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Stienstra, Roxane M.; McHoney, Merrill

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Roxane M. Stienstra & Merrill McHoney

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ORIGINAL ARTICLE

Near-infrared spectroscopy (NIRS) measured tissue oxygenation in neonates with gastroschisis: a pilot study

Roxane M. Stienstra[a,b] and Merrill McHoney[b]

[a]University of Groningen, Groningen, the Netherlands; [b]Department of Paediatric Surgery, Royal Hospital for Sick Children, Edinburgh, Scotland

ABSTRACT

Background: Management of gastroschisis involves either primary or staged closure. Bowel ischemia and abdominal compartment syndrome (ACS) are possible complications that can be related to a method of treatment. NIRS monitoring has never been applied in this group of patients and may allow for earlier detection of complications.
Objective: To assess near-infrared spectroscopy (NIRS) monitoring in neonates with gastroschisis for detecting changes in tissue oxygenation (rSO_2) related to bowel reductions or height of bowel in the silo and for detecting tissue ischemia.
Methods: Patients with gastroschisis and controls underwent continuous multi-channel assessment of oxygenation of the brain ($CrSO_2$), kidney ($RrSO_2$) and bowel ($GrSO_2$) in a prospective pilot study.
Results: Fifteen neonates were treated with primary closure ($n=3$) or staged closure ($n=12$); two had confirmed bowel ischemia, none developed ACS.
Results: There was no significant correlation between height of the bowel and $GrSO_2$ at apex ($p=.72$) or base ($p=.54$) within the silo. During staged reductions there was a clinically non-significant change in $RrSO_2$ (Δ-2.5%, $p=.04$), but no significant changes in $CrSO_2$ ($p=.11$), and $GrSO_2$ of apex ($p=.97$) and base ($p=.31$). Patients with confirmed ischemia had $GrSO_2$ that were lower than controls.
Conclusions: Measuring $GrSO_2$ through a silo is feasible. Staged reduction seems safe based on NIRS measurements, with minimal effect of hydrostatic pressure on bowel oxygenation. NIRS was able to detect subtle changes in intra-abdominal renal perfusion during reduction and could differentiate healthy and ischemic bowel.

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Gastroschisis; NIRS; bowel oxygenation; ischemia; neonates

Introduction

Gastroschisis is a neonatal surgical emergency. Treatment options include primary closure or silo placement with staged reduction and delayed closure [1]. Both methods have been performed at the bedside, with sutureless definitive closure [2]. No studies have demonstrated a preference for either primary or staged closure [3,4]. Placement of a preformed spring silo with staged reduction is now an established treatment option.

Placing the bowel within a silo may introduce a haemodynamic effect due to the hydrostatic pressure of the column of bowel, with increased the risk of ischemia at the apex. Reducing the bowel into the abdomen can increase intra-abdominal pressure, which can be evaluated by monitoring intravesical or intra-gastric pressure, and indirectly by the effect on ventilation pressures [5,6]. Gastroschisis is associated with an incidence of abdominal compartment syndrome of around 1.0%, short bowel syndrome (SBS) of 7.3%, and of necrotizing enterocolitis (NEC) of 11.0% [7]. SBS can be the result of intra-uterine or postnatal intestinal ischemia. This intestinal ischemia can be inherent to the pathophysiology of the disease, or can be a complication of the method of treatment. Clinical methods for evaluating tissue perfusion and oxygen delivery include urine output, blood lactate measurements, capillary refill time, blood pressure and pulse oximetry [8].

Near-infrared spectroscopy (NIRS) is noninvasive and offers continuous monitoring and detection of low tissue perfusion *via* measurement of regional tissue oxygenation (rSO_2); representing the balance between oxygen delivery and consumption [9],

CONTACT Merrill McHoney mmchoney@yahoo.com Department of Paediatric Surgery, Royal Hospital for Sick Children, 9 Sciennes Rd, Edinburgh EH9 1LF, UK

thereby making it more sensitive than blood flow measurements only. NIRS measures mixed venous oxygenation, representing 70–80% of venous oxygenation, 5% from capillaries and 20–25% of arterial oxygenation, and has been shown to correlate with other markers of tissue oxygenation and perfusion for cerebral oxygenation ($CrSO_2$) [10–13], renal ($RrSO_2$) [14–17] and gastrointestinal oxygenation ($GrSO_2$) [18–20] and with functional outcome for cerebral [21–26] and renal measurements [27–31].

Fortune et al. described cerebro-splanchnic oxygenation ratio (CSOR; $GrSO_2/CrSO_2$) [32], suggesting a cut-off value of 0.75 for the prediction of intestinal ischemia in neonates. Individual normalization of rSO_2 by calculation of CSOR may allow a more critical appraisal of local oxygenation and a better estimation of blood flow of the regional tissue bed being studied.

The use of NIRS in patients at risk for intestinal ischemia is not yet in widespread clinical practice, and implications of monitoring $GrSO_2$ in neonates on their clinical outcome have yet to be established. Early detection of the onset of decreased tissue oxygenation by NIRS, may allow intervention before major complications occur. The use of NIRS in surgical neonates is limited but there are calls for more studies looking at the applicability in patients at risk [33]. There are no studies evaluating NIRS in neonates with gastroschisis.

The aims of this pilot study are to investigate the feasibility of measuring bowel oxygenation through a silo using NIRS, to assess the effect of height of the silo and of reductions on oxygenation of tissues, and to evaluate any correlation between NIRS measurements and outcome, specifically the incidence of intestinal ischemia.

Methods

We conducted a prospective cohort pilot study to evaluate the feasibility and applicability of NIRS measurement of intestinal and tissue rSO_2 in gastroschisis at a tertiary referral unit. Research Ethic Committee approval and informed consent were obtained. Routine surgical practice was followed and clinical management was conducted as already practised, with the consultant with clinical responsibility dictating management. The study was registered on clinicaltrials.gov (ID 2013/0117). The authors report no conflicts of interest.

Patients

Inclusion criteria were neonates with gastroschisis between 30 and 42 weeks gestation. We excluded infants with generalized sepsis, cerebral or chromosomal abnormalities or with a significant congenital anomaly affecting the respiratory system or cardiovascular system. Fifteen patients with gastroschisis admitted to the Royal Hospital for Sick Children between November 2013 and July 2017 were enrolled. Four surgical neonates of similar gestation without gastroschisis in the same period of time were enrolled as controls.

Patient and public involvement

Parents of patients with gastroschisis were consulted at the conception of the study to gauge public interest in the importance of the study and the impact of measurements on the care of patients. This was positive. However, given the pilot nature of the study, patients were not directly involved in the study design itself. Patients who have communicated interest in knowing the results will have the results disseminated to them.

Surgical procedure

The choice for either primary closure or staged reduction with a silo was based on clinical findings and condition of the bowel. However, staged reduction after bedside placement of a preformed silo is the preferred approach in our institution. Whenever clinical concern or individual circumstances allowed, a primary closure was performed (e.g. need to go to theater for evaluation or any other reason, or easy return of the bowel into the abdomen).

Data acquisition

Multi-channel monitoring was conducted using the in-vivo optical spectroscopy (INVOS) oximeter (Somanetics, Troy, MI). Measurements were initially analyzed using the INVOS analytics tool, version 1.2. For further analysis, the files were converted into excel databases.

Neonatal NIRS sensors were applied after placement of the silo or primary reduction of the bowel into the abdomen. Sensors were applied on the left forehead to measure $CrSO_2$, on the left flank to measure $RrSO_2$ and at the apex and base of the silo to measure bowel oxygenation ($GrSO_2$) as shown in Figure 1. In the case of a primary closure, a control patient or after

Figure 1. Application of near-infrared spectroscopy (NIRS) sensors at apex and base of silastic silo in a patient with gastroschisis.

delayed closure in the silo group, the abdominal probes were placed on the right-(RLQ) and left lower quadrant (LLQ) measuring $GrSO_2$ through the abdominal wall. Several studies have demonstrated that the combination of two or more NIRS sites increases sensitivity, specificity and the predictive values or NIRS measurements [34]. Measurements were recorded and stored automatically by the software into a continuous string file. Before analysis was conducted, artifacts were manually excluded from the data.

Measurement of the height of the bowel within the silo was done initially and after each reduction, and the change in height of the bowel in the silo (Δheight) was documented, and the change in $GrSO_2$ at apex and base (Δ $GrSO_2$ apex, Δ $GrSO_2$ base) was calculated.

Clinically relevant events and clinical outcome were documented; including the need for return to theater for ischemic bowel or other complications, time to full reduction and time to full feeds. Other clinical events recorded were initiation and increase of feeds, changes in the color or appearance of the bowel, periods of cardiovascular instability.

Statistical analysis

As this is an observational pilot study and not a hypothesis testing study, traditional sample size calculations that are based on statistical tests of hypotheses were not performed. A previous pilot study using similar methodology in neonatal surgery enrolled eight patients undergoing thoracic surgery and identified decreased $CrSO_2$ in these patients [35]. Therefore, we believe having fifteen patients provides us with sufficient data to describe the normal $GrSO_2$ profile and assess the outcome measures.

Normally distributed values were expressed as mean and standard deviation (SD) and non-normally distributed values as median and range. Differences in means were presented with a standard error of the mean (SEM).

Overall oxygenation of the bowel in each patient was calculated as the average of the two bowel measurements. Unless otherwise stated, we calculated the mean and SD for each NIRS channel of the 30-min period before and after each reduction or any other clinical event. We calculated mean rSO_2 of apex and base for the periods in between reductions for all patients. Paired *t*-test was used for paired data and student *t*-test for independent samples. Mann–Whitney-*U* was used to compare groups. Pearson correlation and linear regression analysis, correcting for patient differences, were applied to evaluate the effect of height on bowel oxygenations. Raw rSO_2 data was used to calculate the CSOR, using the formula $CSOR = GrSO_2/CrSO_2$.

All statistical analyses were performed using MicrosoftTM Office: Excel 2013 (Microsoft Corporation, Redmond, WA, USA) and IBM SPSS statistical software version 23 (IBM Corporation, Armonk, NY). The *p*-values of $\leq .05$ were considered significant.

Results

Fifteen patients with gastroschisis and four controls were included. Patient characteristics are presented in Table 1.

Patients undergoing staged reduction had a mean initial height of bowel within the silo of 11 cm (range 3–15 cm) and a median of 5 (range 3–9) reductions per patient, with a mean height of each reduction of 1.8 cm (range 0.5–5.4 cm). Of the gastroschisis group, seven initially received mechanical ventilation. The control patients had esophageal atresia with tracheo-esophageal fistula (OA + TOF), left sided congenital diaphragmatic hernia (CDH), ileal atresia and exomphalos major. The patient with OA + TOF was

Table 1. Demographics of patients.

Patient group	Gastroschisis all patients	Staged closure	Primary closure	Control
n	15	12	3	4
Gestational age (weeks) mean (range)	36.9 (34.7–38.7)	36.9 (34.7–38.7)	36.6 (35.6–37.3)	40.4 (37.1–42.3)
Birth weight (kg)	2.7 (2.0–3.5)	2.6 (2.0–3.0)	3.2 (3.0–3.5)	3.4 (3.1–4.0)
Gender (M:F)	12:3	9:3	3:0	2:2
Time to full feeds (days) median (interquartile range)	27 (15–41)	26 (15–37)	31 (20–41)	17 (5–30)
Time to discharge (days) median (interquartile range)	39 (20–79)	40 (20–79)	33 (23–44)	20 (10–34)
Ventilation (*n*)	7 (47%)	4 (33%)	3 (100%)	3 (75%)
Bowel ischemia (*n*)	2 (13%)	1 (8%)	1 (33%)	0 (0%)
Deceased (*n*)	1 (7%)	0 (0%)	1 (33%)	0 (0%)
First day $GrSO_2$ mean (standard deviation)	68.7% (±11.4)	65.9% (±9.77)	85.2% (±1.8)	67.7% (±3.3)
First day CSOR	0.79 (±0.14)	0.76 (±0.12)	0.97 (±0.03)	0.83 (±0.06)

Mean (standard deviation). $GrSO_2$: bowel oxygenation; CSOR (cerebral splanchnic oxygen ratio): bowel oxygenation/cerebral oxygenation.

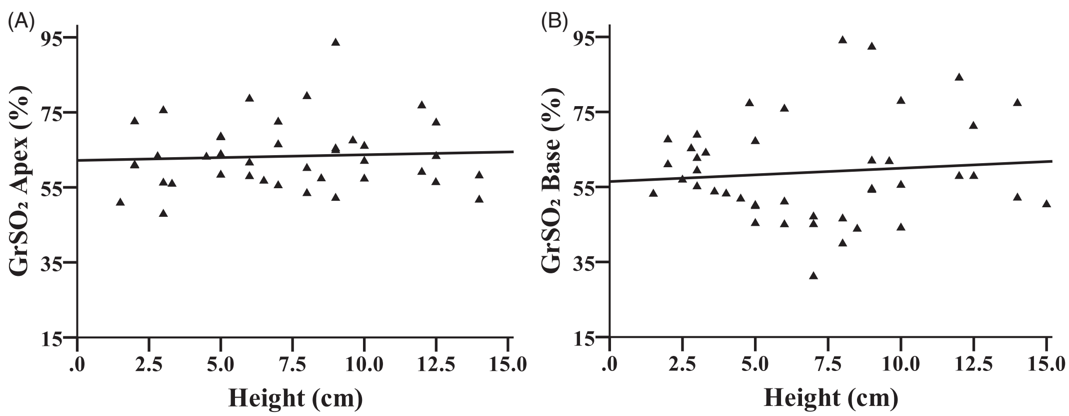

Figure 2. Correlations between height of bowel in silo with bowel oxygenation at apex (A) or base (B). There was no correlation between the height of the bowel within the silo and measured oxygenation. $GrSO_2$: bowel oxygenation.

monitored with a cerebral and gastro-intestinal probe, which was placed infra-umbilical. All other controls had cerebral and renal probes; with gastro-intestinal probes placed on the right and left lower quadrant. In the patient with the CDH, a probe was placed initially on the left chest, to monitor the bowel in the chest pre-operatively.

Day one $GrSO_2$ and CSOR of the control group, primary closure group and staged closure group without ischemia are presented in Table 1. There was no statistically significant difference in $GrSO_2$ between the control and primary closure group ($p = .78$), the control and staged closure group ($p = .58$) and the primary closure and staged closure group ($p = .74$). Similar findings were found with CSOR.

Effects of height of bowel within silo on $GrSO_2$

The effect of height of the bowel in the silo on $GrSO_2$ was assessed (Figure 2). There was no correlation between height of the bowel within the silo and $GrSO_2$ ($r^2 = 0.036$, $p = .72$) or CSOR ($r^2 = 0.008$, $p = .57$) at the apex. There was also no correlation with $GrSO_2$ ($r^2 = 0.009$, $p = .54$) or CSOR ($r^2 = 0.015$, $p = .43$) of the base.

Effects of silo reductions on rSO_2

Figure 3 shows all 4 channel rSO_2 before and after each reduction for each patient. There was no significant change in $CrSO_2$ (pre 84.0%, post 84.6%; SEM 0.37; $p = .11$) or $GrSO_2$ at apex (pre 61.3%, post 61.4%; SEM 2.18; $p = .97$) or base of silo (pre 58.6%, post 55.8%; SEM 2.73; $p = .31$). Similar patterns were found when CSOR data was analyzed. A significant decrease in $RrSO_2$ was found (pre 85.4%, post 82.9%; SEM 1.18; $p = .04$). No patients included in our study suffered from abdominal compartment syndrome.

There was no correlation between Δ height and Δ $GrSO_2$ apex ($r^2 = 0.000$, $p = .994$) or Δ GrSO2 base ($r^2 = 0.065$, $p = .160$; Figure 4).

Functional gastrointestinal outcome

To correlate to outcome, 24 h, 48 h and total period $GrSO_2$ means were calculated. Median time to full feeds was 22 days (IQR 19–34) and did not correlate to mean 24 h $GrSO_2$ ($r^2 = 0.020$ $p = .61$), 48 h ($r^2 = 0.013$, $p = .69$) and total period $GrSO_2$ ($r^2 = 0.006$, $p = .79$). Median time to discharge was 37 days (IQR 24–41) and did not correlate to mean 24 h $GrSO_2$ ($r^2 = 0.047$,

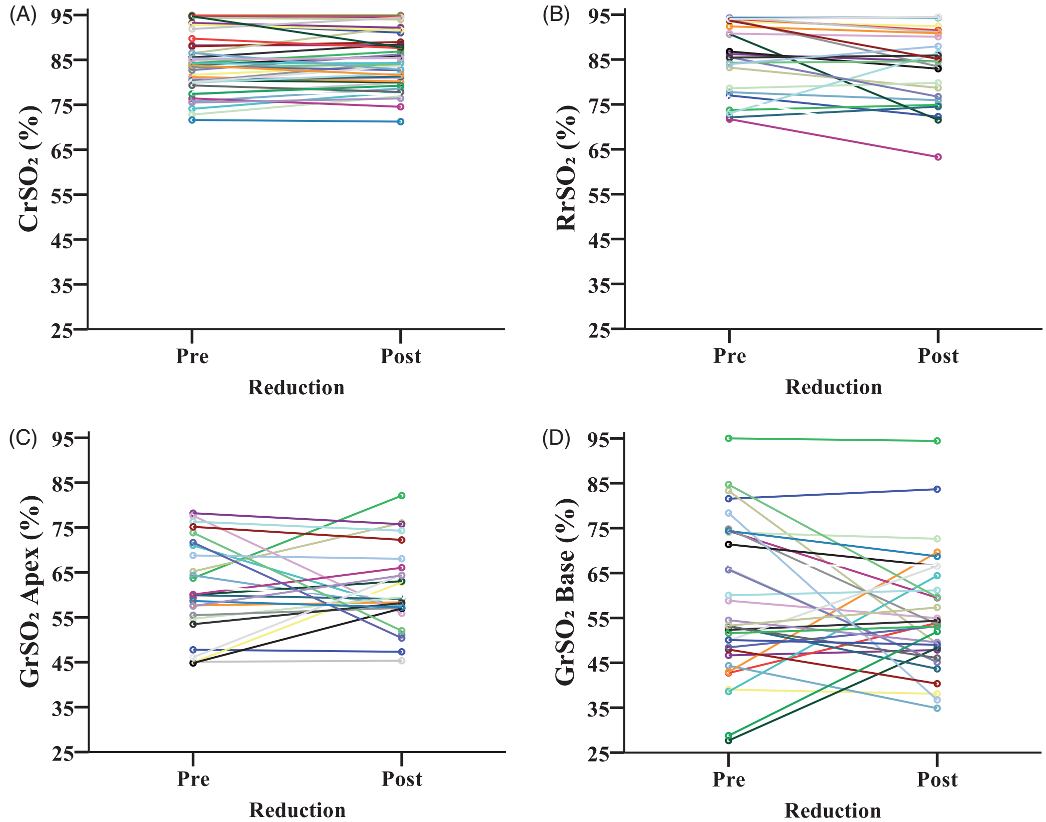

Figure 3. Pre and post reduction NIRS measured oxygenation in the cerebral (A), renal (B), and bowel at the apex (C) and base (D) of the silo. Each line represents one reduction in one patient. There was no consistent or significant change in cerebral or bowel oxygenation at reductions. There was a small decrease in renal oxygenation at reductions. $CrSO_2$: cerebral oxygenation; $RrSO_2$: renal oxygenation; $GrSO_2$: bowel oxygenation.

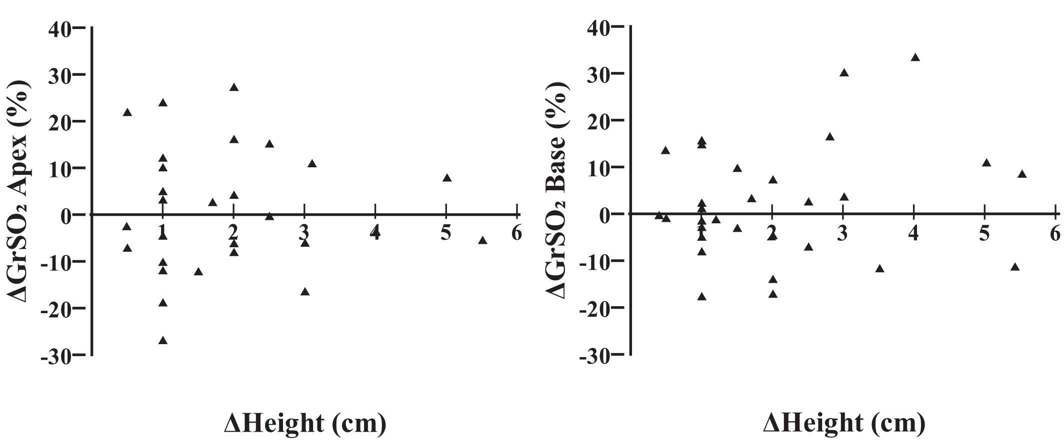

Figure 4. Correlation between change in height of the bowel in the silo (Δ height) and change in bowel oxygenation at the apex and base of the silo during reductions. There was no correlation between the height the bowel was reduced and any change in bowel oxygenation, neither at the apex or the base. Δ $GrSO_2$: change in bowel oxygenation.

$p = .42$), 48 h ($r^2 = 0.029$, $p = .53$) and total period $GrSO_2$ ($r^2 = 0.008$, $p = .74$).

NIRS measured bowel ischemia

Two patients had clinically confirmed intestinal ischemia. Mean $GrSO_2$ for these patients had a range of 15–29% and showed no overlap with mean $GrSO_2$ of the patients without ischemia which had a range of 45–93% (Figure 5). Mean CSOR for the patients with bowel ischemia had a range of 0.24–0.30 and of non-ischemic patients of 0.57–0.99, which again showed no overlap.

In case 1 (Figure 6(A)), a patient treated by staged closure within a silo, recorded a $GrSO_2$ at the base that was significantly lower than the apex.

An ischemic loop of bowel was present in the base and at operation was found to be volvulus of a localized loop. The loop was unvolved and placed in the right lower quadrant (RLQ) and abdominal closure was performed, with probes placed on the right and left lower quadrant (LLQ) of the abdomen. Postoperative $GrSO_2$ in both RLQ and LLQ were comparable. Recovery of blood flow to the loop of bowel was later clinically confirmed by a re-look laparotomy.

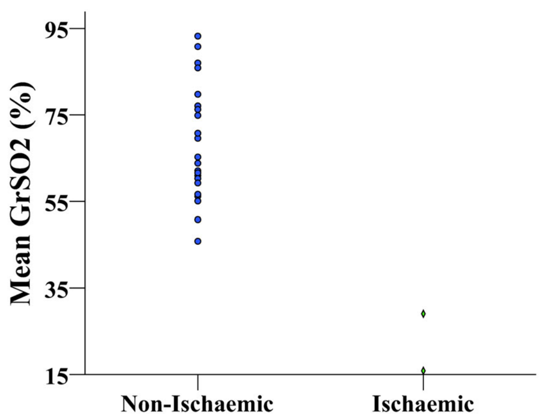

Figure 5. Mean bowel oxygenation for patients with and without bowel ischemia. Measured bowel oxygenation was significantly lower in patients with confirmed ischemia, with no overlap with non-ischemic group. $GrSO_2$: bowel oxygenation.

In case 2 (Figure 6(B)), a patient had generalized hypoxic ischemic injury secondary to severe peripartum hemorrhage from a lacerated umbilical cord. The baby was immediately taken to theater and the bleeding stopped, but with generalized ischemic bowel as a result. The abdomen was closed and the infant was returned to intensive care, with rSO_2 monitored postoperatively. NIRS readings showed markedly reduced cerebral oxygenation and extremely low bowel oxygenation throughout the period of monitoring. A second look laparotomy was performed and showed total bowel necrosis, and the patient had care re-orientated and unfortunately passed away.

Discussion

This pilot study reports the results of multi-channel NIRS monitoring of rSO_2 in neonates with gastroschisis. To date, no studies have assessed the feasibility of NIRS measurements in neonates with gastroschisis, specifically during staged closure and no studies have evaluated the haemodynamic effect caused by hydrostatic pressure on the bowel and reduction of the bowel within the silo.

We found no correlation between height of bowel within the silo and $GrSO_2$ at either apex or base; nor any correlation between changes in height during

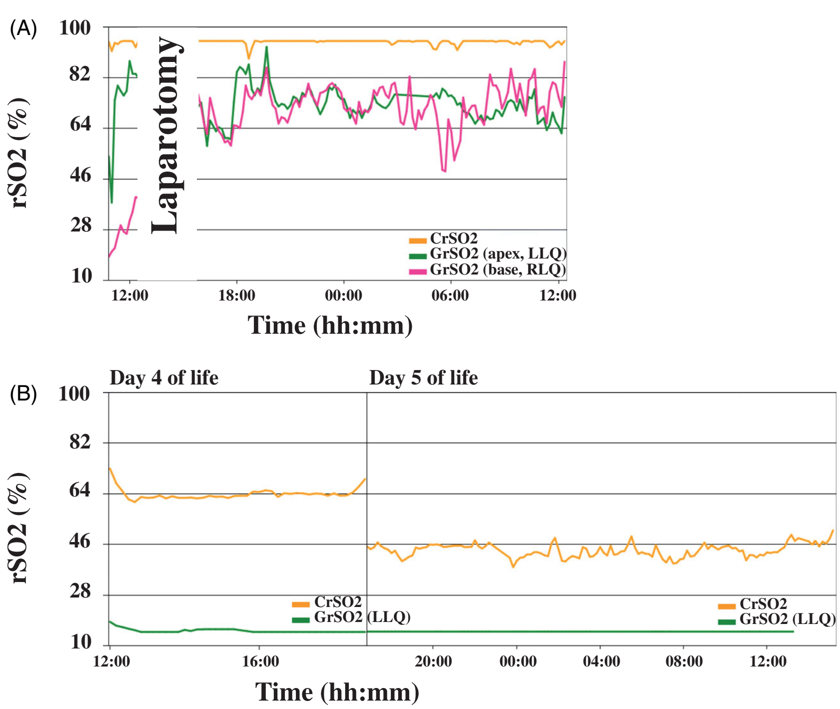

Figure 6. Real time graph of multi-channel monitoring of brain and bowel at apex, base, right (RLQ) and left (LLQ) lower quadrant for case 1 (A) and of brain and bowel in case 2 (B). These two patients had confirmed bowel ischemia. In case 1, bowel ischemia was reversed after correction a twisted loop at laparotomy. In case 2, there were global hypoxic ischemic changes that were not reversible. $CrSO_2$: cerebral oxygenation; $GrSO_2$: bowel oxygenation.

reduction and oxygenation in the bowel at apex or base; with a mean change in height of 1.8 cm and a maximum of 5 cm. These results suggest that the effect of hydrostatic pressure on oxygenation of the bowel in the column of the silo is minimal, and possibly negligible within the limits of the silo heights used in this study. Although NIRS does not only reflect blood flow but also reflects mixed venous oxygenation (which reflects the balance between multiple factors, including blood oxygenation and flow, and tissue oxygen consumption), what can be deduced is that there is no significant change in the balance between oxygen delivery and oxygen consumption or demand in the loops of bowel within the silo. This indicates that silo placement and staged reduction is a safe method of treatment for gastroschisis within the limits used in the study.

Interestingly, the primary closure group had higher $GrSO_2$ values on day one compared to both control group and the staged closure group. However, the numbers were too small (i.e. only three in the primary closure group) to make any significance of this. This observation may represent a change in the bowel oxygenation in primary closure group representing [1] neonatal cardiovascular transitional changes to the bowel; and [2] increased oxygenation as the bowel, which previously was perfused through a tight restrictive ring in the abdominal wall in-utero, now has an increased blood flow after reduction. However, with only three patients having primary closure, this is at most speculative, and possibly coincidence.

There was a statistically significant decrease in $RrSO_2$ during reductions. There was a consistent but minimal (2.5%) decrease at each reduction, giving rise to the statistical significance. Studies have established that persistent and/or frequent decrease in rSO_2 from the baseline of $>$15% to 20% for the brain in children [36] and adults [34,37] are indicative of ischemia. We can infer that the decrease in $RrSO_2$ of 2.5% is clinically insignificant. No signs of abdominal compartment syndrome were observed in any of the patients during this study. This result shows that NIRS allows for measurement of even minimal changes in $RrSO_2$ caused by a minimal increase in intra-abdominal pressure during reduction. Therefore, NIRS measured $RrSO_2$ is a feasible means of documenting renal perfusion and to correlate with abdominal pressure increases that can lead to abdominal compartment syndrome. This may be a useful monitoring aid in patients at risk.

$GrSO_2$ of the patients without confirmed ischemia was lower than those without. Because of the small numbers we did not do a statistical analysis or attempt to determine a clinically relevant level that indicates ischemia. However, we see that NIRS measured $GrSO_2$ can detect clinically confirmed ischemia both through the abdominal wall and through a silo. In case 1, NIRS measurements also seemed to correlate with the return of blood flow to the ischemic loop of bowel. One potential value of NIRS measured $GrSO_2$ is the ability to trend changes and make interventions to reverse any detrimental changes and to see the effects of interventions.

Fortune et al. [32] suggested a cutoff value of 0.75 for CSOR was indicative of ischemia. We found that in our cohort, some of the non-ischemic patients had values below this cutoff CSOR on the first day. Differences in methodology and patient demographics may make this limit not applicable in this group of patients. More data for gastroschisis patients therefore need to be obtained if a specific value is to be suggested. However, the most valuable and reliable use of NIRS will possibly be the real-time trend in rSO_2, in association with other clinical signs. Although the bowel in gastroschisis can occasionally look discolored, this is not usually because of ischemia. Sometimes objective data, as could be obtained by NIRS monitoring, may aid in clinical assessment and management. NIRS may also be relevant to the assessment of intestinal oxygenation in various clinical scenarios across surgical conditions.

Other than the one death in this series, no significant complication was encountered. Although the prevalence of NEC in gastroschisis is as high as 11.0% [7], no patients in this study developed NEC. To establish the relevance of the measured $GrSO_2$ to outcome such as feeding intolerance and NEC, and to establish a cutoff limit to predict bowel ischemia in neonates with gastroschisis a bigger multi-centre study is needed to include a sufficient number of patients.

One limitation of the study is the number of patients, and specifically the number developing ischemia. The number of patients studied may be too small to detect significant differences unless the effect is very strong. The lack of significance in some changes does not mean that there is no difference that might possibly be clinically relevant. Therefore, larger studies are needed. However, as a pilot study we believe the results provides good clinical correlate and data to inform further studies. These measurements through a preformed silo has not been documented before and specificity of $GrSO_2$ may need further investigation, and may not be transferable between different NIRS sensors [38]. Critical $GrSO_2$ levels as a cut of for ischemia cannot be yet determined.

However, the importance of the trend and response to intervention is the more important information to be considered. Recent studies have suggested that the meconium in new-born stools may have a different absorption spectra compared to transitional stool and alter the $GrSO_2$ readings obtained [39]. In this study period all patients had their NIRS measurements performed while still passing meconium, as they were nil orally and still in the ileus stage of their bowel recovery. Therefore, we believe comparisons over the time period are comparable.

Conclusion

Near-infrared spectroscopy allows for noninvasive monitoring of real time regional tissue oxygenation in gastroschisis. NIRS measured renal and cerebral oxygenation were stable during staged reduction, with no signs of abdominal compartment syndrome. Bowel oxygenation within the silo showed no correlation to height of bowel and did not significantly change during reduction. These results indicate that staged reduction within a silo seems a safe method of treatment for gastroschisis, with minimal contribution of hydrostatic pressure on bowel oxygenation. In two patients with clinically confirmed bowel ischemia it was possible to identify reduced oxygenation of bowel using NIRS applied directly on the silo, as well as through the abdominal wall. NIRS monitoring of regional tissue oxygenation may aid in monitoring the bowel and regional perfusion during the management of those at risk of ischemia.

What is already known on this topic

Gastroschisis is known to be associated with postnatal gut ischemia and abdominal compartment syndrome. Limited studies have demonstrated the ability of NIRS to detect significant gut ischemia in neonates. Correlation of NIRS readings with clinically critical events is not always possible.

What this study adds

NIRS measured oxygenation seems reliable both through a silo and through the abdominal wall in neonates with gastroschisis. NIRS is a suitable detector of ischemia associated with critical necrosis confirmed at surgery, and can also confirm the return of bowel oxygenation. It seems a sensitive marker of kidney oxygenation and may be of value in monitoring neonates at risk of gut ischemia and abdominal compartment syndrome.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Merrill McHoney http://orcid.org/0000-0002-0991-6213

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