Pilot study of home phototherapy for neonatal jaundice monitored in maternity ward during the enforced Italy-wide COVID-19 national lockdown

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Abstract

Purpose In Italy, where neonatal jaundice treatment is required, it is largely carried out in hospitals. However, it is possible to safely administer home phototherapy (HPT). We report our pilot centre's experience of HPT and its potential benefits during the COVID-19 enforced national lockdown.

Methods This is an observational study performed at the Policlinic Abano Terme, a suburban hospital that covers a large catchment area near the Euganean Hills in Northeast Italy with around 1,000 deliveries per year. HPT was started after regular nursery discharge, and the mothers brought the neonates back to the hospital maternity ward each day to check infants' bilirubin levels, weight, and general state of health, until it was deemed safe to stop. The efficacy of HPT in bilirubin reduction, hospital readmission rates, and parental satisfaction were evaluated.

Results 30 infants received HPT. In 4 of these infants HPT was associated with total serum bilirubin (TSB) between 75th and 95th percentile (high- intermediate-risk zone) and in 26 infants HPT was associated with TSB >95th percentile (high-risk zone) of the Bhutani nomogram. Among these 30 infants, 27 (90%) completed the HPT with a progressive decrease of TSB levels with 4 neonates requiring a second course and 3 infants requiring a third course of 24-hour HPT. 3 (10%) neonates failed HPT and were readmitted after one 24-hour phototherapy course. No abnormalities of breastfeeding, body weight (defined as >10% decrease), temperature, nor COVID infections were detected following HPT consultation in the neonatal ward. Home treatment efficacy with varying degrees of parental satisfaction occurred in all but 3 cases that involved difficulties with the equipment and inconsistent lamp manipulation practices.

Conclusions Our pilot study suggests that HPT for neonatal jaundice can be carried out effectively and with parental satisfaction as supported by daily back bilirubin monitoring in the maternity ward during the enforced COVID-19 national lockdown in Italy.

Author's Summary

What is known

- No high-quality evidence is currently available to support or refute the practice of phototherapy in patients' own homes.

What is new

- Phototherapy can be delivered at home in a select group of infants and could be an ideal option if parents are able to return with their infants to the hospital maternity ward for daily follow-up.

It can be as effective as inpatient phototherapy and potentially helps in delivering family-centred care.

- It is well-received and viewed positively by parents during COVID-19 pandemic.

Introduction

Phototherapy is the most widely used form of therapy for the prophylaxis and treatment of neonatal hyperbilirubinemia in the first days of life [1]. It is now possible to safely administer home phototherapy (HPT) for jaundice in patients' own homes in several high-income countries as an alternative to hospital-based phototherapy [2,3]. The recent Chu and al. metanalysis [4], including a total of 259 neonates, suggests that home-based phototherapy is even more effective than hospital-based phototherapy in the treatment of neonatal jaundice. Clinical advantages of home-centred phototherapy include reduced cost, avoidance of parent-infant separation to decrease maternal psychoemotional distress and increase mother-infant bonding, breastfeeding success, and parental satisfaction [5].

However, routine in-hospital and at-home neonatal jaundice treatment/surveillance and follow-up strategies have become challenging in the era of COVID-19 owing to rigorous quarantine protocols and other infectious control measures undertaken to decrease the spread of the virus [6]. In response to COVID-19, hospitals changed their policies and protocols regarding perinatal care, cancelling birth center tours as well as barring nonessential visits to the laboring mom, the delivery room, and the postpartum units. This has the effect of increasing stress stemming from isolation, anxiety over disease status, and apprehension in response to new maternal responsibilities, making lockdown in the hospital challenging for maternal mental health [7]. Of note, the hospital where this study took place, the Policlinic Abano Terme is located in an industrialized area of Northeast Italy, which borders the municipalities of the COVID-19 Euganean Hills 'hotspot.' It supports about 1,000 births per year among pregnant women with low and late fertility, good socioeconomic status, employment rate, and with advanced educational levels [7].

In this context, the treatment of hyperbilirubinemia at home may provide a useful way to alleviate postpartum maternal psychoemotional distress in times of widespread lockdown such as the enforced Italy-wide COVID-19 national lockdown [8].

We developed an HPT pilot program for convenient treatment of neonatal hyperbilirubinemia, which was set up in 2021 during the COVID-19 pandemic. This pilot program was staffed by a maternity nursing and consultant team that would monitor bilirubin levels from the infants' backs for 7 days after the start of HPT. The program was designed with prevention of COVID-19 infection specifically in mind. We report on our centre's experience of this HPT service and analyse the outcomes for infants treated at home. The primary outcome was to evaluate the effectiveness of HPT as represented by the rate of fall of bilirubin, duration of HPT, and hospital readmission rates, while paying close attention to the prevention and control of COVID-19 infection. The secondary outcome was evaluation of parental satisfaction.

Patients And Methods

We conducted a pilot study of home phototherapy (HPT) for neonatal jaundice in the context of restrictive strategies adopted for maternity services in Italy during the COVID-19 pandemic. The analysis was

conducted between June 1st and December 31st, 2021, at the Policlinic Abano Terme, Abano Terme, Italy. Policlinic Abano Terme Ethics Committee consent was obtained.

Pregnant women were first given information about the pilot study at the antenatal healthcare centre and again pre-discharge when they gave informed consent to HPT via signature. In accordance with clinical routines, two-step delivery, cord clamping *'not earlier than one minute'* [9], and short hospitalization were the clinical standard procedures in the hospital before and during the study. During their stay, newborns roomed-in with their mothers, who were encouraged to demand-feed them; they received complementary formula milk if breast milk intake was judged to be insufficient. In our maternity ward, at 48 hours of age, capillary heel blood samples for total serum bilirubin (TSB) levels and complementary hematocrit (Hct) levels are obtained by a midwife or neonatal nurse in conjunction with routine metabolic screenings. Healthy near-term and term infants are typically discharged on day 2 taking into account the hour-specific nomogram developed by Bhutani to predict the subsequent hyperbilirubinemia risk zones [10]: 1. TSB level < 75th percentile (low-risk or low–intermediate-risk zone); 2. TCB level between 75 and 95th percentile (high–intermediate-risk zone); and 3. TCB level > 95th percentile (high-risk zone): the risk of subsequent significant hyperbilirubinemia is very high.

The eligibility criteria for HPT included near-term and term infants, body weight decrease of less than 10%, no Rh or major ABO isoimmunisation as would be indexed by a positive direct antiglobulin test, no IUGR and serious congenital malformations, and no syndromes or other congenital diseases that could affect the outcome measures. In addition, to be eligible for HPT, parents needed to be able to converse in Italian, follow instructions regarding the use of portable HPT equipment, have a satisfactory home environment, be able to return to the hospital for follow-up each day after discharge until it was deemed safe to stop, and have no close contact history with any COVID-19 infected person [11], including family members, caregivers, and visitors.

The neonatal phototherapy lamp uses latest LED technology to produce blue therapeutic light (peak 460 nm) transmitted through a flexible fiber optic cable to a lightening element of small dimensions (area pad efficacy 110x160 mm) placed in contact with the skin of the neonate (maximum irradiance of 45 μW/cm2 /nm, according to AAP 2004 Guidelines) [12). The compact design of this wireless device (3 kg) allows executing the therapy in a straightforward fashion for home care.

Parents of neonates fulfilling the inclusion criteria were taught how to use the phototherapy equipment, and again informed about the pilot study, the potential harm of hyperbilirubinemia, the importance of bilirubin monitoring, the availability of HPT, and methods for assessing a neonate's condition. In addition, detailed information about COVID-19 and prevention strategies was provided together with full availability of a telephone call or virtual appointment after infants were discharged home. Signed written consent for HPT use was obtained from parents, who also received a feedback sheet to complete at the end of treatment.

The neonatal staff reviewed infants referred from HPT every day, evaluating COVID-19 risks (for the infants as well as their families and caregivers) and the occurrence of inadequate breast milk intake. The

staff also measured the body temperature of the infants routinely and performed capillary heel TSB and Hct. Once TSB level was below the treatment threshold (< 75th percentile, low-risk or low–intermediate-risk zone) of the Bhutani nomogram [10] across two consecutive samples, HPT was stopped, and a rebound level was taken 24 hours later. If satisfactory, the device and feedback form were collected. The feedback form consisted of two closed question to determine the personal experiences and opinions of parents about the HPT service through open questions: 1. *'Were there any disadvantages to having HPT?'*, structured to allow for a 'yes' or 'no' response; and 2. *'Overall parental experience of HPT service'*, structured as Good, Neutral, and Bad experiences, with a space provided for additional comments if needed.

Statistical analysis. We included in the descriptive analysis all infants who received HPT. Patient characteristics and outcome measures were summarized with a descriptive purpose using mean and standard deviation (continuous data) or frequencies and percentages (categorical data). Data were presented as mean ± SD for normally distributed continuous data and number and % for continuous data. Statistical analysis was performed using R 3.3 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Participants were recruited in a 6-month period, from June to December 2021 during the COVID-19 pandemic. Of the cohort of 462 infants, 30 (6.5%) met the HPT inclusion criteria and received the allocated HPT intervention. Mothers were 32.10 ± 5.64 years old and 19 (63.3%) were nulliparous. Pregnancy was complicated in 8 (26.7%) by gestational diabetes in 5 (16.7%) treated with diet in 2 and diet and insulin in 3, and by oligohydramnios (1 case), polyhydramnios (1 case), and cholestasis (1 case). Most, 26 (6.6%) delivered vaginally, including 1 (3.33%) neonate instrumentally delivered by kiwi. 4 (13%) were delivered via cesarean. Pre-discharge, on the second day postpartum, 16 (53.3%) were feeding exclusively and 14 (46.7%) were mixed feeding.

The anthropometric and clinical features of HPT neonates are included in Table 1.

Table 1
Characteristics, rate of bilirubin fall, and duration of phototherapy for infants treated with home phototherapy.

Neonates	**30/462 (6.49%)**		
Gestational age in weeks	39.21 ± 1.37		
Birth weight in g	3,401 ± 470		
Cord blood gas analysis investigations:			
Bilirubin, mg/dL	3.37 ± 1.23		
pH	7.33 ± 0,58		
Hct, %	51.77 ± 4.63		
Gender	22 (73.33)		
Male			
At discharge on day 2:			
TSB baseline, mg/dL	12.05 ± 1.41		
Hct	54.57 ± 6.59		
Weight loss, %	-6.56		
Breast feeding	16 (53.33)		
Formula	0		
Mixed feeding	14 (46.67)		
	The Bhutani risk groups		
	< 75th centile	75th to 95th centile	> 95th centile
TSB risk zone at phototherapy initiation	0	4 (13.33)	26 (86.67)
Age at phototherapy initiation in days	0		
2nd		4	4
3rd			10
4th			8
> 4th			1

Data were expressed as Mean ± SD or Number (%).

Neonates	30/462 (6.49%)		
Duration of phototherapy in days	0		
1 day		1	10
2 days		3	9
3 days			4
Readmissions	0	1	2
Age in days			
2nd			
3rd			3
4th		4	
> 4th			
Data were expressed as Mean ± SD or Number (%).			

Of the cohort of 462 infants, 30 (6.49%) met the inclusion criteria. At discharge on the second day of life, TSB was 12.05 ± 1.41 mg/dL, Hct 54.57 ± 6.59%, and weight loss was − 6.56%.

HPT was initiated in 4 neonates with TSB between 75th and 95th percentile (high- intermediate-risk zone) and in 26 neonates with TSB > 95th percentile (high-risk zone) of the Bhutani nomogram [10]. Among these neonates, 27/30 (90%) completed the HPT with a progressive decrease of TSB levels, but 4 neonates required a second course and 3 a third course of 24 hours HPT. 3/30 (10%) neonates failed HPT and were readmitted after one 24-HPT course.

No abnormalities of breastfeeding, body weight control (> 10% decrease) or temperature, nor COVID infections, were detected post-HPT consultation in neonatal ward. Overall parental experience of home phototherapy service is reported in Table 2.

Table 2
Overall parental rating of home phototherapy service.

Were there any disadvantages to having HPT?	**Number (%)**
Yes	3 (10)
No	27 (90)
Overall parental experience of HPT service:	
Good	24 (80)
Neutral	4 (13.33)
Bad	2 (6.66)

HPT efficacy with varying degrees of parental satisfaction was reported in all but 3 cases, which involved difficulties with the equipment and inconsistent lamp manipulation practices. The responses to the initial questions '*Were there any disadvantages to having HPT?'* in the questionnaire indicated high levels of satisfaction (27/30, 90%) with the service. Additionally, parental satisfaction regarding *'Overall parental experience of HPT service'* was good in 24/30 (90%), neutral in 4/30 (13.33%) and bad in 2/30 (6.66%).

In the second part of the questionnaire, in the space provided for additional comments, when parents of neonates readmitted for in hospital phototherapy were asked about the overall experience of the HPT service, the most common themes in the responses were concerns about being in the home environment with an at-risk neonate, finding HPT too stressful, and experiencing difficulties with the equipment.

Discussion

Owing to rigorous quarantine and infectious control measures taken in maternity wards during the COVID-19 outbreak, management strategies of neonatal jaundice, almost universal in newborn infants, have become challenging when it comes to providing holistic mother-infant dyad-centred care [3]. This pilot study suggests that HPT for neonatal jaundice can be effectively carried out/administered despite the hospital restrictions imposed by COVID-19 waves, with high levels of parental satisfaction with the service. Having parents return with their neonates on a daily basis for follow-up with frontline clinicians in the neonatal ward, who collect relevant information, is worth consideration as a safe and feasible strategy for determining whether to continue or discontinue phototherapy treatment. Such a strategy works in favour of maternal mental health, bonding, and breastfeeding success [5].

HPT has been available in high-income countries for more than 25 years as an alternative to phototherapy in the hospital [3]. Jaundice treatment at home has potential advantages over treatment in the hospital. Disruptions to breastfeeding and parent–infant bonding are minimized at home, whereas in some hospitals, nursery infants may be moved out of the mother's room for phototherapy, possibly contributing to maternal postpartum psychoemotional distress [4, 5]. Traditional treatment at home may

also be more convenient for families, and less costly than hospitalization [4, 5]. However, HPT use among pediatric providers varies and these assumptions may be related to a paucity of evidence, given that few studies have examined the use of home phototherapy. These studies had small sample sizes or restricted eligibility for HPT, and were carried out with differing follow-up strategies, making it harder to draw meaningful conclusions across studies. Of note, a 2014 Cochrane Review by Malwade and Jardine intending to compare home and hospital-based phototherapy in newborns with non-haemolytic jaundice could not be performed due to insufficient evidence to support or refute the practice of home-based phototherapy for non-haemolytic jaundice in infants more than 37 weeks gestational age [5].

To our knowledge, this is the first cohort study that evaluated the effectiveness of HPT in the current COVID-19 pandemic, based on post-phototherapy neonatal clinical status assessed frontline in the neonatal ward together with the lactation skills of the mothers. While a comprehensive economic analysis was outside the scope of this pilot observational study, baseline data from our combined home and hospital service demonstrated the potential efficiency of delivering care in this manner, so as to give people more personalised, supported, and connected care in their own homes, thereby reducing the need for postpartum hospital visits. Although HPT is not suitable for all infants and families, it may be a convenient alternative to IPT as it resulted successful in 90% of jaundiced infants in this study. Among these, ~ 15%of infants required more than one session of HPT and 10% required readmission for IPT due to non-compliance with the treatment protocol in the presence of a high-bilirubin risk. Chang and Waite reported a readmission rate of 1.9% [3]. However, they used different treatment thresholds and possibly limited non-adherence to the protocol by having a pediatric nurse travel to the home of the neonates to set up the HPT equipment, weigh the infant, check the TSB level at least daily, and provide lactation support as needed. Reducing readmission rates help reduces maternity bed occupancy in pediatric wards, consequently freeing beds for acutely unwell neonates [13].

Given that this a pilot study, it is unable to compare the features, duration, and efficacy of our portable fiber optic phototherapy to other modalities to administer phototherapy in-hospital or at home which may vary in the particular wavelength of the light used and by the intensity of the light source. There are also several important caveats to consider in evaluating its effectiveness, as it relies on parental compliance and confidence in use of equipment without constant supervision. Moreover, the hour-specific nomogram developed by Bhutani et al. to predict hyperbilirubinemia risk is quite different from AAP and NICE treatment thresholds [10, 12, 15]. Whereas NICE guidelines offer gestation-specific thresholds at weekly intervals up to 38 weeks, the AAP guidelines offer a composite guideline for infants ≥ 35week. In addition, although HPT may seem a convenient alternative to in hospital phototherapy, it is not suitable for infants with very high bilirubin levels or families lacking the ability to return to the hospital daily for follow-up. Nevertheless, measurements of parental satisfaction using appropriately designed and delivered surveys may provide robust quality of care measures and can help improve services and their delivery [15, 16]. Of note, in our cohort, parental feedback on HPT in the questionnaire indicated high levels of satisfaction. Similarly, Jackson et al. reported that all parents were highly satisfied that all information concerning the HPT had been supplied to them [17]. Eighty-five per cent found no disadvantages with HPT, but some concerns were expressed. The two main disadvantages were

equipment issues, as well as the baby not settling in the HPT unit. A few parents found being responsible for their baby's care without constant medical supervision anxiety-inducing and thus did not feel entirely confident. This is relevant, considering that a minority of parents in our pilot study did experience some difficulties with the equipment, such as struggling to put the slipping phototherapy pad on their infants during treatment (1 patient), and non-adherence to protocol (2 patients). Therefore, it would be worthwhile sharing these few reported difficulties, especially equipment issues, with families in advance along with suggestions as to how these difficulties can be overcome, which could further reduce the parental discomfort and anxiety HPT might produce.

In conclusion, this pilot study suggests that HPT for neonatal jaundice can be effectively administered in a select group of infants and also that is viewed very positively by families The study also proves that HPT can be incorporated in clinical practice during the COVID-19 pandemic. It enables mothers and their infants to remain at home receiving family support as hospital-based phototherapy can be challenging for maternal mental health, breastfeeding initiation, and bonding. However, inherent limitations of a pilot studies do not make it possible to measure the exact efficacy, satisfaction difficulties, and costs of HPT.

Abbreviations

HPHT, home phototherapy. TSB, total serum bilirubin.

Declarations

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Author contributions statement VZ helped design the study; was responsible for staff training, study management, and data collection; and took part in data analysis and manuscript writing. PG and LS helped design the study; advised on staff training, study management, and data collection; and took part in data analysis and manuscript writing. PM, GG and CMR helped design the study; advised on staff training, study management, and data collection and analysis; and took part in manuscript writing. AS helped design the study; advised on staff training, study management, and data collection; and took part in data analysis and manuscript writing. GS is guarantors for the study.

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