The Role of Intensive Phototherapy Device in Treatment of Neonatal Jaundice

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Abstract

Objectives: To assess the effectiveness of intensive phototherapy in treatment of neonatal jaundice and elimination of exchange transfusion.

Methods: The case control study was conducted at El-Galaa Teaching Hospital, from October 2014 to April 2015, and comprised 200 newborns with indirect hyperbilirubinaemia. The 100 subjects were treated with Bilisphere 360 (Bilisphere group) compared with 100 who had been treated with conventional phototherapy (control group). Both groups were subjected to complete clinical evaluation and laboratory investigations.

Results: Bilisphere 360 decreased the need for exchange transfusion to 16 (16.0%) neonates of the Bilisphere group versus 66 (66.0%) of the control group (p < 0.001); decreased the level of serum bilirubin as exchange transfusion [5.7mg/dl (22.5%) in the subjects vs. 6.0mg/dl (22.8%) in the controls]; shortened the duration of phototherapy (1.7 days in the subjects, vs. 4.1 days in the controls; p < 0.001).

Conclusion: The use of intensive phototherapy (Bilisphere 360) in the treatment of indirect pathological hyperbilirubinaemia is very effective in lowering total serum Bilirubin when its level is within 2-3mg/dl (34-5umol/l) of the exchange transfusion level. Bilisphere 360 has succeeded in reducing exchange transfusion and duration of phototherapy.

Key Words: Exchange transfusion – Neonatal jaundice – Intensive phototherapy.

Introduction

THERE is no doubt that neonatal jaundice is one of the most common diagnoses in the neonatal period; it is estimated to occur in 60% of term newborns in the first week of life. In rare instances, the Total Serum Bilirubin (TSB) reaches levels that can cause kernicterus, a condition characterized by bilirubin staining of neurons and neuronal necrosis involving primarily the basal ganglia of the brain and manifested in athetoid cerebral palsy, hearing loss, dental dysplasia, and paralysis of upward gaze [1].

The most common cause of jaundice in the first 24 hours of life due to Haemolytic Disease of Newborn (HDN) is Rhesus (Rh) haemolytic disease [2] followed by ABO incompatibility that may cause elevated levels of bilirubin and anaemia but less severe than Rh haemolytic disease [3].

For preventing the kernicterus and other complications of hyperbilirubinaemia, jaundice should be managed by phototherapy or Exchange Transfusion (ECT) [4]. Phototherapy is a useful method because it is easily available and devoid of all complications of double volume ECT. The efficacy of phototherapy depends on the dose and wave length of light used and the surface area exposed [5]. Despite ECT being an effective method in decreasing TSB level after failing phototherapy, ECT remains an invasive procedure with associated morbidity and mortality. ECT should be considered only when the benefit of decreasing TSB level to prevent kernicterus outweighs the complications associated with the procedure [6].

Intensive phototherapy is a new modality that can rapidly decrease TSB below the threshold for ECT [7]. The current study aimed at assessing the effectiveness of intensive phototherapy in lowering the level of bilirubin in neonates and reducing the need for ECT and the duration of phototherapy.

Patients and Methods

The prospective study was conducted from October 2014 to April 2015 and comprised all neonates with indirect hyperbilirubinaemia near the level of ECT who were admitted to the Neonatal
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Intensive Care Unit (NICU) of Elgalaa Teaching Hospital, Egypt, and treated with intensive phototherapy (Bilisphere 360). These neonates were compared with a group who had been treated with conventional therapy. Premature newborns (gestational age <33 weeks), cases with direct hyperbilirubinaemia, critically-ill newborns, those with multiple congenital anomalies and inborn errors of metabolism were excluded.

All cases were subjected to detailed perinatal history, including maternal illness, mode of delivery, one and five minutes Apgar scores, history of cyanosis or convulsion, gestational age, weight, gender and age at admission. Comprehensive clinical examination was performed to evaluate general condition and exclude congenital anomalies.

Hundred patients were treated with intensive phototherapy (Bilisphere 360 phototherapy system) which consisted of a chamber containing 16 blue TL 20W/52 fluorescent tubes arranged cylindrically. The baby was laid on a gauze hammock suspended along the centre of the chamber which was illuminated on all sides. The historical control group had received conventional phototherapy. It comprised of two phototherapy units with blue light and was placed 45cm above the neonate. Hyperbilirubinaemia Guidelines of the American Academy of Paediatrics (AAP) 8 were applied at our NICU for the management of admitted newborns during the study period.

Total and direct serum bilirubin, Complete Blood Count (CBC), reticulocyte count, blood group and Rh of mother and neonate were measured for all cases on admission. All of the studied neonates received phototherapy immediately after admission and TSB was measured 6 hours after the initiation of phototherapy. Phototherapy was administered continuously, except during feeding, nursing care and blood sampling. The infants were treated naked except for diapers and eye pads. During phototherapy, total bilirubin was measured at variable intervals on the basis of days of life, gestational age and risk factors. Infants with unresponsive hyperbilirubinaemia underwent urgent ECT using fresh blood type O Rh negative, double the blood volume of the baby (2 X 85ml/kg) [8]. The outcome was assessed and recorded.

The collected data had been analysed and tabulated using SPSS system. The graphs were done using Microsoft Excel 2010. Numerical data was summarised using means and standard deviations. Categorical data was summarised as percentages. Comparisons between categorical data were done using the chi-square test to measure the effect of time on bilirubin and differences between groups [9]. All p-values were two-sided. p<0.05 was considered significant.

Results

Of the 200 infants in the study, the Bilisphere group consisted of 100 (50.0%) newborns (66 (66.0%) males and 34 (34.0%) females) while the control group consisted of 100 (50.0%) newborns (62 (62.0%) males and 38 (38.0%) females).

Both groups were comparable regarding their gender and positive family history of jaundice. The commonest cause for hyperbilirubinaemia in both groups was ABO incompatibility (58 (58.0%) cases vs. 46 (46.0%) controls p=0.499). There was no statistically significant difference between the two groups as regards gestational age, birth weight, onset of jaundice and age on admission. Regarding the baseline laboratory data, including TSB, haemoglobin level, haematocrit, total leucocytic count, platelet count and reticulocyte count, there were no significant statistical differences between the study and control groups (Table 1).

Table (1): Demographic, laboratory data, duration of phototherapy and frequency of exchange transfusion in both groups.

<table>
<thead>
<tr>
<th></th>
<th>Bilisphere group (N=100)</th>
<th>Control group (N=100)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Gestational age (wks)</td>
<td>36.2</td>
<td>1.5</td>
<td>36.30</td>
</tr>
<tr>
<td>Birth weight (Kg)</td>
<td>2.8</td>
<td>1.8</td>
<td>2.9</td>
</tr>
<tr>
<td>Onset of jaundice (days)</td>
<td>2.6</td>
<td>0.9</td>
<td>2.4</td>
</tr>
<tr>
<td>Age on admission (days)</td>
<td>4.9</td>
<td>1.7</td>
<td>5.2</td>
</tr>
<tr>
<td>Total serum bilirubin (mg/dl)</td>
<td>25.32</td>
<td>1.97</td>
<td>26.35</td>
</tr>
<tr>
<td>Haemoglobin (g/dl)</td>
<td>12.4</td>
<td>1.1</td>
<td>12.7</td>
</tr>
<tr>
<td>Haematocrit</td>
<td>39.1</td>
<td>6.2</td>
<td>38.2</td>
</tr>
<tr>
<td>Platelets</td>
<td>275.2</td>
<td>105.6</td>
<td>273.8</td>
</tr>
<tr>
<td>White blood cells</td>
<td>12.75</td>
<td>12.97</td>
<td>11.59</td>
</tr>
<tr>
<td>Reticulocytes</td>
<td>8.39</td>
<td>3.04</td>
<td>8.38</td>
</tr>
<tr>
<td>Duration of phototherapy in days (mean ± SD)</td>
<td>1.76</td>
<td>0.51</td>
<td>4.1</td>
</tr>
</tbody>
</table>

Retics: Reticulocytic Count. *: Significant.
On comparing the decline rate in TSB between the cases and the controls, no statistically significant difference was detected after 6 hours (5.7mg/dl (22.5%) for cases vs. 6.0mg/dl (22.8%) for controls; \( p=0.05 \)). Second assessment at 12 to 48 hours showed a statistically significant difference in the rate of decline (6.6mg/dl (21.3%) for cases vs. 3.5mg/dl (11.4%) for controls, \( p=0.05 \)). The overall rate of decrement of bilirubin from admission to 48 hours was significantly greater in the cases than the controls (48.6% vs. 36.1%; \( p<0.05 \)) Fig. (1).

![Fig. (1): Bilirubin decline rate in both groups.](image)

The Bilisphere group showed a shorter duration of phototherapy with a mean of 1.7 ± 0.5 days when compared with the control group which showed a mean of 4.1 ± 0.71 days, which in turn proved to be statistically highly significant (\( p<0.001 \)). Besides, 16 (16.0%) neonates in the Bilisphere group needed ECT versus 66 (66.0%) in the control group (\( p=0.001 \)).

**Discussion**

Neonatal jaundice is one of the most common conditions needing medical attention in newborn babies. About 60% of term and 80% of preterm babies develop jaundice in the first week of life, and about 10% of breast fed babies are still jaundiced at age 1 month. Neonatal jaundice is generally harmless, but high concentrations of unconjugated bilirubin may occasionally cause kernicterus (permanent brain damage) [10]. High-intensity phototherapy has been shown to be effective in rapidly decreasing TSB levels. Neonatal phototherapy device designed to maximise the irradiance and treatment area coverage [11]. The current study evaluated its effectiveness on 100 newborns with severe indirect hyperbilirubinaemia and compared it to a control group consisting of 100 neonates treated with conventional phototherapy. Both groups were comparable regarding all of the pre-treatment demographic, clinical and laboratory parameters.

Intensive phototherapy (Bilisphere 360) was more effective in decreasing bilirubin levels; the overall bilirubin decline rate from admission to 48 hours was significantly greater in Bilisphere group than the controls (\( p<0.05 \)). The results are in agreement with previous reports proving that serum bilirubin levels in newborns may be controlled more effectively with high-intensity phototherpy than with conventional modalities [12].

In comparing the bilirubin decline rate between Bilisphere group and the control group, it was found that there was no statistically significant difference between them from admission to 6 hours. However, a statistically significant difference between the two groups regarding bilirubin decline rate from 6 hours to 48 hours was obvious. This may be explained by the high percentage of cases that underwent ECT in the control group during the 1st 6 hours of therapy.

Centre National de Reference en Haemobiologie Perinatale [13] studied the time effect of Bilisphere 360 intensive phototherapy on blood levels of TSB over 20 hours treatment in jaundiced newborn, concluding that this device allows an average decrease in TSB levels of 15%, 26% and 37% at hours 4, 10 and 20 exposure respectively. A study [14] reported decrease in the TSB levels after 6 hours of high-intensity phototherapy to be 23%, which was almost the same rate of reduction as in the present study (24.9% after 6 hours).

Bilisphere 360 phototherapy shortens the duration of hospital stay which reflects a higher cost-effect value as the shorter duration of treatment means that more patients can be treated with fewer phototherapy units. Secondly, decreasing the duration of phototherapy may lead to a shorter length of hospitalisation. This would also mean considerably less separation from the mother and less interruption of breast feeding. Previous studies reported a higher rate of bilirubin decline and a shorter duration of action of intensive phototherapy devices when compared with conventional phototherapy [15-17]. In the current study, the Bilisphere group showed a significantly shorter period of hospital stay and duration of phototherapy compared with the control group (\( p<0.001 \)).

Concerning the need for ECT in Bilisphere group, only 16 (16.0%) out of 100 cases required ECT and this was much lower than the control
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group [66 (66.0%) out of 100 cases]. Our results met with the previous reports [14,18].

Conclusion:

The use of intensive phototherapy device in treatment of neonatal jaundice is very effective in lowering TSB. Bilisphere 360 is effective in reducing hazards of exchange transfusion. Long-term follow-up trials should be performed to evaluate the long-term effects in newborn infants with severe indirect hyperbilirubinaemia who are treated with this device [19].

Acknowledgement:

May God bless all staff in our NICU.

References

الملخص العربي

يعد ارتفاع نسبة الصفراء في الأطفال حديثي الولادة من المشاكل كثيرة الخطورة ولكن الارتفاع الشديد قليلاً ما يحدث ولكنه عندما يحدث قد يؤدي إلى ترسب هدة الصباغة في خلايا الدم مما يسبب في الإعاقة الذهنية لهؤلاء الأطفال. النشأة العلاج السريع لكي لا القدرة على تقليل هذه المخاطر في بعض الأطفال. تتعامل الصفراء عادةً مع علاج الصباغة التقليدي والتي قد تفشل بفعالية في خفض نسبة الصفراء بالدم مما يضстрنا إلى عمل تغيير الدم والذي لا يظهر من حدوث آثار جانبية معه، وقد أظهرت الدراسات الحديثة أن استخدام علاج الصباغة المكلف واعداً في علاج مثل تلك الحالات.

يتوقف مدى فعالية علاج الصباغة على الطول المائي للفضوء ومساحة الوعاء المعرض للضوء، وأن مقياس فعالية علاج الصباغة المكلف هو الانخفاض الكبير في عمليات تدليم الدم.

والهدف من هذه الدراسة هو تقييم فعالية علاج الصباغة المكلف (Bilisphere) في الحد من الحاجة إلى تغيير الدم، ومدة العلاج بالضوء، والمقارنة بين كفاءة تغيير الدم والعلاج الصباغة المكلف في خفض مستوي الbilirubin في الأطفال حديثي الولادة الذين يعانون من الارتفاع الشديد في نسبة الصفراء.

طريقة البحث: يتم فحص عدد 100 طفل حديث الولادة مصاب باليركان الدمري ومختبر العمر الرحمي أو أقرب إلى الامتصال وكذلك من عمرهم الرحمي 23 أسبوع بنسبة تقرير من مستوى تدليم الدم والذين تم حجزهم بمستشفي الجلاء التعليمي وتم تعيينهم للعلاج الصباغة المكلف (120 جرعة) وتم مقارنتهم مع مجموعة من الأطفال حديثي الولادة الذين تم علاجهم بالعلاج الصباغة التقليدي.

نتيجة البحث: خصص إلى أن 360 (60٪) بقل الحاجة إلى تغيير الدم (61٪ مقابل 66٪) وكان الفرق في الدالة الإحصائية أقل من 0.001.

ويقصر مدة العلاج الصباغة (7.6 مقابل 1.4 يوم وكان الفرق في الدالة الإحصائية أقل من 0.001).