Original Research Article

Assessment of immunization among newborns: comparison between children delivered vaginally and by cesarean section

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ABSTRACT

Background: Timely administration of vaccines, particularly for hepatitis B birth dose within 24 hours of birth is of immense importance. It is considered as an indicator of quality of immunization programme. This study aimed to assess effect of mode of delivery and type of hospital on immunization among newborns.

Methods: This large multi-site study was conducted in Pune district having population of 9.43 million. A total of 13 hospitals were selected which included all government hospitals performing more than five cesarean sections per month, and one government and one private medical college hospital. Cesarean section and vaginally deliveries were enrolled in 1:1 ratio. Their children were followed till discharge. Data were collected by obstetrician or qualified nurse.

Results: During study period 3,112 women were enrolled. The relative risk of not getting vaccine Hepatitis B birth dose before 24 hours among cesarean delivered newborns was 1.08. The relative risk of not getting zero polio and BCG among cesarean delivered newborns was 0.71 and 0.76 respectively. All these differences were significant. The coverage for all vaccines was better in sub district hospitals than others. Coverage of all vaccines in government teaching hospital was better than private.

Conclusions: Cesarean section enabled better coverage among newborns probably due to length of stay. Whereas the physical and mental stress after cesarean section resulted lesser coverage of hepatitis B birth dose within 24 hours. Opportunities of timely Hepatitis B birth dose administration were missed probably due to lack of knowledge among health workers about ideal timing.

Keywords: BCG, Cesarean, Timely hepatitis birth dose, Vaginal delivery, Zero polio

INTRODUCTION

The universal immunization program in India has been operational since 1985. It has been able to reach and fully immunize about 62 to 65% children.¹² Improving immunization coverage with quality and safety is one of the national priorities. The Ministry of Health and Family Welfare and Government of India have over the period of last five years attempted escalation of the coverage, timeliness and completeness of immunization among children through Mission Indradhanush (MI) and various other initiatives. The National Vaccine Policy 2011, recommended better awareness creation through Information Education Communication (IEC), vaccine management, maintenance of the cold chain with regular monitoring, supervision and feedback for making immunization program more dynamic and vibrant.³
In addition ‘Proactive Governance And Timely Implementation’ (PRAGATI) by the Government of India aims to reach each and every child below two years of age and all those pregnant women have been left uncovered under the routine immunization program. The special drive, MI focused on improving immunization coverage in selected districts and cities to ensure full immunization to more than 90% by December 2020. With the launch of Intensified Mission Indradhanush (IMI), achievement of the target was advanced. With a strong political support, the Ministry of Health and Family Welfare aimed to strengthen the Universal Immunization Program through the IMI to cover 90% of the children by 2018. Prior to MI the increase in immunization coverage was 1% per year; this increased by 6.7% per year with the first 2 phases of IMI.4

All these data pertain to only one indicator, ‘proportion of fully immunized children’. Timely immunization is a quality indicator; however, large scale studies assessing timely administration of vaccines particularly among newborns are few. National level surveys also do not include coverage among newborns and hepatitis B vaccination. Ideal time of giving hepatitis B birth dose is within 24 hours. Studies assessing hepatitis B birth dose coverage within 24 hours are scarce. In this context it was decided to study the immunization status of newborn children. The woman undergoes physical as well mental stress of cesarean operation. Mothers’ acceptance of vaccines to their newborns may have association with mode of delivery. The proportion of cesarean sections in India has doubled in 10 years.1 This substantial rise may have some effects on coverage of vaccination. Authors could not find any large study comparing immunization among cesarean section and vaginal deliveries among newborns.

**Objectives**

The objectives of the study were to compare the proportion of newborns receiving hepatitis B birth dose within 24 hours of birth between cesarean section born and vaginally born children, to compare the proportion of newborns receiving Bacille Calmette Guerin (BCG) vaccine and bivalent Oral Polio Vaccine Zero dose before discharge from the hospital between cesarean section born and vaginally born children and to compare the proportion of newborns receiving above mentioned vaccines among various hospitals.

**METHODS**

This study conducted among mother-newborn duos. Population of Pune district is 94,29,408, as per last census 2011. It includes Pune Municipal Corporation (PMC) and Pimpri-Chinchwad Municipal Corporation (PCMC); together they contribute 51.46% to the district population.

Women and their newborns were enrolled from 1st September 2017 to 31 March 2018. The newborns were followed till their mothers were discharged. From each institution at least one obstetrician and in-charge nurse were trained. The in-charge nurse was made site coordinator. The case report forms were written by obstetricians or trained and qualified nurses under supervision of obstetricians.

Any woman undergoing delivery in the selected hospital was eligible. All mothers who underwent cesarean section with their newborns were enrolled. For each cesarean delivered woman, one age and parity matched vaginal delivered woman was included in comparison group. Their newborns were assessed for their immunization status before/at the time of discharge of the woman. In exposed and comparison group 1,556 women in each were enrolled.

Type of delivery and receipt of three vaccines by newborn were the main variables. Cesarean section operation was exposure and receipt of hepatitis birth dose, zero polio dose and BCG vaccination before mother was discharged, were the outcome variables.

**Data sources and management**

All government hospitals conducting more than five cesarean sections per month were selected. One government medical college hospital and one private medical college hospital were also selected. Thus following 13 sites were included; two medical college hospitals, District Hospital Pune, two corporation hospitals Kamala Nehru Hospital (KNH) in PMC and Yashwantrao Chavan Memorial Hospital (YCMH) in PCMC, 5 Sub District Hospitals (Baramati, Manchar, Indapur, Bhor, and Daund), Women’s Hospital in Baramati, two Rural Hospitals at Junnar and Saswad. Haweli is most populous block, accommodating two Municipal Corporations; five hospitals were included from this block. The map of Pune District showing blocks from where institutions were selected is given in figure 1. With these hospitals a large geographical area of the district was covered.

For all the variables data was collected on validated and pre-tested case record form which included details of immunization. All the case record forms on weekly basis were collected at this center. The forms were entered in excel by trained data entry operators.

**Bias**

The site coordinators were obstetricians or in-charge nurses of maternity wards and they were trained. Case record forms were filled before discharge, hence there were no lost to follow up cases. However, authors noticed that few vaginally delivered women otherwise eligible to be enrolled in comparison group were missed or immediately discharged against medical advice.
This study was part of a larger project wherein 3,112 mothers (1,556 cesarean and vaginally delivered each) were enrolled for estimating maternal morbidity. Authors confirmed the adequacy of sample for estimating proportion of receiving vaccine as well detecting difference of about 10% with 95% confidence and 80% power.

**Statistical methods**

The analysis was carried out in 2018-19. Authors calculated relative risk with 95% confidence interval and probability for each vaccine. For Hepatitis B birth dose, administration was dichotomized within 24 hours and later but before discharge; for BCG and oral polio vaccines administration before discharge was taken into consideration. For comparison the hospitals were grouped into large (more than 200 beds), medium (50-100 beds) and small hospitals (30 beds) categories. Performance of medical college hospitals and corporation hospitals was also compared. Chi square test was applied for comparison between institutions.

**RESULTS**

A total of 3,112 mothers were enrolled. The mean age of the women was 23.96 (SD=3.72) years. Overall proportion of stillbirth was 0.61%; for low birth weight babies was 26.02% and proportion of preterm babies was 25.30%. There was no difference between cesarean delivered and vaginal delivered babies. For all the vaccines the number of children ‘not given’ and ‘data not available’ was clubbed together for analysis purpose; however combined proportion for different vaccines was about 10 to 12% only. The flow chart of follow up is given in table 2. Table one gives information about administration of Hepatitis B, Oral Polio and BCG vaccination by mode of delivery. Table two shows vaccination administration in different types of hospitals. It showed that proportion of children receiving Hepatitis B birth dose vaccine in large hospitals was 48.86%, in medium hospitals was 63.95% and in small hospitals it was 55.41%. Comparison between the private and government medical college showed proportion of 20.6% and 64.1% ($\chi^2= 203.32; p<0.001$). The two corporation hospitals KNH and YCMH had covered 75.2% and 43.0% children respectively ($\chi^2=59.06; p<0.001$).

Out of the children born in large hospitals 89.32% received zero dose of polio vaccine, in medium hospitals 95.39% and in small hospitals 58.11%. Comparison between the Private and Government Medical college showed that the range was from 81.8% to 92% ($\chi^2=29.10; p<0.001$). The gap between the two corporation hospitals KNH (82.0%) and YCMH (95.3%) was 15.3% ($\chi^2=29.12; p<0.001$).

BCG vaccination among newborns before discharge from the hospital varies from hospital to hospital. The proportion of newborn receiving BCG vaccine in large hospitals was 87.84%, in medium hospitals it was 90.67% and in small hospitals it was 54.05%. In the private medical college hospital, the coverage was 81.0% and the coverage in government medical college hospital was 91.9% ($\chi^2= 32.33; p<0.001$). Among the corporation hospitals YCMH and KNH the ranged varied from 91.2 to 79.3% ($\chi^2= 17.50.33; p<0.001$).

**DISCUSSION**

The study sites included all types of hospitals (excepting private hospitals), for obtaining actual information. For all vaccine’s coverage was better in cesarean born children excepting administration of hepatitis B birth dose within 24 hours.

Authors have considered total denominator for analysis as the intent was to vaccinate all newborns. Even the proportion of newborns receiving hepatitis B birth dose within 24 hours, derived from available newborns as per figure two was lower in cesarean section delivered (54.72%) than vaginally delivered newborns (57.71%); however the difference was not significant. The national level surveys estimate proportion of fully immunized children.

| Mode of delivery | Hepatitis B birth dose | Zero polio | BCG |
|------------------|------------------------|------------|-----|
|                  | Not received within 24 hours | Received within 24 hours of delivery | Not received before discharge | Received before discharge | Not received before discharge | Received before discharge | Not received before discharge | Received before discharge |
| LSCS (n=1556)    | 751                     | 805        | 153 | 1403 | 124 | 1432 | 163 | 1393 |
| Vaginal (n=1556) | 695                     | 861        | 187 | 1369 | 175 | 1381 | 214 | 1342 |
|                  | Relative risk= 1.08     | Relative risk= 0.82 | Relative risk= 0.71 | Relative risk= 0.76 |
|                  | 95% CI (1.00 to 1.17); p=0.044 | 95% CI (0.67 to 1.00); p=0.051 | 95% CI (0.57 to 0.88); p=0.002 | 95% CI (0.63 to 0.92); p=0.005 |
### Table 2: Vaccine administration to newborn, in different hospitals in Pune district, 2017-18.

| Name of the hospital    | Hepatitis B Birth dose Within 24 hrs. | %   | Zero polio Before discharge | %   | BCG Before discharge | %   | Total |
|-------------------------|--------------------------------------|-----|-----------------------------|-----|----------------------|-----|-------|
| Bharati Vidyapeeth      | 78                                   | 20.60 | 309                          | 81.70 | 306                  | 81.00 | 378   |
| BJMC Pune               | 595                                  | 64.10 | 854                          | 92.00 | 853                  | 91.90 | 928   |
| District Hospital Pune  | 23                                   | 12.00 | 168                          | 87.50 | 163                  | 84.90 | 192   |
| KNH                     | 167                                  | 75.20 | 182                          | 82.00 | 176                  | 79.30 | 222   |
| YCMH                    | 166                                  | 43.00 | 368                          | 95.30 | 352                  | 91.20 | 386   |
| Women’s Hospital        | 160                                  | 44.00 | 336                          | 92.30 | 323                  | 88.70 | 364   |
| SDH Baramati            | 59                                   | 92.20 | 63                           | 98.40 | 59                   | 92.20 | 64    |
| SDH Bhor                | 81                                   | 96.40 | 83                           | 98.80 | 81                   | 96.40 | 84    |
| SDH Daund               | 17                                   | 13.50 | 124                          | 98.40 | 124                  | 98.40 | 126   |
| SDH Manchar             | 250                                  | 96.90 | 250                          | 96.90 | 249                  | 96.50 | 258   |
| SDH Indapur             | 29                                   | 80.60 | 33                           | 91.70 | 9                    | 25.00 | 36    |
| RH Junnar               | 3                                    | 75.00 | 3                            | 75.00 | 3                    | 75.00 | 4     |
| RH Saswad               | 38                                   | 54.30 | 40                           | 57.10 | 37                   | 52.90 | 70    |
| Total                   | 1666                                 | 53.50 | 2813                         | 90.40 | 2735                 | 87.90 | 3112  |

χ²=59.23 p<0.001 χ²=9.62 p<0.01 χ²=7.85 p<0.01

The latest estimated proportion of fully immunized children exclusive hepatitis B birth dose, in Pune District was 81.0%, in Maharashtra 56.3% and in India 62.0%. Hepatitis B vaccination was started in India in 2002 and birth dose was recommended in 2008. The entire country was covered phase wise by 2011. WHO has recommended birth dose of Hepatitis B within 24 hours for prevention of perinatal transmission and also recommended that coverage of Hepatitis B birth dose should be used as an indicator of performance of immunization program. However occasionally the benefits of preventing perinatal transmission are challenged. In spite of recommendations from WHO, birth dose administration within 24 hours is not seriously evaluated. Studies assessing timing of birth dose are few and assessing timely administration are scarce in India. Even health management information system does not collect and disseminate information about birth dose.

Global coverage with hepatitis B birth dose in 2017 was 43%; the lowest coverage was reported in the WHOs African Region (10%) and the highest coverage in the WHO Western Pacific Region (85%). Which means about 30 million newborns were still unvaccinated in the 105 countries that provided universal Hepatitis birth dose in the national immunization schedule.

A study covering three African countries showed very wide country wise coverage of birth dose of hepatitis. In Gambia total Hepatitis B birth dose estimate was as high as 84%. But the estimate of timely (within 24 hours of birth) vaccination was only 9% among infants in Gambia. Nigeria had total coverage of 23% and timely coverage was also low to the tune of 13%. Botswana had high total coverage (94%) of Hepatitis B; however, timely Hepatitis B birth dose coverage in Botswana was 74%. In VietNam the coverage of hepatitis birth dose within 24 hours was found to be 46.6% to 62.8%; the coverage was better in rural/remote area than urban, mother’s age, education and particularly ethnicity played role. In New Guinea the proportion of children receiving timely birth dose ranged from 31 to33% in different government health care institutions.

Despite introduction of hepatitis B birth dose in national program since 2008 and reaching to 89% institutional deliveries in India; hepatitis B birth dose coverage was 45% in 2015 with wide variation across states. In one study conducted in a private medical college in Karnataka in 2013-2014 timely hepatitis B birth dose vaccination coverage was 56.1%. More infants were born (71.28%) in private facilities than in government facilities (28.71%) but coverage was low (43.35%) in private institutions and high coverage (87.76%) in government institutions. Worldwide many variables like and skilled birth attendance rate, institutional delivery rate, adult literacy rate, total health expenditure per capita and live births are positively correlated with proportion of children receiving birth dose. The area of residence like urban/rural and ethnicity also affects coverage. In a study from Tamil Nadu the coverage of timely Hepatitis B birth dose was higher in urban areas. Although few studies indicate prevention of perinatal transmission of Hepatitis B following cesarean section compared to vaginal; the reason for lower coverage among cesarean delivered children may not be awareness about such findings, leading to late administration of Hepatitis birth dose.

The coverage of zero polio dose hepatitis B in a study from Rajasthan was about 53% among hospital born newborn children. For 2017, WHO and UNICEF, and the official estimates of immunization coverage in India.
as are as follows; BCG coverage 88-91%, and Hepatitis B birth dose only 51-53%. Contrary to Indian situation, in Viet Nam the proportion of children receiving BCG was slightly lesser (44.5%) than Hepatitis B birth dose (46.6%).

For BCG vaccine, estimated national coverage gradually increased from 74% to 91% through 1999 and 2013.

This study shows differential coverage of timely Hepatitis B birth dose with regard to mode of delivery. The only possible reason may be emotional disturbance resulting from physical and mental stress among mothers and relatives immediately after operation, resulting less response to acceptance of injection to new born. This assumption is substantiated by the fact that after 24 hours the coverage improved. The urgency is not essential for other two vaccines. Hence for other two vaccines the duration considered for analysis was immunization before discharge. As the length of stay in hospitals is more among cesarean group, the coverage of all vaccines was better among cesarean delivered children.

For all three vaccines the medium sized hospitals consistently have best coverage whereas small hospitals have poor coverage. The manpower in small hospitals may be the limiting factor and in large hospitals the top priorities are different, and immunization is probably comparatively neglected. The coverage for all vaccines was better in government medical college than private medical college. Similar findings of difference between coverage ownership wise, and differential coverage of these three vaccines have been recorded at other place also. The reports from government institutions are regularly compiled and monitored by higher officers. Such system is virtually absent in private sector. Supportive supervision and interactions with staff may improve to 100% in few months. WHO has recommended 50% coverage of newborn children for hepatitis B birth dose by 2020. The district coverage as recorded in the present study has already achieved this target. In the context of Intensified Mission Indradhanush and Pune being a developed district from Maharashtra State, better performance was expected.

Although small proportion, the cluster, ‘not given’ or ‘data not available’ has multiple subgroups including stillbirths, deaths occurring within some hours and admissions in neonatal intensive care unit for some major problems although the mothers were discharged. There may be apprehension among health care workers about giving vaccines to newborns due to adverse effects following immunization, particularly to premature babies. Health care workers treated all three vaccines in same manner. The proportion of newborns receiving all three vaccines before discharge in both groups was almost similar. It is clear indication that either the hospital staff is not convinced enough or they fail to convince mothers. Lack of coordination between the staff providing immunization and staff in post-natal ward may also be a reason. Primary participants were mothers, the number of children were slightly higher. However the proportions may not vitiate because no mother will differentiate children for vaccination.

Limitations of this study authors did not study reasons of not receiving proper vaccination. Authors have compared the proportions between two modes of delivery but in population cesarean section may not be 50%. Authors followed the newborn till discharge but the follow up period was not similar for the two groups. Women undergoing cesarean section stay longer than vaginal delivery. The assumption that newborns expired within some hours and admitted in NICU did not receive may not be hundred percent valid however the coverage may not be differentially distributed.

CONCLUSION

The reason for not achieving near 100% is probably lack of knowledge about best timing of giving Hepatitis B birth dose vaccine among both health care workers and mothers. Because there was no shortage of supplies, large proportion of children received vaccination after 24 hours. The health care workers did not differentiate the importance of timely vaccination in respect of Hepatitis B birth dose and the opportunities were lost. Hepatitis B birth dose is the first vaccine the newborn receives. Its timely administration is a best gift to the newborns which motivates the parents to achieve full / complete immunization, a public health intervention of immense importance.

Recommendations

Hepatitis B birth dose coverage must be increased and sustained through simple measures as mentioned below in birthing institutions.

Regular and extensive training may be conducted for all the present staffs and subsequently to all new entrants. Uniform service delivery by display of newborn vaccination protocol, so that mothers also become aware and performance review by immediate and higher level in all birthing facilities should be carried out.

Authors also feel that the real reasons for not giving the Hepatitis B vaccine within 24 hours of birth of the baby may be further studied.

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