PROSPECTIVE EVALUATION OF THE IMPACT OF SONOGRAPHY ON THE MANAGEMENT AND SURGICAL INTERVENTION IN NEONATES WITH NECROTIZING ENTEROCOLITIS

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ABSTRACT

Background/Aim: Established indications for surgery in acute necrotizing enterocolitis (NEC) are pneumoperitoneum and failure to improve or clinical deterioration with medical treatment alone. It has been proposed that infants with intestinal necrosis may benefit from surgery in the absence of one of these indications yet the diagnosis of definitive intestinal necrosis is challenging. Recent data suggest that abdominal ultrasound (US) examination focused on the gastrointestinal tract and the peritoneal cavity may be of utility in this regard. The aim of this study was to evaluate the ability of abdominal US to detect intestinal necrosis in infants with radiographically confirmed NEC.

Methods: Twenty-six consecutive infants with Bell stage II or III NEC were prospectively included in the study between September 2013 and July 2014. Infants with a pre-existing indication for surgery were excluded. At least one abdominal US examination was performed in each patient using a standardized previously described method. Surgery was performed at the discretion of the attending surgeon based on clinical and imaging findings. Clinical, radiographic, US, and intra-operative data were recorded to allow comparison between US findings, surgical findings and outcome.

Results: US demonstrated signs of intestinal necrosis in 5 of the 26 patients. All of these 5 had laparotomy. Intestinal necrosis requiring resection was confirmed in 4 and the other was found to have NEC but no necrosis was identified. In 21 patients US did not suggest intestinal necrosis. Of these, only one had surgery in whom NEC but no necrosis was identified. The remaining 20 responded to medical treatment for NEC and were assumed not to have had intestinal necrosis based on improvement without surgical intervention. The sensitivity, specificity, positive predictive value and negative predictive values of US for the detection of bowel necrosis were calculated as 100%, 95.4%, 80.0%, and 100%, respectively.

Conclusion: Our prospective findings suggest that abdominal US can identify those infants with NEC who may need surgery by detecting bowel necrosis (prior to the development of perforation or medical deterioration) with high sensitivity and specificity. Early surgical intervention in the clinical pathway of NEC may lead to improved outcomes.

BACKGROUND

Necrotizing enterocolitis (NEC) is the most common gastrointestinal emergency encountered in a neonatal intensive care unit (NICU). It affects 4% to 13% of very low birth weight infants and 1% to 8% of all infants admitted to the neonatal intensive care unit; its mortality rate can reach 10% to 50% [1-3]. Its clinical presentation is highly variable, ranging from feeding intolerance or abdominal distention to fulminant shock and death. The etiology of the NEC is not clear and its treatment can be difficult. There is no effective universally accepted prevention strategy, therefore early detection and appropriate treatment of NEC is essential to minimize the morbidity and mortality of this condition [2, 4].

Despite over 20 years of improvements in neonatal care and research, the mortality related to NEC has not improved. Novel investigative and therapeutic strategies are required to address this ongoing clinical problem. One particular opportunity for altering current treatment strategy revolves around the criteria for surgery in infants with NEC. Current indications for surgery are debated amongst pediatric surgeons with the only universally accepted criteria for surgical intervention being the presence of pneumoperitoneum, which is indicative of intestinal perforation. Other *relative* indications for surgery exist including continued deterioration or failure to improve on maximal medical treatment and persistent thrombocytopenia [3, 4].

In the absence of pneumoperitoneum, the challenge faced by pediatric surgeons is to be able to reliably identify those infants who would benefit from surgery whilst minimizing the risk of the operation itself. Identifying infants with severe intestinal ischemia or necrosis from NEC and performing a resection of the necrotic bowel would likely be beneficial and may improve outcome. Whilst plain radiographs lack the sensitivity and specificity to detect intestinal ischemia or necrosis, recent data suggest that dedicated abdominal ultrasound (US) examination may be of utility in this regard [1, 8]. Thus far, the validity and the prognostic value of US findings in the course of NEC have not been extensively studied. Data on how US findings affect therapeutic management are limited, and it has not yet been clearly established when and how often US should be performed in the course of NEC to optimize outcomes [1, 5].

The objective of this study was to determine whether US can provide useful information to guide the most appropriate timing for surgical intervention by detection of bowel necrosis in infants with established NEC in the absence of pneumoperitoneum and the absence of clinical deterioration.

MATERIALS AND METHODS

All infants with Bell stage II or III NEC treated in our institution between September 2013 and July 2014 were eligible for inclusion. Infants who had a pneumoperitoneum at admission were excluded as they had an established indication for surgical intervention regardless of US findings. Infants on high-frequency oscillation were also excluded, as interpretation of the US was not reliable due to motion artifact.

An inter-departmental clinical protocol for serial radiological monitoring of infants with NEC was created in 2013 and the data were collected prospectively. The protocol included two-view abdominal X-rays (AP and lateral shoot through) and an abdominal US at admission and once daily (X-rays and US) on the second and third days unless the infant had undergone surgery (laparotomy or insertion of a peritoneal drain) or the clinical condition deteriorated prompting additional imaging. This observational study was part of an approved Quality Improvement Program at our institution.

During the study period surgery was performed at the discretion of the attending surgeon based on clinical and imaging findings. Clinical, radiographic, US, and intraoperative data were recorded to allow comparison between US findings, surgical findings and outcome.

Abdominal radiographs were evaluated for the presence of dilatation of bowel loops, intramural gas, portal venous gas, separation of bowel loops, and for fixed bowel loops on serial exams. Abdominal US including gray scale and Doppler interrogation of the bowel loops and gray-scale US of the peritoneal cavity was performed within 24 hours after diagnosis of NEC by a pediatric radiology fellow with 8 years of experience in

pediatric US and by a pediatric sonographer with 25 years of experience in US using a Toshiba Applio unit (Toshiba Medical Systems) and utilizing convex (3.6-9.2 MHz) and linear-array (7.0-18.0 MHz) multi-frequency probes at the bedside in the NICU while the infant was in the incubator and monitored by a bedside nurse throughout the examination. To limit inter-observer variability, all US scans were performed by the same pediatric radiology fellow or sonographer.

The US were performed using the technique described by Faingold et al [1] in 2005, which has been used successfully in several subsequent studies [6-9] for evaluation of the neonatal abdomen in patients suspected of having NEC or other acute intestinal pathology. Accordingly the US appearance of the intestine was evaluated for the presence or absence of the following 7 abnormalities: (1) increased wall echogenicity (defined as echogenicity higher than that of the anterior abdominal wall musculature), (2) wall thickening (wall thickness greater than 2.7 mm), (3) wall thinning (wall thickness less than 1 mm), (4) intramural gas, (5) increased perfusion on color Doppler, (6) decreased or absent perfusion on color Doppler, (7) bowel peristalsis (evaluated by the operator during real-time scanning). The peritoneal cavity of the abdomen and pelvis was evaluated for the presence or absence of 3 US features: (1) anechoic free fluid, (2) free fluid with echoes, (3) discrete fluid collections. Finally, liver and portal venous system were evaluated for portal venous gas.

A final decision regarding the presence or absence of intestinal necrosis was made based on the US findings alone by observing absence of perfusion and decreased peristalsis. The surgeon was aware of the US findings when making any decisions regarding the possible need for surgery. Patients who recovered from the acute episode of NEC without surgical intervention were assumed not to have intestinal necrosis.

The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the US to detect intestinal necrosis confirmed at surgery were calculated with their 95% confidence intervals (95%CI). Continuous data are presented as median and range.

RESULTS

Twenty-six infants were included (13 male). Median gestational age was 29 weeks and 5 days (range 24 weeks 6 days - 41 weeks and 3 days). The median birth weight was 1350g (730-3420). The age at admission for NEC was median 22.5 days (2-131).

The US findings are summarized in Table 1. US findings were interpreted as showing intestinal necrosis in 5 of the 26 infants primarily on the basis of absence of vascularity and decreased peristalsis. At least three additional abnormal US findings were also present in each case. All of these 5 infants had laparotomy; intestinal necrosis requiring resection was confirmed in 4 (Figures 1-4) and the other (case #24) was found to have NEC but no necrosis was identified, and no resection or diversion was performed (Figure 5). Intestinal necrosis was suspected based on abdominal US findings of mild bowel wall thickening, intramural gas, decreased peristalsis, and absent perfusion. This infant who was also awaiting corrective surgery for a congenital cardiac defect underwent laparotomy but no intestinal necrosis was encountered. Twenty-one infants had an US that did not suggest intestinal necrosis. Of these, only one had surgery based on clinical findings at which NEC but no necrosis was identified and a defunctioning jejunostomy was performed. The remaining 20 responded to medical treatment for NEC and are assumed not to have had intestinal necrosis based on improvement without surgical intervention. Two of these 20 infants subsequently developed an intestinal stricture secondary to NEC and one of them has undergone resection.

The sensitivity, specificity, positive predictive value and negative predictive values of US for the detection of bowel necrosis were calculated as 100% (95%CI 39.8-100%), 95.4% (95%CI 77.2-99.9%), 80.0% (95%CI 28.4-99.5%), and 100% (95%CI 83.9-100%), respectively (Table 2). In this series abdominal US accurately identified the presence and absence of bowel necrosis in 25/26 infants (96%; 95%CI 80.4-99.9%).

DISCUSSION

This prospective observational study shows that abdominal US examination in neonates with NEC can highlight the presence of intestinal necrosis before the onset of intestinal perforation or failure of medical management guiding the operative treatment and avoiding delays.

Whilst abdominal radiographs are typically used to provide radiological confirmation of a suspected clinical diagnosis of NEC (by the presence of pneumatosis intestinalis) and to identify infants with pneumoperitoneum, other information provided by plain radiographs is limited in its ability to guide treatment decisions. Recently US has been shown to be an accurate modality for depiction of various radiological features of NEC, particularly free intraperitoneal gas (for which it may be more sensitive than plain radiographs), as well as being able to document the presence of necrotic bowel [1, 8-12]. We hypothesized that US with color Doppler may be used to guide treatment decisions in infants with NEC specifically by identifying infants with intestinal necrosis who would likely benefit from surgery despite absence of pneumoperitoneum and before clinical deterioration.

In concordance with previous studies [1, 8, 9, 13], our findings demonstrate that abdominal US can identify features typically apparent on plain radiographs (including free intra-peritoneal gas and portal venous gas) as well as additional information that cannot be appreciated on plain radiography (Table 1). Furthermore, in this prospective evaluation, US predicted the presence of intestinal necrosis in 5 infants. In four of these necrosis was confirmed at laparotomy. However one infant had a false positive abdominal US scan (case #24). It is possible that the congenital cardiac disease in this infant contributed to absent intestinal perfusion leading to an erroneous interpretation of necrotic bowel. This case emphasizes the fact that any radiological examination needs to be interpreted in conjunction with the clinical condition of the patient rather than in isolation.

Whilst we embarked upon this study to attempt to identify infants with intestinal necrosis, who may benefit from surgery, the majority of infants included were not suspected to have intestinal based on abdominal US; one had a laparotomy and no

necrosis was found. We believe the remainder did not have necrotic bowel based on their full recovery from NEC with medical treatment alone. It would have not been ethical to expose these infants to confirmative laparotomy in the absence of clinical indication for surgery. However, 2 of these infants presented with intestinal strictures at 1 and 2 months following recovery from the acute episode of NEC. It is impossible to determine with certainty whether these infants had intestinal necrosis during the acute episode that was not identified on abdominal US, whether there was minimal necrosis or whether there was ischaemia rather than necrosis. We believe the fact that both infants avoided surgery during the acute illness suggests there was not significant necrosis at the time of NEC as infants with intestinal necrosis most likely develop a perforation or do not respond to medical treatment. They were therefore likely better served by medical treatment of NEC (avoiding the risks of acute surgery) followed by stricture resection after recovery once clinically stable.

We believe the benefit of US compared to plain radiographs is that US provides an opportunity to image the bowel loops in cross-section with a dynamic evaluation of perfusion and peristalsis. An additional benefit is the absence of ionizing radiation. The estimated effective dose for an AP radiograph of the abdomen in a newborn is 42 micro Sv (range 8-110 micro Sv) with an estimated cancer risk of 1.2-1.6 per million [14]. Minimizing radiation dose is paramount, particularly in preterm newborns who are exposed to multiple X-rays. We believe that shifting from radiographs to US for the diagnosis and follow-up of infants with NEC is prudent and that some X-rays can be replaced with abdominal US depending on the clinical situation. The major drawback of abdominal US is the inter- and intra-observer variability especially for dynamic evaluations. To address this within this study we limited US assessment to 2 individuals. For US to be a valid tool in clinical practice in which a larger number of individuals would likely be performing scans such variability needs to be minimized as much as possible.

This clinical study follows on from the work of other investigators who have proposed Doppler US as a non-invasive method for investigating blood flow within the splanchnic arteries and bowel wall, and for monitoring splanchnic vasoconstriction status in newborns with NEC [1, 15-18]. Choi [15], Deeg [16], and Kempley [17] found that neonates (or animals) with NEC have a significant increase in flow velocity within the SMA in comparison with controls. Resistive index and peak systolic/diastolic velocities were all increased supporting the role of splanchnic vasoconstriction in the pathogenesis of NEC.

Faingold et al [1] documented the utility of Doppler US for the assessment of bowel necrosis in 32 neonates with NEC for the first time in the literature in 2005 and detected isolated or multiple segments of bowel with absent perfusion. Silva et al [9] subsequently demonstrated a correlation between gray-scale and Doppler US findings and outcome in 40 infants with NEC in 2007. According to Silva et al [9], the presence of three or more abnormal findings on abdominal US had a sensitivity of 82% and specificity of 78% for a poor outcome defined as needing acute surgical intervention (laparotomy or placement of a peritoneal drain), death or late surgery for intestinal stricture. In a recent retrospective study Muchantef et al [19] reported good correlation of US findings with clinical outcomes in 44 patients with NEC and suggested the utility of US for the clinical management as it provides more information over radiographs. In this prospective study, we interpreted the US findings prior to any surgical intervention, with confirmation of suspected intestinal necrosis at laparotomy thereby reducing reporting bias. Our findings confirm the relationship between US findings and not only surgical NEC (which may be open to subjective interpretation due to inter-surgeon variability in threshold for surgery) but more specifically direct confirmation of intestinal necrosis at surgery.

The principal limitation of our study is the relatively low number of subjects overall and the even smaller number of infants who had an US that was positive for intestinal necrosis. This is a reflection of the fact that we specifically excluded infants with pneumoperitoneum as we believed they had an accepted and established indication for surgical intervention and interrogation by means of abdominal US was likely to be of limited value. Larger prospective studies are necessary to further evaluate the utility of US at predicting those who would benefit from surgery and to determine

the impact of using US findings routinely in a clinical decision pathway for NEC. Although the sensitivity of US for the detection of bowel necrosis appears to be excellent, the 95% confidence interval is wide (39.8-100%) related to the small number of the study group. However, for 95% confidence interval for its specificity is 77.2-99.9% which implies that abdominal US is much better in identifying patients with NEC who do not have bowel necrosis.

The potential beneficial effects of US scanning before referral to a pediatric surgical centre have not been investigated in this study. However, it is possible that such a diagnostic tool if implemented in a network of neonatal units could highlight a "window of opportunity" for treatment, expedite transfer to a surgical centre and avoid unnecessary transportation for babies with normal investigations.

In summary, these findings suggest that abdominal US can identify or exclude infants with NEC who may need surgery by detecting bowel necrosis (prior to the development of perforation or clinical deterioration) with high sensitivity and specificity. Surgically intervening earlier in the clinical pathway of NEC may lead to improved outcomes.

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TABLES

		Ultrasound Findings													
Patient no	Anechoic free fluid	Free fluid with echoes	Focal echogenic fluid collection	Portal venous gas	Increased wall echogenicity	Bowel wall thickening	Bowel wall thinning	Intramural gas	Increased perfusion	Decreased perfusion	Absent perfusion	Decreased peristalsis	Suspected bowel necrosis on basis of US	Surgery	Bowel necrosis on surgery
1	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-
2	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	-	-	+	-	-	+	+	+	+	+	+	+	+	+	+
4	+	-	-	-	+	+	-	-	-	+	-	+	-	-	-
5	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
7	-	-	+	-	+	+	-	-	-	-	-	+	-	-	-
8	-	-	+	-	+	+	-	+	-	+	+	+	+	+	+
9	+	-	-	-	+	+	-	+	-	-	-	+	-	-	-
10	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-
11	+	-	-	-	-	+	-	+	-	-	-	-	-	-	-
12	-	+	-	-	+	+	+	+	-	+	-	+	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	+	-	-	-	+	-	-	+	+	-	-	-	-	-	-
15	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-

Table 1. Abdominal Ultrasound Findings and correlation with surgical findings.

16	-	-	-	-	-	+	-	+	+	-	-	-	-	-	-
17	-	+	-	+	+	+	-	+	+	+	+	+	+	+	+
18	+	-	-	-	+	+	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
20	-	-	-	-	-	+	-	+	+	-	-	-	-	-	-
21	+	-	-	+	+	+	-	-	+	-	-	-	-	-	-
22	-	+	-	+	+	+	-	+	-	-	-	+	-	+	-
23	+	-	-	+	+	+	-	+	-	-	-	-	-	-	-
24	-	-	-	-	+	+	-	+	-	+	+	+	+	+	-
25	-	+	-	-	-	+	-	+	+	+	+	+	+	+	+
26	-	+	-	-	-	+	-	+	-	-	-	-	-	-	-

Table 2. Table summarizing the number of patients who have bowel necrosis on US and at surgery.

		Bowel necrosis at surgery							
		Positive	Negative						
Ultrasound	Positive	4	1						
diagnosis of bowel necrosis	Negative	0	21						
The sensitivity of US for the detection of bowel necrosis sensitivity 100%, specificity									
95.4, positive predictive value 80.0%, negative predictive value 100%.									

FIGURES LEGENDS

Figure 1. Patient 3. 22-day-old boy (GA: 30 weeks) Frontal abdominal radiograph shows moderate dilatation and separation of bowel loops (A). On US, there were generalized decreased peristalsis, wall thickening and absent perfusion in bowel loops in the right upper (B, C) and lower (D) quadrants, associated with focus of intramural gas (arrow) (E) and focal complex, partly echogenic fluid collection (F). At surgery, there was necrosis in the entire colon including the appendix and ileocecal valve with relative sparing of the rectum (G). A subtotal colectomy and end-ileostomy was performed.

Figure 2. Patient no 8. 42-day-old girl (GA: 26 weeks and 6 days) Frontal abdominal radiograph shows severe dilatation, separation of the bowel loops and intramural gas in the right lower quadrant (A). On US, there were generalized decreased peristalsis, wall thickening and absent perfusion in bowel loops in the right upper and lower quadrants on the longitudinal view (B) associated with multiple foci of intramural gas on the transverse view (C). At surgery, there was necrosis in the cecum, right colon and transverse colon. An ileocecectomy with ileostomy and mucous fistula creation was performed.

Figure 3. Patient no 17. 25-day-old girl (GA: 27 weeks and 1 day) Frontal abdominal radiograph shows moderate dilatation, and separation of the bowel loops (A). On US, there were generalized decreased peristalsis and perfusion (even with absent perfusion in some loops), bowel wall thickening, intramural gas and portal venous gas (arrow) and free intraperitoneal fluid with echoes on the longitudinal images from the right upper quadrant (B-D) and transverse image from the left lower quadrant. At surgery, the cecum, right colon, and transverse colon were necrotic. The entire small bowel was necrotic except for the proximal and distal 35 cm (proximal 35 cm from the ligament of Treitz and distal 35 cm of ileum including the terminal ileum were inflamed but not necrotic).

Figure 4. Patient no 25. 19-day-old girl (GA: 26 weeks) Abdominal radiograph shows moderate dilatation, separation, and intramural gas in bowel loops in the mid-upper, left upper, and left lower abdomen (A). On US, there were generalized decreased peristalsis, bowel wall thickening, absent perfusion, and intramural gas in loops of bowel in the mid-upper abdomen (B), bowel wall thickening and decreased/absent perfusion with increased peripheral perfusion in bowel loops in the right upper quadrant (C), and increased perfusion with wall thickening in loops of bowel in the left lower quadrant (D). At surgery, there was full thickness patches of necrosis at different levels of the jejunum. Extensive small bowel resection with creation of proximal jejunostomy and mucous fistula was performed.

Figure 5. Patient no 24. 7-day-old boy (GA: 34 weeks) with complex cardiac anomalies requiring surgery. AP view abdominal radiograph (A) shows a non-specific bowel gas pattern with suggestion of intramural gas in the right hemi-abdomen. This persisted on follow up 13 hours later (B). US showed a loop with wall thickening, intramural gas, absent perfusion, and decreased peristalsis on the right and this also persisted on follow up (C-E).















































