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OPPORTUNITIES TO INCREASE EARLY DETECTION OF NEONATAL CHOLESTASIS

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Abstract

Objective—To describe primary care management of early and prolonged jaundice in otherwise healthy term infants to identify opportunities to increase early diagnosis of cholestasis.

Methods—Community-based pediatricians in St Louis, MO completed a mailed, anonymous 29-item survey to assess practice demographics, timing of routine newborn office visits and management of early and prolonged neonatal jaundice.

Results—108/230 (47%) of eligible physicians responded (mean years in practice, 15.3, SD, 9.4). More respondents were very familiar with national guidelines for management of early (49%) than prolonged (16%) neonatal jaundice. Eighty six percent reported all newborns were checked with transcutaneous bilirubin (TcB) before hospital discharge. For TcB results at 48 hours of 7, 10, 12 and 15mg/dL, 1%, 25%, 69% and 73% of respondents respectively would order a fractionated bilirubin. While the first routine visit usually occurred in the first week after discharge, 25% of physicians reported the 2nd visit was routinely scheduled after 4 weeks of age. Ninety-two percent reported they would obtain a fractionated bilirubin for infants jaundiced beyond 4 weeks of age. If cholestasis was identified at 6 weeks of age, 32% would obtain additional testing without referral to a subspecialist.

Conclusions—Management of early and prolonged neonatal jaundice is variable. Current practices appear to miss opportunities for early diagnosis of cholestasis and referral that are unlikely to be addressed without redesigning systems of care.

Keywords

biliary atresia; cholestasis; hyperbilirubinemia; kernicterus

INTRODUCTION

In the United States 60% to 80% of newborns will develop jaundice in the first week of life.^{1, 2} Most neonatal jaundice is benign and quickly resolves without sequelae, but for

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those rare cases with underlying liver disease, early identification and treatment can improve outcomes. Biliary atresia (BA), the most common cause of neonatal biliary obstruction and cholestasis, occurs in 1:10,000–1:14,000 live births, causes severe liver injury, and, if untreated, causes death by age two years.³ Although the pathogenesis of BA is unclear, early diagnosis and surgical treatment may forestall liver transplantation and improve survival.^{4–9} Children with rarer causes of cholestasis such as alpha-1-antitrypsin deficiency, Alagille's syndrome, and progressive familial intrahepatic cholestasis also benefit from early diagnosis to prevent complications, most importantly malnutrition and fat-soluble vitamin deficiencies associated with blindness (Vit A), rickets (Vit D), central and peripheral neuropathy (Vit E) and coagulopathy (Vit K).^{10–12} Unfortunately, the diagnosis of cholestasis is often delayed and the benefits of early intervention are not realized.¹³ Despite evidence that surgical intervention before 45 days of age improves outcomes,^{6, 8} the average age at diagnosis of BA in the United States is about 60 days.^{4, 14–16}

Identifying infants with cholestasis among those with neonatal jaundice is difficult. Initially, newborns with cholestasis are likely to have mild jaundice and are otherwise well.¹⁷ Also, typical measures of total bilirubin that are used to identify hyperbilirubinemia (transcutaneous bilirubin, TcB, or total serum bilirubin, TSB) do not distinguish those with cholestasis. In 2004, the American Academy of Pediatrics (AAP) published recommendations for the management of early and prolonged neonatal jaundice in otherwise healthy term and near-term infants, with an update with clarifications in 2009.^{18, 19} The main focus of the guidelines is to reduce the frequency of severe neonatal hyperbilirubinemia and acute bilirubin encephalopathy, thereby preventing kernicterus (estimated incidence, 1:100,000 live births).^{18, 19} Universal predischarge screening of all infants with TcB or TSB is recommended with risk assessment for the development of severe hyperbilirubinemia with phototherapy or exchange transfusion treatment for infants at high risk.¹⁹ For those assessed to be at low risk for severe hyperbilirubinemia follow-up should be timed according to “age at discharge and concerns other than jaundice (e.g., breastfeeding).”¹⁹ At follow up, those with jaundice at or beyond 3 weeks of age should have a fractionated (direct or conjugated) bilirubin measured to assess for cholestasis and underlying liver disease.¹⁸ Compliance with the guideline recommendations is not known and their effectiveness in preventing kernicterus remains controversial.^{19–24} More detailed guidelines for the management of cholestatic jaundice in infants that recommend a fractionated test for bilirubin at 2–3 weeks of age were developed by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.¹³ Although endorsed by the AAP, these guidelines were not published in a general pediatric journal.

Little is known about current management of neonatal jaundice in the community setting. We sought to describe current practice and to identify opportunities to increase the early identification of infants with cholestatic liver disease within the context of routine management of the common clinical problem of neonatal jaundice. The objective of this study was to describe management by office-based general pediatricians of neonatal jaundice in otherwise healthy term infants.

DESIGN AND METHODS

We developed and implemented a survey to assess how community pediatricians routinely diagnose and manage jaundice in a newborn and prolonged neonatal jaundice. The study was approved by the Washington University Human Research Protection Office.

Study Population

Eligible physician subjects were office-based general pediatricians who were affiliated with St. Louis Children's Hospital or Washington University Department of Pediatrics. All

eligible physicians were mailed a written invitation to participate in the survey, together with the self-administered questionnaire. As the questionnaire was anonymous, physicians indicated their participation (yes or no) by returning a postcard separate from the questionnaire. Up to two additional mailings were sent to those who did not return the postcard.²⁵

Study Instrument

The survey was developed by the authors based on the literature and their collective experience in primary and subspecialty care. Survey items were further refined after two rounds of pilot testing to increase usability. Items assessed the physician's usual practice regarding the frequency of newborn office visits and the diagnosis and management of neonatal jaundice in the first 6 weeks of life for a healthy term infant. The 29-item survey took approximately ten minutes to complete and is available in the Appendix.

Respondents indicated their level of familiarity (very, somewhat, not familiar) with AAP recommendations for management of early and prolonged neonatal jaundice, and provided demographic information. They indicated which newborns would routinely get a TcB and a total serum bilirubin prior to hospital discharge, and if they would routinely order a fractionated bilirubin for all infants with jaundice who were 4 weeks old. Participants chose from a list of possible options to indicate their next step in the management of a jaundiced term newborn without any risk factors for severe hyperbilirubinemia with an initial TcB of 7mg/dL, 10mg/dL, 12mg/dL and 15mg/dL measured at 48 hours of age. Testing options included no additional testing, repeat TcB, obtain TSB, or obtain bilirubin panel including direct or conjugated bilirubin, and the treatment option was phototherapy. In a series of three sequential questions describing a developing clinical scenario, respondents selected options from a list (testing with TcB, TSB, or fractionated bilirubin; treatment with phototherapy; primary care follow-up and referral to gastroenterology) to indicate their management of a full term breastfed male infant (otherwise healthy, feeding and voiding well) who had scleral icterus and a TSB of 6mg/dL at 36 hours. At 4-weeks the infant's jaundice remained, but had not worsened. He continued to breastfeed and was gaining weight appropriately and looked well. At 6-weeks, he had a TSB of 6mg/dL and a conjugated bilirubin of 3mg/dL.

Data Analysis

Continuous variables are reported as mean (standard deviation, SD) or median (interquartile, IQ range), and categorical data as percent. We used the chi-squared test to test our hypothesis that management in accordance with guideline recommendations would be more likely for physicians who reported they were very familiar with the guidelines. A probability of $p = 0.05$ (two-tailed) was used to establish statistical significance. All statistical analyses were done using STATA 9.0 (Stata Corp.2001. *Stata Statistical Software*: Release 9.0 College Station, TX: Stata Corporation).

RESULTS

Study Population

Between June 24, 2009 and October 27, 2009, surveys were mailed to 230 eligible pediatricians. One hundred and eight (47%) pediatricians completed the survey (Table 1). Participants were similar with respect to gender, practice type, and practice location to those (n=23) who returned a postcard to indicate they would not participate (data not shown), and for age and gender to the sample of pediatricians who completed the AAP Socioeconomic survey in 2010 (www.aap.org/research/periodicsurvey/ps43soci.htm).

Participants were experienced pediatricians (mean years in practice 15.3, SD 9.4) most of whom worked in suburban practices. The median number of newborns seen per year was 100 (IQ range 60–150). Respondents reported being “very familiar” with current AAP recommendations for management of early (49%) and prolonged neonatal jaundice (16%) (14% both, 49% neither), and reported experience during training or in practice with infants with kernicterus (14%) and BA (45%). Eight (7%) respondents had TcB equipment in their office.

Routine Office Follow Up for All Newborn Infants

Most respondents (75%) reported that they would usually see a newborn for a routine follow-up visit within the first week of life, but scheduling for subsequent visits was variable (Table 2). For both breast and bottle-fed infants, 25% of physicians reported the 2nd follow-up visit was routinely scheduled after 4 weeks of age, but all reported a second office visit would be scheduled for all infants by 2 months of age.

Management of hyperbilirubinemia

Newborns—Eighty-six percent of physicians reported all newborns were routinely checked with TcB prior to hospital discharge. Reported management of hyperbilirubinemia at 48 hours of age (prior to discharge) varied (Table 3).

Follow-up testing: For TcB values below 12 mg/dL, physicians were unlikely to order a blood test to check bilirubin levels or check for cholestasis, preferring instead to repeat the TcB or not order any further tests. For a TcB value of 12 mg/dL, of the 103 who would order further testing, 88% would order a blood test (70% would request a fractionated bilirubin) and 10% would repeat the TcB. At 15 mg/dL, TcB was not used for follow-up testing: 86% respondents reported they would order a follow-up blood test (74% would request a fractionated bilirubin).

Phototherapy: Initiation of phototherapy increased with level of TcB. No respondent stated that they would use phototherapy if the initial TcB level was below 12 mg/dL. With a TcB of 12 mg/dL, 8% would start phototherapy (4% as an inpatient). At 15mg/dL, 61% would initiate phototherapy (24% as an inpatient) with 15 (14%) starting the phototherapy without a blood test to confirm the level of hyperbilirubinemia.

Infants—Ninety-two percent of physicians reported that they routinely obtained a fractionated bilirubin on jaundiced infants 4 weeks of age or older. The most common reason not to obtain a fractionated bilirubin was if the infant was breastfed.

Reported management of a full term breastfed male infant (otherwise healthy, feeding and voiding well) who had scleral icterus and a TSB of 6mg/dL at 36 hours, who remained jaundiced at 4 weeks but was otherwise well, is reported in Table 4. At 36 hours, 57% of respondents would not order any further testing for this infant and 90% would discharge from hospital with a follow-up office visit within a week. When the same infant was seen at 4 weeks of age with persistent jaundice, but otherwise well, 102 (94%) would order a fractionated bilirubin test within a week (100 that day, 2 a week later), 4 (4%) would not order additional testing, 3 of whom would not schedule the follow-up office visit until 4 weeks later. When presented with the continuing clinical story of this infant that included a conjugated bilirubin of 3mg/dL at 6-weeks of age, respondents varied in their next steps: 42% would immediately refer to a gastroenterologist, 26% would refer immediately and order additional testing, and 32% would only order additional testing.

Familiarity with the AAP guidelines did not affect frequency of reporting recommended behaviors (initiating intensive phototherapy for total bilirubin above 15mg/dL; measuring a fractionated bilirubin in patients jaundiced at 4 weeks of age) in clinical scenarios or in direct questioning (data not shown).

DISCUSSION

This study is the first to describe the routine primary care management of early and prolonged neonatal jaundice in otherwise well term infants. Although study findings may not be generalizable to other communities, we identified opportunities for improvement in the early diagnosis of cholestasis and BA that merit further study in a national sample. Further study could serve as a model for the rapid detection of rare illnesses among common signs and symptoms that present to primary care settings.

Opportunities to identify cholestasis occur during routine office visits for neonatal care. Although most pediatricians in this survey reported they were not familiar with national guidelines for management of prolonged neonatal jaundice, most indicated they would order a fractionated bilirubin for any neonate with jaundice persisting at 4 weeks of age. However, not all respondents scheduled routine visits to provide opportunity for such timely assessments to occur. The Bright Futures guidelines for well-child care recommend routine visits at one and two months of age,²⁶ but one in four pediatricians in this study did not routinely see the infant between one and eight weeks of age. Changing the schedule to include an assessment at 3 to 4 weeks of age specifically to rule out BA might be effective,²⁷ but may not be feasible or acceptable to parents or physicians. Even if the infant is seen at 3–4 weeks of age, most patients with BA will be thriving and may only have mild jaundice, a similar presentation to jaundice associated with breast feeding,¹ and the physician may mistakenly think the infant has physiological jaundice and delay testing.²⁸ Additional provider education may be needed to highlight the need for screening for cholestasis with a blood test for conjugated bilirubin in infants with this mild and familiar clinical presentation.

Timing of referral to a subspecialist is critical to early intervention and improved outcomes for children with cholestasis.^{5, 13, 29} Recent summary statements from the North American Society for Pediatric Gastroenterology Hepatology and Nutrition¹³ as well as the NIH Workshop on Screenings and Outcomes in BA¹ have provided guidance on the evaluation of infants with cholestasis and stipulate that evaluation should be carried out at a center with the expertise in diagnosis and treatment for these conditions. Our survey found that nearly one third of respondents would delay referral to a gastroenterologist for a 6-week old with biochemical evidence of cholestasis in order to obtain additional evaluations. Education for primary care physicians regarding appropriate referral strategies as well as ensuring timely access to specialists is needed to expedite recognition and surgical treatment as well as ensure optimal use of resources for additional testing.

Although BA fulfils the criteria for a condition for universal screening (an important health problem with an asymptomatic period when timely interventions can improve outcomes)³⁰, identification of an effective screening test is problematic.²⁸ In our community, TcB was used extensively in the newborn period for diagnosis and initial follow-up of jaundice. TcB is a convenient and non-invasive measure of total bilirubin and provides an estimate for the TSB,¹⁹ but few pediatricians in this study would proceed to order confirmatory blood tests if the TcB reading in the newborn nursery was low, a typical presentation for BA.³¹ It is not known if screening infants for conjugated bilirubin prior to hospital discharge would accurately identify all those with cholestasis, but higher levels of conjugated bilirubin (> 5 mg/dL) in the first 2 weeks of life are associated with increased likelihood of biliary or liver

disease.³¹ A recent study found that infants with BA had elevated levels of direct/conjugated bilirubin that exceeded the laboratory normal values within 24 hours of birth, these levels were significantly higher than controls without BA, and they increased over time.³² Use of a stool color chart has also been proposed for screening to identify the pale stool associated with cholestasis and has been used successfully in Asia and Argentina to improve time to diagnosis as well as surgical outcomes for BA.^{8, 33, 34} Other proposed screening strategies including bile acid analysis with tandem mass spectroscopy and identification of sulfated bile acids in urine are not readily available for routine testing and have not been validated in large populations.^{35–37}

There are limitations to our survey. Our findings may not represent national practice patterns as the study sample is from one community and the response rate was 47%. Although this response rate is similar to those of other primary care surveys for neonatal jaundice,^{38, 39} a national survey of primary care providers including other care providers such as nurse practitioners is needed to validate these findings. In addition, self-reported data may not represent actual practice and may bias results towards an ideal or expected response. We did not assess knowledge of the guideline recommendations and limited the scope of our investigation to primary care management of newborn jaundice. An intense scrutiny of the infants with cholestasis who present late to medical attention would be an opportunity to perform a root cause analysis to identify additional aspects of care that contribute to late presentation. However, a chart review to confirm reported behaviors was beyond the scope of the current study.

Conclusions

Our findings suggest opportunities to improve early identification of infants with cholestasis would involve changes in the systems of care that include routine care schedules for reassessment of prolonged jaundice at 2–3 weeks of age and immediate referral to subspecialist once cholestasis is identified without additional testing.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Dr Garbutt had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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What's New

Care for neonatal jaundice was highly variable. Opportunities for earlier detection of infants with cholestasis include routine follow-up visits at 3–4 weeks of age to facilitate testing for conjugated bilirubin for those with prolonged jaundice and immediate subspecialty referral with no additional testing for patients with documented cholestasis.

Table 1

Characteristics of 108 community pediatricians who responded to the survey

Characteristic	N (%) or mean (SD)
Male Gender	40 (37%)
Age, years	46.3 (9.5)
Years in practice	15.3 (9.4)
Type of practice	
Solo practice	14 (13%)
2-physician practice	12 (11%)
Pediatric group practice	72 (68%)
Multi-specialty group practice	6 (6%)
Practice location	
Urban, inner city	8 (7%)
Urban, not inner city	12 (11%)
Suburban	78 (72%)
Rural	6 (6%)
Ethnicity of patients	
White	66% (24)
Black	24% (24)
Asian	6% (5)
Other	4% (6)

Table 2

Schedule for routine follow-up visits for newborn infants (in days)

	Breast fed infants Median (IQ range) days (N=102 physicians)	Bottle fed infants Median (IQ range) days (N=100 physicians)
1 st visit	5 (4 – 7)	7 (5 – 9)
2 nd visit	14 (14 – 30)	30 (14 – 30)
3 rd visit	60 (30 – 60)	60 (56 – 60)
4 th visit	120 (60 – 120)	120 (112 – 120)

Abbreviations: IQ Interquartile range

Table 3

Physician reported follow-up for abnormal TcB levels assessed at 48 hours in a jaundiced newborn with no risk factors for severe hyperbilirubinemia.

Initial TcB level	Follow-up management			
	No additional testing	Repeat TcB within 24 hours	TSB within 24 hours	Fractionated bilirubin
7mg/dL (N=102)	89%	8%	2%	1%
10 mg/dL (N=104)	37%	28%	10%	26%
12 mg/dL (N=106)	3%	9%	18%	70%
15 mg/dL (N=106)	14%	0	12%	74%

Abbreviations: TcB, Transcutaneous bilirubin; TSB, Total serum bilirubin.

Table 4

Reported management of a full-term breastfed male infant with mild jaundice and otherwise well (n=108 physicians)

Management (Within a week)	36 hours: Well with mild jaundice and TSB 6 mg/DL*	4 weeks: Well, gaining weight. Mild jaundice persists*
No additional testing	62 (57%)	4 (4%)
TcB	14 (13%)	3 (3%)
TSB	24 (22%)	76 (70%)
Fractionated bilirubin	34 (31%)	102 (94%)
Office visit	97 (90%)	10 (9%)
Refer to GI	0	5 (5%)

Abbreviations: TcB, Transcutaneous bilirubin; TSB, Total serum bilirubin; GI, gastroenterologist.

* Percent sum to > 100% due to multiple responses