

“ Child survival ” project report.

**COMPARING THE EFFICACY OF TWO METHODS
TREATED BY BIDIRECTIONAL PHOTOTHERAPY
FOR SEVERE NEONATAL HYPERBILIRUBINEMIA**

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ABSTRACT:

The jaundice is frequent in the newborn and kernicterus is a very dangerous complication. The neonatal jaundice should be diagnosed early and can be treated by the phototherapy for preventing neurotoxic risks .

OBJECTIVE: To evaluate the efficacy of bidirectional phototherapy using the 2 directions-Compact lamp TD and to confirm that the new lamp described have had the same efficacy with Biliblanket phototherapy associated with compact lamp TD 8.9w/71 in the treatment of neonatal hyperbilirubinemia.

DESIGN: Prospective, clinical controlled trial.

METHODE: We studied on 64 full-terms, severe icterus newborns, they were allocated randomly to one of two modes of phototherapy: 32 icterus newborns in study phototherapy groupe using two-directions-Compact lamp TD and 32 other ones in second group using Biliblanket associated with compact lamp TD 6.9w/71 (one side).

RESULT: after 12 hours of therapy, the unconjugated bilirubinemia in the group receiving 2 directions-Compact lamp TD phototherapy was the same with which in the second group (Pvalue = 0.05). These means rates of fall of unconjugated bilirubinemia in the study group were 5.24 ± 4.34 mg% versus 3.84 ± 3.44 mg%, in the second group (Pvalue = 0.05). But after 24 hours of phototherapy the mean rates of fall of unconjugated bilirubinemia in the study group was significant lower than the second group (9.84 ± 4.87 mg% vs 7.00 ± 5.18 mg %) (Pvalue = 0.027) then $13.46 \pm 6,13$ mg% versus 10.69 ± 4.99 mg% after 48 h of phototherapy (Pvalue = 0.029).

The mean time of the phototherapy in the group receiving 2 directions -compact lamp TD was 37.13 ± 15.35 hours versus $46,13 \pm 23.23$ hours in second group.

It was significant lower than the study group (Pvalue = 0.036).

CONCLUSION: two directions-Compact lamp TD was being good efficacy in reducing unconjugated bilirubinemia in double light phototherapy of neonatal jaundice.

It can be easily and economically provided in the most neonatal units.

I. INTRODUCTION

Jaundice caused by indirect bilirubin is commonly in neonates. It occurs to the most of premature babies and also 25-30% of fullterm babies [1],[2],[4]. If it can not be found

and treated timely, this can cause complication such as kernicterus and its consequence is terrible in which these neonates can be died, neurotoxic or cerebral palsy. If it is diagnosed early, however, neonatal jaundice due to indirect bilirubin can be treated effectively by drugs, phototherapy or blood changes in which phototherapy is most effective, simple, safe and economical.

OVERVIEW OF PHOTOTHERAPY

Since 1957, at Rochford General hospital, Essex, United Kingdom, CREMER et al. observed benefits of lights for neonatal jaundice and they began to use artificial lights in order to treat to neonatal jaundice in 1958. Many kind of lamps were made but blue light lamps and their 420-480 nm spectrum were most effective. In 1967, Obes Polleri had applied for phototherapy and the conference of phototherapy was held in Chicago 1969, Jerusalem 1974 and then padua 1983, Creifward 1980, 1985, 1989 and Tieste 1990, 1992. All experiments shown that blue light was most effective in neonatal jaundice and reduced blood change dramatically for icterus newborns.

ACTUAL VIETNAM SITUATION

Currently, neonatal jaundice treatment at basic medical center still have some difficulties, many cases of them have to be transferred the bigger hospitals while these cases were kernicterus. At Tu Du hospital, over 45.000 neonates annually were born, our newborn department has often from 200 – 300 newborn babies. On the other hand, the neonates of some medical centers and other hospitals have been also admitted our department. Therefore, lighting needs are very necessary. Through actual demands, we have made blue light lamp as Compact TD that aims to treat early icterus caused by indirect bilirubin, this prevents kernicterus based on principal: lighting energy of Compact DS 9w/71 and 400 – 500 nm spectrum are used to concert indirect bilirubin in subcutaneous into isomeric optics that can be soluble, nontoxic and clearing through bile duct and urine line.

The distance from under - lamp to babie is 40 cm, it distributes lighting energy measuring equally $\text{mW/cm}^2/\text{nm}$ in 9 squares of cradle as follows:

Compact TD phototherapy (upper - side)		
15.9	17.6	13.2
13.8	16.1	12.8
11.4	14	11.8

This is a phototherapy system experienced successfully from 1997 to 2000 at neonatal department, Tu Du hospital. We have made more 150 phototherapy systems for satellite medical centers in South, North and Centre region of Viet Nam as well. They contribute dramatically jaundice neonates treatment at these centers.



Double Compact TD lamp and two direction phototherapy

This result is appropriate to energy of lamp systems which recently are made, especially Biliblanket (distributed by Ohmeda company) that are most effective in the world and very expensive but they can adjust to low – intermediate and high level in order to replace energy degree from 15 to 35mW/cm²/nm.



Biliblanket phototherapy

At newborn department of Tu Du hospital, however, we have to received many severe jaundice cases in which indirect bilirubin was high level and threaten neurotoxic.

Since 1999, we applied for 2 sides lighting by Biliblanket directly for back of neonates and Compact TD for upper side, this method has been very effective. However, we have only two Biliblanket phototherapy systems because they are very expensive. So that, we have made Compact TD 2 directions phototherapy since 2000. These lamps have used intensively to treat severe jaundice neonates to avoid blood exchange. The upper- side of Compact TD has 8 tubes DS 9w/71 blue light energy and the under side has 6 lamps with energy of Ds 9w/71, blue light energy. The babie is placed in one transparent plastic cradle, the under side distance 10cm from babie. The lighting energy (mW/cm²/nm) is measured 9 squares at back side as follows:

21	24.9	23.2
26.8	29.9	25.2
16.4	18.5	16.8

Under – side box of phototherapy (placed under transparent plastic cradle)

II. PATIENTS AND METHODS

64 jaundice newborns who admitted at Tu Du hospital were examined and divided randomly into 2 neonatal groups: 32 babies in studied group and 32 ones in controlled group.

In the studied group, cases were treated by new device bidirectional phototherapy Compact TD while the jaundice babies in controlled group were treated by Biliblanket device in under side associating with phototherapy by Compact TD on upper side.

The drugs have influenced on bilirubine metabolism are not indicated in 2 groups.

Distance from nude jaundice babies to the light tube is 40 cm upper- side and 10 cm under- side of the babies in studied group. The distance from the babies in controlled group to the light is the same as the studied group but the Biliblanket light is placed directly under back of babies.

Data is collected from admission at 12h, 24h, 48h and 72h after treating by bidirectional phototherapy.

Inclusive criteria: full term neonates with $18 \text{ mg/dl} \leq \text{Bilirubinemia} \leq 24 \text{ mg/dl}$.

Exclusive criteria: babies got congenital malformations, severe infections, other severe diseases or family members of newborn do not agree participate into this program.

Statistical data is analyzed by EPI INFO 2000 program.

III. RESULT

1. Compare the criteria before treatment of two groups

Criteria	Study group	Control group	P value
Mean of weight (gr)	2.990,63 ± 413,18	3023,6 ± 370,17	>0,05
Age at hospitalization (hours)	90,84 ± 50,74	76,41 ± 46,35	>0,05
Sex ratio	0.53%	0.56%	>0,05
Ratio of incompatibility blood group (ABO) between neonate and mother	18 / 32 (56%)	16/ 32 (50%)	>0,05
Unconjugated bilirubinemia at hospitalization	19,4 ± 2,9 mg%	19,25 ± 2,7 mg%	>0,05
Mean of gestational age of babies (w)	39,7 ± 1,55	39,59 ± 1,34	>0,05
Haematocrit in blood (%)	45,19 ± 9,58	47,28 ± 9,69	>0,05

Note: No significant difference between 2 groups before treatment

2. Compare the unconjugated bilirubinemia of 2 groups after treated by bidirectional phototherapy

Unconjugated bilirubinemia	Study group	Control group	P value
At admission (mg%)	23,56 ± 4.07	23,44 ± 3,41	> 0,05
At 12h after treating by bidirectional	18.08 ± 3.67	19,65 ± 4,56	0,05

phototherapy (mg%)			
At 24h after treating by bidirectional phototherapy (mg%)	13,72 ± 4,46	16,44 ± 59	0,02
At 48h after treating by bidirectional phototherapy (mg%)	11,92 ± 4,5	15,23 ± 3,98	0,029
Reduction of unconjugated bilirubinemia at 12 h after phototherapy (mg%)	5,24 ± 4,34	3,84 ± 3,44	0,19
Reduction of unconjugated bilirubinemia at 24 h after phototherapy (mg%)	9,84 ± 4,87	7,00 ± 5,18	0,027
Reduction of unconjugated bilirubinemia at 48 h after phototherapy (mg%)	13,46 ± 6,13	10,69 ± 4,99	0,029
Time of phototherapy (h)	37,13 ± 15,35	46,13 ± 10,69	0,036
Success percentage (%)	100%	100%	1

Note: The treatment efficacy of bidirectional phototherapy Compact TD lamp is better than the Biliblanket lamp (under side) associated with one direction Compact TD lamp (upper - side) at 24th, 48th hours after treating by bidirectional phototherapy.

The time of phototherapy in study group is significantly shorter than the controlled group (37 hours vs 46 hours), (P value = 0.036)

IV. DISCUSSION:

The Biliblanket is a very good device for treating the neonatal jaundice. It is proved by result of many medical researchs in the world^{[5],[9],[10],[11],[12]}.

In 2000, we have studied and proved the efficacy of the Compact TD phototherapy lamp (one side) that was made by Tu Du hospital^{[1],[2]}. It is applied for treatment of neonatal jaundice not only in neonatal department of Tu Du hospital but also in many neonatal units of Viet Nam.

From the good outcome in treatment neonatal jaundice by Compact TD lamp one side. We made the bidirectional phototherapy Compact TD. The result of research showed that:

1. Comparing standards and key factors being influenced on bilirubine metabolism in two groups such as birthweight, delivery or interferred by surgery, sex, the kind of milks, old hours of age, pathology history and drugs being treated for mothers before to begin labour...We reconized there is no difference in statistical analysis.

Comparison of indirect bilirubinemia in 2 groups, the supposed ratio of anti-ABO blood group is no difference in statistical analysis, too.

These results being defined two groups were randomized, controlled was appropriate to clinical and sub-clinical as well.

2. The results shown that the efficacy of double Compact TD lamp is not only as effective as Biliblanket for back side combined with compact TD lamp for abdomen side at 12th hours but also much better than Biliblanket at 24th, 48th hours after phototherapy through features as follows:

- Speed of decreasing indirect bilirubinemia is faster and the time of phototherapy is shorter as well as more succesful.

- During studying, concurrently, we have not found any side effects yet in two

studied groups.

This trial is the same as other authors all the world in neonatal jaundice caused by indirect bilirubinemia that treated by blue and green lights^{[7],[8],[9],[14],[15]}. It is even suitable because double light has blue light while Biliblanket has only green light. Furthermore, the light energy of double light for back side has also the same effect as Biliblanket at intermediate level (approx. 25 mW/cm²/nm).

3. On structure and technique of double compact TD, the basis parameters have also been appropriate to requisites for phototherapy. Especially, 400 – 500nm spectrum is well effective to convert indirect bilirubin into isomeric substance^{[13],[14]}.

4. Besides effective treatment, double Compact TD brings more benefits and much cheaper (approx. USD 600) than Biliblanket device (approx. USD 4500), small size and slight, possible to be produced in local country, easily to be maintained and fixed, less hot, saving power and especially the life – time of Compact light is much longer than fluorescent tube (the time that light energy decreased in half of compact tube is 8.000 hours versus 2000 hours of fluorescent tube).

V. CONCLUSION

According to our study, the double light Compact TD is effective in severe neonatal jaundice caused by indirect bilirubine while neonatal jaundice is often occurred and its dangerous complication is kernicterus.

The bidirectional phototherapy Compact TD is durable longevity. The cost is much cheaper than Biliblanket device. It can be produced in local country and equipped nationwide in order to intensive treatment in severe neonatal jaundice. It can also reduce the percentage of blood exchange and contribute into anti-kernicterus effectively in newborn babies.

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