



## To Study the Effect of Birth Weight, Gender and Race on Pain Perception in Neontes during Vaccination

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### Abstract

**Background and Aims:** Pain has been unrecognized and undertreated throughout the history of neonatal care. Misconceptions about the infant's ability to feel, remember, and express pain contribute to this long-standing problem. Vaccination is one of the most important causes of neonatal pain as all the children are vaccinated throughout the infancy and childhood against the vaccine preventable diseases. So the present study is being planned to study the effects of sex, birth weight and race on pain perception

**Methods:** we observed 400 neonates receiving routine dose of Bcg and Hepatitis B vaccine given at birth. Pain was assessed on NIPS scale 30 second after first injection and 30 seconds after second injection. The two injections were given 2 minutes apart.

**Results:** NIPS at the end of vaccination procedure in male neonates was  $12.52 \pm 5.05$  and in female neonates the score was  $12.57 \pm 4.7$ , with *p* value of 0.823. In neontes with birth weight  $<3\text{kg}$  the NIPS score at the end of vaccination procedure was  $12.44 \pm 4.91$  and in neontes with birth weight  $>3\text{kg}$ , the score was  $12.7 \pm 4.88$  with *p* value of 0.587, which was not significant. In the two race groups, the score in the neontes of Indo-Aryan group was  $13.39 \pm 4.5$  and in mongoloid neontes nips score was  $5.87 \pm 1.89$  with *p* value of  $<0.0001$  which was significant.

**Conclusion:** there was no significant effect of gender and birth weight on pain perceived due to vaccination given at birth in the neontes. Pain perceived was more in the neontes of indo-Aryan race as compared to the neontes of mongoloid race.

**Keywords:** Vaccination, Neonatal Infant Pain Scale Score, Neonate, Pain, Bcg Vaccine, Hepatitis B Vaccine, Race, Gender, Birth Weight.

### Introduction

Pain has been unrecognized and undertreated throughout the history of neonatal care. Misconceptions about the infant's ability to feel, remember, and express pain contribute to this long-standing problem. Recent advances in

neurobiology and clinical medicine have established that the fetus and newborns experience acute, established, and chronic pain. They respond to such noxious stimuli by a series of complex biochemical, physiologic, and behavioral alterations. Studies have concluded that

controlling pain experience is beneficial with respect to short-term and perhaps long-term outcomes. If pain is prolonged or repetitive, the developing pain system may be modified permanently, resulting in altered processing at the spinal and supraspinal levels<sup>1, 2</sup>. The evaluation of pain in the human fetus and neonate is difficult because pain is generally defined as a subjective phenomenon<sup>3</sup>. Early studies of neurologic development concluded that neonatal responses to painful stimuli were decorticate in nature and that perception or localization of pain was not present<sup>4</sup>. Furthermore, because neonates may not have memories of painful experiences, they were not thought capable of interpreting pain in a manner similar to that of adults<sup>5-7</sup>. Several textbooks on pain in neonates and infants have been published<sup>8,9</sup> and measures for assessing pain have been developed and validated<sup>10,11</sup>. Neuroanatomical components and neuroendocrine systems are sufficiently developed to allow transmission of painful stimuli in the neonate. Painful medical procedures such as immunisation, venepuncture and dental procedures are the significant painful events experienced by the children. Vaccination is one of the most important causes of neonatal pain as all the children are vaccinated throughout the infancy and childhood against the vaccine preventable diseases. The present study is being planned to study the effects of sex, birth weight and race on pain perception. The purpose of this study is to help to understand the factors that affect the response to pain in neonates. Thus better understanding of the factors effecting acute response to pain will help in devising methods to reduce pain in neonates. Less painful methods for vaccination will reduce the stress among the children and their parents. Intense anxiety experienced by parents and their children regarding vaccination may result in non-adherence to the recommended vaccination schedule. Thus devising a less painful and less stressful route and method for vaccine administration may help in improving the compliance to vaccination.

### **Aims and objective**

To study the effect of birth weight, gender and race on acute pain response during BCG and Hepatitis B vaccination given at birth.

### **Material and Methods**

The study was conducted at Kamla Nehru State Hospital for Mother and child, a unit of Department of Paediatrics at Indira Gandhi medical College, Shimla. It was a hospital based observational cross-section study.

Inclusion criteria:

1. All full term healthy neonates receiving BCG and Hepatitis B vaccination at birth.
2. Parents consenting to include their newborns in the study.

Exclusion criteria:

1. Sick newborns and newborn on any supportive care
2. Preterm and IUGR newborn
3. Newborns with major congenital anomalies

With confidence limit of 95% and absolute error of 10% the sample size calculated was 384. So, 400 neonates meeting our requisite criteria were included in the study. The demographic profile of the all the cases was recorded as per a structured case recording format Table1. All the infants were dry at the time of procedure. The newborns were laid on the radiant warmer during entire procedure so as to observe pain score correctly. Vaccination was given to the neonate at the Brazelton state 3-4 of arousal. Neonates were breast fed half to one hour prior to vaccination. Same examination room with same radiant warmer and same surroundings was used for all the neonates in a thermo neutral temperature with NIPS of zero prior to vaccination. NIPS score was used to assess the pain in our study. To maintain uniformity the same size needles of same make were used. Vaccination was given by the same health worker to minimise subjective variation. She was not informed about the outcomes of the procedure and was be blinded to the purpose and hypothesis of the study. Standard immunization procedures were used. 0.1ml of BCG vaccine was administered

intradermally at the convex aspect of left shoulder using a tuberculin syringe with 0.45x 13mm needle<sup>12</sup>. 0.5ml of Hepatitis B vaccine was administered intramuscularly at the anterolateral aspect of thigh using 0.60x25mm needle<sup>12</sup>. Pain was assessed using NIPS scale after 30 second of first injection and 30 seconds after second injections. The data analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Statistical analysis of the data was done to find the difference in pain intensity on NIPS scale. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean  $\pm$  SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Qualitative variables were correlated using Chi-Square test /Fisher's exact test. A p value of <0.05 was considered statistically significant.

## Results

In our study total of 400 healthy term neonates fulfilling the inclusion criteria were enrolled, who received the routine dose of BCG and Hepatitis B vaccine at birth. Of all the neonates taken for the study, 245 neonates were with birth weight less than 3kg and 155 were with weight more than

equal to 3kg. on comparing the score after both BCG and Hepatitis B vaccination in the neonates with weight less than 3 kg and more than 3 kg the following results were found; in neonates with weight <3kg the mean score (after BCG+Hepatitis B) was  $12.44\pm 4.91$ , whereas in neonates with weight  $\geq 3$ kg was  $12.7\pm 4.88$  with a p value of 0.587. The p value is not significant statistically, thus indicating that birth weight do not have effect on pain response due to vaccination Table 2.

Gender: In our study there were 173 female and 227 male neonates. On comparing the combined score (BCG plus Hepatitis B), the mean for female neonates was  $12.57\pm 4.7$  and for male neonates the score was  $12.52\pm 5.05$  with a p value of 0.823. Thus, it may be implied that the sex of the neonate does not affect the pain perceived Table 3.

Race: On comparing the combined score, of BCG plus Hepatitis B the mean score was  $13.39\pm 4.5$  for neonates of Indo-Aryan and  $5.87\pm 1.89$  for mongoloids, with a p value of <0.0001. Thus with significant p value, it can be concluded that the race of neonates had definitive relation to the pain response. The men NIPS score was more in the neonates of Indo-Aryan race than the neonates of mongoloid race which implies that the Indo-Aryan neonates more sensitive to pain.

**Table 1:** demographic profile of the newborns enrolled

Characteristic		Frequency	Percentage
gender	Male	173	43.25%
	female	227	56.75%
birth weight	<3kg	245	61.25%
	$\geq 3$ kg	155	38.75%
Race	Indo-Aryan	355	88.75%
	mongoloids	45	11.25%

**Table 2:** NIPS With Respect To Weight (n=400)

Weight	Sample size	Mean $\pm$ SD	Median	Min - max	Inter quartile range	P value
<3kg	245	$12.44\pm 4.91$	12	2-28	9-16	0.587
$\geq 3$ kg	155	$12.70\pm 4.88$	12	2-24	9-15.75	

**Table 3:** NIPS With Respect To Gender (n= 400)

Gender	Sample size	Mean $\pm$ SD	Median	Min - max	P value
females	173	$12.57\pm 4.7$	12	2 – 28	0.823
males	227	$12.52\pm 5.05$	12	2-27	

**Table 4:** NIPS With Respect To Race (n=400)

Race	Sample size	Mean $\pm$ SD	Median	Min -_max	Inter quartile range	P value
Indo Aryan	355	13.39 $\pm$ 4.5	13	4 - 28	10-16.75	0.0001
Mongoloid	45	5.87 $\pm$ 1.89	6	2 - 10	5-8	

### Discussion

This study conducted at Kamala Nehru State Hospital of Mother And Child, Branch of Indira Gandhi Medical College, Shimla describes the effect of birth weight, gender and race on acute pain response to BCG and Hepatitis B vaccination given at birth. When compared the NIPS score at the end of vaccination procedure in the female neonates was 12.57 $\pm$ 4.7 and in the male neonates was 12.52 $\pm$ 5.05, with p value of 0.823. Thus it may be concluded that there was no effect of the gender on the pain perceived due to vaccination. Our findings are in collaboration with Pragya Pathaket al<sup>13</sup> who studied the “Effect Of Needle Gauge On Perception Of Pain Intensity Among Infants Receiving D.P.T” and concluded that the gender of the infant does not influence the pain response to vaccination. Also, our results are comparable to Moshe Ipp<sup>14</sup> who studied the effects of age, gender and holding on pain response during infant immunisation and found no effects of gender on pain response.

Birth weight: out of the 400 neonates on comparing the pain experienced in those with weight <3kg, the NIPS score at the end of vaccination procedure was 12.44 $\pm$ 4.91 whereas in neonates with weight  $\geq$ 3kg the NIPS score was 12.7 $\pm$ 4.88 with p value of 0.587 which is not significant. Thus, concluding that birth weight did not have any effect on the pain response to vaccination in neonates. Although there are studies claiming difference in the pain perceived in term and preterm neonates but in our study preterm and low birth weight neonates were excluded. On extensive research in the literature no studies were found to compare the effect of birth weight on pain response to vaccination given at birth.

Race: in our study neonates of Indo-Aryan and mongoloid race were enrolled. The combined NIPS score at the end of vaccination procedure in neonates of Aryan race was 13.39 $\pm$ 4.5 and in the

neonates of mongoloid race was 5.87 $\pm$ 1.89; the p value was <0.0001. Thus there was a significant difference in the pain perceived after vaccination in neonates of Indo-Aryan race as compared to the neonates of mongoloid race. There was a significant p value of <0.0001 indicating that pain perceived in those of mongoloid race was lower as compared to the other neonates. The cause for this significant difference in pain perception in the neonates of the two racial groups may be due to some inherited genetic difference in either pain pathways or in peripheral pain perception. We could not find any studies in the literature to compare our study findings

### Conclusion

There was no effect of the gender on the pain perceived due to vaccination. Birth weight does not affect the pain perceived due to vaccination in the neonates. The overall pain experienced is more in the Aryan neonates as compared to the neonates of mongoloid origin. Thus race has definitive effect on pain perceived.

### Limitations

In our study, it was found that in mongoloids neonates the pain perceived was less. Although in our study the number of mongoloid neonates was very less and only two races were studied. So to find the exact effect of race on the pain perception larger studies by taking large number of study population and including more races needs to be done.

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