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Clinical and bacteriological characteristics of invasive pneumococcal disease after pneumococcal 10-valent conjugate vaccine implementation in Salvador, Brazil

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ABSTRACT

Invasive pneumococcal disease is a relevant public health problem in Brazil, especially among children and the elderly. In July/2010 a 10-valent pneumococcal conjugate vaccine was introduced to the immunization schedule of Brazilian children under two years of age. Between July/2010 and December/2013 we conducted a case-series study on invasive pneumococcal disease in Salvador, Brazil to describe the clinical and bacteriological profile of invasive pneumococcal disease cases during the post-implementation period. Eighty-two cases were eligible. Mean age was 31 years (interquartile range, 3–42); 17.1% and 30.5% were under 2 years and 5 years, respectively. Pneumococcal meningitis ($n = 64$, 78.1%), bacteraemic pneumococcal pneumonia ($n = 12$, 14.6%) and bacteraemia ($n = 6$, 7.3%) were the clinical syndromes identified. Thirty-three different serotypes were found. Of these, serotype 14 ($n = 12$, 14.6%) was the most common, followed by 23F ($n = 10$, 12.2%), 12F ($n = 8$, 9.8%), 18C ($n = 5$, 6.1%) and 6B ($n = 5$, 6.1%). Investigations conducted in Salvador in the pre-vaccine period did not identify serotype 12F as one of the most prevalent serotypes. Increase of serotype 12F was observed in different regions of Brazil, in the post-vaccine period. Among children under two years of age, the target group for 10-valent pneumococcal conjugate vaccine, 11 (78.6%) of the 14 isolated strains of *Streptococcus pneumoniae* belonged to vaccine serotypes; at least 50% of these children were not vaccinated. The relatively recent implementation of

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10-valent pneumococcal conjugate vaccine in Brazil reinforces the need to maintain an active surveillance of invasive pneumococcal disease cases, considering the possible increase of invasive pneumococcal disease cases related to non-vaccine serotypes and the changes on the clinical presentation of the disease.

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Introduction

Streptococcus pneumoniae is a major cause of meningitis, bacteraemic pneumonia and sepsis,[1] accounting for significant morbidity and mortality rates worldwide.[2] Invasive pneumococcal disease (IPD) is a relevant public health problem in Brazil, especially among children and the elderly.[3] In the decade before the implementation of 10-valent pneumococcal conjugate vaccine (PCV10), *S. pneumoniae* was responsible for 12% of bacterial meningitis in Brazil among children aged under two years and older and adults.[4]

Pneumococcal 7-valent conjugate vaccine (PCV7) was licensed in the United States in 2000 and accounted for significant reduction in incidence and mortality from IPD in the US.[5] A study conducted in the US presented evidence that the vaccine provides herd immunity.[5] However, follow up of IPD in the same country revealed an increased incidence of invasive disease caused by serotypes not included in PCV7 specially 19A,[6] a phenomenon named replacement. Serotype replacement led to the development of vaccines with larger serotype coverage,[7] which are currently available.

In Brazil, PCV7 was incorporated into the National Immunization Program in 2002, available only to children under five years of age at high risk of pneumococcal diseases.[8] In July 2010 PCV10 was introduced to the immunization schedule of Brazilian children under two years of age.[9] In addition to the conjugate vaccines, pneumococcal 23-valent polysaccharide vaccine (PPV23) is offered for individuals over two years of age at high risk of pneumococcal disease.[8]

Initial evaluation of IPD after PCV10 implementation in Brazil was published in 2013. A significant reduction in incidence of IPD caused by vaccine serotypes was observed among children under two years of age in the São Paulo University Hospital.[10] In the same study, there was no significant change in incidence of IPD caused by non-vaccine serotypes. Declines in hospitalizations rates for pneumonia were found in three major cities in Brazil in the year 2011.[11] A short period of observation after implementation of PCV10, however, was emphasized as a limitation in both studies.

The surveillance of IPD and the recognition of serotypes that cause greater morbidity and mortality are essential to assess the effectiveness of the immunization programs.[12,13] Additionally, the vaccine status and presence of comorbidities play a role on the occurrence of IPD. Documentation of IPD cases is insufficient in developing countries.[14] Given the lack of data on IPD in the post-vaccine period in Brazil, there is a strong need for more studies on the clinical presentation of the disease and profile of invasive strains. In this regard, the objective of this study was to describe the clinical and bacteriological profile of IPD cases diagnosed between July 2010 and December 2013 in Salvador, Brazil, through case-series study on IPD.

Material and methods

This was a retrospective observational study, with a prospective component. Between July 2010 and December 2013 we conducted a case-series study on IPD in Salvador, Brazil, involving the Hospital Couto Maia (HCM), the Paediatric Centre Professor Hosannah de Oliveira (CPPHO) and the Cerebrospinal Fluid Laboratory (SINPEL). HCM is the referral hospital for infectious diseases in the state, mainly for the public health care system; CPPHO is the pediatric unit of the Federal University of Bahia Hospital; SINPEL performs cerebrospinal fluid (CSF) analysis of patients seen in the supplementary health care system in the city of Salvador. IPD cases were defined by the isolation of pneumococcus from a normally sterile site (blood or CSF). Patients with diagnosis of IPD with positive CSF or blood cultures for *S. pneumoniae* in HCM, CPPHO or SINPEL, between July 2010 and December 2013 were included in the study. Patients for whom it was not possible to obtain contact information were excluded.

Samples of blood or CSF for culture were obtained from patients with clinical suspicion of IPD, according to the routine of the centers involved. Based on the record of positive cultures for *S. pneumoniae*, isolates were sent to the Pathology and Molecular Biology Laboratory of the Research Centre Gonçalo Moniz CPqGM/FIOCRUZ for confirmation. Identification of *S. pneumoniae* was performed using standard bacteriological techniques, including Gram stain, colony morphology on agar media with 5% of sheep blood, optochin susceptibility (5 μg Oxoid disks) and bile solubility.

Serotyping was performed by multiplex-PCR as described elsewhere.[15,16] The isolates with negative or equivocal results in multiplex-PCR were sent to Adolfo Lutz Institute (National Reference Laboratory, Ministry of Health) and subjected to Quellung reaction for definition of capsular serotype. All isolates identified as serogroup 6 was subjected to wciN6C-specific PCR, for the identification of potential serotype 6C and 6D isolates.[17]

Clinical and demographic data (age, date of admission and diagnosis) were collected by review of the medical charts or from the data recorded on the request of cultures to laboratories. Patients were contacted by telephone and asked to e-mail photo of vaccination card to confirm the use of pneumococcal vaccine prior to the episode of IPD.

Vaccine serotypes are those included in PCV10 (1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F); vaccine related serotypes (6A, 6A/B/C, 6C, 7C, 9L/N, 9N, 18B, 19A, 23B) were defined as those not included in PCV10, but sharing the same serogroup with

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