

**EPIDEMIOLOGY OF SURGICALLY CORRECTABLE GASTROINTESTINAL DISEASE AMONG
NEONATES IN CAPE TOWN, SOUTH AFRICA**

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“Epidemiology of surgically correctable gastrointestinal disease among neonates
in Cape Town, South Africa”

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Abstract

Background/Purpose

A large percentage of neonatal surgery involves gastrointestinal (GI) disease with high disability indexes, leaving opportunity for significant disability-adjusted life year (DALY) reduction in low-middle income countries (LMICs). We aimed to evaluate the impact individual neonatal GI diagnoses and their procedures have on LMIC health systems.

Methods

All neonates who presented with a surgical GI condition at 2 pediatric hospitals in Cape Town, South Africa from 2010-2011 were included and statistically analyzed by diagnosis, case numbers, and individual procedures.

Results

118 neonates and 236 surgical procedures were analyzed. The most common overall diagnoses were anorectal malformations (ARM) (19.5%), necrotizing enterocolitis (NEC) (15.3%), and gastroschisis (9.3%). These same 3 diagnoses represented > 50% of overall total case load. Diagnoses of intestinal atresia, gastroschisis, and NEC were determined to have significantly higher mean number of procedures per patient ($p = 0.002$). Further, 35% of all procedures were related to stages of enterostomy/enterectomy and 18% of all procedures were determined minor in nature.

Conclusions

Our results demonstrate significant burden of congenital conditions with high risk of morbidity and mortality and provide evidence-basis for multi-level interventions. Additionally, our procedural results may improve resource allocation through proper referrals to higher levels of care and the opportunity for task-shifting minor procedures.

KEYWORDS

global surgery, pediatric surgery, global health, gastrointestinal, neonatology, South Africa

1.1 Introduction

In many LMICs, children make up over 50% of the population[1] and up to 85% of children may have a surgically avertable disease by age fifteen.[2] While developed countries like the United States boast an adequate pediatric surgeon: children ratio of 1:100,000, African LMICs struggle to manage this surgical burden with a mere combined ratio of 1 pediatric surgeon:6 million children.[3]

Within pediatric surgery, neonatal surgery in LMICs has been reported to have as low as 3.5% of its avertable surgical burden met.[4] Additionally, neonatal cases in LMICs tend to have high urgency and risk of mortality. One retrospective study in Zaria, Nigeria demonstrated that 40% of neonatal surgeries were emergent with a mortality of 30.5%--postulated to be largely due to late presentation and referral.[5] Congenital anomalies are often the source of these emergencies, ranking among the highest of risk factors for neonatal death in LMICs (RR 14.6).[6] In the frequent context of increased infection and environmental exposure, insufficient access to nutritious foods, and inadequate access to prenatal care,[7] it is not surprising that LMICs carry 94% of the global congenital anomaly incidence.[8] Worse, 95% of deaths secondary to congenital anomalies are in LMICs[9] and anomalies represent 11% of all annual neonatal deaths, globally.[10] While primary prevention of congenital anomalies would be ideal and certainly should be fully attempted, the multifactorial etiologies of congenital anomalies often render this difficult.[7] Fortunately, roughly half of congenital diseases are surgical and can often be easily treated by pediatric surgeons.[11] For this reason it is important to make effort toward improvement of disease screening, access to surgery and quality of care.[12]

Mortality rates are often used to help define disease burden, yet this does not adequately describe the additional burden of disability provided by non-fatal diagnoses. For this reason, particularly when studying neonates who inherently have significant years to live, it is imperative to be cognizant of a disease's potential to cause not only death but also disability.[12] Avertable DALYs are frequently calculated as a way to quantify the public health impact that optimal surgical care would have[13]; a particular opportunity for cost-effective DALY reduction exists in the area of neonatal GI disease as many diagnoses within GI disease are congenital diseases (such as gastroschisis or anorectal malformations) with high disability indexes.[14] Moreover, the disability weights for these congenital GI diseases are often equal to or greater than those of non-GI congenital anomalies and infectious diseases such as club foot, cleft lip/palate, HIV, and tuberculosis.[15,16] Unfortunately, the surgical burden of neonates is not well-described and studies often only discuss common causes for surgery and do not mention surgeries performed.[4,17] Studies on the burden of disease with additional information on procedures used can give rationale for resource allocation as well as help cater useful interventions for improvement of care.[4] This study aims to assess the epidemiology of neonatal correctable GI conditions for Cape Town, South Africa in order to contribute to a more accurate assessment of overall surgical burden in LMICs and provide an evidence-basis for multi-level interventions.

Abbreviations: gastrointestinal (GI); low-middle income country (LMIC); disability-adjusted life years (DALY); anorectal malformation (ARM); necrotizing enterocolitis (NEC)

1.2 Methods

A planned secondary analysis was conducted using data from a retrospective chart review of all pediatric patients who presented at Red Cross War Memorial Children's Hospital and Tygerberg Children's Hospital in Cape Town, South Africa from July 2010 to June 2011 with any diagnosis requiring a surgical intervention during the one year time frame of the study. De-identified study data were collected from patient charts and managed in an excel spreadsheet. For the secondary analysis, all patients ≤ 28 days old at their first procedure for a GI-categorized diagnosis were included (Figure 1). Patient data was extracted from patient records for patient age, date of procedure, surgical facility, primary diagnosis, primary surgical treatments and procedures, related procedures and subsequent procedures within the time frame of the study. Patient surgical treatments were classified post-hoc using a systems-based diagnostic category. Diagnoses were classified using four etiology-based categories: congenital, acquired, indeterminate, or "diagnostic only". For further detail on how patient diagnoses and procedures were classified, see appendix.

Descriptive statistics (mean, median, etc.) were used to compare neonates by diagnostic classification and procedure. For diagnoses with $n > 5$, one-way ANOVA was used to determine significant differences in mean number of procedures. A post-hoc Fisher's least significant difference test was done to determine significant differences between individual diagnoses. All statistical tests were performed with 95% confidence intervals and statistical significance was set at $p < 0.05$. All data analysis was completed using SPSS version 25 statistical software package and Microsoft Excel 2019. This study was approved by the institutional review boards of Red Cross Children's and Tygerberg Children's Hospitals. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

1.3 Results

There were a total of 118 neonates with GI diagnoses that underwent a total of 236 surgical procedures, with the distribution of etiological category outlined by Figure 2. Figure 3 demonstrates the most common primary diagnoses among all 118 patients. ARM was the most common diagnosis among all patients (Figure 3). Of the 8 most frequent diagnoses, six were considered congenital diseases.

Figure 4 demonstrates the diagnoses representing the largest total surgical case share with NEC having the largest share out of 236 surgical procedures. For diagnoses with $n > 5$ patients, a significant difference was calculated using one-way ANOVA ($F(7,82) = 3.491, p = 0.0025$). A post hoc Fisher's least significant difference test ($\alpha = 0.05$) further determined that intestinal atresia (3.14), gastroschisis (3.09), and NEC (2.78) had significantly higher mean number of procedures per patient than all other procedures but were insignificant with each other (Table 1).

Table 2 highlights the most common diagnoses with respect to etiological category. Among 31 total acquired diagnoses, the most common was NEC (58.1%) and of 82 congenital diagnoses, the most common was ARMs. Of 82 congenital diagnoses, the most common diagnosis accounted for 67% of the total surgical case burden while acquired constituted 31% (Figure 5). There were 25 distinct procedures accounted for with the 2 most common overall procedures being enterectomy/enterostomy in its various stages (creation, revision, and closure) and vascular access (Figure 6).

1.4 Discussion

1.4.1 Primary Prevention and Disability Weights of Disease

Though there is limited understanding of the multifactorial causes of our most frequent and burdensome congenital diagnoses, there are some known risk factors beyond genetics. For example, ARMs have been associated with risks such as untreated diabetes, obesity, and paternal smoking [18]; gastroschisis has been associated with maternal malnutrition (low zinc, protein, BMI), smoking, and young maternal age.[19] Further, some acquired diseases such as NEC have a strong association with prematurity, low birth weight, and presence of other congenital anomalies. Unfortunately, untreated disease, lack of proper antenatal education on teratogens, and malnutrition are not newly identified issues and a striking 90% of global premature deliveries occur in LMICs.[20] Indeed, preventative mitigation of these risks should be undertaken and would likely improve many other aspects of public health. The large reality of existing unmet neonatal surgical burden, however, remains and demands evidence-based guidance on how resources should best be allocated to improve systems of surgical care.[4]

As expected, congenital disease represented a majority of patients (Figure 2) and surgical case share (Figure 4). Some of the most frequent primary diagnoses (Figure 3) represent significant disability weights (DW)—a number from 0 (healthy) to 1 (death) that rates the qualitative impact a disease has on a patient. Our top 5 congenital diagnoses (Table 1) have the following DWs based on a 2017 study by Poenaru et al: ARM (0.179-0.249 mild or 0.621-0.756 severe), gastroschisis (0.648-0.758), duodenal atresia (0.834-1), omphalocele (0.394-0.421), and intestinal atresia (0.834-1).[21] These DWs compare to or exceed other frequent non-GI congenital anomalies such as club foot (0.1) or cleft lip/palate (0.05)[15], as well as infectious diseases such as HIV (0.135) and tuberculosis (0.271).[16] With these DWs in mind, it is not surprising that intestinal atresia and gastroschisis required significantly more procedures per patient than all other compared diagnoses.

1.4.2 Procedural Burden and Task Shifting

The variety of acquired disease (Table 1) is evidence in support of the need for inclusion of procedural data in other studies as many of the diagnoses do not include a true primary pathological diagnosis but rather are surgical complications (such as bowel perforations or short bowel syndrome).[4] Moreover, “diagnostic only” procedures, though uncommon in neonates per our data sample, add additional “hidden” strain on LMIC surgeons. At the institutional level, this burden still exists regardless of whether there is a supporting diagnosis.

LMICs have an immense lack of pediatric surgeons to accomplish the overwhelming burden of pediatric surgery; over half of African countries have zero full-time pediatric surgeons available[22,23] and unmet burden is often attributed largely to lack of access.[4] Local health care centers frequently lack pediatric-trained workers and pediatric equipment, shifting burden—whether minor or major—to the major tertiary centers.[24] There have been some promising efforts, however, to improve local access to pediatric care. For example, an initiative in India led a team of pediatric surgery providers from a major Indian tertiary center and high-income countries (HICs) to develop and implement an all-encompassing pediatric training program for adult surgical staff at multiple district hospitals. These district hospitals were given

contact points at tertiary centers and significant increases were seen in appropriate referral rates, remote procedures, and successful resuscitations.

Figure 6 provides significant rationale for procedures that could be included in such a program as enterectomy/enterostomy and vascular access procedures represented over 50% of the total neonatal procedures and were completed for 15 and 7 distinct diagnoses, respectively. Moreover, minor procedures such as vascular access and I&D procedures represent 18% of the total case burden in our sample. Task shifting minor procedures to local hospitals and tertiary paraprofessional providers with less pediatric surgical training may prove useful to reduce patient logistical strains, cost, and burden on overworked pediatric surgeons stationed at tertiary centers. For example, Malawi has a non-physician clinician (NPC) orthopedics supplemental training program that was originally aimed at producing rurally-based health care workers who could treat and prevent disability typically associated with very common musculoskeletal conditions. In 2008, 82 practicing orthopedic NPCs established a patient ratio of 1:159,000 (compare this to 1:500,000 orthopedic surgeons) and covered a broad range of minor procedures such as fracture manipulations, abscess drainages, and joint aspirations.[25] It must not be overlooked, however, that even simple procedures often require complex aftercare and thus a significant degree of planning and additional training would be required if a similar pediatric surgery clinician program were to be created. Recently, a document was created by the Global Initiative for Children's Surgery, the Optimal Resources for Children's surgery (OReCS) document, that outlines the "personnel, equipment, facilities, procedures, training, research, and quality improvement components at all levels of care"[26] and would certainly be useful in such an endeavor.

1.4.3 Screening for Diagnoses with Highest Burden

At the most basic level, Figure 3 and Table 1 provide information on what a pediatrician or rural clinician should hold in highest clinical suspicion when evaluating a newborn in the greater Cape Town area with gastrointestinal symptoms. Improvement in clinical recognition may prove most useful to congenital disease, as delay to diagnosis and treatment is a risk factor frequently associated with increased morbidity and mortality[27]. Further knowledge of the most frequent surgical GI congenital diagnoses may also guide educational efforts and allocation of resources toward prenatal diagnosis of congenital anomalies, allowing for improved outcomes through planned births in centers with access to appropriate postnatal care.[28]

The case burden measure (Figure 4), conversely, demonstrates what diagnoses may put the most strain on a resource-limited health system and may help with planning for allocation of resources and training. Table 2 estimates which diagnoses required significantly higher number of procedures per patient, which may be useful in determining diagnoses that should be referred directly to tertiary centers for higher level of care.

1.4.4 Limitations

There are several limitations to our study. First, the data set is likely incomplete secondary to late detection outside the neonatal period as well as the lack of presentation at all due to a multitude of obstacles such as: financial strain, logistics (distance, ability to travel), social taboo, and inaccurate medical opinions or treatments from local centers.[27,29] For these reasons, in

addition to the emergent nature of our sample, there is always concern of bias with hospital-derived data, warranting further population-based studies.[17,30]

The data is also limited in its demographic information. In addition, the original primary diagnosis was missing for some patients presenting with acquired complications. The lack of outcome and birth data certainly restrained our study as well; this information would have allowed for calculation of DALYs or incidence rates to better quantify burden and compare incidences to those in literature. Another point to be aware of is that this study was done within a particular time frame and therefore would likely not include all additional procedures outside of the time frame that a patient may ultimately require for a diagnosis. Lastly, we recognize that not all procedures are created equal and some inclusion of complexity weights with the procedural totals would have better estimated the impact that diagnoses can have on a resource-constrained system.

1.4.5 Applications

Knowledge of neonatal surgical burden allows for prioritization of interventions that would be most beneficial to both the patient and the health system. Wright et al 2018 discusses a variety of possible interventions specifically for gastroschisis. Some practical macro-level interventions suggested included advocacy for addition of antenatal ultrasound scans to guidelines and improved access to parenteral nutrition at tertiary centers. Micro and meso-level interventions were additionally addressed and included recommendations for primary and secondary center bowel-coverage and IV resuscitation, patient and health worker educational programs, and evidence-based advancements in surgical technique at tertiary centers.[31] It is logical that some of the same or similar interventions would likely have positive impact on other neonatal surgical conditions.

1.4.6 Conclusions

Congenital anomalies are estimated to kill 303,000 newborns within the first 4 weeks of life annually and have as low as 3.5% of surgical burden met by LMIC healthcare systems.[4,8] Local access to high-level pediatric care, particularly neonatal care, is minimal, as evidenced by a 2017 study in West Africa that demonstrated only 51% of surveyed hospitals to have neonatal intensive care support.[32] This study aimed to specifically assess the epidemiology of highly-disabling neonatal GI surgical conditions in order to provide an evidence-basis for multi-level interventions. Our results demonstrate significant burden of congenital conditions with high risk of morbidity and mortality and primarily demand prioritization of local protocols for prenatal detection and early management of congenital disease. Further, our specific procedural results provide an idea of what procedures could be task-shifted to yield the most relief for LMIC pediatric surgeons and how resources might best be allocated to facilities with various levels of care. Our findings urge further study of specific macro-, meso-, and micro-level interventions for the sake of newborns and the future of LMICs that they represent.

1.5 Conflicts of Interest

We have no competing interests to declare.

1.6 Appendix

1.6.1 Etiology Categorization

The congenital and acquired categorizations were based on current understanding of the etiology of the diagnoses. Patients labeled “indeterminate” had diagnoses that were indeterminably consequential of either a congenital or an acquired condition. “Diagnostic only” patients underwent exploratory procedures for suspected diagnoses with no final surgical diagnosis.

Diagnostic categories were decided primarily by systems including: GI, genitourinary, infectious, thoracic, hepatobiliary, hernia, lymph/vascular, neoplasm/malignancy, sexual trauma, skin/soft tissue, Head/eyes/ear/nose/throat (HEENT), heme, trauma, musculoskeletal, pancreatic, pulmonary, renal, or unknown. All categorical decisions were made by 1 pediatric surgeon.

1.6.2 “Other” Categories

The diagnoses (percent total patients) in the other category for Figure 2 consisted of values under 5%: TEF/EA (3.4%); Hirschsprung's (3.4%); cloaca/cloacal extrophy (3.4%); appendicitis (1.7%); pyloric stenosis (1.7%); short bowel syndrome (0.8%); rectal perforation (0.8%); VACTREL (0.8%); hiatal hernia (0.8%); Hirschsprung's – suspected (0.8); ischemic bowel (0.8%); malrotation-suspected, normal rotation (0.8%); pneumoperitoneum (0.8%); prolapse ileostomy (0.8%); rectal bleed (0.8%); stomal break down (0.8%); Zenker's diverticulum (0.8%).

The diagnoses (percent total procedures) in the other category for Figure 2 consisted of values under 2%: appendicitis (0.85%); pyloric stenosis (0.85%); rectal perforation (0.85%); VACTREL (0.85%); hiatal hernia (0.43%); Hirschsprung's – suspected (0.43%); ischemic bowel (0.43%); malrotation-suspected, normal rotation (0.43%); pneumoperitoneum (0.43%); prolapse ileostomy (0.43%); rectal bleed (0.43%); stomal break down (0.43%); Zenker's diverticulum (0.43%).

The procedures (percent total procedures) in the other category for Figure 6 consisted of values under 4%: unspecified (3.4%); omphalocele repair (2.5%); rectal biopsy (2.1%); wound vac (2.1%); Ladd (1.7%); anal dilation (1.3%); TEF repair (1.3%); appendectomy (0.8%); I&D (0.8%); pyloromyotomy (0.8%); colonic interposition (0.4%); open gastrotomy (0.4%); Nissen (0.4%); omental resection (0.4%); Proctorrhaphy (0.4%); Urological (0.4%); abdominal washout (0.4%).

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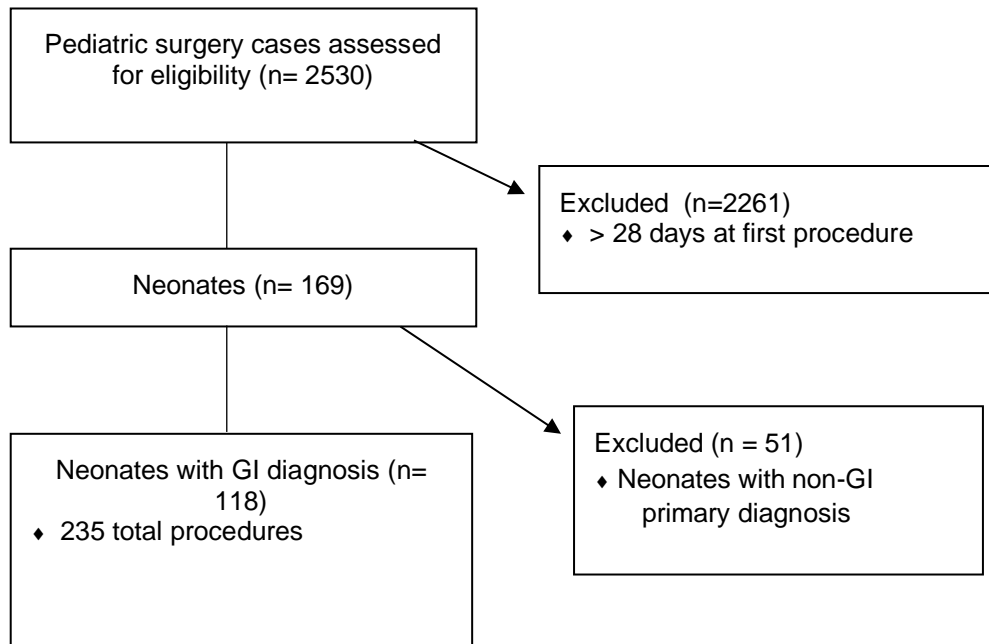


Figure 1. Consort Diagram of inclusion/exclusion criteria for neonatal burden of surgery, South Africa.

118 total neonatal patients with a GI diagnosis first treated at 28 days or less were included, along with all subsequent procedures.

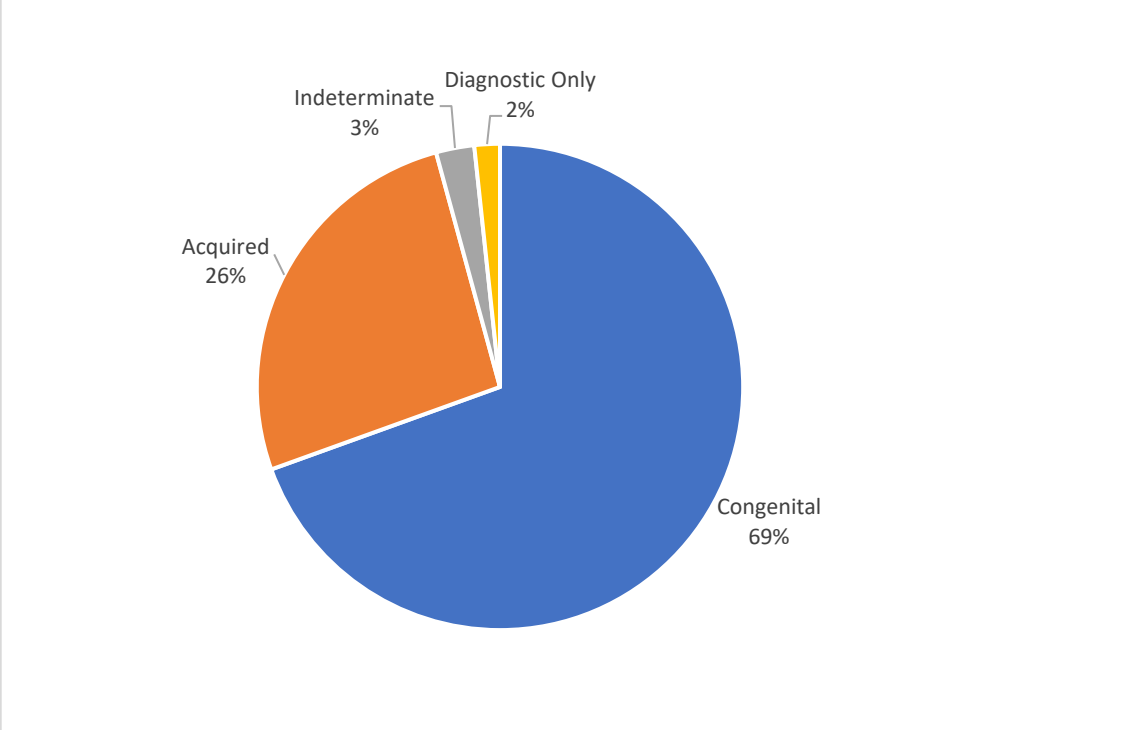


Figure 2: Primary diagnosis etiological category (percent of patients).

A majority (69%) of patients had congenital diagnoses. Indeterminate and “diagnostic only” diagnoses are described in appendix (section 1.6.1).

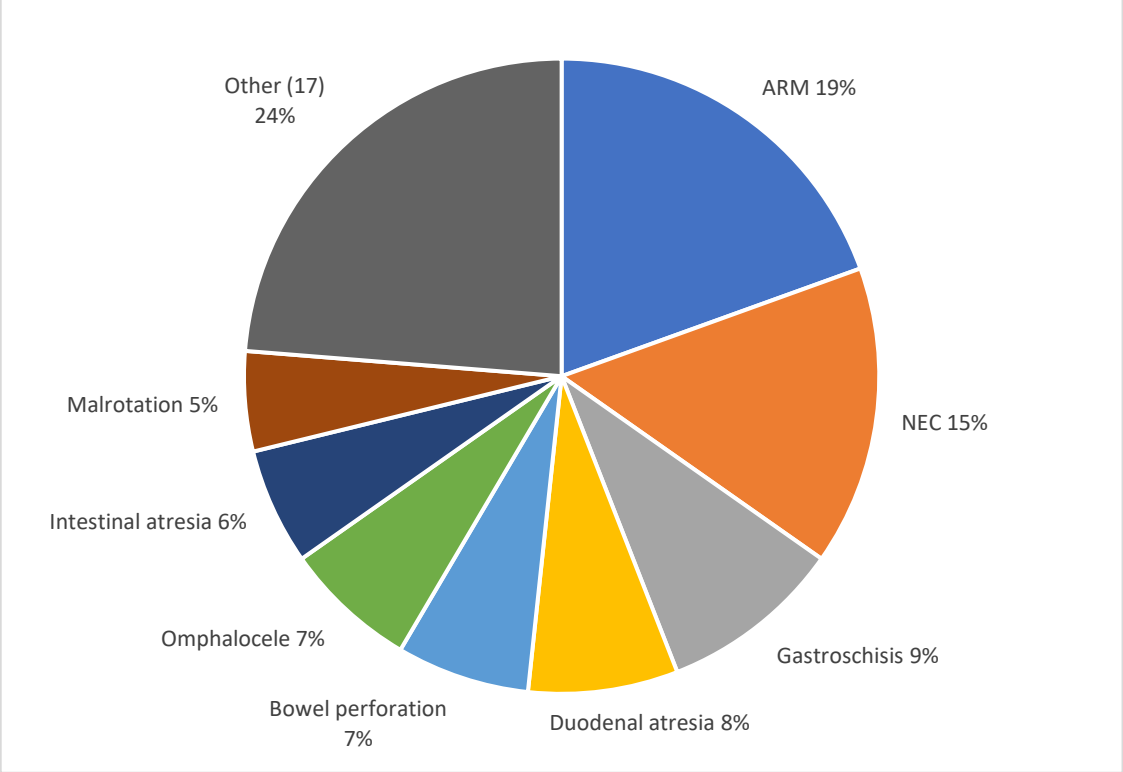


Figure 3: Primary diagnoses (percent of patients).

The 3 most common are NEC, ARM, and Gastroschisis. “Other” category described in appendix (section 1.6.2).

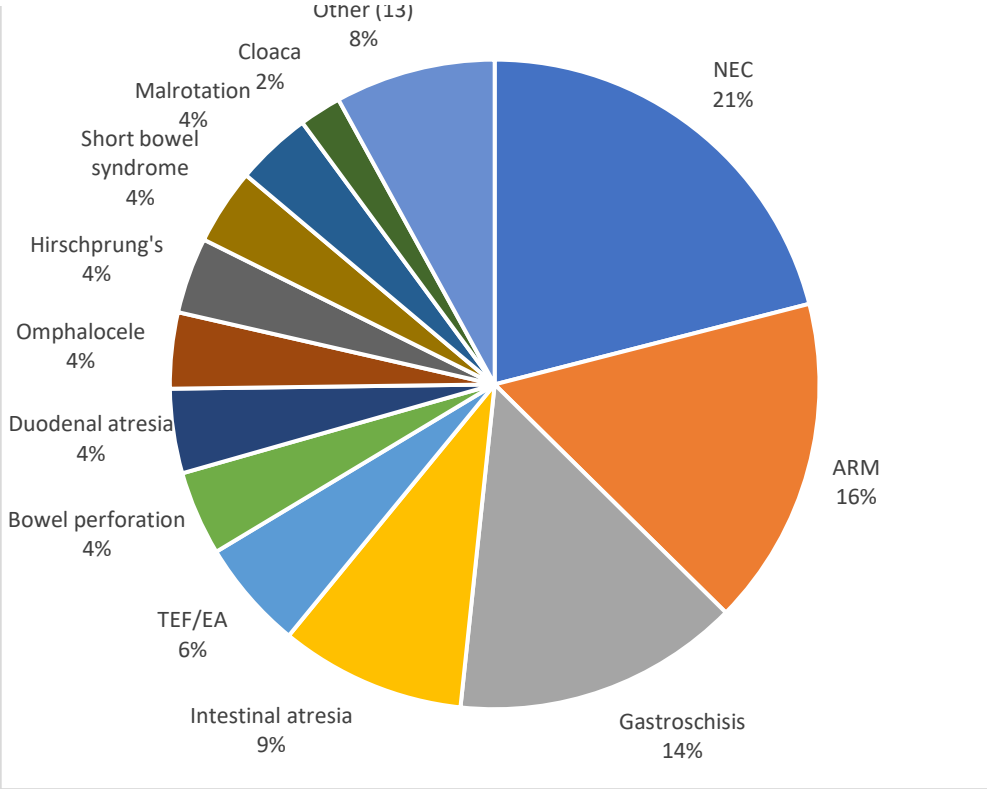


Figure 4: Surgical case share per diagnosis (percent of total procedures). The diagnoses with the largest shares of surgical procedures are NEC, ARM, and Gastroschisis. Diagnoses included in the “Other” category are described in the appendix (section 1.6.2).

Anova: Single
Factor

SUMMARY

<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>
ARM	23	39	1.70	0.95
Bowel perforation	8	10	1.25	0.21
Duodenal atresia	9	10	1.11	0.11
Gastroschisis	11	34	3.09	4.09
Intestinal atresia	7	22	3.14	7.81
Malrotation	6	9	1.50	1.50
NEC	18	50	2.78	3.71
Omphalocele	8	9	1.13	0.13

ANOVA

<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	54.39	7	7.77	3.49	0.0025	2.12
Within Groups	182.51	82	2.23			
Total	236.90	89				

Table 1: One-way ANOVA analysis of mean number of procedures per diagnosis

Averages were calculated for number of procedures per patient, for all diagnoses with n>4 patients. F Calculations were further used in Fisher's least significant difference test.

Category	Primary Diagnosis	Dx Frequency (% of Category)	Surgical Case Share (% of Category)
Congenital (69.5%)	ARM	23 (28%)	39 (24.7%)
	Gastroschisis	11 (13.4%)	34 (21.5%)
	Duodenal atresia	9 (11%)	10 (6.3%)
	Omphalocele	8 (9.8%)	9 (5.7%)
	Intestinal atresia	7 (8.5%)	22 (13.9%)
	Malrotation	6 (7.3%)	9 (5.7%)
	TEF/EA	4 (4.9%)	13 (8.2%)
	Hirschprung's	4 (4.9%)	9 (5.7%)
	Cloaca/Cloacal Extrophy	4 (4.9%)	5 (3.2%)
	Pyloric stenosis	2 (2.4%)	2 (1.3%)
	Bowel perforation	1 (1.2%)	2 (1.3%)
	VACTREL	1 (1.2%)	2 (1.3%)
	Hiatal hernia	1 (1.2%)	1 (0.6%)
	Pneumoperitoneum	1 (1.2%)	1 (0.6%)
	Total	82	158
	Acquired (26.3%)	NEC	18 (58.1%)
Bowel perforation		7 (22.6%)	8 (11%)
Appendicitis		2 (6.5%)	2 (2.7%)
Short bowel syndrome		1 (3.2%)	9 (12.3%)
Rectal perforation		1 (3.2%)	2 (2.7%)
Prolapse ileostomy		1 (3.2%)	1 (1.4%)
Stomal break down		1 (3.2%)	1 (1.4%)
Total		31	73
Indeterminate (2.5%)	Ischemic bowel	1 (33.3%)	1 (33.3%)
	Rectal bleed	1 (33.3%)	1 (33.3%)
	Zenker's diverticulum	1 (33.3%)	1 (33.3%)
	Total	3	3
Diagnostic Only (1.7%)	Hirschsprung's - suspected	1 (50%)	1 (33.3%)
	Malrotation-suspected, normal rotation	1 (50%)	1 (33.3%)
	Total	2	2
Overall Totals	118	236	

Table 2: Diagnostic frequency and case burdens by diagnosis.

This table describes the frequencies and case shares per GI diagnosis, further stratified by their etiology-related category.

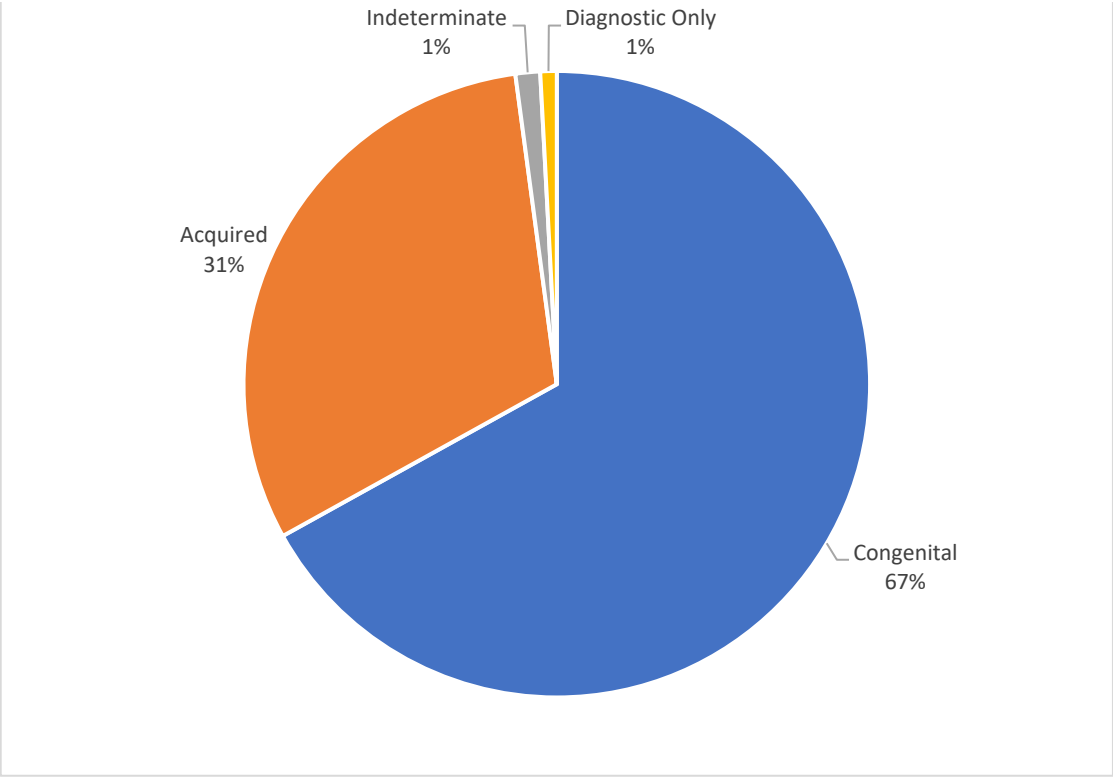


Figure 5: Distribution of surgical cases by etiological category (percent total procedures).

A majority (67%) of surgical cases were for congenital diagnoses. Indeterminate and “diagnostic only” diagnoses are described in appendix (section 1.6.1).

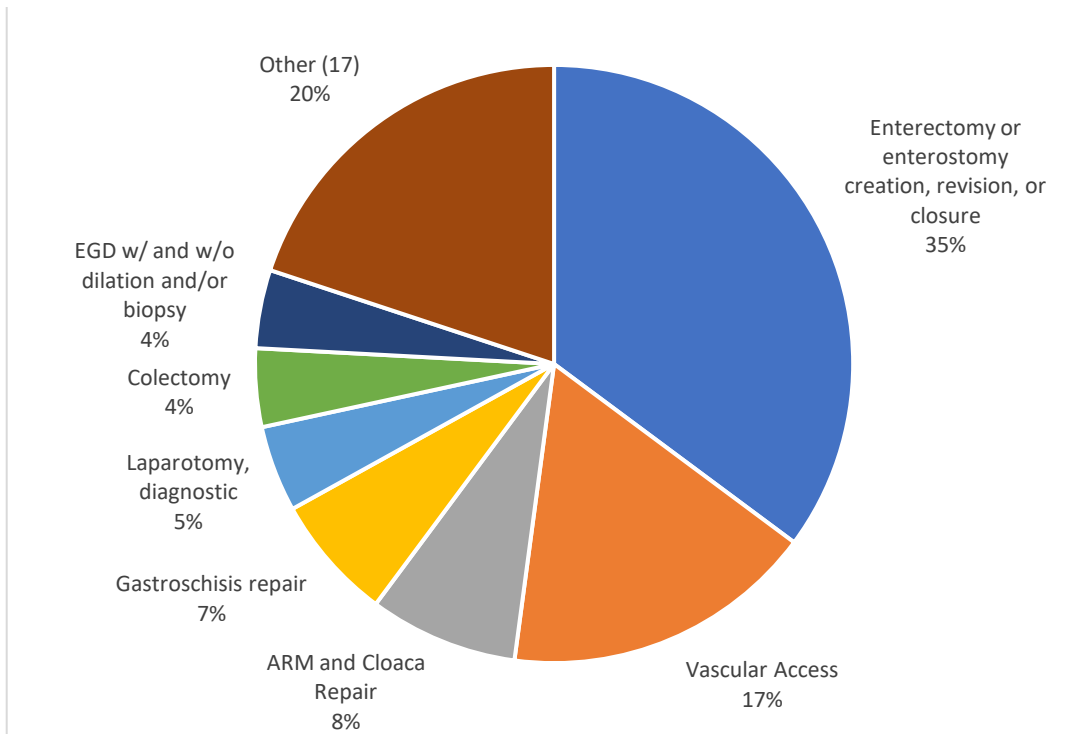


Figure 6: Surgical Procedures performed (percent of total procedures).

The procedures with the largest share of total surgical procedures performed include enterectomy or enterostomy creation/revision/closure (35%), vascular access, and ARM/cloaca repair. Diagnoses included in the “Other” category are described in the appendix (section 1.6.2).