of this study uses the semi-automated biochemical identification system VITEK®2, and the VITEK®MS RUO (bioMérieux) and MALDI Biotyper® (Bruker) for bacterial identification. The objective of this study was to characterize *S. hominis* strains isolated from the production areas of an immunobiological pharmaceutical unit in Rio de Janeiro, Brazil. One hundred and fifty-eight strains isolated from different samples from 2014 to 2022 and previously identified as *S. hominis* by VITEK®2 Compact (bioMérieux) were analysed by time-of-flight matrix-assisted laser ionization/desorption mass spectrometry (MALDI-TOF MS) using VITEK®MS. The strains identified as *S. hominis* were categorized and evaluated with Bionumerics 8.1 for similarity coefficient calculation using Pearson correlation and clustering method UPGMA. The profiles that presented similarity $\geq 85\%$ were clustered in the same group. Further, 14 strains related to a specific productive process of a vaccine and the strains grouped in the same clusters were selected, resulting in 56 strains. These strains were submitted to MALDI Biotyper®, antibiogram analysis using AST cards in VITEK®2 and the biofilm production. Among the 158 strains previously identified as *S. hominis* by VITEK®2, 80.39% were identified as *S. hominis*, 8.23% were not identified, 6.96% were identified as *S. epidermidis*, 2.53% as *S. saprophyticus*, 0.63% as *S. caprae*, 0.63% as *S. lugdunensis* and 0.63% as *Enterococcus casseliflavus* by VITEK®MS. The 127 strains confirmed as *S. hominis* by VITEK®MS and evaluated with Bionumerics 8.1 were clustered in 28 groups and 20 singletons. The 56 selected strains were confirmed as *S. hominis* by MALDI Biotyper®. Regarding biofilm production, 92.86% were weakly adherent, 3.57% were moderately adherent, and 3.57% were non-adherents. About the antibiogram, the majority of strains showed resistance to erythromycin (53,57%), have been positive for cefoxitin screening (66,07%), and some showed resistance to oxacillin (16,07%) and clindamycin (8,93%). There was a 19.61% divergence of VITEK®2 results compared to VITEK®MS, which may be due to the environmental stress experienced by microorganisms in clean areas, because of poverty of nutrients and constant contact with sanitizers, directly impacting their phenotypic characteristics. Genotypic identification methodologies can be used in further studies to confirm the identification of the strains studied in this work as well as to perform the strains typing, assisting in the assessment of possible sources of contamination.

Palavras-chave:

Phenotypical characterization, MALDI-TOF MS, Antibiogram, *Staphylococcus hominis*, Pharmaceutical Industry