



## INTERNATIONAL JOURNAL OF PAEDIATRICS AND GERIATRICS

P-ISSN: 2664-3685

E-ISSN: 2664-3693

IJPG 2020; 3(2): 73-75

Received: 15-05-2020

Accepted: 19-06-2020

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### The efficacy of fenofibrate as an adjunct to phototherapy for neonatal hyperbilirubinemia

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**DOI:** <https://doi.org/10.33545/26643685.2020.v3.i2b.97>

#### **Abstract**

**Background:** Neonatal jaundice is accountable for 70% neonatal morbidity and 10% mortality. It is the most common cause of re-admission after discharge from hospital. Here, we have studied the effect of Fenofibrate as an adjunct to phototherapy in treating neonatal hyperbilirubinemia.

**Materials and Methods:** This study was conducted on 90 neonates with hyperbilirubinaemia requiring phototherapy, they were randomly allocated to two groups, both the groups received phototherapy whereas the intervention group received single dose of fenofibrate (10mg/kg) in addition. Total serum bilirubin after 48 hours and duration of phototherapy was measured in both groups.

**Results:** The study proved that there is a decrease in duration of phototherapy and decline in serum bilirubin after 48 hours of phototherapy in intervention group, but the difference is not statistically significant.

**Conclusion:** There is a non-significant role of Fenofibrate in decreasing neonatal hyperbilirubinemia.

**Keywords:** Fenofibrate, neonatal jaundice, phototherapy

#### **Introduction**

Neonatal jaundice has significant importance in neonatal morbidity and mortality worldwide. Bilirubin is an antioxidant against the free radical which is circulating in neonatal biological system. Elevation in the serum bilirubin levels readily manifest as jaundice in newborns and this could be attributed to the physiological immaturity of the hepato-biliary system in the neonates. Apart from this increased bilirubin production, less effective binding and transportation, inefficient conjugation and excretion and increased entero-hepatic circulation make a newborn vulnerable for hyperbilirubinemia. Management of neonatal jaundice includes identification of neonates at risk, evaluating the underlying cause of pathological hyperbilirubinemia, deciding the thresholds for initiating and stopping treatment and following up of neonates with severe hyperbilirubinemia. Phototherapy remains as the principal modality of treatment in treating severe hyperbilirubinemia where light of blue green spectrum with the wavelength corresponding with peak absorption by bilirubin (450-460nm) is used. Though phototherapy has a relentless use in neonatal jaundice, its cumbersome side effects and the physical separation of baby from the mother eventually result as increase in days of hospitalization adding to the mental anguish of the parents.

The pharmacological treatment now under trial for hyperbilirubinemia are metalloporphyrins, penicillamine, phenobarbitate, zinc sulfate and fibrates. Fibrates induces bilirubin conjugation much more readily and effectively. It converts unconjugated bilirubin to conjugated bilirubin thereby hasten its clearance. Number of trials has been conducted for establishing the use of clofibrate in neonatal jaundice. But clofibrate has many side effects like gastro intestinal upset, leucopenia, alopecia, pruritis, muscle cramps, renal failure. The main advantage of Fenofibrate is that it has minimal to no side effects and hence has a better safety profile compared to clofibrate.

The present study is to determine whether Fenofibrate therapy for neonatal jaundice decreases the duration of phototherapy and decreases serum bilirubin.

#### **Materials and Methods**

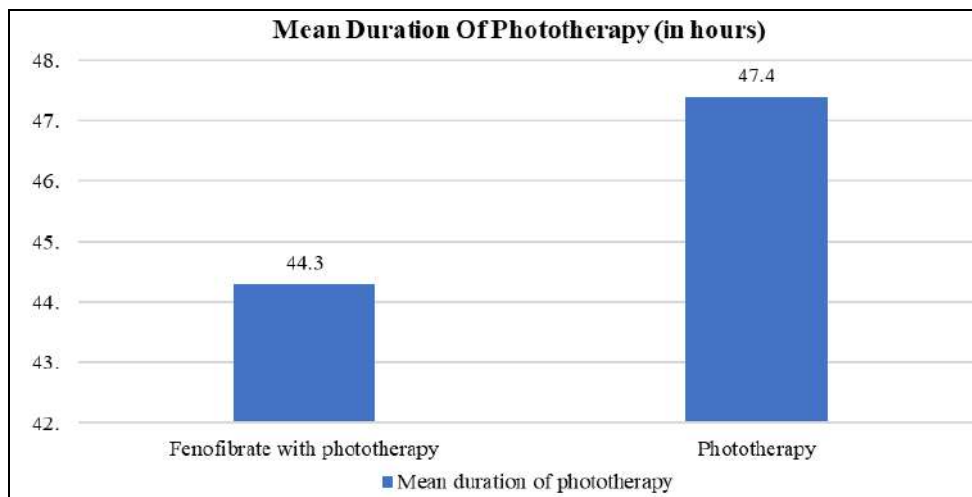
This study is a randomized control study held in a tertiary hospital for two year interval. Ninety neonates were included in the study group. Neonates with significant unconjugated hyperbilirubinemia and neonates meeting the threshold for phototherapy according to age

specified stratification given for phototherapy by American Academy of Paediatrics were included in the group. Neonates who have suspected infections, dehydration, asphyxia, hemolytic jaundice due to Rh incompatibility, inborn errors of metabolism, coagulation disorders and structural anomalies of liver and kidney are excluded from the study. The study population were randomly allocated into two groups, in which one group of 45 neonates received single dose of Fenofibrate at 10mg/kg before the commencement of phototherapy and other group received only phototherapy. The decrease in serum bilirubin between two groups after 48 hours of initiation of phototherapy and decrease in duration of phototherapy between the two groups were studied and statistically analyzed.

**Results**

Ninety neonates were enrolled in the study. In phototherapy group, there were 24 male babies and 21 female babies. In

Fenofibrate group, there were 26 male babies and 19 female babies. The mean hours of life at start of phototherapy was 51.9 hours and 49.6 hours in Fenofibrate group and phototherapy group respectively. Mean value of peak bilirubin was 16.2 and 16.9 in Fenofibrate with phototherapy group and phototherapy only group respectively, which is not statistically significant. Serum bilirubin after 48 hrs of phototherapy was 10.7mg/dl and 11.7mg/dl in Fenofibrate with phototherapy group and phototherapy group respectively, hence the serum bilirubin after 48 hrs of phototherapy was lower in fenofibrate group compared to phototherapy group ,but the difference is not statistically significant. Likewise, The mean duration of phototherapy in the Fenofibrate group was 44.3 hours and it was 47.4 hours in phototherapy only group. Hence the mean duration of phototherapy is less in Fenofibrate group comparing to phototherapy only group but it is not statistically significant.



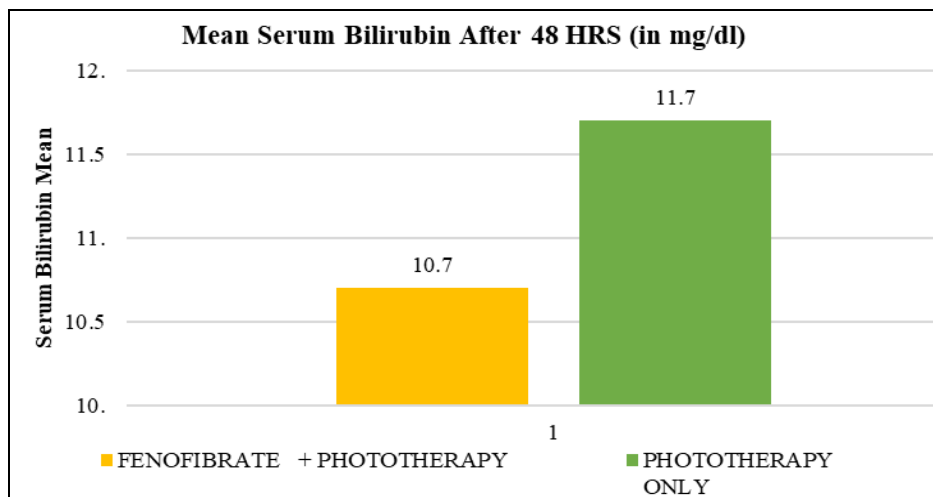
**Fig 1:** Mean duration of phototherapy in either groups

**Table 1:** Number of Neonates Receiving Phototherapy at Various Duration Of Hours In Either Groups

Duration of phototherapy	Fenofibrate with phototherapy	phototherapy	P value
<24 hours	0(0%)	0(0%)	0.056
24-48 hours	30 (66.7%)	21(46.7%)	
48-96 hours	15(33.3%)	24(53.3%)	

The duration of phototherapy in fenofibrate with phototherapy group was less compared to phototherapy only

group but the observed difference was not statistically significant [p=0.056]



**Fig 2:** Mean Serum Bilirubin After 48 Hours of Phototherapy In Either Groups

**Table 2:** mean serum bilirubin after 48 hours of phototherapy in either groups

	Fenofibrate + Phototherapy (mg/dl)	Phototherapy (mg/dl)	P value
Mean serum bilirubin	10.7	11.7	0.082

Though mean serum bilirubin 48 hours after phototherapy was less in Fenofibrate with phototherapy group compared to phototherapy only group, the observed difference was not statistically significant. [P=0.082]

### Discussion

This study was conducted to prove the efficacy of Fenofibrate as an adjunct to phototherapy in treating neonatal jaundice, its efficacy is demonstrated mainly by two variables one being the serum bilirubin after 48 hours of phototherapy and other one being the duration of phototherapy in hours. The mean duration of phototherapy in the Fenofibrate group was 44.3 hours and it was 47.4 hours in phototherapy only group, though the duration of phototherapy is lower in intervention group than in control group the observed difference was not statistically significant but in the study conducted by Chaudary *et al.*,<sup>[3]</sup> involving 50 neonates where the mean duration of phototherapy in Fenofibrate group was 38.40±11.02h, which was lower than that of the control group (46.67±4h) which was statistically significant with P value <0.05 and also in the study conducted by Ahmadpour-kacho *et al.*,<sup>[4]</sup> the duration of phototherapy was 2.5 days and 3.35 days in the intervention and control groups respectively, it also showed a statistically significant difference with P value=0.003, but in the study conducted by Gowda *et al.*,<sup>[5]</sup> in concurrence with our study says that there is no significant difference in phototherapy and Fenofibrate groups though there is a decrease in duration of phototherapy in the group which received both phototherapy and fenofibrate, but in the study conducted by Sawsan *et al.*,<sup>[6]</sup> there was a significant difference in the duration of phototherapy in the group which received Fenofibrate (2.6 days) and in the group which received phototherapy (5.05 days).

The serum bilirubin level after 48 hours of phototherapy in our study was 11.7mg/dl in control group and 10.7mg/dl in intervention group. Though the mean serum bilirubin level after 48 hours of phototherapy was low in intervention group compared to control group, there was no observed statistical difference between them, which disproves the study conducted by Al-Asy *et al.*,<sup>[7]</sup> where the serum bilirubin after 48 hours in intervention group was 12.287 mg/dl and whereas in control group it was 13.58 mg/dl which was statistically significant similar to the results of the study by Kumar *et al.*<sup>[8]</sup> where serum bilirubin level was 14.45 mg/dl in fenofibrate and 16.82 mg/dl in phototherapy group, the value of serum bilirubin is greater in this study than our study because the study conducted by Kumar *et al.*,<sup>[8]</sup> included only term babies weighing more than 2.5kgs, in a study conducted by Pathak *et al.*,<sup>[9]</sup> the serum bilirubin values are 14.8 and 13.3mg/dl in control and intervention group respectively.

Contrastingly, in the study conducted by Shahein *et al.*,<sup>[10]</sup> serum bilirubin after 48 hours was 12.36 mg/dl in study group and 15.59 mg/dl in control group respectively.

### Limitation

1. The study was conducted in small population.
2. The study was conducted in single Institute.
3. Due to methodological constraints, we could compare

only two variables.

### Conclusion

We concluded that Fenofibrate when given as an adjunct to phototherapy reduces serum bilirubin levels and reduces the duration of phototherapy. But for proving its statistical significance the study should be done in a large population.

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