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Physiological Icterus of the Newborn and the Role of Liv.52

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ABSTRACT
Neonatal jaundice can be a major health threat to the newborn. The present study compared the effects of Liv.52 to that of phenobarbitone with a third group serving as control, in a total of 260 newborn babies. It was found that Liv.52 pretreatment has no deleterious effect on development of icterus. Continued treatment with Liv.52 led to early disappearance of icterus. It was also safe, without side effects.

INTRODUCTION
Jaundice during the neonatal period is quite common. Sixty percent of terms infants and 80% of preterm infants develop jaundice (Kivlahane, C., James, E.J.P. 1984). Jaundice may lead to low motor and mental scores later in life (Bougre *et al.,* 1967) by having a toxic effect on the brain (Odell, 1980). Certain Asian groups (Chinese, Indian and Malaysian) and some American Indians and Greeks have a higher peak of physiological jaundice (Johnson, 1975).

Keeping this pathophysiology of physiological jaundice in mind, various management lines were proposed for this condition. Cremer *et al.,* (1957) recommended exposure to sunlight; Srivastava *et al.,* (1972) used Liv.52 drops; agar (Morrer, 1973) and cholestyramine (Micalopaulos, 1978) have also been recommended. Sircar, Bhalla and Chandu (1979) recommended the use of phenobarbital and phototherapy in combination.

The present study was undertaken to compare the effects of Liv.52, an indigenous drug of The Himalaya Drug Co., to that of phenobarbitone in the management of neonatal jaundice.

MATERIAL AND METHODS
This work was carried out on 260 babies weighing 1150 g or more, born in S.V.B.P. Hospital of the L.L.R.M. Medical College, Meerut, during a period of seven months. Antenatal history was recorded with special reference to the use of drugs, exposure to infection and maternal diseases such as diabetes mellitus. A record of the prenatal period regarding birth asphyxia along with the history of jaundice in previous siblings was made.

All children were weighed at birth and clinically assessed for the period of gestation. Of these, forty seven children were later excluded from the study. Five were cases of Rh incompatibility, three were of ABO incompatibility, for two there was history of diabetes mellitus from the mother, four had cephalhaematoma, seven had septicemia and twenty six had diarrhoea.

All children were examined daily for appearance of icterus by pressing the skin of the nose and forehead in good sunlight. The time of appearance of icterus, its daily progression and disappearance were recorded.

Rh and ABO blood grouping of cord blood samples of every child and blood grouping of the mothers was done. Serum bilirubin estimations including total bilirubin and conjugated and unconjugated fractions were carried out on 4th and on 8th day of life. Other investigations like hemoglobin, reticulocyte count, Coomb's test, blood/stool culture and chest X-rays were done as and when required.

The cases were divided into 3 groups. The first group consisted of 73 babies on Liv.52 drops (5 drops TDS) from the first day continued till the 8th day.

The second group consisted of 65 babies who were put on phenobarbitone in a dose of 10 mg twice daily starting with the first day and continuing up to the 8th day.

The third group of 75 babies served as the control.

OBSERVATIONS

There was no significant difference in the occurrence of icterus among the two sexes in term as well as in preterm babies as shown in Table 1.

Table 1: Distribution of cases according to sex and gestation

Gestation	Total deliveries			Cases of physiological icterus		
	Male	Female	Total	Male	Female	Total
Term	70	67	137	36	31	67
Preterm	40	30	70	30	20	50

Table 2 shows the effect of parity on physiological icterus which is significant χ^2=47.12 (p<0.001) i.e. the incidence decreased with increasing parity. One hundred and six babies i.e. 90.6% developed physiological icterus by the 3rd day, and only eleven babies i.e. 9.4% developed icterus on the 4th day as seen in Table 3. 48.36% of the cases had birth weight between 1150 g to 2500 g, while 57.64% of the children had weight of more than 2500 g. Out of the 103 children in group 1-3, 64 i.e. 62.53% developed icterus while in weight group 4 out of 110 only 53 (48.18%) developed icterus. These findings are shown in Table 4.

Table 2: Distribution of cases according to parity

Parity	Total cases studied (213)	Cases who showed physiological icterus ((117)
1	80	65
2	70	37
3	40	10
4 & greater	23	5

Table 3: Distribution of cases according to day of appearance of icterus

Day of appearance of icterus	Number	Percentage
2nd day	31	26.5
3rd day	75	64.1
4th day	11	9.4

Table 4: Birth weight of children in each group					
Birth weight (g)	Total no. (213)	Percentage	Liv.52 group (73)	Phenobarbitone (65)	Control (75)
1150-1500	25	11.75	9	7	9
1500-2000	45	21.11	14	15	16
2000-2500	33	15.50	13	10	10
>2500	110	52.60	37	33	40
t=0.1374; t=0.4123					

There was no significant statistical difference ($p<0.05$) in the 3 groups as far as the occurrence of physiological icterus was concerned as shown in Table 5. There was no significant difference in the disappearance of icterus when the control group was compared with the liv.52-treated and phenobarbitone-treated group. These values are shown in Table 6.

Table 5: Break up of cases of physiological icterus in each group				
Group	No. of cases	Cases with physiological icterus	Percentage of icterus	Cases without icterus
Liv.52	73	36	49.3	37
Phenobarbitone	65	39	60.0	26
Control	75	42	48.0	33
χ^2=1.3363, $p<0.05$				

Table 6: Depicting the day of disappearance of icterus in different groups				
Day of disappearance	Total no. of patients	Liv.52	No. of patients on Phenobarbitone	Control
5th day	20	8	6	6
6th day	10	4	3	3
7th day	17	7	5	5
8th day	50	11	19	20
8-12 day	20	6	6	8
Total	117	36	39	42
Mean	–	7.5	7.5641	7.6905

The mean values of serum bilirubin and indirect bilirubin on the 4th day of life did not show any significant difference between the three groups. Table 7 shows the values on day 4.

Table 7: Depicting mean serum bilirubin values on the 4th day of life in different groups			
Serum bilirubin (Mean)	Liv.52 Group (mg%)	Phenobarbitone (mg%)	Control (mg%)
Total	5.8	6.1	6.0
Direct	0.8	0.7	0.85
Indirect	5.0	5.4	5.15

The values of serum bilirubin total (mean) and indirect (mean) on the 8th day of life was lower in the Liv.52-treated group as compared to the phenobarbitone and control group as seen in Table 8.

Table 8: Depicting the serum bilirubin levels on the 8th day of life in different groups

Serum bilirubin (Mean)	Liv.52 gGroup (mg%)	Phenobarbitone (mg%)	Control (mg%)
Total	2.1	3.0	3.3
Direct	0.6	0.4	0.5
Indirect	1.5	2.6	2.8

DISCUSSION

The present study showed that 81.25% of the first born, 52.85% of the second born and 25% of the third born neonates developed icterus. Of them, 71.43% were preterm and 46.85% were full term infants. Tovey *et al.* (1959), Barton *et al.* (1962) also reported the same pattern. This significant effect of gestational maturity on the incidence of jaundice can be explained by the immaturity of the liver. It was also observed that majority of the neonates (90.6%) who ultimately developed icterus, developed it by the 3rd day of life.

Workers have tried to prevent development of jaundice during the neonatal period., but none of their methods have proved satisfactory.

Brown (1968) suggested avoidance of factors like anoxia, drugs, etc., which aggravate hyperbilirubinaemia. Cremer *et al.* (1958) and Baineha (1971) noted that serum bilirubin came down on exposure to sunlight or phototherapy. Cunningham (1969) observed that serum bilirubin did not regress if phenobarbitone was given after the appearance of icterus.

In the present study, it was observed that 49.3% of the neonates who were getting Liv.52, and 60% of the neonates who were getting phenobarbitone-developed icterus whereas only 48% of neonates who were not getting either of the two drugs (control group) developed icterus. The total mean serum bilirubin percentage value on the 4th day among the icteric neonates was 5.8 mg% in the Liv.52 group, 6.1 mg% in the phenobarbitone group and 6.0 mg% in the control group (Table 7). The mean percentage of conjugated serum bilirubin (Direct) was 0.8 mg% (13.79% of the total) in the Liv.52 group; 0.7 mg% (11.47% of the total) in the phenobarbitone group and 0.85 mg% (14.16% of the total) in the control group. The mean day of disappearance of icterus was observed to be 7.5 days in the Liv.52 group, 7.564 days in the phenobarbitone group and 7.69 days in the control group.

However, on the 8th day, the mean values of the total and indirect serum bilirubin were the lowest in the neonates receiving Liv.52. This showed that in neonates on Liv.52 therapy, the severity of icterus was remarkably checked. It can be concluded that Liv.52 can effectively prevent the progression of physiological jaundice in neonates. Liv.52 might also offer protection from the grave effects of physiological icterus. Liv.52 was also safe and free of side effects.

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