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Review Article

Pneumococcal conjugate vaccines and dosing regimens in India: a perspective on evidence-based choices for pediatric immunization

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ABSTRACT

In India, Pneumococcal infections account for significant under 5 years health burden and mortality. Immunization with the Pneumococcal conjugate vaccine (PCV) is the best prevention method especially in developing countries where complications and hospitalization rates are high. Available vaccines include PCV10, PCV13 and PCV14 while approved dosage regimens range from 2 or 3 primary (p) doses with or without booster. The objective of this review is to compare different valency vaccines based on their serotype data and protection, as well as understand the immune protection of different primary regimens and the importance of the booster dose in the PCV immunization schedule.

Keywords: Pneumococcal, PCV, Primary doses, Booster, Serotypes, Vaccine effectiveness

INTRODUCTION

India accounts for almost a quarter of the global childhood Community acquired pneumonia (CAP) burden, with 16-20% being severe cases.[1] India also contributes the highest number of deaths due to pneumonia, accounting for around 20% of global mortality among under five children with annually 0.35-0.4 million children <5 years dying of pneumonia and its complications.[2] In India, childhood pneumonia contributes to 14-20% of under-5 mortality with overall case fatality rate of around 1-2% (8-10% in children aged 1-6 months), rising in severe CAP cases to >10% and up to an alarming 64% in children <6 months.[3]

Though introduction of the Pneumococcal conjugate vaccine has brought down pneumonia rates globally, in India there are still 4-5 million cases of Pneumococcal Pneumonia, with around 0.1 million pneumococcal (pneumonia and invasive pneumococcal disease -IPD) deaths every year in children <5 years.[4] The overall case fatality rate is 6-7% and ranges from 11% in severe pneumococcal pneumonia to as high as 60% in hospitalized cases and IPD.[5] In low-income countries, fatality due to pneumococcal meningitis is close to 59% and among survivors, about 25-50% suffer serious neurological sequelae. Infant immunization with PCV is the prime and effective preventive measure in India.

PNEUMOCOCCAL SEROTYPES AND COVERAGE BY PCVs IN INDIA

In India, the available PCVs include PCV10, PCV13 and PCV14 formulations. Among the PCV10 vaccines, Synflorix (GSK) is a protein D-conjugated vaccine, with serotype 18C conjugated to tetanus toxoid (TT) and 19F to diphtheria toxoid (DT), while PNEUMOSIL (Serum Institute of India) is a CRM197-conjugated PCV10

vaccine. The available PCV13 vaccines include Prevnar 13 (Pfizer), which is CRM197-conjugated and VAXIMUNE 13 (G C Chemie Pharmie Ltd), a tetanus toxoid (TT)-conjugated vaccine that is also marketed as NUKOVAX 13 by Lupin and PNEUMOGUARD 13 by Dr. Reddy's Laboratories. The PCV14 vaccine available in India is PNEUBEVAX 14 (Biological E), a CRM197-conjugated vaccine that is also co-marketed as PNEUMOShield 14 by Abbott.

Table 1: Pneumococcal serotype prevalence <5 years in India and coverage of different PCVs: (derived from studies over 2017-2025).[5-11]

Serotype	Distribution (%)	PCV10 (p)	PCV10 (s)	PCV13	PCV14
1	4-11	+	+	+	+
3	1-2			+	+
4	1-2		+	+	+
5	7-9	+	+	+	+
6A	6-8	+		+	
6B	7-9	+	+	+	+
7F	1-3	+	+	+	+
9V	5-6	+	+	+	+
14	10-18	+	+	+	+
18C	1-3		+	+	+
19A	4-8	+		+	+
19F	9-10	+	+	+	+
22F	<1				+
23F	5-7	+	+	+	+
33F	1-2				+
***coverage**		70-75%	60-65%	75-80%	70-75%

*Overall coverage of each PCV is derived from prevalence in India of pneumococcal serotypes over last decade including PIDOPS and ASIP studies. Above 15 serotypes account for 62-98% (average 80%) of Pneumococcal disease in India, and individual PCV coverage is derived from taking into account prevalence of each serotype.

Table 1 shows that the top serotypes causing pneumococcal infections (CAP and IPD) in India in children under 5 years are 1, 5, 6A, 6B, 14 and 19F.[9-11] In Nasopharyngeal carriage (NPC), 23F and 18C were seen to be prominent serotypes along with 6A, 6B, 14 and 19F.[12]

PCV14 contains 6B serotype but does not contain 6A serotype due to presumed cross-reactivity between 6B and 6A (while PCV13 contains both 6A and 6B). However, the seroconversion rate was seen to be <70% for 6A after primary immunization with PCV14 as compared to >95% for PCV13 (Both PCV13-CRM and TT conjugated), with Geometrical mean concentration of antibodies (GMCs) and protective opsonophagocytic antibody (OPA) titres for 6A being 50-65% and 80% less respectively, with PCV14 as compared to PCV13.[13-16] Real world data from PCV7 (USA) and the PCV10(s) (Netherlands) have shown significant reductions in the incidence of 6A IPD due to cross protection from 6B, as these vaccines do not contain 6A. However, there has been a significant increase in 6C IPD in these countries, as 6A but not 6B gives cross protection to 6C.[17] Future real-world effectiveness of cross protection of immunization with PCV14, not containing 6A can add further insights. While Serotype 3 (absent in PCV10) has low infectivity, it can cause severe clinical manifestations including empyema, necrotizing pneumonia, bacteraemia, and meningitis, consequently, with a fatality rate of 30%-47%.[18] It was estimated that approximately 8 times more antibody titre was required to confer protection against serotype 3 IPD, due to release of a large amount of free capsular polysaccharide (CPS), which can neutralize antibodies before they reach the bacterium, leading to vaccine escape. Even though the impact on reducing serotype 3 has been minimal with PCVs, primary immunization GMCs have seen to cross 2.8ug/ml in some studies, and OPA levels may confer some protection, therefore its inclusion in PCV is still considered relevant.[15-19]

Therefore, currently from available data, PCV13 gives the highest coverage and optimum protection with respect to the prevalence of all important Pneumococcal serotypes in India. A phase 3 randomized, double-blind, multi-centre, study, to assess and compare the immunogenicity and safety of PCV13-TT conjugated vaccine from G C Chemie pharmie ltd with the reference PCV13-CRM197 conjugated vaccine from Pfizer Inc, performed in 344 healthy infants aged 6 to 8 weeks across six centres in India, showed comparable safety and non-inferiority in rates of seroconversion, GMCs and OPA titres post 3 primary doses at 6, 10 and 14 weeks as well as booster at 15-18 months.[15,16] In real world, post marketing studies from China, there was no statistical difference between the cumulative reported incidence of adverse effects following immunization (AEFI) between the same PCV13-TT and PCV13-CRM197 vaccines from

2020 to 2022 during which a total of 4,76,150 doses of PCV13-TT and 1,439,808 doses of PCV13-CRM197 were administered.[20]

While PCV20 has been introduced for adult immunization in India, it is not approved or available for paediatric immunization.

3 PRIMARY (3P) VERSUS 2 PRIMARY (2P) DOSES

For lower income countries, WHO has recommended that PCVs be administered using a 2p+1 (6, 14 weeks primary dosing; booster at 9 months) or 3p+0 (6, 10, 14 weeks primary dosing; no booster) schedule in infants for economic reasons.[21] Therefore the Indian government follows the same. However, the Indian academy of paediatrics recommends 3 primary doses at 6, 10 and 14 weeks with a booster at 15-18 months to give optimum protection during both the first year of life and thereafter into the 2nd and 3rd year of life and further.[21] Seropositivity and seroconversion rates following 3p and 2p primary schedules were similar but favoured 3p+1 schedules overall.[23-27]

Studies comparing two-primary-dose (2p) and three-primary-dose (3p) pneumococcal conjugate vaccine schedules have generally shown similar seropositivity and seroconversion rates, although the 3p schedule demonstrates superior immunogenicity for certain serotypes. Specifically, 2p schedules produce lower geometric mean concentrations (GMCs) of antibodies against serotypes 6A, 6B, 5, and 23F. Serotypes 6B and 23F, in particular, require at least three primary infant doses to achieve antibody responses above the accepted protective threshold of 0.35 µg/ml. This is clinically important because serotype 6B accounts for up to 11% of invasive pneumococcal disease (IPD), especially during the first year of life and is associated with high levels of antibiotic resistance. The seroconversion rate for serotype 6B has been reported to be substantially lower with a 2p schedule (70%) compared with a 3p schedule (94%). Similarly, protection against serotype 23F is suboptimal following a 2p schedule, and this difference persists even after administration of a booster dose at 15 months of age. In addition, a 3p schedule is associated with greater reduction in pneumococcal nasopharyngeal carriage among infants and significantly fewer breakthrough infections during the first year of life compared with a 2p schedule (incidence rate ratio 12.9; 95% CI: 4.1-40.4). Therefore, the 3p regimen is the preferred recommendation for primary immunization, and this becomes especially important in high-risk groups due to their increased susceptibility to severe disease compared to healthy children and concerns about suboptimal vaccine responses.[28]

IMPORTANCE OF BOOSTER DOSE

A booster dose is an important addition to the PCV schedule in terms of measured immune response and giving a dose after 1 year of age to children who have received the primary series, results in a vigorous antibody response for most serotypes. Studies with 3p-PCV13-TT, 3p/2p PCV13-CRM and 2p-PCV14-CRM showed uniformly that compared to GMCs measured 4 weeks after last primary dose at 14 weeks, the GMCs pre booster at 9-15 months showed up to a 75% decline.[13-16] While most serotypes in these studies still maintained seroconversion rates of GMCs>0.35ug/ml, the sharp dip suggests waning immune response and reduced protection into the 2nd year of life. Administration of booster dose restored the GMC levels thereby increasing vaccine effectiveness and protection after the first year of life. It was also seen that vaccine related side effects were far lesser after the booster dose than after primary series.

Australia uniquely adopted a 3p+0 schedule when it introduced publicly funded PCV immunization in 2005.[29] An 8-fold increase in IPD incidence due to vaccine serotypes among vaccinated children between 2008 and 2017 was seen. Increasing number of vaccine failures were reported, with ~95 % of cases in children >12 months age (40% in 2nd year of life, 30% in 3rd year of life).[30] Vaccine effectiveness (VE) waned by 17 % between 12 and 24 months of age and a further 46 % between 24 and 36 months of age without booster dose, while this rapid waning was not seen if booster dose given. After introducing booster dose schedule in 2018, a ~ 50 % decline in IPD rates was reported.[31] For PCVs in a 3p+0 schedule, progressive increase in breakthrough cases occur, especially in 2nd and 3rd year of life. This supports the importance of a booster dose of PCV13 in the second year of life to maintain protection. The booster dose significantly increases the frequency of specific memory B cells compared to the pre-booster that may impact long-term protective antibody titers.[32] More-over in Low- and middle-income countries (LMIC) invasive pneumococcal disease carries significant morbidity and mortality not only in the first but also into the second and third year of life, highlighting the vulnerability of children in the 1-3 years of the <5 age group, and the need and importance of booster dose.[7]

Currently in India both CRM and TT conjugated PCV13 and PCV10(s) are approved as 3p+1 schedule, while PCV14 and PCV10(p) are approved as 2p+1 or 3p+0 schedule.

LONG-TERM PROTECTION

Long-term follow-up studies for PCV13 has shown that five years after primary vaccination starting at 2 months or earlier in a 3p+1 schedule, except for serotypes 3 and 4, seropositive rates were 100%.[33] The rates for children who started primary immunization later at 7-11 months, seropositivity at 5 years was 100% with exception of serotypes 3, 4, 6 A and 9V. Therefore, data shows that PCV13 has a good immune persistence. More recent TT-conjugated PCV13 has also shown that after complete the dosing schedule of 3p+1 from either 2 or 3 months of

age, the antibody level through 1 year and 2 years post booster dose, IgG GMCs were higher than 0.35 µg/ml, the protective threshold verified by WHO, even after 2 years post booster dose in >90% cases (100% for 6B, 14, 19A, 19B and 23F) except serotype 3, 4 and 18C, showing that the antibody level through 1 year and 2 years post booster dose, still remained at relatively high levels at the two timepoints as compared to those observed at 1 month post booster dose for the majority of serotypes.[34]

Long-term immunogenicity studies to show that GMCs and seroconversion rates are maintained at least 1 year post booster are important as young children under 2 years of age are the most at risk population for invasive pneumococcal disease. The availability of such data for PCV14 in the future can add further insights. There is still a need for studies and data in India on the effectiveness of PCVs in reducing IPD rates, hospitalization and death, as well as antibiotic resistance, and additionally understand the risk-economic benefits of 2p+1 and 3p+1 PCV regimes, which could help policymakers make evidence-based decisions on vaccine procurement and funding.

Since the nationwide rollout in 2021, PCV coverage in India has steadily increased, reflecting successful immunization efforts. WHO and UNICEF estimates of national immunization coverage also show a positive trend in vaccination coverage (PCV booster coverage of 25% in 2021, rising to 83% in 2023), aligning with the goals of the WHO and UNICEF's Global action plan for the prevention and control of pneumonia.[35] However, there is still a need for studies and data in India on the effectiveness of PCVs in reducing IPD rates, hospitalization and death, as well as antibiotic resistance, and additionally understand the risk-economic benefits of 2p+1 and 3p+1 PCV regimes, which could help policymakers make evidence based decisions on vaccine procurement and funding.

CONCLUSION

Among vaccines giving protection across the prominent pneumococcal serotypes in India, PCV13 has the best serotype coverage and immune persistence data 1 year and beyond post-booster dose. PCV13-TT and PCV13-CRM conjugated vaccines have shown comparable efficacy, immunogenicity and safety in the phase 3 Indian study and are approved for 3 primary doses (6,10,14 weeks) and a booster at 15-18 months (3p+1 schedule). While PCV14 is also approved in India, it is not expected to provide adequate protection against 6A serotype which has seen to be an important paediatric IPD, CAP and NPC serotypes in India.

In terms of dosage schedule overall, 2 primary (2p) and 3 primary (3p) dosing regimens may be comparable especially after booster dose, but the 2p dosing may give suboptimal protection for some serotypes especially 6B and 23F, as compared to 3p. Therefore, the 3p dosing is the most recommended regimen for primary immunization series especially in high-risk children to avoid suboptimal response and protection in the first 6-9 months of life. Booster dose is essential to restore waning antibody titers after the first year of life and ensure protection into the 2nd and 3rd year of life. Lack of a booster shot increases breakthrough infections significantly in 2nd year of life due to waning immunity from primary dosing, irrespective of the number of primary doses. More studies are needed on current serotype epidemiology as well as real-world vaccine effectiveness in India after introduction of different PCV vaccines and dosage regimens.

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