THESIS PRESENTATION

TOPIC :

An Observational Study on Neonatal Surgery Complications Using Clavien-Dindo Classification and Its Associated Risk Factors: A Multicentre Study

By Alia Maisyah
(MGU 170001)
Supervisor: Mr Anand

Introduction

- In 2009, Pierre A. Clavien and Daniel Dindo, from University Hospital of Zurich, Switzerland reevaluated and revised a classification system for grading adverse events which occur as a result of surgical procedures which was first described in 1992
- It is based on the type of therapy needed to correct the complication

The Clavien-Dindo Classification of Surgical Complications

Five-Year Experience

Pierre A. Clavien, MD, PhD, Jeffrey Barkun, MD,† Michelle L. de Oliveira, MD, PhD,* Jean Nicolas Vauthey, MD,‡ Daniel Dindo, MD,* Richard D. Schulick, MD,§ Eduardo de Santibañes, MD, PhD,¶ Juan Pekolj, MD, PhD,¶ Ksenija Slankamenac, MD,* Claudio Bassi, MD,‖ Rolf Graf, PhD,* René Vonlanthen, MD,* Robert Padbury, MD, PhD,** John L. Cameron, MD,§ and Masatoshi Makuuchi, MD, PhD††*

Background and Aims: The lack of consensus on how to define and grade adverse postoperative events has greatly hampered the evaluation of surgical procedures. A new classification of complications, initiated in 1992, was

ing terms such as "minor or major" should be removed from the surgical literature.

(*Ann Surg* 2009;250: 187–196)

Clavien-Dindo Classification

APPENDIX A. Classification of Surgical Complications

Grades	Definition
Grade I:	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II:	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III:	Requiring surgical, endoscopic or radiological intervention
Grade III-a:	intervention not under general anesthesia
Grade III-b:	intervention under general anesthesia
Grade IV:	Life-threatening complication (including CNS complications)‡ requiring IC/ICU-management
Grade IV-a:	single organ dysfunction (including dialysis)
Grade IV-b:	multi organ dysfunction
Grade V:	Death of a patient
Suffix 'd':	If the patient suffers from a complication at the time of discharge (see examples in Appendix B, http://Links.Lww-.com/SLA/A3), the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

‡ brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks (TIA); IC: Intermediate care; ICU: Intensive care unit

www.surgicalcomplication.info

Background

Predictors of major postoperative complications in neonatal surgery

Fatores preditivos de complicações graves em cirurgia neonatal

Dora Catre[1]; Maria Francelina Lopes[2]; Angel Madrigal[3]; Bárbara Oliveiros[4]; Antônio Silvério Cabrita[5]; Joaquim Silva Viana[6]; José Farela Neves[7]

ABSTRACT

Objective: To investigate the incidence and severity of early postoperative complications and to identify their risk factors in newborns undergoing surgery under general anesthesia. **Methods**: We conducted a retrospective analysis of data from 437 critically ill newborns undergoing surgery in a tertiary pediatric surgical center, between January 2000 and December 2010. Complications that occurred within the first 30 days after surgery were classified using the Clavien-Dindo system, for which grades III to V were considered severe. We used univariate and multivariate analysis to evaluate pre- and intraoperative variables potentially predictive of severe postoperative complications. **Results**: The incidence of at least one serious complication was 23%, with a median of one complication per patient 1:3. Altogether, there were 121 serious complications. Of these, 86 required surgical, endoscopic or radiological interventions (grade III), 25 endangered life, with uni or multi-organ failure (grade IV) and ten resulted in death (grade V). The most common complications were technical (25%), gastrointestinal (22%) and respiratory (21%). We identified four independent risk factors for severe postoperative complications: reoperation, operation for congenital diaphragmatic hernia, preterm birth less than 32 weeks of gestational age and abdominal surgery. **Conclusion**: The incidence of severe postoperative complications after neonatal surgeries under general anesthesia remains high. The conditions considered independent risk factors for those can guide interventions to improve results.

Work performed in the Pediatric Intensive Care Unit (UTIP) of the Coimbra Pediatric Hospital (HPC).
1. Anesthesiology Department, Tondela-Viseu Hospital Center, EPE, Viseu, Portugal; 2. Pediatric Surgery Service, Coimbra University Hospital Center, EPE, Coimbra, Portugal; 3. Pediatric Anesthesiology Service, Coimbra University Hospital Center, EPE, Coimbra, Portugal; 4. Biostatistics and Medical Informatics Department, Faculty of Medicine, University of Coimbra, Coimbra, Portugal; 5. Faculty of Medicine, University of Coimbra, Coimbra, Portugal; 6. Faculty of Health Sciences (Anesthesiology), University of Beira Interior, Covilhã, Portugal; 7. Pediatric Intensive Care Unit, Coimbra University Hospital Center, EPE, Coimbra, Portugal.

Rev. Col. Bras. Cir. 2013; 40(5): 363-369

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

...tation of the Clavien-Dindo classification to a pediatric ...al network

... Thompson [a], Ceri Jones [b], Caroline Pardy [c], Dorothy Kufeji [c], Eric Nichols [b], ...lurphy [b], Mark Davenport [a,*]

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ABSTRACT

Introduction: A comprehensive validated system to evaluate surgical complications is required in our specialty to facilitate comparison and audit. The Clavien-Dindo (CD) classification of post-surgical complications was originally described in an adult general surgical setting in 1992 and has become widely used. We aimed to apply this to a pediatric surgical setting.
Methods: Data were collected on emergency and elective surgical activity together with complications in a prospective audit over a recent 4-month period in three geographical conjoined regional pediatric surgical units (including two major trauma centres). Briefly the CD classification codes complications according to degree of harm and magnitude of intervention required [I – V (death)] with III and IV sub-divided according to whether general anesthesia was needed]. Length of stay and mode of admission were recorded. Data are given as median (range). Non-parametric comparison was used, and a p value of <0.05 was regarded as significant.
Results: During the period JULY – OCT 2018 (inclusive), there were 1822 admissions (elective, n = 1186; emergency, n = 636) and 1556 operations (elective, n = 1189, and of these 393 were urological). There were 69 patient complications: CDI (n = 7), CD-II (n = 19), CD-IIIa (n = 4), CD-IIIb (n = 28), CD-IV (n = 4), CD-V (n = 7). Deaths were principally in neonates and due to NEC (n = 6) at 2.5 (1–140) days post-operatively. There was a single post-traumatic death in an adolescent. LOS was 9 (0–217) days in CD I-IV.
The incidence of any complication was 4.4%, of serious complication (defined as ≥ CD III) 2.6% (A = 2.1%, B = 2.0%, and C = 3.2%: p = 0.16), and of death 0.45%. The most frequent complications were wound infection (n = 12) and post-appendicectomy collections/abscess (n = 10).
Conclusions: This appears to be the 1st report of the C-D classification in a general pediatric surgery network and can be considered a benchmark. The risk of death or serious harm is very low in such a practice.
Type of Study: Prospective Cohort Study.
Level of Evidence: IIb.

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An Observational Study On Neonatal Surgery Complications Using Clavien-Dindo Classification And Its Associated Risk Factors: A Multicentre Study

Objectives

Primary Objective

❖To ascertain the incidence of complications following neonatal surgeries in three tertiary centers in Malaysia using the Clavien-Dindo classification system.

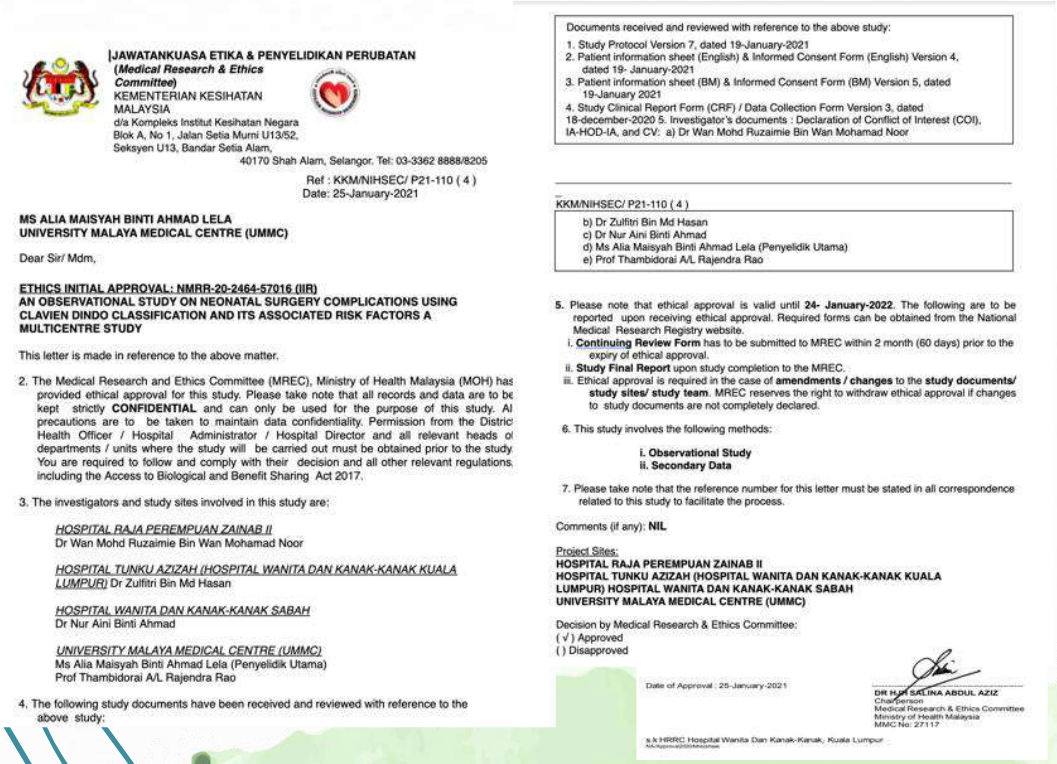
Secondary Objectives

❖To identify independent preoperative risk factors by severity of complications

❖To determine distribution of major complications across surgical diagnosis

Ethics Approval

- NMRR ID : NMRR-20-2464-57016(IIR)



JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(*Medical Research & Ethics Committee*)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Kompleks Institut Kesihatan Negara
Blok A, No 1, Jalan Setia Murni U13/52,
Seksyen U13, Bandar Setia Alam,
40170 Shah Alam, Selangor. Tel: 03-3362 8888/8205

Ref : KKM/NIHSEC/ P21-110 (4)
Date: 25-January-2021

MS ALIA MAISYAH BINTI AHMAD LELA
UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Dear Sir/ Mdm,

ETHICS INITIAL APPROVAL: NMRR-20-2464-57016 (IIR)
AN OBSERVATIONAL STUDY ON NEONATAL SURGERY COMPLICATIONS USING CLAVIEN DINDO CLASSIFICATION AND ITS ASSOCIATED RISK FACTORS A MULTICENTRE STUDY

This letter is made in reference to the above matter.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. Al precautions are to be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator / Hospital Director and all relevant heads o departments / units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations, including the Access to Biological and Benefit Sharing Act 2017.

3. The investigators and study sites involved in this study are:

HOSPITAL RAJA PEREMPUAN ZAINAB II
Dr Wan Mohd Ruzaimie Bin Wan Mohamad Noor

HOSPITAL TUNKU AZIZAH (HOSPITAL WANITA DAN KANAK-KANAK KUALA LUMPUR) Dr Zulfitri Bin Md Hasan

HOSPITAL WANITA DAN KANAK-KANAK SABAH
Dr Nur Aini Binti Ahmad

UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)
Ms Alia Maisyah Binti Ahmad Lela (Penyelidik Utama)
Prof Thambidorai A/L Rajendra Rao

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Study Protocol Version 7, dated 19-January-2021
2. Patient information sheet (English) & Informed Consent Form (English) Version 4, dated 19- January-2021
3. Patient information sheet (BM) & Informed Consent Form (BM) Version 5, dated 19-January 2021
4. Study Clinical Report Form (CRF) / Data Collection Form Version 3, dated 18-december-2020 5. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV: a) Dr Wan Mohd Ruzaimie Bin Wan Mohamad Noor

KKM/NIHSEC/ P21-110 (4)

b) Dr Zulfitri Bin Md Hasan
c) Dr Nur Aini Binti Ahmad
d) Ms Alia Maisyah Binti Ahmad Lela (Penyelidik Utama)
e) Prof Thambidorai A/L Rajendra Rao

5. Please note that ethical approval is valid until **24- January-2022**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry website.
   i. **Continuing Review Form** has to be submitted to MREC within 2 month (60 days) prior to the expiry of ethical approval.
   ii. **Study Final Report** upon study completion to the MREC.
   iii. Ethical approval is required in the case of **amendments / changes** to the **study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.

6. This study involves the following methods:

   i. Observational Study
   ii. Secondary Data

7. Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any): **NIL**

Project Sites:
HOSPITAL RAJA PEREMPUAN ZAINAB II
HOSPITAL TUNKU AZIZAH (HOSPITAL WANITA DAN KANAK-KANAK KUALA LUMPUR) HOSPITAL WANITA DAN KANAK-KANAK SABAH
UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

Date of Approval : 25-January-2021

DR HJH SALINA ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
MMC No: 27117

s.k HRRC Hospital Wanita Dan Kanak-Kanak, Kuala Lumpur

- GCP cert

Certificate of Achievement

This is to certify that

Alia Maisyah Binti Ahmad Lela
NRIC No.: 870702-10-5106

Had successfully participated in a Good Clinical Practice course on

11 - 13 August 2020
Kuala Lumpur

And has fulfilled the condition to be GCP certified on

13 August 2020
Kuala Lumpur

Organised by

Clinical Investigation Centre (CIC)
University of Malaya

Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah
Director General of Health &
Chairman of National Committee for Clinical Research

SCCR2020-00225

Study Design

- Type : Observational Study (Retrospective)
- Patient selection :
  - Inclusion Criteria: All neonates that had underwent surgical intervention under anaesthesia
  - Exclusion Criteria: surgeries involving cardio-related surgery, neurosurgery, orthopaedic surgery are being excluded

Study Centres

- Hospital Tunku Azizah, Kuala Lumpur
- Hospital Raja Perempuan Zainab II (HRPZ II)
- Sabah Women and Childrens Hospital (SWACH), Likas, Sabah

Methodology

Study Period : 15 months
1st July 2020 – 30th September2021

Patient Recruitement :
Identify neonates undergoing surgery and their particulars

INCLUSION CRITERIA : All neonates that had undergoing Paeds surgical intervention under anaesthesia

EXCLUSION CRITERIA : neonates undergoing cardiovascular, neurosurgical and orthopaedic surgeries

Identify complications that had occured within 30 days post surgery

- eg:
- Fever, vomiting ,pain
- wound infection
- Burst abdomen
- Life threatening events
- death

Identify the treatment provided to correct the complications

- eg:
- administration of blood transfusion
- Prolonged NBM requiring TPN
- Requiring re-look surgery

Grade according to CD* classification

Identify the preoperative factors and diagnosis

- that may contribute to the development of complications

Table 1
Clavien-Dindo classification of post-operative complications.

GRADE	DEFINITION
Grade I	Any deviation from the normal post-operative course not requiring surgical, endoscopic or radiological intervention. Accepted therapeutic regimes include drugs as: anti-emetics, anti-pyretics, analgesics, diuretics and electrolytes, treatment with physiotherapy and wound infections that are opened at the bedside
Grade II	Complications requiring pharmacological treatments other than those allowed for Grade I complications; this includes blood transfusion and total parenteral nutrition (TPN)
Grade III	Complications requiring surgical, endoscopic or radiological intervention Grade IIIa - intervention not under general anesthetic Grade IIIb - intervention under general anesthetic
Grade IV	Life-threatening complications; this includes CNS complications which require intensive care Grade IVa - single-organ dysfunction (including dialysis) Grade IVb - multi-organ dysfunction
Grade V	Death of the patient

Sample Size Estimation

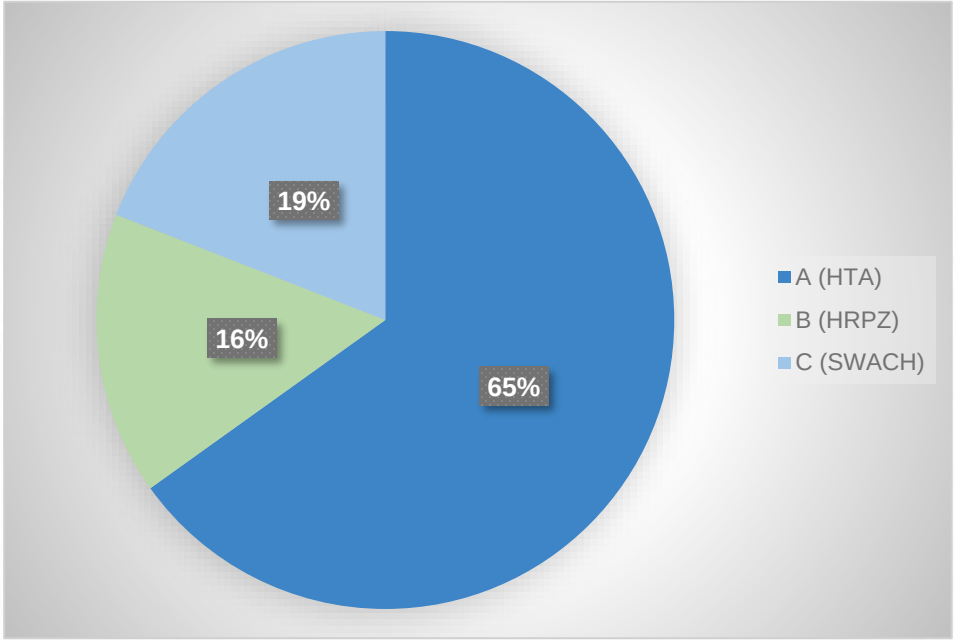
- To determine the incidence of the complications
  - Based on the study by Catre et al. (2013), the sample size was estimated according to the incidence for the last stage of the complications i.e. death (2.7%).
  - The calculation was performed by using single proportion formula and 2.5% was estimated as precision at 0.05 of level of significance and 80% of power of study. A minimum of 180 patients will be recruited based on the sample size calculation (with 10% drops-out considered)

- Below are the calculations for all the degree of complications:
  - Degree I (9.7%): n=44
  - Degree II (57.6%): n=4
  - Degree IIIa (5.9%): n=77
  - Degree IIIb (17.3%): n=23
  - Degree IVa (3.5%): n=162
  - Degree IVb (3.2%): n=148
  - Degree V (2.7%): n=180

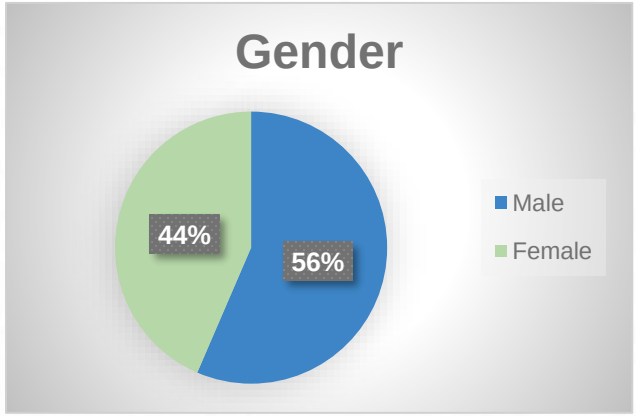
Results

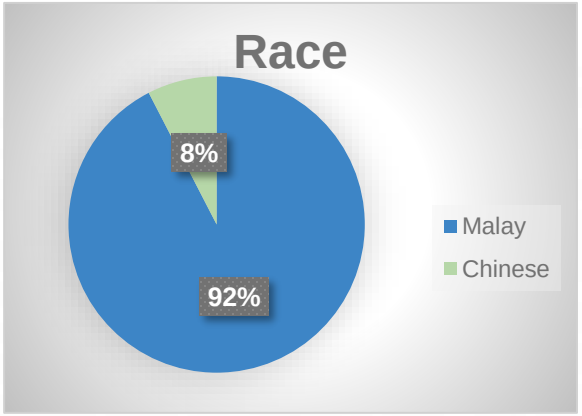
N= 278 patients were recruited in to the study

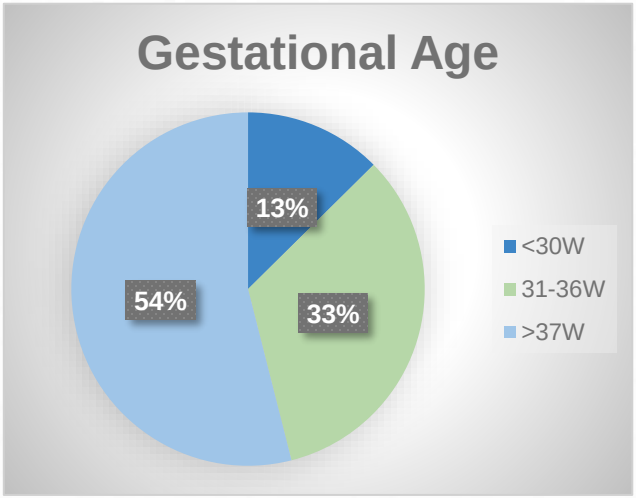
Distribution of Cases Across Centre's

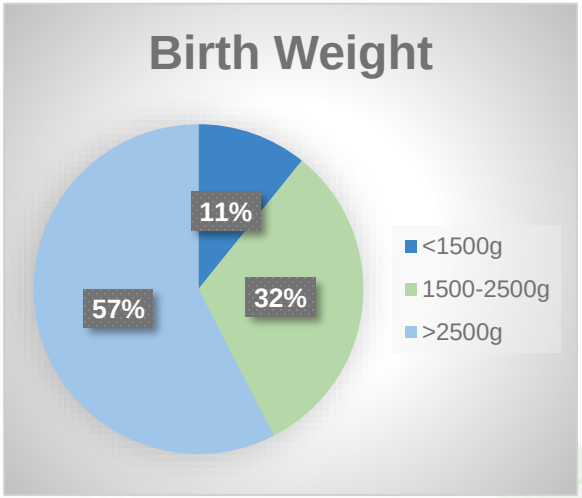


Demographic Breakdown

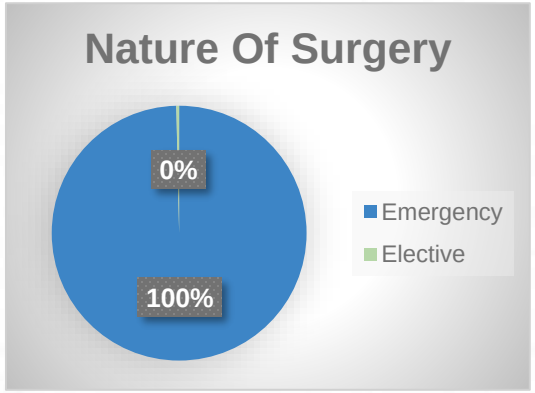


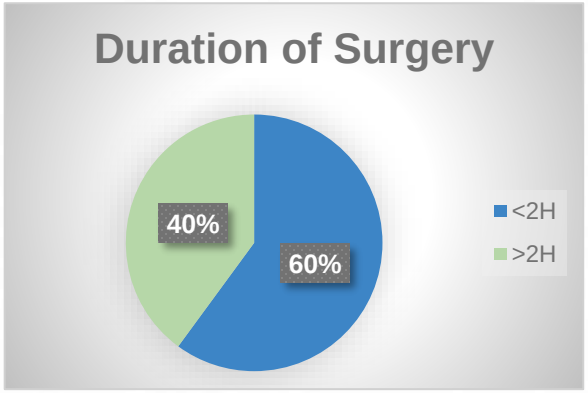


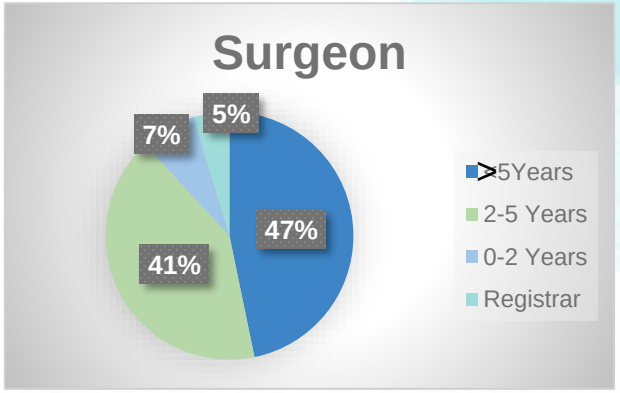


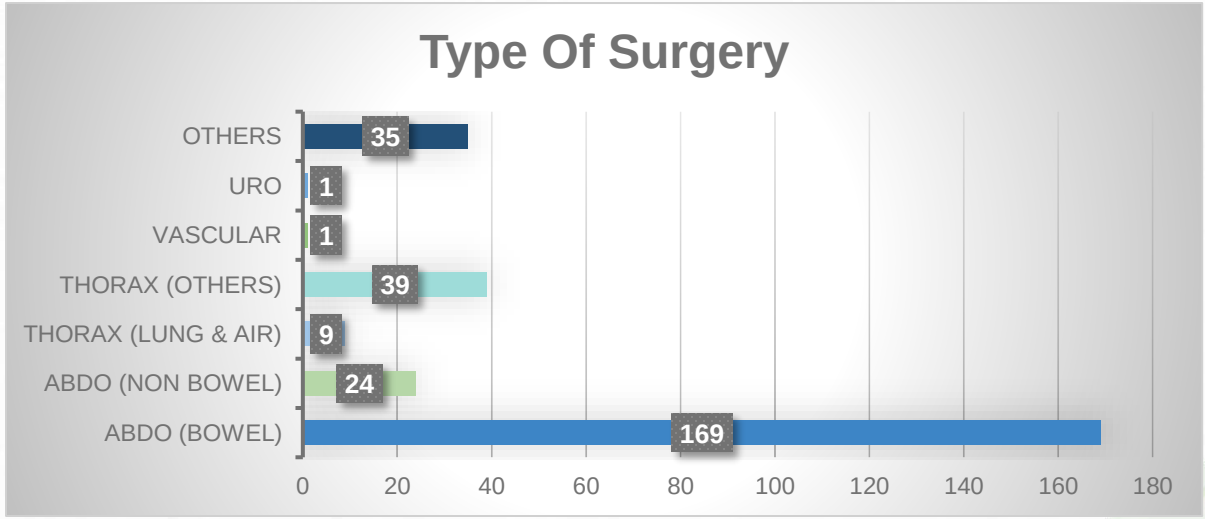


Based on Surgery Particulars

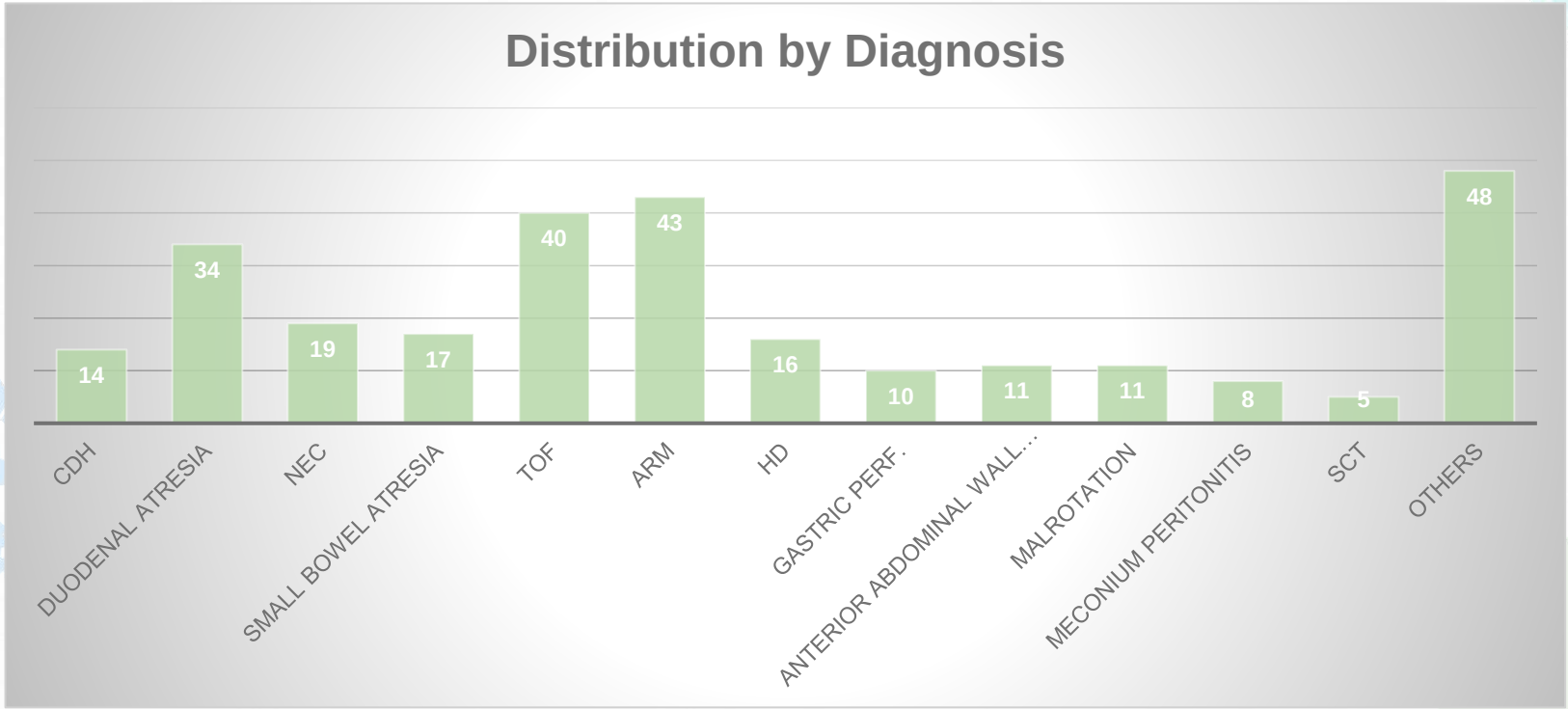








Based on Diagnosis



Clavien Dindo Classification

APPENDIX A. Classification of Surgical Complications

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MINOR COMPLICATIONS

MAJOR COMPLICATIONS

‡ brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks (TIA); IC: Intermediate care; ICU: Intensive care unit

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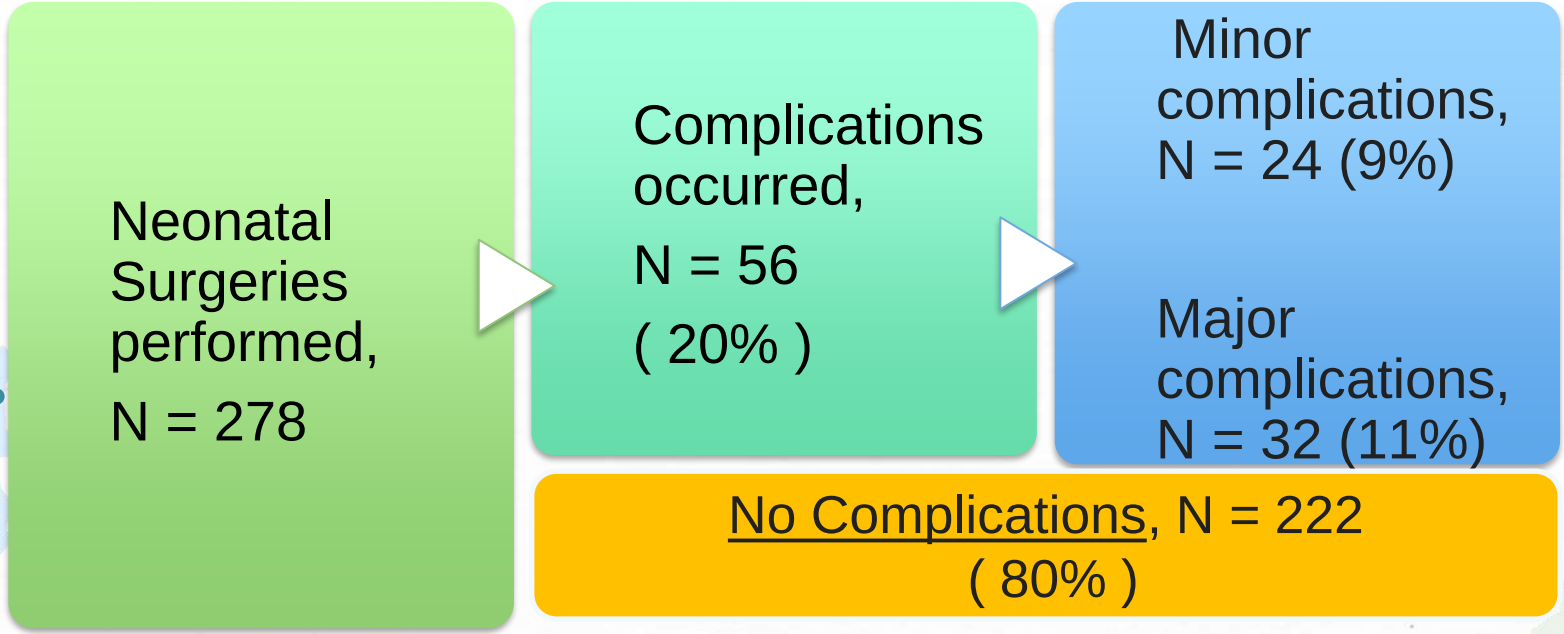
Incidence of Complications



Incidence of Complications

Degree of complications	Total surgeries (n = 278)	
	Number of complications	%
Minor complications		
Grade I	12	4.5%
Grade II	12	4.5%
Major complications		
Grade IIIa	3	1%
Grade IIIb	16	5%
Grade IVa	0	0%
Grade IVb	1	1%
Grade V	12	4%
Total complications	56	20%

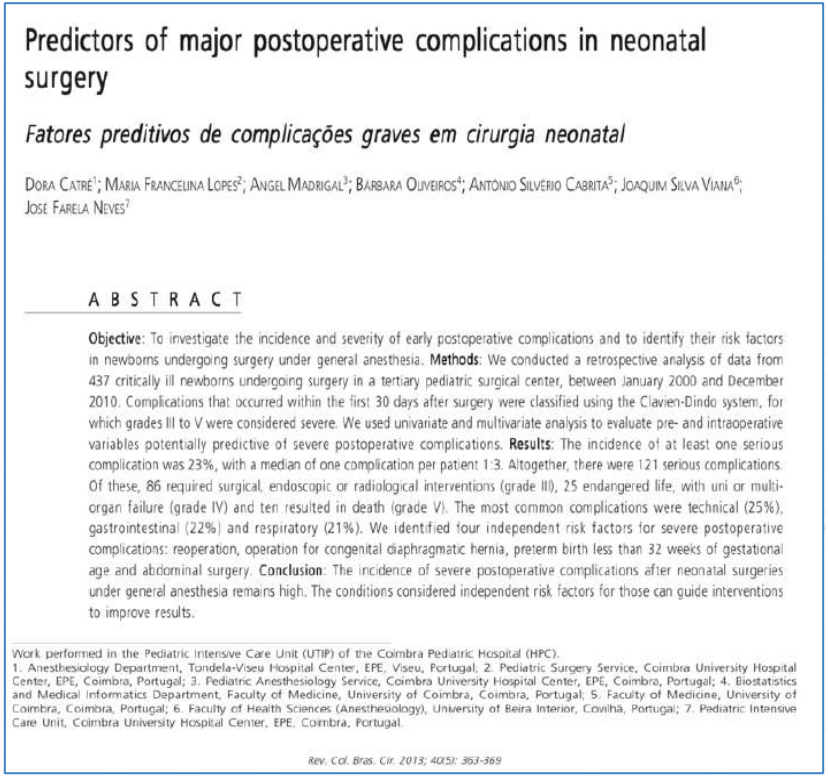
Minor Complications

- Minor complications : Grades I and II of the CD classification
- Grade I : N=12
  - Surgical Site infections was the most common complication which was 81% (n= 10/12)
  - the majority of which occurred within the first week post –operatively
  - all of which required only bedside dressing.
- Grade II: N= 12
  - complications include, nosocomial sepsis, CRBSI and there were 3 cases of anastomotic leak (radiological leak) post TOF repair and primary anastomosis which was treated conservatively with antibiotics and prolonged fasting.

Major Complications

- Major complications : Grade III (A&B), IV (A&B) and V
- CD IIIb for which the intervention required re-surgery under GA, included:
    - relaparotomy for a variety of reasons, namely adhesive obstructions, anastomotic leak, stricture and disease progression like in NEC.
    - The incidence of which occurred both in the first week post op and after 3 weeks post op.
- One CD IVb complications t: patient that developed severe sepsis at about 2 weeks post-op and developed multiorgan failure.
- Grade V accounted for 21% (n = 12/56) and these were mainly due :
    - severe unretractable sepsis with multiorgan failure that occurred within 30days post-operative abdominal surgery for bowel disease like NEC and NOMI.
    - but there was also a case of anterior neck mass and mediastinal tumour that passed within 2 days post operatively.

Identifying Predictors of Complications After Neonatal Surgery



Predictors of major postoperative complications in neonatal surgery

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Dora Catré[1]; Maria Francelina Lopes[2]; Angel Madrigal[3]; Bárbara Oliveiros[4]; Antônio Silvério Cabrita[5]; Joaquim Silva Viana[6]; José Farela Neves[7]

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Rev. Col. Bras. Cir. 2013; 40(5): 363-369

- The Logistic Regression analysis :
  - to identify any associated factor that contributes to the Complications Among Neonatal Surgery
  - Simple Logistic Regression Analysis (univariate analysis)
  - Multiple Logistic Regression Analysis (multivariate analysis)

Univariate Analysis using Simple Logistic Regression

- Four variables were found to have significant value less than 0.25

Predictive factors for developing complications

Variables		Crude OR (95% CI)	p-value
Gest. age	>37w	1	
	31-36w	15.4 (3.446, 68.607)	<0.001
	<30w	55.5 (11.809, 260.842)	<0.001
Baby birth weight	>2500g	1	
	1500-2500g	1.7 (0.758, 3.704)	0.202
	<1500g	1.9 (0.645, 5.794)	0.239
Race	Malay	1	
	Chinese	2.3 (0.600, 8.686)	0.226
	Indian	4.6 (1.276, 16.339)	0.020
	Others	1.9 (0.523, 7.318)	0.319
Gender	Female	1	
			0.812
			>0.999
			0.427
			>0.999
	vascular access surgery	0.0 (0.0)	>0.999
	Thoracic surgery for lung and airway related lesion	0.0 (0.0)	0.999
	Abdominal surgery for non-bowel related problem	0.0 (0.0)	0.998
	Thoracic surgery (others)	4.0 (0.766, 20.712)	0.100
	Abdominal surgery for bowel-related problem	2.7 (0.606, 11.966)	0.193
Surgeon experience	>5 years	1	
	2-5 years	1.1 (0.516, 2.238)	0.848
	0-2 years	0.0 (0.0)	0.998
	Registrar/MO	0.0 (0.0)	0.999
Diagnosis	OTHERS	1	
	ARM	0.1 (0.012, 0.796)	0.030
	small bowel atresia	0.9 (0.238, 4.087)	0.984
	duodenal atresia/stenosis	0.1 (0.018, 1.179)	0.071
	anterior abdominal wall defects	0.0 (0.0)	0.999
	CDH	0.0 (0.0)	0.999
	TOF	1.2 (0.406, 3.499)	0.748
	NEC	2.1 (0.649, 6.941)	0.213
	Perforated Stomach	1.9 (0.433, 8.974)	0.380
	HD	0.4 (0.048, 3.620)	0.429
	Malrotation with MG volvulus	0.0 (0.0)	0.999
	meconium peritonitis	0.6 (0.073, 5.955)	0.709
	SCT	0.0 (0.0)	0.999

Only ***gestational age*** was found to be the strong predictor for major complications after adjusting other variables during Multiple Logistic Regression ($p<0.05$).

Multivariate Analysis

- **Gestational age** was found to be a predictor towards complication stage after other variables were adjusted.
- Neonates who were among ***31-36weeks*** were likely to have 15 times odds to have major complications compared those among >37 weeks.
- Those who were ***< 30 weeks*** of age likelihood to have 54 times of odds major complications compared those among >37 weeks after adjusting other variables.

Multiple logistic regression

Variables		Adjusted OR (95% CI)	p-value
Gest. age	>37w	1	
	31-36w	15.2 (3.399, 67.688)	<0.001
	<30w	54.8 (11.648, 257.347)	<0.001

Discussion

CD Classification System in Neonatal Surgeries

Predictors of major postoperative complications in neonatal surgery

Fatores preditivos de complicações graves em cirurgia neonatal

Dora Catré[1]; Maria Francelina Lopes[2]; Angel Madrigal[3]; Bárbara Oliveiros[4]; António Silvério Cabrita[5]; Joaquim Silva Viana[6]; José Farela Neves[7]

ABSTRACT

Objective: To investigate the incidence and severity of early postoperative complications and to identify their risk factors in newborns undergoing surgery under general anesthesia. **Methods**: We conducted a retrospective analysis of data from 437 critically ill newborns undergoing surgery in a tertiary pediatric surgical center, between January 2000 and December 2010. Complications that occurred within the first 30 days after surgery were classified using the Clavien-Dindo system, for which grades III to V were considered severe. We used univariate and multivariate analysis to evaluate pre- and intraoperative variables potentially predictive of severe postoperative complications. **Results**: The incidence of at least one serious complication was 23%, with a median of one complication per patient 1:3. Altogether, there were 121 serious complications. Of these, 86 required surgical, endoscopic or radiological interventions (grade III), 25 endangered life, with uni or multi-organ failure (grade IV) and ten resulted in death (grade V). The most common complications were technical (25%), gastrointestinal (22%) and respiratory (21%). We identified four independent risk factors for severe postoperative complications: reoperation, operation for congenital diaphragmatic hernia, preterm birth less than 32 weeks of gestational age and abdominal surgery. **Conclusion**: The incidence of severe postoperative complications after neonatal surgeries under general anesthesia remains high. The conditions considered independent risk factors for those can guide interventions to improve results.

Work performed in the Pediatric Intensive Care Unit (UTIP) of the Coimbra Pediatric Hospital (HPC).
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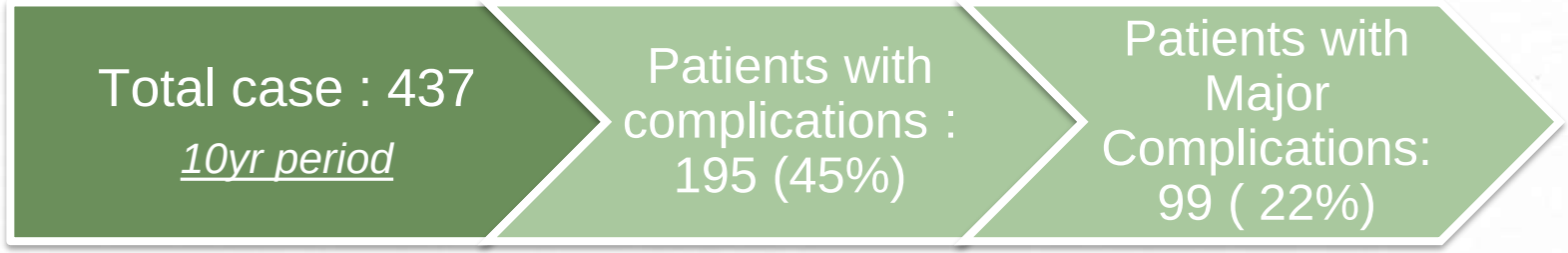
Rev. Col. Bras. Cir. 2013; 40(5): 363-369

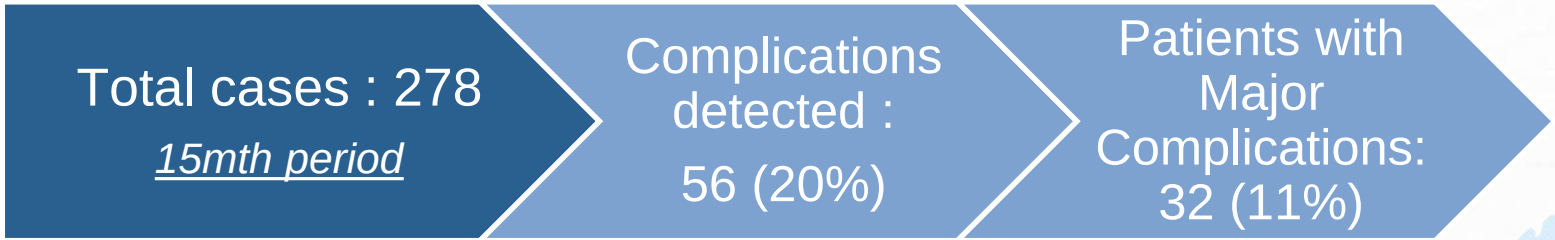
- **Dora Catré, Maria Francelina Lopes**, *et al* (2013) describing complications in neonatal surgery using the CD classification system
- retrospectively looked at data in 437 infants over a 10-year period, of which 45% had a complication
- Complications that occurred within the first 30 days after surgery were classified using the Clavien-Dindo system, for which grades III to V were considered severe
- There were 121 severe complications.
- Grade III - 86 (required surgical, endoscopic or radiological interventions)
- Grade IV - 25 (endangered life, with uni or multi- organ failure)
- Grade V – 10 (resulted in death)
- Also had highlighted diaphragmatic hernia, NEC and reoperations as risk factors

Comparable Outcomes

Catre et al (2013)



Current study (local setting)



Incidence of Complications

- From the paper by *Catre et al*
- Altogether, there **were 121 serious complications**.
- The incidence of at least one serious complication was **22%,**

Table 2 - Categorization of the 370 complications according to the Clavien-Dindo classification system.

Categorization/Degree	n (%)
Minor complications	
Degree I	36 (9.7)
Degree II	213 (57.6)
Severe complications	
Degree IIIa	22 (5.9)
Degree IIIb	64 (17.3)
Degree IVa	13 (3.5)
Degree IVb	12 (3.2)
Degree V	10 (2.7)

- Current study : 32 patients developed major complications.
- But the incidence of major complication was about **11% from the whole series**.

Degree of complications	Total surgeries (n = 278)	
	Number of complications	%
Minor complications		
Grade I	12	4%
Grade II	12	4%
Major complications		
Grade IIIa	3	1%
Grade IIIb	16	6%
Grade IVa	0	0%
Grade IVb	1	1%
Grade V	12	5%
Total complications	56	20%

Prediction of Complications

Table 4 - Characteristics of the neonates presenting with severe complications (degrees of Clavien-Dindo ee III) and of the ones with Clavien-Dindo degrees I or II complications, and their association in the univariate analysis.

Factors	Complications of Clavien-Dindo > III, n=99	None or < II, n=338	P
Characteristics at birth			
Male, n= 244	56	188	0.868
Premature < 32 w GA, n=66	22	44	0.024*
SGA (<percentil10), n=67	18	49	0.371
BGA (>percentile 90), n=17	5	12	0.497
Apgar at 5 min < 7, n=16¥	5/97	11/331	0.403
>1 congenital malformation, n=91	20	71	0.862
Characteristics of the patient at operation			
Age in 1st operation, days of life#	2 (0-8)	3 (1-9)	0.256
Weight in 1st operation, kg #	2.6 (1.8-3)	2.8 (2-3.3)	0.026*
>1 surgical/anesthesia intervention, n=95	56	39	<0.001*
Surgical characteristics (in at least one procedure per patient)			
Acquired surgical disease, n=99	22	77	0.907
ASA Score ee 3, n=207	67	140	<0.001*
Balanced anesthesia, n=37	85	287	0.816
Intravenous anesthesia, n=75	25	50	0.015*
Inhaled anesthesia, n=8	1	7	0.689
Surgery for:Esophageal atresia, n=42	8	34	0.557
Defects of abdominal wall, n=49	17	32	0.033*
Congenital diaphragmatic hernia, n=42	17	25	0.004*
Necrotizing Enterocolitis, n=31	13	18	0.008*
Duodenal obstruction, n=25	8	17	0.250
Small bowel atresia, n=16	7	9	0.040*
Meconial Ileus, n=9	2	7	1.00
Anorectal malformations, n=30	2	28	0.030*
Hirschsprung's Disease, n=6	3	3	0.133
Congenital Hydronephrosis, n=4	2	2	0.222
Cardiac malformations, n=31	6	25	0.649
Acquired Hydrocephaly, n=30	8	22	0.586
Myelomeningocele, n=27	3	24	0.139
Abdominal surgery, n=225	70	155	<0.001*
Thoracic surgery, n=62	12	50	0.503
Duration of the surgery> 2h, n=177	47	130	0.108

*n, number of cases; #, Median and interquartile range; w, weeks; GA, gestational age; ¥, nine cases with values of Apgar lacking were excluded from the analysis of this variable; SGA, small for gestational age; BGA, big for gestational age; min, minutes; >1, more than one; ASA physical status stratified by the classification of the American Association of Anesthesiologists; *, statistically significant.*

- *Catre et al*, identified 4 independent risk factors for severe postoperative complications:
  - Reoperation
  - operation for congenital diaphragmatic hernia,
  - preterm birth less than 32 weeks of gestational age
  - abdominal surgery

Table 5 - Independent predictive factors of early severe postoperative complications among the surgical neonates admitted to the UTIP.

Factor	Early severe postoperative complication			
	Odds Ratio	*95%*	*CI*	*P*
More than one intervention	12.008	6.795	21.223	<0.001
CDH Repair	3.843	1.732	8.526	0.001
Premature <32 s GA	2.666	1.355	5.245	0.005
Abdominal surgery	2.541	1.462	4.416	0.001

Source: UTIP: pediatric intensive care unit; CDH, congenital diaphragmatic hernia; <32 s GA, less than 32 weeks of gestational age; CI, confidence interval.

Prediction of Complications

Predictive factors for developing complications

Variables		Crude OR (95% CI)	p-value
Gest. age	>37w	1	
	31-36w	15.4 (3.446, 68.607)	<0.001
	<30w	55.5 (11.809, 260.842)	<0.001
Baby birth weight	>2500g	1	
	1500-2500g	1.7 (0.758, 3.704)	0.202
	<1500g	1.9 (0.645, 5.794)	0.239
Race	Malay	1	
	Chinese	2.3 (0.600, 8.686)	0.226
	Indian	4.6 (1.276, 16.339)	0.020
	Others	1.9 (0.523, 7.318)	0.319
Gender	Female	1	
	Male	0.9 (0.441, 1.900)	0.812
Operation status	Elective	1	
	Emergency	218486570.8 (0.0)	>0.999
Duration surgery	<2 hours	1	
	>2 hours	1.4 (0.639, 2.885)	0.427
Type of surgery	others	1	
	urological surgery	0.0 (0.0)	>0.999
	vascular access surgery	0.0 (0.0)	>0.999
	Thoracic surgery for lung and airway related lesion	0.0 (0.0)	0.999
	Abdominal surgery for non-bowel related problem	0.0 (0.0)	0.998
	Thoracic surgery (others)	4.0 (0.766, 20.712)	0.100
	Abdominal surgery for bowel-related problem	2.7 (0.606, 11.966)	0.193
Surgeon experience	>5 years	1	
	2-5 years	1.1 (0.516, 2.238)	0.848
	0-2 years	0.0 (0.0)	0.998
	Registrar/MO	0.0 (0.0)	0.999
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Prediction of Complications

Multiple logistic regression

Variables		Adjusted OR (95% CI)	p-value
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Incidence of Complications

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

Application of the Clavien-Dindo classification to a pediatric surgical network

Hannah Thompson [a], Ceri Jones [b], Caroline Pardy [c], Dorothy Kufeji [c], Eric Nichols [b], Felim Murphy [b], Mark Davenport [a,*]

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Points comparable to study by Thompson.H et al, in 2019, where

- The most frequent complications were wound infection (n = 12) and post-appendicectomy collections/abscess (n = 10)
- Complications occurred in 21 (1.15% overall) neonatal admission across the three units. The median grade of complication in neonates was IIIb compared to II in older children.
- Six neonates died following operations

Degree of complications	Total surgeries (n = 278)	
	Number of complications	%
Minor complications		
Grade I	12	4%
Grade II	12	4%
Major complications		
Grade IIIa	3	1%
Grade IIIb	16	6%
Grade IVa	0	0%
Grade IVb	1	1%
Grade V	12	5%
Total complications	56	20%

Conclusion

- First multicentre report of neonatal surgical outcomes in Malaysia
- The Clavien-Dindo classification system is a robust system that reports types of outcomes and enables identification of risk factors.
- Individual risk factors predictive of all types of complications include low birth weight, abdominal surgery (bowel) and thoracic (non airway/lung related) surgery and a diagnosis of NEC.
- Only gestational age was considered a strong and independent risk factor for severe complications
- The recognition of poor prognostic factors may enable:
  - ✓ Efficient resource allocation and management
  - ✓ Tailored approach to care of neonates with specific risk factors
  - ✓ Accurate counselling to caregivers with regards to adverse outcomes

THANK YOU
for your attention

Special thanks to my supervisor Mr Anand, thanks and major love to my co-investigators that helped with data collection:
Dr Zulfitri, Dr Jun yi
Dr Meryem, Dr Naveena
Dr Kuhan, Dr Sandhya

And to Surgeons who have allowed me to conduct my study at their centre
Mr Yusof, Dato Zakaria
Mr Tarmizi, Mr Ruzaimie, Mr Razin
Mr Mughni, Ms Hazlina, Ms Aini, Mr Fadli