PREDICTION OF NEONATAL JAUNDICE BY STUDY OF CORD BLOOD BILIRUBIN AND SERUM BILIRUBIN AT 24 HOURS OF LIFE

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ABSTRACT

BACKGROUND

Jaundice is yellowish discolouration of the skin, the mucous membranes or the eyes. It is caused by high levels of the chemical bilirubin in blood, a by-product of destruction of old red blood cells. A newborn baby's liver is not fully matured, so jaundice is common during a baby's first few days of life¹ Since bilirubin is potentially toxic to the central nervous system, early detection and appropriate management of neonatal jaundice (NNJ) is of paramount importance². Hence early detection of neonatal jaundice is an important issue. The present study was conducted to find out the critical value of serum bilirubin in the cord blood and at 24 hrs. in predicting the subsequent development of hyperbilirubinemia in healthy newborn babies.

METHODS

Cord blood sample and blood sample at 24 hours were collected from all 200 babies. After 24 hours and up to 5th post-natal day, blood samples for serum bilirubin estimation were taken from those babies who were clinically suspected to be having jaundice.

RESULTS

Total serum bilirubin > 2.3 mg/dl has sensitivity of 75.3% (95% CL 65.2% to 83.6%), specificity of 81.3% (95% CL 72.6% to 88.2%), positive predictive value of 77.8 (67.8 to 85.9), negative predictive value of 79.1% (70.3% to 86.3). The diagnostic ability of TSB at 24 hrs. to predict the need for phototherapy shows that TSB > 5.3 mg/dl, has sensitivity of 87% (95% CL 78.5% to 93.2%), specificity of 67.3% (95% CL 57.5% to 76%), positive predictive value of 69.8 (60.6 to 78.0), negative predictive value of 85.7 (87.5 to 85.4).

CONCLUSIONS

The time to reach maximum total serum bilirubin level after birth is 3rd postnatal day in our study. So, the baby in need of phototherapy has to be identified earlier to 3rd postnatal day. A total serum bilirubin level prior to 3rd day which can predict the later need of photo-therapy in a given baby will have clinical utility. The optimum cut off value of total serum bilirubin in cord blood which can predict the need for phototherapy is > 2.3 mg/dl and value of total serum bilirubin at 24 hrs which can predict the need for phototherapy is > 5.3 mg/dl. So, these at-risk babies should be observed carefully for the need of phototherapy.

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BACKGROUND

Jaundice is yellowish discolouration of the skin, the mucous membranes or the eyes. Jaundice comes from the French word "Jaune" which means yellow. It is also known as icterus. When a baby has jaundice, either too much bilirubin is being produced or the liver does not get rid of it quickly enough. A newborn baby's liver is not fully matured, so jaundice is common during a baby's first few days of life.¹ Since bilirubin is potentially toxic to the central nervous system, early detection and appropriate management of neonatal jaundice (NNJ) is of paramount importance.² Hence early detection of neonatal jaundice is an important issue.

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Early discharge of healthy term newborns after delivery has become a common practice, because of medical and social reasons and economic constraints.³ Thus, the recognition, follow up and early treatment of jaundice has become more difficult as a result of early discharge from the hospital. The prevention of bilirubin encephalopathy is based on the detection of infants at risk of developing significant hyperbilirubinaemia and early treatment of this condition. Therefore, it is difficult to predict which infants are at increased risk for significant and relatively late hyperbilirubinaemia.⁴ And as such, from the obvious need to design and implement a follow up programme, the present study was conducted to find out the critical value of serum bilirubin in the cord blood and at 24 hrs in predicting the subsequent development of hyperbilirubinemia in healthy newborn.

Epidemiology of Neonatal Jaundice

Neonatal hyperbilirubinemia is a commonly diagnosed phenomenon in the Neonate with potential serious consequences. Recent studies have estimated incidence of 6% to 10% in the general population.^{5,6} Jaundice is the most

common condition in newborns that requires medical attention. About 50% to 70% of term babies and 80% of preterm babies develop jaundice in the first week of life.⁷ Jaundice usually appears 2 to 4 days after birth and resolves 1 to 2 weeks later without the need for treatment. The incidence of hyperbilirubinaemia varies. A study in the UK and Ireland showed an incidence of severe hyperbilirubinaemia (Maximum unconjugated serum bilirubin ≥ 510 micro-mol/L [29.8 mg/dL]) of 7.1 per 100,000.⁸ A study in Denmark showed an incidence of extreme hyperbilirubinaemia (492 micro-mol/L [28.8 mg/dL]) of 25 per 100,000.⁹ In the US, severe hyperbilirubinaemia (Total serum bilirubin >95th percentile) occurs in 8% to 9% of neonates during the first week; approximately 4% after 72 hours of life.¹⁰

Risk Factors for Hyperbilirubinemia in Newborns^{11,12,13}

Maternal Factors

- Blood type ABO/Rh incompatibility.
- Breast feeding.
- Diazepam, Oxytocin.
- Ethnicity: Asian, Native American.
- Maternal illness: Gestational Diabetes.

Neonatal Factors

- Birth trauma: cephalohematoma, cutaneous bruising.
- Instrumented delivery.
- Drugs: Sulfoxazole, Erythromycin.
- Excessive weight loss after birth.
- Infections: TORCH.
- Infrequent feedings.
- Male gender.
- Polycythaemia.
- Prematurity.
- Previous sibling with Hyperbilirubinemia.

Aims and Objectives

1. To identify the post-natal age at which the total serum bilirubin {T.S.B.} reaches its peak.
2. To observe differences in T.S.B. between babies that needed phototherapy and did not need it, from birth to five days after birth.
3. To find the phototherapy need predictive ability of T.S.B. values those are lower and earlier to the peak T.S.B.

METHODS

Study Design

Longitudinal comparative study.

Study Period

From January 2013 to February 2014 with a total period of 13 months.

Study Setting

Study was conducted at Dr. Pinnamaneni Siddhartha Institute of Medical Sciences, Gannavaram, Vijayawada.

Sample

200 newborn babies born in Dr. PSIMS & RF.

Inclusion Criteria

Healthy new born babies born in our hospital from June 2011 to August 2013.

Exclusion Criteria

Sick babies are excluded. Any newborn requiring admission in our newborn intensive care unit like.

1. Preterm babies <34 weeks.
2. Newborns with respiratory distress (rate >60/min).
3. Babies with congenital anomalies.
4. Babies with maternal infection.
5. Birth weight <2500 g and weight >4000 g.
6. Babies with severe birth asphyxia were excluded.

Method of Sample Collection

Cord blood sample and blood sample at 24 hours were collected for all the 200 babies to identify their ability to distinguish a baby who needs phototherapy from a baby who does not need phototherapy in next 5 days of life. After 24 hours and up to 5th post-natal day blood samples for serum bilirubin estimation were taken for those babies who were clinically suspected to be having jaundice. Serum bilirubin is measured by spectrophotometry by Van den Bergh test

Statistical Analysis

Data were documented in the case record form and converted into electronic data base using Microsoft excel 2007. Statistical analysis was done using Epi info 7.1.2.0 of Centre for Disease Control, USA and Medical 12.7.5 Belgium.

Numerical continuous variables were summarized as mean or median with corresponding 95% Confidence limit, standard deviation and range. Normality of distribution was tested by D'Agostins – Pearson test which computes a single P value for the combination of coefficients of Skewness and kurtosis. As the continuous variables are having a non-normal distribution despite logarithmic transformation, median and corresponding 95% confidence limit are considered for further statistical analysis. The Mann – Whitney test is used to test the significance of the difference between medians of the two independent samples.

Serial measurement analysis was done to know the time at which mean total serum bilirubin reached its maximum value. The degree of association between total serum bilirubin values from birth to 5th postnatal day was analysed by Spearman's rank correlation as the distribution of means of total serum bilirubin values are non-normal in distribution.

Phototherapy predictive utility of total serum bilirubin values of different times which identifies a baby that is likely to need phototherapy was evaluated with ROC curve analysis. Categorical variables were summarized by frequency, percentage and 95% confidence limit.

RESULTS

Variable	Sample Size	Lowest	Highest	EAN	95% CL Mean	Median	95% CL Median	D	Distribution
GA	200	33	41	8.75	38.55-38.94	39	39- 39	.42	(P<0.0001) reject normality
GA Term	184	37	41	9.05	38.91- 39.19	39.00	39.0 - 39	.97	(p= 0.0222) reject normality
GA Preterm	16	33	36	5.19	34.74-35.63	35	35-36	.83	(P = 0.0341)reject normality
Birth WT	200	1.5	3.8	.77	2.75 –2.8	2.75	2.75 – 2.8	.40	W = 0.9569. reject normality (P < 0.0001)
BW Term	184	2.0	3.8	.88	2.78 - 2.88	2.75	2.75- 2.8	.33	W = 0.935 Reject normality(p= 0.0014)
BW Preterm	16	1.5	3.2	.09	1.79 -2.38	1.88	1.6 -2.64	.55	W = 0.8756 reject normality (P = 0.332)
Group		Frequency		Percent		95% Confidence Limits			
Sex	Female	89		44.5%		37.5%		51.7%	
	Male	111		55.5%		48.3%		62.5%	
Maturity	Preterm	16		8.00%		4.6%		12.7%	
	Term	184		92%		87.3%		95.36%	

Table 1. Base Line Characteristics of Study Population [n = 200 Neonates]

In this study of 200 newborn babies the median gestational age is 39 weeks, 95% confidence limit is 39 – 39 weeks and the range is 33-41 weeks. Out of 200 neonates, 184 (92%, 95% CI 87.3% to 95.4%) are full term and 16 (8%, 95% 4.6% to 12.7%) are preterm, indicating predominance of full-term babies. Median gestational age of full-term group is 39 weeks, 95% confidence limit is 39 – 39 weeks and range is 37 – 41 weeks. Median gestational age of preterm group is 35 weeks, 95% confidence limit is 35 – 36 weeks and range is 33 – 36 weeks. [Table 1] Median birth weight of whole group of 200 babies is 2.75 Kg (95% CL 2.75 Kg to 2.8 Kg, range 1.5 Kg to 3.8 Kg). Median birth weight of term group is 2.75 Kg (95% CL 2.75 Kg – 2.8 Kg, range 2 Kg – 3.8 Kg). Median birth weight of preterm group is 1.87 Kg (95% CL 1.6 Kg – 2.6 Kg, range 1.5 Kg – 3.2 Kg). Out of 200 babies, males are 111 [55.5%, 95% CL 48.32%- 62]

TSB at Postnatal Age	TSB Levels Observed in Our Study					TSB at which Standard Guidelines Recommend Phototherapy (in Low Risk Healthy Infants)
	Phototherapy Yes	Phototherapy No	Mann Whitney U	Z Score (Corrected for Ties)	Probability	
TSB CORD (mg/dl)	2.8 (2.6-2.9)	1.9 (1.8-2)	1858	7.65	P< 0.0001	7
TSB at 24 hrs (mg/dl)	6.2 (6-6.4)	4.6 (4.4-5)	1748	7.911	P< 0.0001	12
TSB on 3 rd day (mg/dl)	18 (18-19)	12 (11-13)	140	8.45	P< 0.0001	15
TSB 4 th day (mg/dl)	17 (16-17)	12 (11-13)	110	7.929	P < 0.0001	17.5
TSB 5 th day (mg/dl)	13 (12-13)	11.35 (11-13)	987.5	2.324	P = 0.0201	20

Table 2. Serum Bilirubin Differences Since Birth Between Phototherapy Needed and Not Needed Babies

Table 2 shows relationship between Serum Bilirubin levels and the management with Phototherapy need or not needed. The median serum bilirubin from birth to 5th day of life is significantly more in the group of babies who needed phototherapy compared to those babies who did not need phototherapy, even before the indication for phototherapy is evident at that time.

Variable Y (data)			Total Serum Bilirubin			
Variable X (time)			Day of Bilirubin			
Variable for cases			Case			
Summary measure of interest			Time to reach maximum			
Group	N	Mean	95% CI	SD	Median	95% CI
(All cases)	200	3.415	3.287 to 3.543	0.915	3.000	3.000 to 3.000

Table 3. Time to Reach Peak of Serum Bilirubin [Serial Measurement Analysis]

Serial measurement analysis showed that in our study, the median time for total serum bilirubin to reach maximum is 3 days.

Time of Bilirubin	TSB Range (mg/dl)	+LR Range	Probability (PPV) Range	-LR Range	Probability (NPV) Range
Cord Blood at Birth	≥0.5 to >1.0	1 to 1.5	46.5 to 50	0.00 to 0.077	100 to 93.7
	>1.1 to >1.6	1.16 to 1.52	50.3 to 56.9	0.072 to 0.17	94.1 to 87.2
	>1.7 to >2.2	1.52 to 3.66	57 to 76.1	0.19 to 0.31	85.7 to 78.7
	>2.3	4.03	77.8	0.3	79.1
At 24 hrs	≥2.4 to >3.5	1 to 1.15	46.5 to 50	0.00 to 0.14	100 to 88.9
	>3.6 to >4.5	1.22 to 1.82	51.4 to 61.3	0.11 to 0.13	91.3 to 89.7
	>4.6 to >5.2	1.92 to 2.52	62.5 to 68.6	0.16 to 0.2	87.5 to 85.4
	>5.3	2.66	69.8	0.19	85.7

Table 4. Phototherapy Predictive Ability of TSB Ranges

Variable (Phototherapy)	Prevalence (%)	AUC (95%CL; Z statistic; P [Area=0.5])	You den index j; Associated Criterion	Optimal criterion	Sensitivity (95%CL)	Specificity (95%CL)	+LR (95%CL)	-LR (95%CL)	PPV (95%CL)	NPV (95%CL)
TSB Cord Blood (Yes: 93; No: 107)	46.5	0.813 (0.752 to 0.865; 10.153; P<0.0001)	0.5658; >2.3	>2.3	75.27 (65.2 – 83.6)	81.31 (72.6- 88.2)	4.03 (2.7 – 6.1)	0.30 (0.2 – 0.4)	77.8 (67.8 – 85.9)	79.1 (70.3 – 86.3)
TSB at 24 hours (Yes: 93; No: 107)	46.5	0.824 (0.764 to 0.874); 10.890; P<0.0001	0.5439; >5.3	>5.3	87.10 (78.5 to 93.2)	67.29; (57.5 to 76.0)	2.66 (2.0 to 3, 5)	0.19 (0.1 to 0.3)	69.8 (60.6 to 78.0)	85.7 (76.4 to 92.4)
TSB 3 rd day (Yes: 85; No= 42)	66.9	0.961 (0.911 to 0.987); 22.922; P<0.0001	0.9053; >14.5	>14	96.47 (90.0 to 99.3)	92.86 (80.5 to 98.5)	13.51 (4.5 to 40.2)	0.038 (0.01 to 0.1)	96.5 (90.0 to 99.3)	92.9 (80.3 to 98.5)
TSB 4 th day (Yes: 72; No: 38)	65.5	0.960 (0.904 to 0.988); 28.958; P<0.0001	0.8114; >13	>13	91.67 (82.7 to 96.9)	89.47 (75.2 to 97.1)	8.71 (3.4 to 22.1)	0.093 (0.04 to 0.2)	94.3 (86.0 to 98.4)	85 (70.2 to 94.3)
TSB 5 th day (Yes: 80; No: 34)	70.2	0.637 (0.542 to 0.725); 2.415; P=0.0157	0.2169; >11.7	>8	98.75 (93.2 to 100.0)	11.76 (3.3 to 27.5)	1.12 (1.0 to 1.3)	0.11 (0.01 to 0.9)	72.5 (63.1 to 80.6)	80 (22.8 to 99.8)

TSB=Total Serum Bilirubin; CL= Confidence Limits; AUC=Area Under Curve; p=P value; +LR=Positive Likelihood ratio; -LR=Negative Likelihood ratio; PPV=Positive Predictive Value; NPV=Negative Predictive Value.

Table 5. Phototherapy Predictive Utility of Total Serum Bilirubin at Different Points of Time Since Birth

TSB in cord blood >2.3 mg/dl and TSB at 24 hours >5.3 mg/dl can satisfactorily estimate the probability of phototherapy need.

ROC curve analysis is done to know diagnostic (predictive) ability of TSB in cord blood to identify the need for phototherapy. The cut off value found is total serum bilirubin > 2.3 mg/dl. Its sensitivity is 75.3% (95% CL 65.2% to 83.6%), specificity 81.3% (95% CL 72.6% to 88.2%), PPV is 77.8 (67.8 to 85.9), NPV is 79.1% (70.3% to 86.3%), positive likelihood ratio is 4.03 (95% CL 2.7 to 6.1) and negative likelihood ratio is 0.3 (95% CL 0.2 to 0.4).

ROC curve analysis to know the diagnostic ability of TSB at 24 hrs. to predict the need for phototherapy shows that TSB > 5.3 mg/dl, has sensitivity of 87% (95% CL 78.5% to 93.2%), specificity of 67.3% (95% CL 57.5% to 76%), Positive predictive value (PPV) of 69.8 (60.6 to 78.0), Negative predictive value (NPV) of 85.7 (76.4 to 92.4) positive likelihood ratio of 2.7 (95% CL 2 to 3.5) and negative likelihood ratio of 0.2 (95% CL 0.1 to 0.3).

Figure 1. Sensitivity and Specificity of Cord Blood TSB

Figure 2. Sensitivity and Specificity of TSB at 24 hrs.

DISCUSSION

Sl. No.	Author	Year	Sample	Population	TSB Cord	TSB at 24 Hours
1.	Present	2013	200	Healthy term	TSB > 2.3 mg/dl; Sensitivity 75.3%; Specificity 81.31%; PPV 77.8%; NPV 79%	TSB > 5.3 mg/dl Sensitivity 97.1%, specificity 67.3%, PPV 70%, NPV 85.7%
2.	Siwiluckkanchanabat et al	2010	289	Healthy term	TSB > 2.3 mg/dl: Sensitivity-14.6%, Specificity-91.3%, PPV-25%, NPV-84%	-----
3.	Zakia Naha et.al	2009	200	newborns	TSB >2.5	-----
4.	Sun G, Wang YL	2007	523	Healthy newborns		-----
5.	Amar Tisane et al	2005	200	Healthy term	TSB > 2 Specificity; 89.5%; NPV - 98.7%; PPV-38.6%	-----
6.	Bernaldo AJ	2004	400	newborns	TSB >2 PPV - 53%	-----
7.	Aage Knudsen et al	1989	291		TSB >2.35 mg/dl, PPV - 57 %	-----
8.	Rostani N et al	2005	643	Healthy term	TSB > 3 Specificity 92.4%	-----
9.	ShivaniRandev et al	2010	200		-----	TSB > 6.4, Sen. 87.5%, Specificity 80.11%, PPV 37.5%, NPV 98%

10.	Rajesh Agarwal et al ¹⁸	2002	220	Healthy newborns	-----	TSB >6 mg/dl, Sensitivity 95%, Specificity 71%, PPV 27%, NPV 99.3%
11.	X Carbonel et al	2001	610			TSB > 6 mg/dl, Sensitivity 94%, Specificity 62%
12.	Faro Allay et al	2000	498	Healthy term	-----	TSB > 6 mg/dl, Sensitivity 90%, NPV 98%, PPV 26.2% ¹⁹
13.	Sideman Ds et al	1999				TSB > 5 mg/dl, Sensitivity 63%, Specificity 94%.
14.	ShallyAvasti et al	1998	274		-----	TSB > 3.99 mg/dl, Sensitivity 64%, spe 68%
Table 6. Phototherapy Predictive Ability of TSB in Cord Blood and at 24 Hours, in Different Studies						

In the management of neonatal jaundice, a paediatrician comes across certain dilemmas. In routine practice, using standard guidelines of neonatal hyperbilirubinemia management, a clinician can take a decision whether a baby needs phototherapy or exchange transfusion only when the total serum bilirubin reaches certain critical levels. Thus, a clinician so far has therapeutic levels of TSB but not Phototherapy predictive levels of TSB for the management of neonatal hyperbilirubinemia. Hence there is a need to identify TSB values, at a much earlier time and lower than the critical therapeutic TSB levels, which have Phototherapy predictive ability. So, it helps to distinguish a baby who needs in hospital observation from a baby who can be sent home in a short time after birth. Results of our study show that it is possible to recognize a good predictive or diagnostic TSB value for identifying a baby that later needs phototherapy.

In our study, cord blood total serum bilirubin > 2.3 mg/dl is having a Predictive utility for the need for phototherapy, with sensitivity 75.3% (95% CL 65.2% to 83.6%) In Siwiluckkanchanabat study a cord blood TSB > 2.3 mg/dl has sensitivity of 14.6%¹⁴. In a clinical problem like neonatal hyperbilirubinemia reliable prediction of a baby needing phototherapy is vital and the sensitivity of the test should be high so that babies who need phototherapy should not be missed. High sensitivity which may lead to prolonged hospitalization of some babies who may not actually need phototherapy for a few more days is preferable to low sensitivity which leads to discharge of a few babies who may need phototherapy after a few days. According to our observation, predicting need of phototherapy by cord TSB of > 2.3 mg/dl is likely to miss only 25% of babies who may need phototherapy, unlike in study of Siwiluck where the risk is very high.

In our study the total serum bilirubin at 24 hrs of > 5.3 mg/dl is also useful in predicting the need for phototherapy with a sensitivity of 87.1% (95% confidence limit 78.5 to 93.2). Ramesh Agarwal et al found that 24 hour total serum bilirubin >6 mg/dl has sensitivity of 95%.¹⁵ In Carbonel et al study 24 hour total serum bilirubin >6 mg/dl has sensitivity of 94%¹⁶ FarukAlpay et al's study found a sensitivity of 90% with 24 hour total serum bilirubin >6 mg/dl.¹⁷ Shivani Ramdev et al found a total serum bilirubin > 6.4 mg/dl at 24 hrs is having diagnostic value with sensitivity of 87.5%.¹⁸

ShallyAvasti et al in their study found a total serum bilirubin > 4 mg/dl at 24 hours is having a sensitivity of 64%.¹⁹ In Seidman Ds et al's study, 24-hour total serum bilirubin > 5 mg/dl has sensitivity of 63%.²⁰

This indicates that including our study many research workers find TSB of 24 hours is having higher sensitivity and more useful than TSB in cord blood in identifying a baby not needing phototherapy. As per our observation using the cut-off of TSB at 24 hours >5.3 mg/dl may lead to missing about only 13% of babies who may need phototherapy. As per many others' observations risk of discharging a baby needing phototherapy is small if decision is based on TSB at 24 hours.

Bhutanivk et al's hour specific bilirubin nomogram facilitates a clinician in taking a discharge decision by predicting the possibility of subsequent neonatal hyperbilirubinemia basing on post-natal age (hours) specific serum bilirubin. At 24 hours a TSB of 5 mg/dl located at 40th centile curve of Bhutani's nomogram suggests a low risk of phototherapy and it corresponds closely with our phototherapy need predicting value of >5.3 mg/dl. Probability of phototherapy by our value (5.3 mg/dl) is 70%. Bhutani's 75th centile TSB value suggestive of intermediate risk corresponds to nearly 6 mg/dl at 24 hours. As per our study the probability of phototherapy need is about 83% when TSB is 6 mg/dl at 24 hours.²¹

CONCLUSIONS

Most babies, who needed phototherapy, needed the intervention on 3rd postnatal day. The time to reach maximum total serum bilirubin level after birth is 3rd postnatal day. So, the baby in need of phototherapy has to be identified earlier to 3rd postnatal day. A total serum bilirubin level prior to 3rd day which can predict the later need of phototherapy in a given baby will have clinical utility. Total serum bilirubin in cord blood and at 24 hrs is having correlation with total serum bilirubin on 3rd day. Temporally also total serum bilirubin in cord blood and at 24 hrs are earlier values compared to total serum bilirubin on 2nd day and helps in earlier prediction.

Hence, total serum bilirubin in cord blood and at 24 hrs is evaluated for its ability to predict the need for phototherapy. The optimum cut off value of total serum bilirubin in cord blood which can predict the need for phototherapy is > 2.3 mg/dl and value of total serum bilirubin at 24 hrs which can predict the need for phototherapy is > 5.3 mg/dl. One can minimize risk of missing needed phototherapy by discharging a baby only when the likelihood or probability of phototherapy is very low. When a baby is healthy without any risk factors, a liberal cut off value of TSB can be used with a relatively higher likelihood of phototherapy, with an advice for follow up. The likelihood of need for phototherapy helps in advising frequency of follow up. Thus, all babies need not be in hospital, for considerable number of post-natal days,

with its attendant risk of infection to the baby, if one has predictive TSB values suitable to one's hospital.

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